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I. INTRODUCTION

The Centers for Medicare and Medicaid Services ("CMS"), formerly the Health Care Financing Administration ("HCFA"), estimates that by the year 2021, health care spending will account for 19.6% of gross domestic product, 0.3% higher than projected before reform.1 With federal spending for the Medicare and Medicaid programs projected to reach $1.09 trillion in 2013,2 Medicare and Medicaid comprise the largest single purchaser of health care in the world.3 Thus, it is no surprise that criminals view health care fraud as a lucrative field for illicit profit.4 The National Health Care Anti-Fraud Association ("NHCAA") estimates that health care fraud accounts for at least 3% of total health care expenditures, or more than $60 billion each year.5 Because about $36 billion of that is fraud against public health care programs,6 federal and state agencies have made health care

1. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS 2011–2021, 1 (2012), available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and Reports/NationalHealthExpendData/Downloads/Proj2011PDF.pdf (predicting that health spending will grow at an average annual rate of 5.7% during the forecast period, 0.4% slower than estimated before the Affordable Care Act).
2. See id. tbl.17 (projecting that in 2013, Medicare spending will reach $598 billion and Medicaid spending will reach $491 billion).
4. See Medicare at Risk: Emerging Fraud in Medicare Programs: Hearing Before the Permanent Subcomm. on Investigations of the S. Comm. on Governmental Affairs, 105th Cong. 67 (1997) (statement of Michael F. Mangano, Principal Deputy Inspector General, HHS) ("[T]here will always be individuals or companies that attempt to game the program purely for their own profit.").
fraud prosecution a primary focus.7 In fiscal year 2012, the federal government negotiated or won approximately $3 billion in judgments and settlements, plus additional administrative measures in health care fraud cases and proceedings.8 In addition, the Department of Health and Human Services ("HHS") is referring more health care fraud cases for criminal prosecution.9 Even before the recent comprehensive health care reform, countering fraud and abuse remained a priority.10 Implementation of the Patient Protection and Affordable Care Act will allow the government agencies and private insurers to "better detect, investigate and prosecute suspected fraud," as well as provide substantial additional funding for the Health Care Fraud and Abuse Control Program.11 A major change may come when the government begins to use predictive modeling techniques to help combat fraud. These techniques have often been used in the private sector and can increase efficient identification of fraud.12

The federal government concentrates on detecting and prosecuting health care fraud in its health care insurance programs.13 Statutes enacted to deal with fraud in

7. See Criminal Prosecution as a Deterrent to Health Care Fraud: Hearing Before the Subcomm. on Crime & Drugs of the S. Comm. on the Judiciary, 111th Cong. 38 (2009) [hereinafter Criminal Prosecution as a Deterrent Hearing] (statement of Lanny A. Breuer, Assistant Att'y Gen., Criminal Division, DOJ) (noting that in 2009 Congress appropriated $198 million for joint HH$ and DOJ health care antifraud programs); see also Dep't of Justice, U.S. Attorney's Manual § 9-44.100 (1997), available at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/44mcrm.htm#9-44.100 (stating that health fraud enforcement has been a top priority since 1993).


9. Compare id. (reporting that in 2012, the DOJ opened 1,131 new criminal health care fraud investigations, had 2,032 investigations pending, filed criminal charges in 452 cases involving 892 defendants, and secured convictions against 826 defendants), with Criminal Prosecution as a Deterrent Hearing, supra note 7, at 30 (statement of Lanny A. Breuer, Assistant Att'y Gen., Criminal Div., DOJ) (noting that in 2008 the DOJ filed criminal charges in 502 health care fraud cases involving charges against 797 defendants and obtained 588 convictions, representing an "all time high" count), and Dep't. of Health and Human Servs. & Dep't. of Justice, Health Care Fraud & Abuse Control Program, Annual Report[s] for Fiscal Year[s] 1999-2008, available at http://www.usdoj.gov/archive/dag/pubdoc.html (explaining that 396 defendants were convicted of health care fraud-related crimes in 1999, a number that increased steadily in subsequent years).

10. See Criminal Prosecution as a Deterrent Hearing, supra note 7, at 62 (statement of Patrick Leahy, Chairman, S. Comm. on the Judiciary) ("I believe that strengthening our enforcement efforts to crack down on rampant fraud, waste, and abuse in the health care system is vital to the success of health care reform"); see also Medicare and Medicaid Fraud Hearing, supra note 5, at 34 (statement by R. Alexander Acosta, U.S. Attorney for S.D. Fla.) (emphasizing that the DOJ remains committed to rooting out health care fraud).


13. Medicare primarily reimburses health care providers for the costs of services and equipment for the elderly and disabled, while Medicaid supplies individual states with federal funds to subsidize the distribution of medical services and equipment to people with incomes below set cut-offs. See Health Insurance for the Aged Act of 1965, Pub. L. No. 89-97, 79 Stat. 290 (1965) (codified as amended in scattered sections of Titles 26, 42 and 45 U.S.C.);
these programs are necessary because, "[a]s the government's second largest social program, Medicare continues to be an attractive target for fraud and abuse."14

Persons and organizations certified by HHS to receive payment under the Social Security Act are the most likely targets for Medicare and Medicaid fraud investigations.15 Persons and organizations include hospitals, nursing and rehabilitation centers, managed care entities, health maintenance organizations ("HMOs"), and intermediate carriers such as private insurance companies, private and public clinics, medical laboratories, durable medical equipment ("DME") providers, physicians, and physician practice groups.16

Several government agencies are involved in decreasing health care fraud. The Department of Justice ("DOJ") and HHS provide monitoring and enforcement of health care fraud regulations.17 Individual states assist the HHS Office of the Inspector General ("OIG") and CMS to initiate and pursue investigations of Medicare and Medicaid fraud.18 In addition, the OIG uses its permissive exclusion authority to induce providers to help track fraud through a voluntary disclosure program.19 In prosecutions of fraud, the DOJ employs the resources of its own criminal and civil divisions, as well as those of the U.S. Attorneys' Offices, HHS, and the FBI.20

42 U.S.C. § 1320a-7b (2012) (false statements or representations and Anti-Kickback Statute); id. § 1395nn (Self-Referral/Stark Amendments).


15. See 42 U.S.C. § 1320a-7 (2012) (detailing extensively how fraudulent conduct can exclude an individual or entity from participation in health care programs).


17. See Medicare and Medicaid Fraud Hearing, supra note 5, at 10 (statement of R. Alexander Acosta, U.S. Attorney for the S. Dist. of Fla.) (stating that the DOJ collaborates with HHS, the CMS, the Food and Drug Administration, the Federal Employees Health Benefits Program, and state law enforcement); DEP'T. OF HEALTH AND HUMAN SERVS. AND DEP'T. OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM, ANNUAL REPORT FOR FISCAL YEAR 2011 8–10 (2012), available at https://oig.hhs.gov/publications/docs/hcfac/hcfacreport20l1.pdf (providing an overview of the Health Care Fraud Prevention & Enforcement Action Team ("HEAT"), a recent effort to enhance collaboration levels between HHS and the DOJ).

18. DEP'T. OF HEALTH AND HUMAN SERVS. OFFICE OF THE INSPECTOR GEN., STATE MEDICAID FRAUD CONTROL UNITS, ANNUAL REPORT FOR FISCAL YEAR 2008, at 3 (noting that Medicaid Fraud Units operate in forty-nine states and the District of Columbia and recovered more than $1.3 billion for the Medicaid program in fiscal year 2008 and obtained more than 1300 convictions); 42 U.S.C. § 1396h (2012) (incentivizing states to create state-level liability for filing false or fraudulent claims).

19. Former HHS Inspector General June Gibbs Brown believed that the government cannot tackle all of these problems successfully without the help of the providers who have daily contact with and exposure to fraudulent dealings. See Alice A. Love, Leniency Offered Health Care Providers that Admit Federal Fraud, S.D. UNION TRIB., Oct. 22, 1998, at A16 (reporting Inspector General Brown's thoughts on voluntary disclosure guidelines); see also DOJ Releases Guidelines for Sharing Fraud Investigation Information with Insurers, 7 Health Law Rep. (BNA) No. 43, at 1711 (Oct. 29, 1998) (discussing guidelines to state and federal prosecutors instructing them how to share health care fraud investigation information with private insurers).

20. See Overlapping Jurisdiction a Factor in Health Fraud Cases, Attorneys Say, 7 Medicare Rep. (BNA), No. 20, at D-31 (May 17, 1996) (noting HHS's OIG has jurisdiction over federal program fraud, while FBI has jurisdiction over all federal and private program health care fraud); cf Carrie Johnson, DOJ Posts Record For
This Article examines federal and state efforts to combat health care fraud. Section II of this Article discusses the statutes specifically enacted to address Medicare and Medicaid fraud and reviews the elements, defenses, penalties, and safe harbor provisions for each statute. Section III of this Article discusses general federal statutes used to prosecute health care fraud, including those regulating false claims, false statements, and mail and wire fraud. Section III describes the elements of the offenses, available defenses, and penalties applicable under each statute. Section IV provides an overview of federal and state government agencies' efforts to investigate and prosecute health care fraud.21

II. STATUTES ADDRESSING MEDICARE AND MEDICAID FRAUD

Congress responded to increasing Medicare and Medicaid fraud primarily by strengthening existing statutes.22 The result is a statutory and regulatory scheme that creates civil and criminal sanctions for any person or legal entity that provides health care goods or services in a fraudulent or abusive manner.23 The federal government may also bring criminal prosecution under the False Claims Act24 or other criminal fraud statutes,25 which are addressed in Section III.

In four parts, this Section discusses statutes enacted to fight Medicaid and Medicare fraud and abuse. Part A discusses the 42 U.S.C. § 1320a-7b(a), which


21. Where applicable, this Article discusses conflicts among federal circuit courts. Although this Article focuses on the criminal aspects of health care fraud, the Article also discusses important civil consequences because parallel proceedings have become standard practice for government health care fraud investigations and prosecutions.


23. See Kelly, supra note 22, at 304 (discussing Congress’s strengthening of Medicare and Medicaid anti-fraud and abuse statutes).

24. See 18 U.S.C. § 287 (2012) (sanctioning a sentence of up to five years and a fine imposed upon any person who presents a false claim to the United States government); Kaz Kikkawa, Note, Medicare Fraud and Abuse Qui Tam: The Dynamic Duo or the Odd Couple?, 8 Health Matrix 83, 84–85 (1998) (discussing various statutes in place “to protect the purses of Medicare and Medicaid”).

criminalizes false statements or representations in connection with federal health care programs.\textsuperscript{26} Part B addresses the Anti-Kickback Statute.\textsuperscript{27} Part C examines the amendments limiting physician referrals.\textsuperscript{28} Finally, Part D discusses relevant provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").\textsuperscript{29}

A. 42 U.S.C. § 1320a-7b(a)

Section 1320a-7b(a) criminalizes false statements and representations in connection with any application for claim of benefits or payment\textsuperscript{30} under a federal health care program.\textsuperscript{31} While § 1320a-7b(a) was enacted to target false statements or representations specifically related to health care, the majority of prosecutions related to health care fraud and abuse continue to be brought under other statutes.\textsuperscript{32} Congressional directives for increased enforcement of health care fraud statutes, including § 1320a-7b(a), led the United States Sentencing Commission to increase

\textsuperscript{26} 42 U.S.C. § 1320a-7b(a) (2012).
\textsuperscript{27} Id. § 1320a-7(b). Proposed legislation would strengthen penalties for the illegal distribution of a Medicare, Medicaid, or CHIP beneficiary identification or billing privileges. S. 1123, 113th Cong. § 1 (2013).
\textsuperscript{28} 42 U.S.C. § 1395nn (2012).
\textsuperscript{30} 42 U.S.C. § 1320a-7b(a) (criminalizing the making of false claims against federal health programs or presenting a claim for services not furnished by a licensed physician). The statute also criminalizes presenting assisting individuals in disposing of assets to ensure eligibility for a state health care plan. Id. § 1320a-7b(a)(6). However, that restriction is rarely enforced and likely unconstitutional. Zahner ex rel. Zahner v. Mackreth, Civil No. 11-306, 2014 WL 198526, at *6 (W.D. Pa. Jan. 16, 2014) (noting "there has been no known prosecution of this statute to date" and holding that the statute is unconstitutional as applied to a financial planner); N. Y. State Bar Ass'n v. Reno, 999 F. Supp. 710, 713, 716 (N.D.N.Y. 1998) (inferring from Attorney General Janet Reno's refusal to defend the statute's constitutionality that the plaintiff would likely prove it to be an unconstitutional infringement on the freedom of speech, and enjoining the DOJ from enforcing 42 U.S.C. § 1320a-7b(a)(6)(ii)).
\textsuperscript{31} Id. § 1320a-7b(a)(1). "Federal health care program" is defined as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government . . . or any State health care program, as defined in section 1320a-7(h) of this title." Id. § 1320a-7b(f).
\textsuperscript{32} Frequently used criminal statutes for prosecuting health care fraud include federal mail fraud, wire fraud, and money laundering statutes, the False Statements Act, [RICO], the . . . Anti-Kickback Statute, the False Claims Act, the conspiracy to commit an offense against the United States statute, and conversion." Corey D. Babington, Note, Preserving the Attorney-Client Relationship After United States v. Anderson, 49 U. Kan. L. Rev. 221, 233 (2000); see A. Craig Eddy, The Effect of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) on Health Care Fraud in Montana, 61 Mont. L. Rev. 175, 183 (2000) (discussing most commonly used civil statutes, including the False Claims Act ("FCA"), along with civil RICO and money laundering); see also Devin S. Schindler, Pay for Performance, Quality of Care and the Revitalization of the False Claims Act, 19 Health Matrix 387, 394–395 (2009) (noting that the federal government can prosecute individuals for false statements to obtain payments from a health care program under Submitting False Claims, 18 U.S.C. § 287, False Statements, 18 U.S.C. § 1001, Mail Fraud, 18 U.S.C. § 1341, and the Civil False Claims Act, 31 U.S.C. §§ 3729–3733).
penalties for health care fraud violations in November 2011.\textsuperscript{33} The United States Sentencing Guidelines ("Guidelines") institute a two to four level increase for any "Federal health care offense involving a Government health care program" and resulting in a loss of over $1,000,000 to the program.\textsuperscript{34}

1. Elements of the Offense

Under § 1320a-7b(a), the government\textsuperscript{35} must prove four elements to sustain a conviction: (i) the defendant made, or caused to be made, a statement or representation of material fact in an application for payment or benefits under a federal health care program;\textsuperscript{36} (ii) the statement or representation was false;\textsuperscript{37} and (iii) the defendant knowingly and willfully made the false statement.\textsuperscript{38}

a. Statement of Material Fact

In most situations, materiality is a mixed question of law and fact requiring a finding of fact, existing where the statement has a natural tendency to make "a difference to the decision[-]-making body."\textsuperscript{39} Only the potential for a statement to influence a government agency needs to be demonstrated; actual reliance on the false statement is unnecessary.\textsuperscript{40}

\begin{itemize}
\item \textsuperscript{34} See U.S. SENTENCING GUIDELINES MANUAL § 2B1.1(8) (2013) [hereinafter U.S.S.G. MANUAL] (increasing penalties for health care offenses in proportion to the net loss to the Government health care program).
\item \textsuperscript{35} Under 42 U.S.C. § 1320a-7b(a), only the government can prosecute health care fraud and abuse. This distinguishes § 1320a-7b(a) from the FCA, which allows either the government or private individuals to bring claims for fraud and abuse. See STAMAN, supra note 25, at i, 9 (discussing PPACA and 2009 Fraud Enforcement Recovery Act’s expansion of the qui tam provisions of the FCA, which enable private individuals ("whistle blowers") to sue parties perpetrating health care fraud against the United States, and retain 15–30% of the suit’s proceeds).
\item \textsuperscript{36} 42 U.S.C. § 1320a-7b(a)(1); see United States v. Laughlin, 26 F.3d 1523, 1526–27 (10th Cir. 1994) (noting that the jury instruction regarding § 1320a-7b(a) was insufficient because it failed to note that the defendant must have known that the statement was false when the claim was submitted).
\item \textsuperscript{37} 42 U.S.C. § 1320a-7b(a)(1); Laughlin, 26 F.3d at 1526–27.
\item \textsuperscript{38} See 42 U.S.C. § 1320a-7b(a); Laughlin, 26 F.3d at 1526–27; cf. 42 U.S.C. § 1320a-7b(h) (discussing the specific knowledge or intent required); United States v. Johnson, 464 F. App’x 175, 176 (4th Cir. 2012) (per curiam) (dismissing the defendant’s claim that the district court failed to specifically instruct the jury that the making and presenting of false claims under the statute must have been willful); United States v. Catton, 89 F.3d 387, 392 (7th Cir. 1996) (finding false statement need only be knowing, not willful under 18 U.S.C. § 287, the False Claims Act, which has language similar to 42 U.S.C. § 1320a-7b).
\item \textsuperscript{39} United States v. Gaudin, 28 F.3d 943, 948 (9th Cir. 1994), aff’d, 515 U.S. 506 (1995) (finding materiality in another false claims context to be a mixed question of law and fact because it was an element of the crime); see United States v. Njoku, 737 F.3d 55, 66 (5th Cir. 2013) (concluding that nursing notes describing symptoms and services were material because they were capable of influencing a third-party’s determination that they had a right to bill Medicare).
\item \textsuperscript{40} United States v. Steele, 933 F.2d 1313, 1319 (6th Cir. 1991).
\end{itemize}
b. False Representation

To meet the statutory requirement, the false claim must have actually been submitted to the federal government for reimbursement.\(^4\) This includes, but is not limited to: (i) billing Medicaid for procedures or tests not performed;\(^2\) (ii) falsely claiming that a series of procedures were needed due to "accidents";\(^43\) (iii) submitting claims for patients never seen;\(^44\) and (iv) submitting claims for services not personally rendered.\(^45\)

c. Knowing and Willful

Sanctions for violating \(\S\) 1320a-7b(a) apply to whoever "knowingly and willfully makes or causes to be made any false statement or representation . . ."\(^46\) In general, "a 'willful' act is one undertaken with a 'bad purpose.'"\(^47\) The knowing and willful requirement is satisfied as long as the defendant is aware her conduct is unlawful; she need not know which statute she is violating.\(^48\) She does, however, need to know that the statement is false at the time the statement is made.\(^49\)

2. Penalties

In addition to criminal penalties,\(^50\) the administrator of the federal program may limit, restrict, or suspend a person found guilty under 42 U.S.C. \(\S\) 1320a-7b(a) from participating in Medicaid and Medicare programs for a period not to exceed

\(41\) See Laughlin, 26 F.3d at 1525–26 (discussing elements of offense under 42 U.S.C. \(\S\) 1320a-7b(a)).
\(42\) Id. (discussing charges against defendant for fraudulently billing Medicaid for procedures defendant did not perform); see United States v. Boesen, 541 F.3d 838, 849 (8th Cir. 2008) (upholding physician’s conviction for health care fraud after billing nasal endoscopies he did not actually perform); cf. United States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1303 (11th Cir. 2002) (explaining defendant overbilled for unauthorized, unnecessary, or excessive medical tests).
\(43\) Laughlin, 26 F.3d at 1525 (noting charges against defendant included falsely claiming series of procedures were necessitated by "accidents at home").
\(44\) See United States v. Larm, 824 F.2d 780, 782 (9th Cir. 1987) (stating defendant was charged in Medicaid false claim case for submitting claims for office visits although defendant never saw patients).
\(45\) United States v. Davis, 471 F.3d 783, 785 (7th Cir. 2006); Larm, 824 F.2d at 782 (discussing allegations that defendant submitted claims for injections that patients self-administered).
\(46\) 42 U.S.C. \(\S\) 1320a-7b(a).
\(48\) 42 U.S.C. \(\S\) 1320a-7b(h) (2012); see United States v. Starks, 157 F.3d 833, 837–38 (11th Cir. 1998) (discussing the knowing and willful requirement in the context of the Anti-Kickback Statute, which also uses the knowing and willful requirement from 42 U.S.C. \(\S\) 1320a-7b(a)). See generally Sale, supra note 33.
\(49\) United States v. Laughlin, 26 F.3d 1523, 1525 (10th Cir. 1994); Larm, 824 F.2d at 783 (discussing elements of \(\S\) 1320a-7b(a) and holding sufficient evidence of knowledge of falsity was present); People v. Kanaan, 751 N.W.2d 57, 65 (Mich. Ct. App. 2008) (interpreting \(\S\) 1320a-7b(a) to require knowledge of falsity).
\(50\) If the defendant is the person furnishing items or services, she is guilty of a felony punishable by a fine of up to $25,000, imprisonment of up to five years, or both. If the defendant is someone other than the provider, she is guilty of a misdemeanor punishable by a fine of up to $10,000, imprisonment of up to one year, or both. 42 U.S.C. \(\S\) 1320a-7b(a).
one year.\textsuperscript{51} Civil sanctions, like this suspension, can violate the Double Jeopardy Clause of the Fifth Amendment if they are punitive in nature. However, most circuits have held the suspension from participating in Medicaid and Medicare is remedial rather than punitive and, therefore, does not violate the Double Jeopardy Clause of the Fifth Amendment.\textsuperscript{52}

\textbf{B. Anti-Kickback Statute}

The Anti-Kickback Statute\textsuperscript{53} prohibits knowingly and willfully paying or receiving any remuneration—directly or indirectly, overtly or covertly, in cash or in kind—in exchange for prescribing, purchasing, or recommending any service, treatment, or item for which payment will be made by Medicare, Medicaid, or any other federally-funded health care program.\textsuperscript{54} The statute applies to virtually all sectors of the health care industry.\textsuperscript{55} Section 1320a-7b(b) prohibits not only patently illegal actions, such as kickbacks and bribes, but also an array of economic relationships significantly more complex than simple direct payments for services.\textsuperscript{56} As a result, the statute applies to previously-common business practices, including discount arrangements, incentives to pharmacists, and manufacturers giving gifts and offering business courtesies.\textsuperscript{57} The statute seeks to ensure that referrals are based on the patients’ wellbeing and not the referring parties’ economic interests. Referral of Medicare and Medicaid patients to health

\begin{footnotes}
\item[51] 42 U.S.C. § 1320a-7(b)(a) (noting exclusion from federal program is at discretion of program’s administrator).
\item[52] See Manocchio v. Kusserow, 961 F.2d 1539, 1542–43 (11th Cir. 1992) (finding suspension from participation in Medicare program is remedial because the legislature’s primary goal was remedial); accord Erickson v. United States ex rel. HHS, 67 F.3d 858, 864 n.2 (9th Cir. 1995); Bae v. Shalala, 44 F.3d 489, 494 (7th Cir. 1995) (upholding as remedial a drug company president’s permanent suspension from providing services to anyone selling FDA-approved drugs, where Congress’s intent was to remove doctors “whose participation in [the generic drug industry was] detrimental to public purposes”); cf. United States v. Stoller, 78 F.3d 710, 720, 724 (1st Cir. 1996) (rejecting Manocchio’s per se rule in favor of a totality-of-the-circumstances test, but finding the instant suspension to be remedial in nature).
\item[53] 42 U.S.C. § 1320a-7b(b).
\item[54] Id. § 1320a-7(b)(a) (HIPAA extended coverage of the anti-kickback statute to cover all federal health care programs); see Douglas A. Blair, The “Knowingly and Willfully” Continuum of the Anti-Kickback Statute’s Sciente Requirement: Its Origins, Complexities, and Most Recent Judicial Developments, 8 ANNALS HEALTH L. 1, 2–6 (1999) (describing history of Anti-Kickback Statute and discussing "knowingly and willfully" element in particular); Thomas N. Bulleit, Jr. & Joan H. Krause, Kickbacks, Courtesies or Cost-Effectiveness?: Application of the Medicare Anti-Kickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers, 54 FOOD & DRUG L.J. 279, 282–285 (1999) (summarizing purposes and history of anti-kickback law); see also infra Section II.D (discussing the expansion of the anti-kickback legislation).
\item[55] See Bulleit & Krause, supra note 54, at 281 (noting broad applicability of statute in virtually all sectors of the health care industry and focusing on prescription drug and medical device manufacturing sectors); Kucera, supra note 22, at 414 (describing the statute as expansive in scope and application).
\item[56] See Bulleit & Krause, supra note 54, at 280 (noting that the OIG takes the broad language of the Anti-Kickback Statute seriously and applies it to various manufacturer practices).
\item[57] Id. (discussing common practices to which Anti-Kickback Statute applies).
\end{footnotes}
care providers with whom the referring physician has a financial relationship is also prohibited under the “Stark II” amendments to the statute.58

1. Elements of the Offense

To convict under the federal Anti-Kickback Statute, the government must prove three elements—it must show that the defendant: (i) knowingly and willfully59 (ii) solicited or received remuneration60 (iii) in return for, or to induce, referral of program-related business.61

a. Knowing and Willful

The “knowing and willful” requirement is satisfied by showing that the defendant was aware that his conduct was unlawful and acted voluntarily and purposely—specific knowledge of the statute is not required.62 In the past, courts interpreted the mens rea requirement of “knowingly and willfully” in different ways, resulting in a circuit split over whether specific knowledge of the legal provision violated was required.63 The 2010 Patient Protection and Affordable Care Act addressed this split, removing any requirement to prove actual knowledge of the legal provision violated or specific intent to violate the Anti-Kickback Statute.64 In considering potential defenses, certain circuits have found that

58. See 42 U.S.C. § 1395nn (2012); Joan H. Krause, A Conceptual Model of Health Care Fraud Enforcement, 12 J.L. & Pol’y 55, 77 (2003) (explaining that the statute was enacted in response to studies showing an unexplained increase in the use of Medicare laboratory services where the referring physician had a financial interest in the laboratory to which patients were referred); Joshua E. Perry, An Obituary for Physician-Owned Specialty Hospitals, 23 HEALTH LAw. 24, 26-29 (2010) (discussing rise and fall of the exploitation of the “whole hospital exception” wherein so long as the physician had a financial interest in the whole hospital, rather than the specific laboratory, his referral was legal).

59. 42 U.S.C. § 1320a-7b(b).

60. Id.

61. Id. See generally United States v. Vernon, 723 F.3d 1234 (11th Cir. 2013) (discussing the inducement, remuneration, and scienter requirements). Other circuits have utilized this three-pronged approach, which follows the statutory elements. See, e.g., United States v. Jain, 93 F.3d 436, 440 (8th Cir. 1996); Am. Acad. of Ophthalmology, Inc. v. Sullivan, 998 F.2d 377, 385 (6th Cir. 1993).

62. 42 U.S.C. § 1320a-7b(b).

63. See Andrea Tuwiner Vavonese, Comment, The Medicare Anti-Kickback Provision of the Social Security Act—Is Ignorance of the Law an Excuse for Fraudulent and Abusive Use of the System?, 45 CATH. U. L. REV. 943, 947 (1996) (noting that definitions of “knowingly and willfully” have been unclear in many areas of criminal law, including Medicare fraud, and that “the issue is whether the prosecutor must prove that the defendant consciously and intentionally committed the act or whether the defendant knew the act was in violation of the law”). Compare United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (holding that the Anti-Kickback Statute only requires knowledge that one’s conduct is unlawful, as opposed to knowledge that one violated specific statute because a kickback scheme is malum in se), with Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (requiring that defendants: (i) knew statute prohibits offering, paying, or soliciting remuneration in return for referrals or to induce referrals; and (ii) “engage[d] in prohibited conduct with the specific intent to disobey the law”).

64. 42 U.S.C. § 1320a-7b(h) (“With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”).
good-faith reliance on counsel’s advice can negate the mens rea element of willfulness. 65

b. Solicitation or Receipt of Remuneration

The Anti-Kickback Statute prohibits “any remuneration” 66 both “in return for” 67 and “to induce” 68 referrals of program-related business. 69 This includes kickbacks, bribes, rebates, 70 and transfers of anything of value in any form or manner. 71 Courts have sought to determine fair market value in adjudicating whether a particular transaction falls within a safe harbor provision of the Anti-Kickback Statute. 72

65. See United States v. Petrie, 302 F.3d 1280, 1287 (11th Cir. 2002) (requiring that to argue good-faith reliance on advice of counsel, defendant must have fully disclosed all material facts to his attorney); Covey v. United States, 377 F.3d 903 (8th Cir. 2004) (affirming the district court’s jury instruction regarding evidentiary predicate for the reliance on the advice of counsel); United States v. DeFries 129 F.3d 1293, 1308 (D.C. Cir. 1997) (noting that good-faith reliance upon advice of counsel establishes a defense to specific intent crimes).

66. 42 U.S.C. §§ 1320a-7b(1)–(2).

67. Id. § 1320a-7b(1).

68. Id. § 1320a-7b(2).

69. See Hanlester Network v. Shalala, 51 F.3d 1390, 1396 (9th Cir. 1995) (finding defendants violated the statute by offering to pay remuneration to induce business referrals).

70. 42 U.S.C. § 1320a-7b(1).

71. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,958 (July 29, 1991) (codified at 42 C.F.R. § 1001 (2013)) (clarifying that the form or manner of payment includes indirect, covert, and in kind transactions); see United States ex rel. Fry v. Health Alliance of Greater Cincinnati, No. 1:03-CV-00167, 2009 WL 485501, at *2–4 (S.D. Ohio Feb. 26, 2009) (holding that the benefit of heart station time was a remuneration as the mere opportunity to work can be something of value); Mark Learn, Comment, Applying Medicare and Medicaid Anti-Kickback Laws to Disease Management Programs: Ramifications for the Pharmaceutical Industry and a Regulatory Proposal, 69 Temp. L. Rev. 245, 252 (1996) (noting that while the Act, in its original form, only prohibited kickbacks, bribes, and rebates, the phrase “any remuneration” was added to extend the reach of the law to include transfers of anything of value in any form or manner).

72. See United States ex rel. Goodstein v. McLaren Reg’l Med. Ctr., 202 F. Supp. 2d 671, 674 (E.D. Mich. 2002) (noting “remuneration” does not include payment made by lessee to lessor for use of medical office space if aggregate rental charge is set in advance, is consistent with fair market value in arms-length transaction, and is not determined in a manner that takes into account volume or value of any referrals); Linda A. Baumann, Court Provides Guidance on Determining “Fair Market Value” Under the Stark and Anti-Kickback Laws, 14 HEALTH LAW. 1, 1 (2002) (stating McLaren is especially important because there is so little guidance on the meaning of the Stark and Anti-Kickback Statute and that fair market value is important for providers attempting to structure their agreements in compliance with these laws); accord United States ex rel. Drakeford v. Tuomey Healthcare Sys., 675 F.3d 394, 409 (4th Cir. 2012) (instructing the jury to determine whether contracts violates the fair market value standard by taking into account anticipated referrals in computing the physicians’ compensation); United States ex rel. Osheroff v. Tenet Healthcare Corp., No. 09-22253-CIV, 2013 WL 1289260, at *7 (S.D. Fla. March 27, 2013) (interpreting the Anti-Kickback Statute to prohibit medical providers from entering into lease agreements with referring physicians for an amount that is far below fair market value); DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OIG ADVISORY OPINION NO. 12-10 (2012) (noting that the general rule of thumb is that to avoid posing significant risk of violation, any remuneration flowing between hospitals and physicians should be at fair market value).
c. For the Purpose of Inducing Referral of Business

Most courts have adopted a "one purpose" standard, whereby the Anti-Kickback Statute is violated if one purpose of the offer or payment was to induce referrals.73 While some circuits have yet to decide between "one purpose" and "primary motivation" interpretations, the OIG has interpreted the statute using the "one purpose" standard.74 There is no current circuit split on the issue, as no Circuit Court of Appeals has adopted the "primary motivation" doctrine.75 The Ninth Circuit adopted the Secretary of HHS's position that "to induce" means "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business."76 In addition, the OIG has issued advisory bulletins addressing illegal inducements.77

2. Defenses

There are three common defenses to a prosecution under the Anti-Kickback Statute: (i) the statute is unconstitutionally vague; (ii) entrapment by estoppel; and (iii) good faith belief that one's conduct was not forbidden by the statute.

a. Unconstitutional Vagueness

The Supreme Court has stated that "a criminal statute must be sufficiently definite to give notice of the required conduct to one who would avoid its penalties ..."78 A vagueness claim charges that a statute does not give fair warning of the standards by which conduct will be judged because its text yields varying possible interpretations.79 Defendants have argued both that the Anti-Kickback

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73. See, e.g., United States v. Borrasi, 639 F.3d 774, 782 (7th Cir. 2011) (rejecting adoption of a "primary motivation doctrine" in favor of a "one purpose" standard); United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000) (holding the government must only establish that "one purpose" of the contract was to induce referrals to demonstrate a violation of the Act); see also United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998) (ruling that as long as benefits to the defendant are, in part, an inducement to refer patients to the hospital, the Anti-Kickback Statute is violated). But see Michael E. Paulhus, Note, The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age, 59 Wash. & Lee L. Rev. 677, 695 (2002) (arguing that the McClatchy court's failure to elaborate on the distinction between "hoping" and "intending" inadvertently confused the single purpose test).

74. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OIG ADVISORY OPINION NO. 12-10 (2012).

75. See Borrasi, 639 F.3d at 781–82.

76. Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) (discussing inducement under the Anti-Kickback Statute).

77. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN, OFFERING GIFTS AND OTHER INDUCEMENTS TO BENEFICIARIES (2002) (stating that "unless [otherwise exempt] ... any gifts or free services to beneficiaries should not exceed the $10 per item and $50 annual limits" per patient); see also DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, OIG ADVISORY OPINION NO. 12-10 (2012) (refraining from possible sanctions on a radiology group's inducement of providing free pre-authorization work for referring physicians because it was transparently performed for patients from all referral sources, regardless of volume).


79. See Hanlester Network, 51 F.3d at 1397–98 (describing vagueness claims).
Statute is generally vague and that its specific terms—including the safe harbor provisions and the term “kickback” itself—are unconstitutionally vague.\textsuperscript{80} Both general and specific claims of vagueness have been rejected.\textsuperscript{81} However, because the only vagueness challenges to be rejected have been those as applied to specific claims and facts in a particular case (as opposed to vagueness on the face of the statute), vagueness may still be a possible defense in some individual cases.\textsuperscript{82}

\textit{b. Entrapment by Estoppel}

Defendants have also sought dismissal under the previous Medicaid fraud prohibition\textsuperscript{83} by claiming entrapment by estoppel.\textsuperscript{84} The four necessary elements of entrapment by estoppel include: (i) the government must have announced directly to the defendant that the charged criminal act was legal;\textsuperscript{85} (ii) the defendant relied on the government announcement; (iii) the defendant’s reliance was reasonable; and (iv) given the defendant’s reliance, the prosecution would be unfair.\textsuperscript{86} In \textit{United States v. Levin}, the Sixth Circuit upheld the dismissal of an indictment based on this defense,\textsuperscript{87} finding that a surgical supply company could
not be prosecuted for a sales inducement package after the HCFA had stated that it did not consider such package inducements to be reimbursement abuse. 88

c. Good Faith

While the statute requires “knowing and willful” violation, it also disclaims any requirement that the defendant be aware of the specific statutory provision. 89 Because the dividing line between general and specific willfulness is unclear, a good faith defense may be difficult to assert unless a defendant was ignorant of the law and ignorant of the “wrongful” nature of his conduct. 90 Alternatively, if the good-faith belief is the result of government assurances, it could give rise to an entrapment by estoppel defense. 91

3. Penalties

Violations of the Anti-Kickback Statute may result in criminal and civil penalties. Violators may be fined up to $25,000, imprisoned for up to five years, or both. 92 In addition, the OIG has the authority to limit, restrict, or suspend a violator from participating in Medicare and Medicaid programs for up to one year. 93


a. Purpose

The Anti-Kickback Statute is broad enough that it may inhibit innocuous conduct. 95 Because of this potential, the OIG has chosen to allow twenty-five

88. Id. at 465.
89. 42 U.S.C. § 1320a-7b(h) (2012).
90. Compare United States v. Yielding, 657 F.3d 688, 708 (8th Cir. 2011) (holding a good faith defense could be presented if the defendant did not know his conduct was wrongful and did not know his conduct was unlawful), with United States v. St. Junius, 739 F.3d 193, 210 (5th Cir. 2013) (holding that the government need only prove a defendant “willfully committed an act that violated the Anti-Kickback Statute,” not knowledge that the acts were illegal).
91. See supra Section II.B.2.b. (discussing the entrapment by estoppel affirmative defense).
93. 42 U.S.C. § 1320a-7b(a)(6)(ii) (noting that exclusion from federal health programs is at the discretion of the program’s administrator); see also Rabecs, supra note 92, at 6 (stating that the OIG is responsible for civil enforcement of statute).
payment practices that might otherwise fall under the auspices of the anti-kickback laws.\footnote{96} At the same time, the OIG issues special fraud alerts and guidelines for activities it believes implicate the Anti-Kickback Statute.\footnote{97}

b. Uncertainty in the Regulations

There are twenty-five regulatory safe harbor provisions and one statutory safe harbor provision.\footnote{98} However, due to the substantial uncertainty in the safe harbors since 1999, providers who attempt to structure their arrangements to fall within a safe harbor may not actually be protected, and each transaction will likely be evaluated on a case-by-case basis to determine whether the transaction constitutes an anti-kickback violation.\footnote{99} Incorporation of draft regulations by several safe harbors has introduced further uncertainty.\footnote{100}

It should be noted that 42 U.S.C. § 1395nn ("the Stark statute") and the anti-kickback provisions are not entirely consistent with one another.\footnote{101} Thus, arrangements that comply with one may still violate the other.\footnote{102} According to the OIG, these discrepancies are the result of congressional intent.\footnote{103} There are two major differences between the anti-kickback provisions and the Stark statute. First, because the Anti-Kickback Statute is a criminal law, an improper intent is necessary to violate its provisions.\footnote{104} This is not true of the Stark statute, a civil law.\footnote{105} Second, arrangements must fall entirely within an exception to the Stark statute to be legal, but arrangements that fall outside of the scope of the anti-kickback law's safe harbor protections are not necessarily unlawful.\footnote{106} Compliance with the safe harbor provisions detailed below does not necessarily mean that the arrangement or transaction is also protected under the Stark statute.\footnote{107}
c. Enumerated Safe Harbors

Individuals or entities are exempt\textsuperscript{108} from prosecution under anti-kickback laws if their activities satisfy the requirements of any of the following safe harbor provisions.\textsuperscript{109} Although working outside the safe harbor provisions does not mean a practice is per se illegal, the anti-kickback laws' harsh penalties incentivize caution, making transactions more complex, costly, and risky for providers.\textsuperscript{110}

\textit{i. Investment Interest}

The investment interest safe harbor,\textsuperscript{111} protects an investor who holds a security issued by an entity, provided he satisfies the specific requirements enumerated in the statute.\textsuperscript{112} The investment interest safe harbor was created because a literal interpretation of the anti-kickback laws would prohibit physicians from receiving remuneration from many investment activities.\textsuperscript{113}

This safe harbor distinguishes between three types of securities: investments in entities with more than $50 million in assets,\textsuperscript{114} investments in entities with less

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\textsuperscript{108} The burden of proof lies with the entity claiming a safe harbor as a defense. See United States v. Campbell, Civ. Action No. 08-1951, 2011 WL 43013, at *5 (D.N.J. Jan. 4, 2011); see also United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 95 (3d Cir. 2009) ("Once the plaintiff or the government has established proof of each element of a violation under the Act, the burden shifts to the defendant to establish that the conduct was protected by an exception."); United States v. Rogan, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006) ("The United States need not prove, as an element of its case, that defendant's conduct does not fit within a safe harbor or exception.").

\textsuperscript{109} Failure to comply with a safe harbor provision does not necessarily mean that the Anti-Kickback Statute has been violated. Wallander, \textit{supra} note 101, at 14. The OIG encourages entities with questions about whether specific transactions or arrangements are lawful to utilize the advisory opinion process. 42 C.F.R. § 1008.1 (2013) (outlining advisory opinion process).


\textsuperscript{111} 42 C.F.R. § 1001.952(a) (2013).

\textsuperscript{112} Id. § 1001.952(a)(4) (defining investment interest and describing examples including shares in corporation, interests or units in partnership or limited liability company, bonds, debentures, notes, or other debt instruments). An "investor" is anyone who holds a security interest, either directly or indirectly. \textit{Id.} Holding an investment interest indirectly could include investing in another entity such as a trust or holding company that holds an investment interest or having a family member hold the investment interest. \textit{Id.} The investor may be either active (involved in the management of the entity or a partner of the company) or passive. \textit{Id.}

\textsuperscript{113} See 42 U.S.C. § 1320a-7b(b) (2012) (describing illegal kickback arrangements often involving investment interests). For example, the Anti-Kickback Statute is written broadly enough to conceivably "prohibit a physician from receiving dividend payments from a large publicly traded pharmaceutical company if he or she prescribed one of the company's products for a Medicaid patient, knowing that ordering that product would increase his or her dividend payment." Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3090 (Jan. 23, 1989) (codified at 42 C.F.R. § 1001 (2013)).

\textsuperscript{114} This is understood to mean $50 million in undepreciated net tangible assets, and to require that the assets be related to the provision of health care items or services. 42 C.F.R. § 1001.952(a)(1). The OIG clarified the definition of health care "items or services" in regulations. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63521 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952).
than $50 million in assets,\textsuperscript{115} and investments in entities that are located in a HHS-designated Medically Underserved Area (MUA).\textsuperscript{116} While investments in each type of entity—large entities,\textsuperscript{117} small entities,\textsuperscript{118} and entities in MUAs\textsuperscript{119}—must meet different criteria for this safe harbor to apply, there are some similarities among the three. First, for returns on investment to qualify for the investment interest safe harbor, an entity’s products or services cannot be marketed or provided to passive investors in a manner different from their marketing to non-investors.\textsuperscript{120} Second, neither the entity nor any investor (nor anyone acting on

\textsuperscript{115} See 42 C.F.R. § 1001.952(a)(2) (outlining requirements).

\textsuperscript{116} Id. § 1001.952(a)(3) (outlining requirements in underserved areas).

\textsuperscript{117} Returns on investments in large entities with more than $50 million in health care assets will not subject the investor to prosecution or exclusion as long as the three common conditions and these two additional criteria are met: (i) if the investment interest is a security, it must be registered with the SEC; and (ii) if the investor is in a position to generate business for the entity, her investment interest must be obtained on terms and at a price equally available to the public. Id. § 1001.952(a)(1).

\textsuperscript{118} Investors in entities with less than $50 million in assets must meet five conditions in addition to the three common conditions: (i) no more than 40% of the entity's investment interest may be owned by investors with an ability to generate business for the entity; (ii) no more than 40% of the entity’s gross revenue can come from business generated by investors; (iii) a passive investor's status cannot be conditioned on generating business for the entity; (iv) the terms on which the investment interest is offered may not be related to generating referrals; and (v) the investment interest offered to passive investors who are able to generate business for the entity must be offered on terms available to all other passive investors. Id. § 1001.952(a)(2). But see Office of Inspector Gen., HHS, Advisory Opinion No. 98-19 (Dec. 21, 1998), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_19.htm (allowing independent physician association to acquire investment interest in managed care organization though the arrangement did not meet the requirements for safe harbor investment interests in small entities). The first two of these requirements are the conditions that practitioners often find most difficult to meet. See Ball, supra note 95, at 36 (asserting these regulations present difficulties for investor-owned small entities). They preclude a health care service that receives most of its business from referrals by its owners from receiving the protection of the safe harbor. See id. However, if a health care service receives more than 40% of its business from referrals but makes good-faith efforts to expand this base through marketing efforts, the OIG has said that it is "highly unlikely" that an investigation would be launched against the service. Id. (quoting comments section to 1991 regulations).

\textsuperscript{119} The safe harbor regulations promulgated in 1999 protect investments in entities located in HHS-designated MUAs. See 42 C.F.R. § 1001.952(a)(3). Remuneration for investment in such entities is shielded from prosecution if the three common conditions, the final three conditions for entities with less than $50 million in assets listed supra in note 118, and the following additional criteria are met: (i) no more than 50% of investment interests can be held by those with the ability to generate business for the entity, and (ii) at least 75% of the entity’s business must be derived from people who live in underserved areas or who are members of an underserved population (as designated by HHS). See id. The OIG states that the incorporation of the modified 60-40 investment interest rule required of small entity investment interests was inspired by concern that new entities funded entirely by referring investors would create unfair competition in areas with a limited number of referring providers. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63532 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952). If the area in which an entity is located ceases to be considered an underserved area, investments in the entity will still be protected through the current investment term or up to three years, whichever is less. 42 C.F.R. § 1001.952(a)(3)(ii).

\textsuperscript{120} 42 C.F.R. § 1001.952(a)(1)(iii), (a)(2)(v), (a)(3)(i)(E). The 1991 Regulations required an interested investor to acquire his interest on "terms equally available to the public." See Baumann, supra note 100, at 4. This language was narrowed in the 1994 proposed clarifications to require that the investment be acquired in the "same way" as the public would acquire such an investment. See id. The 1999 Regulations are slightly more flexible. The
an investor’s behalf) may make or guarantee a loan that will allow anyone with the 
ability to generate business for the entity to acquire an investment interest.121
Third, an investor’s return must be directly proportional to his capital invest-
ment.122

In addition to the similarities that the three categories share, a large entity must 
demonstrate that (i) the equity interest is registered with the SEC; 123 and (ii) the 
investment interests of an investor in a position to make or influence referrals to 
the entity were obtained on terms and at a price available to the public.124

A small entity must demonstrate that: (i) no more than 40% of the value of the 
investment interest of each class of investments was held in the previous fiscal or 
calendar year by investors in a position to make a referral for the entity; (ii) the 
terms on which an investment interest is marketed to a passive investor who is in 
a position to make referrals for the entity cannot be different from the terms offered 
to other passive investors; (iii) the terms on which an investment interest is 
marketed to an investor who is in the position to make referrals to the entity should 
not turn on the investor’s ability to generate business for the entity; (iv) there is no 
requirement that a passive investor make referrals, give items, or furnish services 
to the entity to remain an investor; and (v) no more than 40% of the entity’s gross 
revenue related to health care may come from referrals generated by investors.125

Finally, an entity located in a MUA must also demonstrate that: (i) no more than 
50% of the value of the investment interests of each class of investments was held 
in the fiscal or calendar year by investors in a position to influence referrals to the 
entity; (ii) the terms on which an investment interest is marketed to a passive 
investor who is in a position to make referrals to the entity are not different from 
the terms offered to other passive investors; (iii) the terms on which an investment 
interest is marketed to an investor who is in the position to make referrals to the 
entity should not turn on the investor’s ability to generate business for the entity; 
(iv) there is no requirement that a passive investor make referrals or furnish items 
or services to the entity to remain an investor; and (v) at least 75% of the dollar 
volume of the entity’s business in the previous fiscal or calendar year must be

precise intent of these subtle changes in language is thoroughly discussed in the preamble to the 1999 
Regulations. See id. at 4–5.
121. 42 C.F.R. § 1001.952(a)(1)(iv), (a)(2)(vii), (a)(3)(i)(G). This restriction was added in the 1999 modifica-
tions to the safe harbor provisions. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of 
the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions under the 
Anti-Kickback Statute, 64 Fed. Reg. 63518, 63522–23 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952). Although this restriction was not intended to prohibit bank loans, it does exclude loan guarantees and other similar 
arrangements made by an entity or its investors. See Baumann, supra note 100, at 5.
123. Id. § 1001.952(a)(1)(i).
124. Id. § 1001.952(a)(1)(ii).
125. Id. § 1001.952(a)(2)(i)–(iv), (vi) (2013); see Robin Locke Nagele, Hospital-Physician Relationships 
After National Health Reform: Moving From Competition to Collaboration, 82 Pa. B. Ass’n Q. 1, 7–9 (2011) 
(providing an example of the challenges physicians face in meeting the criteria for the investment safe harbor).
derived from the service of persons who reside in an underserved area or are members of Medically Underserved Populations (MUPs).126

ii. Sale of Physician Practices, Practitioner Recruitment, and Obstetrical Malpractice Insurance Subsidies

Additional safe harbors regarding the sale of physician practices,127 practitioner recruitment,128 and obstetrical malpractice insurance subsidies129 also provide for MUAs.

The safe harbor provision regarding the sale of physician practices130 is divided into two sections: (i) sales to another practitioner,131 and (ii) sales to a hospital or other entity.132 Each type of sale has different requirements, but sales to a hospital are generally not protected by the safe harbor provision unless the practice is located in a Health Professional Shortage Area ("HPSA") for that practitioner's specialty area.133 While a sale to a hospital is generally not within the safe

127. Id. § 1001.952(e).
128. Id. § 1001.952(n).
129. Id. § 1001.952(o).
130. Id. § 1001.952(e).
131. A physician who sells his practice to another doctor upon retirement but continues to be paid in a consulting role may violate the Anti-Kickback Statute. See Ball, supra note 95, at 35 (describing common arrangements possibly violating the Anti-Kickback Statute). This safe harbor is designed to allow physicians to sell their practices to other practitioners if the potential for abuse involved in such a relationship is eliminated. A practitioner selling his practice to another practitioner must fulfill two requirements for the payments from the sale to be protected by this safe harbor: (i) the sale must be completed within a year of the first agreement related to the sale; and (ii) after that one year period expires, the seller must not be in a position to generate business for the purchasing practitioner. 42 C.FR. § 1001.952(e)(1).
132. Prior to 1999 there was no safe harbor protection for the sale of a practice to a hospital. See Ellen L. Janos & M. Daria Niewenhous, White Coat Crime or Hospital-Physician Financial Relationships in the '90s, Bos. B.J., May/June 1996, at 8, 20 (stating HHS "specifically declined" to provide this protection). The OIG does not generally protect hospital purchases of physician practices because it believes that hospitals often purchase physicians' practices in order to ensure the hospital of a steady stream of referrals. [The OIG] continue[s] to believe that such practices lead to increased program costs and potential conflicts between the patient's best interests and the physician's business relationship to the hospital. Accordingly, we decline to protect a practice that often leads to the very abuses that the statute is designed to prevent. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,975 (July 29, 1991) (codified at 42 C.F.R. § 1001) (responding to comments on 42 C.F.R. § 1001.952 (1992)).
133. See 42 C.F.R. § 1001.952(e)(2) (2013). This exception is made for practices with specialties that are in short supply in the area where the practice is located. If the practice is sold to a hospital or other entity, it will be protected by this safe harbor if: (i) the sale is completed within three years of the first agreement related to the sale; (ii) the seller will not be in a position to generate business for the hospital or entity once the sale has been completed; (iii) the practice is in a Health Professional Shortage Area (as defined by HHS) for the practitioner's specialty; and (iv) the purchasing hospital or entity has attempted diligently and in good faith to recruit a new practitioner who will take over the practice within a year of the sale and adhere to the guidelines established in the recruitment safe harbor. Id.
harbor provision, referrals to a purchasing hospital may not violate anti-kickback laws so long as the purchase is for fair market value and there are no additional economic inducements for the referrals after the purchase price has been paid.\textsuperscript{134}

The safe harbor protecting practitioner recruitment activities\textsuperscript{135} was designed to allow areas that have difficulty attracting physicians\textsuperscript{136} to offer incentives to potential practitioners without being criminally liable under the Anti-Kickback Statute.\textsuperscript{137} Payments to induce a practitioner to locate in a HPSA for the practitioner's specialty area will be protected by this safe harbor provision if nine conditions are met: (i) the arrangement is recorded in a written contract specifying the benefits provided, terms under which they are provided, and obligations of each party; (ii) at least 75\% of the revenues of a practitioner who is leaving an established practice must come from patients that the practitioner has not previously seen; (iii) at least 75\% of the revenues of the new practice must come from patients residing in the HPSA or a MUA or who are part of a MUP, as defined by HHS; (iv) the benefits paid by the entity to the practitioner must not be provided for longer than three years and the contract cannot be renegotiated during this term; (v) the practitioner cannot be required to generate business for the entity as a condition for receiving benefits, but the practitioner may be required to maintain staff privileges at the entity; (vi) the practitioner cannot be prevented from establishing staff privileges at or referring business to any other entity; (vii) the payments to a practitioner cannot be tied to the amount of business that the practitioner generates for the entity if that business is (even partially) reimbursed by Medicare or a state health program; (viii) the practitioner must treat any patient receiving medical benefits or assistance under any federal health care program in a non-discriminatory manner; and (ix) the agreement between the entity and the

\textsuperscript{134} See United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045, 1049–50, (N.D. Ill. 2002) (finding that a doctor’s sale of his practice and subsequent referrals to the purchasing hospital did not violate anti-kickback laws despite a mandatory referral clause in the sale contract).

\textsuperscript{135} 42 C.F.R. § 1001.952(n).

\textsuperscript{136} The recruitment arrangement between a practitioner and a health center should result in savings that benefit a MUP. 72 Fed. Reg. 56,632, 56,637 (Oct. 4, 2007) (discussing comments to 42 C.F.R. § 1001.952). While the proposed rules applied only to rural areas, the 1999 regulations base the qualification for this safe harbor on the HPSA standards and thus include some urban centers as well as rural areas. Some rural areas are not HPSAs, however, and thus would not qualify under this safe harbor, even if they did qualify under the proposed rules. Further, HPSAs only apply to a limited number of practitioner specialties, so particular types of physicians will not qualify for this safe harbor provision. See Baumann, supra note 100, at 13.

\textsuperscript{137} Outside of this exception, practitioner recruitment practices are generally not protected. The OIG insists that “its experience over the past few years has shown that practitioner recruitment is an area frequently subject to abusive practices.” 64 Fed. Reg. 63,518, 63,543 (Nov. 19, 1999) (discussing comments to 42 C.F.R. § 1001.952); see also Jeremy Fine Bollinger, Doctoring Fraud & Abuse: Enforcement of Stark and the Anti-Kickback Law in Physician Recruitment May be Bad for Your Health, 38 Loy. L.A. L. REV. 485, 491–92 (2004) (describing the “arsenal” of laws that are available to address recruitment fraud and abuse and noting that the “multiplicity and diversity of federal health care fraud and abuse enforcement provisions is truly remarkable”).
practitioner may not benefit a third party who has power to generate business for the entity.\textsuperscript{138}

The obstetrical malpractice insurance subsidies safe harbor\textsuperscript{139} was designed to allow hospitals or other entities to cover malpractice insurance costs for obstetricians practicing in HPSAs.\textsuperscript{140} An entity may subsidize malpractice insurance premiums for a practitioner in a primary care HPSA who engages in obstetrical practice as a routine part of his practice if the seven conditions of the obstetrical malpractice insurance subsidies safe harbor are met.\textsuperscript{141}

\textit{iii. Contracts for Space, Equipment, Services, and Employment}

A separate collection of safe harbor provisions specifies how contracts with providers must be written to ensure immunity from anti-kickback laws. The safe harbors created for space rental agreements,\textsuperscript{142} equipment rental agree-

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  \item \textsuperscript{138} 42 C.F.R. § 1001.952(n); see also Baumann, supra note 100, at 13 (describing the limitations of the physician recruitment safe harbor). The safe harbor protection offered through compliance with these standards lasts for three years and protects only recruitment, not retention agreements. Comments received in 1999 supported a physician retention safe harbor, and retention agreements were mentioned as a potential subject for future rulemaking. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,543 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001.952). No rulemaking regarding the Anti-Kickback Statute has been proposed, but there is an exception for Stark Act purposes if the retention payments are made by hospital in MUA and meets other requirements. 42 C.F.R. § 411.357(t) (2013).
  \item \textsuperscript{139} 42 C.F.R. § 1001.952(o).
  \item \textsuperscript{140} Full time obstetricians and nurse midwives can have their entire insurance costs covered. \textit{Id.} Other practitioners can have a portion of their insurance costs covered as long as the obstetrical portion of their practice is conducted in an HPSA. \textit{Id.}
  \item \textsuperscript{141} To qualify, (i) a written agreement must establish the payments to be made by the entity and the terms under which the payments will be provided; (ii) payments must be made to a bona fide malpractice insurance policy or program whose premium is calculated on an assessment of the liability risk covered; (iii) the practitioner must certify that for the initial coverage period (not to exceed one year), she has reason to believe that at least 75% of her patients will either reside in a HPSA or MUA or be part of a MUP and for each subsequent coverage period (not to exceed one year), at least 75% of the practitioner’s patients in the previous coverage period must have either lived in a HPSA or MUA or been part of a MUP; (iv) the practitioner’s benefit cannot be conditioned upon generating business for the entity; (v) the practitioner cannot be prevented from establishing staff privileges at, or referring business to, any other entity; (vi) the amount of insurance payment cannot be tied to referrals that the practitioner makes to the entity if that business will be reimbursed by Medicare or a state health program; and (vii) obstetrical patients receiving benefits or assistance from a federal health program must be treated in a non-discriminatory manner. \textit{Id.}
  \item \textsuperscript{142} \textit{Id.} § 1001.952(b). Anti-kickback legislation regarding space rental is designed to prohibit arrangements where the rental agreement is used to induce business. The OIG is concerned that rental fees “may be disguised kickbacks to the doctor-landlord to induce referrals.” Publication of OIG Special Fraud Alert on Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, 65 Fed. Reg. 9274, 9275 (Feb. 24, 2000), available at http://oig.hhs.gov/authorities/docs/fraudalert.pdf [hereinafter Rental Space Fraud Alert]. A physician-as-tenant arrangement could also violate anti-kickback laws. For example, a clinical laboratory offering to lease office space to a physician at below market value, hoping to receive referrals from that physician, may violate anti-kickback laws. \textit{See Ball, supra note 95 (describing common arrangements threatened by the Anti-Kickback Statute).}
ments, personal services and management contracts are similar. Those safe harbors require that: (i) the contract is in writing and signed by all parties; (ii) the written contract covers all of the property or services exchanged between the parties, and the contract specifies what it covers; (iii) if the property or services are to be used periodically, the schedule of use, the length of each use, and the exact rent is established in the contract; (iv) the contract is for at least one year; (v) the payments are equal to fair market value and established in advance; and (vi) the space or amount of services covered by the contract is no more than necessary for a reasonable business purpose.

Case law guides which contracts are eligible for the safe harbor provision. The contract must specify all services provided by the physician and all remuneration.


144. 42 C.F.R. § 1001.952(d) (regulating personal service and management contracts because of their potential for abuse).

145. Contracts may be terminated for cause as long as the conditions under which the contract could be terminated for cause were specified and there is a prohibition on renegotiation of the arrangement before the completion of the original one-year term. See Baumann, supra note 100, at 6 (explaining OIG's concern that termination provisions could be used to create "sham leases and contracts"); see also 42 C.F.R. § 1001.952(b)(1), (c)(1), (d)(1).

146. This requirement prevents providers from entering multiple contracts with overlapping terms in an effort to circumvent the one-year requirement. See Baumann, supra note 100, at 6.

147. 42 C.F.R. § 1001.952(b)(3), (c)(3), (d)(3).

148. Contracts may be terminated for cause if such termination conditions were specified and there is a prohibition on renegotiation of the arrangement before the completion of the original one-year term. See Baumann, supra note 100, at 6 (explaining the OIG's concern that termination provisions could be used to create "sham leases and contracts").

149. Fair market value is defined as "the value of the rental property for general commercial purposes," and the value cannot "be adjusted to reflect the additional value that one party ... would attribute to the equipment [or property] as a result of its proximity or convenience to sources of referrals or business otherwise generated ...." 42 C.F.R. § 1001.952(b)(6), (c)(6). Fair market value is a question of fact that must be determined based on the circumstances of each case. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,956 (July 29, 1991) (codified at 42 C.F.R. § 1001.952 (2013)) ("[A] single set of standards for all business arrangements would be of extremely limited value because the subjectivity or arbitrariness in applying the standards to individual fact situations would make such standards of extremely limited value."). Although few cases have interpreted "fair market value" as used in the Anti-Kickback Statute, a federal district court in Michigan has clarified the term. United States ex rel. Goodstein v. McLaren Reg'l Med. Ctr., 202 F. Supp. 2d 671 (E.D. Mich. 2002) (comparing expert valuations and appraisals in a comprehensive analysis of whether the lease was obtained at a fair market value).

150. Establishing the method of calculating the charge, and not the specific money amount, will not necessarily satisfy this provision's requirements. See Baumann, supra note 100, at 6. The OIG noted, "[p]ayments of 'rent' for space that traditionally has been provided for free or for a nominal charge as an accommodation between the parties for the benefit of the physicians' patients ... may be disguised kickbacks. In general, payments for rent of consignment closets in physicians' offices are suspect." Rental Space Fraud Alert, supra note 142, at 9276.

151. 42 C.F.R. § 1001.952(b)(6), (c)(6), (d)(7). The OIG states that "[r]ental of space that is in excess of suppliers' needs creates a presumption that the payments may be a pretext for giving money to physicians for their referrals." Rental Space Fraud Alert, supra note 142, at 9276.
to be received.\textsuperscript{152} A contract does not qualify for the safe harbor provision if compensation for services is directly tied to the number of referrals or sales made by a party.\textsuperscript{153} Because application of these safe harbor provisions depends on the interpretation of contract provisions, seemingly irreconcilable results may occur due to different states’ contract law.\textsuperscript{154}

The OIG has provided guidance on arranging employment contracts to ensure compliance with the employee payments safe harbor.\textsuperscript{155} The terms of this safe harbor are broad enough to easily cover most employment relationships,\textsuperscript{156} but it does not reach independent contractors.\textsuperscript{157} When there is a question as to a referral source’s employment status, a reviewing court may look at factors including control over the referral source’s marketing activities, providing the source with training, setting the source’s work schedule or hours, the location of the source’s work, who bears expenses incurred in referring customers, and whether payment is determined on a commission basis.\textsuperscript{158}

\textit{iv. Advertisements and Promotions}

Providers may generate business through advertising directly to patients or using referral services. A hospital that attempts to attract patients by advertising that it will waive coinsurance or deductible payments potentially violates the

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\item \textsuperscript{152} See United States \textit{ex rel.} Koseneske v. Carlisle HMA, Inc., 554 F.3d 88, 96–97 (3d Cir. 2009) (holding that arrangement did not qualify for the personal services safe harbor because the only written contract referred to a then non-existent facility and did not provide the details of the actual arrangement).
\item \textsuperscript{153} In one case, a district court held that a marketing agreement whereby a hospital recommended medical equipment, which was produced by supplier, in exchange for a disproportionate share of the supplier’s net profits violated anti-kickback provisions because “compensation was directly pegged to the number of sales generated” by the hospital See Nursing Home Consultants, Inc. \textit{v.} Quantum Health Servs., Inc., 926 F. Supp. 835, 844 (E.D. Ark. 1996), aff’d, 112 F.3d 513 (8th Cir. 1997) (unpublished table decision).
\item \textsuperscript{154} Cf Woundkair Concepts, Inc. \textit{v.} Walsh, No. 02-10-00349-CV, 2012 WL 955388, *4–5 (Tex. App. Mar. 22, 2012) (distinguishing a contract where compensation included 20% of sales generated by the referrals based on common law upholding a contract as legal if there is any way to perform it legally).
\item \textsuperscript{155} 42 C.F.R. § 1001.952(i). This provision was intended to permit “an employer to pay an employee in whatever manner he or she chooses.” Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provision, 54 Fed. Reg. 3088, 3093 (Jan. 23, 1989) (codified at 42 C.F.R. § 1001.952).
\item \textsuperscript{156} See Ball, \textit{supra} note 95, at 37 (describing the ease with which bona fide employment contracts meet requirements of this regulation); \textit{see also} United States \textit{ex rel.} Obert-Hong \textit{v.} Advocate Health Care, 211 F. Supp. 2d 1045, 1050–51 (N.D. Ill. 2002) (holding (i) employment contracts that require physicians to refer patients to their employer-hospital are not inducements if the compensation arrangement is not contingent on the value or volume of referrals; and (ii) percentage compensation contracts that base compensation on the value of personally-performed services do not constitute referrals under the statute).
\item \textsuperscript{157} The services of independent contractors may be protected under the safe harbor for personal services and management contracts. See State v. Harden, 938 So. 2d 480, 493 ( Fla. 2006) (explaining exclusion of independent contractors from safe harbor for bona fide employment relationships, but noting that other types of personal relationships may be protected under the personal services and management contracts safe harbor); Ball, \textit{supra} note 95, at 37.
\item \textsuperscript{158} See United States \textit{v.} Job, 387 F. App’x 445, 455–56 (5th Cir. 2010).
Anti-Kickback Statute. While the OIG has proposed broadening the coinsurance and deductible safe harbor provision, such waivers are presently only protected from prosecution under the Anti-Kickback Statute if the beneficiary for whom fees are waived qualifies for subsidized services under the Public Health Services Act or Titles V or XIX of the Social Security Act, or if: (i) the waived amount is not later claimed as bad debt or the cost of the waiver otherwise shifted onto a government health plan; (ii) the waiver is made irrespective of the reason for admission, length of stay, and diagnosis; and (iii) the hospital’s offer to waive fees is not part of a price reduction agreement with a third-party payer, unless the agreement is part of a Medicare supplemental policy.

An additional safe harbor allows health plans with agreements with the CMS or a state health care program to provide care for beneficiaries to increase coverage, reduce cost sharing amounts, or reduce premium amounts for enrollees under certain conditions. If the plan is an HMO, competitive medical plan (“CMP”), prepaid health plan (“PHP”), or other plan that has a contract with the CMS or a state health care program, it must offer identical increased coverage or decreased cost-sharing or premiums to all Medicare or state health program enrollees, unless the CMS or the state approves otherwise.

If the plan has entered an agreement with the CMS or a state to provide services on a reasonable cost or similar basis, it must offer the same coverage increase or reduced cost-sharing or premium to all enrollees covered by the contract, and must not claim the costs of the increased coverage or decreased cost-sharing or premiums as a bad debt.

v. Electronic Prescription Systems

In an effort to promote the use of electronic prescription systems, the Medicare Modernization Act required the promulgation of a new safe harbor. This safe harbor protects non-monetary remuneration (in the form of hardware, software, or information technology and training services) that is necessary and used solely for

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159. See Ball, supra note 95, at 34 (describing common arrangements that potentially violate the Anti-Kickback Statute).
161. 42 C.F.R. § 1001.952(k).
162. Id. § 1001.952(l)(1)(i).
163. Id. § 1001.952(l)(1)(ii).
164. Id. § 1001.952(l)(1)(ii).
receiving and transmitting electronic prescription information, as long as it complies with the specified conditions.\textsuperscript{166} Such remuneration is permitted when: (i) a hospital provides the items or services to members of its staff, a group practice provides the items or services to a member of the group practice, or a prescription drug plan sponsor or Medicare Advantage organization provides the items or services to prescribing health care professionals or to pharmacists and pharmacies participating in the organization’s network; (ii) the items and services are provided as part of or used to access an electronic prescription drug plan that meets the standards under Medicare Part D; (iii) the donor of the items or services does not restrict the donated items’ or services’ use or compatibility with other electronic prescription or health record systems; (iv) the donor does not restrict use of the donated items or services to certain patients if the items or services are the type that can be used for any patient regardless of payor status; (v) the recipient does not make receiving the items a condition of doing business with the donor; (vi) the recipient’s eligibility for receiving items or services is not determined by the volume or value of business generated between two parties; (vii) the donation is pursuant to a written agreement that specifies all items and services provided; and (viii) the donor does not know or is not reckless to the fact that the recipient currently possesses\textsuperscript{167} or has already obtained the items or services provided by donor.\textsuperscript{168}

Another safe harbor protects services in the form of software or information technology that is necessary for and used predominantly to create, maintain, transmit, or receive electronic health records as long as the services are provided either by health plans, or by individuals and entities that provide services covered by or request payment from a Federal health care program.\textsuperscript{169} The conditions for this safe harbor mirror the conditions for the safe harbor for the use of electronic prescriptions, but also require that: (i) the software is interoperable at the time that it is provided to the recipient; (ii) the items and services do not include staffing of the recipient’s office and are not used to conduct personal business; (iii) the recipient pays 15\% of the donor’s cost of the items or services prior to receiving them; (iv) the donor does not shift the costs to any Federal health care program;

\textsuperscript{166} See 42 C.F.R. § 1001.952(x).

\textsuperscript{167} This condition is meant to insure that items and services that would duplicate items or services already possessed by the recipient are not covered by this safe harbor. See Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45,110,45,114 (Aug. 8, 2006) (codified at 42 C.F.R. § 1001.952(x)).

\textsuperscript{168} 42 C.F.R. § 1001.952(x).

\textsuperscript{169} 42 C.F.R. § 1001.952(y). After this article’s writing, regulations updated this provision to establish the role of the Office of the National Coordinator for Health Information in authorizing certifying bodies that deem software to be interoperable; adjust the time period within which software must be certified to correspond to the most currently applicable definition of Certified EHR Technology in 45 C.F.R. § 170; and remove the electronic prescribing requirement of § 1001.952(y)(10). Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 21,314-01 (codified at 42 C.F.R. § 1001.952).
and (v) the transfer of the items or services occurs before December 31, 2016.\(^{170}\) Congress has explained its intent to promote such technology in the interests of efficiency and accuracy; it is not intended as a marketing platform to induce referrals.\(^{171}\)

**vi. Referral Services**

The referral services safe harbor protects organizations that operate referral services for a fee, such as professional societies or consumer groups.\(^{172}\) The safe harbor is also implicated where indirect forms of remuneration are given for referrals.\(^{173}\) The harbor does not extend to situations where the operator of the referral service adjusts the fees that it charges participating physicians based on the number of referrals the physician makes to the operator of the service.\(^{174}\) In addition to protecting organizations, the referral services safe harbor also allows providers to refer patients to one another.\(^{175}\)

Distinct from the referral services safe harbor, the referral agreement safe harbor\(^{176}\) allows a practitioner to refer a patient to another party to provide a specialty service, with an agreement that the patient will be referred back at a specified time or under certain conditions.\(^{177}\) Without the ability to create referral

\(^{170}\) 42 C.F.R. § 1001.952(y).


\(^{172}\) See 42 C.F.R. § 1001.952(f).

\(^{173}\) Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,976 (July 29, 1991) (codified at 42 C.F.R. § 1001.952) (providing an example where hospitals operate free referral services for which physicians in return are expected to fulfill obligations such as sitting on hospital committees).

\(^{174}\) Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provision, 54 Fed. Reg. 3088, 3091 (Jan. 23, 1989) (describing limits of referral safe harbor) (codified at 42 C.F.R. § 1001.952). To qualify for protection from anti-kickback prosecution, referral service agreements must meet the following criteria: (i) no practitioner who meets the qualifications for participation can be excluded; (ii) payments made by practitioners to the service must be based only on the cost of operating the referral service (not on the volume of business generated) and must be assessed equally against all participating practitioners; and (iii) the referral service cannot establish requirements for the way that a practitioner serves a referred person. 42 C.F.R. § 1001.952(f). Additionally, the referrer must keep records that indicate patients seeking referral were informed how practitioners are selected for participation, whether the practitioner paid a fee to the service, how the service matched the patient with a particular practitioner, the nature of the relationship between the service and participating practitioners, and what restrictions would exclude a practitioner from participation in the referral service. Id.

\(^{175}\) Id.

\(^{176}\) Id. § 1001.952(s).

\(^{177}\) Id. § 1001.952(s).
agreements, physicians might hesitate to refer patients to specialists for fear that they would lose their patients to the specialist, which could inhibit patient access to appropriate care.178

vii. Relationships Between Providers

In addition to the safe harbor protecting referrals, several other safe harbors address the relationships between providers. Safe harbors protect group practices, cooperative hospital service organizations, and ambulatory surgical centers ("ASCs") as long as the arrangements meet OIG regulations.179 Revenues generated from referrals between members of a group practice could create incentives other than patient health because all members of the practice eventually share these revenues. The safe harbor for investments in group practice—substantially narrowed in the 1999 revisions180—protects revenue from a group practice if: (i) the equity interests in the practice are held by licensed medical professionals who practice in the practice or group; (ii) the equity interests are in the entire practice, not in a particular subset; (iii) the practice, if it is a group practice, is a unified business characterized by centralized decision-making, pooling of expenses and revenues, and a compensation system that is not based on satellite offices operating independently; and (iv) revenues from ancillary services only come from in-office ancillary services.181

Cooperative Hospital Service Organizations ("CHSOs") are created by two or more tax-exempt hospitals to provide services such as purchasing and billing for their patron hospitals.182 Payments exchanged between a CHSO and its patron hospital may be protected under the CHSO safe harbor.183 The payments are protected if the CHSO is owned by at least two patron hospitals, and if the payment the patron hospital makes to the CHSO is for bona fide operating expenses, or if the payment the CHSO makes to the patron hospital is for the purpose of paying a distribution of its net earnings.184
The safe harbor for ASCs\textsuperscript{185} was originally proposed because the return on any investment that a physician might make in such a center would be relatively small in comparison to the physician’s payment for performing surgery at the facility.\textsuperscript{186} This makes it unlikely that the prospect of a return on the facilities fee would induce a physician-investor to make referrals to the center.\textsuperscript{187} Recognizing the possibility of changing fee schedules, the OIG’s 1999 revisions to the safe harbor provisions enlarged the protection of the ASCs and focused on criteria establishing that the ASC operates as an extension of a physician’s office practice.\textsuperscript{188} Under the conditions outlined in this provision, an ASC may be supported by physicians who refer business to the center without violating anti-kickback laws. Payments made as a return on a provider’s investment in an ASC are protected if: (i) the center is a certified ASC whose entire operating and recovery space is devoted to the ASC; (ii) any patient referred to the ASC by an investor is informed of the referring provider’s investment interest; (iii) the offer terms for investing are not tied to the amount of business the investor generates for the ASC; (iv) neither the ASC nor an investor, nor anyone acting on their behalf, makes or guarantees a loan that will be used by another investor to gain an investment interest; (v) the return on the investment is directly proportional to the investor’s capital investment; (vi) any ancillary services performed at the ASC are directly related to the primary procedures performed at the ASC, and they are not billed separately to Medicare or other federal programs; and (vii) patients receiving benefits or assistance under any federal program are not treated in a discriminatory manner.\textsuperscript{189}

\textbf{Footnotes:}

\textsuperscript{185} 42 C.F.R. § 1001.952(r).
\textsuperscript{186} See Baumann, supra note 100, at 10 (describing rationale for ASC safe harbor).
\textsuperscript{187} Id.
\textsuperscript{188} Id. (comparing enlarged ASC safe harbor to narrow provisions for group practices).
\textsuperscript{189} 42 C.F.R. § 1001.952(r). In addition to the requirements above, physician-investors in surgeon-owned, single-specialty, or multi-specialty ASCs must have earned at least one-third of their medical-practice income from the previous year from the performance of surgical procedures. Id. § 1001.952(r)(1)-(3). Additionally, at least one-third of the procedures performed by the physician investor for the previous year must be performed at the ASC. Id. § 1001.952(r)(3). While a hospital could invest under any of these safe harbors, the OIG also created a hospital-specific safe harbor. See id. § 1001.952(r)(4). If at least one investor in the ASC is a hospital and all other investors are physicians or physician groups, the following additional standards must be met under the hospital specific safe harbor: (i) the ASC must not use the hospital’s space or equipment without a lease that conforms to the space or equipment rental safe harbor provisions; (ii) unless otherwise required by a federal program, the hospital cannot claim any costs associated with the ASC on any cost report or claim for payment; and (iii) the hospital cannot be in a position to directly or indirectly generate business for the ASC or any of its investors. Id.; see also OFFICE OF INSPECTOR GEN., HHS, ADVISORY OPINION NO. 98-12 (Sept. 16, 1998), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_12.htm (allowing ownership of ASCs by referring physicians where physicians were making significant financial investment and incurring substantial risk, where returns on investment would be proportional to original investment, and where patients were informed of physician’s ownership interests).
viii. Arrangements Between Providers and Health Plans

Providers who contract with health plans to provide services for reduced fees may be protected by a safe harbor covering price reductions offered to health plans.190 The requirements vary depending on the health plan and the arrangement made with the government. If the plan is an HMO, CMP, or PHP that has entered a contract with the CMS or a state agency, it will be protected if it does not claim payment from HHS or a state agency without prior approval or otherwise attempt to shift the burden of the agreement onto Medicare or a state health program.191 Plans that are not HMOs, CMPs, or PHPs have different requirements.192

Payments between eligible managed care organizations (“MCOs”)193 and contractors, and payments between contractors and sub-contractors, are protected under the safe harbor for price reductions offered to eligible MCOs if a signed, written agreement between the parties for at least one year specifies covered items and services.194 Neither party to such an agreement may exchange payment for referring business outside of the agreement’s scope if a federal health care program may reimburse that business.195 The financial burden of such an agreement may not be shifted to a federal health care program.196

190. 42 C.F.R. § 1001.952(m).
191. Id. § 1001.952(m)(1)(i). If the plan receives payment for enrollees on a reasonable cost or similar basis, the following requirements must be fulfilled: (i) the contract between the health plan and health care provider must be for at least one year; (ii) the contract must specify the items or services that the provider will offer; (iii) the health plan must report the amount that it has paid the provider completely and accurately on cost report or claim forms filed with HHS or state health care program; and (iv) the provider must not claim payment from HHS or the state for any items or services provided under the agreement without approval from HHS or the state. Id. § 1001.952(m)(1)(ii).
192. If they are not paid on an at-risk basis, both the provider and the plan must fulfill these six conditions: (i) the contract’s duration must be for at least a year; (ii) the contract must specify the items and services that the provider will offer, which party will file requests for payment, and the schedule of fees that the provider will charge for the services provided; (iii) the fee schedule must remain in effect for the entire contract term unless Medicare or the state health program authorizes a payment update; (iv) the party filing requests for payment from Medicare or the state health care program must not claim amounts in excess of the fee schedule; (v) the party not responsible for filing payment requests must not request payment for services provided in accordance with the agreement; and (vi) the provider and the plan must accurately report the fee schedule amounts charged on any cost report filed with Medicare or a state and must report the terms of the agreement and the amounts paid under it upon request. 42 C.F.R. § 1001.952(m)(1)(iii). If they are paid on an at-risk basis, the plan and provider must comply with five standards, three of which are the same as those outlined for plans on a non-at-risk basis (i, ii, and vi). Id. § 1001.952(m)(1)(iv). The other requirements are that: (i) the payment amount in agreement between the plan and provider remains in effect throughout the agreement, (ii) the provider cannot claim or request payment from the state, federal government, or enrollee and (iii) the plan cannot pay the provider more than what is contained in the schedule. Id.
193. Eligibility requirements are defined at 42 C.F.R. § 1001.952(t)(2)(ii).
194. Id. § 1001.952(t)(1)(i)(A)(1)–(3). This rule was one of the two interim final rules published on the same day as the new safe harbors. See Wallander, supra note 101, at 18 (explaining two interim final rules).
196. Generally, a first-tier contractor cannot claim payment from the federal health program for items or services provided under its agreement with the MCO. Id. § 1001.952(t)(1)(A)(4). Special rules apply if: (i) the contractor is an HMO or CMP with a cost-based contract under the Social Security Act; (ii) the contractor is a
A separate safe harbor protects arrangements between MCOs and contractors and subcontractors if the contracting entities bear some of the risk of patient care. Payments between qualified managed care plans and first-tier contractors are protected if a signed, written agreement between the parties: (i) covers at least a year; (ii) specifies the items and services covered by the agreement; (iii) requires participation in a quality assurance program; and (iv) specifies how fees will be determined and assessed. If the first-tier contractor has an investment interest in the health plan, the interest must fulfill the requirements of the investment interest safe harbor.

ix. Relationships Between Providers and Suppliers

Several safe harbors guide the relationships between providers and suppliers. Regulations governing warranties, discounts, and group purchasing organizations ("GPOs") outline the steps necessary to avoid anti-kickback inquiry into supplier arrangements. Suppliers or manufacturers of medical equipment and other supplies may offer warranties to purchasing health care providers or beneficiaries that either guarantee replacement of the supplier or manufacturer’s own product, or even another entity’s defective product. These warranties become abusive when a provider receives an item for a reduced price because of a warranty, but then, for reimbursement purposes, reports the purchase of the item as though the item were new. Another abusive warranty arrangement occurs when a supplier offers to honor another manufacturer’s warranties, but instead of repairing the item, replaces it with her own brand and bills Medicare for the replacement value. Anti-kickback provisions punish such arrangements unless they fall within the

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federally qualified HMO without a cost-based contract; or (iii) the contractor is a federally qualified health center claiming supplemental payments from a federal health care program. Id. § 1001.952(t)(1). In these situations, first-tier contractors may claim for payment (as long as the agreement between the MCO and an HMO or CMP specifies that the first-tier contractor is responsible for making the reimbursement claim). Id. Payments between a first-tier contractor and a subcontractor or between two subcontractors are only protected if the first-tier contractor is not one of these types of entities. Id. § 1001.952(t)(1)(ii), (2)(i).

197. Id. § 1001.952(u).

198. Id. § 1001.952(u)(2)(vi) (defining qualification requirements).

199. 42 C.F.R. § 1001.952(u)(1)(i)(A) (2013). Payments made between plans and first-tier contractors as well as those made between first-tier contractors and subcontractors or between two subcontractors must be made on a per-patient fixed charge, for a percentage of the premium, using diagnosis-related groups, or through bonus and withhold arrangements. See also § 1001.952(u)(1)(i)(C)(4) (outlining the additional standards for bonus and withhold arrangements).

200. § 1001.952(a), (u)(1)(i)(B) (defining investment interest criteria as those in § 1001.952(a)(1)).


202. Id.

203. Id.
protection of the warranty safe harbor.\(^{204}\) The safe harbor regulations impose requirements on both the seller and the buyer. The seller must: (i) accurately report any price reduction that results from the warranty on the invoice that it presents to the buyer; (ii) clearly report the existence of a warranty on the invoice and provide supplemental documentation to the buyer once the price reduction is known, if the reduction amount is not known at the time of sale; (iii) not pay for anything under the warranty other than the cost of the item itself; and (iv) inform the buyer of its obligations under this provision.\(^{205}\) The buyer must: (i) accurately report any price reduction that it received on an item to HHS or a state agency on the applicable cost reporting mechanism; and (ii) upon request, provide HHS or a state agency with the manufacturer’s invoice and any supplemental documentation for products under warranty.\(^{206}\)

The safe harbor for discounts\(^{207}\) was created to “encourag[e] price competition that benefits the Medicare and Medicaid programs.”\(^{208}\) The OIG encourages discount arrangements, but considers situations where the government receives less than its proportional share of the benefit of the discount to be “seriously abusive.”\(^{209}\) Reductions in price that a buyer is granted for an item or service will not be prosecuted under anti-kickback laws if the provisions of this safe harbor are

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\(^{204}\) See 42 C.F.R. § 1001.952(g) (2013).

\(^{205}\) Id. § 1001.952(g)(3)–(4). The OIG attempted to clarify the relationship between rules imposed on the buyer and seller in its 1994 proposed rules:

In the safe harbor regulation itself, we state that discounts will be safe harbored if both the seller ‘and the buyer comply with the applicable standards as described in the rule. Yet in the preamble we state that sellers should not be held liable for the omissions of buyers. If a seller has done everything that it reasonably could under the circumstances to ensure that the buyer understands its obligations to accurately report the discount, the seller is safe harbored irrespective of the omissions of the buyer.


\(^{207}\) 42 C.F.R. § 1001.952(g)(1)–(2) (2013).

\(^{208}\) Id. § 1001.952(h). The 1999 Regulations expanded the definition of discount under this provision to include bundled sales arrangements, where a supplier provides a free good or service to induce the subsequent purchase of another good or service that is reimbursed by the same federal health care program in the same way. Id. § 1001.952(h)(5)(ii). The regulations do not include the provision against sham transactions that was in the 1994 rules, but the OIG has indicated that it looks at the substance as well as the form of a transaction when determining its eligibility for safe harbor protection. See Baumann, supra note 100, at 8 (describing why sham transaction provision was withdrawn).


\(^{209}\) Wallander, supra note 101, at 20 (describing limits to safe harbor for discounts); see OFFICE OF INSPECTOR GEN., HHS, ADVISORY OPINION NO. 99-1 (Jan. 20, 1999), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_1.htm (declining to allow arrangement for discounted ambulance services directed specifically toward residents of Medicare skilled-nursing facilities because the discount was offered to one payor, but not to all of Medicare and Medicaid). But see OFFICE OF INSPECTOR GEN., HHS, ADVISORY OPINION NO. 99-3 (Mar. 16, 1999), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_3.htm (allowing pricing arrangement for mattresses directed at skilled-nursing facilities despite arrangement’s failure to meet all requirements of safe harbor for discounts).
met.\textsuperscript{210} Separate rules are established for buyers, sellers, and those who offer the discount but do not fall into either of the other two categories (often termed “offerors”).\textsuperscript{211} The safe harbor conditions depend on whether the buyer is a competitive plan or HMO acting in accordance with a risk contract,\textsuperscript{212} a plan that submits cost reports to HHS or state governments,\textsuperscript{213} or a plan that submits requests for payment on a per-charge basis.\textsuperscript{214}

Payments made to the GPOs by a vendor of goods or services will fall within the GPO safe harbor\textsuperscript{215} if two criteria are met. First, for each entity for whom it provides items or services, the GPO must have a written agreement that either: (i) specifies that the GPO’s fee will be no more than 3\% of the purchase price; or

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\textsuperscript{210} Payments in cash or cash equivalents (other than rebates) are not protected by this safe harbor. 42 C.F.R. § 1001.952(h)(5). If a good or service is provided free or for a reduced price in order to induce the purchase of a different good or service, the arrangement will not be protected unless both the goods and services are reimbursed by the same federal program using the same methodology and the reduction is accurately reported. \textit{Id.} Reductions in price that apply to one payer but not to Medicare, Medicaid or other federal health programs, routine reductions or waivers of coinsurance or deductibles, warranties, and services provided through a personal or management services contract are also not protected. \textit{Id.}

\textsuperscript{211} \textit{Id.} § 1001.952(h).

\textsuperscript{212} When an HMO or a competitive plan that has established a risk contract with the government purchases an item or service and gets a discount, there is no need for the buyer to report the discount unless such reporting is required under the risk agreement. \textit{Id.} § 1001.952(h)(1)(i). There is also no need for the seller, \textit{Id.} § 1001.952(h)(2)(i), or the offeror, \textit{Id.} § 1001.952(h)(3)(i), to report the discount for purposes of satisfying the requirements of this safe harbor.

\textsuperscript{213} Buyers that submit cost reports to HHS or state governments (hospitals and nursing homes) must fulfill four requirements: (i) earn the discount on a good or service based on purchases of the same good or service made within a fiscal year; (ii) claim the discount in the fiscal year in which it was earned or the following year; (iii) fully and accurately report the discount; and (iv) provide the information that the seller and/or offeror provides upon any such request from HHS or a state agency. \textit{Id.} § 1001.952(h)(1)(ii). Sellers’ cost-report to buyers must fully report any discount on the invoice given to the buyer and must inform the buyer of its obligation to report discounts to HHS and state agencies upon request. \textit{Id.} § 1001.952(h)(2)(i). If the amount of the discount is not known at the time of the sale the seller must provide the buyer documentation of the calculation of the discount as soon as its value is known. \textit{Id.} Any other entity offering a discount to a buyer that submits cost reports must inform the buyer of its responsibility to report the discount and must do nothing to interfere with either the buyer’s or seller’s ability to meet its obligations under this safe harbor. \textit{Id.} § 1001.952(h)(3)(ii).

\textsuperscript{214} Buyers submitting requests for payment for discounted items or services on a per-charge basis (physicians and pharmacies) must: (i) have set the amount of the discount or rebate at the time of the sale; and (ii) provide HHS or the state health department with the information that the seller and/or offeror provides in accordance with the requirements of this safe harbor. \textit{Id.} § 1001.952(h)(1)(iii). This type of buyer is no longer required to report discounts on claims submitted to federal health care programs. \textit{See} Baumann, \textit{supra} note 100, at 7. These protections differ substantially from the 1994 proposed rules in that they protect both up-front discount and retroactive rebate arrangements. \textit{Id.} Sellers are protected under the safe harbor if they record the discount on an invoice provided to the buyer, inform the buyer of its obligation to report the discount, and provide any information that is provided by the offeror at the request of HHS or a state health agency. 42 C.F.R. § 1001.952(h)(2)(iii). Other entities offering discounts to buyers submitting requests for payment to Medicare or state health programs must fulfill the same rules as if they were selling to cost-report buyers. \textit{Id.} § 1001.952(h)(3)(iii). They must inform the buyer of its obligation to report discounts and do nothing to interfere with the buyer's ability to fulfill its obligations under this provision. \textit{Id.}

\textsuperscript{215} \textit{Id.} § 1001.952(j)(1).
(ii) establishes the maximum amount that the GPO will be paid as a fixed sum or a fixed percentage of the value of the purchases.216 Second, the GPO must disclose to the entity for which the goods or services are purchased the amount received from each vendor to that entity annually, and disclose the same to HHS upon request, if the entity is a provider of health care services.217

x. Ambulance Replenishing

The regulations also provide a safe harbor for ambulance restocking arrangements.218 The transfer of drugs or supplies from a hospital to an ambulance service will not violate the statute when the following four requirements are satisfied: (i) both the ambulance and the hospital do not each bill for the same replenished drugs; (ii) the receiving facility or ambulance provider, or both, must maintain records of the replenished drugs and medical supplies that were restocked; (iii) the replenishing arrangement must not take into account the volume or value of a business that is generated by either party; and (iv) the receiving facility and the ambulance provider otherwise comply with all federal, state, and local laws.219 In addition to these requirements, the arrangement must satisfy all of the standards of one of the three qualified types of replenishing agreements: general, fair market value, or government mandated.220

C. Self-Referral/Stark Amendments

Congress enacted the Omnibus Budget Reconciliation Act of 1989 (containing “Stark I”)221 to counteract the burgeoning cost of health care resulting from physician self-referrals.222 Stark I prohibits physicians from referring Medicare patients to clinical laboratories in which the physician has a financial interest, absent a safe harbor provision.223 When Stark I proved insufficient to curtail the

216. Id.
217. Id. § 1001.952(j)(2).
218. Ambulance restocking is the common practice among hospitals or other receiving facilities to restock ambulance providers with drugs and supplies used during the transport of a patient to the hospital. Id. § 1001.952(v).
219. Id. § 1001.952(v)(2). In addition to these four requirements, the ambulance must service the hospital an average of three times per week (as measured by a reasonable period of time), and the supplies replenished must be used by the ambulance during the transportation of the patient. Id. § 1001.952(v)(1).
220. Id. § 1001.952(v)(3).
continuing abuses of self-referrals, Congress enacted the Omnibus Reconciliation Act of 1993 (containing "Stark II"),224 which significantly expanded the scope of Stark I.225

1. Elements of the Offense

To establish a Stark violation, the government must show: (a) a financial relationship between a health care entity and physician; (b) a referral by the physician to the entity for designated health services; and (c) the submission of a claim for services.226

a. Financial Relationship

A financial relationship includes an ownership or investment interest in an entity by a physician or his immediate family member, or a compensation arrangement between a physician or his immediate family member and the entity.227
b. Referral

A referral includes a request for any designated health service payable under Medicare or Medicaid.\(^{228}\) Because Stark II does not have an intent requirement, strict liability is imposed for referrals if a financial relationship exists.\(^{229}\)

c. Submission of a Claim for Services

An entity receiving a prohibited referral may not make a Medicare claim.\(^ {230}\) Such an entity is also forbidden from billing any individual, third party payer, or other entity for designated health services\(^ {231}\) for which the physician made the referral.\(^ {232}\)

2. Absence of an Exception or Safe Harbor

Once the government demonstrates that an individual or entity has violated the Stark statute, the burden shifts to the defendant to establish that the defendant's conduct falls within one of the established exceptions.\(^ {233}\) The Stark amendments contain several exceptions for certain financial arrangements.\(^ {234}\) These exceptions fall into three categories: (i) exceptions applicable to both physician ownership or investment interests and compensation arrangements; (ii) exceptions for ownership or investment interests only; and (iii) exceptions for compensation arrangements only.\(^ {235}\) The Secretary of HHS is authorized to make additional exceptions by regulation where the "financial relationship . . . does not pose a risk of program

\(^{228}\) See Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 63 Fed. Reg. at 1722-23.


\(^{230}\) 42 U.S.C. § 1395nn(a)(1)(B) (barring claims for services rendered pursuant to a prohibited referral); see, e.g., United States ex rel. Roberts v. Aging Care Home Health, Inc., 474 F. Supp. 2d 810, 815 (W.D. La. 2007) (discussing Stark II's prohibition on a home health services provider from billing the Medicare program when the patients were referred by physicians who had a financial relationship with the provider).

\(^{231}\) Health services covered by the statute include clinical laboratory services, physical therapy services, occupational therapy services, radiology services, radiation therapy services, durable medical equipment (DME), parenteral and enteral nutrients, prosthetics and orthotics, home health services, outpatient prescription drugs, both inpatient and outpatient hospital services, and outpatient speech-language pathology services. 42 U.S.C. § 1395nn(h)(6); see Am. Lithotripsy Soc'y v. Thompson, 215 F. Supp. 2d 23, 27-34 (D.D.C. 2002) (examining the legislative history and statutory construction of Stark II to hold that lithotripsy is not a "designated health service" as defined by the statute). A proposed bill would also add ambulance services and home infusion therapy services to the list of designated health services. H.R. 1200, 113th Cong. (2013). Additional proposed legislation would amend § 1395nn(h)(6) to include audiology services. H.R. 2330, 113th Cong. (2013).

\(^{232}\) 42 U.S.C. § 1395nn(a)(1)(B) (barring claims for services rendered pursuant to a prohibited referral).


\(^{234}\) See Robert Wild et al., Government Audits Probe Potential Fraud and Abuse by Physicians and Health Facilities, N.Y. St. B.J., July/Aug. 2002, at 8, 14 (listing the enumerated exceptions to Stark II).

\(^{235}\) See 42 U.S.C. § 1395nn(b)-(e); Maria A. Morrison, An Analysis of the Stark II Proposed Rule, 67 UMKC L. Rev. 613, 615 (1999) (discussing exceptions under Stark II); Klein, supra note 225, at 512 (same).
or patient abuse." The amendments also contain several important safe harbor provisions. A medical entity must also recognize that in some circumstances a transaction might comply with the Stark rules while falling outside any of the anti-kickback safe harbors.

3. Penalties

Section 1395nn provides four sanctions. First, claims filed for services in violation of the self-referral laws will result in non-payment. Second, if a person collects money in violation of Stark II, that person is liable for and must refund the money on a timely basis. Third, civil monetary penalties and exclusion from participation in Medicaid and Medicare programs may result from improper claims. The civil penalty applies if the person who bills or presents the claim "knows or should know" that the bill or claim violates the statute; the penalty may not exceed $15,000 per violation. In addition, a civil penalty not to exceed $100,000 applies to circumvention schemes, such as cross-referral arrangements, when a physician or entity "knows or should know" that the arrangement has a principal purpose of assuring referrals by the physician to the entity, which if the physician made directly would violate the statute. Fourth, any person who is...
subject to and fails to meet the reporting requirements faces a civil penalty not to exceed $10,000 per day in which reporting was required.\footnote{244}

\textbf{D. The Health Insurance Portability and Accountability Act of 1996}

In 1996, Congress enacted the Health Insurance Portability and Accountability Act ("HIPAA").\footnote{245} HIPAA is the most comprehensive attempt to fight fraud in federal health care programs,\footnote{246} and it expands the scope of health care fraud and abuse prevention in several ways.

First, HIPAA established the first stable source of funding to fight health care fraud.\footnote{247} Second, HIPAA extended the scope of the Anti-Kickback Statute to cover all federal health care programs\footnote{248} and expanded the definition of "kickback."\footnote{249} Third, HIPAA was "the first federal statute to regulate private health care and markedly increased the government’s power to prosecute health care fraud."\footnote{250} HIPAA increased the enforcement power of the federal government by establishing programs to coordinate efforts and facilitate prosecution of health care fraud at both state and federal levels.\footnote{251}

For example, the Health Care Fraud and Abuse Control Program, under the direction of HHS, the Inspector General, and the Attorney General, coordinates anti-fraud and abuse efforts at federal, state, and local levels.\footnote{252} The program conducts investigations, audits, inspections, and evaluations of health care providers,\footnote{253} and maintains a national database of providers who have been sanc-
tioned for health care fraud. The program also establishes and modifies safe
harbors, and issues advisory opinions.

HIPAA created two other notable programs. First, the Medicare Integrity
Program ("MIP") authorizes HHS to enter into contracts with private agencies to
carry out Medicare investigation activities. This includes fraud and abuse
detection, utilization review, education, audits, provider payment determinations,
and recovery of improper payments. MIP is also responsible for educating
providers, beneficiaries, and the public. From 2006 to 2010, CMS used
increased funding to expand MIP, particularly the oversight of Medicare benefits
managed through private plans ("Part C"), the outpatient prescription drug benefit
("Part D"), and agency efforts to examine claims of Medicare beneficiaries who
also participate in Medicaid. The Patient Protection and Affordable Care Act
("PPACA") requires CMS to report the use and effectiveness of MIP funds.
Further, because MIP will be central to reducing improper payments through
Medicare, MIP staff must understand how their work supports these goals in the
context of the PPACA.

Second, HIPAA created the Beneficiary Incentive Program, which offers incen-
tives for beneficiaries to provide information that may lead to monetary recovery,
criminal sanctions, or civil sanctions under the Medicare program. An individ-
ual whose report leads to the recovery of over $100 (excluding criminal
penalties) may receive a share of the recovery.

Under HIPAA, enforcement efforts are bolstered by giving the DOJ authority to

254. HIPAA § 221 (codified at 42 U.S.C. § 1320a-7e (2012)) (authorizing creation of database); see also
Radinsky, supra note 253, (discussing requirements HIPAA created for HHS and the DOJ); Faddick, supra note 22, at 79 (discussing HIPAA provisions).

255. HIPAA § 205 (codified at 42 U.S.C. § 1395ddd (2012)) (establishing the Medicare Integrity Program);
see also Faddick, supra note 22, at 80 (discussing programs created under HIPAA); Eddy, supra note 32, at 201 (describing the Medicare Integrity Program).

256. See Eddy, supra note 32, at 201–02 (describing the Medicare Integrity Program); Faddick, supra note 22, at 80 (same).

257. See Faddick, supra note 22, at 80 (discussing the Medicare Integrity Program and its components).


260. Id.

261. Id. at 21.


263. See Faddick, supra note 22, at 81 (discussing the Beneficiary Incentive Program).
issue administrative subpoenas for federal health care fraud investigations involving private or public sector fraud. The DOJ may issue investigative demands for records relating to federal health care fraud offenses and exempt those records from the normal grand jury secrecy constraints of Federal Rule of Criminal Procedure 6(e). Those who comply with the subpoenas in good faith are immune from related federal and state civil liability.

1. **Offenses**

HIPAA federalized health care-related crimes by creating four new felonies and one new misdemeanor: (i) health care fraud; (ii) theft or embezzlement in connection with health care; (iii) false statements relating to health care matters, and (iv) obstruction of criminal investigations of health care offenses.

   a. **Health Care Fraud**

To convict a defendant of health care fraud, the government must prove that the defendant knowingly and willfully executed or attempted to execute a scheme to defraud any health benefit program, or obtained by false representations any

264. HIPAA § 248 (codified at 18 U.S.C. § 3486(a) (2012)) (authorizing the Attorney General to issue subpoenas); see also In re Admin. Subpoena, 289 F.3d 843, 844 (6th Cir. 2001) (upholding the DOJ’s subpoena authority under HIPAA); Eddy, supra note 32, at 202 (describing various investigative subpoenas authorized under HIPAA).


266. HIPAA § 248 (codified at 18 U.S.C. § 3486(d)).

267. Id. §§ 241-246 (codified as amended in scattered sections of 18 U.S.C.); see also Eddy, supra note 32, at 195-97 (defining felonies and misdemeanors under HIPAA). HIPAA also expanded the definition of "unlawful activity" targeted by the money laundering statute to include "any act or activity constituting an offense involving a Federal health care offense." HIPAA § 246 (codified as amended at 18 U.S.C. § 1956(c)(7)(F) (2012)).

268. HIPAA § 242 (codified at 18 U.S.C. § 1347 (2012)).

269. Id. § 243 (codified at 18 U.S.C. § 669 (2012)). HIPAA created both felony and misdemeanor charges under this provision. Id.

270. Id. § 244 (codified at 18 U.S.C. § 1035 (2012)).

271. Id. § 245 (codified at 18 U.S.C. § 1518 (2012)).

272. To violate the statute, an individual must know that the submitted claims were false. United States v. Medina, 485 F.3d 1291, 1297 (11th Cir. 2007); United States v. Laughlin, 26 F.3d 1523, 1525-26 (10th Cir. 1994). In 2010, Congress clarified that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section." Patient Protection and Affordable Care Act, Pub. L. 111-148, § 10606, 124 Stat. 119, 1008 (2010) (codified at 18 U.S.C. § 1347(b)).

273. Because the offense is complete upon the execution of the scheme and schemes can be executed multiple times, an individual can be charged with a count of health care fraud for each time that the individual executed the scheme. United States v. Awad, 551 F.3d 930, 937 (9th Cir. 2009); United States v. Hickman, 331 F.3d 439, 446 (3d Cir. 2003) (finding that each submission of a fraudulent claim to Medicare was an execution of defendant’s fraudulent scheme).

274. Health care benefit programs include "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity
property owned by a health benefit program in connection with the delivery or payment of health care benefits, items, or services. This provision has been interpreted broadly to include a wide variety of fraud and is not limited to doctors, health care providers, or health insurance companies but applies to anyone who attempts to defraud a health benefit program.

b. Theft or Embezzlement in Connection with Health Care

To convict an individual or entity of theft or embezzlement in connection with health care, the government must show that the individual knowingly and willfully embezzled, stole, intentionally misapplied, or otherwise converted any of the property or assets of a health care benefit program.

c. False Statements Relating to Health Care Matters

To convict someone of making false statements relating to health care matters, the government must show that "the defendant knowingly and willfully made false statements or representations 'in connection with the delivery of or payment for health care benefits, items, or services' and in a 'matter involving a health care benefit program.'"

d. Obstruction of Criminal Investigations of Health Care Offenses

To convict someone of obstruction of criminal investigations of health care offenses, the government must prove that the defendant willfully prevented, obstructed, misled, delayed, or attempted to prevent, obstruct, mislead, or delay,
the communication of information or records relating to a violation of a federal health care offense to a criminal investigator. 281

2. Defenses

In addition to the other defenses discussed in this article, organizations with an “effective” corporate compliance program in place may receive a reduced criminal penalty after a conviction for health care fraud, 282 or the DOJ may choose not to prosecute. 283 An effective compliance program includes at least five elements: (i) an internal audit of the current processes; (ii) a determination of what current practices may be illegal or potentially abusive; (iii) a written code of conduct for management and staff; (iv) a training program for employees; and (v) a periodic audit to ensure that the adopted standards are being followed. 284

3. Exemptions

HIPAA’s so-called “Granny Goes to Jail” law criminalized the transfer of assets by a prospective nursing home patient to her relatives to shield those assets from being used to pay her nursing home expenses. 285 Congress replaced HIPAA § 217 in August 1997 with a provision that no longer criminalizes asset transfers made by the patient but instead penalizes a professional, such as an attorney or accountant, who “for a fee knowingly and willfully counsels or assists an individual to dispose of assets . . . in order for the individual to become eligible for medical assistance.” 286 However, DOJ has declined to enforce the provision and at least one court has noted that it was an unconstitutional abridgement of free speech. 287

281. 18 U.S.C. § 1518(a). “Criminal investigator” is defined by the statute to include “any individual duly authorized by a department, agency, or armed force of the United States to conduct or engage in investigations for prosecutions for violations of health care offenses.” Id. § 1518(b).

282. See Jerome T. Levy, Use of Compliance Programs Offers Benefits to Providers, N.Y. L.J., Aug. 3, 1998, at 7 (stating existence of well designed compliance program may elicit more lenient treatment by the DOJ in prosecutions for health care fraud).

283. Id. (noting implementation of compliance programs may deter federal prosecution).

284. Id.; see Faddick, supra note 22, at 97.

285. HIPAA § 217 (codified at 42 U.S.C. § 1320a-7b(a)(6)) (making it criminal for anyone to “knowingly and willfully . . . dispose of assets . . . to become eligible for medical assistance under a State plan”); see Daniel G. Fish, Criminal Penalties for Medicaid Motivated Transfers, N.Y. L.J., Sept. 23, 1996, at 1 (describing the criminal sanctions of this provision).

286. 42 U.S.C. § 1320a-7b(a)(6); see Terry Carter, Mum’s the Law: Lawyers Protest Statute Gagging Medicaid Advice, A.B.A. J., Jan. 1998, at 20 (“But in amending the so-called bastard law, for which no member of the legislative body claimed parentage, Congress threw granny’s lawyer from the train.”).

287. Zahner ex rel. Zahner v. Mackreth, Civil No. 11-306, 2014 WL 198526, at *6 (W.D. Pa. Jan. 16, 2014) (noting “there has been no known prosecution of this statute to date” and holding that the statute is unconstitutional as applied to a financial planner); N.Y. State Bar Ass’n v. Reno, 999 F. Supp. 710, 713, 716 (N.D.N.Y. 1998) (inferring from Attorney General Janet Reno’s refusal to defend the statute’s constitutionality that the plaintiff would likely prove it to be an unconstitutional infringement on the freedom of speech, and enjoining the DOJ from enforcing 42 U.S.C. § 1320a-7b(a)(6)(ii)).
4. Penalties

HIPAA also expanded the list of program abuses subject to civil monetary penalties to include any state or federally funded health care program, except the Federal Employee Health Benefit Plan. Further, the statute increased the civil monetary penalties for fraud and abuse from $2000 to $10,000 per count. HIPAA also expanded the list of program abuses subject to civil monetary penalties to include any state or federally funded health care program, except the Federal Employee Health Benefit Plan. Further, the statute increased the civil monetary penalties for fraud and abuse from $2000 to $10,000 per count. HIPAA sets mandatory exclusion periods for certain felony offenses, while providing permissive exclusion for misdemeanor offenses. The mandatory exclusion periods are subject to the discretion of the Secretary of HHS in cases with mitigating or aggravating circumstances. Under these provisions, which seek to hold individuals accountable, those who control a sanctioned entity may be subject to exclusion.

HIPAA provides for injunctive relief to enjoin ongoing violations and freeze assets for anyone committing a "federal health care offense." Additionally, HIPAA provides for asset forfeiture of real or personal property when those assets have been acquired during the commission of federal health care offenses. Finally, the DOJ and OIG require all organizations settling health care fraud charges to adopt government supervised corporate integrity programs.

III. PROSECUTING HEALTH CARE FRAUD WITH GENERAL FEDERAL STATUTES

In addition to using statutes specifically targeting Medicare and Medicaid fraud, government prosecutors can bring charges for health care fraud under a variety of

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288. See Faddick, supra note 22, at 82, 90–93 (discussing civil monetary penalties under HIPAA).

289. 42 U.S.C. § 1320a-7a (2012). Legislation has been proposed that would enhance both the criminal and civil penalties for those who violated the Act. S. 1123, 113th Cong. (2013); H.R. 418, 113th Cong. (2013).

290. Faddick, supra note 22, at 87 (discussing criminal penalties under HIPAA).

291. Id. The minimum period for mandatory program exclusion is five years. Id. The maximum period for permissive exclusion is three years. 42 U.S.C. § 1320a-7c(3) (2012).

292. Faddick, supra note 22, at 87; see Patel v. Thompson, 319 F.3d 1317, 1319 (11th Cir. 2003) (explaining that exclusion of individuals from medical programs for a certain period of time is "not punitive, but rather remedial in nature and purpose" (citing Manocchio v. Kusserow, 961 F.2d 1539, 1543 (11th Cir. 1992))).


294. HIPAA § 249 (codified at 18 U.S.C. § 982(a)(2) (2012)) (providing asset forfeiture may serve as penalty for federal health care offenses); see also Eddy, supra note 32, at 198 (describing how HIPAA changed existing health care fraud law).

295. Thomas E. Bartrum & L. Edward Bryant, Jr., The Brave New World of Health Care Compliance Programs, 6 ANNALS HEALTH L. 51, 57–61 (1997) (discussing requirements by the DOJ and the OIG to include compliance programs in settlement agreements to prevent future wrongdoing).
other statutes.\footnote{296} Criminal prosecutions can be based on the False Claims Act,\footnote{297} the False Statements Act,\footnote{298} the Social Security Act,\footnote{299} and other criminal fraud statutes.\footnote{300} Criminal violations under these statutes can result in fines, imprisonment, or both.

Additionally, the OIG has administrative authority to impose monetary sanctions or, more seriously, to exclude the provider from further participation in Medicare and Medicaid programs.\footnote{301}

Providers who falsify claim reimbursement submissions are generally subject to prosecution under two statutes: the False Claims Act\footnote{302} and the federal prohibition on false statements contained in 18 U.S.C. § 1001.\footnote{303} Further, because most Medicare and Medicaid fraud occurs within legitimate business contracts between providers, insurance companies, and the federal government, the federal mail fraud\footnote{304} and wire fraud\footnote{305} statutes provide additional options for prosecutors.\footnote{306}

\footnote{296} See Pamela H. Bucy, \textit{Crimes by Health Care Providers}, 1996 U. ILL. L. REV. 589, 591–630 (1996) (describing the panoply of federal and criminal statutes under which health care fraud is prosecuted, noting that federal prosecutions, which account for most of the criminal prosecutions of health care providers, have been brought under thirty different statutes). Bucy's article was written prior to the enactment of HIPAA, which added five new crimes aimed at health care fraud. See \textit{supra} Section II.D (discussing HIPAA).


\footnote{301} Exclusion from participation in Medicare and Medicaid programs is the equivalent of "capital punishment" for health care entities. Nalven, \textit{supra} note 299, at 16; see Erickson v. United States \textit{ex rel.} HHS, 67 F.3d 838, 863 (9th Cir. 1995) (holding that defendant's due process rights were not violated by fifteen-year exclusion from federally and state funded health care programs because of the jury conviction following a fair trial and the administrative need for speedy exclusions); Seide v. Shalala, 31 F. Supp. 2d 466, 469 (E.D. Pa. 1998) (holding twenty-six-month gap between defendant's conviction and his receipt of Inspector General's notice of exclusion reasonable because (i) exclusions are remedial, not punitive, and therefore not connected to convictions; and (ii) Inspector General is not obligated to adhere to any deadlines).


\footnote{303} 18 U.S.C. § 1001 (2012). For more information on false claims and false statements generally, see the \textit{False Statements and False Claims} article in this issue.

\footnote{304} 18 U.S.C. § 1341. \textit{But see} United States v. Saathoff, 708 F. Supp. 2d 1020 (S.D. Cal. 2010) (holding that mail and wire fraud statutes were void for vagueness as applied to municipal officials).

\footnote{305} 18 U.S.C. § 1343 (2012). For more information on mail and wire fraud generally, see the \textit{Mail and Wire Fraud} article in this issue.

A. False Claims Act

The False Claims Act is a federal fraud statute frequently used in prosecuting Medicare and Medicaid fraud. Prosecutors favor this statute over others given its success as a deterrent.\(^\text{307}\)

1. Elements of the Offense

The government must prove three elements to obtain a conviction for Medicare or Medicaid fraud under the False Claims Act: (i) the defendant presented a claim (demand for money or property) to the government seeking reimbursement for medical services or goods; (ii) the claim was false, fictitious, or fraudulent; and (iii) the defendant had both knowledge of the claim’s falsity and an intent to submit the claim.\(^\text{308}\) In addition to a criminal action, the government may bring a parallel civil action.\(^\text{309}\)

a. Presentation of a Claim

To prosecute a defendant for health care fraud under the False Claims Act, the government can prove a defendant presented a false claim by either (i) showing that the defendant directly sought payment from the government for services or equipment,\(^\text{310}\) or (ii) demonstrating that a defendant presented a claim by causing an intermediary business, such as an insurance carrier, to submit a false claim.\(^\text{311}\)

\(^{307}\) See McNutt ex rel. United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1259 (11th Cir. 2005) (“The False Claims Act is the primary law on which the federal government relies to recover losses caused by fraud.”); Nalven, supra note 299, at 9–10 (noting False Claims Act litigation is the most promising and successful means of deterring Medicare and Medicaid fraud).


\(^{309}\) See Hudson v. United States, 522 U.S. 93, 105 (1997) (holding that parallel civil and criminal sanctions do not violate the Double Jeopardy Clause); see also Gordon E. Roundtree, Health Care Providers and Fraud Investigations: What Can You Do When the Government Changes the Rules in the Middle of the Game?, 8 ANNALS HEALTH L. 97, 120–21 (1999) (“[I]f the government is successful in obtaining a criminal conviction, the defendant is then collaterally estopped from re-litigating the substantive issues in a subsequent civil FCA action.”); Federal Officials Using Unconventional Laws to Fight Health Care Fraud Abuse, 7 Medicare Rep. (BNA) No. 18, at D-40 (May 3, 1996) (referring to OIG regional inspector general Michael Dyer’s view that federal officials bring civil false claims charges to take advantage of cash penalties and lower burden of proof). See generally Ryan, supra note 308, at 129 (noting False Claims Act of 1863 permits government to bring civil action and seek double damages).

\(^{310}\) 18 U.S.C. § 287.

\(^{311}\) See United States v. Gumbs, 283 F.3d 128, 131, 136 (3d Cir. 2002) (stating that defendant could be convicted of willfully causing an intermediary to present a false claim to someone, even if she does not know that she is causing the intermediary to submit a false claim to a federal department); United States v. Causey, 835 F.2d 1289, 1292 (9th Cir. 1987) (holding that the government need not allege nor prove that intermediary who actually submitted the false claim knew it to be false). Physicians, practitioners, or directors of a corporate entity are
b. False, Fictitious, or Fraudulent Nature of a Claim

To prove the false, fictitious, or fraudulent nature of a Medicare or Medicaid claim, the government must show that the medical procedure or the provision of equipment (i) did not occur, \(^{312}\) (ii) did not occur as stated, \(^{313}\) or (iii) was not medically necessary. \(^{314}\) Whether the government ultimately honored the defendant’s claim for reimbursement is irrelevant to a false claims prosecution. \(^{315}\) The circuit courts are split on the issue of whether materiality \(^{316}\) is a required element of a violation of this provision. \(^{317}\)

personally responsible for the internal procedures by which bills are submitted to the government. See United States v. Nazon, 940 F.2d 255, 260 (7th Cir. 1991) (finding liability even though physician claimed he left billing arrangements to clerical staff, because Medicaid provider agreement imposes duty on physician to monitor billing requirements, and staff billed according to physician’s instructions). Additionally, presentation of evidence or information to prevent the government from pursuing an investigation of erroneous overpayments is treated as a false claim for purposes of the statute. See United States v. Garrison, 133 F.3d 831, 845, 853 (11th Cir. 1998) (upholding conviction of owner and CEO of home health care provider who directed employees to rectify false cost reports when scheme was about to be exposed).

312. See, e.g., United States v. Awad, 551 F.3d 930, 933–35, 942 (9th Cir. 2009) (affirming defendant’s Medicare fraud conviction for billing respiratory treatments when such treatments never occurred and providing unnecessary services); United States v. Srinam, 147 F. Supp. 2d 914, 931 (N.D. Ill. 2001) (finding evidence that doctor submitted claims for Medicare reimbursement for patients who were deceased at the time of claimed services to support order requiring preservation of records and asset freeze).

313. See United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 498 (6th Cir. 2007) (noting that defendant’s fraudulent activities included billing for non-billable items, billing for fictitious continuous heart monitoring, and improper changing of patients’ status from outpatient to inpatient); United States v. R&F Props. of Lake Cnty., Inc., 433 F.3d 1349, 1356 (11th Cir. 2005) (“Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed.”).

314. See United States ex rel. Riley v. St. Luke’s Episcopal Hosp., 355 F.3d 370, 376–77 (5th Cir. 2004) (holding that appellant sufficiently stated False Claims Act claims when she alleged defendants knowingly ordered medically unnecessary services); United States v. Rutgard, 116 F.3d 1270, 1290 (9th Cir. 1997) (reversing defendant’s convictions in part because government failed to show surgeries were not medically necessary).

315. See United States v. Gieger, 190 F.3d 661, 666 (5th Cir. 1999) (upholding conviction whether or not government was actually defrauded because knowledge of claim’s falsity sufficed to support judgment).

316. The materiality of a false statement depends on whether the falsehood has a “natural tendency to influence, or [is] capable of influencing, the decision of the . . . body to which it was addressed.” United States v. Wells, 519 U.S. 482, 489 (1997) (internal citations omitted).

317. The Supreme Court has not uniformly read a materiality requirement into all sections of the U.S. Code that criminalize false statements. Most circuits have held that materiality is not an element of § 287. See United States v. Saybolt, 577 F.3d 195, 206 (3d Cir. 2009) (“We hold that Section 287 does not require proof of materiality.”); United States v. Allen, 116 F. App’x 210, 215 (10th Cir. 2004) (noting that materiality is also not an element in the Second, Fifth, and Ninth Circuits); United States v. Logan, 250 F.3d 350, 358 (6th Cir. 2001) (finding materiality is not an element of § 287); United States v. Harvard, 103 F.3d 412, 419 (5th Cir. 1997) (“Had Congress intended to reserve punishment for only those individuals who made material fraudulent entries, it could easily have done so.”); United States v. Taylor, 66 F.3d 254, 255 (9th Cir. 1995). Other circuits have held that materiality is required for a violation of this provision. See United States v. Wells, 63 F.3d 745, 750 (8th Cir. 1995) (equating 18 U.S.C. § 287 with “similarly worded” 18 U.S.C. §§ 1001 and 1014, stating “we see no reason to treat the statutes differently.”), vacated on other grounds 519 U.S. 482 (1997); United States v. Snider, 502 F.2d 645, 652 n.12 (4th Cir. 1974) (equating 18 U.S.C. § 1001 and 18 U.S.C. § 287). Two federal circuits have expressly declined to reach the question of whether materiality is generally required. See United States v. Foster, 229 F.3d 1196, 1197 (D.C. Cir. 2000) (holding that the court did not have to decide whether jury should have received materiality instruction because error would be harmless on facts); United States v. Durenberger, 48 F.3d
Claims under the False Claims Act can be "factually false" if the claimant misrepresents the goods or services provided to the government, or they can be "legally false" if a claimant falsely certifies that she has complied with a statute or regulation required for government payment. The circuit courts are split on whether to apply this certification theory of liability only to expressly certified claims or if submitting a claim itself implies compliance with governing statutes, regulations, or contract provisions.

**c. Intent**

The defendant must know the claim is false, fictitious, or fraudulent. The "duty to know" standard requires that providers know and understand the proper billing procedures and regulations for Medicare and Medicaid. Knowledge and intent are often determining factors in whether federal authorities pursue a false claims case. Requisite intent can be inferred from circumstantial evidence. However, liability does not extend to providers whose records are incorrect due to good faith miscalculations. Additionally, a government agency's prior knowl-

1239, 1243 (D.C. Cir. 1995) (requiring materiality for purposes of case at bar but refusing to decide issue generally); United States v. White, 27 F.3d 1531, 1535 (11th Cir. 1994) ("Because the misrepresentations were material [here], it does not matter whether materiality is an element of a § 287 charge.").


320. 18 U.S.C. § 287; see also United States v. Medina, 485 F.3d 1291, 1297 (11th Cir. 2007) (adopting holding of United States v. Laughlin, 26 F.3d 1523, 1526 (10th Cir. 1994), that in a health care fraud case, it must be shown that the defendant knew claims submitted were false).

321. See United States v. Custodio, 39 F.3d 1121, 1125 (10th Cir. 1994) (holding that physician's failure to raise legitimacy of billing practices with Army hospital staff indicated desire to avoid confirming whether his billing practices were improper); United States v. Nazon, 940 F.2d 255, 258-60 (7th Cir. 1991) (noting duty to know and understand billing practices was relevant in determining whether physician had requisite knowledge when submitting false claims and in determining appropriateness of "conscious avoidance" jury instruction). But see Siddiqi v. United States, 98 F.3d 1427, 1439 (2d Cir. 1996) (finding government's "dishonest intent" evidence insufficient to uphold jury conviction of physician who billed supervisory services performed while out of country).

322. See Fraud and Abuse: Quick Start Key to Defense of Fraud Allegations, Defense Attorneys Say, 4 Medicare Rep. (BNA) No. 19, at D-20 (May 7, 1993) [hereinafter Quick Start Key] (quoting an Assistant U.S. Attorney as saying, "[o]ften, intent to defraud is the determining factor in whether such a case is pursued by federal authorities").

323. See United States v. Boring, 557 F.3d 707, 711 (6th Cir. 2009) ("Because intent to defraud is difficult to prove by direct evidence, a jury may consider circumstantial evidence of fraudulent intent and draw reasonable inferences therefrom").

324. See United States v. Nash, 175 F.3d 429, 436-37 (6th Cir. 1999) (holding good faith is a valid defense to § 287); United States ex rel. Hochman v. Nackman, 145 F.3d 1069, 1074 (9th Cir. 1998) (indicating accounting
edge and approval of the particulars of an allegedly false claim negates the intent requirement.  

2. Defenses

A person charged with health care fraud can assert the same general defenses used in a defense of a false claims prosecution. A provider may use misunderstanding as a defense, but deliberate ignorance of regulations is no defense. While a claim that the statutory language is void for vagueness is a difficult defense to win, prosecutors may be less likely to bring false claim charges when the relevant administrative or statutory requirements are ambiguous.

3. Penalties

Each count for which the defendant is convicted is considered a separate offense and carries its own sentence. When a defendant is convicted of presenting false claims, she may be imprisoned for up to five years and fined subject to the amount established in the statute. Under the United States Sentencing Guidelines
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("Guidelines"), violations of the False Claims Act are treated as offenses involving fraud and deceit, governed by § 2B1.1.332

B. False Statements

The False Statements Act333 is a companion statute to the False Claims Act. The False Statements Act criminalizes false statements made to the government either directly or through a third party.334

1. Elements of the Offense

To obtain a false statement conviction, the government must prove that: (i) the defendant submitted a statement to a governing agency; (ii) the statement was false; (iii) the statement was material; (iv) the statement was made knowingly and willfully; and (v) the statement pertained to an activity within the jurisdiction of a federal agency.335

a. Statement to a Governing Agency

Section 1001 requires that the defendant make a false statement "in any matter within the jurisdiction of any department or agency of the United States."336 Because courts have broadly interpreted this element in the context of health care fraud, a statement made to an intermediary of the government, such as a private insurance company, nonetheless constitutes a violation of this provision.337

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332. U.S.S.G. MANUAL app. A. For a full discussion of sentencing under this provision, see the False Statements and False Claims article in this issue. For an example of how health care fraud in connection with the False Claims Act is treated under the United States Sentencing Guidelines ("Guidelines"), see United States v. Klein, 543 F.3d 206, 213–15 (5th Cir. 2008).

333. 18 U.S.C. § 1001 (2012). For a thorough discussion of this statute, see the False Statements and False Claims article in this issue.

334. See United States v. White, 492 F.3d 380, 396 (6th Cir. 2007) (holding that Medicare claim forms prepared according to defendant’s instructions constitute statements for purposes of prosecution under § 1001); United States v. Oren, 893 F.2d 1057, 1064–65 (9th Cir. 1990) (affirming conviction for false statements when appellant submitted false offer letter to non-profit corporation and the non-profit subsequently conveyed false letter to National Park Service). False statement prosecutions are occasionally brought under 18 U.S.C. § 1035, whose language mirrors § 1001. See United States v. Mermelstein, 487 F. Supp. 2d 242, 256, 260 (E.D.N.Y. 2007) (stating that false statements are proscribed by § 1035 only if they are made in connection with “any matter involving a health care benefit program” or “the delivery of and payment for health care benefits, items and services”).

335. See White, 492 F.3d at 396.


337. See United States v. Lutz, 154 F.3d 581, 587 (6th Cir. 1998) ("False statements made in any matter within the agency's jurisdiction are within the scope of § 1001, and courts have upheld § 1001 convictions for false statements made to private entities receiving federal funds or subject to federal regulation or supervision.").
b. Falsity of Statement

A statement violates § 1001 if it is false, conceals a material fact, or uses a writing or document that is false in a material manner. To be “material,” the statement need not actually influence government function, but only have a natural tendency or capacity to do so. The government may need to prove an affirmative act of concealment to support this type of violation.

c. Intent

Under § 1001, the defendant must make the false statement both “knowingly and willfully.” Although the provision requires proof that the defendant willfully made a false statement, the government need not establish that the defendant was aware of the illegality of the act or had knowledge that it involved a government agency.

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338. 18 U.S.C. § 1001; see United States v. Calhoon, 97 F.3d 518, 524 (11th Cir. 1996) (affirming § 1001 conviction of defendant who made false statements by seeking Medicare reimbursement for non-reimbursable costs); see also United States v. Brown, 151 F.3d 476, 485 (6th Cir. 1998) (holding that implied falsity is a basis for conviction under § 1001); cf. United States v. Hunt, 521 F.3d 636, 648 (6th Cir. 2008) (stating that, in a prosecution under 18 U.S.C. § 1035, a rational jury could conclude that defendant knowingly made false representations of the medical necessity of tests by signing orders without actually examining patients or determining necessity).

339. See Neder v. United States, 527 U.S. 1, 16 (1999) (noting that a false statement is material if it has a natural tendency or capacity to influence the decision at issue); United States ex rel Homecare, Inc. v. Medshares Mgmt. Grp., Inc., 400 F.3d 428, 445 (6th Cir. 2005) (concluding that the natural tendency test is appropriate in civil False Claims Act context because it focuses on the potential effect of the false statement when it is made, not the actual effect when it is discovered); United States v. Harrod, 981 F.2d 1171, 1176 (10th Cir. 1992) (finding defendant’s assertion material because agency had relied on identical information in past two years to determine payment amount); cf. Calhoon, 97 F.3d at 530 (holding that the government does not have to show actual reliance on the false statements).

340. E.g., Calhoon, 97 F.3d at 524 (holding that concealment “must be established through evidence of willful nondisclosure by means of a ‘trick, scheme, or device’”).

341. 18 U.S.C. § 1001; see United States v. Gonsalves, 435 F.3d 64, 72 (1st Cir. 2006) (holding that willfulness “means nothing more in this context than that the defendant knew that his statement was false when he made it,” or that the defendant “consciously disregarded or averted his eyes from its likely falsity”); United States v. Curran, 20 F.3d 560, 567 (3d Cir. 1994) (“[T]he government is required to show that the misrepresentation was not made innocently or inadvertently.”); Timothy S. Jost & Sharon L. Davies, The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement, 51 ALA. L. REV. 239, 301 (1999) (noting that this willfulness requirement is “more formidable” mens rea than is required for false claims conviction).

342. See United States v. Duclos, 214 F.3d 27, 33 (1st Cir. 2000) (holding defendant’s admission that “he knew the nature of his act, and that he knew [its] likely effect” sufficient to show intent); United States v. Hsia, 176 F.3d 517, 522 (D.C. Cir. 1999) (holding that government need not prove that defendant knew her acts were unlawful, only that she knew her statements were false).

343. United States v. Herring, 916 F.2d 1543, 1548 (11th Cir. 1990) (holding that notice of a federal agency’s involvement is not an essential element of a § 1001 conviction); see also United States v. Oren, 893 F.2d 1057, 1065 (9th Cir. 1990) (holding that defendant did not have to have actual knowledge that his false statements would be submitted by third party to government agency).
2. Defenses

The general defenses to a false statement prosecution can also be asserted by one charged with health care fraud.\textsuperscript{344} However, making a false statement to a state agency or an intermediate carrier rather than directly to the federal government is not an available defense to health care fraud.\textsuperscript{345}

3. Penalties

A defendant convicted under § 1001 shall be fined, imprisoned for up to five years, or both.\textsuperscript{346} The Guidelines consider a violation of the False Statements Act to be an offense involving fraud and deceit, governed by section 2B1.1.\textsuperscript{347}

C. Mail and Wire Fraud

Health care providers who use the mail\textsuperscript{348} or interstate wire communication\textsuperscript{349} in their schemes to defraud can also face charges of mail and wire fraud.\textsuperscript{350} One can be convicted of mail or wire fraud without being convicted of the primary charge of false claims or false statements and without violating an anti-kickback provision.\textsuperscript{351} Prosecutors can also bring charges under a specialized mail and wire fraud provision in HIPAA that is specific to health care fraud.\textsuperscript{352}

\textsuperscript{344} For a full discussion of defenses, see the False Statements and False Claims article in this issue.
\textsuperscript{345} See United States v. Huber, 603 F.2d 387, 390 (2d Cir. 1979) (affirming conviction of defendant who sold medical equipment to hospitals, which then billed Medicaid and Medicare at a premium).
\textsuperscript{347} U.S.S.G. MANUAL § 2B1.1. For a full discussion of sentencing under this provision, see the False Statements and False Claims article in this issue.
\textsuperscript{350} See United States v. Peterson, 223 F.3d 756, 762 (8th Cir. 2000) (upholding defendants' convictions of mail fraud because their scheme to defraud, which violated the False Claims Act, was accomplished using the mail); United States v. Lewis, 156 F.3d 656, 658 (6th Cir. 1998) (upholding sentence of dentist convicted of mail fraud for submitting thousands of claims by mail certifying that he had performed procedures on Medicaid patients which he had in fact not performed). For more discussion, see the Mail and Wire Fraud article in this issue.
\textsuperscript{351} See United States v. Azad, 809 F.2d 291, 296 (6th Cir. 1986) (holding that false statement need not be established in prosecution for mail fraud); see also United States v. Calhoon, 97 F.3d 518, 523 (11th Cir. 1996) (basing mail fraud conviction on false statement convictions when defendant used the mails to submit false Medicare claims); United States v. Precision Med. Labs., 593 F.2d 434, 438 (2d Cir. 1978) (holding that submission of claims based on the rate for a manual reimbursement process is sufficient for a mail fraud conviction when an automated process is used).
\textsuperscript{352} 18 U.S.C. § 1347 (2012). Congress passed this provision as § 242 of HIPPA. See supra Section II.D for further discussion of HIPAA.
1. Elements of the Offense

To prosecute a defendant for either mail or wire fraud, the government must prove that the defendant: (i) intentionally participated in a scheme or artifice to defraud; and (ii) used the mails or wire to execute the scheme.\(^{353}\) Unlike the mail fraud statute, which requires only the use of the mails (whether intrastate or interstate), § 1343 specifies that wire fraud must involve the interstate use of wire, radio, or television communication in furtherance of the scheme.\(^{354}\)

a. Scheme or Artifice to Defraud

Several different variations of health care fraud can serve as the basis of the scheme or artifice to defraud in a mail or wire fraud conviction, including billing for services not rendered,\(^{355}\) false descriptions of services rendered,\(^{356}\) and false representations that services were medically necessary.\(^{357}\) Furthermore, a health-care professional’s scheme to defraud a patient of her intangible right to honest services may also support a mail or wire fraud conviction.\(^{358}\) In contrast to the requirements of the false claim and false statement provisions, mere intent to defraud using the mails is, in itself, unlawful.\(^{359}\) The success of the scheme is irrelevant to a mail or wire fraud conviction.\(^{360}\) Similarly, a defendant’s effort to repay the funds obtained through the scheme does not necessarily indicate absence of fraudulent intent.\(^{361}\)

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355. See United States v. Sherman, 160 F.3d 967, 971 (3d Cir. 1998) (affirming mail fraud conviction of physician who submitted insurance claims for therapy sessions and equipment he did not provide).
356. See United States v. Peterson, 223 F.3d 756, 763 (8th Cir. 2000) (affirming mail fraud conviction of defendants who overbilled Medicare by falsely representing that they saw only one patient on each trip of their mobile X-ray van so that Medicare would not prorate the transportation fee among the multiple patients seen during each visit); United States v. Sidhu, 130 F.3d 644, 656 (5th Cir. 1997) (upholding mail fraud conviction of psychiatrist who billed for face-to-face psychotherapy when patient did not visit defendant’s office or received only injections during visit).
357. See United States v. Khan, 53 F.3d 507, 520 (2d Cir. 1995) (affirming mail fraud conviction for physician’s assistants who performed medically unnecessary procedures to facilitate a scheme orchestrated by Medicaid indigent patients to obtain prescriptions without medical need, which would then be sold on the street); see also United States v. Shetty, 76 F. App’x 842, 845 (9th Cir. 2003) ("[A] false pretense of medical necessity that is made to obtain money from an insurer may support a conviction for mail fraud.").
358. For a discussion on honest services fraud, as codified in 18 U.S.C. § 1346 (2012), see the Mail and Wire Fraud article in this issue. See also Gregory D. Jones, Primum Non Nocere: The Expanding ‘Honest Services' Mail Fraud Statute and the Physician-Patient Fiduciary Relationship, 51 Vand. L. Rev. 139 (1998) (discussing application of mail fraud statute to violations of patient’s intangible right to honest services).
359. See United States v. Sloan, 492 F.3d 884, 891 (7th Cir. 2007) (stating requisite intent to defraud using the mails can be provided through circumstantial evidence).
360. United States v. Tadros, 310 F.3d 999, 1006 (7th Cir. 2002); United States v. Hooshmand, 931 F.2d 725, 731 (11th Cir. 1991) (explaining that success of plan is not a necessary element of mail fraud).
361. See United States v. Suba, 132 F.3d 662, 677 (11th Cir. 1998) (holding fraud established where defendants repaid fraudulently obtained funds only after government’s investigation was complete).
b. Use of the Mails or Wire in Furtherance of the Scheme

The second element of the mail or wire fraud statutes requires the government to establish that the use of mails or wire was reasonably foreseeable as a result of the scheme to defraud. The defendant need not have personally used the mails or wire, nor must the defendant have intended that the mails or wire be used.

2. Defenses

The defendant's good faith belief that the representations were true when made can serve as a defense to a mail or wire fraud prosecution. Additionally, a defendant's mistake or carelessness would not support a conviction because the government must establish that the defendant devised the scheme or artifice to defraud "knowingly, willfully, or unlawfully."

3. Penalties

A defendant convicted under §1341 or §1343 shall be subject to a fine, a prison term of up to twenty years, or both. For purposes of the Guidelines, a conviction under §1341 or §1343 constitutes an offense involving fraud and deceit, which is governed by §2B1.1.

IV. ENFORCEMENT

A. Introduction

Criminal indictment for an offense related to Medicare or Medicaid typically inspires a three-pronged federal enforcement attack in addition to any proceedings at the state level. First, the DOJ may file criminal charges to determine the guilt or innocence of the provider. Second, the government may seek to recover

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362. See United States v. Peterson, 223 F.3d 756, 760 (8th Cir. 2000) ("The government need not prove that a defendant personally mailed a document but only that a defendant committed 'an act with knowledge that the use of the mails [would] follow in the ordinary course of business, or where such use [could] reasonably be foreseen, even though not actually intended.'" (quoting Pereira v. United States, 347 U.S. 1, 8-9, (1954))); United States v. Perkal, 530 F.2d 604, 608 (4th Cir. 1975) (upholding mail fraud conviction of physician who staged automobile accidents even though he did not personally use mail because it was reasonably foreseeable that attorney involved in scheme would submit defendant's false medical treatment information to insurance companies).

363. See, e.g., Pereira, 347 U.S. at 8-9; Peterson, 223 F.3d at 760.

364. See United States v. Morris, 80 F.3d 1151, 1165 (7th Cir. 1996) (noting that defendants' good faith defeats intent to defraud if they genuinely believe their submissions are true).

365. See United States v. Sheiner, 273 F. Supp. 977, 982-83 (S.D.N.Y. 1967) ("If the defendants' acts were done inadvertently, mistakenly, or in good faith without an intention to defraud, then the government has not sustained its burden of proof, and the defendants must be acquitted.")


367. U.S.S.G. MANUAL §2B1.1. For a full discussion of sentencing under these provisions, see the Mail and Wire Fraud article in this issue.

damages and assess civil penalties by bringing civil charges or by instituting an administrative hearing. 369 Finally, an administrative procedure may determine whether the provider should be excluded from participation in Medicaid or Medicare. 370

The submission of false statements or claims to Medicare or Medicaid and violations of Medicare or Medicaid anti-kickback provisions are the two primary areas of criminal enforcement in the health care sector. 371 Aside from anti-kickback violations, most criminal cases arise out of one of the following five misrepresentations: (i) claiming reimbursement for procedures not medically necessary; 372 (ii) claiming reimbursement for medically necessary services not covered by Medicare; (iii) using a code for a higher reimbursement level than the code for the services actually provided; 373 (iv) billing one bundled procedure as a group of smaller procedures; 374 or (v) inflating cost reports. 375

B. Entities Responsible for Enforcement

1. Federal Enforcement

The DOJ, HHS, and private citizens participate in fraud enforcement at the federal level.

a. Department of Justice

The detection and elimination of health care fraud and abuse has historically been a top priority of the DOJ, 376 which has focused resources on halting systematic abuse practiced by nationwide health care providers. 377 DOJ policy

369. Id. Health fraud statutes actually encourage the DOJ to seek civil rather than criminal remedies because financial recovery is often much greater and because once a criminal conviction has been obtained, civil recovery is often unavailable. See Nalven, supra note 299, at 17 (describing DOJ incentives for pursuing civil remedies).

370. See O'Leary, supra note 368, at 211 (discussing scope of administrative procedure).

371. Id. at 212–18; see also Robert Salcido, Mixing Oil and Water: The Government's Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Prosecutions, 6 ANNALS HEALTH L. 105, 105 (1997) (describing split in authority regarding the appropriateness of basing False Claims Act cases on Anti-Kickback Statute violations).

372. See Ken Blickestaff, Strong Medicine: The Evolution of Healthcare Fraud Enforcement, ADVOC. Sept. 1999, at 15, 16 (describing "Labscam" cases involving bundling or unbundling laboratory tests to get higher levels of reimbursement).


374. Id. at 330 (describing unbundling).

375. See O'Leary, supra note 368, at 212.


instructs that all "United States Attorneys' Offices, the Criminal Division and the Civil Division should work as partners to ensure a vigorous national health care fraud enforcement program."³⁷⁸

In May 2009, the DOJ and HHS announced the joint Health Care Fraud Prevention & Enforcement Action Team ("HEAT"), which was created to enhance collaboration between enforcement agents, prosecutors, and staff from the DOJ and HHS.³⁷⁹ HEAT's mission is to prevent waste, fraud, and abuse in the Medicare and Medicaid programs; reduce health care costs and improve the quality of care by ridding the system of perpetrators who prey on Medicare and Medicaid beneficiaries; highlight best practices by providers and public sector employees working to end fraud and abuse in Medicare; improve information and data sharing procedures between HHS and the DOJ to help identify patterns of fraud and abuse more rapidly; and increase the efficacy of investigations and prosecutions in complex cases.³⁸⁰

In 2007, the DOJ and HHS had launched the Medicare Fraud Strike Force to combat Medicare fraud and abuse among durable medical equipment ("DME") suppliers and HIV infusion therapy providers.³⁸¹ It "[uses] advanced data analysis techniques to identify high-billing levels in health care fraud hot spots so that interagency teams can target emerging or migrating schemes along with chronic fraud by criminals masquerading as health care providers or suppliers."³⁸² Other national initiatives for combating health care fraud have addressed prospective payment system transfers³⁸³ and pneumonia upcoding.³⁸⁴

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³⁷⁸. U.S. ATTORNEYS' MANUAL, supra note 376, § 9-44.160(I).
³⁸⁰. Id. at 9–10. HEAT initiatives promoted during the fiscal year included expanding the Medicare Fraud Strike Force to Detroit and Houston and continuing a series of regional fraud prevention summits to improve the exchange of information and educate beneficiaries, providers, and the public to better identify and prevent health care fraud. Id. As part of the interagency effort, the DOJ and HHS "submitted a joint budget request to the Office of Management and Budget for FY2011 that reflects the joint resource needs for the initiative." DOJ FY 2009, supra note 377, at IV-23.
³⁸¹. HHS & DOJ FY 2012, supra note 379, at 10. As of February 2012, the DOJ and HHS expanded the Strike Force to include teams of investigators and prosecutors in a total of nine cities. Id. at 11.
³⁸². Id. at 10.
³⁸⁴. Id. at 15 (describing the Pneumonia Upcoding Initiative, also started in 1999, which targets inappropriate inpatient coding and billing for a more expensive type of pneumonia to be reimbursed at higher rates).
The DOJ can seek civil damages or penalties for Stark and false claim violations or it can prosecute under several criminal statutes. During fiscal year 2012, the federal government won or negotiated approximately $4.2 billion in judgments and settlements, the Medicare Trust Fund received transfers of approximately $2.4 billion, the DOJ opened 885 new civil health care fraud investigations, and opened 1131 new criminal health care fraud investigations involving 2148 potential defendants.

b. Department of Health and Human Services

Within HHS, the Centers for Medicare and Medicaid Services ("CMS") and OIG are responsible for anti-fraud measures.

i. Health Care Financing Administration

CMS administers Medicare, Medicaid, and the State Children's Health Insurance Program ("SCHIP"). By using various improper payment calculations, CMS seeks to identify problematic areas where errors occur and to reduce the error rate through provider education and claims reviews. The same data is also used to discover trends in claims that may signify potential fraudulent activities. When providers and suppliers are found to be deliberately defrauding the federal health care programs, CMS partners with the DOJ and the OIG to aggressively pursue enforcement actions.

ii. Office of the Inspector General

Many of the OIG's activities are directed toward the prevention of criminal prosecutions. To help providers avoid unintentional fraud, the OIG publishes

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385. The most common civil statute is the False Claims Act, 31 U.S.C. § 3729 (2012) (prohibiting knowing submission of false, fictitious, or fraudulent claims and providing fines of $5000–$10,000 per claim plus treble damages and costs). Civil False Claims Act actions are important in criminal law because they are often combined with criminal charges. Nalven, supra note 299, at 10; see also Robert T. Rhoad & Matthew T. Fornataro, A Gathering Storm: The New False Claims Act Amendments and Their Impact on Healthcare Fraud Enforcement, 21 HEALTH LAW. 14, 14–15 (2009) (observing that the Fraud Enforcement and Recovery Act of 2009 significantly expanded the scope of the civil False Claims Act by eliminating the intent and presentment requirements, redefining claim, and expanding liability for retaining government overpayments).


387. HHS & DOJ FY 2012, supra note 379, at 1.


389. Id.

390. Id.

391. Id.
compliance procedure guides, releases Medicare fraud alerts addressing particularly problematic practices, and develops work plans that highlight particular problem areas for providers. Enhanced enforcement tools available under the PPACA include the ability to obtain information from providers, contractors, and other entities involved in providing medical items or services payable by federal programs. Once a fraud is committed, the OIG encourages voluntary disclosure and settlement in exchange for a reduced chance of criminal prosecution.

Faced with a fraudulent claim, the OIG can assess administrative penalties against the entity involved. Because each falsely claimed line in an itemized bill is treated as a separate violation, these fines can be enormous. Anti-kickback sanctions can be even larger. The OIG may assess a $50,000 sanction for each anti-kickback violation in addition to a total of up to three times the amount of remuneration paid, offered, or solicited in violation of anti-kickback laws.

Despite the potential magnitude of these fines, the OIG’s real power comes from its ability to exclude providers from Medicare and Medicaid programs. The Medicare and Medicaid Patient and Program Protection Act of 1987 allows HHS to exclude any provider it determines has violated a criminal fraud statute. This power allows HHS to prosecute violations of criminal statutes under administrative law rules of procedure and evidence and to sanction those found to be in violation.


394. Morris Testimony, supra note 392, at 4. The PPACA also enhances the OIG’s ability to impose civil monetary penalties for “failing to grant [upon reasonable request] timely access to the OIG for investigations, audits, or evaluations.” Id.

395. See id. at 16.

396. See id.

397. See id.

398. 42 C.F.R. § 1003.103(h) (2013); see also id. § 1003.102(b)(11) (2013).

399. Congress gave the OIG this power because it determined that the DOJ’s insufficient resources for prosecuting a large number of cases were hampering the enforcement potential of the Anti-Kickback Statute. See R.P. Kusserow, The Medicare and Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What’s Next?, 2 HEALTH MATRIX 49, 51 (1992) (asserting exclusion “can be as significant as a criminal sentence”). The PPACA authorizes the OIG to exclude from the federal health care programs any entities that provide false information on applications to enroll or participate in a federal health care program. Morris Testimony, supra note 392, at 4.

400. 42 U.S.C. § 1320a-7(b)(7) (2012), see Manocchio v. Kusserow, 961 F.2d 1539, 1540 (11th Cir. 1992) (affirming three years probation and fines as well as five years of exclusion from Medicare for $62.40 in false claims).
violation with exclusion—a method considered “capital punishment” for institutional health care providers.\textsuperscript{401}

In addition to its exclusion power, the OIG can suspend and withhold a provider’s payments under Medicare upon indictment or other reliable evidence of fraud.\textsuperscript{402} In most circumstances, the maximum suspension period is 180 days.\textsuperscript{403} This ability to suspend payments allows the OIG to exert considerable pressure on indicted entities to plead guilty and begin settlement negotiations.\textsuperscript{404}

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  \item[c. Private Parties and Qui Tam Actions]

  The False Claims Act allows private relators to pursue enforcement of the statute.\textsuperscript{405} An individual with knowledge of fraudulent practices first files a complaint under seal.\textsuperscript{406} The government then investigates the complaint\textsuperscript{407} and can intervene in the action and prosecute the claim itself if it chooses to do so.\textsuperscript{408} If the government intervenes and wins, the relator receives 15–20\% of the government’s recovery, plus costs and fees.\textsuperscript{409} If the government does not intervene, the
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\textsuperscript{401} See Nalven, supra note 299, at 16. HHS cannot impose fines or jail time on providers found guilty of criminal violations in administrative proceedings. For most providers, however, a Medicare or Medicaid exclusion, which HHS can impose, may be a more severe punishment.

\textsuperscript{402} See Morris Testimony, supra note 392, at 6; O’Leary, supra note 409, at 211 (citing 42 C.F.R. §§ 405.370 and 405.371(b)(2013)).

\textsuperscript{403} 42 C.F.R. § 405.372(d) (2013); see also Diagnostic Cardioline Monitoring of N.Y., Inc. v. Shalala, 2000 WL 1132273, at *3, n.2 (E.D.N.Y. June 26, 2000) (noting that 42 C.F.R. § 405.372 was amended in 1996 to limit suspensions to 180 days with certain exceptions available).


\textsuperscript{405} 31 U.S.C. § 3730(b) (2012); see Salcido, supra note 371, at 106 (describing qui tam actions); Robert Salcido, Screening Out Unworthy Whistleblower Actions: An Historical Analysis of the Public Disclosure Jurisdictional Bar to Qui Tam Actions Under the False Claims Act, 24 PUB. CONT. L.J. 237, 238–45 (1995) (discussing history of qui tam actions); Nalven, supra note 299, at 10 (describing role of private citizens in fraud enforcement).

\textsuperscript{406} 31 U.S.C. § 3730(b)(2); see also Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Sanders, 545 U.S. 409, 414–15 (2005) (holding that False Claims Act’s six-year statute of limitations does not govern FCA civil actions for whistleblower retaliation, which should be brought in time provided by most closely analogous state limitations period).

\textsuperscript{407} 31 U.S.C. § 3730(b)(2)–(4).


\textsuperscript{409} 31 U.S.C. §§ 3729(a), 3730(d)(1) (2012) (establishing recovery rules, and noting if relator’s claim is primarily founded on public information, recovery is limited to 10\%).
relator can still choose to bring the suit on behalf of the government,\textsuperscript{410} and if victorious, the relator will reap 25–30% of the recovery.\textsuperscript{411}

The Anti-Kickback Statute contains no \textit{qui tam} provision.\textsuperscript{412} However, the Anti-Kickback Statute has been combined with the False Claims Act to allow \textit{qui tam} prosecutions\textsuperscript{413} under the rationale that a request for reimbursement of a service or product obtained as a result of a kickback scheme is a false claim under the False Claim Act.\textsuperscript{414} Debate exists at the district court level whether to allow such actions.\textsuperscript{415}

\textit{Qui tam} actions are a growing method of healthcare fraud enforcement. From 1987 to 2008, the annual number of \textit{qui tam} actions jumped from 31 to 375.\textsuperscript{416}

2. State Level Enforcement

Although they originally were exclusively responsible for the costs of investigations despite the shared benefits of their efforts with the federal government, states have become increasingly active in investigating Medicaid fraud and abuse.\textsuperscript{417} In 1977, Congress created the Medicaid Fraud Control Units ("MFCU") and funded 90% of their operating costs for the first three years and 75% thereafter.\textsuperscript{418} Federal

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\item \textsuperscript{410} 31 U.S.C. § 3730(b)(4)(B).
\item \textsuperscript{411} Id. § 3730(d)(2); see also \textit{For Some Whistle-blowers, Big Risk Pays Off}, \textit{Associated Press}, Nov. 29, 2004, (describing one private relator’s recovery of $70 million), available at http://www.nytimes.com/2004/11/29/politics/29whistle.html.
\item \textsuperscript{412} 42 U.S.C. § 1320a-7(b) (2012).
\item \textsuperscript{413} See Salcido, supra note 371, at 107 (noting the trend of basing False Claims Act cases on anti-kickback violations and arguing that the combination is inappropriate); see also United States v. Rogan, 517 F.3d 449, 451–52 (7th Cir. 2008) (charging defendant with submitting false Medicare claims for patients who had been referred through a kickback scheme).
\item \textsuperscript{414} See Ryan, supra note 308, at 146 (describing application of False Claims Act to health care fraud); Salcido, supra note 371, at 107 (same).
\item \textsuperscript{415} See United States \textit{ex rel.} Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902–03 (5th Cir. 1997) (allowing the government’s claim that defendant’s alleged violations of the Anti-Kickback Statute constituted a false claim because Medicare payments were conditioned on defendant’s certification that illegal inducements had not been used); United States \textit{ex rel.} Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1509–10 (M.D. Tenn. 1996) (holding that in \textit{qui tam} case that anti-kickback violation could support False Claims Act violation); United States \textit{ex rel} Roy v. Anthony, 914 F. Supp. 1504, 1506–07 (S.D. Ohio 1994) (refusing to dismiss an FCA claim based on alleged violations of anti-kickback statute). But see Salcido, supra note 371, at 107–08 (arguing that allowing anti-kickback violations to constitute False Claims permits the broadly worded Anti-Kickback Statute to be prosecuted using the “knowing” intent standard of the FCA rather than the “knowing and willful” intent standard required by the Anti-Kickback Statute). See generally Rabecs, supra note 92, at 43–55 (summarizing relevant district court cases).
\item \textsuperscript{416} See Press Release, Dep’t of Justice, More than $1 Billion Recovered By Justice Department in Fraud & False Claims in Fiscal Year 2008 (Nov. 10, 2008), available at http://www.justice.gov/opa/pr/2008/November/08-civ-992.html.
\item \textsuperscript{417} See Blickenstaff, supra note 372, at 15.
and state governments share any recovery from MFCU investigations. As of 2012, forty-nine states and the District of Columbia had MFCUs.\textsuperscript{419}

MFCU activities focus on three principle areas: (i) investigating and prosecuting provider fraud; (ii) investigating and prosecuting patient abuse in facilities funded by Medicaid; and (iii) investigating and prosecuting fraud within Medicaid's administration.\textsuperscript{420} MFCUs fulfill these aims using a strike-force concept, which involves attorney-led investigations that determine prosecution potential early in the investigation.\textsuperscript{421} When prosecution is deemed appropriate, MFCUs pursue convictions in state courts using state law.\textsuperscript{422} Some MFCUs have criminal jurisdiction while others work directly with local prosecutors.\textsuperscript{423}

The jurisdiction of MFCUs expanded somewhat in late 1999.\textsuperscript{424} Upon obtaining approval from the OIG, MFCUs may investigate Medicare fraud that is discovered while investigating Medicaid cases.\textsuperscript{425} They may also investigate and prosecute abuse and neglect cases against “board and care” facilities that are not funded by Medicaid.\textsuperscript{426}

3. Federal and State Cooperation

Multi-state corporations increasingly force MFCUs to look beyond their state boundaries to investigate fraud and abuse.\textsuperscript{427} State and local law enforcement officials oftentimes are part of Medicare Fraud Strike Force teams, along with special agents from OIG and FBI and DOJ prosecutors.\textsuperscript{428} Federal agencies and MFCUs from different states have also worked together in “global” working groups.\textsuperscript{429} One of the most recognized successes of such a working group involved

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\item \textsuperscript{420} See Carolyn J. McElroy, State Perspective on Health Care Enforcement—Medicaid Fraud Control Units (1999) (outlining activities MFCUs are both required to undertake and restricted to performing). Ms. McElroy's presentation was part of a Continuing Legal Education class on October 14, 1999. It is available on WestlawNext by searching for the following citation: SE34 ALI-ABA 493.
\item \textsuperscript{421} Id. at 496.
\item \textsuperscript{422} Id.
\item \textsuperscript{423} See Blickenstaff, supra note 372, at 15 (describing the “unprecedented commitment to prosecuting corrupt health care providers” of many state attorneys general).
\item \textsuperscript{425} See Office of Inspector Gen., Dep't of Health & Human Servs., State Medicaid Fraud Control Units Annual Report 2003, at 4, available at http://oig.hhs.gov/publications/docs/mfcu/MCFU2003.pdf [hereinafter State Medicaid Fraud Control Units]. This expanded power is limited to those situations where, despite the Medicare claim, the case is “primarily related to Medicaid.” Id.
\item \textsuperscript{426} Id.
\item \textsuperscript{427} See McElroy, supra note 420, at 502 (describing global partnerships between federal agencies and MFCUs).
\item \textsuperscript{428} Morris Testimony, supra note 392, at n.1. For more information on the activities of the HEAT Task Force, including state-specific developments, see http://www.stopmedicarefraud.gov/HEATnews/index.html.
\item \textsuperscript{429} See McElroy, supra note 420, at 502.
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the prosecution of National Health Laboratories and subsequent "Labscam" cases. These prosecutions were the result of cooperative efforts by the U.S. Attorney's Office in Los Angeles and MFCUs from several states.\footnote{430}{Id.}

Significant cooperative efforts aimed against health care fraud were born out of the National Health Care Fraud and Abuse Program contained in HIPAA.\footnote{431}{STATE MEDICAID FRAUD CONTROL UNITS, supra note 425, at 3 (describing growth and successes of the National Health Care Fraud and Abuse Program).} This program was designed to promote coordination of efforts at the federal, state, and local levels.\footnote{432}{Id.} In 1999, the program resulted in the establishment of a Health Care Fraud Task Force.\footnote{433}{Id.; see also Press Release, Dep't of Justice, DOJ & HHS Highlight Latest Efforts to Fight Fraud by Clinical Laboratories (Feb. 24, 1997) (explaining that the federal government prosecuted National Health Laboratories in 1992 for submitting false claims to the government—"shortly after the NHL settlement, the [DOJ] formed a working group of federal and state investigators to address ... any and all violations of civil and/or criminal law").} This, along with data sharing and joint training, allowed for coordination of investigations, outreach programs, and prevention efforts.\footnote{434}{STATE MEDICAID FRAUD CONTROL UNITS, supra note 425, at 3.}

Another collaborative effort in health fraud detection came with the opening of the Healthcare Integrity and Protection Data Bank on October 26, 1999.\footnote{435}{See 45 C.F.R. § 61 (2013); see also Healthcare Integrity and Protection Data Bank, http://www.npdb-hipdb.hrsa.gov (last visited Dec. 2, 2013).} This national data collection program gathers information about civil judgments, criminal convictions, licensing and certification actions, exclusions from participation in federal or state health care programs, and any other final action designated by regulation to be reported.\footnote{436}{Healthcare Integrity and Protection Data Bank, http://www.npdb-hipdb.hrsa.gov/ (last visited Dec. 2, 2013).} Reports of adverse final actions against providers, suppliers and practitioners are made available to federal and state agencies and to health plans.\footnote{437}{Id.}

4. Compliance Programs

Corporate compliance programs were historically not required, though many health care providers developed them.\footnote{438}{See Blickenstaff, supra note 372, at 16–17.} However, the PPACA authorizes the Secretary of Health and Human Services "to require providers and suppliers to adopt, as a condition of enrollment, compliance programs that meet a core set of requirements, to be developed in consultation with the OIG."\footnote{439}{Morris Testimony, supra note 392, at 5. The PPACA also requires skilled nursing facilities and nursing facilities to implement compliance and ethics programs. Id. According to Morris, "[t]hese provisions are also consistent with recent developments in States that have made compliance programs mandatory for Medicaid providers." Id.} Additionally, compliance programs are often required during sentencing in criminal cases or
settlements of civil cases, and mandatory compliance programs are becoming increasingly common at the state level.\footnote{440. See Blickenstaff, supra note 372, at 16. But see Minnesota v. United States, 102 F. Supp. 2d 1115, 1121–22 (D. Minn. 2000) (explaining that Medicare Choice “does not require state officials to assist in the enforcement of federal statutes regulating private individuals” (quoting Reno v. Condon, 528 U.S. 141, 142 (2000))); Kathleen M. Boozang & Simone Handler-Hutchinson, Monitoring Corporate Corruption: DOJ’s Use of Deferred Prosecution Agreements in Health Care, 35 Am. J.L. & Med. 89, 90–97 (2009) (discussing DOJ’s increased reliance on deferred prosecution agreements in conjunction with federal monitors and the enormous power that monitors have). According to Morris, federal compliance provisions are “consistent with recent developments in States that have made compliance programs mandatory for Medicaid providers.” Morris Testimony, supra note 392, at 5.}}