PUBLICATION

Senate Finance Committee Report Concludes Stark Law Change Is Necessary to Drive Health Care Reform [Ober|Kaler]

2016: Issue 11 - Focus on Fraud and Abuse

In its report, Why Stark, Why Now? [PDF], released June 30, 2016, the Senate Committee on Finance outlines suggested changes to the physician self-referral law, 42 U.S.C. § 1395nn, (the Stark law) in order to facilitate and encourage health care reform and in particular participation in alternative payment models (APMs).

The report is significant, not only for the numerous policy recommendations it sets forth, but due to its stinging critique of the Stark law as a barrier to APM provider participation. Indeed, the report characterizes the Stark law as "increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted." It further highlights a growing consensus that the Stark law, created to "address overutilization in [a fee-for-service (FFS)] environment," does not have a place in the "pay-for-value world."

The report reflects the culmination of a subject matter expert round table, convened in December 2015 by the Senate Finance Committee and House Ways and Means Committee, to address potential improvements to the Stark law.

Current APM-Specific Fraud and Abuse Waivers Do Not Go Far Enough

The Senate report acknowledges that the Department of Health and Human Services (HHS) Secretary has already issued regulatory fraud and abuse waivers for certain APMs led by the Centers for Medicare and Medicaid Services (CMS) – e.g., the Medicare Shared Savings Program (MSSP), the Bundled Payments for Care Improvement (BPCI) initiative, and the Comprehensive Care for Joint Replacement (CJR) program. Congress granted the HHS Secretary the authority to do so in recognition that APMs would be "difficult or impossible to establish in the current FFS enforcement environment."

Nonetheless, the report concludes that such waivers do not go far enough. Specifically, the report states that the regulatory waivers fail to protect all APMs under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and any APMs with commercial payers. This reliance on HHS Secretary-issued regulatory waivers, the report notes, offers a patchwork solution and instead may serve only to "undercut[] hospitals' ability to provide uniform and consistent incentives for physicians across all patient populations."

Overview of Suggested Improvements to the Stark Law

As noted above, the Senate report decidedly rejects CMS's current piecemeal approach to provider participation in APMs (i.e., via program-specific, regulatory fraud and abuse waivers). In doing so, the Senate report examines alternatives, setting forth numerous proposals to overhaul the Stark law.

Examples of such proposals include the following:

- *Repeal*. The report notes that many commenters suggested repealing the Stark law outright. Others advocated for the repeal of the Stark law compensation arrangement prohibition, and limiting the applicability of the Stark law to ownership and investment interests. In both instances, commenters stated that the federal anti-kickback statute is, in its present form, adequate to address many, if not all, of the fraud and abuse concerns initially present at the time of the Stark law's passage.
- *Create new or expand existing waivers*. The report notes that the majority of commenters suggested "extending the waivers that are currently highly limited to CMS-run programs to all payers," in particular the MSSP waivers. Other commenters noted that Congress should provide CMS with the express authority to "create broader waivers than currently authorized by law."
- *New Stark law exception*. In the alternative, some commenters suggested creating a new Stark law applicable to, for example, the (a) Merit Based Incentive Payment System (MIPs), part of MACRA, (b) physician-focused payment models, and/or (c) payments associated with APMs. This new exception would potentially allow for compensation arrangements that take into account the volume or value of referrals, and would exclude a fair market value requirement.
- *Modify existing exceptions*. The report notes that some commenters suggested that CMS revisit existing statutory and regulatory exceptions and enact changes that would promote integration and alignment of providers. As examples, the commenters noted both the prepaid plan exception and the risk sharing exception as exceptions that with modification could accommodate APMs while still protecting against patient and program abuse.
- *Percentage savings can be fair market value and commercially reasonable*. Ambiguity related to fair market value and commercial reasonableness remains a significant compliance concern for those providers considering APMs. Accordingly, the report highlights one commenter's suggestion that Congress amend the Stark law to state that an "arrangement under which a physician receives a percentage of saving realized by a provider can satisfy the fair market value and commercial reasonableness requirements of an applicable exception."

The report states that the above suggestions (among others) reflect the provider community's ever-increasing frustration with the ambiguity and inflexibility of the Stark law in its current form, particularly with respect to several "key standards" of the Stark law – namely, fair market value, "takes into account" volume or value of referrals, and commercially reasonable.

Substantive versus Technical Violations

In addition to the focus on potential modification of the Stark law to facilitate APMs, the Senate report also highlights the round table discussion and commenters' statements related to distinguishing between "technical" versus "substantive" violations of the Stark law. While noting that not all commenters advocated such an approach, the report stated that commenters "generally agreed" that technical violations should be subject to a separate set of sanctions that would "not give rise to either [False Claims Act] exposure or potentially ruinous repayment liability."

In making such a distinction between *technical* and *substantive*, the report further notes that comments focused on documentation requirements, which are irrelevant to the concern over arrangements incentivizing referrals, contrasted against adherence to fair market value, the volume or value of referrals, and/or harm to beneficiaries or federal health care programs. Along these same lines, Commenters recommended clarification of the terms: *fair market value*, *takes into account the volume or value* of referrals, and *commercially reasonable*, noting that these terms are key to compliance with the compensation exceptions yet confusion exists as to their precise meanings.

Ober|Kaler's Comments

In recent years, both Congress and CMS have signaled to the provider community the value and importance of APMs in fundamentally reshaping not only the way health care is paid for, but delivered. Yet, and as the Senate Committee on Finance itself has recognized in this very report, the current health care fraud and abuse regime has not kept pace.

To truly effectuate health care reform, the provider community must be incentivized to align otherwise divergent financial interests. Despite this, and as the report notes, the Stark law continues to stand as a "significant impediment to value-based payment models that Congress, CMS, and commercial health insurers have promoted."

With this report, the potential exists that change to and modernization of the Stark law will (at long last) be brought to the forefront of Congress's legislative agenda.