The “Stark Law”
Opportunities to Address Barriers to Clinical Integration
January 29, 2016

There are several rules governing compensation relationships between hospitals, physicians and other caregivers, including the Anti-kickback Statute, the Stark Law, and the Civil Monetary Penalty (CMP) Law. While all of these laws serve important functions, they have not been revised to reflect new payment and delivery system models that emphasize value over volume. The Stark Law, which has been described as simple in concept but “maddeningly complex in its application,” is in particular need of review and reform.

The purpose of this concept paper is to provide some background relating to changes to health care payment models, provide an overview of the Stark Law, and discuss the specific changes that should be made to this law to reflect changes to the health care delivery system.

The recommendations relating to the specific changes that could be made to the Stark Law address the two areas in which feedback is sought by the U.S. Senate Finance and House Ways and Means Committees (i.e. technical violations vs. more serious or problematic violations and changes that need to be made to implement Medicare Access and Chip Reauthorization Act of 2015 (MACRA) in its current form and Accountable Care Organizations (ACO)/shared savings programs).

Overview

The health care field is rapidly changing, and is moving from a “fee-for-service” methodology toward new payment and delivery system models that emphasize value over volume. As part of this change, hospitals are embracing “clinical integration,” which is essentially a move away from working in silos toward emphasizing teamwork to coordinate care. In addition, public and private payers are holding hospitals accountable for reducing costs and improving quality in ways that can be accomplished only through teamwork with physicians and other health care professionals within and across sites of care, including the alignment of financial incentives.

Hospitals attempting to seize opportunities to improve care and care coordination for Medicare beneficiaries and other patients, however, face significant legal barriers. Recognizing this tension, Congress made an important reform in the MACRA that will facilitate clinical integration by amending the Gainsharing Civil Monetary Penalty law. Gainsharing arrangements allow physicians to receive a share of any reductions in a hospital’s patient care costs that are attributable to the actions of the physician. These agreements between hospitals and physicians can reduce unnecessary costs by aligning interests. In order to protect patients, federal law subjects hospitals and physicians to civil monetary penalties for “knowingly [make] a payment, directly or indirectly, to a physician as an inducement to reduce or limit services” to Medicare beneficiaries. The MACRA amendment refines the scope of the language by ensuring the Gainsharing CMP law only applies to reductions or limitations of medically necessary services.
Additionally, MACRA calls for a report to be submitted to Congress with options for amending existing fraud and abuse laws and regulations to permit certain gainsharing arrangements otherwise subject to the Gainsharing CMPs. Congress’s attention to the legal barriers imposed by the Gainsharing CMPs and consideration of Stark Law reforms will further support the coordination of care.

Stark Law Barriers to Clinical Integration

**Background.** Originally enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) and later expanded in the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993), the Stark Law originally was enacted to ban doctors from referring patients to facilities in which the doctor has a financial interest (known as “self-referral”). The law was adopted in response to concerns that certain ancillary service—such as clinical laboratories, diagnostic imaging facilities, and durable medical equipment companies—were subject to overutilization when the referring physician had a financial interest in the service. However, the actual impact of the Stark Law has been not only to limit physician ownership of these ancillary services, but to impede physicians’ ability to participate in beneficial relationships between physicians and hospitals, particularly in emerging population health initiatives.

**Stark Law Requirements.** Specifically, the Stark law requires that hospital compensation for health care providers be fixed in advance and, except for limited circumstances, paid only for directly personally performed services. As a result, payments that are tied to achievements in quality and efficiency instead of hours worked may not meet the law’s strict standards. One of the unintended consequences of Stark is that it inhibits collaboration among providers that would otherwise promote the "triple aim" of health care—better care for individuals, improved health for communities and lower costs in care delivery. For example, a hospital or clinic that rewards a physician, and the physician who earns the reward, for following protocols that guide the clinical integration program, can be found in violation. Stark impedes innovation in care delivery. As an example, a doctor who receives a bonus as part of a clinical integration program that helps patients manage their diabetes according to a well-designed medical protocol, risks being in violation of the Stark law. Stark also inhibits collaboration. It is recognized that the use of electronic medical records can improve care while reducing duplicative tests. However, hospitals that seek to provide electronic medical record systems to independent physician practices may be prevented from doing so, unless they meet onerous requirements.

It is also worth noting that the law is so strict that, in order to launch demonstration projects supporting clinical integration, the Centers for Medicare & Medicaid Services (CMS) had to waive elements of the law. Without this waiver, a program in which hospitals shared cost savings with non-employed physicians who participated in a well-designed effort to enhance quality and efficiency would not have been possible. However, even this proposed exception contained numerous hurdles from a compliance perspective and are limited to Medicare ACOs and expire once the ACO no longer is involved in the Medicare Shared Savings Program. As such, they do not allow providers to build sustainable relationships that promote the triple aim.

**Penalties.** Those found in violation of the law face severe consequences. In addition to civil penalties, providers can be barred from serving Medicare, Medicaid and other federal program
patients for years, effectively shutting down the hospital and ending the doctors’ careers. Understandably, providers are spending substantial amounts of money for legal advice regarding compliance with the Stark Law’s complex provisions and addressing inevitable compliance failures.

Implications. The Stark Law’s prohibitions (and the requirements of the applicable exceptions) make it difficult for providers to work together to develop or implement various arrangements designed to improve health care quality and control costs, such as pay-for-performance arrangements, gainsharing, or bundled payments. Cooperative arrangements among providers will be necessary to improve quality and manage costs and the Stark Law—which is based upon the assumption that cooperative arrangements among health care providers may create incentives for overutilization—is explicitly designed to discourage such relationships. Fundamental changes to the law are necessary.

Comments from “the Field”

To learn more about the implications of the Stark Law, HAP reached out to a number of hospital chief counsels. Comments included the following:

- Recent changes to the Stark Law are “just chipping away” at pieces of the law, and are “not tackling the big issues that would really make significant improvements in today’s environment.”
- My hospital does “all kinds of cartwheels” to fit current arrangements into the Stark Exceptions, and this work is “very time consuming and administratively difficult.”
- Currently, if you “do everything right ninety nine fully compliant things—but the government can find one potentially bad intention and prove it, you are in trouble.”
- “Unfortunately the [Stark Laws] are so complex that they can be very difficult even for an experienced health attorney to understand and apply. There are many technical requirements that make it almost inevitable that unintentional violations will be made, with potentially serious financial consequences.”
- “The regulations seem to have strayed very far from the original concern about physicians being motivated by ownership/profit to over utilize certain types of items or services.”
- Our hospital “has formed an ACO, and fortunately for purposes of the Medicare Shared Savings Program, certain waivers permit certain types of incentives to be paid to physicians for achieving quality and performance measures. However, it is not clear that Stark Law exceptions exist that would allow similar incentives to be paid under our contracts with commercial payers.”
- “We have formed risk pools and seek to distribute any cost savings in comparison to budget to ACO-participating providers on a pro rata basis based upon attributed lives, subject to satisfactorily meeting certain quality measures. Unfortunately, the Stark Law leaves us somewhat uncertain as to whether such distributions would fall within the Stark Law exception for Risk Sharing Arrangements.”
Recommended Solutions

The Stark Law (and similar state self-referral laws) must be modified in order to permit the type of cooperative arrangements that are necessary to improve the quality of health care services and to control the cost of care.

The most complete and effective solution—which has been embraced by the American Hospital Association (AHA)—is to revise the structure of the law to prohibit only certain specified relationships, such as physician ownership of clinical laboratories, outpatient diagnostic imaging facilities, and similar ancillary services which may be subject to overutilization, rather than setting forth a blanket prohibition of referrals if there is a financial relationship between the parties (and then identifying a series of exceptions).

The AHA specifically recommends the removal of compensation arrangements from the definition of “financial relationships” that are subject to the Stark Law. These same compensation arrangements would still be regulated, but by other federal laws already on the books, such as anti-kickback and civil money penalty laws, that are better equipped to do so.

Absent this solution, more modest changes can be made to minimize the impact of technical violations of the law and permit relationships to implement MACRA in its current form and promote ACOs/shared savings programs.

1) **Technical v. Material Violations**—As to the issue of technical versus material violations, HAP suggests that the Stark Law be amended by inserting into the text of the law a statutory exception that covers technical failures. The statutory exception that currently exists (See Attachment A, 42 C.F.R. Section 411.353(f)) could be used as the model from which to craft the statutory exception, with the following changes:

- Eliminate the requirement that the financial relationship have complied with an exception for no less than 180 consecutive days prior to becoming noncompliant.
- Eliminate the requirement that the period of noncompliance not exceed 90 consecutive calendar days following the date on which the relationship became noncompliant. Instead, the period of noncompliance should begin upon discovery of the noncompliance and the provider should be given a one year period to cure, after which no claims may be submitted.
- Eliminate the prohibition on the use of the exception to only once every three years with respect to the same referring physician. Or, in the alternative, allow the use of the exception on a more frequent basis than every three years.
- Broaden the exception to include every exception for any financial relationship. Right now, the non-signature noncompliance exception cannot be used in connection with the exceptions listed in 411.357(k) or (m). Those are the exceptions for nonmonetary compensation and incidental medical staff benefits.

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1 For the Pennsylvania law, see 55 PA Code § 1101.51 (c) (5).
As to the noncompliance for failure to comply with signature requirements, the signature requirement should be treated the same as other instances of noncompliance (so long as the parties have been performing under the contract).

2) **Alternative Payment Models**— With respect to alternative payment models, the statutory prepaid plan exception in the Stark Law itself (See Attachment B, 42 U.S.C. Section 1395nn(a)(3)) should be broadened so that the prohibition on referrals for designated health services (DHS) does not apply to services rendered by an entity that has a contract with CMS or its agent and that contemplates the use of payment models alternative to fee-for-service (and not only tied to projects under 204 (a) or 222(a) under the 167 and 1972 amendments to the Social Security Act, respectively, as it is currently drafted):

- The prohibition on referrals for DHS does not apply to: DHS furnished by any entity (and whether directly, or indirectly, through arrangements with physicians or group practices, physician hospital organizations, independent physician associations, health systems, downstream providers or any intermediate organizations) receiving payments (i) on a prepaid basis, (ii) that combine fee for service payments and outcome or quality-based payments, or (iii) for specific sets of services made on a bundled basis, whether or not prepaid, under any contract with the Centers for Medicare & Medicaid Services or any of its departments or offices which contract with CMS or its agent seeks innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care.

3) **Refocus Stark on Risk Areas**—As noted, the Stark Law has expanded dramatically over the years. Stark prohibits physicians from making referrals for “designated health services” (DHS). Originally designed to prevent over utilization of laboratory services and radiology, the definition of DHS has expanded to essentially include all clinical services. There may be an opportunity to examine whether certain DHS services truly are at risk. For example, is it necessary to include all inpatient and outpatient hospital services in the DHS definition? This particularly impacts the ability of hospitals to engage in pioneering efforts with physicians to promote triple aim efforts.

4) **Penalties and Disclosure**—While we applaud the efforts to facilitate self-disclosure under Stark pursuant to the self-referral disclosure protocol, the process itself needs to be streamlined and improved. A provider who discloses not only is required to repay the amount in controversy but is likely to be subject to penalties as the government typically expects a penalty equal to 1.5 times the damages. We believe the focus of disclosure should be on reimbursing the government for actual losses and promoting compliant conduct, not a punitive approach.

The other exceptions could remain as is, with the above exception added, or subsection (c) could be replaced with the language proposed above.