

January 12, 2007

**Summary CMS Teleconference
Deficit Reduction Act - Employee Information Requirements
January 11, 2007
1:00 – 2:45 pm**

Covered Entities

Many questions focused on the types of covered entities and the calculation of the \$5 million threshold. The majority of these questions focused on how to aggregate payments for entities that may have multiple subsidiaries or provider numbers, or the types of payments that are to be included in assessing application of the \$5 million threshold.

- **Aggregating Payments.** Callers asked specific questions about whether Medicaid revenues received by certain types of separate but affiliated entities were to be aggregated to determine whether the \$5 million threshold had been met, particularly where affiliates bill a state Medicaid program under more than one provider number. For example, one caller asked about aggregating payments for a hospital and separately by its individual LLCs. In this case, Mr. Miller indicated that the Medicaid payments for each entity should be aggregated. According to Mr. Miller, if, in aggregate, payments from a state Medicaid plan total \$5 million, then the DRA requirements apply to both the hospital and each separate entity. The DRA also would apply if the payments to the hospital and each separate LLC individually totaled \$5 million. One caller asked whether this would be the case if the parent corporation was not a provider. Mr. Miller indicated that he would give this issue further consideration and would include a response in the agency's additional guidance.
- **Payments Included in the \$5 Million Threshold.** Here, several callers inquired as to whether the \$5 million threshold applies to amounts billed by the entity or actual payments received, and whether individual payments from Medicaid patients also would be included. Mr. Miller indicated that the payment threshold applies to actual payments received and that co-payment or deductible amounts received from individual Medicaid patients are not included. Importantly, for entities that operate in multiple states, Mr. Miller indicated that the entity should look only at the payments received from each individual

state in determining whether the \$5 million threshold has been met for that state.

- **Distribution to Non-Healthcare Affiliates.** County and university representatives inquired as to whether DRA-compliant materials had to be distributed to non-healthcare components of county governments or universities. Mr. Miller advised that the materials need only be distributed to healthcare components of mixed-function organizations.

Contractors and Agents

Responses to questions in this area brought some good news, but also raised additional issues, particularly for suppliers and manufacturers who supply healthcare items to covered entities.

- **Entity Flexibility.** On the positive side, the theme of CMS's response to the multitude of questions regarding an entity's obligation to provide contractors and agents with the entity's policy and procedures was that the agency has deliberately chosen not to be prescriptive in this area, leaving entities the freedom and flexibility to incorporate these requirements into their individual business practices. For example, Mr. Miller indicated that entities are not required to amend contracts to comply.
- **Scope of Covered Contractors and Agents.** The responses here were somewhat of a mixed bag. On the positive side, for hospitals and other entities that may have attending or medical staff physicians, Mr. Miller indicated that these physicians would not be considered the entity's agent solely by virtue of their being credentialed members of a medical staff; however, the agency will be considering the issue further and expects to provide a more formal response to this question in the additional guidance issued. Mr. Miller expressed the view that physicians on staff who also received compensation from the entity under a contract would need to be covered by the entity's policy. Unfortunately, such a narrow view was not taken with respect to suppliers and manufacturers who provide healthcare items to an entity. Here, Mr. Miller indicated that suppliers who have a contract to provide items such as "pressure bandages" that may be used on Medicaid patients would be furnishing Medicaid healthcare items on behalf of an entity and thus would fall within the agency's definition of a contractor. Mr. Miller took a similar view for medical device manufacturers; in this regard, he indicated that manufacturers who have a direct contract with an entity would be considered a contractor, but manufacturers that sell through a distributor or that do not have a direct contract with an entity, would not fall within the definition of a contractor. The response in this area raised enough concern that Mr. Miller indicated the agency would further consider the issue and add this to the list of areas that it will address in its additional guidance.

- **Requirement for Contractors and Agents to “Adopt” an Entity’s Policies.** Several callers questioned CMS’s requirement that contractors and agents “adopt” an entity’s policies and procedures. Initially, Mr. Miller stood by the agency’s guidance and explicitly indicated that the agency had no intention of changing the language in either the guidance or the State Plan Preprint. When pressed further about the challenges presented to contractors who may be faced with “adopting” multiple versions of similar policies and procedures, and the absence of an apparent statutory basis for the requirement, Mr. Miller conceded that the agency recognizes these concerns and will further address the issue in its additional guidance. In this regard, Mr. Miller noted that some states had expressed an interest in the development of a uniform description of the federal False Claims Act. Mr. Miller indicated that the agency is exploring the idea with the Department of Health and Human Services, Office of Inspector General and the Department of Justice, stating that such a description was beyond the expertise of CMS. Most notably, when pressed, Mr. Miller offered no clear articulation of how CMS expects contractors who “adopt” an entity’s policies to behave. While Mr. Miller seemed to indicate that merely providing a copy of the entity’s policy would not alone be enough, he did not suggest what additional steps might satisfy the guidance. As noted, further guidance on this topic was promised.

In summary, a number of questions remain open with respect to identifying and doing business with contractors and agents. CMS did at least clarify that the DRA does not require entities to amend contracts and that the agency’s guidance is intended to avoid being “overly prescriptive.” Mr. Miller explained that CMS intended to leave entities latitude to effectively incorporate the DRA requirements into individual circumstances and business practices.

Employee Training

Mr. Miller made clear that employee training on an entity’s policies is not required.

Application to Pharmaceutical Manufacturers. One caller explicitly asked whether the DRA requirements apply to pharmaceutical manufacturers by virtue of rebate payments alone. Surprisingly, Mr. Miller’s response was “no.” We note that Mr. Miller’s response appears to be inconsistent with the language of the statute, which applies to any entity that receives or makes annual payments under a State Plan of at least \$5 million. Because Mr. Miller’s statements during the call are not a formal agency position, we believe the issue should be clarified to confirm the agency’s official position.

Effective Date for Compliance

The text of the DRA requires that states participating in the Medicaid program amend their State Plans to mandate that any entity that receives or makes annual payments of at least \$5 million under a state’s Medicaid program establish written

policies and procedures addressing various federal and state laws, relevant whistleblower protections, and a company's procedures for detecting and preventing fraud, waste and abuse for their employees, contractors and agents. The DRA required state Medicaid agencies to implement these requirements by Jan. 1, 2007. Although the statutory requirement applies only to the state, Mr. Miller stated several times during the call that the agency believes these requirements apply separately to covered entities and required them to act by January 1, 2007, even absent action by a particular state to amend its State Plan and inform its covered entities of their actual obligations. (Mr. Miller noted several times, however, that specific requirements for implementation of the statute were left to the states). Although this position is questionable, given the agency's view, the conservative approach is, to the extent possible, to develop a DRA-compliant policy until further action is taken by the states.

Submission of Additional Questions to CMS

Mr. Miller indicated that those with additional questions could submit them to Medicaid_Integrity_Program@cms.hhs.gov. Mr. Miller indicated that individual responses may not be provided, but any questions submitted will be considered in developing the agency's additional guidance.