

March 2012

MEDICARE

Implementation of Financial Incentive Programs under Federal Fraud and Abuse Laws



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Why GAO Did This Study

GAO has long expressed concern that increases in Medicare spending are unsustainable and do not necessarily enhance health care quality.

Traditional Medicare provider payment systems reward the volume of services instead of the quality or efficiency of care by paying physicians for each service provided. Some health systems, which can be hospitals, physicians, health plans, or a combination, use financial incentive programs to reward physicians for improving quality and efficiency with the goal of better outcomes for patients and savings for hospitals and payers. Federal laws that protect patients and the integrity of federal programs, including Medicare, limit health systems' ability to implement financial incentive programs. These fraud and abuse laws include the physician self-referral law, or Stark law; the anti-kickback statute; and the Civil Monetary Penalties (CMP) law. The Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS), and the Department of Justice oversee and enforce these laws.

GAO examined how federal fraud and abuse laws affect the implementation of financial incentive programs, stakeholders' perspectives on their ability to implement these programs, and alternative approaches through which HHS has approved implementation of these programs. GAO analyzed relevant laws and agency guidance and documentation; and interviewed agency officials, legal experts, and provider stakeholders.

View [GAO-12-355](#). For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

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Implementation of Financial Incentive Programs under Federal Fraud and Abuse Laws

What GAO Found

Certain financial incentive programs are permitted within the framework of federal fraud and abuse laws, but stakeholders GAO spoke with reported that the laws, regulations, and agency guidance have created challenges for program design and implementation. The Stark law and anti-kickback statute, which restrict financial relationships among providers, have statutory and regulatory exceptions and safe harbors, respectively, that permit financial incentive programs that meet specific criteria. However, there are no exceptions or safe harbors specifically for financial incentive programs intended to improve quality and efficiency, and legal experts reported that the constraints of existing exceptions and safe harbors make it difficult to design and implement a comprehensive program for all participating physicians and patient populations. The CMP law prohibits hospitals from paying physicians to reduce or limit services, and OIG has interpreted the law to apply to the reduction or limitation of any services, whether or not those services are medically necessary. The CMP law does not include statutory exceptions to this prohibition, and OIG does not have the authority to create exceptions through regulation. Through its advisory opinion process, OIG, however, has indicated that it would not impose sanctions for specific financial incentive programs that otherwise violated the CMP law but presented a low risk of fraud and abuse. Legal experts stated that innovative arrangements are difficult to structure and that the advisory opinion process is burdensome.

Through alternative approaches, HHS has approved implementation of otherwise prohibited financial incentive programs that incorporate safeguards, under its statutory authority to conduct demonstrations and other initiatives. Specifically, CMS has conducted demonstration projects to test financial incentive programs that reward quality and efficiency. These demonstration projects included safeguards, such as linking payments to quality measures, to protect program and patient integrity. CMS has incorporated safeguards into the Medicare Shared Savings Program, which allows eligible providers to participate as accountable care organizations to share savings with the Medicare program. As specifically authorized for the Medicare Shared Savings Program, CMS and OIG will waive fraud and abuse laws for, among other things, the distribution of shared savings in the Medicare Shared Savings Program, subject to certain requirements. The Center for Medicare and Medicaid Innovation within CMS is also implementing programs to test financial incentives.

GAO's work suggests that stakeholders' concerns may hinder implementation of financial incentive programs to improve quality and efficiency on a broad scale. Stakeholders—government agencies and health care providers—likely will continue to have different perspectives about the optimal balance between innovative approaches to improve quality and lower costs and retaining appropriate patient safeguards. HHS reviewed a draft of this report and in its written comments, clarified its position on CMS's authorities to create exceptions and issue waivers to permit certain financial incentive programs, noting that its authority to issue waivers is broader than its authority to create Stark exceptions. We modified the draft to reflect the Department's position.

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Abbreviations

ACO	accountable care organization
CMP	Civil Monetary Penalties
CMS	Centers for Medicare & Medicaid Services
CT	computed tomographic
DOJ	Department of Justice
FCA	False Claims Act
GDP	gross domestic product
HEDIS	Healthcare Effectiveness Data Information Set
HHS	Department of Health and Human Services
IOM	Institute of Medicine
MCO	managed care organization
OIG	Office of Inspector General
PIP	physician incentive plan
PPACA	Patient Protection and Affordable Care Act
SAB	Special Advisory Bulletin
SSA	Social Security Act

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United States Government Accountability Office
Washington, DC 20548

March 30, 2012

Congressional Requesters

For many years the United States has devoted an increasing proportion of its gross domestic product (GDP) and federal budget to the provision of health care services. National health expenditures rose from approximately 7 percent of GDP in 1970 to approximately 18 percent—\$2.5 trillion—in 2009. Over this same period, the proportion of federal budget outlays devoted to health care increased even more rapidly from approximately 8.3 to 26.9 percent.¹ Medicare spending, which represents a large share of federal health care expenditures, is projected to increase from approximately \$519 billion in 2010 to approximately \$922 billion in 2020.² We have long expressed concern that the increases in Medicare spending are unsustainable, especially in light of evidence that suggests that greater spending does not necessarily translate to better health care quality.³

The Medicare Payment Advisory Commission, Institute of Medicine (IOM), and other experts have recommended that payments for health care should contain stronger incentives for quality and efficiency. IOM, in its 2001 report “Crossing the Quality Chasm: A New Health System for the 21st Century”, recommended that payment methods should, among other things, provide an opportunity for providers to share in the benefits of quality improvement, align financial incentives with the implementation of care processes based on best practices and the achievement of better patient outcomes, and enable providers to coordinate care for patients across settings and over time. However, current provider payment

¹Office of the Actuary, Centers for Medicare & Medicaid Services, *National Health Expenditure Tables*, table 1, accessed October 18, 2011, <https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf>. Total federal budget outlays obtained from U.S. Budget for Fiscal Year 2011, Table 3.2—Outlays By Function and Subfunction: 1962–2015, accessed January 25, 2011, www.gpoaccess.gov/usbudget/fy11/sheets/hist03z2.xls.

²Medicare is the federal health insurance program serving individuals aged 65 and older, individuals under 65 with certain disabilities, and individuals diagnosed with end-stage renal disease. In 2011, Medicare covered 48.9 million beneficiaries.

³GAO, *The Federal Government's Long-Term Fiscal Outlook: January 2010 Update*, [GAO-10-468SP](#) (Washington, D.C.: Mar. 2, 2010).

systems used by traditional Medicare create conflicting incentives and contribute to the growth in spending by rewarding volume of services regardless of quality and cost,⁴ leading to duplication and overutilization of services that is wasteful and potentially harmful.⁵ Specifically, under traditional Medicare, hospitals are paid a predetermined fixed amount for each hospital stay regardless of the number of services provided, but physicians receive payment for each service delivered and have little incentive to coordinate the provision of care or control the volume of services.

Physicians play a central role in the generation of health care expenditures, and the incentive for physicians to order more services has a broad impact on total spending. While the services they provide directly to patients account for an estimated 20 percent of total health care expenditures, their influence is estimated to account for up to 90 percent of these expenditures because they either directly or indirectly control or influence most of the health services that are provided.⁶ For example, physicians admit patients to hospitals, and they order services such as imaging studies and laboratory tests. As some policy experts have noted, many factors give physicians an incentive to order more services than may be necessary, including a physician culture that values meticulousness, the scarcity of data comparing the effectiveness of different treatments and interventions, and the fear of malpractice lawsuits. In conjunction with these factors, paying physicians for an intervention that may only be justified by a slim clinical rationale adds a strong financial incentive to deliver more services.⁷

⁴Medicare Parts A and B, under which Medicare pays hospitals and physicians, respectively, are known as traditional Medicare.

⁵For example, studies have shown that unnecessary imaging tests, such as computed tomographic (CT) scans, can result in an increased cancer risk for patients. A 2007 study estimated that up to 2 percent of all cancers in the United States may be attributable to radiation from CT scans.

⁶GAO, *Medicare: Per Capita Method Can Be Used to Profile Physicians and Provide Feedback on Resource Use*, [GAO-09-802](#) (Washington, D.C.: Sept. 25, 2009).

⁷E.J. Emmanuel, and V.R. Fuchs. "The Perfect Storm of Overutilization." *Journal of the American Medical Association*, vol. 299, no. 23, (2008): 2789-2791.

Faced with these challenges, policymakers, health care providers, and others have sought ways to improve the quality of care and at the same time reduce costs. While the federal government examines various reforms to payment mechanisms, some health systems⁸ are implementing financial incentive programs to promote the quality and efficiency of care by rewarding physicians for meeting quality benchmarks and improving efficiency. Proponents of these programs believe they have the potential to result in better health outcomes for patients, and savings for hospitals and third-party payers, such as private health plans and public health programs including Medicare. Congress has included various reforms in the Patient Protection and Affordable Care Act (PPACA), including those that align incentives for hospitals and physicians to improve health care quality and efficiency in conjunction with efforts to develop collaborative care models for the Medicare program. For example, PPACA requires that the Department of Health and Human Services (HHS) establish a shared savings program—the Medicare Shared Savings Program—that encourages coordination of care under Medicare Parts A and B and promotes accountability for patient populations. Under the Medicare Shared Savings Program, eligible health systems that achieve savings for Medicare by improving quality and efficiency may receive a share of the savings they generate as financial incentive payments.⁹ Health systems that implement other financial incentive programs must comply with various federal laws in their efforts to reward quality and efficiency.

A number of federal laws apply to financial relationships among hospitals, physicians, health plans, and other entities. Among other things, these laws limit health systems that deliver care to Medicare beneficiaries from implementing financial incentive programs that could, for example, influence providers to recommend medically inappropriate services or withhold costly services that are medically necessary. These federal laws were designed to protect patients and the integrity of federal health care programs, including Medicare. They include, among others, the physician

⁸For the purposes of our study, health systems can include hospitals, physicians, and health plans, or any combination thereof.

⁹Pub. L. No. 111-148, §§ 3022, 10307, 124 Stat. 119, 395, 940 (codified at 42 U.S.C. § 1395jjj). In addition to eligible health systems, other organizations may be included in the Medicare Shared Savings Program. PPACA also includes numerous provisions affecting Medicare payments, payment rules, covered benefits, and the delivery of care.

self-referral law (known as the Stark law),¹⁰ the anti-kickback statute,¹¹ and the Civil Monetary Penalties (CMP) law.^{12,13} For purposes of this study, we refer to these three laws as the fraud and abuse laws. Federal agencies with oversight and enforcement responsibilities under these laws—including the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) within HHS—have issued regulations and guidance regarding financial incentive programs, while guarding against patient and program abuse. The Department of Justice (DOJ) also enforces the anti-kickback statute.¹⁴

You asked us to review how federal laws and regulations may affect the development of collaborative health care delivery arrangements designed to promote quality and efficiency, specifically financial incentive programs. Our report examines (1) how federal fraud and abuse laws, regulations, and guidance affect the implementation of financial incentive programs, and the perspectives of stakeholders on their ability to implement such programs; and (2) alternative approaches to the federal fraud and abuse laws through which HHS has approved certain financial incentive programs.

To determine how federal fraud and abuse laws, regulations, and guidance affect the implementation of financial incentive programs, and the perspectives of stakeholders on their ability to implement such programs, we interviewed officials from CMS, HHS's OIG, and DOJ who

¹⁰42 U.S.C. § 1395nn.

¹¹42 U.S.C. § 1320a-7b(b).

¹²42 U.S.C. § 1320a-7a. The CMP law provides for penalties for a variety of activities specified in the statute. In this report, we focus on the penalties that may apply to hospitals that pay physicians to induce a reduction or limitation of services. 42 U.S.C. § 1320a-7a(b).

¹³These three laws apply to various federal health care programs. For example, the CMP law applies to both the Medicare and Medicaid programs. For the purpose of our study, we focused on Medicare because all three laws apply to Medicare, and GAO has identified the program as being at high risk for fraud, waste, and abuse.

¹⁴Additionally, violations of the Stark law and anti-kickback statute may result in violations of the civil False Claims Act (FCA), which provides for civil penalties and triple damages for knowingly presenting or causing to be presented, a false or fraudulent claim for payment or approval by the United States. DOJ is the government agency responsible for enforcing the FCA. Private parties may also bring actions on behalf of the government, which DOJ can elect to join. 31 U.S.C. §§ 3729-3733.

have responsibility for enforcing the federal fraud and abuse laws.¹⁵ We also analyzed relevant federal laws, regulations, and advisory opinions. To obtain the stakeholders' perspectives, we interviewed eight legal experts about their experiences in advising clients in implementing financial incentive programs,¹⁶ and representatives from five health care industry groups that represent hospitals, physicians, and the health insurance industry. We also reviewed stakeholders' published statements on fraud and abuse laws. Additionally, we interviewed officials of 10 health systems to obtain illustrative examples of financial incentive programs to improve quality and efficiency,¹⁷ and a prominent financial incentive program expert with experience designing financial incentive programs to improve efficiency.

To identify alternative approaches to federal fraud and abuse laws through which HHS has approved certain financial incentive programs, we interviewed CMS officials, including officials responsible for Medicare demonstrations,¹⁸ for the Medicare Shared Savings Program, and from the Center for Medicare and Medicaid Innovation (Innovation Center). We also reviewed CMS documentation on selected Medicare demonstrations¹⁹ and proposed and final rules for the Medicare Shared

¹⁵As part of our work, for fiscal years 2005 through 2010, we requested that OIG identify any Stark law or anti-kickback statute enforcement actions on the basis of providers' implementation of pay-for-performance programs or gainsharing arrangements. Similarly, we requested that DOJ officials identify any FCA settlements involving the Stark law or anti-kickback statute against providers who implemented such programs during the same time period.

¹⁶To determine which legal experts to interview, we identified individuals who have counseled health systems on these issues, conducted a literature review to identify individuals who made contributions to the study of federal fraud and abuse laws within the context of health systems, and solicited recommendations from legal experts during interviews.

¹⁷To select the health systems, we requested recommendations from legal experts and industry group representatives. We also used a judgmental sampling technique to achieve variation in the type of health system, such as physician groups, hospital-based systems, and systems that include a health plan and size of the system.

¹⁸CMS uses demonstrations, which are typically time-limited programs, to test payment methods.

¹⁹We identified relevant Medicare demonstrations and other projects through our research and interviews with CMS officials on financial incentive program demonstrations.

Savings Program.²⁰ Finally, we reviewed the joint CMS and OIG notice and final rule regarding the waiver of certain federal fraud and abuse laws for the Medicare Shared Savings Program.²¹

We conducted this performance audit from October 2010 through February 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Health systems may use a variety of financial incentive programs to encourage improvements in the quality and efficiency of health care delivery. The payment of rewards to physicians, however, creates financial relationships that may implicate, that is, give rise to concern under, federal fraud and abuse laws designed to protect against undue influences on medical judgment.

Financial Incentive Programs

Health systems may offer a variety of financial incentive programs to encourage improvements in quality and efficiency, including those that help align incentives between hospitals and physicians. Health systems can use pay-for-performance programs to reward physicians for adherence to clinical protocols or objective improvement in individual patient care outcomes. They can also use shared savings programs to align physician incentives with those of hospitals by offering physicians a percentage of the hospitals' cost savings attributable to the physicians'

²⁰ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 *Fed. Reg.* 19,528 (Apr. 7, 2011); Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 *Fed. Reg.* 67,802 (Nov. 2, 2011).

²¹ Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, 76 *Fed. Reg.* 19,655 (Apr. 7, 2011); Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 *Fed. Reg.* 67,992 (Nov. 2, 2011).

efforts in controlling the costs and improving or maintaining the quality of patient care. These are often referred to as gainsharing arrangements.²²

Although results from financial incentive programs tried to date have been mixed, some experts believe they have the potential to increase quality and efficiency.²³ While pay-for-performance programs tend to have explicit goals of quality improvement rather than efficiency improvement, these programs can improve quality and efficiency by rewarding physicians for adhering to clinical protocols.²⁴ For example, these programs may result in savings for Medicare if the programs lead to better patient health outcomes, fewer medical interventions, and a reduction in the provision of services that are not medically necessary. Similarly, shared savings programs that reward physicians for using less expensive hospital supplies may result in savings for Medicare by lowering hospital costs. Specifically, shared savings programs, if implemented on a broad scale, could lower hospital costs sufficiently to reduce Medicare's hospital payments.²⁵

The availability of financial incentives, however, may affect a physician's judgment, introducing a profit motive that may lead to inappropriate referrals or reductions or limitations in services. In this respect, financial incentive programs may implicate federal fraud and abuse laws designed to protect patients and the integrity of the Medicare program.

²²For the purposes of our study, we use the term "financial incentive program" to refer to pay-for-performance programs, shared savings programs, and gainsharing arrangements.

²³In its January 2012 issue brief on programs tested by CMS, the Congressional Budget Office examined, in part, independent evaluations of four CMS programs where health care providers were given financial incentives to improve the quality and efficiency of care rather than payments based strictly on the volume and intensity of services delivered. The Congressional Budget Office concluded that results of these four programs were mixed. In one program where payments were bundled to cover all hospital and physicians services for heart bypass surgeries, Medicare spending was reduced by 10 percent, and there were no apparent adverse effects on patients' outcomes. The remaining three programs appeared to have produced little or no savings for Medicare. Of these three programs, two slightly improved quality of care based on the measures adopted for the program. The third program had little or no effect on Medicare spending or quality in its first year.

²⁴Pay-for-performance programs may result in increased costs if the clinical protocols result in the use of more services or more expensive services.

²⁵Since Medicare hospital payments are based in part on the estimated average hospital cost per admission, reduced hospital costs, over time, may be reflected in Medicare's payment updates.

Federal Fraud and Abuse Laws and Enforcement Mechanisms

Federal fraud and abuse laws designed to protect the integrity of services that are reimbursed under federal health care programs, including Medicare, regulate certain types of conduct, including financial relationships that may influence the delivery of care. Health systems must operate within the framework of federal fraud and abuse laws when designing and implementing financial incentive programs. Table 1, which follows the section on advisory opinion authority, summarizes the federal fraud and abuse laws and enforcement mechanisms.

Stark Law

The Stark law and its implementing regulations prohibit physicians from making referrals for certain “designated health services” paid for by Medicare, including hospital services, to entities with which the physicians (or their immediate family members) have a financial relationship,²⁶ unless the arrangement satisfies a statutory or regulatory exception.^{27,28} Studies have found that these self-referrals encouraged overutilization and increased health costs.^{29,30} The Stark law also prohibits these entities that perform the designated health services from presenting, or causing to

²⁶A financial relationship is an ownership or investment interest—through equity, debt, or other means—in the entity or a compensation arrangement between the physician or immediate family member and the entity. CMS regulations further define financial relationship as direct compensation, indirect compensation, direct ownership, and indirect ownership. 42 C.F.R. § 411.354.

²⁷42 U.S.C. § 1395nn.

²⁸The Social Security Act (SSA) prohibits payments to states for Medicaid services that would be prohibited by Medicare under the Stark law. 42 U.S.C. § 1396b(s).

²⁹See Medicare Program; Physician Ownership of, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services, 57 *Fed. Reg.* 8,588 (proposed Mar. 11, 1992). In June 1988, Congress mandated that the HHS OIG conduct a study on physician ownership of and compensation from health care entities to which the physicians make referrals. OIG reported that patients of referring physicians who owned or invested in independent clinical laboratories received 45 percent more laboratory services than Medicare patients generally. OIG found similar effects on utilization associated with the existence of compensation arrangements between laboratories and physicians. Patients of these physicians used 32 percent more laboratory services than all Medicare patients in general. Based in part on the results of this study, Congress passed the Stark law in November of 1989. Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 63 *Fed. Reg.* 1659, 1661 (Jan. 9, 1998).

³⁰Similarly, GAO found that physicians with financial interests in entities to which they can refer patients may have higher referral rates. See GAO, *Medicare: Referrals to Physician-Owned Imaging Facilities Warrant HCFA’s Scrutiny*, GAO/HEHS-95-2 (Washington, D.C.: Oct. 20, 1994).

be presented, claims to Medicare or billing any individual, third-party payer, or other entity for these services.³¹ The Stark law includes a number of exceptions³² and authorizes the Secretary of HHS to create regulatory exceptions for financial relationships that do not pose a risk of patient or program abuse.^{33,34} The Stark law was enacted to prevent physicians from referring patients and ordering tests and services that may be unnecessary—and result in overutilization—for the purpose of financial gain. Financial incentive programs implicate the Stark law because they create a financial relationship between the entity paying the incentive and the physician who receives it, which could give the physician an incentive to refer patients to that entity.

The Stark law prohibits physicians from making referrals to entities with which they or their immediate family members have a financial relationship, regardless of whether that relationship is intended to result in these referrals. In this regard, the Stark law is a strict liability statute. Those physicians or health systems that violate the Stark law by either making prohibited referrals or billing for the services for which the referral was made may be subject to a number of sanctions. Any amounts received for claims in violation of the Stark law must be refunded. Those who know or should know that they are submitting (or causing to be submitted) a claim in violation of the Stark law may be subject to civil monetary penalties of up to \$15,000 for each service, an assessment of three times the amount claimed, and exclusion from federal health care programs.³⁵ CMS is responsible for issuing regulations under the Stark law and collecting payments made in violation of the law. OIG is responsible for enforcing the Stark law's civil monetary penalties.

³¹42 U.S.C. § 1395nn(a)(1)(B).

³²42 U.S.C. §§ 1395nn(b)-(e).

³³There are more than 20 Stark law statutory and regulatory exceptions that may apply generally, to ownership or investment, or to compensation arrangements.

³⁴42 U.S.C. § 1395nn(b)(4). Stark law regulations are located at 42 C.F.R. §§ 411.350-411.389.

³⁵Civil monetary penalties of up to \$100,000 may be imposed on those who enter into arrangements that they know or should know have the principal purpose of assuring referrals that would violate the Stark law if made directly.

Anti-kickback Statute

The anti-kickback statute makes it a criminal offense for anyone to knowingly and willfully solicit, receive, offer, or pay any remuneration to induce or reward referrals of items or services reimbursable under Medicare,³⁶ subject to statutory exceptions and regulatory safe harbors promulgated by OIG.³⁷ The law helps to limit the potential for money to influence providers' health care decisions, and, in this respect, helps to prevent overutilization of services, the provision of unnecessary or substandard services, and the inappropriate steering of patients.

A financial incentive program under which a hospital paid physicians who referred patients for admission would implicate the anti-kickback statute. Unlike the Stark law, the anti-kickback statute is intent-based; the action must be knowing and willful. Penalties under the anti-kickback statute include imprisonment for up to 5 years and criminal fines of up to \$25,000. In addition, those individuals and entities violating the anti-kickback statute are subject to civil penalties of up to \$50,000 per act, an assessment of three times the remuneration, and exclusion from participation in federal health care programs.³⁸ OIG and DOJ are charged with enforcing the anti-kickback statute. OIG is responsible for issuing regulatory safe harbors under the anti-kickback statute and, as under the Stark law, has administrative enforcement responsibilities. DOJ prosecutes cases under the anti-kickback statute.

CMP Law

In addition to providing for the imposition of civil monetary penalties for certain enumerated activities, such as knowingly presenting a Medicare claim that is part of a pattern of claims for items or services that a person knows are not medically necessary, the CMP law provides penalties for hospitals that knowingly make an indirect or direct payment to a physician as an inducement to reduce or limit services to hospital patients, and for physicians who accept such payments.³⁹ The statute does not contain

³⁶The anti-kickback statute applies to payments made under federal health care programs. We focused on Medicare because all three laws apply to Medicare, and GAO has identified the program as being at high risk for fraud, waste, and abuse.

³⁷42 U.S.C. § 1320a-7b(b). For the purposes of this study, we refer to anti-kickback statutory exceptions and regulatory safe harbors as safe harbors.

³⁸42 U.S.C. §§ 1320a-7a(a)(7), 1320a-7(a)-(b).

³⁹42 U.S.C. § 1320a-7a(b). The CMP law applies to the Medicaid and Medicare programs. We focused on Medicare because all three laws apply to Medicare, and GAO has identified the program as being at high risk for fraud, waste, and abuse.

False Claims Act –
Enforcement Mechanism for
Federal Fraud and Abuse Laws

exceptions for this prohibition and does not authorize OIG to establish exceptions by regulation. Like the Stark law and the anti-kickback statute, the CMP law reflects congressional concern that incentive payments may create a conflict of interest that may limit the ability of the physician to exercise independent professional judgment in the best interest of the patient.⁴⁰ Financial incentive programs that reward physicians with a share of hospital cost-savings realized through a reduction or limitation of items and services implicate the CMP law. In addition, payments from a hospital to a physician designed to reward quality that lead to a reduction or limitation of services furnished to hospital patients also implicate the CMP law. Hospitals or physicians who violate the CMP law are subject to civil penalties of up to \$2,000 per patient covered by the payments, and exclusion from participation in federal health care programs.⁴¹ OIG is responsible for enforcing the CMP law.

The False Claims Act (FCA) serves as another enforcement mechanism for federal fraud and abuse laws. Claims that are submitted in violation of the Stark law or the anti-kickback statute may also be considered false claims and, as a result, create additional liability under the FCA.⁴² FCA prohibits certain actions, including the knowing presentation of a false claim for payment by the federal government.⁴³ For example, a financial incentive program under which a hospital submitted a claim to Medicare for a service provided by a physician when the physician and hospital had a financial relationship in violation of the Stark law, would implicate the FCA if the requisite intent were present.

Penalties under the FCA include triple damages, plus an additional penalty for each false claim filed up to \$11,000.⁴⁴ DOJ is charged with enforcing the FCA and enforces the Stark law and the anti-kickback statute through the FCA. FCA claims also may be brought by third parties

⁴⁰H.R. Rep. No. 99-727, at 444 (1986), *reprinted* in 1986 U.S.C.C.A.N. 3607, 3841.

⁴¹42 U.S.C. §§ 1320a-7a(b), 1320a-7(b)(7).

⁴²31 U.S.C. §§ 3729-3233.

⁴³31 U.S.C. § 3729(a)(1)(A).

⁴⁴Those who violate the FCA are liable for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by inflation, plus three times the amount of damages the government sustains, though the court may reduce damages. 31 U.S.C. § 3729(a)(1)-(2). Violators are also liable for the cost of the action. 31 U.S.C. § 3729(a)(3).

alleging the submission of false claims and these “whistleblowers” can receive between 15 and 30 percent of a monetary settlement or recovery plus expenses and attorneys’ fees and costs.⁴⁵

Advisory Opinion Authority

In response to requests for specific guidance from providers on whether an existing or proposed financial arrangement, including a financial incentive program, violates the fraud and abuse laws, CMS and OIG have the statutory authority to issue advisory opinions.⁴⁶ CMS is required to issue advisory opinions on the Stark law,⁴⁷ and OIG is required to issue advisory opinions on the CMP law and the anti-kickback statute, among other matters.⁴⁸ Advisory opinions are issued only in response to a request regarding an existing or proposed arrangement to which the requester is a party. Advisory opinions are binding on the Secretary of HHS and the individual or entity requesting the opinion; no other parties can rely on an advisory opinion. The time between when CMS and OIG receive an advisory opinion request and when the advisory opinion is released can depend on, for example, the information contained in the request and the amount of time needed for the agencies to obtain additional information from the requester. Requesters must submit certified written requests that include information specified in regulations. If the initial request for an advisory opinion does not contain all the information the agencies need, the agencies may request whatever additional information is necessary to respond to the request. When requesting an advisory opinion, requesters must agree to pay all costs the

⁴⁵31 U.S.C. § 3730(d).

⁴⁶CMS and OIG consult with DOJ in issuing advisory opinions. CMS and OIG do not consider requests that present a general question of interpretation or pose a hypothetical situation through the advisory opinion process.

⁴⁷CMS will not address whether fair market value will be, or was, paid or received for goods, services, or property, or whether an individual is a bona fide employee through the advisory opinion process. 42 C.F.R. § 411.370(c).

⁴⁸42 U.S.C. § 1320a-7d(b)(2). OIG is prohibited from addressing whether fair market value will be, or was, paid or received for goods, services, or property, or whether an individual is a bona fide employee through the advisory opinion process. 42 U.S.C. § 1320a-7d(b)(3). OIG has also issued compliance guidance and special advisory bulletins. OIG is also authorized to issue special fraud alerts in response to a request to inform the public of practices considered to be suspect or of particular concern. 42 U.S.C. § 1320a-7d(c).

agencies incur in responding to the request.⁴⁹ CMS has 15 days and OIG has 10 days to notify the requesters whether their requests have been formally accepted or declined or whether additional information is needed. Once a request has been accepted, CMS has 90 days and OIG has 60 days to respond, with certain exceptions.

⁴⁹OIG currently charges \$86 per hour to prepare an advisory opinion. The actual cost of an opinion will vary based upon the amount of work required to prepare the opinion. Requesters may set a cap by designating the maximum amount that they are willing to spend on an advisory opinion. OIG will stop processing the request once this amount is reached, at which point, the requester has the option to withdraw the request or continue.

Table 1: Summary of Federal Fraud and Abuse Laws and Enforcement Mechanisms

Law	Summary	Exceptions	Agency oversight	Penalties
Stark law	Prohibits physicians from making referrals for certain services to entities with which they have a financial relationship to prevent financial incentives from affecting physicians' medical judgment; prevents overutilization	Statutory and regulatory exceptions	Regulatory exceptions created by, advisory opinions issued by, and overpayment amounts collected by CMS; enforced by OIG	Civil monetary penalties, assessment of three times the amount claimed, denial of payments and refunds of amounts collected from individuals, and exclusion from federal health care programs
Anti-kickback statute	Prohibits offers and receipts of remuneration to induce or reward of referrals for services to prevent financial incentives from affecting physicians' medical judgment; prevents overutilization	Statutory exceptions and regulatory safe harbors	Regulatory safe harbors created and advisory opinions issued by OIG; enforced by OIG and DOJ	Criminal penalties; civil monetary penalties, assessment of three times the remuneration, and exclusion from federal health care programs
CMP law	Prohibits payments by hospitals to physicians to induce reduction or limitation of services to hospital patients to prevent financial incentives from affecting physicians' medical judgment; prevents underutilization	None	Advisory opinions issued by OIG; Enforced by OIG	Civil monetary penalties and exclusion from federal health care programs
False Claims Act (FCA)—used as enforcement mechanism for federal fraud and abuse laws	Prohibits knowingly presenting or causing to be presented a false claim for payment to the federal government; additional mechanism to enforce the Stark law and anti-kickback statute	None	Enforced through lawsuits brought by DOJ and whistleblowers	Civil penalties and triple damages

Source: GAO analysis of the federal fraud and abuse laws and the FCA.

CMS's Demonstration and Waiver Authority

CMS has general statutory authority to test new payment methods and other alternatives to payment policies, with Medicare providers, through demonstration projects.⁵⁰ Generally, such demonstrations are time-limited to test program changes, but some have been extended. In connection with such demonstration projects, the Secretary of HHS may waive certain payment and reimbursement requirements, including the Stark law.⁵¹ The Secretary of HHS has also been required by statute to conduct specific Medicare demonstrations, which provide implicit or express authority for waivers of federal fraud and abuse laws.⁵²

In addition, PPACA requires that HHS establish the Medicare Shared Savings Program, which will provide financial incentive payments to eligible groups of providers and suppliers that join together in what are called accountable care organizations (ACO) and that achieve savings for Medicare by improving the quality and efficiency of care delivered to assigned traditional Medicare beneficiaries. PPACA authorizes HHS to waive fraud and abuse laws as may be necessary to carry out the Medicare Shared Savings Program.

PPACA also established the Innovation Center within CMS specifically to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare and Medicaid beneficiaries.⁵³ The Innovation Center can test new payment methods, including financial incentive programs, by

⁵⁰The SSA authorizes the Secretary of HHS to develop and engage in experiments and demonstration projects to determine whether changes in methods of payment or reimbursement would increase the efficiency and economy of Medicare health services through the creation of additional incentives for these purposes without adversely affecting the quality. 42 U.S.C. § 1395b-1(a)(1)(A).

⁵¹The Stark law may be waived under this authority because it is a payment and reimbursement provision located in title XVIII of the SSA. 42 U.S.C. § 1395b-1(b). However, because the anti-kickback statute and CMP law are located in title XI of the SSA, they cannot be waived under this authority.

⁵²See, e.g., 42 U.S.C. § 1395cc-3, which provides that the Secretary of HHS will establish a demonstration program that examines health delivery factors that encourage the delivery of improved quality in patient care, including the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources. For demonstrations conducted under 42 U.S.C. § 1395cc-3, the Secretary of HHS may waive the Stark law, anti-kickback statute, and CMP law.

⁵³Pub. L. No. 111-148, §§ 3021, 10306, 124 Stat. 119, 389, 939 (codified at 42 U.S.C. § 1315a).

implementing models and expanding successful models nationwide.⁵⁴ The Secretary of HHS has the authority to waive certain federal fraud and abuse laws for time-limited models, but not for successful model expansions.⁵⁵

Medicare Managed Care Organizations

Medicare beneficiaries can opt to enroll in private plans administered by Medicare managed care organizations (MCO) to receive covered benefits.⁵⁶ These MCOs, also known as Medicare Advantage Plans or Medicare Part C, provide both hospital (Part A) and medical insurance (Part B).⁵⁷ MCOs may offer lower out-of-pocket costs and more benefits than traditional Medicare. Once enrolled, however, choices that beneficiaries would traditionally make may be subject to the MCO's approval. For instance, MCOs may utilize primary care physicians as gatekeepers to manage patient access to specialty services, may require beneficiaries to pay higher out-of-pocket costs if they choose a provider not on the preferred list, and may require patients and doctors to obtain organizational approval for elective hospitalization, certain expensive diagnostic tests, or specific medical procedures.⁵⁸

MCOs have an incentive to limit services because of the way they are paid by Medicare. MCOs receive a monthly payment for each enrollee. Medicare makes the same monthly payment to the MCO for the enrollee regardless of how many or few services the enrollee actually uses. If an MCO's expenditures for its enrollees are less than its monthly payments, the MCO retains the excess. To help protect beneficiaries, MCOs are required to operate quality assurance programs. CMS is responsible for monitoring MCOs to ensure that MCOs are providing quality, timely, and appropriate services. In addition to day-to-day monitoring, CMS selects

⁵⁴42 U.S.C. § 1315a(b)-(c).

⁵⁵42 U.S.C. § 1315a(d).

⁵⁶See 42 U.S.C. § 1395w-21.

⁵⁷Nearly two-thirds of MCOs include Medicare prescription drug coverage (Part D).

⁵⁸M.A. Rodwin, *Consumer Protection and Managed Care: Issues, Reform Proposals, and Trade-Offs*. 32 *Hous. L. Rev.* 1319 (1996).

organizations each year for an on-site audit based on a risk assessment and other criteria.⁵⁹

MCOs employ various techniques to control costs and manage health service use, such as implementing financial incentive programs with their providers. Like other financial incentive programs, MCOs' physician incentive plans (PIP) must comply with the Stark law and anti-kickback statute.⁶⁰ However, unlike financial incentive programs between hospitals and physicians, PIPs are not subject to the same provision of the CMP law. Congress crafted a separate law, under which MCOs can implement PIPs as long as payments are not made to reduce or limit medically necessary services to individual patients. If physicians are placed at substantial financial risk, that is more than 25 percent of their payment is at risk, MCOs must provide stop-loss protection based on the number of patients, and MCOs must also conduct periodic surveys of current and prior enrollees to address enrollees' access to and satisfaction with the quality of services. MCOs must provide CMS with information about financial incentive programs for approval.⁶¹ MCOs that violate this provision are subject to civil monetary penalties of up to \$25,000 and suspension of enrollment activities, Medicare payment, or marketing activities.⁶²

⁵⁹As part of its monitoring activities, CMS conducts financial audits, audits of plan bids, and audits of the accuracy of health status data submitted by plans.

⁶⁰"Physician incentive plan" means any compensation arrangement between an eligible organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization.

⁶¹42 U.S.C. § 1395mm(i)(8). As initially enacted, the CMP law prohibited hospitals and MCOs from paying physicians to reduce services, regardless of whether the services are medically necessary. Congress subsequently amended the CMP law to remove MCOs and passed a separate provision that permits MCOs to implement incentive plans as long as plans do not induce the reduction or limitation of medically necessary services.

⁶²42 C.F.R. § 422.752(a)(1).

Certain Financial Incentive Programs Are Permitted under Federal Fraud and Abuse Laws, Regulations, and Guidance, but Stakeholders Reported Challenges in Designing and Implementing Programs within This Framework

Certain financial incentive programs are permitted within the framework of federal fraud and abuse laws through various Stark law and anti-kickback statute exceptions and safe harbors, respectively or because they do not implicate one or more of the laws in the first instance. OIG has interpreted the CMP law to prohibit hospitals from rewarding the reduction or limitation of services, but permits certain financial incentive programs through its advisory opinion process. However, stakeholders we spoke with reported that the laws, regulations, and agency guidance have created challenges for financial incentive program design and implementation, and some health systems have terminated or refrained from implementing these programs. Neither OIG nor DOJ took any enforcement actions against financial incentive programs in fiscal years 2005 through 2010.

Financial Incentive Programs May Be Permitted under Stark and Anti-kickback Exceptions and Safe Harbors; Stakeholders Nevertheless Reported Challenges Structuring Permissible Programs

CMS and OIG have acknowledged new exceptions and safe harbors may be necessary to facilitate financial incentive programs. CMS has acknowledged that existing Stark law exceptions may not be sufficiently flexible to encourage a wider array of nonabusive and beneficial incentive programs that both promote quality and achieve cost savings. CMS can create additional exceptions as long as the exception does not pose a risk of program or patient abuse.⁶³ According to CMS officials, this “no risk” requirement is high and limits their ability to create new regulatory exceptions to the Stark law. In 2008 CMS attempted to use its authority to propose a new exception covering financial incentive programs.⁶⁴ However, the “no risk” requirement necessitated a narrow exception with many structural safeguards in light of the risk that financial incentive programs could be used to disguise payments for referrals or adversely affect patient care. In its proposed rule, CMS noted that the design of the proposed exception created a challenge in providing broad flexibility for

⁶³42 U.S.C. § 1395nn(b)(4).

⁶⁴Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B, 73 *Fed. Reg.* 38,502, 38,604 (proposed July 7, 2008).

innovative, effective programs while at the same time protecting the Medicare program and patients from abuses. The agency solicited comments, and many of the comments it received criticized the number and complexity of safeguards needed to achieve the “no risk” standard. To date, the agency has taken no further action to finalize this regulatory exception, and CMS officials told us the agency has no plans to do so in the near future. Similarly, OIG officials told us that they recognize that industry innovation may be significant enough to warrant new anti-kickback safe harbors, and the agency annually solicits input from providers on potential safe harbors, as required by statute.⁶⁵

The Stark law and anti-kickback statute apply variously to provider financial relationships, and their respective exceptions and safe harbors are not specific to financial incentive programs focused on quality and efficiency, such as pay-for-performance or gainsharing arrangements, between hospitals and physicians. As a result, financial incentive programs that implicate these laws must be structured to fit into applicable exceptions and may be structured to fit into applicable safe harbors,⁶⁶ which some legal experts we spoke with characterized as narrow in scope.⁶⁷ To illustrate, an official from an urban health system in the Southwest told us that to improve the quality of care, they implemented a financial incentive program to reward physicians who met certain quality measures. To comply with the Stark law, the health system structured its program to comply with the bona fide employment

⁶⁵OIG received a letter from a provider stakeholder in response to the agency’s 2010 solicitation of new safe harbors requesting a safe harbor specifically for financial incentive programs. The agency is considering but has not taken action on this request.

⁶⁶Financial incentive programs could be structured so that they do not implicate one or more of these laws. For example, HHS stated that a program limited to commercial patients might not implicate any of the laws.

⁶⁷Legal experts told us that while the anti-kickback statute is complicated, they find it easier to comply with than the Stark law due to the anti-kickback statute’s intent requirement.

exception.⁶⁸ Employed physicians are rewarded for meeting certain clinical outcome quality measures, such as diabetes glucose measures and pediatric immunizations, as well as patient satisfaction measures. The program only includes the hospital's employed physicians, who constitute less than 10 percent of the physicians who provide services at the hospital. As a result, this financial incentive program does not align incentives between the health system and independent physicians who have privileges at the hospital. To incentivize quality improvement on a broader scale, hospital officials told us they were able to use another Stark law exception to implement a separate financial incentive program to include independent physicians. Specifically, because the health system had a health plan component, the health system was able to use the physician incentive plan exception in creating a financial incentive program for independent physicians to reward them for meeting a separate set of quality measures—the Healthcare Effectiveness Data Information Set (HEDIS).⁶⁹ The physician incentive plan exception permits financial incentive plans that are administered and paid through health plans under certain conditions. Hospitals or health systems without a health plan component would have to design a financial incentive program to fit into other exceptions to include independent physicians.⁷⁰ Additionally, operating multiple financial incentive programs covering different populations of physicians may create potential inefficiencies through redundancy or conflicting program objectives.

⁶⁸An official told us the health system was not concerned about implicating the anti-kickback statute with the implementation of their program because of the anti-kickback statute's intent requirement. The Stark law's bona fide employment exception conditions the exception on the employment being for identifiable services, the remuneration paid under the employment being consistent with fair market value and not determined in a way that takes into account the volume or value of referrals, and the remuneration provided being commercially reasonable even if no referrals were made to the employer. 42 C.F.R. § 411.357(c). Generally, the bona fide employment safe harbor permits amounts paid by an employer to an employee who has a bona fide employment relationship for the furnishing of services for which payment is made under Medicare. 42 C.F.R. § 1001.952(i).

⁶⁹HEDIS contains 75 measures, including blood pressure control measures, cancer screenings, immunizations, and comprehensive diabetes care measures.

⁷⁰Legal experts we spoke with told us they can rely on the following Stark exceptions and anti-kickback safe harbors: risk-sharing exception and safe harbor, personal services arrangement exception and safe harbor, fair market value exception, indirect compensation exception, prepaid plan exception, academic medical center exception, physician incentive plan exception, and the managed care safe harbor.

In addition, most of the legal experts we spoke with told us that it is difficult for health systems to navigate the Stark law, and one legal expert told us that as a result health systems have terminated existing financial incentive programs or refrained from starting new programs. Some legal experts also told us that the requirements for complying with the Stark exceptions are difficult to apply when crafting financial incentive programs. In particular, they told us it is challenging to establish whether incentive payments meet the Stark fair market value exception, which in part requires that compensation be consistent with fair market value of services provided.⁷¹ One legal expert we spoke with noted that the Stark law's fair market value exception potentially applies to payments from hospitals to physicians. For salary, the fair market value exception can be satisfied by using published surveys of wages to determine the fair market value of services provided. However, according to this legal expert, the exception becomes more difficult to apply when trying to determine the fair market value in connection with incentive payments, separate from compensation, for meeting performance goals. Specifically, some legal experts told us that the exception is unclear about how to measure the fair market value of services when those services involve meeting a clinically based outcome measure for a financial incentive program to improve quality. Additionally, it would be difficult to calculate the value of services not provided as a result of the physician providing higher quality care leading to better health outcomes.

Some legal experts also told us that many of the Stark exceptions on which they rely require that compensation, including incentive payments from hospitals to physicians, not reflect the volume or value of referrals made by the physician.⁷² To comply with this requirement, financial incentive programs may be structured so that incentive payments are distributed to all participating physicians without being directly related to any individual physician's compliance with quality improvement criteria. Therefore, all participating physicians would receive the same payment without necessarily contributing the same level of effort. As a result, according to some of the legal experts we spoke with, an underperforming physician would not have an incentive to change his or her practices to improve the quality of care.

⁷¹42 C.F.R. § 411.357(l).

⁷²*E.g.*, 42 U.S.C. §§ 1395nn(e)(2)(ii), 1395nn(e)(3)(A)(v), 1395nn(e)(5)(B).

Financial incentive programs limited to commercial patients may also implicate federal fraud and abuse laws. Some legal experts and health systems we spoke with told us it is difficult to separate commercial patients from Medicare patients for the purposes of financial incentive programs. Financial incentive programs limited to commercial patient populations may “spill over” to Medicare patients. For example, a financial incentive program that rewards quality improvement for commercial patient outcomes may influence how a participating physician treats Medicare patients. To protect themselves from Stark law and anti-kickback statute violations, health systems may structure their programs to fit into an exception or safe harbor in case a Medicare patient is inadvertently included in the program. For example, officials from a hospital system in a major urban area in the Midwest told us the hospital entered into a financial incentive program to share savings with a commercial payer for its commercial patient population only. These officials told us their program only includes employed physicians to further protect the providers from Stark law or anti-kickback statute violations if a Medicare patient is inadvertently included in the program.

Financial incentive programs limited to commercial patients also might include Medicare patients in other ways. For example, a commercial insurer that used a hospital’s achievement of quality benchmarks could include the hospital’s Medicare patients in determining whether the benchmarks are met. In 2008, OIG issued a favorable advisory opinion in response to a request from a hospital seeking to implement a financial incentive program to reward physicians for meeting quality targets for commercial patients.⁷³ The requester-hospital was participating in a pay-for-performance program with a private insurer, under which the hospital would be rewarded with a bonus payment for achieving quality targets based on health outcomes of all patients, including Medicare patients.⁷⁴ The hospital stated that it needed to implement a financial incentive program with its physicians in order to achieve those quality targets and would reward physicians with a share of the bonus payment received from the private insurer. OIG determined that the program implicated the anti-kickback statute because the program relied on all hospital patient

⁷³U.S. Dept. of Health and Human Services, Office of Inspector General, *OIG Adv. Op. 08-16* (Washington, D.C.: Oct. 14, 2008).

⁷⁴In addition, the arrangement between the insurer and the hospital would reward the hospital for meeting efficiency measures.

data, which included data for Medicare patients, instead of using only commercial patient data, to determine incentive payments for physicians.⁷⁵ In its advisory opinion on the matter, however, OIG elected not to impose sanctions for this program.

OIG officials told us that they did not take any Stark law or anti-kickback statute enforcement actions on the basis of providers' implementation of pay-for-performance programs or gainsharing arrangements from fiscal years 2005 through 2010. Additionally, DOJ officials were unable to identify any DOJ FCA settlements involving the Stark law or anti-kickback statute that were based on the implementation of such programs during the same time period. However, some legal experts we spoke with told us that although there have not been any FCA cases or settlements, the threat of being the first case has created a chilling effect for providers. Some legal experts told us that as a result, their clients were conservative when implementing such programs.

Stakeholders Reported That OIG Interpretation of CMP Law Diminished Ability to Reward Any Service Reduction or Limitation, Including Services Not Medically Necessary

In addition to the Stark law and anti-kickback statute, hospitals must comply with the CMP law, which OIG interpreted in a 1999 Special Advisory Bulletin (SAB) as prohibiting payments from hospitals to physicians to induce a reduction or limitation in Medicare services for hospital patients, even if the services are not medically necessary.⁷⁶ A violation of the CMP law may result if the hospital knows that the payment may influence the physician to reduce or limit services, even if the payment is not tied to a specific patient or to an actual diminution in care. Any hospital financial incentive program that encourages physicians through payments, indirectly or directly, to reduce or limit clinical services violates the CMP law. Unlike the Stark law and anti-kickback statute, the CMP law does not have any statutory exceptions nor does it give OIG the authority to create regulatory exceptions. However, OIG has issued

⁷⁵OIG determined that the program also implicated the CMP law because adherence to quality standards under the program could induce physicians to reduce or limit current levels of items or services provided to Medicare patients, but elected not to impose sanctions. For example, if adherence to a quality standard results in physicians discontinuing an item or service sooner than would be their practice in the absence of the financial incentive program, then a limitation of items or services would occur.

⁷⁶Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 *Fed. Reg.* 37,985 (July 14, 1999).

advisory opinions effectively permitting certain financial incentive programs that would otherwise violate the CMP law.

OIG considers the CMP law a reflection of congressional concern that payments from hospitals to physicians may result in stinting on care.⁷⁷ In its SAB, OIG stated that the CMP law is intentionally broad, and noted in the SAB that the plain language of the statute does not limit its application to those services that are “medically necessary.” According to OIG officials, historically the CMP law developed as a patient quality of care law, not just a restriction on financial relationships. In addition, the SAB indicated that OIG’s interpretation of the CMP law was based, in part, on Congress’s inclusion of “medically necessary” in the law for MCOs. According to OIG officials, OIG interpreted the enactment of a separate law for MCOs to reflect the difference between MCOs and hospitals. They stated that MCOs, unlike hospitals, can more readily identify the patients participating in the network. OIG further reasoned that patients who enroll in an MCO understand that their physicians will have an economic incentive with respect to managing their care, and in return, patients share in any savings through increased benefits, such as reduced copayments and the addition of outpatient prescription drug coverage.⁷⁸ By contrast, in OIG’s view, patients in traditional Medicare incur substantial additional financial obligations in exchange for access to physicians of their choice.

According to OIG, hospitals may align incentives with physicians to achieve cost savings through means that do not violate the CMP law. For example, depending on the circumstances, an arrangement where the hospital pays the physicians a fixed fee that is fair market value for specific services rendered would compensate the physicians for their effort and not for a reduction or limitation in services. Achieving savings through actions that do not adversely affect the quality of patient care

⁷⁷In the SAB, OIG pointed to a congressional report noting that a committee of jurisdiction believed that such incentive payments created a conflict of interest that may limit the ability of the physician to exercise independent professional judgment in the best interest of the patient. Additionally, OIG cited a 1986 GAO report that evaluated the potential for abuse in financial incentive programs. See GAO, *Medicare: Physician Incentive Payments by Hospitals Could Lead to Abuse*, [GAO/HRD-86-103](#) (Washington, D.C.: July 22, 1986).

⁷⁸U.S. Dept. of Health & Human Services, Office of Counsel to the Inspector General, Recent Commentary Distorts HHS IG’s Gainsharing Bulletin, *available at* <http://oig.hhs.gov/fraud/docs/alertsandbulletins/bnagain.htm>.

may require substantial effort on the part of the physicians. Depending on the circumstances, if the financial incentive program is based on the physician's efforts rather than a percentage of cost savings, the program may not violate the CMP law.⁷⁹ According to OIG officials, even if the program leads to a reduction or limitation of services, as long as the payment is not for the purpose of reducing services, the program would not violate the CMP law. For example, a hospital could pay a physician to complete his or her rounds by a specific time, which may result in patients being evaluated for discharge earlier. The payment is not tied to a reduction or limitation of services, but if patients are not hospitalized longer than necessary, this arrangement makes it possible for the hospital to be efficient and reduce costs.

One legal expert and an industry group stakeholder we spoke with consider OIG's interpretation of the CMP law overly broad—prohibiting payment from hospitals to physicians to induce the reduction or limitation of any service, regardless of medical necessity. In February 2009, an industry group stakeholder wrote to OIG contending that the agency should interpret the CMP law in the context of Medicare's requirements that only medically necessary services are covered by the program. Since Medicare only covers medically necessary services, and the CMP law prohibits reduction or limitation of Medicare services, according to this stakeholder, the CMP law should be interpreted as prohibiting a reduction or limitation of medically necessary services.

Some legal experts we spoke with and two industry group stakeholders consider the CMP law a major hurdle to the development and implementation of financial incentive programs that allow the hospital to reward physicians for lowering hospital costs and improving quality by reducing medically unnecessary services. Similarly, an industry group stakeholder, in a September 2010 statement to OIG, claimed that the CMP law constrains the development of financial incentive programs that would align hospital and physician incentives to provide more cost-effective care by, for example, encouraging more careful choice among available generic and brand name drugs or use of outpatient rather than inpatient services. This stakeholder noted that physicians are concerned that participation in such gainsharing arrangements exposes them to

⁷⁹These financial incentive programs would need to comply with the Stark law and anti-kickback statute.

liability under the CMP law. Another industry group stakeholder, in a May 2008 statement, asserted that the CMP law has dissuaded providers from pursuing financial incentive programs using specific practice protocols, even those based on clinical evidence and recognized as best practices, because of provider concern that OIG might find that the program provided an incentive to reduce or limit services.

Some legal experts told us that their health system clients have implemented financial incentive programs to reward quality, and they also include efficiency measures that could reduce or limit services but do not tie incentive payments to these measures to avoid implicating the CMP law. Although physicians are not rewarded for meeting these efficiency measures, their performance in meeting these benchmarks may be monitored and information may be shared with the physician as feedback,⁸⁰ possibly providing a nonfinancial incentive to improve efficiency. For example, one legal expert described an arrangement between a hospital and its independent physicians to reward quality. The original goal of the program was to reduce the length of stay for patients. In addition to quality measures such as adhering to clinical protocols and meeting patient satisfaction benchmarks, the hospital wanted to include efficiency measures, such as standards for inpatient admission that could have limited admissions, but the physicians' attorney was concerned that the program would violate the CMP law. Specifically, the attorney was concerned that including standards for inpatient admissions could lead to a reduction of services if, for example, a patient who did not meet these standards was denied admission to the hospital even if admission was not necessary. In response to these concerns, the hospital tied incentive payments only to quality measures.⁸¹ Although the program retained the

⁸⁰In our work on physician profiling, a review of the literature suggested that without other incentives, feedback alone has no more than a moderate influence on physician performance. However, the potential influence of feedback from CMS regarding Medicare costs is uncertain, and may be greater than that of feedback from other sources, because Medicare reimbursement typically represents a larger share of physicians' practice revenues than that from other insurers. Factors that appear to influence the effectiveness of feedback include its source, frequency, and intensity. See [GAO-09-802](#). CMS is implementing a feedback program with physicians. GAO, *Medicare Physician Feedback Program: CMS Faces Challenges with Methodology and Distribution of Physician Reports*, [GAO-11-720](#) (Washington, D.C.: Aug. 12, 2011).

⁸¹This legal expert told us that clients tend to be conservative and are reluctant to move forward with the financial incentive program even when he advises them that the arrangement would not violate the CMP law.

efficiency measures, such as medically inappropriate days, these measures were tied to widely used clinical standards,⁸² no payment was tied to them, and they were used only to collect information on physician performance.⁸³

OIG Permits Certain Financial Incentive Programs through Its Advisory Opinion Process, but Stakeholders Reported Challenges in Implementing These Programs

In its 1999 SAB, OIG interpreted the CMP law to prohibit gainsharing arrangements in response to hospitals' implementation of "black box" gainsharing arrangements in the 1990s. In OIG's view, those gainsharing arrangements, in which physicians were paid for overall cost savings without the hospitals determining the specific actions the physicians took to generate the savings, posed a high risk of abuse.⁸⁴ According to OIG, the black box gainsharing arrangements provided little accountability, insufficient safeguards against improper referral payments, and lacked objective performance measures to ensure that quality of care was not adversely affected.⁸⁵ In various documents addressing the matter, OIG has noted its concern with the potential effect gainsharing has on the quality of care provided to Medicare patients. Specifically, OIG's concerns

⁸²Specifically, this financial incentive program included the InterQual criteria as its measures. The InterQual criteria represent criteria to evaluate the appropriateness of medical care, based on an assessment of the patient's clinical status, and include, as part of clinical or quality protocols, standards for appropriate admissions and avoidable days of stay. Additionally, CMS uses the InterQual criteria as part of its inpatient services auditing program.

⁸³The legal expert who described this arrangement told us that the program had reduced the average length of stay by 2 days while maintaining quality of care for patients

⁸⁴OIG was concerned that in order to retain or attract high-referring physicians, hospitals would be under pressure from competitors and physicians to increase the percentage of savings shared with the physicians, manipulate the hospital accounts to generate phantom savings, or otherwise game the arrangement to generate income for referring physicians.

⁸⁵OIG advisory opinions have noted that many gainsharing arrangements contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, a lack of a demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs and any corresponding gainsharing payment; the individual actions that would give rise to the savings are not identified with specificity; there are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any savings; the quality-of-care indicators are of questionable validity and statistical significance; and there is no independent verification of cost savings, quality-of-care indicators, or other essential aspects of the arrangement. See, e.g., U.S. Dept. of Health & Human Services, Office of Inspector General, *OIG Adv. Op. 05-04* (Washington, D.C.: Feb. 10, 2005).

include stinting on patient care, “cherry picking” healthy patients and steering sicker and more costly patients to hospitals that do not offer such arrangements, payments in exchange for patient referrals, and unfair competition among hospitals offering cost-sharing programs to foster physician loyalty and to attract more referrals.

OIG has recognized, however, that certain gainsharing arrangements may reduce costs and improve quality without compromising care or rewarding referrals. Specifically, OIG has recognized that certain gainsharing arrangements, while potentially violating the CMP law and the anti-kickback statute, present a minimal risk of fraud and abuse that these laws were intended to address. On this basis, OIG has indicated that it would not subject specific arrangements approved in advisory opinions to sanctions. Through its advisory opinion process, OIG has evaluated certain gainsharing arrangements that could implicate the CMP law and anti-kickback statute. Since 2001, OIG has issued 14 advisory opinions on specific gainsharing arrangements.⁸⁶ In these opinions, OIG concluded that the arrangements presented a low risk of abuse and that they would not, therefore, be subject to sanction. While OIG advisory opinions provide important guidance to providers about what may or may not be sanctioned by OIG, the opinions only address the anti-kickback statute and the CMP law. Because CMS, not OIG, has responsibility for interpreting the Stark law, OIG gainsharing opinions do not address the legality of these arrangements under the Stark law. CMS has not received any requests to issue advisory opinions on gainsharing arrangements, and therefore has not done so.

In evaluating the risks posed by these gainsharing arrangements, OIG looked for measures that promote accountability, provide adequate quality controls, and protect against payments for referrals. The cost saving measures included in the approved gainsharing arrangements can generally be categorized as product standardization measures, product substitution, opening packaged items only when needed, or limiting the

⁸⁶U.S. Dept. of Health & Human Services, Office of Inspector General, *OIG Adv.Op. 01-01* (Washington, DC: Jan. 11, 2001); *OIG Adv.Op. 05-01* (Jan. 28, 2005); *OIG Adv.Op. 05-02* (Feb. 10, 2005); *OIG Adv.Op. 05-03* (Feb. 10, 2005); *OIG Adv.Op. 05-04* (Feb. 10, 2005); *OIG Adv.Op. 05-05* (Feb. 18, 2005); *OIG Adv.Op. 05-06* (Feb. 18, 2005); *OIG Adv.Op. 06-22* (Nov. 9, 2006); *OIG Adv.Op. 07-21* (Dec. 28, 2007); *OIG Adv.Op. 07-22* (Dec. 28, 2007); *OIG Adv.Op. 08-09* (July 31, 2008); *OIG Adv.Op. 08-15* (Oct. 6, 2008); *OIG Adv.Op. 08-21* (Nov. 25, 2008); *OIG Adv.Op. 09-06* (June 23, 2009).

use of certain supplies or devices.⁸⁷ The arrangements included similar features that, when taken together, OIG determined they provided sufficient safeguards to reduce the risk of program and patient abuse so that OIG would not seek sanctions against the health system for violation of the CMP law. These safeguards include

- specific cost-saving actions and resulting savings that are clearly and separately identified;
- credible medical support that implementation of the arrangement would not adversely affect patient care;
- payments that are based on all procedures and do not reflect the differences among individual patients' insurance coverage;
- protection against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds below which no savings accrue to the physicians;
- protections in the product standardization portion of the arrangement to further protect against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the arrangement as before;
- written disclosure provided to patients whose care may be affected by the arrangement and an opportunity for patients to review the cost savings recommendations prior to admission to the hospital;
- financial incentives that are reasonably limited in duration and amount; and

⁸⁷Examples of cost-saving measures included in gainsharing arrangements permitted by OIG: Product standardization and substitution include standardizing the types of cardiac catheterization devices, such as stents and balloons, which are used by the physicians, and substituting types of items and services for which product substitution will have no appreciable clinical significance, such as utilizing reusable warming blankets to maintain body temperature. Opening packaged items only when needed includes having disposable equipment available to the physician, but only opening the packaging when needed. Use-as-needed measures include limiting the use of a specific medication given to many surgical patients preoperatively to prevent hemorrhaging to patients that are at higher risk of perioperative hemorrhage as indicated by objective clinical standards.

-
- profits that are distributed to the physicians on a per capita basis, mitigating any incentive for an individual physician to generate disproportionate cost savings.

According to OIG, improperly designed or implemented arrangements could be vehicles to disguise payments for referrals. OIG found that the specific gainsharing arrangements evaluated in the advisory opinions could violate the anti-kickback statute, but the agency stated it would not impose sanctions for those arrangements because they included safeguards that reduced the likelihood that the arrangement would be used to attract referring physicians or to increase referrals from existing physicians. Due to the circumstances of the arrangements, as well as the included safeguards, OIG determined that the arrangements presented a low risk of fraud or abuse under the anti-kickback statute. Although the advisory opinions have focused on specific service lines, such as cardiac and orthopedic surgery, OIG officials stated that they are willing to evaluate gainsharing arrangements for other service lines. However, to date, OIG has not been asked to do so.

In February 2009, one industry group stakeholder asked OIG in writing to withdraw the agency's SAB that interpreted the CMP law as prohibiting gainsharing. The industry group asserted that the agency's subsequent advisory opinions permitting implementation of certain gainsharing arrangements represent an "implicit acknowledgment that the experiences and context that gave rise to the 1999 Bulletin [SAB] have changed significantly." Specifically, according to this stakeholder, tools, such as the proliferation of quality measures, are now available to prevent financial incentives from causing harm to patients. However, according to OIG officials, although the health care delivery environment has changed since the CMP law was enacted, the payment systems that led to the enactment of the CMP law are still in use.

Legal experts and stakeholders told us that multiple challenges are associated with implementing gainsharing arrangements since OIG issued its SAB, despite the availability of OIG's advisory opinion process. Some legal experts told us they were reluctant to use the advisory opinion process because it is expensive and time-consuming. Some experts noted that, in their experience, legal expenses incurred in obtaining an advisory opinion ranged from \$15,000 to over \$50,000 depending on the complexity of the arrangement, in addition to other costs associated with

developing arrangements.⁸⁸ The financial incentive program expert we spoke with reported that it took over a year of review before OIG issued its first advisory opinion approving a novel gainsharing program.⁸⁹ Some industry group stakeholders said that because the advisory opinions are only applicable to the requesting health system, other health systems cannot rely on the advisory opinions for assurance that OIG will not enforce the CMP law, even though OIG officials told us the agency did not take any enforcement actions against financial incentive programs for fiscal years 2005 through 2010.

Health systems implementing gainsharing arrangements have structured their arrangements to be identical to those already approved, thereby lowering but not eliminating the overall risk that the arrangement would result in sanction for violating the CMP law. For example, we spoke with officials from a health system in the Northeast that is implementing a gainsharing arrangement with its orthopedics division. According to these officials, the health system is relying exclusively on the elements of previous OIG gainsharing advisory opinions to define the parameters of its gainsharing arrangement. Officials told us that they will not be pursuing areas for savings that OIG has not previously approved. However, even when implementing a gainsharing arrangement that has already been approved, legal experts told us there are challenges. Some legal experts told us that gainsharing arrangements permissible under OIG's advisory opinions are narrow, and the approved gainsharing arrangements focus on certain procedural areas and include specific measures, such as limiting the use of certain surgical supplies and substitution of less costly items for those items currently used by the physicians. In addition, financial incentives to physicians must be distributed equally per capita regardless of the level of effort on the part of the physician.

⁸⁸In addition to legal fees, health systems looking to develop financial incentive programs, including gainsharing arrangements, may have other expenses such as consulting fees and other internal system costs. One legal expert we spoke with told us that his clients' reluctance to implement these gainsharing arrangements was due, in part, to business considerations. Specifically, the costs associated with developing the arrangement may outweigh the potential quality and efficiency benefits of the arrangement. According to him, these costs are inherent to the development of gainsharing arrangements and not due to the requirements of OIG advisory opinions.

⁸⁹One legal expert told us that during this review process, a program can be started while waiting for the advisory opinion to be issued; however, money cannot be shared with the physicians during this time. Instead, the money can be put in an escrow account and distributed after a favorable advisory opinion is issued.

HHS Has Approved Otherwise Prohibited Financial Incentive Programs That Incorporate Safeguards, under Demonstration Project and Other Authorities

HHS has permitted implementation of certain financial incentive programs that otherwise might not be permitted under federal fraud and abuse laws, but it has required safeguards to protect program and patient integrity. CMS has conducted these programs through authorized demonstration projects, the Medicare Shared Savings Program, and the Innovation Center. These demonstration projects and programs are designed for specific types of providers and health systems, and some health systems may not be willing or eligible to participate.

CMS has conducted demonstration projects to test financial incentive programs that include safeguards to protect program and patient integrity. For example, CMS, as authorized by the Deficit Reduction Act of 2005,⁹⁰ designed the Medicare Hospital Gainsharing Demonstration to determine whether gainsharing arrangements could align incentives between hospitals and physicians to improve the quality and efficiency of care as well as hospital operation and financial performance.⁹¹ The demonstration project involved arrangements between hospitals and physicians under which the hospitals made gainsharing payments to physicians that were a share of the savings incurred directly as a result of collaborative efforts to improve overall quality and efficiency. CMS officials told us that this demonstration incorporated safeguards to protect program and patient integrity. Specifically, these safeguards included the requirement that providers meet quality thresholds by linking incentive payments to quality measures; that the financial incentive payment be limited to 25 percent of the amount normally paid for similar cases; and that payments not be based on the volume or value of referrals. CMS monitored physician referral and admission patterns throughout the demonstration to ensure that care provided to patients was not compromised. Although CMS has not completed its evaluation of this demonstration, officials told us they had not observed participants engaging in fraudulent behavior or become aware of harmful effects on patients.

According to CMS officials, CMS has incorporated safeguards from previous demonstrations and MCOs in its rule for the Medicare Shared Savings Program, which allows ACOs to participate in a shared savings arrangement with the Medicare program. The Medicare Shared Savings Program is designed to pay providers on a fee-for-service basis, and will,

⁹⁰Pub. L. No. 109-171, § 5007, 120 Stat. 4, 34 (2006).

⁹¹This project began October 1, 2008, and expired on September 30, 2011.

at least in theory, help align incentives by sharing potential savings with providers that agree to meet quality and efficiency standards. According to CMS, the program incorporates the following broad categories of safeguards: quality measures;⁹² legal structure and governance requirements;⁹³ patient-centeredness;⁹⁴ monitoring;⁹⁵ disclosure and transparency requirements;⁹⁶ and program integrity screens.⁹⁷ These safeguards are intended to protect patient and program integrity by ensuring that patient needs and experiences inform the delivery of care and ACO governance. An ACO's continued participation in the Medicare Shared Savings Program is contingent on its performance. CMS has the authority to terminate an ACO's participation in the program based on the agency's findings.

⁹²There are 33 quality measures across four domains: Patient/Caregiver Experience, Care Coordination/Patient Safety, Preventive Health, and At-Risk Population.

⁹³Each ACO must establish a mechanism for shared governance and have a leadership and management structure that includes clinical and administrative systems. An ACO's governing body should include ACO participants and a Medicare beneficiary.

⁹⁴Among other things, an ACO must have processes in place to promote patient engagement that address the following: compliance with beneficiary experience of care survey requirements; compliance with the beneficiary representation requirements; a process for evaluating the health needs of the ACO's population, including consideration of diversity in its patient populations and a plan to address the needs of its population; communication of clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them; beneficiary engagement and shared decision making that takes into account the beneficiaries' unique needs, preferences, values, and priorities; and written standards for beneficiary access and communication, and a process for beneficiaries to access their medical records.

⁹⁵CMS will use a range of methods to monitor and assess the performance of ACOs, including but not limited to any of the following, as appropriate: (1) analysis of specific financial and quality measurement data reported by the ACO as well as aggregated annual and quarterly reports; (2) analysis of beneficiary and provider complaints; and (3) audits, including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits, and on-site compliance reviews.

⁹⁶In addition to the data ACOs must report to CMS, ACOs must report specified information publicly.

⁹⁷According to CMS officials, among other things, CMS will screen ACOs and ACO participants during its review of ACO applications and throughout the course of the ACOs' participation in the Medicare Shared Savings Program against the List of Excluded Individuals and Entities (those excluded from federal health care programs).

CMS and OIG have issued an interim final rule with comment period that establishes waivers of the fraud and abuse laws for the Medicare Shared Savings Program, including, among others, a shared savings distribution waiver.⁹⁸ This waiver applies to distribution of shared savings from the ACO and within the ACO to ACO participants or ACO providers or suppliers. It also applies to the distribution of shared savings to providers outside the ACO but only for activities that are reasonably related to the purposes of the Medicare Shared Savings Program. In both cases, among other requirements,⁹⁹ CMS and OIG require that the ACO does not limit or reduce medically necessary services.¹⁰⁰ The waiver covers the distribution of savings accrued during the period in which the ACO is

⁹⁸Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 *Fed. Reg.* 67,992 (Nov. 2, 2011). CMS and OIG included the following additional waivers for ACOs participating in the Medicare Shared Savings Program: (1) an “ACO pre-participation” waiver of the fraud and abuse laws that applies to ACO-related start-up arrangements in anticipation of participating in the Medicare Shared Savings Program, subject to certain limitations, including limits on the duration of the waiver and the types of parties covered; (2) an “ACO participation” waiver of the fraud and abuse laws that applies broadly to ACO-related arrangements during the term of the ACO’s participation agreement under the Medicare Shared Savings Program and for a specified time thereafter; (3) a “compliance with the Stark law” waiver of the anti-kickback statute and CMP law for ACO arrangements that implicate the Stark law and meet an existing exception; and (4) a “patient incentive” waiver of the anti-kickback statute and the provision of the CMP law addressing inducements to beneficiaries for medically related incentives offered by ACOs under the Medicare Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

⁹⁹In order for the fraud and abuse laws to be waived for the distribution or use of shared savings under this particular waiver, the ACO must meet the following conditions: (1) the ACO has entered into a participation agreement and remains in good standing under its participation agreement; (2) the shared savings are earned by the ACO pursuant to the Medicare Shared Savings Program; (3) the shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement; (4) the shared savings are (a) distributed to or among the ACO’s ACO participants, its ACO providers or suppliers, or individuals and entities that were its ACO participants or its ACO providers or suppliers during the year in which the shared savings were earned by the ACO, or (b) used for activities that are reasonably related to the purposes of the Medicare Shared Savings Program; and (5) payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.

¹⁰⁰Payments made by a hospital to induce a physician to reduce or limit medically necessary care without providing acceptable alternative medically necessary care would not qualify for the waiver. For example, payments to discharge patients without regard to appropriate care transitions or payments to use a drug or device known to be clinically less effective do not qualify for the waiver.

participating in the Medicare Shared Savings Program, even if those savings are distributed after this period. According to CMS and OIG, the waiver for the distribution of shared savings within the ACO is premised, in part, on recognition that an award of shared savings necessarily reflects the collective achievement by the ACO and its constituent parts of the quality, efficiency, and cost reduction goals of the Medicare Shared Savings Program. These goals are consistent with interests protected by the fraud and abuse laws.¹⁰¹

CMS officials told us the Innovation Center is also developing programs that use financial incentives and include safeguards used in CMS demonstrations and the Medicare Shared Savings Program. The programs will include safeguards such as using patient-centered factors including beneficiary survey results, provider profiles, and risk scores to monitor the success of these programs. For example, the Innovation Center has selected 32 organizations to participate in the Pioneer ACO Model.¹⁰² Unlike ACOs formed under the Medicare Shared Savings Program,¹⁰³ the Pioneer ACO Model is targeted at organizations that are already coordinating care for a significant portion of patients under financial risk-sharing contracts and are positioned to transform both their care and financial models from fee-for-service to a value-based model.¹⁰⁴ CMS plans to safeguard against a reduction in necessary care in the

¹⁰¹According to HHS, PPACA provided the Department broad waiver authority for financial incentive programs under the Medicare Shared Savings Program. HHS used this authority to allow many relationships that would have been covered under CMS's proposed 2008 Stark law exception.

¹⁰²See Medicare Program; Pioneer Accountable Care Organization Model: Request for Applications, 76 *Fed. Reg.* 29,249 (May 20, 2011).

¹⁰³The Pioneer ACO Model and the Medicare Shared Savings Program are distinct programs, and ACOs cannot participate in both programs; however, both programs share the same goals to improve care for individuals, improve health for populations, and slow growth in expenditures. The Pioneer ACO Model will complement the Medicare Shared Savings Program by testing models that may later be adopted in the Medicare Shared Savings Program.

¹⁰⁴The Pioneer ACO Model offers multiple payment options. In the first 2 years, all payment options involve fee-for-service payments during the performance year with the opportunity to generate shared savings or shared losses at year-end (with higher levels of risk than in the Medicare Shared Savings Program). In the third year, Pioneer ACOs that have shown savings over the first 2 years will be eligible to receive population-based payments. Population-based payment is a per beneficiary per month payment intended to replace a significant portion of the ACO's fee-for-service payment with a prospective payment.

models it tests through multiple mechanisms, including routinely analyzing data on service utilization, measuring beneficiary experience of care through surveys, and assessing beneficiary complaints. In the Pioneer ACO Model, CMS stated it will determine whether there are systematic differences in health status or other characteristics between patients who remain aligned with a given ACO over the life of the Pioneer ACO Model, and those who do not. ACOs that participate in the Pioneer ACO Model will also conduct surveys of their aligned beneficiaries on an annual basis, and according to CMS, the agency may investigate the practices of ACOs that generate beneficiary complaints. CMS stated it will also publicly report the performance of ACOs on quality metrics, including patient experience ratings, on its website.

Concluding Observations

CMS and OIG recognize that properly structured financial incentive programs have the potential to improve quality and reduce costs but that improperly structured programs can disguise payments for referrals or adversely affect patient care. The federal fraud and abuse laws discussed in this report apply variously to financial relationships among hospitals, physicians, and health plans, among other entities. As a type of financial relationship, health systems must take these laws into account when structuring financial incentive programs. Health systems can implement certain types of financial incentive programs through, for example, various Stark law exceptions, anti-kickback safe harbors, or the agencies' advisory opinion processes, although hospitals may not reward the limitation or reduction of services—even those services that are not medically necessary—without first obtaining OIG approval.

Although health systems can implement certain types of financial incentive programs that may result in better patient health outcomes and lower health care costs, the challenges of implementing these programs within the current legal framework may, for some health systems, outweigh the potential benefits of doing so. As the stakeholders we spoke with reported, there are significant challenges to designing and implementing financial incentive programs through the available options. There are no exceptions and safe harbors specifically for financial incentive programs, and the Stark law's "no risk" requirement for new exceptions, makes it difficult for CMS to craft an exception that allows for innovative, effective programs while ensuring that the Medicare program and patients face no risk from abuses. As such, the constraints of existing exceptions and safe harbors make it difficult to design and implement a comprehensive program for all participating physicians and patient populations. Furthermore, for some health systems, OIG's interpretation

of the CMP law constrains the development of financial incentive programs that would align hospital and physician incentives to provide more cost-effective care, and hospitals may be reluctant to pursue an advisory opinion because of the time, expense, and uncertainty involved. As a result, health systems are more likely to implement only those programs that mirror already approved programs or none at all.

CMS's various demonstrations, the Medicare Shared Savings Program, and programs implemented by the Innovation Center provide other opportunities for some health systems to implement these programs without the associated challenges of conforming to some of the federal fraud and abuse laws. The demonstrations, however, are time-limited and not all health systems are eligible or willing to participate. Under the Medicare Shared Savings Program, which is a permanent program, CMS and OIG will waive fraud and abuse laws for financial incentive programs under certain circumstances, but there may be limits on health systems' ability to participate.

Our work suggests that stakeholders' concerns may hinder implementation of financial incentive programs to improve quality and efficiency on a broad scale. Different stakeholders—government agencies and health care providers—will likely continue to have differing perspectives about the optimal balance between innovative approaches to improve quality and lower costs and retaining appropriate patient and program safeguards.

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reprinted in appendix I. HHS and DOJ provided technical comments which we incorporated as appropriate.

In its written comments, HHS sought to clarify the Department's position on CMS's use of its authorities to permit certain financial incentive programs—using regulatory exceptions and waivers—that the Department did not believe we had clearly described in the draft. Specifically, we had attributed the narrowness of the proposed 2008 Stark law exception to agency concern that financial incentive programs could be used to disguise payments for referrals or adversely affect patient care, as the agency had noted in the proposed rule. HHS clarified that the SSA requirement that Stark law exceptions pose “no risk of patient or program abuse” is a high standard that prevents the agency from balancing flexibility with beneficiary protection in creating exceptions. HHS commented that the narrowness of the proposed 2008 Stark law

exception was dictated by this strict legal standard. HHS also commented that CMS has much greater authority in balancing flexibility with beneficiary protection under its waiver authority, and crafted much broader waivers when authorized to do so by the statutory authorities of the Medicare Shared Savings Program and Innovation Center. We modified the draft to reflect the agency's position on this issue.

In addition, HHS commented that our draft focused on the shared savings-only waiver, rather than the full scope of waivers that CMS and OIG determined were necessary for the success of the program. We highlighted the shared savings distribution waiver as an example of a waiver of the fraud and abuse laws that ACOs can use when distributing savings to providers and suppliers, and included a description of the additional waivers in a footnote, which we determined was sufficient detail for this report.

HHS also commented that our discussion of the proposed 2008 Stark law exception does not include a discussion of the Medicare Shared Savings Program or Innovation Center waivers, which cover substantially the same gainsharing arrangements addressed in the proposed exception. We added a footnote addressing this issue but maintain that organizations that do not have programs under either the Medicare Shared Savings Program or Innovation Center are still required to comply with the Stark Law and its existing exceptions, which our stakeholders noted was challenging.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the date of the report. At that time we will send copies of the report to the Secretary of Health and Human Services and the U.S. Attorney General. This report also will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

A handwritten signature in black ink, appearing to read 'James Cosgrove', written in a cursive style.

James Cosgrove
Director, Health Care

List of Addressees

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate

The Honorable Michael F. Bennet
United States Senate

The Honorable Al Franken
United States Senate

The Honorable Kirsten Gillibrand
United States Senate

The Honorable Kay Hagan
United States Senate

The Honorable Mark Udall
United States Senate

The Honorable Tom Udall
United States Senate

The Honorable Mark R. Warner
United States Senate

Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

MAR 09 2012

James Cosgrove
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "MEDICARE: Implementation of Financial Incentive Programs under Federal Fraud and Abuse Laws" (GAO-12-355).

The Department appreciates the opportunity to review this draft section of the report prior to publication.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT CORRESPONDENCE ENTITLED, "MEDICARE IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS" (GAO-12-355)

Thank you for the opportunity to review and comment on GAO draft report entitled, "MEDICARE: Implementation of Financial Incentive Programs Under Federal Fraud and Abuse Laws" (GAO-12-355). In the report, GAO examined how fraud and abuse laws affect the implementation of financial incentive programs, stakeholders' perspectives on their ability to implement these programs, and alternative approaches through which the Department of Health and Human Services (HHS) had approved implementation of these programs. The report explained that the Secretary has authority to create regulatory exceptions to the physician self-referral law and that certain provisions in the Social Security Act permit the waiver of the fraud and abuse laws, including the physician self-referral law, in some cases.

The Centers for Medicare & Medicaid Services (CMS) creates physician self-referral law policy and works closely with the HHS Office of the Inspector General (OIG) to develop that policy. We would like to clarify the distinction between the creation and implementation of a waiver and a regulatory exception to achieve the goal of improvements in the quality and efficiency of health care delivery on a broad scale. With regard to waivers, the Affordable Care Act authorized the Secretary of HHS to waive fraud and abuse laws as necessary to carry out the provisions of the Medicare Shared Savings Program and the testing of models by the Center for Medicare and Medicaid Innovation (Innovation Center), among other provisions. CMS worked in conjunction with several other agencies, including OIG, to provide waivers linked to safeguards to achieve the successful creation and implementation of Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program. We note that GAO focused on the shared savings-only waiver, rather than the full scope of waivers that CMS and OIG determined were necessary for the success of the program. A full description of the waivers involving ACOs is available at <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf>. The waivers were subject to several public comment periods. These waivers were generally received positively by public stakeholders, including healthcare industry stakeholders, with recognition that CMS exercised its waiver authority to both encourage ACO development and protect beneficiaries and the Medicare program. In addition, CMS and OIG issued waivers for ACOs participating in the testing of the Pioneer ACO model by the Innovation Center.

On page 18 of the GAO draft report, we would like to clarify that the first paragraph of this page is unclear about the two different authorities CMS has attempted to use to accommodate financial incentive programs, including ACOs. GAO suggests that CMS' decision not to finalize the proposed 2008 gainsharing regulatory exception reflected an attempt to balance flexibility with beneficiary protections. In fact, the Social Security Act¹ only authorizes the agency to create Stark law exceptions that pose "no risk of patient or program abuse." This high standard prevents the agency from conducting such a balance. GAO correctly states, "CMS crafted this proposed exception narrowly," without noting that narrowness was dictated by this strict legal standard. While CMS has much greater authority in conducting a balancing test for the exercise

¹ 42 U.S.C. section 1395nn(b)(4).

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT CORRESPONDENCE ENTITLED, "MEDICARE IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS" (GAO-12-355)

of waiver authority, it cannot apply this test when creating new regulatory exceptions.

This discussion also does not reflect the fact that CMS and OIG crafted much broader waivers when authorized to do so by the statutory authorities of the Medicare Shared Savings Program and Innovation Center. GAO states that "CMS officials told us the agency had no plans to [finalize the gainsharing exception] in the near future, citing the Medicare Shared Savings Program and other payment model programs as priorities." We are concerned that this sentence may be confusing, since it does not discuss the fact that the waivers CMS and OIG have produced for these initiatives have covered substantially the same gainsharing relationships addressed in the 2008 proposed exception.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

James Cosgrove, (202) 512-7114, cosgrovej@gao.gov

Staff Acknowledgments

In addition to the contact named above, Christine Brudevold, Assistant Director; Helen Desaulniers, Assistant General Counsel; Jasleen Modi; Elizabeth T. Morrison; Sarah Resavy; Lillian Shields; Hemi Tewarson; and Jennifer Whitworth made key contributions to this report.

Related GAO Products

Medicare Physician Feedback Program: CMS Faces Challenges with Methodology and Distribution of Physician Reports. [GAO-11-720](#). Washington, D.C.: August 12, 2011.

Value in Health Care: Key Information for Policymakers to Assess Efforts to Improve Quality While Reducing Costs. [GAO-11-445](#). Washington, D.C.: July 26, 2011.

High-Risk Series: An Update. [GAO-11-278](#). Washington, D.C.: February 2011.

Medicare: Private Sector Initiatives to Bundle Hospital and Physician Payments for an Episode of Care. [GAO-11-126R](#). Washington, D.C.: January 31, 2011.

Medicare: Per Capita Method Can Be Used to Profile Physicians and Provide Feedback on Resource Use. [GAO-09-802](#). Washington, D.C.: September 25, 2009.

Medicare Physician Payment: Care Coordination Programs Used in Demonstration Show Promise, but Wider Use of Payment Approach May Be Limited. [GAO-08-65](#). Washington, D.C.: February 15, 2008.

Medicare: Focus on Physician Practice Patterns Can Lead to Greater Program Efficiency. [GAO-07-307](#). Washington, D.C.: April 30, 2007.

Medicare: Advisory Opinions as a Means of Clarifying Program Requirements. [GAO-05-129](#). Washington, D.C.: December 8, 2004.

Medicare: Referrals to Physician-Owned Imaging Facilities Warrant HCFA's Scrutiny. [GAO/HEHS-95-2](#). Washington, D.C.: October 20, 1994.

Medicare: Physician Incentive Payments by Prepaid Health Plans Could Lower Quality of Care. [GAO/HRD-89-29](#). Washington, D.C.: December 12, 1988.

Medicare: Physician Incentive Payments by Hospitals Could Lead to Abuse. [GAO/HRD-86-103](#). Washington, D.C.: July 22, 1986.

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