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Courtesy or liability?

The legal implications of a pharmacy waiving co-payments

- » Co-payment waivers for Medicare and Medicaid patients can result in legal exposure under federal fraud and abuse laws.
- » DHHS OIG guidance states that a non-routine co-payment waiver in a particular case of financial hardship will not be deemed to violate federal fraud and abuse laws.
- » Co-payment waivers are prohibited and/or deemed insurance fraud under various state laws.
- » Co-payment waivers could result in civil litigation for breach of contract, violation of the Robinson Patman Act, or the Racketeer Influence and Corrupt Organizations Act.
- » Pharmacies should develop, distribute, and enforce policies and procedures that address co-payment waivers.

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An independent grocery store pharmacy, in an effort to compete with the big chain pharmacies and discount stores, advertises that it will provide up to \$25 off the first three fills of a prescription. The \$25 can be used not only by self-pay individuals, but also as a credit toward any co-payment or co-insurance obligation under the individual's insurance.



Trunk

A pharmacist fills a prescription and it adjudicates with an individual co-payment obligation of \$20. When the individual comes to the pharmacy to obtain the prescription, he explains to the pharmacist that he doesn't have \$20, but he needs the medication. The pharmacist, trying to assist the individual who is having a financial hardship, forgives the \$20 co-payment obligation and allows him to take the medication.

What might seem like a good business practice or even a common courtesy, a pharmacy's

waiver of an individual's cost sharing obligation—whether a co-payment, co-insurance, or deductible—can result in significant legal exposure for the pharmacy. Health plans, pharmacy benefit managers (PBMs), and managed care organizations (MCOs) have long argued that the waiver of a patient's cost sharing obligation undermines a health plan's design features (i.e., tiered formularies and stepped co-payments and/or co-insurance) intended to align the financial interests of individual insured members and their health plan. In addition to potential lawsuits by private litigants (e.g., health plans, PBMs, and MCOs), the waiver of some or all of an individual's cost sharing obligation under his/her insurance by a pharmacy (regardless of the pharmacy's intentions) creates legal exposure under various federal and state laws, and potential enforcement actions by federal and state governmental entities.

Federal laws implicated by the waiver of cost sharing obligations

When federal health care programs such as Medicare or Medicaid are involved,

co-payment waivers can implicate the federal Anti-Kickback Statute (AKS), the Beneficiary Inducement Statute, and the federal False Claims Act (FCA).¹ The federal AKS prohibits knowingly offering, giving, or receiving any remuneration to induce the referral or purchase of a product or service that is later reimbursed by a federal health care program. In the case of a co-payment waiver by a pharmacy for a patient who has coverage under Medicaid or Medicare Part D, the waiver is remuneration that could be construed as an inducement to the patient to utilize the pharmacy to dispense the drug for which the pharmacy is subsequently reimbursed by Medicaid or Medicare.

The federal Beneficiary Inducement Statute prohibits transferring any remuneration to a Medicare or Medicaid beneficiary that may influence the beneficiary's selection of a particular provider, practitioner, or supplier of an item or services reimbursed by a federal health care program. Waivers of co-payments and deductibles are specifically included under the definition of "remuneration" for purposes of the Beneficiary Inducement Statute.

A co-payment waiver can also implicate the federal FCA if a pharmacy reports its "usual and customary charge" to a federal health care program or the federal government (e.g., Medicare, Medicaid, Federal Employees' Health Benefits Plan) and the pharmacy's reported "usual and customary charge" is not net of the waived co-payment. Note that pharmacies are not generally reimbursed based on their "usual and customary" charges submitted to health plans. Rather, pursuant

to its contracts with health plans or program fee schedules, a pharmacy is generally reimbursed an ingredient cost that represents a discounted rate off a given pricing metric (such as Average Wholesale Price or Wholesale Acquisition Cost) plus a dispensing fee or an ingredient cost based on the pharmacy's actual acquisition cost plus a dispensing fee, unless the usual and customary charge is lower than the discounted rates set forth in the pharmacy's contract with a given health plan or the program's fee schedule. However, even though a pharmacy's usual and customary charge

may not frequently be the basis for reimbursement by a federal health care program or the federal government, each pharmacy does submit its usual and customary charge with each pharmacy claim and, therefore, if the usual and customary charge reported by a pharmacy includes a co-payment amount waived by the

pharmacy, the reported usual and customary charge could be deemed a false statement made to the federal government.

Although the routine waiver of co-payments does implicate the aforementioned federal fraud and abuse laws, the Department of Health and Human Services Office of Inspector General (DHHS OIG) has recognized in guidance that the non-routine waiver of co-payments and deductibles in cases of financial hardship will generally not be deemed as a violation of such laws. Pursuant to 42 U.S.C. § 1320a-7a(a)(5) and the OIG Special Advisory Bulletin titled "Offering Gifts and Other Inducements to Beneficiaries," the non-routine waiver of cost-sharing amounts based on financial need or following exhaustion of reasonable

Waivers of co-payments and deductibles are specifically included under the definition of "remuneration" for purposes of the Beneficiary Inducement Statute.

collection efforts will not constitute a violation of the Beneficiary Inducement Statute.

The OIG Special Fraud Alert titled “Routine Waiver of Copayments or Deductibles Under Medicare Part B” also notes that it is acceptable for a provider to waive a copayment or deductible in a particular case of financial hardship, and such waiver will not result in a violation of the federal AKS or federal FCA. Pursuant to the OIG Special Fraud Alert, the financial hardship exception may not be used routinely; rather it should be used occasionally to address the specific financial needs of a particular patient. Except in such special cases of financial hardship, a good faith effort to collect deductibles and co-payments must be made.

In addition, the Medicare Prescription Drug, Improvement, and Modernization Act added an exception to the federal Anti-Kickback Statute for the waiver of co-payments by pharmacies for Medicare Part D enrollees. This permits the unadvertised waiver of cost sharing obligations for low-income subsidy recipients on a routine basis without ascertaining financial need.² In other words, Medicare Part D low-income subsidy recipients are deemed to be in financial need, given their low-income subsidy status.

Of note, from a practical standpoint, it appears the Centers for Medicare and Medicaid Services (CMS) and the OIG may not pursue pharmacies for unadvertised, non-routine cost sharing waivers of \$10 or less. Pursuant to CMS Change Request 2174 titled “Audit Guidance Pertaining to Write-offs of Small Debit Balances in Patients’ Account Receivable,” CMS has instructed auditors to forgo a review of provider policies that routinely write off balances of \$10

or less. This is consistent with the OIG Special Advisory Bulletin titled “Offering Gifts and Other Inducements to Beneficiaries,” which states that OIG will not impose civil monetary penalties on providers for violation of the Beneficiary Inducement Statute related to inexpensive gifts and services provided to patients as long as the value is no more than \$10 individually and \$50 in the aggregate annually for each patient.

State laws implicated by the waiver-of-cost-sharing obligations

Massachusetts is known for its broad sweeping “all payor” anti-kickback act, which offers virtually no exceptions, and for which a violation could result in imprisonment for up to 5 years and/or a fine of \$10,000.

In addition to potentially implicating the aforementioned federal fraud and abuse laws, co-payment waivers can also implicate state anti-kickback acts. The overwhelming majority of states have some version of an anti-kickback act. Some of those state laws mirror the federal AKS and apply only when the state Medicaid program subsequently reimburses

a pharmacy for an item or service. Other states have what are commonly referred to as “all payor” anti-kickback acts that prohibit offering, giving, or receiving any remuneration to induce the referral or purchase of product which is reimbursed by any health insurer in the state. In addition, states also have laws prohibiting health care providers licensed in the state from offering, giving, or receiving anything of value for a referral. Massachusetts is known for its broad-sweeping “all payor” anti-kickback act, which offers virtually no exceptions, and for which a violation could result in imprisonment for up to 5 years and/or a fine of \$10,000. California has a good example of a state law prohibiting any “licensee” from offering or receiving any remuneration to induce the referral of patients.³

Similar to implicating the federal FCA, a pharmacy's practice of waiving patient cost sharing obligations could also implicate state false claims acts if "usual and customary" charges reported by the pharmacy to the state Medicaid program or state government are not net of the waived co-payments. Some states have false claims acts that are Medicaid-specific, but many other states have false claims acts that mirror the federal FCA. Section 6031 of the Deficit Reduction Act of 2005 (DRA) encouraged states to pass false claims acts with whistleblower provisions similar to the federal FCA, in exchange for increased financial recoveries from damages collected in federal FCA suits involving Medicaid claims. Currently, 28 states and the District of Columbia have false claims acts with whistleblower provisions like those found in the federal FCA. The OIG, in consultation with the Attorney General of the United States, determined that 14 of these state false claims acts met the DRA requirements prior to the amendments to the federal FCA, resulting from passage of the Fraud Enforcement and Recovery Act of 2009 and, in 2010, the Patient Protection and Affordable Care Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Currently, OIG has only approved two state false claims acts (Connecticut and Iowa) as having met the heightened requirements under the amendments to the federal FCA combined with the requirements under the DRA.

Many states also maintain laws that explicitly prohibit pharmacies from waiving patient cost sharing obligations. For instance Connecticut, Ohio, Nebraska, Texas and West Virginia all have laws prohibiting pharmacies from waiving co-payments established under the state Medicaid programs.⁴ Connecticut also

Every pharmacy should carefully review with legal counsel its policies and procedures that address the waiver of co-payments.

bars the waiver of co-payments by pharmacies for individuals receiving assistance under the Connecticut Pharmaceutical Assistance Contract to the Elderly and Disabled Program, and New Jersey bars the waivers of co-payments by pharmacies for individuals enrolled in the New Jersey FamilyCare program.⁵ In addition, some states, including Colorado and Idaho, have made it illegal for providers

to routinely waive co-payments or deductibles regardless of the patient health insurance policy or plan.⁶ Although some states (Colorado among them) do have exceptions for the waiver of a co-payment on a case-by-case basis due to

financial hardship, others have no exceptions. Many states also expressly prohibit providers, including pharmacies, from advertising the practice of routinely, or occasionally in good faith, waiving co-payments.⁷ Violations of these laws usually result in a civil or administrative penalty and may also include jail time.

In addition, Florida and New York have declared the practice of a provider waiving patient cost sharing obligations to be insurance fraud, as it results in an inflation of the provider's usual and customary charge (i.e., the charge includes the patient co-payment or deductible even though the provider waived the co-payment or deductible and, as a result, the patient did not pay the corresponding co-payment or deductible).⁸ In Florida, insurance fraud is penalized as a felony, which can be punishable by a \$10,000 fine and 30 years in prison.

Potential causes of action by private litigants

Private litigants, such as group health plans, could also potentially bring civil suits against pharmacies related to the practice of waiving patient cost sharing obligations. First,

pharmacies maintain participating agreements with MCOs and PBMs who provide services to insured and self-insured employer groups. Those contracts typically require the collection of the applicable enrollee co-payment, co-insurance, or deductible at the time of dispensing, and permit contract termination in the event a pharmacy has waived a patient's cost sharing obligation under his/her applicable plan. As such, these MCOs and PBMs could bring suit for breach of contract, seeking to recover the waived patient cost sharing amounts and other applicable damages, which might include the price differentials between generic and brand drugs in a therapeutic category, under the theory that the waived co-payments incentivized patients to utilize more expensive brand name drugs over generics and less costly brand alternatives.

In addition to bringing a breach of contract action, group health plans, PBMs, and MCOs might bring a private action under the Robinson Patman Act and/or the Racketeer Influence and Corrupt Organizations Act (RICO). Section 2(c) of the Robinson Patman Act prohibits brokers, agents, and other intermediaries between sellers and buyers from receiving payments that are not for services rendered. A co-payment waiver by a pharmacy "seller" could be constructed as a payment to a patient "intermediary" that is not for services rendered. Furthermore, group health plans, PBMs, and MCOs could also allege that a pharmacy violated RICO by waiving co-payments, because it utilized United States wires to engage in insurance fraud. In fact, four health benefit plans (the New England Carpenters Health and Welfare Fund; the Plumbers and Pipefitters Local 572 Health and Welfare Fund; the Sergeants Benevolent Association; and the AFSCME District Council 37 Health and Security Plan Trust) recently filed lawsuits alleging these exact theories, except instead of bringing the suits against pharmacies for waiving patient cost sharing obligations, the suits were brought against eight pharmaceutical

manufacturers (Abbott Laboratories; Amgen, Inc.; AstraZeneca; Bristol-Myers Squibb; Co.; GlaxoSmithKline; Merck & Co., Inc.; Novartis Pharmaceutical Corp; and Pfizer, Inc.) for paying pharmacies' patient cost sharing obligations under their co-payment assistance programs, essentially waiving patient cost sharing obligations by remitting the applicable patient cost sharing amounts to the pharmacies.⁹

In short, pharmacies should be very skeptical of the practice of waiving an individual's co-payment or cost sharing obligation. It is clear that there is significant legal exposure under federal and state laws and also the potential for civil litigation brought by health plans, PBMs, and MCOs related to the routine waiver of co-payments. That being said, a one-time co-payment waiver in the case of an individual financial hardship may be acceptable under certain federal and state laws. Depending upon the pharmacy's location, the individual's specific health care coverage (whether a commercial plan or federally funded health plan such as Medicare or Medicaid) and the pharmacy's contractual commitments, there could be diminished legal exposure associated with such a one-time waiver. Every pharmacy should carefully review with legal counsel its policies and procedures that address the waiver of co-payments. In addition, pharmacies should take care to train all pharmacists on the policies and procedures governing the waiver of co-payments, and routinely and consistently enforce such policies and procedures. ☐

1. 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1320a-7a(a)(5); 31 U.S.C. §§ 3729.
2. 42 U.S.C. § 1320a-7b(b)(3)(G).
3. M.G.L.A. 175H § 3; California Business and Professional Code Section 650(a).
4. Conn. Agencies Regs. § 17b-262-497(e); Ohio Rev. Code § 5111.0112(B) (3) & (C); Neb. Admin. R. & Regs. Tit. 471, Ch. 2, § 001.03(11) and Neb. Admin. R. & Regs. Tit. 471, Ch. 3, § 008.04; Tex. Ins. Code Ann. § 1204.055; W. Va. Code § 9-2-10.
5. Conn. Agencies Regs. § 17b-491(a) and N.J. Admin. Code tit. 10, 10:51-1.12(e).
6. C.R.S.A. § 18-13-119
7. Neb. Admin. R. & Regs. Tit. 471, Ch. 2, § 001.03(11) and Neb. Admin. R. & Regs. Tit. 471, Ch. 3, § 008.04; C.R.S.A. § 18-13-119; Ga. Code Ann. § 43-1-19.1; Tex. Occ. Code § 101.201(6) & (7).
8. F.S.A. 817.234(7)(a); New York Penal Law §176.05.
9. See, e.g., *New England Carpenters Hlth. & Welfare Fund v. AstraZeneca, Inc.*, 2:12-cv-01192-PD (E.D. Pa.) (Mar. 7, 2012).