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Expert Analysis

Momentum Building for Changes To Fraud and Abuse Laws

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When the Medicare and Medicaid programs were created in the 1960s, medical services were paid for almost entirely on a fee-for-service basis. For example, Medicare would pay a certain amount for a check-up in a physician's office, another amount for a physician's reading of an X-ray film, and so on (less any applicable co-pay or deductible). Most private insurers paid for medical services this way for generations, and fee-for-service would continue to be the payment method of choice for many more years to come.

This fee-for-service model has been fraught with problems. It provided incentives to health care providers to over-utilize services, encouraged episodic rather than coordinated care, and it has been a significant factor in the ever-escalating costs of health care services. It also gave rise to many varieties of fraudulent and unethical practices that not only harmed patients but drained massive amounts of money from the Medicare and Medicaid programs.

> All new gainsharing or incentive payment arrangements must be carefully vetted for compliance with current fraud and abuse laws, and as necessary, an appropriate waiver obtained from HHS.

Over the years, Congress provided the federal government with a number of powerful weapons to combat fraud and waste in the Medicare, Medicaid and other government health care benefit programs. Among these weapons are the so-called fraud and abuse laws, which penalize—and in some cases criminalize—certain types of arrangements by and among health care providers. However, many providers and their counsel have complained for years that the broad wording of these fraud and abuse laws has prohibited many arrangements that actually could improve the quality and reduce the costs of health care services paid for by Medicare and other government health care programs.

In 2015, Congress enacted and President Barack Obama signed into law the Medicare Access and Childrens' Health Insurance Program (CHIP) Reauthorization Act[1] (MACRA). MACRA was the most significant health care legislation since the enactment of the Affordable Care Act in 2010. Among other things, MACRA transitions Medicare away from straight fee-for-service payments and towards a Merit-based Incentive Payment System

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(MIPS) whereby physicians and other professionals receive annual payment increases or decreases based upon their performance as measured by standards established by the secretary of Health and Human Services (HHS) in four areas: quality; resource use; clinical practice improvement activities; and meaningful use of an electronic health record system. MACRA also required the secretary of HHS, in consultation with HHS' Office of Inspector General, to submit a report with options for amending the fraud and abuse laws and pertinent regulations to permit certain types of arrangements between physicians and hospitals that "would improve care while reducing waste and increasing efficiency." A report to Congress[2] (Report) issued last month by the Centers for Medicare and Medicaid Services (CMS) of HHS has confirmed that some of these laws do in fact hinder certain kinds of health care innovations that the federal government itself wants to encourage. Although the Report has not gotten much publicity, it may be a step towards some needed revisions of the fraud and abuse laws.

Background

Let's briefly summarize the fraud and abuse laws addressed in the Report. Under the Anti-Kickback Statute,[3] it is a criminal offense to knowingly offer, pay, solicit or receive any remuneration to induce referrals of items or services payable by Medicare or any other federal health care benefit program. The statute covers all parties to a kickback arrangement, and the term "remuneration" includes giving or receiving anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Violation of the Anti-Kickback Statute is a felony punishable by up to five years in prison, up to a $25,000 fine, and exclusion from participating as a provider in Medicare, Medicaid and other government payment programs ("exclusion").

The statute authorizes and HHS has promulgated certain "safe harbors" to the Anti-Kickback Statute which are very narrowly tailored exceptions to the broad wording of the law. For example, a properly structured sale of a physician's medical practice to another physician does not constitute a payment for patient referrals, and would not violate the Anti-Kickback Statute.

The Stark Anti-Referral Law[4] (Stark) prohibits physicians and other health care practitioners from making referrals for certain designated health services payable by Medicare to an entity with which the practitioner (or immediate family member) has an ownership, investment or compensation arrangement. The designated health services include:

- clinical laboratory services
- radiology and imaging services
- physical and occupational therapy services
- radiation therapy services
- outpatient speech-language pathology services
- durable medical equipment and supplies
- home health services
- parenteral and enteral nutrients
- prosthetics, orthotics and prosthetic devices and supplies
- outpatient prescription drugs
- inpatient and outpatient hospital services

Penalties under Stark include denial of claims, recovery of paid claims, imposition of a civil monetary penalty (up to $23,863 in 2016) for each referred service, and exclusion. Stark contains certain exceptions to the broad wording of the statute, and HHS also has created some further exceptions. For example, a physician's performance of X-rays on a patient in the physician's own office does not constitute a prohibited referral for radiology services.

The Civil Monetary Penalty Law[5] (CMP) prohibits a hospital from knowingly making a payment directly or indirectly as an inducement to reduce or limit medically necessary services to Medicare or Medicaid beneficiaries who are under the physician's care. Hospitals and physicians involved in

prohibited payments are subject to civil monetary penalties of up to $2,000 per patient covered by such payments.

Arrangements

As noted earlier, these and other fraud and abuse laws were enacted to target serious abuses that have plagued the Medicare and Medicaid programs during the many years when the programs paid providers for health care services primarily on a fee-for-service basis. With the shift away from fee-for-service payments towards more cost-effective capitation and risk-based payments, these fraud and abuse laws may now implicate and hinder perfectly legitimate arrangements that Congress and the Executive Branch want to see expanded. As Congress requested, the CMS Report focuses on so-called "gainsharing" and "incentive compensation" arrangements. Gainsharing, the Report explains, is:

> an arrangement between entities and individuals that furnish health care services—often a hospital and the physicians who treat the hospital's patients—that establishes a formal reward system wherein participants share in cost savings or increased profits resulting from the efforts or actions of the provider receiving the payment.

Incentive compensation arrangements, which are similar to gainsharing, include so-called "pay for performance" arrangements and "value-based purchasing." The Report explains that these arrangements "involve payment for performing certain actions or achieving quality, cost or performance goals, regardless of whether cost savings are achieved." As examples, the Report points to hospitals that, in addition to a salary and productivity bonus, pay incentive compensation to their physicians for efforts in reducing the rate of infections or in waste control. Similarly, a physician group may make incentive payments to its physicians for their efforts to improve the quality of care provided to the group's patients.

> While some are calling for the complete repeal of the Stark Law, that is not likely to happen as long as there is still any fee-for-service component to Medicare payments and the attendant possibility of abusive referral practices.

The Report notes that a payment by a hospital or other entity to a physician as part of a gainsharing or incentive payment arrangement constitutes a compensation arrangement for purposes of the Stark law and would have to fit into one of the applicable exceptions to Stark if the physician makes referrals to the hospital for services covered by the Stark law. The Report concedes:

> This is true even if the arrangement relates only to the reduction or limitation of medically unnecessary services. Existing exceptions to the [Stark] self-referral law, while useful, may not be sufficiently flexible to encourage a variety of nonabusive and beneficial gainsharing, [pay-for-performance], and similar arrangements.

The Report relates that in 2008, HHS proposed a new exception to protect gainsharing and other arrangements that would improve quality standards, save money and reduce waste, but the proposed exception was never finalized. HHS concluded at the time that the variety and complexity of gainsharing arrangements made it difficult to create what it called a "one-size-fits-all" set of exceptions that would permit innovation while not risking program or patient abuse.

Although Congress required that HHS provide it with "options" in the Report, the Report unfortunately contains no options or recommendations for revisions to the fraud and abuse laws, or even for consideration of new exceptions. Instead, HHS simply provides "observations." One observation is the acknowledgment

that "the fraud and abuse laws may serve as an impediment to robust, innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings, and reduce waste." The other observation recognizes that "the [Stark] anti-referral law presents a particularly difficult obstacle to structuring effective programs that do not run afoul of the fraud and abuse laws."

In December 2016, the Majority Staff of the Senate Finance Committee,[6] chaired by Sen. Orrin Hatch, (R-Utah) issued a summary of comments and suggestions from a round-table discussion by a group of experts on the problems that the Stark law is causing for value-based payment arrangements and other alternatives to the fee-for-service model. In it, the Majority Staff commented:

> 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. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services.

While the Majority Staff acknowledged that the Affordable Care Act authorized and the HHS Secretary has issued waivers from Stark and other fraud and abuse laws for innovative payment and service delivery models, it noted that the very fact that waivers are necessary illustrates that the Stark law continues to pose significant risks for other models:

> Importantly, Medicare waivers do not protect all alternative payment models under MACRA or with commercial payers, undercutting hospitals' ability to provide uniform and consistent incentives for physicians across all patient populations.

Conclusion

While some are calling for the complete repeal of the Stark law, that is not likely to happen as long as there is still any fee-for-service component to Medicare payments and the attendant possibility of abusive referral practices. What is more likely is that carefully drafted amendments to Stark and other fraud and abuse laws will be proposed to remove obstacles to more gainsharing and value-based payment arrangements. At some point in the future when there is no longer a fee-for-service component to Medicare, and no more incentives for self-referral of medical items and services, Stark may either be repealed or allowed to sunset. In the meantime, however, all new gainsharing or incentive payment arrangements must be carefully vetted for compliance with current fraud and abuse laws, and as necessary, an appropriate waiver obtained from HHS.

1. Public Law No. 114-10, (2015), §512(b).
2. Centers for Medicare and Medicaid Services, "Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals" February 2017.
3. 42 USC §1320a-7b
4. 42 USC §1395nn
5. 42 USC §1320a-7a
6. Senate Committee on Finance, Majority Staff, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models."