



Recent News Highlights that Pharmacy Activity at the Center of Copay Coupon Controversy

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Executive Summary

Two recent news events evidence that there is a continuing struggle over the use of copay coupons for prescription drugs, and that the activities of pharmacies are at the center of the action. The September 19, 2014 Office of Inspector General (OIG) publication of a Special Advisory Bulletin¹ (Bulletin) and Report² and the September 25, 2014 ruling by the United States District Court for the Northern District of Illinois granting in part Abbott Laboratories and AbbVie, Inc.'s Motion to Dismiss, throwing out the coalition of payors' RICO claims³ indicate that pharmacies must pay close attention to movements by both federal and commercial payors in regard to copay coupon use. This article explores some of the trends involving efforts to comply with copay coupon prohibitions, commercial payor prohibitions, and commercial payor lawsuits. Further, this article analyzes the implications for pharmacies from a compliance, business, and operational perspective, recommending a focused approach to contracting strategies, communications among the compliance, business, and operations teams regarding prohibition obligations, and exploration of workable protocols for honoring both federal program prohibitions and contractual obligations with commercial payors.

As explained more fully below, pharmacies may benefit from the following:

- Require review notices on coupon to ensure they are prominently placed and provide meaningful notice; consider providing notice of commercial payor exclusions

¹ https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf

² <https://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf>

³ See *New England Carpenters Health And Welfare Fund v. Abbott Laboratories*, 1:12cv1662 (N.D. Ill) dkt#158.

- Institute policies and procedures that lower your risk of willingly or knowingly processing copay coupons for federal program beneficiaries; for example, require an affirmative certification for each patient over 65 that he or she is not a Part D beneficiary
- Institute policies and procedures that require the business and operations teams to communicate about all new (and previously undiscussed) commercial payor copay coupon prohibitions
- Facilitate compliance and operations communications about the best way to segregate out dispenses with associated copay coupon prohibitions (by patient, disease state, drug, payor, etc.)
- In the contracting process with manufacturers, carefully consider copay coupon terms and any needed carve-outs for federal or commercial prohibitions
- In the contracting process with manufacturers, carefully consider allocating the risk and responsibility of processing copay coupons

Background

There is an ongoing movement in the pharmaceutical industry to curtail the use of copay coupons, which is being pushed forward on several fronts by both federal and commercial payors. While manufacturers have historically been the focus of payor efforts, the role of pharmacies, particularly specialty pharmacies that frequently process the coupons for the high-cost branded drugs, are at the center of the scrimmage. For commercial payors, the battlefield has been through contract negotiation and in the courtroom. In the negotiating room with pharmacies, payors are insisting on contract terms that prohibit the use of copay coupons for their insureds. Using litigation as their weapon, payors have filed several lawsuits against manufacturers alleging Racketeering Influence and Corrupt Organization Act (RICO) violations and tortious interference with contract (between payors and pharmacies), among others.⁴ In fact, on September 25, 2014, the United States District Court for the Northern District of Illinois ruled on defendants, Abbott Laboratories and AbbVie, Inc.'s Motion to Dismiss, throwing out the coalition of payors plaintiffs' RICO claims.⁵ While the OIG has not necessarily stepped up enforcement efforts on copay coupon use by federal program beneficiaries, the September 19, 2014 OIG Bulletin⁶ and Report⁷ (together, OIG publications) on copay coupon use highlights its continued focus on the issue in the federal payor arena.

⁴ See generally, *Pfizer, Abbott, Glaxo Sued Over Brand-Drug Co-Pay Discounts*, Bloomberg News, Phil Milford and Dawn McCarty, March 7, 2012, available at <http://www.bloomberg.com/news/2012-03-07/pfizer-abbott-face-allegations-over-co-pay-coupon-promotions.html>

⁵ See *New England Carpenters Health And Welfare Fund v. Abbott Laboratories*, 1:12cv1662 (N.D. Ill) dkt#158.

⁶ https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf

Historically, manufacturers have been put on the defense with copay coupon efforts—manufacturers are the targets of commercial payor lawsuits and the OIG publications focus on manufacturers' efforts. However, there is reason for specialty pharmacies to pay attention. Specialty pharmacies administering manufacturer copay coupon programs are often the entities tasked with ensuring against use by Part D beneficiaries or use by insured prohibited by payor/pharmacy contract. Some commercial payors may restrict copay coupon use for their insureds or for certain drugs; however, in their lawsuits, commercial payors are alleging that pharmacies are involved in a scheme with manufacturers to inappropriately process the copay coupons, driving up payor costs, and that pharmacies are in breach of the terms of payor manual terms, which payor plaintiffs claim are incorporated into network contract obligations.⁸ The allegations involving pharmacy action is particularly significant given that payors are not getting traction in their litigation efforts against manufacturers.

Compounding this hot button issue is the difficulty in operationalizing copay coupon prohibitions. The OIG publications highlights the difficulties faced by manufacturers and pharmacies in ferreting out Part D beneficiaries when administering copay coupon programs. Similar problems arise in ensuring payor prohibitions are honored. The problems associated with sequestering patients with copay coupon prohibitions may give rise to tension between manufacturers and pharmacies during contract negotiations in regard to allocating responsibility and risk. However, ultimately the interests of pharmacies and manufactures are aligned in the continued use of copay coupons, which facilitate patient compliance and adherence to medication therapies and a workable method for compliance with prohibitions of their use.

Copay Coupons and Federal Program Beneficiaries

There is a longstanding prohibition on allowing federal program beneficiaries' use of copay coupons.^{9¹⁰} The recent OIG publications provide background on the copay coupon

⁷ In crafting the report, the OIG gave an online survey of 34 pharmaceutical manufacturers of drug coupons to which 30 responded. The response rate to the 30 completed was 80%. The OIG also attempted to obtain 50 coupons to examine, but only 40 coupons were obtained. Additionally, the OIG conducted interviews with organizations involved in the pharmacy claim transaction process, including pharmacists, coupon vendors, a switch company, and NCPDP. OIG report, *Manufacturers Safeguard May Not Prevent Co-Payment Coupon Use for Part D Drugs*, September 19, 2014, page 8; available at <http://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf>

⁸ See generally, Abbott Labs, dkt #158 at 3.

⁹ See 59 Fed. Reg. 65372 (Dec. 19, 1994); Advisory Opinion 97-4 (Sept. 25, 1997); Advisory Opinion 99-1 (Jan. 20, 1999).

¹⁰ It is noteworthy that a “win” of sorts for copay coupons was had on March Oct. 30, 2013, when then Health and Human Services Director, Kathleen Sebelius, responded to Rep. Jim McDermott’s inquiry, opining that Qualified Health Plans are not federal health programs, and thus are not subject to the Anti-Kickback Statute. Letter available at <http://mcdermott.house.gov/images/The%20Honorable%20Jim%20McDermott.pdf>; see *Branded Drugs Chalk Up a Win Under Health Law Producers Can Assist on Copays; PBMs Object, Preferring*

prohibition, citing both legal and policy rationales for the restriction. The OIG publications warn that copay coupon use violates the Anti-Kickback Statute,¹¹ may constitute a false or fraudulent claim under the False Claims Act, and is ground for imposition of civil money penalties because the provision of coupons to a federal program beneficiary may induce the brand-name, more expensive drug over a less expensive generic version. The Anti-kickback Statute is intent-based. The March 23, 2010 Patient Protection and Affordable Care Act revised the intent requirement such that actual knowledge of or specific intent to violate the Anti-kickback Statute is not required; thus, merely the intent to induce the referral or purchase of items or services for which payment may be made in whole or in part by a federal or state healthcare program is sufficient.¹²

From a policy perspective, it is argued that copay coupons undermine the patient cost-sharing mechanism, which is intended to influence beneficiaries make more efficient healthcare decisions by requiring them to pay a portion of their medication costs. This rational has been previously highlighted in regulatory guidance¹³ and OIG advisory opinions.¹⁴ As the Report explains, copay coupons may induce the use of more expensive brand of drugs over generic equivalents because the copay coupons lower the copay for brand drug to the same or less than generics.¹⁵ In support of this theory, the Report notes an increase in the use of copay coupons from 86 in July of 2009 to 525 in December 2012,¹⁶ which coincides a rise in generic equivalents for “blockbuster” drugs from 2009 to 2012.¹⁷ The Report also noted that 58% of coupons were for brand named drugs for which a lower cost generic was available.¹⁸ While the Report focuses on manufacturer interventions, it

Generics, The Wall Street Journal, Jonathan D. Rockoff and Peter Loftus, Nov. 3, 2013, available at <http://online.wsj.com/news/articles/SB10001424052702303843104579172090415391168>.

¹¹ The federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)) makes it a criminal felony offense for *anyone* to knowingly and willfully offer, pay, solicit or receive anything of value, directly or indirectly, in cash or in kind, overtly or covertly in return for or to induce (1) patient referrals, or (2) the purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering items or services for which payment may be made in whole or in part by any federal or state healthcare program (e.g. Medicare, Medicaid and TRICARE).

¹² 18 U.S.C. § 1347(b).

¹³ 59 Fed. Reg. 65372 (Dec. 19, 1994) provides the following in regard to Part B copay waivers, “At first glance, it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. By waiving Medicare copayments and deductibles, the provider of services may claim that the beneficiary incurs no costs. In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free. 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.”

¹⁴ See Advisory Opinion 97-4 (Sept. 25, 1997); Advisory Opinion 99-1 (Jan. 20, 1999).

¹⁵ OIG report, *Manufacturers Safeguard May Not Prevent Co-Payment Coupon Use for Part D Drugs*, September 19, 2014, p 4.

¹⁶ *Id.* at 5.

¹⁷ *Id.*

¹⁸ *Id.* at 2.

acknowledges that patients typically redeem co-payment coupons at pharmacies when they purchase their drugs.¹⁹

The interventions to weed out Part D beneficiaries addressed in the Report can be characterized as mechanical and technical. The mechanical efforts include notice to beneficiaries and pharmacists, as well cross-checking questions on coupon access websites. The technical efforts include the use of claims edits.²⁰ Suggestions for the improvement of mechanical efforts are based upon the observation that while most coupons provide notice to Part D beneficiaries, but that the notice could be more effective.²¹ Improvement methods include things such as giving bigger, bolder, and better placed notice to beneficiaries, as well as providing safeguards on websites to keep patients from changing their answers on questions designed to cull out Part D recipients. Of the coupons reviewed by the OIG, 80% had a notice on the coupon website indicating the prohibition on use by part D beneficiaries.²² Additionally, 75% also had an eligibility prompt question online or over the phone; however, only 3% had a mechanism to prevent patient from going back to the prompt question and changing his or her answer to allow use of the co-payment coupon.²³ The Report also notes that notices to beneficiaries tended to be in small font and sometimes on the back of the coupon or on information pages following the coupons.²⁴

As for the technical efforts, the Report focuses on the claims edits process, which the OIG recognizes is difficult, if not practically impossible to use to effectively isolate all Part D beneficiaries.²⁵ Moreover, the sample size for the claims edits process was not substantial; while 28 of the manufacturers surveyed used claims processing edits for at least one of the coupon formats they offer, only 13 offered specific information about their claims processing edits in their survey response.²⁶ The claims edits process generally utilizes the entry of bank identification number (BIN); primary insurers, including Part D plans, utilize a BIN in the claims process.²⁷ However, use of the insurer's BIN only gives visibility to whether the patient is enrolled in a plan that includes Part D coverage; the pharmacy does not have visibility to whether the patient is enrolled in the Part D portion or the commercial portion of the plan.²⁸ Some manufacturers also reported using patient age as an identifier, excluding anyone over 65.²⁹ However, the Report emphasizes that 17% of

¹⁹ *Id.* at 6.

²⁰ *Id.* at 10-12.

²¹ *Id.*

²² *Id.* at 10.

²³ *Id.*

²⁴ *Id.* at 12.

²⁵ *Id.* at 18-21.

²⁶ *Id.* at 15.

²⁷ *Id.* at 7.

²⁸ *Id.* at 17.

²⁹ *Id.*

Medicare beneficiaries are under the age of 65; thus, relying solely on age will not ensure no beneficiaries utilize co-pay coupons.³⁰

Far from offering any direction on a fail-safe approach to enforcing the copay coupon prohibition for Part D beneficiaries, the report acknowledges that “coupons are not transparent in the pharmacy claims transactions system to entities other than manufacturers.”³¹ Ultimately, the OIG recommends that the CMS cooperate “with industry stakeholder efforts to improve the reliability of mechanisms to determine when copayment coupons are used in connection with the purchase of drugs paid for, in part, by Part D.”³²

Commercial Payor Actions Against the Use of Copay Coupons

On the commercial side, there may be a growing trend among some payors to contractually prohibit pharmacies’ processing of copay coupons for their insureds or for specific high-cost brand drugs for which there are generic equivalents. Additionally, some commercial payors are attempting to limit copay coupon use through litigation against manufacturers. While the courts have been reluctant to prohibit copay coupon use and commercial payor contracting efforts to limit the use of copay coupons has been limited, there appears to be a developing trend.

For example, beginning on January 1, 2013, UnitedHealthcare disallowed the use of copay coupons for Extavia, Gilenya, Cellcept, Humira, Victrelis, and Peg-Intron, specialty drugs for which UnitedHealthcare asserted lower cost alternatives were available.³³ In a publication explaining the prohibition, UnitedHealthcare wrote that the prohibition was intended to provide a “financial incentive for members participating in our Specialty Pharmacy Program to choose a lower tier, lower cost drug alternative, as appropriate,” noting that it estimated that 45% of its members were choosing higher cost medication, despite available lower cost alternatives.³⁴ UnitedHealthcare noted that its prohibition “follows the U.S. government’s long-time practice of not allowing coupons to be redeemed for patients covered by Medicare, Medicaid and other federal health care programs.”³⁵ Beginning January 1, 2014, UnitedHealthcare expanded the list of specialty drugs for which it would not accept copay coupons to more than thirty (30) drugs.³⁶ However, UnitedHealthcare has stepped back from its March 11, 2014 announcement that it beginning July 1, 2014 it would partner with the retail pharmacies to discontinue the use of

³⁰ *Id.*

³¹ *Id.* at 19.

³² Special Advisory Bulletin available at

https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf

³³ See <http://broker.uhc.com/assets/Specialty%20PDL%20Coupons.pdf>

³⁴ *Id.*; Benefit Plans Can Influence Specialty Patients to Switch to Less Costly Alternatives, Specialty Pharmacy Times, Oct. 31, 2013, available at <http://www.specialtypharmacytimes.com/news/Benefit-Plans-Can-Influence-Specialty-Patients-to-Switch-to-Less-Costly-Alternatives#sthash.etf8Qsr7.dpuf>

³⁵ *Id.*

³⁶ See <http://broker.uhc.com/assets/Coupon%20Policy%20Drug%20List.pdf>

co-pay programs entirely.³⁷ While UnitedHealthcare has been public about its prohibition of copay coupon use for certain drugs, its approach is not unique in the industry. Pharmacies may have several payor contracts that prohibit copay coupon use based on the drug dispensed.

In the courtroom, the campaign against copay coupons became apparent in early March 2012, when a coalition of national, state and local groups, including health care foundations, health providers, and payors filed lawsuits against Abbott Laboratories, Amgen Inc., AstraZeneca PLC, Bristol-Myers Squibb Co., GlaxoSmithKline PLC, Merck & Co. Inc., Novartis AG and Pfizer Inc.³⁸ Many of these cases have concluded with dismissal by Plaintiff either after partially negative rulings from the Court³⁹ or with manufacturer dispositive motions pending,⁴⁰ while others battles continue to rage on.⁴¹ The general inclination of the courts has been to dismiss the RICO claims under Rule 12, but find that Plaintiffs properly state a claim for tortious interference.

This direction, albeit through a technicality,⁴² was also the one taken by the United States District Court for the Northern District of Illinois on September 25, 2014, granting Defendant, Abbott Laboratories and AbbVie, Inc.'s Motion to Dismiss plaintiff's RICO claims, but declining to address the tortious interference claims.⁴³ In the Abbott/AbbVie litigation, the Plaintiff made allegations similar to the other copay coupon lawsuits—that (i) manufacturers violate RICO by instructing pharmacies to conceal the use of copay coupons by processing as secondary insurance rather than as a regular coupon and (ii) manufacturers' copay coupons interfere with pharmacies contractual obligations to collect copays directly from patients.⁴⁴ Plaintiff claimed that the copay coupons should be processed as a coupon, reducing the total price of the drug, but not affecting the patient's copay. Mimicking the cost sharing policy concerns that form the foundation of the federal program prohibition, Plaintiff alleged that patients choose brand name drugs over generics when copay coupons are available.⁴⁵

³⁷ See <http://broker.uhc.com/articleView-13383> and <http://broker.uhc.com/articleView-13481>

³⁸ Consumer group sues 8 drugmakers over drug coupons, USA Today, Linda A. Johnson, March 7, 2012, available at <http://usatoday30.usatoday.com/money/industries/health/drugs/story/2012-03-07/drug-coupons-lawsuit/53400686/1>

³⁹ American Federation of State et al v. Bristol-Myers Squibb Co. et al 1:12cv2238 (S.D.N.Y) (Plaintiff taking nonsuit after Court granted Defendant's Motion to Dismiss, but later granted Plaintiff leave to amend as to its tortious interference claim, but not its RICO claim).

⁴⁰ See American Federation of State et al v. Amgen, Inc., et al, 1:12cv2237 (S.D.N.Y) dkt # 41 (Plaintiff taking a voluntary nonsuit with Amgen's pending Motion to Dismiss).

⁴¹ See Plumbers And Pipefitters Local 572 Health And Welfare Fund v. Merck & Co., Inc., 3:12cv1379 (D. NJ).

⁴² Plaintiff claimed supplemental jurisdiction for its tortious interference claims; thus, with the dismissal of the federal question RICO claims, the Court questioned its jurisdiction over the tortious interference issue. The ruling references an October 7, 2014 status conference, during which the issue of continued jurisdiction may be resolved. *Id.* at 16.

⁴³ See New England Carpenters Health And Welfare Fund v. Abbott Laboratories, 1:12cv1662 (N.D. Ill) dkt#158.

⁴⁴ See *id.* p. 1-2.

⁴⁵ See *id.* p.2.

These claims may give pause to pharmacies; while Abbott and AbbVie are the target of the lawsuit, the allegations are inextricably tied to pharmacies' acts, and are predicated on presumed breaches of contract by pharmacies. The Plaintiff alleges that "pharmacies are contractually obligated to collect ... copay[s] directly from the patient."⁴⁶ Moreover, the RICO allegations are predicated on Plaintiff's allegations that pharmacies work in concert with Abbott and AbbVie to inappropriately process the coupons. Pharmacies may not be named defendants, but their actions are the cornerstone of Plaintiff's claims.

Ultimately, in the Abbott/AbbVie litigation, the Court found that Plaintiff's RICO claims failed because it failed to sufficiently allege that the pharmacies joined with the manufacturers "to create a distinct entity" for the purpose of processing the copay coupons as secondary insurance rather than coupons to increase sales of Humira and AndroGel, the drugs at issue.⁴⁷ This line of reasoning is significant in that it requires future Plaintiffs to come to the table with allegations of a more detailed and collusive relationship between manufacturers and pharmacies, in order draft a complaint that meets the relevant pleading standards.

Issues Facing Pharmacies Regarding Copay Coupons

As the OIG publications highlight, there is no clear method to segregate patients that should not receive the benefit of manufacturer copay coupons. Therefore, pharmacies must be diligent and creative about putting in place policies to comply with their legal and contractual obligations. Further, pharmacies should be mindful of the difficulties associated with operationalizing copay coupon prohibitions when negotiating contracts with payors and manufacturers. The federal program and commercial payor prohibitions on the use of copay coupons effects the compliance, operations, and business teams within pharmacies; there is benefit to involving members of each team in crafting a comprehensive approach to copay coupons.

Business teams should also be mindful of the implications of copay coupons when negotiating contracts. While business teams may find little negotiating room with payors regarding copay coupon prohibitions, the operations team needs to be looped in on any prohibitions and should be consulted on any contractual details about how the prohibition will be operationalized to ensure the contract terms are in line with the pharmacy's capabilities. Business teams may find more negotiating room with manufacturers, but regardless, copay coupon terms should be a talking point in manufacturer contract negotiations. Targeted contracting strategies, as highlighted below, can equitably allocate

⁴⁶ 3(Plaintiff cited to pharmacy manuals, which it claimed supplement network agreements, as the source of this contractual obligation.).

⁴⁷ *Id.* 9-11. It is noteworthy that the Court was bound by Seventh Circuit precedent, which is more restrictive than other Circuits, such as the Eleventh Circuit, in requiring "an ascertainable structure, including sufficient relationships among the enterprise participants." *Id.* p. 12

responsibility and risk between manufacturers and pharmacies. Moreover, discussions about copay coupons with manufacturer partners during the contracting process may clarify areas of alignment with pharmacies around patient compliance with and adherence to medication therapies.

Just as business must be sure to keep the operations team abreast of copay coupon prohibitions, the compliance teams also play an integral role in ensuring protocols are in place to appropriately mitigate the risk improper use of copay coupons. The OIG publications offer guidance on methods that may increase the effectiveness of protocols to sift out federal program beneficiaries from patients that may use copay coupons. In concert with the operations teams, policies must be crafted that can be operationalized over a wide range of dispense categories. Consequently, comprehensive strategic planning around pharmacy's approach to copay coupons is key to compliance with contractual network requirements, avoiding FCA, AKS, and CMP liability, and avoiding recoupments from commercial payors.

While each each payor and manufacturer relationship will require a unique analysis, below are some focus points, which may assist in navigating copay coupon prohibitions:

- Review coupon notices to ensure they are prominently placed and provide meaningful notice; consider providing notice of commercial payor exclusions
- Institute policies and procedures that lower your risk of willingly or knowingly processing copay coupons for federal program beneficiaries; for example, require an affirmative certification for each patient over 65 that he or she is not a Part D beneficiary
- Institute policies and procedures that require the business and operations teams to communicate about all new (and previously undiscussed) commercial payor copay coupon prohibitions
- Facilitate compliance and operations communications about the best way to segregate out dispenses with associated copay coupon prohibitions (by patient, disease state, drug, payor, etc.)
- In the contracting process with manufacturers, carefully consider copay coupon terms and any needed carve-outs for federal or commercial prohibitions
- In the contracting process with manufacturers, carefully consider allocating the risk and responsibility of processing copay coupons

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