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HEALTH CARE FRAUD UNDER THE NEW MEDICARE PART D PRESCRIPTION DRUG PROGRAM

ROBERT N. RABECS*

I. INTRODUCTION

The investigation and prosecution of health care fraud over the last several years has resulted in significant recoveries and settlements by the government. The United States recovered approximately \$1.5 billion in fraud settlements and judgments for the fiscal year ending September 30, 2005, the Department of Justice (“DOJ”) announced on November 7, 2005. “As in the last several years, health care accounted for the lion’s share of fraud settlements and judgments,” amounting to \$1.1 billion, according to a DOJ press release.¹ The DOJ stated that the Department of Health and Human Services’ (“HHS”) biggest recoveries were largely attributable to the Medicare and Medicaid programs.² According to the Health Care Fraud and Abuse Control (“HCFAC”) program report released October 27, 2005 by the HHS Office of Inspector General (“OIG”), the federal government won or negotiated \$605 million in judgments and settlements in 2004 related to the Medicare and Medicaid programs.³

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¹ *DOJ Cites \$1.4 Billion in Fraud Recovery in FY 2005, Including Health Care Cases*, 16 MEDICARE REP. (BNA) 1321 (2005).

² *Id.*

³ *Report Says Anti-Fraud Efforts at HHS, DOJ Returned \$1.5 Billion to Medicare Program*, 16 MEDICARE REP. (BNA) 1288 (2005). The HCFAC program was established by Congress in the Health Insurance Portability and Accountability Act of 1996 to provide more federal dollars to anti-fraud efforts by HHS and DOJ. The departments are required to provide Congress an annual reporting on HCFAC program activities. *Id.*

The level of investigation and enforcement activity involving health care fraud is only likely to increase in the next several years as a result of the new Medicare prescription drug program which went into effect on January 1, 2006.⁴ The new program, known as Medicare Part D, was created pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA").⁵ Under the program, Medicare beneficiaries will be able to obtain partial Medicare coverage and reimbursement for their outpatient prescription drugs. Some studies have estimated that the Part D program will cost an estimated \$720 billion over its first ten years.⁶ Lewis Morris, chief counsel to the HHS OIG, has said that by far the largest enforcement challenge facing his office is the rollout of the Part D program. "We expect the Part D program to be the focus of bad actors because of its size alone," Morris said.⁷ Thus, because of the increased money involved, the scrutiny into fraud and abuse may be much more intense.

Implementation of Part D changes the enforcement landscape by creating a new Medicare benefit to which the fraud and abuse authorities will apply. Many Medicare beneficiaries will now have (or be eligible for) Medicare coverage for prescription drugs who did not have coverage in the past. The framework for fraud and abuse investigation and enforcement will not necessarily change with Medicare Part D. Very little has changed in terms of government enforcement weapons involving the Medicare Part D program. The Federal Healthcare Programs' Anti-Kickback Statute⁸ (the "Anti-Kickback Statute"), the False Claims Act,⁹ and the civil money penalties law¹⁰ will likely continue to be the main enforcement tools. In fact, Morris has said that, as the Part D program is implemented, the OIG will continue to focus on practices it has targeted in the past, including kickbacks.¹¹

However, the application of the existing authorities will necessarily have to focus on new abuses that may arise by virtue of the relationships

⁴ M. William Salganik, *Medicare Drug Plan Starts Today*, BUFF. NEWS, Jan. 1, 2006, at A1.

⁵ Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-73, 117 Stat. 2066 (codified as amended at 42 U.S.C. § 1395w-101-52 (2000 & Supp. 2005)).

⁶ *Enforcement Officials Detail Weapons, Concerns Posed by Rx Benefit*, 16 MEDICARE REP. (BNA) 849 (2005).

⁷ *Id.*

⁸ 42 U.S.C. § 1320a-7b(b) (2000 & Supp. 2005).

⁹ 31 U.S.C. §§ 3729-33 (2000).

¹⁰ 42 U.S.C. § 1320a-7a.

¹¹ *Enforcement Officials Detail Weapons, Concerns Posed by Rx Benefit*, *supra* note 6.

and incentives unique to the Part D program.¹² In this regard, according to James G. Sheehan, associate U.S. attorney in Philadelphia, “[t]he Medicare Part D program involves specifically vulnerable beneficiaries, high-cost populations, substantial control by providers, and creates a whole new category of payments and financial relationships.”¹³ Consequently, those involved in the program will need to engage in very close scrutiny of their operations and compliance obligations.

The types of fraud and abuse which may arise under the Part D program are varied and may include: (1) pharmaceutical manufacturer inducements paid to private insurance plans and pharmacy benefit managers that will administer the Part D program in return for placement of the manufacturer’s drugs on plan formularies; (2) pharmaceutical manufacturers and/or health plans paying subsidies to employers to keep their Medicare-eligible employees/retirees on employer-sponsored prescription drug plans; (3) health plan marketing of the Part D benefit to Medicare beneficiaries (including cherry picking enrollees, shifting patients between plans to generate commissions, and providing beneficiaries with distorted information); and (4) health plan efforts to manipulate the period during which Part D enrollees are responsible for paying 100% of their drug costs.¹⁴

This article will discuss two areas in which fraud and abuse may arise under the new Part D program and which, therefore, could be subject to government scrutiny and enforcement action. Both of these areas involve the potential application of the Anti-Kickback Statute to cost-sharing assistance provided to Part D enrollees by pharmacies and pharmaceutical manufacturers which contract with Part D health plans.

II. MEDICARE PART D PRESCRIPTION DRUG BENEFIT

Medicare is a federally-funded insurance program that provides health care coverage to most of America’s senior citizens.¹⁵ To be eligible, an individual must be a citizen or resident alien,¹⁶ and at least sixty-five years

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*; HHS OIG to Expand Use of Administrative Sanctions for Receiving, Seeking Kickbacks, 16 MEDICARE REP. (BNA) 688 (2005).

¹⁵ See 42 U.S.C. §§ 1395 to 1395hhh (2000); Centers for Medicare & Medicaid Services, Medicare Program - General Information, <http://www.cms.hhs.gov/MedicareGenInfo/> (last visited Jan. 29, 2006) (noting that Medicare provides coverage to those aged sixty-five and older, individuals with certain disabilities, and individuals with end-stage renal disease).

¹⁶ 42 U.S.C. § 1395i-2(a)(3).

of age (or satisfy other qualifying conditions).¹⁷ Prior to passage of the MMA, the Medicare program consisted of Parts A, B and C. Part A generally pays for inpatient care, such as hospitalizations.¹⁸ Part B generally covers outpatient care and physician services.¹⁹ Historically, Parts A and B have not provided Medicare coverage and reimbursement for the entire range of available medical services, including outpatient prescription drugs.

Policymakers have debated the need to add prescription drug coverage to Medicare since the program's original enactment in the 1960s. However, the costs associated with providing such coverage, as well as disagreement over the role of the private sector in administering the coverage, proved to be obstacles to extending Medicare program coverage and reimbursement to outpatient prescription drugs.²⁰ The 1967 amendments to the Social Security Act called for the creation of a Task Force on Prescription Drugs to study the possibility of adding a prescription drug benefit to Medicare.²¹ However, not until two decades later did Congress make the first of two major attempts to pass legislation providing a prescription drug benefit under Medicare.

In 1988, Congress passed the Medicare Catastrophic Coverage Act ("MCCA"),²² which would have phased in "catastrophic" prescription drug coverage beginning in 1991.²³ Due to a number of reasons, including a major increase in cost estimates and opposition to a supplemental premium charge to higher income beneficiaries, the MCCA was repealed before it

¹⁷ *Id.* § 1395i-2(a)(1).

¹⁸ *Id.* § 1395d-(a)(1). Payroll tax contributions to the Medicare trust fund primarily finance Part A. *Id.*

¹⁹ *Id.* § 1395k. General tax revenues and enrollee premiums primarily finance Part B. *See id.* § 1395j.

²⁰ JENNIFER O'SULLIVAN, CONG. RESEARCH SERV., MEDICARE PRESCRIPTION DRUG COVERAGE FOR BENEFICIARIES: BACKGROUND AND ISSUES 1 (2003); Centers for Medicare & Medicaid Services, Overview, <http://cms.hhs.gov/about/history/ssachr.asp> (last visited Feb. 26, 2006).

²¹ Centers for Medicare and Medicaid Services, *supra* note 20.

²² Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, 102 Stat. 683 (codified as amended in scattered sections of 42 U.S.C.).

²³ *Id.* "Catastrophic" coverage would cover the full costs of medications once the beneficiary reached a specified amount of out-of-pocket drug expenses, often referred to as the catastrophic limit or out-of-pocket limit. The benefit under the MCCA was to cover all outpatient medicine expenses above a deductible amount of \$600 (in the first year), subject to a 50% coinsurance cost. The deductible for future years was indexed so that 16.8% of Medicare beneficiaries would have prescription drug costs that met the deductible each year. The coinsurance was also scheduled to be progressively lowered to 20% by 1993. *Id.*

even began.²⁴ The second major attempt to add Medicare prescription drug coverage came as part of the Clinton administration's comprehensive health care reform package in 1993. Introduced in Congress as the Health Security Act,²⁵ the Clinton plan called for the addition of a prescription drug benefit to Medicare.²⁶ However, after months of extensive hearings and debate, the Clinton proposal failed to generate enough support to make it to the floor of either house of Congress for a vote.²⁷

Despite the failure to add prescription drugs as a basic Medicare benefit, Medicare beneficiaries were eventually permitted to purchase supplemental benefits, called Medigap plans, that provided beneficiaries with extra coverage for additional services (including prescription drugs).²⁸ In addition to Medigap, Medicare Part C allowed seniors to opt out of traditional fee-for-service Medicare through enrollment in privately operated managed care plans, called Medicare+Choice plans.²⁹ Some Part C enrollees received additional benefits not included in traditional fee-for-service Medicare, including prescription drug coverage.³⁰ However, Medicare+Choice plans typically required patients to choose a primary care physician from a list of plan-approved doctors, and often mandated plan approval in order to see a specialist.³¹ Furthermore, since many of the plans faced financial difficulties, some plan operators chose to discontinue

²⁴ Medicare Catastrophic Coverage Repeal Act of 1989, Pub. L. No. 101-234, 103 Stat. 1979.

²⁵ Health Security Act, H.R. 3600, 103d Cong. (1st Sess. 1993); Health Security Act, S. 1757, 103d Cong. (1st Sess. 1993).

²⁶ *Id.* The Clinton plan would have included a \$250 deductible and a 20% coinsurance cost, with Medicare picking up the remaining 80% of beneficiaries' drug costs above the deductible amount. *Id.* The proposed benefit also included an out-of-pocket limit of \$1,000. *Id.*

²⁷ See Dana Priest, *Democrats Pull the Plug on Health Care Reform*, WASH. POST, Sept. 27, 1994, at A1; Dana Priest, *Where Health Care Reform Effort Failed; Some Officials Blame White House as Plan Appears Dead for Year*, WASH. POST, Aug. 27, 1994, at A1.

²⁸ 42 U.S.C. § 1395ss (2000). Services available through Medigap varied by plan, and only some Medigap plans provided drug coverage. However, some seniors found these plans either unaffordable or altogether unavailable. See THE LEWIN GROUP, RESTRICTING UNDERWRITING AND PREMIUM RATING PRACTICES IN THE MEDIGAP MARKET: THE EXPERIENCE OF THREE STATES 11-21 (2001), available at http://assets.aarp.org/rgcenter/health/2001_01_medigap.pdf.

²⁹ 42 U.S.C. § 1395w-21(a).

³⁰ *Id.* § 1395w-21(a)(1)(B).

³¹ See GERALDINE DALLEK, CONSUMER PROTECTIONS IN MEDICARE+CHOICE (1998), available at <http://www.kff.org/insurance/1449-protection.cfm>.

coverage in certain geographic markets, leaving many beneficiaries without Part C coverage.³²

The MMA makes sweeping changes to the Medicare program by establishing a new Medicare Part D prescription drug benefit.³³ Effective January 1, 2006, the Part D program provides Medicare coverage and reimbursement for prescription drugs dispensed on an outpatient basis.³⁴ Any individual entitled to coverage under Medicare Part A or enrolled in Medicare Part B will be eligible to obtain Part D coverage of outpatient prescription drugs effective January 1, 2006.³⁵ The basic Part D benefit will cover insulin, vaccines, certain biological products, and any other medically-necessary drugs not currently covered under Medicare that are: (a) dispensed according to a prescription; (b) administered on an outpatient basis; and (c) mandated Medicaid-covered drugs.³⁶

Medicare beneficiaries are not required to elect coverage under Part D.³⁷ However, if they do wish to obtain Part D benefits they must enroll in

³² See TIMOTHY LAKE & RANDALL BROWN, *MEDICARE+CHOICE WITHDRAWALS: UNDERSTANDING KEY FACTORS* 10-11 (2002), available at <http://www.kff.org/medicare/6046-index.cfm>; see also Robert A. Berenson, *Medicare+Choice: Doubling or Disappearing?*, HEALTH AFF., Nov. 28, 2001, available at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w1.65v1/DC1>.

³³ Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066; see 42 U.S.C. § 1395w-101-52. On January 28, 2005, the Centers for Medicare and Medicaid Services ("CMS") within HHS published a final regulation to implement the Part D program. Medicare Program, Medicare Prescription Drug Benefit, 70 Fed. Reg. 4193 (Jan. 28, 2005); see Volunteer Medicare Prescription Drug Benefit, 42 C.F.R. pt. 423 (2005). In addition, CMS has compiled Part D implementation guidance on its website. Centers for Medicare and Medicaid Services, Prescription Drug Coverage - General Information, <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/> (last visited Jan. 27, 2006).

³⁴ Until then, Medicare beneficiaries could receive assistance with their outpatient prescription drug costs beginning in June 2004 through the implementation of a prescription drug discount card program. During the two-year period before the Part D drug benefit took effect, a Discount Card Program provided enrollees with access to negotiated discounted prices for prescription drugs. Press Release, Ctrs. for Medicare & Medicaid Servs., Medicare Drug Discount Cards Continue to Drop Prices and Offer Better Savings, (May 14, 2004), available at <http://www.cms.hhs.gov/media/press/release.asp?Counter=1049>.

³⁵ 42 U.S.C. § 1395w-101.

³⁶ *Id.* § 1395w-102.

³⁷ The Bush Administration has maintained that Part D will provide Medicare beneficiaries maximum flexibility by allowing them to choose their optimal plan. Press Release, President George W. Bush, Keeping Our Promise to America's Seniors: President Signs Medicare Legislation (Dec. 8 2003), available at <http://www.whitehouse.gov/news/releases/2003/12/20031208-2.html>. President Bush stated,

either: (1) a qualified prescription drug plan (“PDP”); or (2) an existing Medicare Advantage (“MA”) plan that includes prescription drug coverage (“MA-PD”) (PDP and MA-PD are referred to collectively as “Plans”).³⁸ Medicare prescription drug coverage under Part D will be administered through the Plans. Each Plan must enter into a contract with HHS to provide Part D covered drugs.³⁹ Plans must meet numerous design requirements, including the ability to: ensure beneficiary access to a sufficient network of pharmacies; provide beneficiaries with access to negotiated prices for covered outpatient prescription drugs; establish cost-effective utilization management programs and quality assurance measures (including a medication therapy management program); meet patient safety and the quality standards; and meet detailed statutory and regulatory standards with respect to the prescription drug coverage offered, the setting of premiums, enrollment periods and late enrollment penalties.⁴⁰ A beneficiary must be given the opportunity to choose between at least two qualifying Plans offered by at least two different entities in the region where the beneficiary resides.⁴¹ Enrollment in approved Plans began on November 15, 2005.⁴² Although participation in Part D is voluntary, eligible beneficiaries enrolling after May 15, 2006 could be subject to higher premiums.⁴³ Generally, Medicare will reimburse Plans for providing

Every senior needs to know if you don't want to change your current coverage, you don't have to change. You're the one in charge. If you keep your Medicare the way it is, along with the new prescription benefit, that is your right

. . . For the seniors of America, more choices and more control will mean better health care.

Id.

³⁸ 42 U.S.C.S. § 1395w-101. A PDP is a stand-alone insurance benefit offered by a private entity licensed to offer health insurance under state law. An MA plan is a comprehensive managed care program analogous to the former Medicare Part C (Medicare+Choice) program. MA plans not only provide the same range of services available to recipients collectively enrolled in Parts A, B and D, but also may offer additional benefits not featured in Parts A, B, and D.

³⁹ *Id.* § 1395w-111.

⁴⁰ *Id.* §§ 1395w-111-12.

⁴¹ Medicare beneficiaries will be able to choose from at least two plans (one of which must be a PDP), but many more choices will be available in most areas. *Id.* § 1395w-102(a). Peter Young, *Medicare Prescription Drug benefit*, CURRENT SOC. SEC. NEWS, Oct. 2005, at 4. Under the MMA, if adequate private market options fail to materialize then government officials may supplement regions that are not adequately covered by the private market with additional coverage to ensure that each geographic region features a minimum of two prescription drug plans. 42 U.S.C.S. § 1395w-103(a).

⁴² 42 U.S.C.S. § 1395w-101(b)(2).

⁴³ *Id.* § 1395w-113(b); 42 C.F.R. § 423.38 (2005); see also H.R. Rep. No. 108-391, at 9-11, 39-41 (2003) (Conf. Rep.), reprinted in 2003 U.S.C.C.A.N. 1407, 2073-75, 2102, 2104.

drug coverage on a per enrollee basis (although other reimbursement methodologies exist).

Plans contract with drug manufacturers to purchase drugs directly from the manufacturers for their Part D enrollees. The Plans (and not HHS) will negotiate for discounts from the manufacturers on behalf of Medicare beneficiaries.⁴⁴ In turn, Plans will contract with prescription drug managers, pharmacies or other providers to dispense medications to Part D enrollees.⁴⁵ Plans must include in their network “any willing pharmacy” meeting the Plan’s standard terms and conditions.⁴⁶ It will be up to the Plans to determine the discounts and reimbursement rates that pharmacies will receive.⁴⁷ Since being an enrolled provider in the traditional Medicare Part A or Part B programs does not impart Part D billing privileges, the pharmacy must have a contractual relationship with a Plan to bill and receive payment from the Plan for an individual’s Part D covered prescription drugs.⁴⁸ This is true whether or not the pharmacy is enrolled in the fee-for-service Medicare program and billing for Medicare Part B covered drugs.⁴⁹

Pursuant to the MMA, standard coverage under Part D features a number of beneficiary premiums, co-payments, and coverage gaps.⁵⁰ The law does not specify a monthly premium amount that beneficiaries will be required to pay, thus allowing individual Plans the discretion to determine premium amounts. Some national and regional Medicare Part D

⁴⁴ 42 U.S.C. § 1395w-111(i); H.R. REP. NO. 108-391, at 35 (2003) (Conf. Rep.), reprinted in 2003 U.S.C.C.A.N. 2098.

⁴⁵ *Id.*

⁴⁶ 42 U.S.C. § 1395w-104(b)(1)(A).

⁴⁷ *Id.* § 1395w-104(b).

⁴⁸ Central to the Part D program is the MMA’s “noninterference” provision, which expressly prohibits CMS from (1) interfering with negotiations among drug manufacturers, PDPs, and pharmacies, (2) requiring PDPs to use a particular formulary, or (3) instituting a price structure for the reimbursement of drugs provided under Part D. 42 U.S.C.S. § 1395-111(i). This provision is intended to stimulate competition and provide Medicare beneficiaries and the Medicare program the benefit of any discounts that the Plans are able to obtain through private negotiations. *See* H.R. CONF. REP. No. 108-391, at 461 (2003); 149 CONG. REC. S15,886 (daily ed. Nov. 25, 2003) (statement of Sen. Grassley).

⁴⁹ For example, a pharmacy may currently receive payment under Medicare Part B for an individual’s covered drug, albuterol, delivered through a nebulizer, which is considered to be durable medical equipment (“DME”). The pharmacy bills the Medicare DME carrier for this drug pursuant to Part B. The same individual has joined a PDP and has coverage of albuterol delivered through a metered dose inhaler (which is not considered DME under Part B). The pharmacy can only bill the MA-PD or PDP under Part D for covered albuterol delivered through a metered dose inhaler if the pharmacy has a contractual relationship with that MA-PD or PDP.

⁵⁰ 42 U.S.C. § 1395w-102(a)(2)(A)(i)(I).

prescription drug plans will use a combination of lower premiums and higher copays or coinsurance on certain drugs as part of their strategy to attract beneficiaries. This strategy, they hope, will help them grab market share and give them greater leverage in negotiating prices with pharmaceutical manufacturers. However, the Congressional Budget Office (“CBO”) estimates the average monthly premiums will be \$35 in 2006, rising to \$58 by 2013.⁵¹ This is in addition to the standard premium for Medicare Part B.

In 2006, the annual deductible for standard Part D coverage is \$250.⁵² Once the beneficiary meets the annual deductible, the Plan will cover 75% of drug costs incurred between \$251 to \$2,250. The beneficiary generally will be responsible for the remaining 25% of the costs. Once the \$2,250 coverage limit is met, the beneficiary will be solely responsible for paying all of the next \$2,850 in potentially covered drug costs.⁵³ In other words, no coverage will be provided beyond the \$2,250 initial coverage limit until the beneficiary reaches \$3,600 in out-of-pocket costs for 2006 (i.e., \$250 deductible + \$500 total co-payments for drug costs up to the initial \$2,250 coverage limit + \$2,850). This coverage gap is typically known as the “donut hole.” Thus, when beneficiaries are in the donut hole, they must pay 100% of their prescription drug costs until their True Out of Pocket Costs (“TrOOP”) reaches \$3,600. Out-of-pocket costs exceeding \$3,600 will be covered by the Plan, except for a nominal beneficiary cost-sharing amount equal to the greater of: (1) \$2 for a generic drug or preferred multiple source drug and \$5 for any other drug, or (2) 5% co-payment.⁵⁴ The size of the donut hole coverage gap is expected to grow each year since its upper and lower bounds are indexed for inflation.

To assist certain low income individuals, the MMA provides a subsidy that either reduces or eliminates a beneficiary’s annual deductible, monthly Part D premium, and out-of-pocket expenses.⁵⁵ Low-income Medicare beneficiaries who are also eligible for Medicaid (so-called dual eligibles) lose Medicaid drug coverage on January 1, 2006, but will be enrolled

⁵¹ *Id.* § 1395w-113(a); *see also* REP. PETE STARK, JOINT ECON. COMM. DEMOCRATS, THE NEW MEDICARE PRESCRIPTION DRUG ACT: INDEXING EFFECT ERODES BENEFIT 2 (2004). This brief cites a CBO study which projects that the average premium for a Part D PDP plan will be \$35 per month in 2006. Furthermore, the CBO study projects that over the next decade per capita drug spending will increase by about 8.5% annually. Thus, taking these two findings together, the CBO estimates monthly premium will reach \$58 by 2013.

⁵² *Id.* § 1395w-102(b)(1)(A).

⁵³ *Id.*

⁵⁴ *Id.* § 1395w-102(b)(4)(A)(i).

⁵⁵ *Id.* § 1395w-114(a)(1). Assistance is available on a sliding scale with the maximum income for eligibility of 150% of the federal poverty line. *Id.* § 1395w-114(a)(2)(A).

automatically in a Medicare Part D Plan and the federal government will subsidize their out-of-pocket costs detailed above.⁵⁶ State Medicaid programs will share in the costs of providing prescription drug coverage to dual eligibles under Part D.⁵⁷ Finally, employers who maintain retiree health plans that offer actuarially equivalent prescription drug coverage will receive a 28% subsidy for drug expenses between \$250 and \$5100.⁵⁸

III. FEDERAL HEALTH CARE PROGRAMS ANTI-KICKBACK LAW

A. STATUTORY PROHIBITION

The Anti-Kickback Statute provides criminal and civil penalties for whoever:

(1) . . . knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal Health Care Program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal Health Care Program[;]⁵⁹ [or]

(2) . . . knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal Health Care Program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering

⁵⁶ *Id.* § 1396u-5.

⁵⁷ Dual eligibles with incomes below 100% of the federal poverty level will have no premium costs and no initial coverage limit. They will pay copayments of \$3 for brand name drugs and \$1 for generics up to the catastrophic limit (\$5,100 in total drug spending) and no copays thereafter. *See* H.R. CONF. REP. No. 108-391, at 44-45, *reprinted in* 2003 U.S.C.C.A.N. at 2107-08. Beneficiaries whose incomes fall below 135% of poverty and who also meet an assets test (\$6,000 per individual/\$9,000 per couple) will pay \$5 for brand name drugs and \$2 for generic, with no deductible, no premium costs, and no cost-sharing beyond the catastrophic limit. *Id.* Those beneficiaries who have incomes between 135-150% of the federal poverty level and meet an assets test (\$10,000 per individual/ \$20,000 per couple) will be required to pay a \$50 deductible, a sliding scale premium, and a 15% copayment up to the catastrophic limit, with copayments of \$5 and \$2 thereafter. *Id.* at 45-46.

⁵⁸ *Id.* at 63; *see* 42 U.S.C. § 1395w-132.

⁵⁹ 42 U.S.C. § 1320a-7b(b)(1).

any good, facility, service, or item for which payment may be made in whole or in part under a Federal Health Care Program⁶⁰

Violations of the Anti-Kickback Statute can result in severe criminal and civil penalties. The DOJ is responsible for criminal enforcement of the statute. Each violation of the statute is a felony punishable upon conviction by up to five years imprisonment and/or fines of up to \$25,000.⁶¹ The OIG is responsible for civil enforcement of the statute. The OIG has the authority to exclude an individual or entity from participation in an FHCP (e.g., Medicare, Medicaid) if the OIG determines that the individual or entity has violated the statute. The exclusion remedy may be imposed by the OIG pursuant to an administrative proceeding and absent a criminal conviction or investigation.⁶² Finally, a violation of the statute constitutes grounds for imposition of a civil monetary penalty (“CMP”) and other civil monetary assessments.⁶³

The statute contains a number of exceptions that describe certain practices that are immune from either criminal or civil prosecution. Statutory exceptions exist for, among other things: (1) discounts or other reductions in price obtained by a provider of services or other entity under a FHCP if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity to a FHCP;⁶⁴ (2) any amount paid by an employer to a *bona fide* employee for employment in the provision of items or services reimbursable under a FHCP;⁶⁵ and (3) any amount paid by a vendor of goods or services to a

⁶⁰ *Id.* § 1320a-7b(b)(2). The term “Federal Health Care Program” (“FHCP”) is defined as: (1) any plan or program, other than the Federal Employees Health Benefits Program, that provides health benefits either directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government (e.g., Medicare, the Civilian Health and Medical Program of the Uniformed Services (“CHAMPUS”), Department of Veterans Affairs health programs); and (2) any “State Health Care Program,” defined as a state program funded under United States Code Title 42, Chapter 7, Subchapter XIX (i.e., Medicaid), Subchapter V (i.e., Maternal and Child Health), or Subchapter XX (Social Services Block Grants). *Id.* § 1320a-7b(f)(1) (definition of Federal Health Care Program); *id.* § 1320a-7(h) (definition of State Health Care Program).

⁶¹ *Id.* § 1320a-7b(b)(1)-(2).

⁶² *Id.* § 1320a-7(b)(7); Fraud and Kickbacks and Other Prohibited Activities, 42 C.F.R. § 1001.951 (2005).

⁶³ 42 U.S.C. § 1320a-7a(a). Specifically, for each violation of the Anti-Kickback Statute, a party is subject to a \$50,000 CMP, plus an assessment of up to three times the total amount of remuneration offered, paid, solicited, or received in violation of the Anti-Kickback Statute. *Id.*

⁶⁴ *Id.* § 1320a-7b(b)(3)(A).

⁶⁵ *Id.* § 1320a-7b(b)(3)(B).

purchasing agent acting for a group of individuals or entities who furnish services reimbursed under a FHCP.⁶⁶

B. SAFE HARBOR REGULATIONS

Congress recognized that the Anti-Kickback Statute's broad language had the potential to create confusion in the health care industry regarding the legality of many commonplace business arrangements. Consequently, in 1987 Congress expressly directed HHS to promulgate regulations defining certain payment practices that would not violate the law.⁶⁷ These regulations have become popularly known as "safe harbors," since parties who structure their business arrangements to satisfy all the criteria of an applicable safe harbor are sheltered from liability under the anti-kickback law.⁶⁸

The safe harbor regulations do not purport to represent the only types of arrangements that are permissible under the Anti-Kickback Statute. In other words, the failure of an arrangement to meet all of the criteria of an applicable safe harbor does not necessarily mean that the arrangement violates the statute. In the preamble to the final safe harbor regulations issued in 1991, the OIG states that the failure of an arrangement to qualify for a safe harbor can mean one of three things:

First, . . . it may mean that the arrangement does not fall within the ambit of the statute. In other words, the arrangement is not intended to induce the referral of business reimbursable under [a Federal Health Care Program]; so there is no reason to comply with the safe harbor standards, and no risk of prosecution. Second, at the other end of the spectrum, the arrangement could be a clear statutory violation and also not qualify for safe harbor protection. In that case, assuming the arrangement is obviously abusive, prosecution would be very likely. Third, the arrangement may violate the statute in a less serious manner, although not be in compliance with a safe harbor provision. Here there is no way to predict the degree of risk. Rather, the degree of the risk depends on an evaluation of the many factors which are part of the decision-making process regarding case selection for investigation and prosecution.⁶⁹

Where a particular practice "falls within the ambit of the statute" and does not qualify for a safe harbor, the OIG and DOJ will consider a variety of factors in determining whether the arrangement is abusive and a

⁶⁶ *Id.* § 1320a-7b(b)(3)(C).

⁶⁷ Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 680, 697-98.

⁶⁸ The OIG published an initial set of final safe harbors in July 1991. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991); *see* 42 C.F.R. § 1001.952 (2005).

⁶⁹ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,954.

candidate for investigation and prosecution. Specifically, consideration is given to: (1) the potential for increased charges or reported costs to a FHCP; (2) the possible encouragement of overutilization; (3) the potential for adversely affecting competition by freezing competing suppliers out of the marketplace; and (4) patient freedom of choice.⁷⁰ No one factor is dispositive, and the OIG and DOJ have considerable discretion in bringing enforcement actions.

C. OIG SPECIAL FRAUD ALERTS AND ADVISORY OPINIONS

The OIG has issued a number of "Special Fraud Alerts" to identify certain practices that may violate the Anti-Kickback Statute. Although Special Fraud Alerts are not regulations having the force of law, they are significant since they offer insight into the OIG's enforcement priorities and provide the OIG's interpretation of the Anti-Kickback Statute as applied to various factual situations.⁷¹ Special Fraud Alerts have been issued to address the application of the Anti-Kickback Statute to a number of areas, including joint venture arrangements, routine waivers of beneficiary copayment and deductible obligations under Part B of the Medicare program, hospital incentives to physicians, prescription drug marketing practices, and clinical laboratory arrangements.⁷²

The OIG is also required to issue written advisory opinions to private parties in response to requests regarding whether existing or proposed transactions violate the Anti-Kickback Statute.⁷³ Advisory opinions will address, among other things, what constitutes "remuneration" under the Anti-Kickback Statute and whether an arrangement satisfies the criteria for

⁷⁰ *Id.* at 35,954, 35,956, 35,978; see *United States v. Rutenberg*, 625 F.2d 173, 177 n.9 (7th Cir. 1980).

⁷¹ See *Publication of OIG Special Fraud Alert*, 64 Fed. Reg. 1813 (Jan. 12, 1999); *Publication of OIG Special Fraud Alert*, 63 Fed. Reg. 20,415 (Apr. 24, 1998); *Publication of OIG Special Fraud Alert*, 61 Fed. Reg. 30,623 (June 17, 1996); *Publication of OIG Special Fraud Alert*, 60 Fed. Reg. 40,847 (Aug. 10, 1995); *Publication of OIG Special Fraud Alert*, 59 Fed. Reg. 65,372 (Dec. 19, 1994) (setting forth previously issued Special Fraud Alerts).

⁷² *Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services*, 59 Fed. Reg. 65,377 (Oct. 1994); *Special Fraud Alert: Prescription Drug Marketing Schemes*, 59 Fed. Reg. 65,376 (Aug. 1994); *Special Fraud Alert: Hospital Incentives to Physicians*, 59 Fed. Reg. 65,375 (May 1992); *Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B*, 59 Fed. Reg. 65,374 (May 1991); *Special Fraud Alert: Joint Venture Arrangements*, 59 Fed. Reg. 65,373 (Aug. 1989).

⁷³ *Health Insurance Portability and Accountability Act of 1996*, Pub. L. No. 104-191, § 205, 110 Stat. 2000 (adding 42 U.S.C. § 1320a-7d(b), which requires the issuance of advisory opinions by the OIG). The OIG has issued a rule specifying the process for seeking an advisory opinion. *Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG*, 63 Fed. Reg. 38,311, 38,324 (July 16, 1998).

a statutory exception or a regulatory safe harbor.⁷⁴ However, advisory opinions will not address questions involving the intent of parties to an arrangement, the fair market value of goods, services, or property, or whether an individual is a bona fide employee.⁷⁵

D. CASE LAW

Federal case law has provided broad interpretations of the Anti-Kickback Statute. The statute has been held applicable to a wide variety of relationships that are quite different from an obvious kickback for a patient referral or a bribe to recommend the purchase of specific items or services. Federal courts and administrative bodies considering the statute in the context of actual enforcement proceedings have established several important interpretive principles:

- The statute is violated if even “one purpose” (as opposed to the sole or primary purpose) of a payment is in exchange for or to induce the referral of patients or the ordering, purchasing, or recommending of items or services, although it may be a defense that an improper purpose was “incidental,” “minor,” or not “material.”⁷⁶
- Although some financial benefits may be too remote or *de minimis* to affect referral practices, the threshold appears to be relatively low; a payment or other benefit may violate the statute when the amount is sufficient to influence the customer’s reason or judgment;⁷⁷

⁷⁴ DEP’T OF HEALTH AND HUMAN SERVS., RECOMMENDED PRELIMINARY QUESTIONS AND SUPPLEMENTARY INFORMATION FOR ADDRESSING REQUESTS FOR OIG ADVISORY OPINIONS IN ACCORDANCE WITH SECTION 1128D OF THE SOCIAL SECURITY ACT AND 42 CFR PART 1008, available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm>.

⁷⁵ Matters Subject to Advisory Opinions, 42 C.F.R. § 1008.5 (2004); Medicare and State Health Care Programs, 62 Fed. Reg. 7350, 7351 (Feb. 19, 1997).

⁷⁶ See *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (approving a jury instruction that guilt could be found “if you find beyond reasonable doubt that one of the *material* purposes for the solicitation was to obtain money for the referral of services”) (emphasis added); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989) (noting that the “issue of the sole versus primary reason for payments is irrelevant since *any* amount of inducement is illegal,” but also approving a jury instruction that prohibited conviction if the improper purpose was “incidental” or “minor”); *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (noting that “[i]f the payments were intended to induce the physician to use [defendant’s] services, the statute was violated, even if the payments were also intended to compensate for professional services”), *rev’d on other grounds*, *United States v. Gaudin*, 515 U.S. 506 (1995).

⁷⁷ *Inspector General v. Hanlester Network*, Dec. No. 1275 (HHS Departmental Appeals Bd., Appellate Div., Sept. 18, 1991) at 57 & n.34, *reprinted in* [1992-1 Transfer Binder]

- Giving a potential referral source the opportunity to earn a fee that exceeds the reasonable value of any services provided (or return on investment made) will constitute evidence that the payment is unlawful; however, even if the fee earned is reasonable in amount, this in itself will not serve as a defense if the intent underlying the arrangement can be shown to be an exchange of payment for referrals;⁷⁸
- There need be no proof of an agreement to make referrals, or to order, purchase, or recommend medical items or services, for illegal intent and a violation to be found; intent may be inferred from the circumstances of the case;⁷⁹
- The mere potential for increased costs to, or a payment to be made by, an FHCP may be enough to violate the law; no actual payout by an FHCP is necessary as long as the challenged remuneration is for an item or service that could be paid for by an FHCP;⁸⁰ and
- The fact that a particular arrangement is common in the health care industry is *not* a defense to an Anti-Kickback Statute violation.⁸¹

Medicare & Medicaid Guide (CCH) ¶ 39,566 at 27,763, no. 34, *on remand*, Doc. C-448, Dec. No. CR181 (HHS Departmental Appeals Bd., Civil Remedies Div., Mar. 10, 1992), *reprinted in* [1992-2 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 40,064, *aff'd in part and rev'd in part*, Dec. No. 1347 (HHS Departmental Appeals Bd., Appellate Div. July 24, 1992), *reprinted in id.* at ¶ 40,406B, *aff'd sub nom.* Hanlester Network v. Sullivan, No. CV 92-4552-LHM, 1993 WL 78299 (C.D. Cal. Feb. 10, 1993), *aff'd in part and rev'd in part sub nom.*, Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).

⁷⁸ *Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d at 29; *United States v. Lipkis*, 770 F.2d 1447, 1449 (9th Cir. 1985).

⁷⁹ *Hanlester Network*, Dec. No. 1275 ¶ 39,566 at 27,740, 27,748, 27,759, 27,763.

⁸⁰ *United States v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980).

⁸¹ *Hanlester Network*, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,566 at 27,763. In 1995, the Ninth Circuit Court of Appeals held that a violation of the Anti-Kickback Statute cannot be found absent a showing that the defendant both: (1) knew that the law prohibited giving or receiving remuneration for referrals, and (2) acted with a specific intent to violate the law. *See Hanlester Network*, 51 F.3d at 1400. However, several courts in other jurisdictions have declined to follow this approach. *See, e.g.*, *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (finding that Anti-Kickback Statute is not a highly technical regulation “that poses a danger of ensnaring persons engaged in apparently innocent conduct”); *United States v. Jain*, 93 F.3d 436, 440-41 (8th Cir. 1996) (distinguishing *Hanlester* as an administrative debarment proceeding and rejecting application of the main case on which the *Hanlester* court relied); *United States v. Neufeld*, 908 F. Supp. 491, 497 (S.D. Ohio 1995) (declining to follow *Hanlester*), *aff'd*, 149 F.3d 1185 (6th Cir. 1998); *Med. Dev. Network, Inc. v. Prof'l Respiratory Care/Home Med. Equip. Serv., Inc.*, 673 So. 2d 565, 567 (Fla. Dist. Ct. App. 1996) (“[The statute] is directed at punishment of those who perform specific acts and does not require that one engage in the

IV. ANALYSIS

Each year, Medicare beneficiaries enrolled in the Part D program will be responsible for paying 100% of eligible drug costs during the donut hole period. The payment of these expenses is required before Part D catastrophic coverage is triggered (which will cover most of any additional drug costs for the remainder of the year).⁸² Many beneficiaries may have difficulty paying drug expenses during the donut hole period, and these beneficiaries may not qualify for government subsidies under Part D.

Plans will have an obvious financial incentive to keep beneficiaries in the donut hole because the Plans will not incur any payment responsibility during this time.⁸³ In this regard, the OIG's Lew Morris has stated that "[t]here will certainly be some financial pressure for Plans to keep beneficiaries in this hole, where the plan has no reimbursement obligations."⁸⁴

Conversely, pharmaceutical manufacturers and pharmacies contracting with Plans have an incentive to move patients through the donut hole quickly since doing so will trigger catastrophic coverage, which could result in increased usage and Plan reimbursement of covered medications. In other words, during the catastrophic coverage period, pharmacies will be able to seek reimbursement directly from the Plans for dispensed medications (other than negligible copayments amounts collected from enrollees). Furthermore, without having to incur any significant cost-sharing obligations during the catastrophic coverage period, enrollees will have no disincentive to continue taking Part D eligible medications for chronic conditions (and their physicians will have no disincentive to continue prescribing such medications).

prohibited conduct with the specific intent to violate the statute."); *cf.* *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) ("[E]ven the *Hanlester* court requires knowledge only that the conduct in question was unlawful, and not necessarily knowledge of which particular statute makes the conduct unlawful.").

⁸² As noted above, Medicare beneficiaries enrolled in a Plan offering the standard benefit must pay an annual deductible of \$250 and 25% of initial drug costs up to \$2,250. *See supra* note 52 and accompanying text. After that level is reached, beneficiaries will be responsible for paying 100% of the prescription drug costs while they are in the donut hole—the zone in the drug cost coverage continuum between where Medicare coverage stops and catastrophic coverage begins after the beneficiary has paid an additional \$2,850, for a total of \$3,600 in out-of-pocket expenses. After that, the government will pay 95% of all prescription drug costs.

⁸³ In other words, during the time a beneficiary is in the donut hole, the beneficiary will be responsible for paying 100% of their eligible drug costs. Plans, therefore, will not incur any payment obligation during this time.

⁸⁴ *Enforcement Officials Detail Weapons, Concerns Posed by Rx Benefit*, *supra* note 6 (quoting Lewis Morris).

An issue that has arisen is whether pharmacies and drug manufacturers can assist beneficiaries with their Part D cost-sharing obligations, particularly while enrollees are in the donut hole. In other words, in what manner can companies assist enrollees in meeting their TrOOP expenses in order to make the enrollees eligible for Part D catastrophic coverage (which takes effect after a patient has incurred \$3,600 in TrOOP for 2006)? This question is significant because CMS has made clear in the final rule implementing the Part D program that assistance provided on behalf of a beneficiary by any person or organization (other than insurers, group health plans or similar third party payers) will count towards an enrollee's required TrOOP expenses.⁸⁵

The manner in which manufacturers or pharmacies assist Part D enrollees in meeting TrOOP and passing through the donut hole will implicate the Anti-Kickback Statute and, therefore, could subject manufacturers and pharmacies to government scrutiny and enforcement action. In fact, the OIG's Lew Morris has said that the OIG will be on the lookout for scams aimed at inflating a person's out-of-pocket expenses to move them through the donut hole more quickly.⁸⁶ The type of possible assistance offered to enrollees by drug manufacturers and pharmacies could vary. Among other things, pharmacies may seek to waive beneficiary cost-sharing obligations for covered medications, while drug manufacturers may seek to offer direct subsidies or free medications to enrollees. When a pharmacy waives cost-sharing obligations, or a drug manufacturer provides assistance with cost-sharing obligations, the Anti-Kickback Statute is implicated because such assistance could be viewed as an inducement for the enrollee to use that pharmacy and/or the manufacturer's products. In other words, such assistance could present an opportunity for abuse if it inappropriately influences the use of provider or the purchase of drugs by Part D enrollees.

A. PHARMACY COST-SHARING WAIVERS

In an effort to help Part D enrollees who cannot afford to pay part or all of the \$3,600 true out-of-pocket costs, pharmacies may be inclined to waive enrollee cost-sharing obligations. As a general matter, remuneration under the Anti-Kickback Statute "includes the waiver of coinsurance and

⁸⁵ Benefits and Beneficiaries Protection, 42 C.F.R. § 423.100 (2005); Coordination of Benefits, 42 C.F.R. § 423.464 (2005); *see* Final Rule, 70 Fed. Reg. 4193, 4239 (Jan. 28, 2005); Proposed Rule, 69 Fed. Reg. 46,631, 46,650 (Aug. 3, 2004).

⁸⁶ *HHS OIG to Expand Use of Administrative Sanctions for Receiving, Seeking Kickbacks*, *supra* note 14.

deductible amounts (or any part thereof).”⁸⁷ In 1991, the OIG issued a Special Fraud Alert which identified the health fraud implications of providers routinely waiving Medicare beneficiary copayment and deductible obligations.⁸⁸ At first glance, it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. However, if patients are required to pay even a small portion of their care, they may become better health care consumers, and select items or services because they are medically needed, rather than simply because they are free.⁸⁹ Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services.⁹⁰

According to the Special Fraud Alert, “[w]hen providers, practitioners or suppliers forgive [patients’] financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them[,]” in violation of the Anti-Kickback Statute.⁹¹ Thus, a good faith effort should be made to collect deductibles and copayments in most cases; however, it is permissible to forgive a particular patient’s copayment and deductible obligations based upon a showing of financial hardship.⁹² The Special Fraud Alert identifies certain practices which indicate that providers, practitioners, or suppliers are routinely waiving Medicare deductibles and copayments:

advertisements which state “Medicare accepted as payment in full,” “insurance accepted as payment in full,” or “no out-of-pocket expense”; routine use of “financial hardship” forms which state that the beneficiary is unable to pay the coinsurance/deductible amounts (*i.e.*, there is no good faith attempt to determine the

⁸⁷ 42 U.S.C. § 1320a-7a(i)(6) (2000). Additionally, the routine waiver of cost-sharing obligations of Medicare or Medicaid beneficiaries who are enrollees of health plans potentially violates the federal Civil Monetary Penalties law. Specifically, 42 U.S.C. § 1320a-7a(a)(5) provides for the imposition of civil monetary penalties against anyone who:

[o]ffers to or transfers remuneration to any individual eligible for benefits under [federal health care programs (including Medicare or Medicaid)] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, [by a Federal Health Care Program].

“Remuneration,” for purposes of this prohibition, is expressly defined to include the routine waiver of coinsurance and deductible amounts (or any part thereof). *Id.* § 1320a-7a(i)(6).

⁸⁸ Routine Waiver, 59 Fed. Reg. 65,374 (Aug. 1989).

⁸⁹ See Evan Melhado, *Economists, Public Provision, and the Market: Changing Values in Policy Debate*, 23 J. HEALTH POL. POL’Y & L. 215, 231-32 (1998).

⁹⁰ Routine Waiver, 59 Fed. Reg. at 65,374.

⁹¹ *Id.* at 65,375.

⁹² *Id.*

beneficiary's actual financial condition); collection of copayments and deductibles only where the beneficiary has Medicare supplemental insurance coverage [that pays the copayments and deductibles]; higher charges to Medicare beneficiaries than those made to other persons in order to offset the waiver of coinsurance; failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (*e.g.*, a supplier waives coinsurance or deductible obligations for all patients from a particular hospital . . .); and sham insurance programs which cover copayments or deductibles only for items and services provided by the entity offering the insurance, where the premium is insignificant (*e.g.*, \$1/month) and not based on actuarial risks.⁹³

Significantly, given the OIG's position with regard to cost-sharing waivers, the MMA added the following statutory exception to the Anti-Kickback Statute prohibitions:

the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under Part D of subchapter XVIII of [this chapter], if the conditions described in clauses (i) through (iii) of section [1320a-7a(i)(6)(A) of this title] are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section [1395w-114(a)(3) of this title]), section [1320a-7a(i)(6)(A) of this title] shall be applied without regard to clauses (ii) and (iii) of that section).⁹⁴

This exception essentially permits pharmacies to waive or reduce cost-sharing amounts for Part D enrollees, provided certain conditions are met.⁹⁵ Any cost-sharing waivers must be provided in an unadvertised, non-routine manner.⁹⁶ Furthermore, the waiver should only be granted after the pharmacy has either: (i) determined that the enrollee in question is financially needy, or (ii) failed to collect the cost-sharing amount despite reasonable collection efforts.⁹⁷ Thus, cost-sharing waivers which are offered to Part D enrollees on a routine or advertised basis or provided

⁹³ *Id.* (emphasis added).

⁹⁴ 42 U.S.C. § 1320a-7b(b)(3)(G) (2000). Pursuant to 42 U.S.C. § 1320a-7a(i)(6),

[t]he term "remuneration" does not include

(A) the waiver of coinsurance and deductible amounts by a person, if

(i) the waiver is not offered as part of any advertisement or solicitation;

(ii) the person does not routinely waive coinsurance or deductible amounts; and

(iii) the person

(I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need, or

(II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

⁹⁵ *Id.* § 1320a-7b(b)(3)(G).

⁹⁶ *Id.* § 1320a-7a(i)(6).

⁹⁷ *Id.* § 1320a-7b(b)(3)(G).

where enrollees are in the donut hole (and without regard to the enrollees' ability to pay) would be problematic under the Anti-Kickback Statute and a potential enforcement target.

B. MANUFACTURER PATIENT ASSISTANCE PROGRAMS

If a Medicare Part D enrollee cannot afford to pay the \$3,600 TrOOP amount, and a pharmacy does not waive the cost-sharing amount, then the enrollee may seek assistance from other sources. In this regard, there is nothing in the Part D program or any OIG regulations that prevents Medicare beneficiaries from seeking outside assistance in meeting their cost-sharing obligations. However, some types of cost-sharing assistance, particularly assistance provided by drug manufacturers, may be problematic under the Anti-Kickback Statute. Specifically, if the cost-sharing assistance comes directly or indirectly from a drug company that stands to benefit from the beneficiary's use of its drug, the Anti-Kickback Statute will be implicated.

Historically, many pharmaceutical companies have operated Patient Assistance Programs ("PAPs") designed for low-income individuals who do not have insurance and need help with high drug costs.⁹⁸ Generally, PAPs have provided cash subsidies and/or free or discounted drugs for financially needy individuals. Some PAPs are affiliated with pharmaceutical manufacturers, while others are independent charitable organizations. Typically, in order to be eligible for free products under the PAP, a patient must have either no health insurance coverage or no prescription drug coverage. Before passage of MMA, the OIG had very little interest in PAPs that provided free drugs directly to uninsured patients because there were no FHCP dollars involved. In other words, prior to enactment of the Part D program, PAPs raised few legal issues under the Anti-Kickback Statute, in part because there was no involvement by FHCPs (or any other payers). Consequently, since the free products were provided without expectation of payment (for current or future product uses) by any person or entity, there was no real risk of fraud or abuse to FHCPs or other payers.

Implementation of Part D changes the enforcement landscape by creating a new Medicare benefit to which the Anti-Kickback Statute now applies. Many Medicare beneficiaries will now have (or be eligible for) insurance coverage for prescription drugs who did not have coverage in the

⁹⁸ See, e.g., *Part D Drug Benefit: PAPs Should Not Assist Part D Enrollees*, OIG Says in *Special Bulletin*, 16 MEDICARE REP. (BNA) 1317 (2005); Partnership for Prescription Assistance, <http://www.pparx.org/intro.php> (last visited April 6, 2006).

past. Thus, under Part D, drug companies have a substantial financial interest in influencing decisions pertaining to drugs covered under the program. In this regard, it is important to understand that when a manufacturer provides assistance to a Medicare beneficiary it could be viewed as an inducement for the beneficiary to use that company's products, thus implicating the Anti-Kickback Statute. In other words, a PAP presents an opportunity for abuse if the cost-sharing subsidies are used inappropriately to influence the purchase of drugs by Part D participants.

The Part D final regulation did not directly address the potential application of the fraud and abuse laws to PAPs operated under Part D. Pharmaceutical manufacturers had hoped the regulation would offer guidance regarding how they could assist Part D enrollees in the form of cash assistance for cost-sharing obligations and/or free product without running afoul of the fraud and abuse laws, including the Anti-Kickback Statute. The urgency of the guidance was necessitated by several factors: (1) many patients who have been receiving free product through manufacturer PAPs are now eligible for prescription drug coverage under Part D; (2) the Part D benefit requires significant cost-sharing obligations by enrollees, including during the donut hole when enrollees are responsible for 100% of their drug expenses; and (3) although CMS has issued guidance about what counts toward a patient's TrOOP under Part D, CMS has deferred to the OIG regarding the fraud and abuse issues involved when an entity or person other than the patient incurs the out of pocket expense on behalf of the patient.⁹⁹

On November 22, 2005 the OIG issued a Special Advisory Bulletin ("Bulletin") warning of potential fraud and abuse issues raised by PAPs for Medicare Part D enrollees.¹⁰⁰ The Bulletin represents the first major fraud and abuse guidance from the OIG regarding the Part D program. The Bulletin, titled Patient Assistance Programs for Medicare Part D Enrollees, focuses on PAPs that are sponsored by pharmaceutical companies.¹⁰¹ The OIG warns that PAPs operated and controlled by pharmaceutical companies risk running afoul of fraud and abuse laws, particularly the Anti-Kickback Statute, if they subsidize only their own products that are reimbursable by

⁹⁹ It is important to recognize the differences between CMS' authority and OIG's authority in these matters. CMS can decide whether certain expenditures count toward TrOOP (and related issues), but the OIG has the final say regarding the degree of risk under the fraud and abuse laws.

¹⁰⁰ Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005).

¹⁰¹ *Id.*

the Medicare Part D program.¹⁰² However, cash donations to independent, charitable PAPs that subsidize drugs regardless of the manufacturer should not be problematic.¹⁰³ The specific programs addressed by the Bulletin are discussed below.

1. Manufacturer PAPs

In the Bulletin, the OIG states that “cost-sharing subsidies provided by pharmaceutical manufacturer PAPs pose a heightened risk of fraud and abuse under the Federal anti-kickback statute.”¹⁰⁴ The OIG adds that “the subsidies would be squarely prohibited by the statute, because the manufacturers would be giving something of value (i.e., the subsidy) to beneficiaries to use its product.”¹⁰⁵ In the OIG’s view,

[w]here a manufacturer PAP offers subsidies tied to the use of the manufacturer’s products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries incentives to locate and use less expensive, equally effective drugs.¹⁰⁶

Where manufacturers use subsidies to help beneficiaries meet the TrOOP amounts, there may be an increase in the number of patients who use the manufacturer’s product who reach the catastrophic limit. The OIG believes that this would be problematic because reimbursement for drugs is cost-based under the catastrophic benefit, and, in the OIG’s view, cost-based reimbursement is inherently prone to abuse because it does not provide any incentive to limit costs.¹⁰⁷ For example, subsidies could insulate beneficiaries from the economic effects of drug pricing, thus eliminating a safeguard against price inflation. This potentially would increase Medicare costs because increased prices would be reflected in increased beneficiary subsidies and other payments made by Medicare under Part D in subsequent years. Of equal concern to the OIG is the potential for subsidies to lock Part D beneficiaries into the manufacturer’s product even if equally efficacious and less costly alternatives are available.¹⁰⁸

¹⁰² *Id.*

¹⁰³ *Id.* at 70,626.

¹⁰⁴ *Id.* at 70,625.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 70,625-26; see Determination of Payments, 42 C.F.R. § 423.329 (2005).

¹⁰⁸ Publication, 70 Fed. Reg. 70,626 (Nov. 22, 2005).

2. *Independent Charity PAPs*

Although manufacturer PAPs may not provide cost-sharing assistance to Medicare beneficiaries, the OIG historically has permitted such assistance to be provided through independent, bona fide charitable assistance programs.¹⁰⁹ These PAPs typically are funded by several manufacturers (and possibly other entities), but operate independently and develop their own financial need criteria for patients to participate.

Under the Bulletin's guidelines, there are no constraints on the ability of pharmaceutical manufacturers to support cost sharing subsidies through cash contributions to independent, bona fide charities that do not discriminate among different drug manufacturer products.¹¹⁰ The Bulletin expresses concerns with the potential for pharmaceutical companies to create and control charitable PAPs as a way to subsidize Part D cost sharing. To address these concerns the Bulletin reiterates guidance from previous OIG advisory opinions for determining whether PAPs receiving manufacturer contributions are, in fact, bona fide charities. Manufacturer contributions to a charity will not pose Anti-Kickback Law problems if neither the manufacturer nor any affiliates exert any direct or indirect control or influence over the charity or the assistance program. Awards of assistance from the charity must be made in a truly independent manner that does not attribute the assistance to the donating manufacturer. In addition, charitable entities are obligated to award assistance without consideration of the manufacturer's interests and without regard to the beneficiary's choice of product, supplier, or Part D plan. The PAP should provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied consistently. The manufacturer is not guaranteed that the amount of its donations will correlate in any way with the number of subsidized prescriptions for its products. In this regard, the Bulletin notes that the manufacturer should not solicit or receive data from the PAP that would facilitate such a correlation. In previous advisory opinions, the OIG has recommended that manufacturers limit themselves to the receipt of aggregate data in the form of monthly (or less frequent) reports of the total number of applicants in a particular disease category and the number of patients qualifying for assistance in that disease category.¹¹¹

¹⁰⁹ See, e.g., OIG Advisory Opinion 04-15 (Oct. 29, 2004); OIG Advisory Opinion 02-1 (Apr. 4, 2002).

¹¹⁰ Publication, 70 Fed. Reg. 70,626.

¹¹¹ *Id.* at 70,626-27; see OIG Advisory Opinion 02-1 (Apr. 4, 2002); OIG Advisory Opinion 04-15 (Oct. 29, 2004); OIG Advisory Opinion 02-13 (Sept. 27, 2002).

In order to fully understand the OIG's views regarding the use of independent charities to administer PAPs, consideration should be given to previous OIG Advisory Opinions on this model. In fact, the Bulletin expressly references past Advisory Opinions.¹¹² Taken together, these opinions provide a useful framework for evaluating the type of PAPs that the OIG would be likely to view favorably if they provided cost-sharing assistance to Part D enrollees.¹¹³

The OIG has issued three Advisory Opinions that address this issue. In two of the opinions, the OIG approved the arrangements, based on the facts presented; in the other, the OIG concluded that the arrangement potentially violated the Anti-Kickback Statute and could be subject to sanctions. In Advisory Opinions 02-1 and 04-15, the OIG evaluated proposed arrangements involving independent, non-profit, charitable organizations that provided certain patient assistance services, including assistance with copayment obligations for prescription drugs.¹¹⁴ The organizations received funding from a variety of donors, including several pharmaceutical manufacturers. In other words, the manufacturers pooled their donations, and the independent foundation administered the assistance. In these opinions, the OIG went through very similar analyses and came to the same outcome, ultimately approving the arrangements. Several factors appear to have been important for the OIG:

- The charitable organizations were truly independent entities, not subject to control, directly or indirectly, by any donor that was affiliated in any way with any pharmaceutical company;
- The charitable organizations made all financial eligibility determinations using their own criteria, not taking into account the identity of any physician, provider, supplier, or drug that the patient may use, or the amount of any contribution made by a donor whose services or products could be used;

¹¹² Publication, 70 Fed. Reg. at 70,627 n.17.

¹¹³ It is important to note that Advisory Opinions are issued only to the requesting parties, and technically may not be relied upon by any other individuals or entities. They are posted on the OIG web site for informational purposes only. Moreover, the OIG frequently points out that the opinions are limited in scope to the specific arrangements described, and any change in facts or circumstances could change the agency's analysis. Finally, Advisory Opinions do not bind any other government agency, including the DOJ. The DOJ has the authority to enforce the criminal provisions of the Anti-Kickback Statute, and, while probably unlikely, it could choose to prosecute an entity notwithstanding a positive Advisory Opinion from the OIG.

¹¹⁴ OIG Advisory Opinion 04-15 (Oct. 29, 2004); OIG Advisory Opinion 02-1 (Apr. 4, 2002).

- All patients remained free, while receiving financial assistance, to change their health care providers, suppliers, or products;
- The charitable organizations did not refer patients to any donor or other provider, supplier, or product; and
- Donors were not assured that the amount of financial assistance their patients, clients or customers received would bear any relationship to the amount of their donations. In fact, donors were not guaranteed that any of their patients, clients, or customers would receive any financial assistance whatsoever from the foundation.¹¹⁵

In contrast, the OIG gave a “negative” opinion (i.e., said that sanctions could be warranted) in Advisory Opinion 02-13.¹¹⁶ In that arrangement, a single pharmaceutical company proposed to establish and fund its own non-profit foundation that would pay all or part of the cost-sharing amounts for financially needy patients using one of the company’s products. The OIG indicated that it would consider the foundation’s grants to be payments by the drug company itself. Importantly, the foundation’s financial assistance would be funded solely by the drug company and would be available only to patients receiving (or willing to receive) the company’s product.¹¹⁷ In summarizing its position, the OIG noted that there are non-abusive alternatives to the proposal under consideration that could be permissible, including: (1) the type of arrangement approved in other advisory opinions (e.g., “in OIG Advisory Opinion No. 02-1, we approved an arrangement for drug manufacturers to pool contributions in an independent foundation that awards grants based on need, without reference to any specific contributing drug manufacturer”); and (2) manufacturer PAPs in which companies provide free drugs to financially needy beneficiaries, as long as no FHCP is billed for the drugs.¹¹⁸

There is a noteworthy discussion in the Bulletin regarding the ability of manufacturers to “ earmark ” their donations for certain disease categories.¹¹⁹ Although the Advisory Opinions had suggested that

¹¹⁵ OIG Advisory Opinion 04-15 (Oct. 29, 2004); OIG Advisory Opinion 02-1 (Apr. 4, 2002). This criterion suggests that there should be at least two competing drugs in the particular disease category for which the donation is made. Otherwise, the donating company would be assured that its donations would be used only for patients using its product.

¹¹⁶ OIG Advisory Opinion 02-13 (Sept. 27, 2002).

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ Publication, 70 Fed. Reg. 70,626, 70,627 (Nov. 22, 2005).

earmarking could be permissible (and this is how most independent charity PAPs currently operate), the OIG previously had not provided much guidance on this particular issue. In the Bulletin, the OIG confirms that earmarking contributions for the support of patients with a particular disease is generally permissible. However, it also expresses a concern with disease categories that are defined very narrowly:

[W]e are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products. For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases.¹²⁰

The Bulletin suggests two ways to manage this risk: (1) pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories; and (2) pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.¹²¹

3. "Coalition Model" PAPs

Another alternative discussed in the Bulletin involves a group of manufacturers offering needy Part D enrollees a card or similar vehicle that would entitle them to subsidies of their cost-sharing obligations for the manufacturers' products, typically in the form of discounts off the negotiated price otherwise available to the enrollee under the Part D plan.¹²² The OIG notes that, under this type of program, a manufacturer effectively would underwrite only the discounts on its own products. This would appear to conflict with one of the key elements supporting the independent charity model: namely, that the manufacturer is not assured that its donations will assist patients using its products. Nevertheless, the OIG

¹²⁰ *Id.*

¹²¹ *Id.* While these suggestions sound reasonable, they raise additional questions. For example, is it permissible for a manufacturer to make suggestions to independent PAPs regarding the creation of general disease categories? Is a manufacturer required to passively wait until a relevant category is created by a PAP before it can offer donations? What constitutes "widely recognized clinical standards" in the context of disease category definitions? Without further guidance from the OIG, manufacturers will struggle with these issues. As a result, it would be helpful for the OIG to provide additional guidance on a few issues, including its concerns about: (1) "narrow" disease categories established by independent charity PAPs; and (2) the involvement of manufacturers in identifying potential disease categories.

¹²² *Id.*

notes that the risk of an illegal inducement may be reduced if certain safeguards are in place, including: (1) the program contains features that adequately safeguard against incentives for card holders to favor one product over another; (2) the program includes a large number of manufacturers; and (3) each participating manufacturer offers subsidies for all of its products that are covered by any Part D plan formulary.¹²³ Although it suggests these features for coalition model PAPs, the OIG still concludes that “it is premature to offer definitive guidance on these evolving programs.”¹²⁴

4. Bulk Replacement Models

Another PAP model considered by the OIG involves “bulk replacement,” in which manufacturers would provide in-kind donations of free drugs to pharmacies, clinics, or other entities that dispense drugs to qualifying patients.¹²⁵ The Bulletin appears to contemplate two possibilities: (1) the bulk replacement product would replace product dispensed without charge to uninsured patients; and (2) the bulk replacement product would cover cost-sharing amounts (owed but not collected) for Medicare Part D enrollees.¹²⁶ In either case, the bulk replacement programs would implicate the Anti-Kickback Statute since the replacement drugs would be provided by the manufacturer to entities that are in a position to generate business for it. The Bulletin indicates that, like the coalition model PAPs, such programs would be analyzed on a case by case basis. Safeguards would be necessary to ensure that: (1) patients were not “steered” to particular drugs; (2) federal health care programs did not incur increased costs; and (3) bulk replacement drugs were not improperly charged to federal health care programs.¹²⁷ Notwithstanding these safeguards, the OIG appears to still have significant concerns about using the bulk replacement model to subsidize only the Medicare Part D cost-sharing amounts. Specifically, according to the OIG, such programs “raise substantial risks related to accounting for the amount of replacement drug that would be equivalent to the cost-sharing amount owed by the beneficiary; properly attributing that amount to specific beneficiaries; and properly calculating TrOOP.”¹²⁸ These negative comments suggest that manufacturers use caution in implementing any program of this type.

¹²³ *Id.* at 70,627-28.

¹²⁴ *Id.* at 70, 627.

¹²⁵ *Id.* at 70,628.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

5. *Manufacturer PAPs Operating Outside Part D*

The OIG notes that manufacturer-sponsored PAPs need not remove all Medicare beneficiaries from their existing programs to be compliant with the Anti-Kickback Statute.¹²⁹ Because enrollment in Part D is voluntary, existing manufacturer PAPs may continue to provide assistance, including free or reduced outpatient prescription drugs, to Medicare beneficiaries who have not yet enrolled in Part D. Occasional inadvertent cost-sharing subsidies to Part D enrolled beneficiaries also will not be problematic if the PAP did not know, and should not have known that the patient enrolled in Part D.¹³⁰ However, patients who are enrolled in Part D, but do not have coverage because they have reached the donut hole, are considered insured by the OIG because they are still enrolled in Part D and are paying premiums.¹³¹

The Bulletin also suggests that a manufacturer PAP operating outside of Part D could provide donated product in compliance with the Anti-Kickback Statute.¹³² Specifically, a Medicare beneficiary would obtain drugs through the PAP without using his or her Part D benefit. Accordingly, no claims for payment would be filed with a Part D plan, and the assistance would not count toward TrOOP. The Bulletin states that, as long as certain safeguards exist, providing free product outside the Part D benefit poses a reduced risk under the Anti-Kickback Statute.¹³³ Required safeguards would include the following: (1) the PAP ensures that Part D plans are notified that the drug is being provided outside the Part D benefit so that no payment is made for the drug and the subsidy does not count toward TrOOP; (2) the PAP provides assistance for the whole Part D coverage year (or the portion of the coverage year remaining after the beneficiary first begins receiving the PAP assistance); (3) the PAP assistance remains available even if the beneficiary's use of the subsidized drug is periodic during the coverage year; (4) the PAP maintains accurate and contemporaneous records of the subsidized drugs to permit the government to verify the provision of drugs outside the Part D benefit; and (5) assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the providers,

¹²⁹ *Id.* at 70,627.

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled.¹³⁴

6. *Transitioning Patients from Existing Manufacturer PAPs*

The OIG recognizes the difficulties with disenrolling patients who currently receive medications or financial assistance through a manufacturer PAP and advises that manufacturer-affiliated PAPs do not have to immediately disenroll Medicare beneficiaries.¹³⁵ Rather, because participation in Part D is voluntary, affected PAPs may continue to provide subsidies to beneficiaries until they enroll in Part D.

Manufacturers will effectively have a one-year grace period following the January 1, 2006 start of the Part D benefit to transition Medicare beneficiaries away from manufacturer-sponsored PAPs to independent programs. For manufacturer-affiliated PAPs that were in existence prior to the date of the Bulletin's publication, the OIG will exercise its enforcement discretion with regard to administrative sanctions under the Anti-Kickback Statute.¹³⁶ In the Bulletin, the OIG indicates that, for 2006, it will "take into consideration in exercising its enforcement discretion . . . whether the [manufacturer] PAP is taking prompt, reasonable, verifiable, and meaningful steps to transition patients who enroll in Part D to alternative assistance models, such as independent charities."¹³⁷ In addition, the OIG suggests other ways for manufacturer PAPs to reduce their fraud and abuse exposure, including: (1) adjusting their financial need criteria to reflect lower drug costs incurred by Part D enrollees; (2) subsidizing other drugs in the same class as the manufacturer's products covered by the PAP if a beneficiary's physician prescribes an alternate product; and (3) checking CMS eligibility files, to the extent available, on a regular basis to determine whether PAP patients have enrolled in Part D and should be transitioned to other assistance programs.¹³⁸

V. CONCLUSION

The level of investigation and enforcement activity involving health care fraud is likely to increase in the next several years as a result of the new Medicare Part D program. Implementation of Part D alters the health fraud enforcement environment by creating a new Medicare benefit to

¹³⁴ *Id.*

¹³⁵ *Id.* at 70,628.

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

which the fraud and abuse authorities will apply. One of the government's main weapons in combating fraud, the Anti-Kickback Statute, figures to be used by enforcement officials in fighting fraud and abuse within the Part D program. Consequently, participants in Part D, such as pharmacies and drug manufacturers, must take care to ensure that their operations are structured in a compliant manner, including any programs intended to assist Medicare beneficiaries with meeting their Part D cost-sharing obligations. Specifically, cost-sharing waivers offered by pharmacies, as well as PAPs underwritten by pharmaceutical manufacturers, should be structured to comply with recent OIG guidance.