

# HEALTH LAW

## Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

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## Further Guidance from CMS on False Claims Act Education Requirements for Medicaid Providers

April 26, 2007

In March of 2007, the Centers for Medicare & Medicaid Services (CMS) issued a letter to all State Medicaid Directors (the March Guidance) providing further guidance on new false claims recovery education requirements that took effect at the beginning of this calendar year under the Deficit Reduction Act of 2005 (DRA). Section 6032 of the DRA (the DRA Education Provision) requires every entity that makes or receives at least \$5 million annually in Medicaid payments to establish, by January 1, 2007, written policies for all of its employees, contractors, and agents providing “detailed information” about false claims, false statements, and whistleblower protections under federal and state fraud and abuse laws. These policies must also describe the entity’s policies and procedures for preventing and detecting fraud, waste, and abuse.

At the end of last year, many healthcare organizations found themselves struggling to interpret and correctly implement these new requirements. Although CMS issued certain initial guidance in the form of a letter to state Medicaid agencies dated December 13, 2006 (the December Letter), and also sponsored a teleconference on the DRA Education Provision on January 11, 2007 (the January Teleconference), questions have lingered. The March Guidance, which represents CMS’ latest round of guidelines on this topic, contains CMS’ answers to certain frequently asked questions about the DRA Education Provision and also contains a uniform summary of the Federal False Claims Act (FCA) prepared by the Department of Justice (DOJ). This *Health Law Update* summarizes certain highlights of the March Guidance.

**Which “entities” meet the \$5 million threshold?** The first step in determining whether the \$5 million threshold is met is to define the “entity.” The March Guidance indicates that, for purposes of the DRA Education Provision, an entity is the largest separate organizational unit that furnishes Medicaid healthcare items or services and includes all sub-units of that organizational unit that furnish Medicaid healthcare items or services. This definition applies even if the components are separately incorporated, located in different states, have separate employer identification numbers, or bill under separate provider numbers.

With respect to a health system, CMS views both the parent and its sub-units as integrally involved in furnishing Medicaid services, and therefore the March Guidance clarifies that the entire health system is the entity. If the organizational unit is not part of a health system, each organizational unit is viewed separately for purposes of determining whether the \$5 million threshold has been met. Note the comment in the March Guidance that pharmaceutical manufacturers are not “entities” solely by virtue of making Medicaid drug rebate payments to states.

**How is the \$5 million threshold calculated?** An entity is subject to the DRA Education Provision if it annually receives or pays \$5 million in Medicaid payments. The annual measuring period is the federal fiscal year, i.e., from October 1 to September 30. With respect to compliance as of January 1, 2007, entities should look to payments received or made between October 1, 2005 and September 30, 2006. Similarly, for compliance as of January 1, 2008, entities should look to the period from October 1, 2006 through September 30, 2007.

The March Guidance indicates that an entity need not combine Medicaid payments from multiple states to meet the \$5 million threshold; however, if the \$5 million threshold is met with respect to one state, then the entity must comply with the DRA Education Provision in all states in which the entity operates. Furthermore, only money received from a state’s Medicaid agency, and not from Medicaid managed care organizations (MCOs), should be counted toward the \$5 million threshold. In addition, the March Guidance clarifies that an entity should count only the amount actually received from Medicaid and not the amount billed. Patient co-payments do not count toward the threshold and Medicare payments generally do not count toward the threshold, unless the payments consist of Medicare deductibles or co-insurance paid by the state Medicaid agency for dual-eligible individuals or Qualified Medicare Beneficiaries.

The March Guidance also indicates that an entity that both makes and receives Medicaid payments, e.g., a Medicaid MCO, should not aggregate these amounts to meet the \$5 million threshold. Therefore, a Medicaid MCO receiving \$3 million in payments and paying out \$2 million during a relevant federal fiscal year will not have to aggregate these amounts to meet the \$5 million threshold.

**What are the responsibilities of an entity’s contractors and agents under the DRA Education Provision?** As mentioned above, the DRA Education Provision requires an entity meeting the annual \$5 million threshold to disseminate detailed information about the entity’s internal policies regarding false claims and fraud and abuse to all of the entity’s employees, contractors, and agents. The March Guidance indicates that the term “contractors” for this purpose encompasses all contractors who furnish or authorize the furnishing of Medicaid healthcare items and services or who are involved in the monitoring of healthcare on behalf of the entity. These contractors include, but are not limited to, contract therapists, physicians (including, according to the March Guidance, “house staff, hospitalists, and independent contractors”), pharmacies, and billing and coding vendors.

Note that all such vendors who have a contractual relationship with the entity are considered “contractors” even if the contract has been reduced to writing. However, individuals or businesses performing functions that are not associated with the provision of Medicaid healthcare items or services, such as copy or shredding services, grounds maintenance, or hospital cafeteria or gift shop

services, are not encompassed within this definition. Also, the March Guidance observes that, in the case of a group purchasing organization (GPO) arrangement, the medical supply vendors that contract with the GPO to serve the entities who are the members of the GPO will “in most instances” be the contractor of the GPO, not of the entities (although CMS cautions that there may be exceptions to this general observation).

CMS had stated in its December Letter that an entity’s written policies must be “adopted” by the entity’s contractors and agents. During the January Teleconference, CMS informally reaffirmed that contractors must “adopt” the entity’s policies. This wording led to concerns that requiring such adoption by contractors, who did not themselves meet the \$5 million threshold, might constitute an expansion of the DRA Education Provision’s applicability that was not authorized or intended by Congress. In the March Guidance, CMS avoids the word “adopt” and explains that an entity must disseminate its policies to contractors and agents, which must then “abide by” the policies relevant to the work the contractor or agent performs for the entity. There is no requirement, according to the March Guidance, that an entity’s contracts with its vendors and other contractors be amended to recite the language of the DRA Education Provision.

The entity must also make its policies available to the contractor’s or agent’s employees involved in performing the work for the entity. To the extent that an entity’s policies provide for reviews or audits of claims or services, contractors and agents must participate in those reviews or audits.

Thus, a contractor who contracts with multiple entities will be required to comply with the various respective compliance policies of the entities (presumably even if they contain conflicting provisions). In disseminating policies—whether to employees, contractors, or agents—CMS stated that the policies may be in written or electronic form, so long as employees, contractors, and agents are aware of and have ready access to the policies.

**Model language for entities and the scope of “detailed information.”** Accompanying the March Guidance, CMS included the DOJ’s “official description of the Federal False Claims Act.” Entities should consider adopting the DOJ’s language into their respective employee education materials. At least for now, CMS expressly has declined to provide any other model language for policies implementing the DRA Education Provision. In addition, CMS has declined to specify the level of detail for the required “detailed information” to be given to employees, contractors, and agents. Furthermore, the March Guidance states that CMS will not prescribe the specific manner, frequency, or form in which entities should disseminate their policies or how they should document the dissemination of policies to employees, contractors, and agents.

If you have questions or would like a copy of the DOJ’s official description of the FCA, or if you would like assistance in incorporating any of this additional guidance into your compliance policies, please contact one of the Bass, Berry & Sims attorneys in our Healthcare Practice Area listed at the end of this Update.

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