CHAPTER 10

FRAUD AND ABUSE UPDATE

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§ 10.01 INTRODUCTION

One of the fiduciary duties of the federal government is to ensure the integrity of the Medicare Trust Fund and other government-sponsored health benefits so that beneficiaries may continue to receive health care services and taxpayer money is not wasted. In 2010, the Fraud Prevention System, created by the Small Business Jobs Act[1] and the Patient Protection and Affordable Care Act,[2] provided the Centers for Medicare & Medicaid (CMS) with additional resources to prevent, detect, and penalize individuals who defraud the Medicare program. CMS partners with the Office of Inspector General (OIG) and the Department of Justice (DOJ) to educate, prevent, identify, and penalize health care fraud and abuse. Examples of fraudulent actions may include submitting claims for services that never occurred, services that were overbilled to reflect a level of service that did not actually occur, or services performed on fictitious individuals.

Additionally, the Stark[3] and Anti-Kickback[4] Laws were also created to prevent health care providers and other persons from referring to health care providers such as hospitals, home health agencies, and nursing homes in which the referring provider has a financial interest, unless an exception applies. These laws attempt to prevent arrangements that may incentivize a physician to disregard independent medical judgment in favor of financial gain and overutilize government resources. The government sees all these practices as wasteful to taxpayer dollars and has made extended efforts in the last several years to identify and penalize those who participate in such schemes.

However, not all fraud is intentional. Because some regulations can be ambiguous, health care providers can unknowingly fail to comply with regard to their billing practices or contractual arrangements. CMS defines this type of noncompliance as abuse. Regardless of the reason for the fraud or abuse, CMS requires anyone who suspects or knows about an incorrect or fraudulent reimbursement to notify the necessary authorities for further investigation and recovery. CMS emphasizes a proactive approach to avoid a harsher penalty than if the noncompliance is identified by the government first. Penalties for fraud and abuse include civil and criminal liability and may also involve sanctions, exclusion from participation in government health programs, and even the loss of professional licenses. This chapter begins with an overview of the key statutes typically invoked in health care fraud and abuse cases.

[1] H.R. 5297.
[2] H.R. 3590.
[3] 42 U.S.C.S. § 1395nn.
[4] 42 U.S.C. § 1320a-7b.

§ 10.02 PRIMARY FRAUD AND ABUSE STATUTES OVERVIEW

[A] Stark Law

[1] Stark I

The Stark Law was originally drafted in 1988 as the "Ethics in Patient Referrals Act." Named after United States Congressman Pete Stark, the sponsor of the bill, Congress passed the version known as Stark I under the Omnibus Budget Reconciliation Act of 1990 to prohibit a physician from referring a Medicare patient to a laboratory company if the physician had any financial interest in that lab.[5] The premise of the law was that referrals motivated by anything other than what physicians rendered medically necessary would perpetuate overutilization of government resources and waste Medicare resources funded by taxpayer dollars. A financial interest, as defined by the legislation, included not only the physician's ownership, but also any family member's interest. This bill was introduced during a time when physicians began to explore creative ownership arrangements to establish alternative revenue streams by owning or managing ancillary health services companies such as laboratories and therapy and radiology companies. The theory of this law is that physician self-referral creates a conflict of interest when physicians use their medical license and position as a health care provider to refer a patient to another entity in which the physician obtains a financial benefit. The idea that physicians may be motivated by financial incentives and not strict medical judgment created the basis for what ended up being the first of several iterations in the Stark Law.

This early version of the Stark Law included several exceptions to the self-referral prohibition and further defined compensation arrangements in an effort to restrict arrangements only as necessary. For example, another physician in a medical group practice could refer a patient to his colleague's ancillary company. Physicians who owned investments in certain securities funds were not considered in violation of the Stark Law when they referred to those entities. Prohibited compensation arrangements also excluded the leasing of space from another health care provider or entity, renting or leasing equipment from same, or the employment of health care providers if the compensation was fair market value and did not take into account any volume of services in the arrangement. These exceptions were intended to allow for appropriate, medically necessary referrals and referrals to an entity in which physicians had legitimate ownership or responsibility.

[5] 42 U.S.C. § 1395nn.

[2] Stark II

Congress included Stark II as an amendment to the Omnibus Budget Reconciliation Act of 1993 and expanded Stark I violations not just to Medicare patients, but to Medicaid patient as well. Additionally, Stark II broadened the list of prohibited referral services to include certain "designated health services" (DHS). These additional services include the following:

- Clinical Laboratory Services
- Physical therapy services
- Occupational therapy services
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
- Outpatient speech-language pathology services[6]

However, after this second version of the Stark Law was passed, new and evolving business arrangements in the health care field, such as increased physician employment by hospitals and managed care companies created situations where physicians inadvertently violated the Stark Law. The law quickly became cumbersome for physicians and other health care entities to remain in compliance due to newly developed arrangements not addressed by the law, but inherent to the health care field.

[3] Stark III

Congress passed Phase III of the Stark Law in 2007. In response to some of the stakeholder concerns about the law, Congress attempted to clarify and liberalize some of the definitions in the earlier versions; however, as with many regulatory clarifications, Stark III left many questions unanswered and generated many, but different, questions than the previous versions of the law engendered.

[6] 42 U.S.C. § 1395nn(h)(6).

For example, the drafters provided an example calculation method for fair market value but left calculations under any other method unclear as to their legality. Another major change in this version was the introduction of a phrase known as "stand in the shoes." The analogy intended to clarify the relationship of a physician within a group and the respective referral limitations for individual physicians and the group as a whole. This phrase would then be used to determine whether a financial relationship between one physician or the group practice and a third-party health care entity violated the self-referral prohibition.

[4] Stark IV

Phase IV of the Stark Law, passed in 2008, also contained delayed provisions due to the practical implications required by health care providers to remain compliant. Of note, this amended bill made changes to the "stand in the shoes" provision, such as adding a new requirement mandating that hospitals disclose their financial relationships with physicians. Of particular significance, the definition of "entity" was expanded to include not just the entity that bills Medicare for services, but also to include the entity that actually performs the DHS. As in previous versions of this law, Congress attempted to address a myriad of contractual arrangements within a health care setting to ensure that the statute was thorough enough to address any opportunity for a physician self-referral.

[5] Stark V

In the latest iteration of the Stark Law, which in the present day, is usually amended as part of the annual CMS physician fee schedule, was published in 2015 with effective dates in 2016. CMS began to recognize the regulatory burden and inadvertent compliance issues that the Stark Law created and drafted a rule that purported to make a positive change to the ease of compliance. The timing of this version of Stark came when the number of legal cases increased as a result of the ambiguous language. The judge in *United States ex rel. Drakeford v. Tuomey* held that "This case is troubling. It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby-trap rigged with strict liability and potentially ruinous exposure . . . "[7]

As such, this most recent version loosens earlier requirements, such as through the addition of a new exception for the recruitment of nonphysician practitioners to physician practices, which allows physician practices to obtain recruitment support from a hospital entity to help onboard a mid-level practitioner like a nurse practitioner.[8] Another change was the Writing Requirement provision.

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[7] 792 F.3d 364, 395 (4th Cir. 2014).

[8] https://www.federalregister.gov/documents/2015/11/16/2015-28005/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

The original Stark Law required the documentation of compliance within a physician compensation agreement. The term *agreement* was used throughout the legislation. Parties struggled to define how much detail was required, whether it was to be in one document or multiple, and what constituted an "agreement." Stark V clarified that contemporaneous documents could satisfy the requirement.[9] Furthermore, the new legislation replaced the word "agreement" with "arrangement" to encompass other documents that may have been used during the course of the negotiation to determine the parties' intentions.[10] Several definitions were clarified in Stark V such as the word "term" in the term requirement provision. The latest version of the rule removed the word "term" and replaced it with "duration of the arrangement."[11] The definition of *Locums Tenens*, a phrase used to define physicians who are filling in temporarily for other physicians, was clarified to remove the language "stand in the shoes" to avoid misapplication of the actual "stand in the shoes" doctrine with the same name, as described above. A new exception was also created to permit a "hotel"-style office rental arrangement for physicians who would rent office space on a limited basis in order to bring otherwise unavailable physician expertise to an underserved area.[12] During this time when physician-owned hospitals were popular, the latest version of the Stark Law clarified more specifically what constitutes a public disclosure of the financial relationship in this situation. It also redefined the "ownership or investment interest" as it relates to physician ownership.[13] Many other modifications were made in this version of the Stark Law indicating an evolving need to clarify expectations for affected parties.

[B] Anti-Kickback Statute

The policy behind the Anti-Kickback Statute as we know it today, dates back further than the current statute. As early as 1972, in the Social Security Act amendments, Congress introduced language that made what was already an unethical act now illegal if a person knowingly gave or received bribes or kickbacks in return for referral of services reimbursable by a government payor. This offense was considered a misdemeanor.

The penalties increased to felony offenses punishable by up to $25,000 and up to five years in prison for individuals who knowingly and willingly entered into illegal kickback arrangements. Like with the Stark Law, many routine, but practical business relationships between physicians and other entities were now in violation of the Anti-Kickback Statute. The leading case on this statute was

[9] 42 C.F.R. Part 405, 410, 411, *et al*.
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*

United States v. Greber[14] in which a diagnostic company paid a cardiologist 40 percent of the billed charges for interpreting diagnostic tests. The Third Circuit Court of Appeals held that if one purpose of the payment to the physician was intended to induce referrals, then the payment violated the Anti-Kickback Statute.[15] Using this case as an example, the OIG recognized that the language of the Anti-Kickback Statute was too broad and attempted to further clarify what constituted a kickback in 1989[16] but the legal standard used in *Greber* set the precedent for courts considering Anti-Kickback Statute violations.[17]

The OIG has continued to create "safe harbors" to the Anti-Kickback Statute to protect certain compensation arrangements if the arrangement meets the criteria of a safe harbor. Examples of the safe harbors include the following:

- Space rental
- Equipment rental
- EHR items and services
- Electronic prescribing items and services
- Discounts
- Health centers
- Payments made to bona fide employees
- Personal services and management contracts
- Warranties
- Investment interests
- Referral services
- Practitioner recruitment
- Ambulatory surgical centers

The most recent and significant change to the Anti-Kickback Statute was made in 2011 under the Patient Protection and Affordable Care Act when the law changed the intent requirement to clarify that the government was no longer required to prove that the defendant intended to violate the Anti-Kickback Statute itself, just that the defendant intended to violate the law and paid for business reimbursable by Medicare or Medicaid. Additionally, the law made a violation of the Anti-Kickback Statute an automatic violation of the False Claims Act, which will be discussed in detail below.

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[14] 760 F.2d 68 (3d Cir.1985).
[15] https://oig.hhs.gov/fraud/docs/safeharborregulations/012389.htm.
[16] https://oig.hhs.gov/fraud/docs/safeharborregulations/012389.htm.
[17] 217 F.3d 823 (10th Cir. 2000).

[C] The False Claims Act

The False Claims Act (FCA)[18] dates back to 1863 and was created to prevent fraud by suppliers of goods to the Union Army during the Civil War.[19] Despite its age, the concept behind the statute remains the same—to make it a criminal offense to purposely defraud the government. Under the False Claims Act, any person who knowingly submits or causes to be submitted, to any government agency, a false or fraudulent claim for payment or approval, gives false information to obtain said payment, or conspires to defraud the government, or any concealment of such fraudulent behavior and is liable for a civil penalty ranging between $5000 and $10,000 plus an additional multiplier of three times the damages sustained by the government.[20] Over time, the penalties have increased. In the more recent versions of the False Claims Act, the knowledge requirement is defined as "actual knowledge, deliberate ignorance of the truth or falsity of the information, or reckless disregard of the truth or falsity of the information."[21] This act also has a "reverse" false claims element for failure to disclose and return an overpayment to the government.[22] Overpayments are discussed in detail below.

What makes this law challenging in today's health care environment is that a billing practice that originates from an illegal arrangement results in a substantial recovery process. In other words, the False Claims Act is often violated in addition to a Stark or Anti-Kickback Statute violation because any Medicare or Medicaid payment that resulted from an illegal arrangement under the Stark or Anti-Kickback Statute is considered a false claim.

[D] Common Issues

[1] Physician Compensation

One of the challenges in health care is that the dynamics between a hospital and physicians is interdependent, meaning one cannot exist without the other. Even the most critical observer of these regulations readily agrees that intentionally defrauding the government is wrong and should be penalized. Where most disagree is on the unintentional attempt to secure physician services and an inadvertent violation of Stark and Anti-Kickback laws. As such, most physician employment or compensation arrangements immediately invoke strict scrutiny in terms of the amount of compensation and party obligations. Like in many situations, the definitions of "fair" and "value" and "knowingly" are key to determining whether any illegal activity has occurred.

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[18] 31 U.S.C. § 3729.

[19] https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

[20] https://downloads.cms.gov/cmsgov/archived-downloads/smdl/downloads/smd032207att2.pdf.

[21] https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

[22] 31 U.S.C. § 3729(a)(1)(G).

[2] Fair Market Value

How do we define *fair market value* (FMV)? First, the Anti-Kickback Statute defines *remuneration* as the "transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual or person for the furnishing or arranging of the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program."[23] There are some exceptions to this rule; however, the calculations involved in the determination of the value and benefits exchanged must stand independently of any value related to a referral or potential referral for services. The difficulty in establishing the latter is oftentimes the subjective nature of the value. For example, the value of a real estate transaction may be worth $10,000 to a physician and $20,000 to its health system owner for reasons outside the independent appraisal value. These can include location, ease of access to other nearby services, or diminished competition risk, all of which have a relative value depending on the viewer. However, it is this type of quandary that health entities find themselves in when determining a fair market value. If not appropriately documented or otherwise supported in justifiable calculations, the arrangement may be deemed illegal by the DOJ.

As an alternative, one might think that offering conservative fair market values is another option; however, the Anti-Kickback Statute also recognizes that undervaluing or discounting services when not clearly justified constitutes a violation because the benefit encourages the physician to send referrals as a perceived payback.

For these reasons, it is always advisable to seek the expertise of a third-party opinion from a professional to evaluate the arrangement independently and provide an arms-length transaction that meets the requirements of fair market value. In most cases, independent professionals may have the most experience in drafting a fair market value assessment based on their expertise with similar transactions and perhaps the testing of those arrangements.

[3] Physician Practice and Hospital Employment

Another highly scrutinized arrangement among physicians and hospitals is the financial position of the physician practices employed by a hospital system. Physician employment tends to be a cyclical trend in health care, but when at its peak, creates more risk for Anti-Kickback Statute and Stark Law violations. As a background, health care reimbursement has been in slow decline over time while the operating expenses have continued to rise. According to CMS in February 2017, under then current legislation, health care spending was projected to outpace our national gross domestic product (GDP) by 1.2 percentage points and by

[23] 42 U.S.C. § 1320a-7b.

2025 will make up nearly 20 percent of our GDP.[24] On a basic level, operating expenses, such as wages, typically increase by the average inflation rate of 2 percent each year.[25] However, the reimbursement from insurance companies either remains flat or declines. Additional factors such as high-deductible health insurance plans and uninsured patients affect the health care provider's ability to collect payment on the services it provides to these individuals. All these, and many more factors considered, cause a physician practice to operate at a loss. Given that scenario in the context of fair market value, Anti-Kickback and Stark Law regulations, is paying a physician a fair market value salary knowing that her practice operates at a loss a per se violation?

In analyzing this question, we look again to the definition of a financial arrangement that induces physicians to make referrals under the influence of other benefits. In a physician employment arrangement, a physician's compensation must be fair market value—meaning within the range of similarly licensed physicians in similar practice areas. Furthermore, the employment agreement with the physician may not include any restrictions on the physician's ability to make independent medical decisions and referrals to necessary entities, including any arrangement that would unfairly benefit the employing entity by way of the physician practice patterns. Any arrangement where either party is unfairly compensated in return for the expectation of business will be viewed as a violation of these laws. As such, it is critical to engage the appropriate professionals in the creation and deployment of these arrangements to ensure compliance with these laws.

[E] Enforcement Update

Since the passing of the Fraud Prevention System, the federal government has used additional resources to seek out and penalize those in violation of fraud and abuse laws. In the first three years of its implementation, CMS identified or prevented $820 million in improper Medicare payments using predictive analytics and other data mining tools to detect potential patterns of fraud or abuse.[26] In July 2017, the DOJ carried out the largest health care fraud enforcement action in its history. More than 400 individuals were charged with defrauding federal health care programs in 41 federal districts in the United States.[27] The claims included identity theft in billing for services that never occurred, services that were billed

[24] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-02-15-2.html.

[25] https://www.clevelandfed.org/en/newsroom-and-events/publications/economic-trends/2016-economic-trends/et-20160114-recent-inflation-trends.aspx.

[26] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-07-14.html.

[27] https://www.justice.gov/usao-ndil/pr/national-healthcare-fraud-takedown-results-charges-against-more-400-individuals.

by a provider who did not provide them, and kickbacks for referrals to home health agencies.[28]

[F] Key Cases

Unlike schemes that are clearly established under false pretenses, many business arrangements between hospitals and physicians occur as a practical matter and oftentimes unintentionally implicate the fraud and abuse laws. Since the Fraud Prevention System was implemented, several key cases have been brought by the government resulting in new interpretations of the laws and the penalty systems for enforcement. In *United States v. Halifax Hospital*,[29] an executive whistle-blower filed suit against Halifax Health Hospital based on the Stark Law for allegedly providing illegal physician bonuses. Halifax used a bonus compensation arrangement for a group of employed oncologists that paid them an additional amount based on the operating margin of their oncology department allocated on a percentage of their contribution. In a settlement of $85 million, the government alleged that the physicians were indirectly incentivized to increase volume in order to increase the department's operating margin. Thus, this arrangement violated the Stark Law.[30]

In *United States v. Tuomey*,[31] Tuomey Healthcare System allegedly paid 19 physicians more than fair market value compensation in exchange for requiring referrals of a certain procedure to the hospital in an effort to maintain the hospital's market share. A physician whistleblower filed the original lawsuit in 2005 and the government then charged Tuomey with Stark Law and False Claims Act violations for the illegal referral arrangement and then subsequently for billing Medicare for the services referred.[32] Tuomey settled for $237 million, and the high penalty forced the hospital to sell to another hospital system.[33]

From a different health care sector, the government alleged violations of the False Claims Act against medical device company Medtronic in 2015 for causing physicians in more than twenty states to submit claims for a procedure using its stimulation devices.[34] Because the procedure was deemed investigational and not approved by the Food and Drug Administration, the government argued that Medtronic's liability stemmed from promoting the procedure to physicians at training

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[28] *Id.*

[29] United States v. Halifax Hosp. Med. Ctr., No. 6:09-CV-1002-ORL-31, 2013 WL 6017329 (M.D. Fla. Nov. 13, 2013).

[30] http://www.modernhealthcare.com/article/20140308/MAGAZINE/303089982.

[31] 792 F.3d 364 (4th Cir. 2015).

[32] https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital.

[33] *Id.*

[34] https://www.justice.gov/opa/pr/medtronic-inc-pay-28-million-resolve-false-claims-act-allegations-related-subq-stimulation.

events causing physicians to perform and bill a procedure that was not approved. Because the procedure had not been proven safe and effective by the necessary governing bodies, CMS and the DOJ intervened to protect the integrity of federal funding to health care beneficiaries.

Finally, in 2017, Indiana University Health Inc. and HealthNet Inc. settled for $18 million on a whistleblower case that alleged that their financial arrangement violated the Anti-Kickback Statute and False Claims Act.[35] According to the DOJ, Indiana University Health offered an interest-free line of credit to HealthNet as remuneration for obstetric and gynecological referrals by HealthNet to Indiana University Health's Methodist Hospital. The DOJ also alleged that HealthNet was not required to repay most of the loan and determined that by permitting nonpayment, Indiana University Health induced referrals. The Attorney General continues to affirm that these types of arrangements undermine the independent medical judgment of physicians by providing opportunities for them to make medical decisions regarding patient care using ulterior motives.

§ 10.03 WHEN FRAUD OR ABUSE IS IDENTIFIED

[A] Self-Reporting

Self-reporting is the appropriate path to pursue when a criminal violation of a federal administrative, criminal or civil law has been or likely has been committed where civil monetary penalties are permitted.[36] The OIG and its affiliates encourage a proactive approach, referred to as voluntary reporting, when potentially fraudulent activities are identified, and to subsequently return any payments made as a result of those actions. Many of the recent cases involving Stark, Anti-Kickback, and False Claims Acts were filed by whistleblowers, who reportedly attempted to resolve potential violations with their employers and after being unsuccessful, filed a lawsuit, also known as a qui tam action. In other cases, the fraudulent activity was detected by data analytics or other similar means and government officials initiated their own investigations. The OIG, CMS, and the DOJ emphasize that a proactive approach to investigation and reporting often reduces the harsh penalties that may otherwise be invoked if identified in other ways.

In order to provide a "friendly" approach to self-reporting instances of error or potentially fraudulent actions, many government agencies created self-reporting systems. The Patient Protection and Affordable Care Act included legislation that required CMS to establish a Medicare self-referral disclosure protocol (SRDP) to be used for reporting actual or potential violations of the Stark

[35] United States *ex rel*. Robinson v. Indiana University Health, Inc. *et al*., Case No. 1:13-cv-2009-TWP-MJD (S.D. Ind. 2017), *available at* https://www.justice.gov/opa/pr/indiana-university-health-and-healthnet-pay-18-million-resolve-allegations-false-claims.

[36] https://www.oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf.

Law.[37] The OIG gives medical providers a self-disclosure protocol (SDP) to report actual or potential fraudulent activities for any activity that relates to health care services.[38] Once the unlawful practice is reported, the payments received for those services, known as overpayments, must be paid back to the respective agency that issued them.

Preventing ambiguity and promoting adherence often starts with a good compliance program. Compliance programs are a chapter all their own, but providers must have some system for establishing policies and procedures and then routinely follow up to ensure appropriate implementation and cooperation.

[B] 60-Day Overpayment Rule

Civil monetary penalties are not always the most equitable outcome regarding all the different abuses to the system. It is not uncommon for a health care provider to misunderstand billing requirements and to inadvertently be noncompliant in its practice. When a provider identifies a billing process or payment that was incorrectly billed and paid even unknowingly, it is still obligated to notify CMS and return the overpayment. For purposes of this obligation, an overpayment is defined as a payment received for a service that is higher than what Medicare would have reimbursed under the actual circumstances or guidelines. Under the False Claims Act, CMS can impose civil monetary penalties on providers who have knowledge of an overpayment and do not report and return it. However, promptly recognizing the error and returning the overpayment will not implicate the False Claims Act.

To establish a process whereby an overpayment should be reported and returned, Congress created the 60-Day Overpayment Rule as part of Section 6402(a) of the Affordable Care Act.[39] This rule requires a provider to report and return any overpayments to Medicare within 60 days of identification; however, the definitions in the original rule were ambiguous. Subsequently, in 2016, CMS published a final rule providing clearer guidance to health care providers who identify overpayments in their practices.[40] Oftentimes the identification of an overpayment or incorrect billing practice evolves over time. Once a trigger event or one-time claim is identified, researching the situation and determining whether or not the service was billed in a compliant manner, and if so, to what extent, takes time. Depending on the complexity and uniqueness of the situation, this process can take days or even weeks. Furthermore, because health care is often a process-intense industry, it is more likely than not that there are more noncompliant claims of a similar nature. CMS recognized that the due diligence required in researching

[37] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

[38] https://www.oig.hhs.gov/compliance/self-disclosure-info/protocol.asp.

[39] 6402(a) Affordable Care Act Section 1128j.

[40] 81 Fed. Reg. 7653.

these types of situations takes time and it clarified in this final rule that "identification" includes a period of time under which research occurs in order to capture the entire impact of the billing practice and define exactly how many claims were involved and the total amount of the overpayment. As such, CMS defined this timeliness as within six months of the trigger event that prompted the investigation. After this original 60-day period, the provider then has 60 days to report and return the overpayment.

The 60-Day Overpayment Rule not only requires that a provider report and return the overpayment, but also that it conducts a review of its compliance practices, including staff education. A provider must also look back for six years to determine for how long the incorrect practice occurred. CMS takes fraud and abuse seriously and is not only interested in financial recovery, but also in promoting best business practice for compliance and operating procedures.

[C] How to Report

CMS is the federal governing body of the Medicare and Medicaid programs; however, it delegates its authority for claims processing and payments by geographic regions to Medicare Administrative Contractors, known as MACs. Because the financial transactions occur at the MAC level, any identified overpayment must be reported and returned to the MAC that paid out the original claim. CMS has given MACs some general guidelines for operating procedure, but each MAC can define its own processes for handling the overpayments. When a provider identifies an overpayment situation, it should perform the due diligence to investigate the scope of the noncompliant practice and then follow its MAC procedures to report and return the overpayment.

Generally, the 60-Day Overpayment Rule applies in an unintentional event and the scope is relatively small. If at any time, intentional or knowingly fraudulent activity was performed by any individual involved in the delivery of health care services, the 60-Day Overpayment Rule is likely not sufficient. The OIG maintains a Provider Self Disclosure Protocol (SDP) that is the more comprehensive of self-reporting mechanisms and is typically used when reporting a potentially fraudulent or unlawful activity. In addition to the provider-initiated action steps in the 60-day Overpayment Rule, the Office of Inspector General (OIG) may conduct its own audit. This audit can extend beyond the scope of the original identified issue. The OIG may also invoke a Corporate Integrity Agreement as an exchange for release from other potential liabilities. This process generally takes longer than the overpayment recovery process, can be much more intrusive, and risk additional liability. On the contrary, OIG encourages resolution when appropriate via this process as a matter of good faith efforts. Some of the benefits of SDP may include lesser civil monetary penalties than are otherwise required, the reduction in individual employee liability risk, and a limit on additional corporate liability from any qui tam suits. Similar due diligence is required

in the SDP process including a summary of the potentially fraudulent activity, the patient scenarios affected, and the estimated financial overpayment as a result. While other self-disclosure reporting mechanisms are available, the only one that suspends the 60-Day Overpayment Rule is the OIG's SDP.

§ 10.04 CRITICAL TAKEAWAYS AND PRACTICAL IMPLICATIONS

[A] To Report or Not to Report?

Self-disclosure reporting has continued to perplex even the most experienced health care professionals. A clear violation of the law mandates a disclosure. For example, a rogue employee who knowingly embezzles money or egregiously posts claims for services that were clearly never rendered is an obvious self-disclosure. But what about those acts that were not intentional? How do we define a "potential" breach?

The OIG provided health care entities with open letters to try to clarify when to use the OIG self-reporting protocol.[41] But for most, the situations are not clear. The agency is clear that mere mistakes are not eligible for self-disclosure. This protocol is also not to be used for Stark-only violations. However, there are risks and benefits in choosing to self-disclose. In other words, if you choose to be conservative and report an activity that may not necessarily fall into the required reporting, you risk opening your facility or practice up to additional scrutiny. However, if your potential violation was realized, you may be protected with limited or reduced penalties should you choose to step forward and voluntarily disclose.

Either way, in making the choice to disclose, there are specific steps that must be followed. First, you must conduct a thorough assessment of your situation. What agreements were involved? What parties? What was the initial intention? What were the ramifications of the arrangement in terms of billing impacts downstream? How do the physicians get paid? Is it fair market value? What is the total monetary impact? These are all questions that need to be vetted and documented. Additionally, if a compliance plan was not already in place at the creation of the arrangement, one must be at least drafted. In any self-disclosure, it is best to file armed with as much factual information as possible in order to be prepared for the OIG or other agency. The OIG has a checklist of items that are required, most of which you will need to submit with your disclosure anyway. Be thorough with the items. Have documentation to support your calculations and research. If you choose not to disclose, document your legal counsel opinion and the research used in making the determination. The government is working hard to prevent not only intentional fraud, but also a disregard for the best practices in compliance all of which lead to wasting of taxpayer dollars.

[41] https://www.oig.hhs.gov/compliance/open-letters/index.asp.

If you choose to voluntarily disclose, you will likely see a reduction in civil monetary penalties. The law calls for three times the damages, so you may only be required to pay one to two times the damages. While no one wants to pay any damages, if the OIG initiates an investigation without your disclosure, your risks for the full penalty are likely higher. Additionally, voluntary disclosure may also increase the chances of avoiding the requirement to enter into a Corporate Integrity Agreement. Those agreements will place strict limits on your facility or practice to ensure that this violation does not occur again. They are typically time and resource intensive and can last for several years, not to mention that their implementation is typically a public relations problem. Finally, the OIG self-reporting process will stop the toll on the time to return the overpayments, meaning that until the OIG investigation process is over, your practice is not bound to the 60-day overpayment rule requirements, which are sometimes difficult to make when the amount of claims and refund are substantial.

However, if you do choose to disclose, there are also risks you should consider. For one, if any of your employees is aware of the details of the practice, they can file a qui tam action against you for violation of the False Claims Act, also referred to as a whistleblower suit. The other risk is that the government when investigating one issue for your practice may also then more broadly inquire about other issues and your exposure is greater than what you originally anticipated.

In deciding whether to self-disclose, to any agency, you must do your own investigation, get legal counsel involved, and determine whether a violation was actually committed and weigh the risks and benefits mentioned above in your decision.

§ 10.05 THE COMPLIANCE PROGRAM

Health care providers should have a compliance plan in place and should routinely use the plan to prevent fraud and abuse. The plan should be reviewed periodically as the law is regularly changing and health care constantly involves new business relationships that did not previously exist.

A few examples of policies that should be in every practice are specific self-referral and anti-kickback policies. The policies need to state the current law and how the practice plans to ensure that it is meeting that requirement. Additionally, staff members, including physicians need to understand and sign an employee handbook to provide documentation that the policy has been disseminated. Other policies include ethics in billing practices.

Finally, annual compliance training on fraud, waste, and abuse, and general compliance are all requirements of CMS.[42] Despite the challenge of organizing a staff and physicians meeting to address these concerns, make the idea of

[42] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html.

compliance something that each person understands by offering a thorough training on the issues. The CMS website provides tools for compliance.[43] The goal of most of these laws is to protect government funding as it is used to provide care to beneficiaries who need it. Mistakes will occur, but being proactive and making every effort to follow and maintain guidelines will improve a provider's odds of a palatable agreement should the practice be found in violation.

§ 10.06 THE ROAD AHEAD

In mid-2017, Congress was nearly weekly, if not daily, rolling out new proposals to repeal and replace the Affordable Care Act (ACA). With the election of President Donald J. Trump, a Republican, the current administration is Republican-heavy. As with any shift in political party, the current administration intends to turn the tide from the previous administration and reduce the amount of regulation imposed by the federal government in many areas including health care. Since the beginning of 2017, the House of Representatives has made several proposals to alter health care regulations. It is important for compliance professionals to closely track the activities in Washington D.C. in order to understand any potential changes to the government's plans for detecting and enforcing fraud and abuse violations.

If the last year is any indication of the varying degrees of opinion regarding health care and the government's role in it, the future is bound to hold unprecedented change, particularly as we look to increase value and reduce cost in the U.S. health care system. Medicare leads the charge in volume to value initiatives and as new approaches to these goals are introduced, it will be critical to look back on existing regulation to ensure continued compliance.

One area of recent focus has been violations with regard to incentive-based violations, such as meaningful use incentives and value-based reimbursements. Recently, the government has undertaken various activities that verify the accurateness and appropriateness of incentive-based payment systems. Because of the complexities inherent in health care compliance and the stiff penalties instituted by the regulatory agencies, strong and active compliance programs and continued review of new payment systems are the best courses of action to prevent unwanted ramifications.

[43] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html.