FALSE CLAIMS ACT EDUCATION REQUIREMENTS UNDER THE DEFICIT REDUCTION ACT: COMPLIANCE GUIDANCE FOR HEALTH CARE ORGANIZATIONS IN THE WAKE OF UNCERTAINTY

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Introduction

On January 1, 2007, a key provision of the Deficit Reduction Act of 2005 ("DRA" or "the Act"), went into effect. Section 6032 of the DRA, titled "Employee Education About False Claims Recovery (the "Employee Education Provision"), requires most health care organizations that operate under the Medicaid program, i.e., those organizations that receive or make annual Medicaid payments of at least $5 million, to establish and implement an education plan for their employees, managers, contractors and agents, which includes written policies and detailed guidance on the federal False Claims Act ("FCA"), state false claims laws, and the rights and protections afforded whistleblowers under the FCA and its state counterparts.

The DRA's Employee Education Provision is of great importance to health care organizations because it imposes upon them new and significant Medicaid program compliance burdens and, concomitantly, exposes them to Draconian sanctions if they fail to fully and timely comply. If the government determines that a health care organization covered under the Act (a "Covered Entity") knows or should know that it is not meeting the requirements of the DRA's Employee Education Provision, then the government may assert that all Medicaid claims made by the Covered Entity during the period of noncompliance are "false," subjudicing the Covered Entity not only to the significant damages and penalties under the FCA, but also to the forfeiture of payments on such claims and disqualification from further participation in the Medicaid program. Thus, a full and immediate understanding of what is required under the DRA's Employee Education Provision and full and immediate compliance with its mandates are imperative.

Unfortunately, the statutory language contained in the DRA's Employee Education Provision lacks detailed descriptions of what exactly the government requires of Covered Entities to demonstrate full compliance. Although clarifying regulations are expected in the near future, the timing for the issuance of such regulations is still unknown. What is known, however, is that the delayed implementation of regulations does not excuse a Covered Entity that fails to comply in the interim. Many in the health care community hoped and expected that, in light of the absence of clarifying regulations, there would be agency-level guidance offered prior to the DRA's January 1, 2007 effective date providing necessary direction as to how best to comply with the law in the absence of such regulations. The agency "guidance" that was provided around this time, however, failed to meet these hopes and expectations.

On December 13, 2006, the United States Department of Health and Human Services ("DHHS") Centers for Medicare and Medicaid Services ("CMS") issued a public letter to the state Medicaid directors ("CMS Letter"), and on January 11, 2007 hosted a teleconference for Medicaid providers ("CMS Teleconference") in an effort to provide the guidance sought by the health care community. To the dissatisfaction of many, neither CMS nor the DHHS Office of Inspector General ("OIG") clarified or provided much needed guidance on many key aspects of the DRA's requirements. Thus, in the "here and now" – roughly three months after the DRA's January 1, 2007 effective date – there are many questions that remain unanswered, and many Covered Entities left frustrated with an urgent need for compliance guidance.

To account for the current compliance guidance void, this article endeavors to provide practical suggestions to health care organizations as to how to best comply with the DRA's Employee Education Provision. It begins with a brief background of the DRA, and overviews of the Medicaid program, the federal FCA, and state false claims laws. It then specifically addresses the requirements under the DRA's Employee Education Provision. Most importantly, it also provides pragmatic compliance guidance Covered Entities should consider when trying to minimize exposure to potential violations of the DRA's Employee Education Provision in the wake of poorly drafted statutory language, the absence of clarifying/implementing regulations, and insufficient agency direction.

Background Regarding The DRA

On a broad level, the DRA, as its name suggests, makes massive cuts to federal budgetary line items for various programs, including the Medicaid program. The Congressional Budget Office ("CBO") estimates that these cuts and related reforms will reduce Medicaid spending by over $11 billion in the first five years and by over $40 billion in the first ten years. In addition to making cuts, however, the DRA also endeavors to reform the Medicaid program in two primary ways: first, by providing an incentive to states to enact
false claims laws of their own to support the federal government’s efforts toward combating fraud, waste, and abuse in the Medicaid program; and second, by mandating new and significant Medicaid program compliance requirements for certain health care organizations, including the mandate that Covered Entities establish and implement a comprehensive employee education program as described in the DRA’s Employee Education Provision.

The DRA’s Incentive For States To Enact Qualifying False Claims Laws

Section 6031 of the DRA, titled Encouraging the Enactment of State False Claims Acts, amends Title XIX of the Social Security Act by adding a new section, which provides a financial incentive for states to enact false claims laws that are comparable to the FCA and establish liability to the State for those who submit false or fraudulent claims to the State’s Medicaid program. In order to qualify for this incentive, a state’s false claims law must essentially mirror and be as effective as the enforcement provisions contained in the FCA, including the allowance for qui tam enforcement. Effective January 1, 2007, if the OIG determines that a state’s false claims act qualifies under this standard, then the federal government will give to the state, as an incentive, 10% of any funds recovered as part of Medicaid enforcement actions brought under that state’s qualifying false claims law that would otherwise go to the federal government.

Section 6031(b) of the DRA specifies four requirements for determining whether a state false claims law qualifies for the 10% financial incentive:

- It must establish liability to the state for false claims described in the FCA with respect to any expenditure described in the Medicaid program;
- It must contain provisions that are at least as effective in rewarding and facilitating qui tam (i.e., whistleblower) actions for false claims as those described in the FCA;
- It must allow whistleblowers to file actions under seal, with a sixty-day review period by the State Attorney General; and
- It must include a civil penalty that is not less than that authorized by the FCA.

As of early 2007, twelve jurisdictions have false claims laws that are similar to the FCA and contain qui tam enforcement provisions: California, Delaware, the District of Columbia, Florida, Hawaii, Illinois, Indiana, Massachusetts, Montana, Nevada, Tennessee, and Virginia. Six states have false claims laws with qui tam enforcement provisions that are more narrowly tailored to the extent that they apply only to health care fraud: Louisiana, Michigan, New Hampshire, New Mexico, Tennessee, and Texas. In addition, eight states have false claims laws without any qui tam enforcement provisions: Arkansas, Colorado, Maine, Nebraska, North Carolina, Ohio, Utah, and Washington.

In order to take advantage of the increased recovery share offered under the DRA’s financial incentive to states, a state must have false claims laws that are as stringent as the FCA. Therefore, those states that either do not have false claims laws at all or have false claims laws that do not meet this standard must take action to qualify for the DRA’s financial incentive by enacting new false claims laws that qualify or by amending existing false claims laws to qualify. In recognition of this requirement, several states currently have new legislation and/or regulations pending designed to create or amend false claim laws to qualify.

On August 21, 2006, OIG published a notice in the Federal Register that sets forth OIG’s guidelines for reviewing state false claims acts. States were invited to request an OIG review of their false claims laws to determine if they meet the requirements of the DRA. As of early this year, the OIG has reviewed state false claims laws from California, Florida, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Nevada, Tennessee, Texas, and Virginia. In December 2006, the OIG approved the state false claims laws of Illinois, Massachusetts, and Tennessee. Also in December 2006, the OIG rejected the false claims laws of California, Florida, Indiana, Louisiana, Michigan, Nevada, and Texas. The OIG issued letters to these states specifying the reason(s) their state false claims laws did not meet all of the DRA’s requirements enumerated in Section 6031(b), and that amendments would be necessary in order to be eligible for the incentive bonus. In March of this year, the OIG approved the state false claims laws of Hawaii and Virginia. Of course, this will be an ongoing process as states continue their efforts to enact or amend false claims laws. Health care organizations should closely monitor state legislation and the status of the OIG’s review process of such legislation in the states in which they operate to ensure that they account for such laws in conjunction with their overall compliance program and, as discussed below, in the establishment and implementation of their DRA required employee education plan.

Rationale Behind the DRA’s Financial Incentives

The DRA’s financial incentives to states and its Employee Education Provision were both enacted to address the rapid growth of Medicaid spending and to provide an additional layer of enforcement to deal with a perceived growth in fraud, waste, and abuse in the Medicaid program. Indeed, testimony and discussion suggesting that there is an enormous amount of fraud, waste, and abuse in the Medicaid program – particularly in prescription drug spending under the program – was the focus of two consecutive days of hearings on Medicaid fraud conducted by the United States Senate’s Committee on Finance (“Senate Finance Committee” or “Committee”) in the Summer of 2005. During the hearings, there was also a recognition that, while the FCA is an effective tool for combating such fraud, waste, and abuse, the federal government was neither maximizing the FCA’s potential nor doing enough to

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enlist the support of the states in responding to Medicaid fraud and the increased spending associated with it.

The Senate Finance Committee hearings appear to have been prompted in part by a report issued by the United States Government Accountability Office ("GAO") on June 28, 2005, titled Medicaid Fraud and Abuse: CMS’s Commitment to Helping States Safeguard Program Dollars is Limited (hereinafter the "GAO Report"). The GAO Report implies that CMS should bear some blame for – or at least increased responsibility for correcting – fraud, waste, and abuse in the Medicaid program and insufficient enforcement. Among other things, the GAO report found that: (1) CMS lacked specific goals for Medicaid fraud and abuse control; (2) the federal government’s oversight of a state’s Medicaid fraud, waste, and abuse programs was insufficient; and (3) despite CMS’s annual receipt of millions of dollar for such programs, it had not used or adequately allocated those funds towards enforcement initiatives that would assist states in increasing the effectiveness of their programs to combat Medicaid fraud, waste, and abuse. Following the issuance of the GAO Report and in conjunction with hearings held before the Senate Finance Committee, Senator Charles Grassley (R-IA), the Chairman of the Committee, authored Section 6032 of the DRA.

The DRA’s Employee Education Provision

In tandem with providing a financial incentive to states to enact qualifying false claims laws, the DRA also amends the state Medicaid requirements in the Social Security Act by requiring Covered Entities to establish and implement an employee education plan in strict accord with its mandates. The apparent purpose of the mandatory employee education plan is to ensure that all individuals involved in the provision of health care services under the Medicaid program are fully informed about the FCA and applicable state false claims laws, including those sections allowing for qui tam enforcement and protection for whistleblowers. Although many health care organizations have utilized employee education programs that addressed the federal FCA and state false claims laws as part of their internal compliance programs in the past, this marks the first time that they have been specifically required by law to essentially educate individuals on how to “blow the whistle.”

Medicaid Program Overview

The Medicaid program is a health care benefit program jointly financed by both the federal government and the states. The federal government regulates the program through CMS, and the states directly administer the program under their individual state Medicaid plans. Each state Medicaid plan establishes: (1) its own eligibility qualifications; (2) the type, amount, duration, and scope of health care services covered; and (3) payment rates for covered health care services.

The federal government matches state Medicaid spending for health care services according to a formula based on each state’s per capita income and contributes to each state’s costs for administering the program. In fiscal year 2004, the federal contribution rate ranged from 50% to 76% for state funds spent on health care services under the Medicaid program. Generally, the federal contribution rate for administrative costs is approximately 50%. Regardless of how the federal government and the states apportion the costs for Medicaid, however, neither these contribution rates nor overall Medicaid spending are static. On the contrary, the state portion of Medicaid spending is estimated to have grown faster than the federal portion, and overall spending is growing rapidly. In 2005 alone, Medicaid spending grew at a rate of 7.7%.

False Claims Act Overview

Congress enacted the federal FCA in 1863 to combat abuse of federal government funded programs in the Civil War reconstruction era. Although its use as an enforcement tool diminished greatly over the century that followed, its use by the federal government re-emerged as a mechanism for addressing abuses in the defense contracting industry in the 1980s. This was due, in part, to amendments to the FCA made in 1986, which significantly expanded the incentives (i.e., monetary awards, damages, and penalties) and reduced the barriers to bringing actions against entities alleged to have engaged in fraud.

In essence, the FCA prohibits the submission of false claims to the federal government for payment. Violations of the FCA are subject to treble damages, penalties of between $5,500 to $11,000 per violation above and beyond the damages subject to the FCA’s trebling provision, as well as attorneys’ fees and costs to successful whistleblowers if they file suit under the qui tam provisions of the FCA. In addition to increasing damages and penalties, the 1986 amendments lowered the standards for intent and burden of proof required to establish liability under the FCA. Some commentators suggest that, as a result of these changes, the FCA’s character has shifted from a true fraud statute into what is, in essence, a “recklessness” statute.

Since the early 1990s, the FCA has expanded well beyond the defense contracting industry and has become the primary enforcement tool used by the federal government in the ever-growing health care industry to combat fraud, waste, and abuse in federal health care programs, including Medicaid and Medicare. Over the past two decades, monetary recoveries have increased sharply, as has FCA litigation involving the health care industry. This is mostly attributable to the 1986 amendments to the FCA and to the increasingly
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complex regulatory environment in which health care organizations operate. This environment presents enormous compliance challenges for health care organizations serving Medicaid and Medicare patients and, concomitantly, heightened exposure to FCA and state false claims law liability. It also creates enormous opportunities for whistleblowers and the federal government to make allegations of regulatory non-compliance under the FCA’s qui tam provisions.

**Qui Tam Enforcement Under The FCA**

The popularity and strength of the FCA as an enforcement tool is a result of its extensive reach. It permits private individuals to act in place of government enforcement agencies under the FCA’s qui tam provisions and gives financial incentives to them to investigate and bring to the federal government allegations of abuse – or perceived abuse – of public funds. The FCA’s qui tam provisions allow these individuals – colloquially referred to as “whistleblowers” and referred to under FCA law as “relators” – to bring and litigate enumerated categories of civil claims on behalf of the federal government.

Qui tam actions are brought under the FCA “for the person and for the United States,” in the name of the United States. The FCA requires a relator to file the complaint under seal, and gives the government sixty (60) days to investigate the relator’s allegations and determine whether to intervene in the suit and take over responsibility for the litigation, or dismiss the suit and take over responsibility for the litigation; 31 in addition to serving the federal government with a copy of the complaint, a relator is required to file with the federal government before filing suit a “written disclosure of substantially all material evidence and information the [relator] possesses.”

After the federal government fully investigates the allegations made by the relator in the complaint and written disclosure, it has several options. It may: (1) notify the court that it will intervene in the suit and take over responsibility for the litigation; (2) formally decline intervention, thus allowing the relator to conduct the litigation on his or her own; (3) move to dismiss the litigation, even over the relator’s objection; or (4) seek to settle the case. If the federal government elects to intervene in the suit, then it takes over control and, importantly for the relator and his or her counsel, the bulk of the work and costs attendant to the litigation. If the federal government declines intervention, then the FCA allows the relator to continue the litigation without the active participation and financial support of the government. If successful, a relator may receive between 15 and 30 percent of any recovery obtained on the government’s behalf, in addition to attorneys’ fees and costs. Once the government makes its decision and determines whether to intervene in the case or decline intervention, the case is unsealed and the litigation – regardless of the government’s election – proceeds very similarly to any other federal case under the Federal Rules of Civil Procedure.

**Primary Liability Provisions Under The FCA**

Under the FCA, liability arises primarily under the provisions of 31 U.S.C. §§ 3729(a)(1)-(7). The government and/or the relator bear the burden of proving by a preponderance of the evidence each element of a FCA violation, including damages. The four most commonly invoked liability provisions of the FCA include:

- Section 3729(a)(1), also known as “direct” false claims to the federal government, which imposes liability for submitting or causing another to submit a false claim;
- Section 3729(a)(2), which imposes liability for the making of false records or false statements to support a false claim;
- Section 3729(a)(3), which imposes liability for participation in a conspiracy to submit a false claim for payment; and
- Section 3729(a)(7), also known as “reverse false claims provision,” which imposes liability for the submission of a false claim or statement to avoid payment of, or to decrease, an obligation to the government.

**DRA Employee Education Provision Requirements**

As mentioned earlier, the DRA’s Employee Education Provision requires most health care organizations that operate under the Medicaid program to establish and implement an education plan for employees, managers, contractors, and agents. This plan must include written policies and detailed guidance on the FCA, state false claims laws, and the rights and protections afforded to whistleblowers under the FCA and its state counterparts. The statutory language related to the Employee Education Provision, however, is vague and lacks detailed descriptions of what is required by Covered Entities to ensure full compliance with its mandates. Although CMS issued a letter to state Medicaid directors on December 13, 2006 and hosted a January 11, 2007 teleconference in an effort to provide guidance, key portions of the Employee Education Provision remain unclear and many questions of Covered Entities unanswered.

**What Are The Specific Requirements Of The Employee Education Provision?**

The Employee Education Provision of the DRA, codified at Section 6032, amends Section 1902(a) of the Social Security Act by, among other things, directing the states to:

Provide that any entity that receives or makes annual payments under the State plan of at least $5,000,000, as a condition of receiving such payments shall –

(A) establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about the [federal] False Claims Act … any State laws pertaining to civil or criminal penalties for false claims continued on page 22
Employee Education Provision.

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December 13, 2006 attempted to offer

at least $5,000,000" be subject to the
annual payments under the State plan of
that "any entity that receives or makes
payments, under a State plan approved under title XIX or under
waiver of such plan, totaling at least
$5,000,000 annually.

If an entity furnishes items or services
at more than a single location or
under more than one contractual or
other payment arrangement, the
provisions of section 1902(a)(68)
apply if the aggregate payments to
that entity meet the $5,000,000
annual threshold. This applies
whether the entity submits claims
for payments using one or more
provider identification or tax
identification numbers.

A government component providing
Medicaid healthcare items or
services for which Medicaid
payments are made would qualify as
an entity (e.g., a State mental health
facility or school district providing
school-based health services). A
government agency which merely
administers the Medicaid program,
in whole or part (e.g., managing the
claims processing system or deter-
mining beneficiary eligibility), is not,
for these purposes, considered to be
an entity.

An ‘entity’ includes a governmental
agency, organization, unit, corpora-
tion, partnership, or other business
arrangement (including any Medi-
caid managed care organization,
irrespective of the form of business
structure or arrangement by which it
exists), whether for-profit or not for
profit, which receives or makes
payments, under a State plan
approved under title XIX or under
waiver of such plan, totaling at least
$5,000,000 annually.

and statements, and whistleblower
protections under such laws, with
respect to the role of such laws in
preventing and detecting fraud,
trade, and abuse in federal health-
care programs.…

(B) include as part of such written
policies, detailed provisions regard-
ing the entity’s policies and
procedures for detecting and
preventing fraud, waste, and abuse; and

(C) include in any employee hand-
book for the entity, a specific
discussion of the laws described in
 subparagraph (A), the rights of
employees to be protected as
whistleblowers, and the entity’s poli-
cies and procedures for detecting and
preventing fraud, waste, and abuse.42

What Health Care
Organizations Are Covered
Entities Under The Employee
Education Provision?

Statutory Language

Section 6032(a)(3) of the DRA
adds language to Section 1902(a) of the
Social Security Act,43 which provides
that “any entity that receives or makes
annual payments under the State plan of
at least $5,000,000” be subject to the
Employee Education Provision.44

CMS Guidance

The CMS Letter issued on
December 13, 2006 attempted to offer
guidance to state Medicaid directors for
implementing the Employee Education
 Provision into their state plans, which
are binding on Medicaid providers in
their states.45 For the most part, the
CMS Letter essentially reiterates the
elements of Section 6032 and confirms
the January 1, 2007 deadline for compli-
ance. One area specifically addressed in
the CMS Letter, however, is which
“entities” constitute Covered Entities
subject to the requirements of the
Employee Education Provision.

Based on the foregoing guidance by
CMS, Covered Entities should be
considered to include an entity formed
under any type of business arrange-
ment as long the aggregate annual Medicaid
reimbursement totals at least $5 million
during the preceding fiscal year. Thus, it
makes no difference whether an entity
meeting the $5 million threshold
provides Medicaid services at multiple
locations within a state; whether it oper-
ates using multiple provider or tax
identification numbers; or whether
multiple contractual or other arrangements are involved. CMS’s broad definition is at odds with other laws and regulatory provisions that specifically recognize that many related, but separate entities have their own individual provider numbers or tax identification numbers and operate as separate entities. It also casts an overly broad net to the extent that it regards numerous related entities operating separately as a single unit. Nonetheless, without further guidance and/or the implementation of laws or regulations limiting this definition, health care organizations that serve as Medicaid providers/beneficiaries should err on the side of caution and heed CMS’s expansive interpretation to assess whether they constitute a Covered Entity for purposes of the Employee Education Provision. The risks of any other approach at this time include potential exposure to action under the FCA and/or state false claims laws, forfeiture of Medicaid payments, and exclusion from the Medicaid program altogether. These risks are simply too great to ignore.

To Whom Is A Covered Entity Required To Convey The Information Required Under The Employee Education Provision?

Statutory Language

Section 6032(a)(3) of the DRA adds language to Section 1902(a) of the Social Security Act mandating that Covered Entities convey the information specified in the Act to “all employees of the entity (including management), and of any contractor or agent of the entity.”

CMS Guidance

Under a strict interpretation of the applicable statutory language, a Covered Entity is required to convey the information included in its written policies and provided definitions for “employee,” “contractor,” and “agent.” As described in the CMS Letter, an “employee” for purposes of the Employee Education Provision is defined by CMS to include “any officer or employee of the [Covered] Entity.” As to “contractor” and “agent,” the CMS Letter offered the following:

A “contractor” or “agent” includes any contractor, subcontractor, agent, or other person which or who, on behalf of the entity, furnishes, or otherwise authorizes the furnishing of Medicaid healthcare items or services, performs billing or coding functions, or is involved in monitoring of healthcare provided by the [Covered] Entity.

During the CMS Teleconference, some Medicaid providers asked questions regarding the definitions contained in the CMS Letter. One participant asked if billing and coding vendors would constitute “contractors” under the Employee Education Provision. CMS confirmed that billing and coding vendors are considered contractors, but that copying and shredding service providers or manufacturers who are not directly paid by Medicaid are not considered contractors. Another participant in the CMS Teleconference sought guidance as to whether a Medicaid managed care health plan with thousands of contracts with participating providers would be required to amend all of these contracts to comply with the DRA’s Employee Education Provision, while another asked whether a hospital’s medical staff members were considered contractors. Rather than provide a direct response to these inquiries, CMS stated that they were in areas requiring further analysis by CMS and indicated that follow-up guidance would be provided.

In addition to the foregoing areas of inquiry during the CMS Teleconference, a question was posed as to whether an entity’s contractors were required to adopt the policies of the entity based on the use of the term “adopt” in the CMS Letter, which conspicuously is a term not employed in the DRA itself. In response, CMS indicated that the CMS Letter language would remain unchanged and that adoption by contractors is required. CMS’s position on this point was challenged when a participant pointed out that, if enforced, the use of the term “adopt” would mean that, if an entity requires FCA education for its employees as part of its compliance program as mandated by the DRA, its contractors would also be required to educate their employees about the FCA. Moreover, it would require all providers that contract with a Medicaid managed care organization ("MCO") that reaches the $5 million threshold to comply with the MCO’s policies. Compounding this would be the problem encountered by a provider who contracts with several covered MCOs with different and even contradictory policies. It was asserted that requiring such adoption by contractors, who did not themselves meet the $5 million threshold would constitute an impermissible and exponential expansion of the DRA’s coverage.

Consistent with its other responses – or non-responses as it were – CMS indicated that the issue of coverage would require further analysis by CMS and indicated that follow-up guidance would be forthcoming. Importantly, however, CMS did not relent in its insistence that, despite its infirmities, the statutory language and prior CMS guidance would remain enforceable in the interim. As the Acting Director of the CMS Medicaid Integrity Group, Robb Miller, reportedly stated to participants in the CMS Teleconference, “I understand your consternation about having to have additional communication with thousands of physicians and hospitals, but the law says you will, and I don’t know how to get around that ….

Your contractors would need to adopt [your policies],” adding that CMS has “already recognized that this will create some further challenges and will address that in the very near future.”

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Practical Guidance

Although broad, the guidance provided in the CMS Letter through its definitions of “employee,” “contractor,” and “agent,” is helpful as it does serve to limit these otherwise expansive terms to those individuals and entities that actually have a relationship to the provision of Medicaid health care items or services. Even with these definitions and limitations, as made clear in the CMS Teleconference, the scope of those to whom the information contained in the written policies is required to be conveyed is broad because it extends not only to employees of the Covered Entity, but also to all employees of any contractor or agent of the Covered Entity related to the provision of Medicaid health care items or services. Consequently, Medicaid providers that are subject to the Employee Education Provision must ensure that the required information is: (1) contained in written policies; (2) disseminated to employees, managers, contractors, and agents; and (3) adopted by all contractors.

What Information Is A Covered Entity Required To Convey Under The DRA’s Employee Education Provision?

Statutory Language

The exact language of Section 6032(a)(3) of the DRA, requiring Covered Entities to “establish written policies” for all employees, management, contractors, and agents, is quoted above.

CMS Guidance

The CMS Letter is of limited use in providing direction to Covered Entities as to the information required to be conveyed under the DRA’s Employee Education Provision, in that it provides neither specific guidance nor model language. Rather, it simply states:

[A Covered] [E]ntity shall establish written policies for all employees (including management), and of any contractor or agent of the entity, that include detailed information about the False Claims Act and the other provisions named in section 1902(a)(68)(A). The [Covered] [E]ntity shall include in those written policies detailed information about the [Covered] [E]ntity’s policies and procedures for detecting and preventing waste, fraud, and abuse. The [Covered] [E]ntity shall also include in any employee handbook a specific discussion of the laws described in the written policies, the rights of employees to be protected as whistleblowers and a specific discussion of the [Covered] [E]ntity’s policies and procedures for detecting and preventing waste, fraud, and abuse. The Centers for Medicare & Medicaid Services (CMS) is not providing model language, though States may elect to do so.51

During the CMS Teleconference, questions were posed by Medicaid providers as to the level of specificity required in the written policies mandated by the Employee Education Provision. In response, CMS stated that it would not provide model language to be used by Covered Entities in these written policies. CMS explained that it was not qualified to provide such model language, but that it was, in response to requests by some Medicaid State Agencies for model language, working with the OIG and the United States Department of Justice to obtain a uniform description of the FCA so that Medicaid providers and states do not incorrectly interpret the FCA in their written policies. It remains unclear, however, if and when such a uniform description of the FCA will be made available.

Practical Guidance

Based on the statutory language and the limited guidance provided by CMS, it is clear that a Covered Entity is required to establish written policies that, at the very least:

• Provide detailed information about the FCA, including the role of the FCA in preventing and detecting Medicaid fraud, waste, and abuse;
• Describe available remedies for false claims and statements covered by the FCA;
• Provide detailed information about state false claims laws, including laws pertaining to civil or criminal penalties for false claims and statements and the role of such laws in preventing and detecting Medicaid fraud, waste, and abuse;
• Explain qui tam provisions applicable to the FCA and/or state false claims laws;
• Provide information regarding whistleblower protections under the FCA and/or state false claims laws;
• Describe the Covered Entity’s own detailed compliance policies and procedures for detecting and preventing Medicaid fraud, waste, and abuse; and
• Set forth in the Covered Entity’s employee handbook, if any, a specific discussion of the FCA and any applicable state false claims laws in existence, the rights of whistleblowers, and the Covered Entity’s policies and procedures for detecting and preventing Medicaid fraud, waste, and abuse.

How Should A Covered Entity Convey The Information Specified Under The DRA’s Employee Education Provision?

Statutory Language

As noted above, Section 6032(a)(3) of the DRA adds language to Section 1902(a) of the Social Security Act requiring that a Covered Entity must establish written policies for all employees, management, contractors, or agents and “include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the
The CMS Letter states:

It is the responsibility of each [Covered] [E]ntity to establish and disseminate written policies, which must also be adopted by its contractors or agents. Written policies may be on paper or in electronic form, but must be readily available to all employees, contractors, or agents.

Although section 1902(a)(68)(C) refers to “any employee handbook,” there is no requirement that an entity create an employee handbook if none already exists.54

During the CMS Teleconference, CMS confirmed that Covered Entities are not required to conduct training or education programs for employees, management, contractors, and/or agents. As to the issue of employee handbooks, one participant asked whether a compliance plan could be amended instead of the entity’s employee handbook. In response, CMS made clear that, although the law does not require a Covered Entity to create an employee handbook if one does not already exist, if a Covered Entity has an employee handbook, the required information must be included in the handbook and simply amending a compliance plan in this situation would not suffice.

Practical Guidance

Importantly for Covered Entities, there is no explicit training requirement contained within the DRA’s Employee Education Provision.55 Although language was offered to address such a requirement, this language was deleted before the DRA was enacted.56 In addition, although Section 6032 of the DRA bears the title “Employee Education About False Claims Recovery,” it does not utilize the term “educate” or any derivative thereof. Indeed, there is no requirement in the statutory language of Section 6032 or CMS guidance that requires providers to “educate” their employees. The only requirement related to any type of affirmative education steps is not found in the statutory language, but rather in CMS’s recent guidance stating that “[i]t is the responsibility of each [Covered] [E]ntity to establish and disseminate written policies which must also be adopted by its contractors or agents.”57

Setting aside the fact that there is no explicit training or education requirement under the statutory language of Section 6032 and/or the CMS guidance provided, a Covered Entity must still establish and disseminate the required information contained in required written policies to employees, management, contractors, and agents. As recognized by CMS, the dissemination of the required information is necessary to effectuate the intent underlying the DRA’s Employee Education Provision. As with many other provisions of the DRA’s Employee Education Provision, however, there is a conspicuous lack of guidance on this issue. While it is clear that the Employee Education Provision requires Covered Entities that utilize employee handbooks to include the described information in them, Covered Entities that do not have such handbooks are not required to create and/or utilize one. Thus, many questions remain, including how a Covered Entity – particularly one without an employee handbook – should disseminate the required information.

The challenges to Covered Entities are how to inform employees of the required information without encouraging frivolous reporting or claims of fraud; how to disseminate the required information to employees, managers, contractors, and agents; whether and how to train these individuals; and how to track and record this for compliance audit purposes. In endeavoring to meet these challenges, Covered Entities should consider:

- Creating an employee handbook if one doesn’t already exist or updating an existing one and using this as a vehicle to disseminate the written policies required under the DRA’s Employee Education Program to current and new employees, managers, contractors, and agents;
- Incorporating the required written policies into existing corporate, compliance, Code of Conduct, and/or human resource policies and/or manuals (as described by CMS, the policies can be in hardcopy and/or electronic form);
- Incorporating the required written policies in a written notice to current and new employees, managers, contractors, and agents, including dissemination (hardcopy or electronic form) of a handbook including the required written policies; and
- Utilizing an intranet or internet-based distribution and acknowledgement/adoption process regarding handbooks and/or written policies, to facilitate logistics, tracking, and compliance auditing.

Because compliance with the DRA is a condition of Medicaid reimbursement as of January 1, 2007, failure to comply could result in FCA and state false claims law exposure. Therefore, Covered Entities that have not already done so should move forward with adopting and distributing the required written policies and amending employee handbooks (if any) based on the limited information and guidance provided to date. Of course, revised written policies and subsequent amendments to any employee handbooks will likely be necessary to comply with state Medicaid plan amendments, once issued, and to comply with follow-up guidance from CMS once it becomes available.

Conclusion

The DRA’s Employee Education Provision places significant compliance burdens upon Covered Entities and, in conjunction, exposes them to

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Draconian penalties if they fail to fully and immediately meet these burdens. The specific requirements Covered Entities must meet to satisfy these new compliance burdens, however, are anything but clear. The statutory language is vague, there are no clarifying regulations implemented, and there is a paucity of agency-level “guidance.” In contrast, there has been abundant clarity regarding both the January 1, 2007 effective date for enforcement of the DRA’s Employee Education Provision and the significant sanctions health care entities could face if they fail to fully and immediately comply. The effect has been and continues to be high anxiety among those in the health care community about what is needed to comply, whether they are in compliance, and whether they will be the target of a compliance audit and/or enforcement action. This heightened state of anxiety will not subside unless and until further clarification and/or seeking of outside counsel should be encouraged.

Thus, Covered Entities are currently left to their own devices to do their best to ensure compliance and minimize exposure risks. Following the suggestions outlined in this article and/or seeking the assistance of outside counsel should help in this endeavor, but ultimately, unless and until further clarification and compliance guidance is provided, nothing can ensure full compliance and/or provide affected health care organizations with the assurance and certainty they need and rightly deserve.

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Endnotes

1 Deficit Reduction Act of 2005, Pub. L. 109-171 (2006) (“DRA”). The validity of the DRA has been challenged on the basis that, due to a clerical error, on February 8, 2006, President Bush signed the Senate version of the bill, which differed from the version approved by the House of Representatives. See, e.g., Jonathan Weisman, Spending Measure Not a Law, Suit Says, WASH. POST, Mar. 22, 2006 at A4. Technically, the House never voted on the exact version approved by the Senate and signed by the President, due to a clerical error in the formal “enrolling” of the Senate and signed by the President, due to a clerical error in the formal “enrolling” of the House of Representatives. See, e.g., Jonathan Weisman, Spending Measure Not a Law, Suit Says, WASH. POST, Mar. 22, 2006 at A4. Technically, the House never voted on the exact version approved by the Senate and signed by the President, due to a clerical error in the formal “enrolling” of the bill after its Senate approval in December 2005. This is problematic because, pursuant to Article 1, Section 7, the Bicameral Clause of the Constitution, before a bill may signed into law by the President, it must have been passed in identical form by both the House and the Senate. See U. S. Const. art. I, § 7. See also Immigration and Naturalization Service v. Chadha, 462 U.S. 919, 948-951 (1983). The provisions of the bill discussed herein, however, are the same in both the signed Senate version of the bill and the bill passed by the House.

2 31 U.S.C. §§ 3729 et seq.


4 See infra n. 39.


6 42 U.S.C. §§ 1396 et seq.

7 See DRA § 6031 (amending Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq., by adding Section 1909).

8 See DRA § 6031(b). Although states generally have until January 1, 2007 to enact a qualifying state false claims law to be eligible for the financial incentive, the DRA allows a state additional time if state legislation is needed in order for the state’s Medicaid plan to meet the DRA requirements. In such cases, the state will not be deemed out of compliance with the DRA until the first day of the first quarter after its next regular legislative session after the DRA’s enactment (i.e., February 8, 2006).

9 Id. See also DRA § 6031(d). This section, titled No Preclusion of Broader Laws, states that the DRA shall not be construed as prohibiting a state from having a law that is broader than the FCA, as long as it meets the DRA’s requirements.


States- which have introduced new legislation, include Mississippi, Missouri, North Dakota and South Carolina.

14 Publication of OIG’s Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48552 (Aug. 21, 2006). Subsection (1) of DRA Section 6032(b) contemplates that the OIG, in consultation with the United States Attorney General, will determine whether a state false claims law complies with the DRA’s mandates. Senator Grassley, who authored the relevant provisions of the DRA, has taken an active role in ensuring that rigorous reviews are conducted of state false claims laws to ensure that they contain expansive qui tam provisions and other enforcement provisions as stringent, if not more stringent, than those contained in the FCA. He has written two letters, addressed to the Inspector General and the Attorney General, to compel states to adopt laws that meet or exceed the FCA’s provisions by stressing that the DRA requires that state false claims provisions be “at least as effective in rewarding and facilitating qui tam actions” as the federal qui tam provisions. See, Frank E. Sheeder III, The Medicaid Fraud and Abuse Provisions of the Qui Tam Actions, 28 U.S.C.A. § 2461 note (2002); 28 C.F.R. § 85.3(9) (2000). The FCA previously provided for the imposition of a civil penalty “of not less than $5,000 and not more than $10,000 for each false claim.” 31 U.S.C. § 3729(a). This penalty range was adjusted for inflation under the Federal Civil Monetary Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410, Title III, § 31001, and the Debt Collection Improvement Act of 1996, Pub. L. No. 104-134, to between $5,500 and $11,000 for conduct occurring after September 29, 1999. 28 U.S.C.A. § 2461 note (2002); 28 C.F.R. § 85.3(9) (2000). The next inflationary increase that could have been implemented under the Inflation Adjustment Act was due, according to the analysis of a General Accounting Office report, on August 30, 2003, Gen. Acct. Off., GAO-03-409, Agencies Unable to Fully Adjust Penalties for Inflation Under Current Law, at 13 (Mar. 2003), but no additional penalty increase was announced by the Department of Justice by that date. The Medicare prescription drug bill that was passed by the Senate in June 2003 contained provisions that would have increased the statutory minimum penalty from $5,000 to $7,500 and the maximum from $10,000 to $15,000, Prescription Drug and Medicare Improvement Act of 2003, S. 1, 106th Cong. § 612 (2003), but that language was ultimately omitted from the final legislation. The imposition of at least the minimum FCA penalties is generally accepted to be mandatory, United States v. Bornstein, 423 U.S. 303 (1976); Brown v. United States, 524 F.2d 693 (Ct. Cl. 1975), although some courts have either not imposed any penalties and others have reduced the FCA’s penalties below the minimum provided for under the FCA citing. See, e.g., United States v. Cabrera-Diaz, 106 F. Supp. 2d 234 (D.P.R. 2000) (refusing to impose any penalties at all, because they would be excessive). See also United States v. Mackby, 261 F.3d 821 (9th Cir. 2001) (holding that FCA damages and penalties are subject to Eighth Amendment protections against excessive penalties).


26 28 U.S.C.A. § 2461 note (2002); 28 C.F.R. § 85.3(9) (2000). The FCA previously provided for the imposition of a civil penalty “of not less than $5,000 and not more than $10,000 for each false claim.” 31 U.S.C. § 3729(a). This penalty range was adjusted for inflation under the Federal Civil Monetary Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410, Title III, § 31001, and the Debt Collection Improvement Act of 1996, Pub. L. No. 104-134, to between $5,500 and $11,000 for conduct occurring after September 29, 1999. 28 U.S.C.A. § 2461 note (2002); 28 C.F.R. § 85.3(9) (2000). The next inflationary increase that could have been implemented under the Inflation Adjustment Act was due, according to the analysis of a General Accounting Office report, on August 30, 2003, Gen. Acct. Off., GAO-03-409, Agencies Unable to Fully Adjust Penalties for Inflation Under Current Law, at 13 (Mar. 2003), but no additional penalty increase was announced by the Department of Justice by that date. The Medicare prescription drug bill that was passed by the Senate in June 2003 contained provisions that would have increased the statutory minimum penalty from $5,000 to $7,500 and the maximum from $10,000 to $15,000, Prescription Drug and Medicare Improvement Act of 2003, S. 1, 106th Cong. § 612 (2003), but that language was ultimately omitted from the final legislation. The imposition of at least the minimum FCA penalties is generally accepted to be mandatory, United States v. Bornstein, 423 U.S. 303 (1976); Brown v. United States, 524 F.2d 693 (Ct. Cl. 1975), although some courts have either not imposed any penalties and others have reduced the FCA’s penalties below the minimum provided for under the FCA citing. See, e.g., United States v. Cabrera-Diaz, 106 F. Supp. 2d 234 (D.P.R. 2000) (refusing to impose any penalties at all, because they would be excessive). See also United States v. Mackby, 261 F.3d 821 (9th Cir. 2001) (holding that FCA damages and penalties are subject to Eighth Amendment protections against excessive penalties).

30 31 U.S.C. § 3730(d)(1). The FCA also provides, on a very limited basis, for the possibility of the recovery of fees and expenses if the government does not intervene, and if the court finds that the relator’s claim was “clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.”

31 Id.

40 On January 11, 2007, CMS held a national teleconference for Medicaid providers to address the Employee Education Provision as contained in Section 6032 of the DRA. The teleconference was a question and answer format and CMS made clear at the outset that answers provided by CMS during the call did not constitute CMS’s official policy. Not only did this caveat ecate the utility of the teleconference, there were other limitations that diminished its potential. For instance, although over 800 callers participated, only 43 callers were able to pose questions in the time allotted for the teleconference. Moreover, during the course of the teleconference, representatives of CMS were unable to answer many questions, advising callers that many of the issues raised would require further analysis and follow-up by CMS. CMS representatives advised callers during the course of the teleconference that they could submit additional questions to them via the following website: medicaid_integrity_program@cms.hhs.gov. Callers were advised that CMS would consider such questions in preparing its next “guidance.”


51 CMS Letter.
During the January 11, 2007 teleconference, CMS reiterated that no formal training is required for compliance with the Employee Education Provision.

The offered language would have added a subparagraph (D), which would read as follows, “require mandatory training for all employees of the entity and of any contractor or agent of the entity, at the time of hiring, with respect to the laws described in subparagraph (A) (including the whistleblower protections under such laws) and the entity’s policies and procedures for detecting fraud, waste, and abuse.” If not deleted, it would have required covered entities to not only inform, but also train new hires, and those of their contractors and agents, regarding the applicable false claims statutes and the provider’s fraud detection and prevention policies and procedures. Some of the reporting has indicated, incorrectly, that the training provisions were part of the legislation enacted; they were not. The House-Senate Conference Agreement deleting the affirmative training requirement contained in subpart (D) explains that the amendment agreed upon “does not require the establishment of protocols and procedures for training of employees (i.e., only written policies are required).” H.R. Rep. No. 109-362, at 305 (2005).

This article should not be construed as constituting legal advice on any specific facts or circumstances. Its contents are intended for general information purposes only and are specifically not intended to constitute legal advice. The author encourages entities that receive Medicaid reimbursement to review their applicable policies, and to seek out legal guidance in order to ensure that any proposed policies to be adopted by the entity adequately comply with the DRA’s Employee Education Provision.