Despite HHS’ authority to establish such exceptions for incentive compensation, the OIG Advisory Process is available to any provider, it is an arduous, expensive process that may take months to complete.

If a financial relationship exists between a physician and a DHS entity, in order for a gainsharing arrangement to be permissible under the Stark Law, the arrangement must be properly structured to satisfy the requirements of an applicable exception to the physician self-referral law and not violate the Federal Anti-Kickback statute. All provider clients should be warned of the Fraud and Abuse implications of the value-based payment initiatives.

For now, when advising clients on value-based payment initiatives, including MACRA, it is best to ensure arrangements are structured in a manner that does not fall within the scope of the Stark Law. However, such waivers are only applicable to specific alternative payment and care delivery models, such as the MSSP and CMS Innovation. CMS recently wrote, “the fraud and abuse laws need to be adapted to support not hamper the new payment models. Waivers for Medicare Shared Savings Program and Center for Medicare and Medicaid Innovation Initiatives are the personal views of the author and do not necessarily reflect those of the firm. This site may contain hypertext links to information created and maintained by other entities. Carlton Fields does not control or endorse these links, and disclaims responsibility for the content and performance of these sites. Providers should seek assistance of qualified counsel in connection with any issues discussed herein. Congress anticipated such conflicts with CMP. Prior to MACRA, CMP prohibited a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit any services to Medicare or Medicaid beneficiaries under the physician’s care.

As MACRA necessarily induces physicians to limit unnecessary services to Medicare beneficiaries, §512(a) of MACRA amends §§1128A(b)(1) and (2) of the Civil Monetary Penalty Law to prohibit hospitals from knowingly making a payment directly or indirectly to a physician as an inducement to refer or limit medically necessary services to Medicare or Medicaid beneficiaries under a physician’s care.

However, MACRA has not altered the Anti-Kickback Statute or Stark Law. Thus, MACRA incentive programs must meet a safe harbor under the Anti-Kickback Statute and an exception of Stark Law to comply with the law.

The Anti-Kickback Statute

Under the Anti-Kickback Statute (AKS), it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services payable by a Federal health care program. Pursuant to AKS, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.
Courts have held that AKS covers any arrangement under which one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. Thus, financial incentives shared amongst referring providers may be viewed as an inducement for referrals. For example, MACRA compensation arrangements that distribute cost savings generated by referrals to providers with proven cost-efficient services may implicate AKS.

Although 42 C.F.R. §1001.952 provides safe harbors for various payment and business practices, no safe harbor specifically exempts cost-saving financial incentive programs tied to MACRA or alternative payment model implementation. Similarly, the OIG has issued a number of Advisory Opinions approving gainsharing arrangements; however, each Advisory Opinion is limited to the specific set of circumstances presented, and protects only the hospital or provider making the request. Although the OIG Advisory Process is available to any provider, it is an arduous, expensive process that may take years to complete.

The Stark Law presents similar barriers to MACRA compensation arrangements.

The Physician Self-Referral Law (Stark Law)

Stark is a strict liability statute, meaning proof of specific intent to violate the law is not required. The Stark law prohibits a physician from making referrals for “designated health services” (DHS) to an entity with which he or she (or an immediate family member) has a financial relationship (including compensation or ownership) that are payable by Medicare; and prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for DHS furnished as a result of a prohibited referral. If a financial relationship exists between a physician and a DHS entity, in order for a physician to refer to the DHS entity and for such entity to bill for the service, an applicable exception must be met.

The Stark Law grants the Secretary of HHS the authority to create regulatory exceptions for financial relationships that “pose no risk of program or patient abuse.” Despite HHS’ authority to establish such exceptions for incentive compensation arrangements under MA-CRA, no such exception exists. HHS has argued that providing such an exception “would not provide sufficient flexibility for innovative, effective gainsharing and incentive compensation programs.” The agency added that “[t]he variety and complexity of gainsharing and similar arrangements would make it difficult to craft a “one-size-fits-all” set of conditions that are sufficiently “bright line” to facilitate compliance and enforceability, yet sufficiently flexible to permit innovation without any risk of program or patient abuse.”

Thus, MACRA compensation arrangements must fit into an existing Stark exception, many of which require that the volume or value of a physician’s referrals or other business generated between the parties must not be a consideration when determining physician compensation. Thus, Stark Law presents a particularly difficult obstacle to structuring effective value-based payment programs that necessarily take into consideration the “value” of referrals.

HHS recently admitted the difficulty of structuring MACRA compensation arrangements to comply with Stark Law stating to Congress that “[e]xisting exceptions to the physician self-referral law, while useful, may not be sufficiently flexible to encourage a variety of non-abusive and beneficial gainsharing, P4P [pay for performance], and similar arrangements.”

HHS added that the prohibition on considering “volume or value” of referrals when formulating physician compensation “can pose impediments for the implementation of gainsharing arrangements, because compensation paid to a physician for reducing costs or increasing profits through changes to his or her patient care practice could be interpreted to take into account the volume or value of the physician’s referrals of DHS for Medicare beneficiaries.”

Waivers for Medicare Shared Savings Program and Center for Medicare and Medicaid Innovation Initiatives

Recognizing the barriers that AKS and Stark Law pose to implementation of value based payment models, HHS has issued certain waivers of the physician self-referral law and AKS to allow gainsharing and similar arrangements in connection with certain APMs, including an “ACO pre-participation waiver”, and an “ACO participation waiver.”

Fraud and Abuse waivers issued to date are available at:


However, such waivers are only applicable to specific alternative payment and care delivery models, such as the MSSP and bundled payment programs. Although such waivers are essential for facilitating these programs, the program-by-program
waiver approach may not provide sufficient protection from the overall vulnerability of the implication of Fraud and Abuse Laws.

The American Hospital Association and other provider association groups continue to advocate for HHS to grant broad waivers of Fraud and Abuse Laws for new payment models necessary for MACRA implementation. The American Hospital Association recently wrote, "[t]he fraud and abuse laws need to be adapted to support not hamper the new payment models. To that end, Congress should create legal safe zones to support and foster arrangements designed to achieve the goals of payment-for-value rather than volume-based programs.... There should be clear and comprehensive protection for arrangements designed and implemented to meet those goals."\textsuperscript{14}

Conclusion
For now, when advising clients on value based payment initiatives, including MACRA, it is best to ensure arrangements are properly structured to satisfy the requirements of an applicable exception to the physician self-referral law and not violate the Federal Anti-Kickback statute. All provider clients should be warned of the Fraud and Abuse implications of the value-based reimbursement paradigm.

Endnotes
1. Elizabeth “Beth” Scarola is an associate in the Health Care Practice Group of Carlton Fields. Beth brings an insider’s perspective to her health care practice, with a strategic and operational background in health management and policy. Ms. Scarola counsels health administrators and providers, helping them navigate the complexity of healthcare regulation and policy.
5. Id.
6. See OIG Advisory Opinions 01-01, 05-02, 05-03, 05-04, 05-05, 05-06, 06-22, 07-21, 07-22, 08-09, 08-15, 08-21, and 09-06
8. Id.
  . Id.
  . "Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them (2016), www.aha.org/content/16/barrierstocare-full.pdf.

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