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Senate Finance Committee Publishes Report on Stark Law Reform - Are Changes to the Stark Law on the Way?

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Last December, the Majority Staff of the Senate Finance Committee invited a select group of experts to participate in discussions regarding the need for reforms to the Stark law, which prohibits physicians and their immediate family members from referring patients to any entity in which the physician has a financial relationship, subject to certain exceptions. Financial relationships include both ownership and investment interests, as well as compensation arrangements. Billing Medicare for services provided pursuant to a financial arrangement that violates Stark is also prohibited and can subject providers to mammoth penalties under the False Claims Act. Over recent years, the breadth and complexity of the Stark law's strict liability regime, along with its draconian penalties and myriad ambiguities, has had a decidedly chilling effect on the implementation of innovative payment models.

The round table participants addressed these concerns, noting that the Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. While the Stark law was originally enacted to curb the risk of overutilization inherent in the fee-for-service payment model, that risk is largely mitigated in alternative, value-based payment models.

With respect to the kinds of revisions to the Stark law that might be necessary in order to implement health care reforms aimed at promoting alternative payment models, commenters generally focused on:

1. Creating new waivers or exceptions;

2. Expanding existing waivers or exceptions;

3. Revising and clarifying standard Stark law definitions; and

4. Broadening the Secretary's authority to create waivers, exceptions, and advisory opinions.

Not surprisingly, the comments also focused on repealing the law, or at least the compensation arrangement prohibition, with several commenters noting that the compensation arrangement prohibitions are no longer necessary because the Anti-kickback Statute is adequate to curtail the

conduct prohibited by Stark and can be enforced in a civil context through both the FCA and the CMP law.

Commenters also generally agreed that “technical” violations should be subject to a separate set of sanctions that would not give rise to either FCA exposure or potentially ruinous repayment liability, and that the Secretary should have explicit authority to reduce penalties associated with technical violations or apply CMPs in lieu of penalties.

Despite having made these and a number of other recommendations, it remains to be seen whether and to what extent Congress will act on these recommendations. Nevertheless, now that Congress has acknowledged that the Stark law is standing in the way of the healthcare industry’s transition to alternative, value-based payment models, meaningful reform may soon be on the horizon.

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