



Drug Rebate for Families or “Copay Accumulator Prohibition” Legislation – HB 4353 MAHP Position – Oppose

General Comments – Prescription Costs:

Prescription drug costs now account for 21% of total health care costs, compared to just 6% in 2006. The rate of drug price increases has outpaced the Consumer Price Index by 150% over the last decade. The drug rebate for families’ legislation, or prohibition against “copay accumulator programs,” does not get at the “heart” of the issue, the high cost of manufacturers’ prescription drug products.

Concerns with Pharmaceutical Copay Coupons:

- Pharmaceutical manufacturers offer billions of dollars in “copay coupons” as one way to increase sales and profits of more expensive brand drugs over less costly generics or alternative therapies.
- At first glance, these coupons appear to benefit patients, but in reality the ugly truth is that they result in higher spending by payers and insurers and result in higher premiums for businesses and individuals struggling to make each health care dollar efficient.
- A National Bureau of Economic Research study found that coupons increased brand drug sales by over 60% by reducing the sales of generic drugs, and drug manufacturers received a return of up to six-to-one on every dollar spent on copay coupons. During the five years following generic drug entry, coupons increased total drug spending by \$30-\$120 million per drug, or \$700 million to \$2.7 billion; a significant negative economic impact to health care¹
- An additional study noted that coupons allow manufacturer drug prices to grow more quickly than they would otherwise. Branded prescription drugs with coupons experienced a cost increase of 12-13% per year, compared to 7-8% per year for drugs without coupons.²
- Manufacturer prescription drug coupons act as a form of unauthorized, unregulated insurance, operating as a “secondary insurance” and circumventing the terms and conditions of health benefits plans that include cost-sharing for covered prescription drugs. Prescription drug copay coupons act as “secondary insurance” because the manufacturer agrees to cover a portion of the insured’s prescription drug expenses.

State Copay Accumulator Prohibition Legislation Would Violate Several Federal Statutes:

- The Center for Medicare and Medicaid Services (CMS) has barred coupons for patients in Federal Programs, Medicare, Medicaid and Veterans Affairs, because they serve as an economic inducement. Use is a violation under the Anti-Kickback Statute and inducement provisions of the Civil Monetary Penalties statute (OIG 2014a, OIG 2014b).

¹ <https://www.nber.org/papers/w22745>

² <https://insight.kellogg.northwestern.edu/article/prescription-drug-copay-coupons-hurt-generic-competition>

- HHS Notice of Benefit and Payment Parameters for 2021 Final Rule, May 17, 2020, allows health plans to implement copay accumulator programs, regardless if generic is available. Plans and employers can limit out-of-pocket expenses on prescriptions to those actually incurred by the patients and not consider any copay assistance the patient may receive from drug manufacturers.³
 - Coupon program utilization also violates IRS rules for Health Savings Accounts and the eligibility criteria for high-deductible health plans.
 - Significant DOJ Health Care Fraud Recoveries have resulted due to drug manufacturers illegal payments of patient copays and resultant False Claims Act (FCA) violations. DOJ identified that copay coupons are a direct inducement to buy a specific product and influence a patient's drug choice. Further, manufacturers' donations to charities paying copay assistance to determine product choice were an indirect remuneration, also a violation of anti-kickback statute.
- Drug manufacturer enforcements account for the highest healthcare recoveries:
 - 2018: 2 drug manufacturers paid \$234 million to resolve illegal copay remuneration (Pfizer & United Therapeutics)
 - 2019: 8 drug manufacturers paid \$646 million to resolve claims of illegal copay remuneration (Actelion, Amgen, Astellas, Alexion, Biogen, Jazz, Lundbeck & US Worldmeds)
 - 2020: 3 drug manufacturers paid \$170 million to resolve claims they illegally used copay remunerations (Biogen, Gilead & Novartis)
 - Charitable foundations and other healthcare providers were also implicit FCA violations by paying for patient copays for manufacturer specific drugs using the independent foundations as conduits for the illegal coupon remuneration:
 - 2019: 4 charitable foundations paid \$13 million to resolve claims enabling pharmaceutical companies to provide a kickback by paying patient copays (Patient Services Inc., Chronic Disease Fund, Patient Access Network Foundation and The Assistance Fund).
 - 2019: Advanced Care Scripts, a specialty pharmacy, paid \$1.4 million to resolve claims they acted as a vendor on behalf of pharmaceutical manufacturers to transfer patients to foundations that illegally paid patient copays.

Michigan Shortcomings - State False Claims Act Recoveries:

States can receive a 10% point increase in their share of any amount recovered under false claims law. State statute must contain provisions that are "at least as effective in rewarding and facilitating qui tam actions" as those in federal FCA and must contain civil penalties at least equivalent to those imposed by the federal FCA.⁴ A similar requirement is that a state's statute must provide for civil penalty increases "at the same rate and times as those under the federal FCA" pursuant to the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.⁵ **Michigan is one of 8 states that have not yet been deemed to meet federal standards, and is leaving money on the table.**

³ <https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021>

⁴ <https://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp>

⁵ <https://www.federalregister.gov/documents/2016/06/27/2016-14973/federal-civil-penalties-inflation-adjustment-of-2015>

HOUSE BILL NO. 4353

February 24, 2021, Introduced by Reps. Kahle, Brann, Whiteford, Borton, Lightner, Frederick, Bollin, Bezotte, Allor, Glenn, Farrington, Bellino, Wozniak, Yaroch, Martin, O'Malley and Calley and referred to the Committee on Health Policy.

A bill to amend 1956 PA 218, entitled
"The insurance code of 1956,"

(MCL 500.100 to 500.8302) by adding section 3406v.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 3406v. (1) Subject to section 4 of the health care false claims act, 1984 PA 323, MCL 752.1004, a health insurance policy delivered, issued for delivery, or renewed in this state that provides coverage for prescription drugs must apply any amount paid by the insured or paid on behalf of the insured by another person when calculating the insured's overall contribution to any out-of-pocket maximum or any cost-sharing requirement **except;**

- (a) for any prescription drug if: a lower cost brand name or nonbrand name prescription drug is available that is designated therapeutically equivalent as indicated by the United States Food and Drug Administration's "Approved Drug and Products with Therapeutic Equivalence Evaluations" or
- (b) the active ingredients of the drug are available without prescription at a lower cost and are not otherwise contraindicated for treatment of the condition for which the prescription drug is approved.
- (c) The prohibition in (a) and (b) shall not apply to a discount, rebate, product voucher, or other reduction in an individual's out-of-pocket expenses required under a United States Food and Drug Administration Risk Evaluation and Mitigation Strategy for the purpose of monitoring or facilitating the use of that prescription drug in a manner consistent with the approved labeling of the prescription drug.

(2) This section applies to a health insurance policy delivered, issued for delivery, or renewed in this state after December 31, 2022.

(3) If any provision of this section conflicts with a federal law, the federal law prevails.

(4) As used in this section:

(a) "Cost-sharing requirement" means any copayment, coinsurance, deductible, or annual limitation on cost sharing, including, but not limited to, a limitation subject to 42 USC 18022(c) and 300gg-6(b), required by or on behalf of an insured in order to receive a

specific health care service, including a prescription drug, covered by a health insurance policy.

(ii) The rebate, discount, product voucher, or other reduction is made available to all eligible individuals **FOR A PERIOD OF NO LESS THAN ONE YEAR** regardless of how the drug is paid for when it is provided to the consumer.

(b) "Prescription drug" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708. However, prescription drug does not include a drug with ~~an AB-rated~~ a generic equivalent unless the insured obtains access to the drug though any of the following:

(i) Prior authorization.

(ii) A step therapy protocol.

(iii) The insurer's exception process.

Enacting section 1. This amendatory act does not take effect unless Senate Bill No. ____ or House Bill No. ____ (request no.

Note: AB rated generic is not define or used anywhere in the Michigan Public Health Code of 1978 nor in the Michigan Insurance Code of 1956; therefore its inclusion here is not appropriate. In addition will severely limit the scope of generic substitution if this is included (See FDA equivalence ratings <https://www.fda.gov/media/71474/download>)

Documented Evidence: Drug Copay Coupons Increases Overall Drug Costs

- **Prescription Drug Coupons Actually Increase Healthcare Spending by Billions: Northwestern University Kellogg School of Management – Oct. 2017**

<https://insight.kellogg.northwestern.edu/article/prescription-drug-copay-coupons-hurt-generic-competition>

The researchers estimate that for brand-name drugs facing generic competition, these coupons boost retail sales by 60 percent or more. And they increase spending by anywhere from \$30 million to \$120 million per drug during the five years studied. That translates to as much as a \$2.7 billion increase in spending for the 23 drugs they studied over five years.

- **Copay Assistance for Expensive Drugs, A Helping Hand That Raises Costs: P. Ubel, MD & P. Bock, MD: Ann Intern Med. 2016; 165:878-879. doi:10.7326/M16-1334**

<https://www.acpjournals.org/doi/10.7326/M16-1334>

Copay assistance programs help people who either cannot afford expensive medications or who would experience significant financial distress from their portion of the cost. However, in addressing these financial needs, copay assistance programs create broader problems in health care markets and encourage further price inflation

- **When Discounts Raise Costs, The Effect of Copay Coupons on Generic Utilization: L. Dafny, Harvard Business School NBER; C. Ody, Northwestern University Kellogg School of Management; M. Schmidt, UCLA Anderson School of Management - Oct. 2016**

https://www.hbs.edu/ris/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf

The researcher found that copay coupons correlated with faster branded price growth. Prices of branded drugs with coupons grow over 12 percent per year, while prices of branded drugs without coupons grow 7–8 percent per year.

- **Prescription Drug Coupons – No such Thing as a Free Lunch: J. Ross, MD & A. Kesselheim, MD, New England Journal of Medicine – Sept. 2013**

<https://www.nejm.org/doi/full/10.1056/NEJMp1301993?af%3DR%26rss%3DcurrentIssue=#t=article>

Many coupons for brand-name drugs are available in the US but since many are for medications for which lower-cost alternatives are available, this marketing practice threatens to increase societal costs in the long run.

- **How Copay Coupons Could Raise Prescription Drug Costs By \$32 Billion Over the Next Decade: Visante Analysis – Nov. 2011**

<https://www.pcmanet.org/wp-content/uploads/2016/08/visante-copay-coupon-study-nov-2011.pdf>

Analysis identifies copay coupons undermine employers' ability to use different copay amounts to reduce drug costs. Employer costs rise dramatically when enrollees choose expensive brands over more affordable options. Copay coupons will increase ten-year prescription drug costs by \$32 billion for employers, unions and other plans sponsors if current trends continue.



Reasons for Limiting Drug Coupon Use Supplied by Organizations

Caution must be used when drug coupons are distributed for patient use. Significant Department of Justice (DOJ) Health Care Fraud Recoveries have resulted over the past several years due to drug manufacturers illegal payments of patient copays and resultant False Claims Act (FCA) violations.

DOJ identified that a critical distinction with copay coupons is the manufacturers' ability to influence patient's choice of a specific drug. Coupons are a direct inducement to buy a specific product; a violation of the federal anti-kickback statute.

Further, manufacturers' donations to charities that cover part or all of an individual's copay are also in violation of the anti-kickback statute. Manufacturers are still, although indirectly, paying to drive which products are purchased

Copay Assistance Fraud – False Claims Act Recoveries:

Pharmaceutical manufacturer enforcements account for the highest healthcare recoveries:

- 2018: 2 drug manufacturers paid \$234 million to resolve illegal copay remuneration (Pfizer & United Therapeutics)
- 2019: 8 drug manufacturers paid \$646 million to resolve claims illegal copay remuneration (Actelion, Amgen, Astellas, Alexion, Biogen, Jazz, Lundbeck & US Worldmeds)
- 2020: 2 drug manufacturers paid \$148 million to resolve claims they illegal copay remunerations (Gilead & Novartis)

Charitable foundations and other healthcare providers were also implicit FCA violations by paying for patient copays for manufacturer specific drugs using the independent foundations as conduits for the illegal coupon remuneration:

- 2019: 4 charitable foundations paid \$13 million to resolve claims enabling pharmaceutical companies to provide a kickback by paying patient copays (Patient Services Inc., Chronic Disease Fund, Patient Access Network Foundation and The Assistance Fund).
- 2019: Advanced Care Scripts, a specialty pharmacy, paid \$1.4 million to resolve claims they acted as a vendor on behalf of pharmaceutical manufacturers to transfer patients to foundations that illegally paid for patient copays.

Michigan Shortcomings - State False Claims Act Recoveries:

Michigan needs to align with federal fraud false claims act provisions to capture the maximum allowable penalty recoveries. States can receive a 10% point increase in their share of any amount recovered under false claims law if state statute contains provisions that are "at least as effective in rewarding and facilitating qui tam actions" as those in federal FCA and must contain civil penalties at least equivalent to those imposed by the federal FCA.¹ A similar requirement is that a state's statute must provide for civil penalty increases "at the same rate and times as those under the federal FCA" pursuant to the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.² Michigan is one of 8 states that have not yet been deemed to meet federal standards.

¹ <https://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp>

² <https://www.federalregister.gov/documents/2016/06/27/2016-14973/federal-civil-penalties-inflation-adjustment-of-2015>



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



Special Advisory Bulletin

Pharmaceutical Manufacturer Copayment Coupons

September 2014

Pharmaceutical manufacturers offer copayment coupons to insured patients to reduce or eliminate the cost of their out-of-pocket copayments for specific brand-name drugs.¹ These coupons constitute remuneration offered to consumers to induce the purchase of specific items.

When the item in question is one for which payment may be made, in whole or in part, under a Federal health care program (including Medicare Part D), the anti-kickback statute is implicated. The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program. Section 1128B(b) of the Social Security Act (the Act).² Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated.

A claim that includes items or services resulting from a violation of the anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Section 1128B(g) of the Act.³ The False Claims Act imposes liability for knowingly presenting or causing to be presented a false claim for payment by the United States. 31 U.S.C. § 3729.⁴

¹ For purposes of this Special Advisory Bulletin, copayment coupons are any form of direct support offered by manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription medications. They include print coupons, electronic coupons, debit cards, and direct reimbursements, as described in OIG report entitled, *Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs*, OEI-05-12-00540 (OEI Report).

² 42 U.S.C § 1320a-7b(b). “Federal health care program” is defined at section 1128B(f) of the Act and includes programs such as Medicare and Medicaid. 42 U.S.C. § 1320a-7b(f).

³ 42 U.S.C. § 1320a-7b(g).

⁴ In addition, section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is

Cost-sharing requirements for Federal health care program drugs serve an important role in protecting both Federal health care programs and their beneficiaries. These cost-sharing requirements promote: (1) prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market. While copayment coupons provide an immediate financial benefit to beneficiaries, they ultimately can harm both Federal health care programs and their beneficiaries.⁵ The availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices. Excessive costs to Federal programs are among the harms that the anti-kickback statute is intended to prevent.

The pharmaceutical industry is aware of the anti-kickback statute and its application to copayment coupons. Copayment coupons typically bear a statement that the coupon may not be used by beneficiaries of Federal health care programs.

The Office of Inspector General, Office of Evaluation and Inspections (OEI), conducted a study analyzing the measures pharmaceutical manufacturers use to prevent their coupon programs from inducing the purchase of drugs paid for by Part D. We are issuing this Special Advisory Bulletin concurrently with the OEI Report.⁶

likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid) (the beneficiary inducement CMP). 42 U.S.C. § 1320a-7a(a)(5). In circumstances in which the offer or acceptance of copayment coupons may induce a beneficiary to use a particular practitioner or pharmacy, a violation of this statute may occur.

⁵ We recognize that copayment support may benefit beneficiaries by encouraging adherence to medication regimens, particularly when copayments are so high as to be unaffordable to many patients. Manufacturers that desire to assist Federal health care program beneficiaries who cannot afford their copayments have the option of donating to independent charities that provide financial support to patients without regard for the particular medication a patient may be using. For guidance specifically related to such charities, see OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 26, 2014) available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf> and OIG Special Advisory Bulletin on Patient Assistance Programs of Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf>.

⁶ Like the OEI report, this Special Advisory Bulletin focuses on the measures used by pharmaceutical manufacturers in connection with the copayment coupons they offer. However, pharmacies that accept manufacturer coupons for copayments owed by Federal health care program beneficiaries also may be subject to sanctions under the anti-kickback statute, the beneficiary inducement CMP, and the False Claims Act.

The OEI Report describes measures that surveyed manufacturers report they have in place to prevent use of copayment coupons to fund copayments for drugs paid for by Part D and concludes that these measures may not prevent all such use. It states that all manufacturers place notices on the coupons or coupon materials that Federal program beneficiaries are not eligible to use them, for at least some coupon formats. However, not all manufacturers use such notices on all coupon formats. In addition, while most manufacturers also use claims edits in the processing of at least some of their coupons, the OEI Report concludes that these claims edits may not reliably identify all claims submitted in connection with drugs paid for by Part D. The OEI Report also finds that coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers, which impedes Part D plans and others from identifying and monitoring the use of coupons for drugs paid for by Part D. The OEI Report recommends that the Centers for Medicare & Medicaid Services (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. These mechanisms include improving the reliability of claims edits and making copayment coupons universally identifiable in pharmacy claims transactions. Such transparency with respect to coupon use would permit all Federal health care program payors—not just the sponsors of Part D plans—to recognize coupon transactions.

Regardless of future actions by CMS, the offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the anti-kickback statute.

