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By: S. Craig Holden and William T. Mathias

PPACA's New Medicaid Exclusion Authority Jeopardizes Existing and Future Corporate Criminal Dispositions

By S. Craig Holden

Often, a corporate system will resolve a government criminal investigation by agreeing to have an expendable subsidiary plead guilty. Section 6501 of PPACA may change this strategy.

In one example, in 2006, Schering Plough and several subsidiaries entered into a global resolution of a federal government investigation of alleged off-label marketing. The structure of the disposition fits what has become a template for the resolution of large, corporate health care criminal investigations. Under the terms of the agreement, a Schering subsidiary, presumably an expendable one, pled guilty to a felony conspiracy charge involving off-label marketing. Large criminal and civil fines were paid, and the subsidiary was excluded from Medicare and Medicaid participation. Schering agreed to enter into an expansive Corporate Integrity Agreement with the OIG, but was not excluded.

Individuals or entities convicted of criminal offenses related to the Medicare or Medicaid programs are subject to mandatory exclusion from those programs for at least five years. 42 U.S.C. § 1320A-7(a)(1). By statute, the OIG does not have the discretion not to exclude in such situations. For a variety of reasons, government prosecutors desire criminal disposition, yet understand that exclusion of a major drug manufacturer or other significant health care provider would deprive Medicare and Medicaid beneficiaries of needed services and could effectively destroy a major employer. In order to avoid this, pleas are often taken by a non-operating subsidiary. That subsidiary is then excluded; an event that has no practical effect. The parent corporation and its remaining subsidiaries continue to be eligible for participation in the Medicare and Medicaid programs, albeit subject to the scrutiny apparent in a Corporate Integrity Agreement.

Section 6501 of PPACA calls the continued viability of this settlement structure into question. Specifically, that provision amends the State Plan, which governs the relationship between the federal government and state Medicaid programs, to require that State Medicaid agencies exclude from Medicaid participation any individual or entity "if such individual owns, controls or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that) - . . . is ***affiliated*** with an individual or entity that has been suspended or excluded from . . . ." (emphasis added) While the language of this provision is less than clear, if read literally it would seem to mandate exclusion from Medicaid of any parent or sister corporation in the same corporate family as an excluded entity. Thus, in the Schering example, the exclusion of the dormant subsidiary seems to mandate the Medicaid exclusion of the Schering parent and all subsidiary corporations.

The impact of the provision would not stop there. There are ripple effects. Individuals and entities subject to Medicaid exclusion may also be excluded from the Medicare program. 42 U.S.C. § 1320A-7(b)(5). Moreover, the existence of a Medicare exclusion operates government-wide to disqualify an entity for consideration for the award of new government contracts. Executive Order No. 12689, August 16, 1989, and 48 C.F.R. §§ 9.405; 9.407-1(d).

This provision becomes effective January 1, 2011, "without regard to whether final regulations to carry out [the provision] have been promulgated by that date." PPACA § 6507.

Ober|Kaler's Comments: If this provision ultimately is read as expansively as its language would appear to permit,

there are potentially far-reaching implications for both the resolution of currently ongoing investigations, as well as for prior resolutions. While the provision does not become effective until 2011, there is no express limitation for exclusions occurring before that date as a basis for prospective exclusion of "affiliated" entities after that date.

Congress' thinking underlying this provision is unclear. Its impact would seem to be far more problematic for the government than for defendants. Its implementation will need to be monitored carefully to see if the frighteningly broad language set forth in the statute ultimately becomes effective.

Slow March Toward Mandatory Compliance Programs Continues

By William T. Mathias

The health care reform legislation continues the slow march of the health care industry toward mandatory compliance programs. The OIG issued its first compliance program guidance in 1997. At the time, the OIG stated clearly that the adoption of compliance program was "voluntary." Just last year, New York began requiring Medicaid providers to have a compliance program. With the enactment of PPACA, the road to mandatory compliance programs is set.

Section 6401 of PPACA makes the establishment of a compliance program a condition of enrollment under the Medicare, Medicaid, and SCHIP programs. The law requires the Secretary of HHS to establish "core elements" for compliance programs and requires providers and suppliers to establish compliance programs containing those core elements. This provision does not include a specific effective date and requires regulations. Thus, the mandatory compliance program requirement will only become effective after the government issues regulations.

Ober|Kaler's Comments: The time has come for everyone in the health care industry to have a formal compliance program. Because the timing of the compliance program requirement is dependent on HHS action, it may turn out that guidance comes without adequate lead time and many providers may be left scrambling to implement an effective compliance program. To avoid this predicament, providers should implement a compliance program today based on existing guidance from OIG, the Federal Sentencing Commission, and various industry groups. It may be that HHS guidance requires some tweaking of your compliance program, but it is better to be tweaking an existing program than crafting a program from whole cloth.