

November 9, 2017

New Legislation Offers Major Reforms to the Physician Self-Referral Prohibition (the 'Stark Law')

Last week, bipartisan legislation was introduced in the House and Senate to make significant reforms to the Stark Law, which bars a physician from referring patients to an entity with which the physician has a financial relationship, subject to certain limited exceptions. These bills ([H.R. 4206](#) and [S. 2051](#)) recognize that some aspects of the Stark Law interfere with the more recent federal policy that the development and widespread use of innovative alternative payment models (APMs) should be fostered.

Under the [Stark Law](#), the entity receiving a prohibited referral cannot bill or collect for designated health services performed in connection with the referral. For this purpose, the term “financial relationship” includes direct and indirect ownership or investment interests and direct or indirect compensation arrangements between a referring physician and the entity providing a designated health service. The Stark Law, however, authorizes certain exceptions (i.e., waivers). For example, under the physician services exception, physicians may self-refer for services personally performed or supervised by the physician or a member of his or her group practice. The in-office ancillary services exception allows a physician to self-refer specified designated health services rendered or supervised by the physician, or a member of their group practice, in either the same building that contains the physician’s office or a specific centralized building that are billed for by their group practice, and not by a separate provider or entity.

The [Centers for Medicare & Medicaid Services](#) (CMS) has authority to conduct APM demonstration projects to move the Medicare and Medicaid programs away from the traditional procedure-by-procedure, fee-for-service (FFS) payment system and toward value-based approaches that reward physicians for achieving savings while maintaining or improving the quality of care. These demonstration projects include the Shared Savings program, which addresses Accountable Care Organizations (ACOs). Another is the Bundled Payments for Care Improvement (BPCI) initiative, which offers rewards for providing quality care for a particular episode (e.g., a joint replacement) below the target historical price for that type of episode.

In authorizing ACOs, BPCI models, and other types of APM demonstration projects, Congress recognized that participation would require providers to integrate in ways that would normally implicate fraud and abuse laws, such as the prohibitions on physician self-referrals, kickbacks and beneficiary inducements. Therefore, Congress authorized CMS to grant waivers for these demonstration projects.

H.R. 4206 and S. 2051 take important steps toward making Stark waivers available beyond the confines of these demonstration projects. In other words, the bills potentially would allow waivers for APMs that are not demonstration projects, although the APMs would have to meet criteria established by CMS.

The current-law waivers offer limited relief for a few specific delivery models, but the waivers do not offer sufficient latitude for providers to broadly integrate in an effort to rein in costs. Without greater latitude, providers face regulatory obstacles to collaboration and integration. The new legislation would open the door for providers to increase integration and innovation in the name of achieving greater efficiency.

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