



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

General Comments – Prescription Costs:

Prescription drug costs now account for 23% 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 a generic is available. The rule allow plans and employers to limit out-of-pocket expenses on prescription drugs 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: 2 drug manufacturers paid \$148 million to resolve claims they illegally used 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 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>



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:

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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.**

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The Hidden Costs Behind Prescription Drug Company Discounts

Coupons and charity keep list prices high, costing insurers and governments more

by Helaine Olen, [AARP \(http://www.aarp.org\)](http://www.aarp.org), April 30, 2019 | Comments: 12



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[En español \(/espanol/politica/derechos-activismo/info-2019/costo-oculto-descuentos-medicamentos-recetados.html?intcmp=AE-POL-TOESP-TOGL\)](/espanol/politica/derechos-activismo/info-2019/costo-oculto-descuentos-medicamentos-recetados.html?intcmp=AE-POL-TOESP-TOGL) | After [Pamela Holt, a retired teacher in Granger, Ind. \(/politics-society/advocacy/info-2019/prescription-drugs-holt-story.html\)](/politics-society/advocacy/info-2019/prescription-drugs-holt-story.html), was diagnosed with multiple myeloma in 2016, she was soon overwhelmed by the cost of her medications. The largest expense? A \$640-a-month copay for Celgene's Revlimid. Holt, who lives on Social Security and a pension, quickly found herself racking up thousands of dollars in credit card debt.

So Holt sought help from the pharmaceutical company. A Celgene employee directed her to the HealthWell Foundation, a non-profit group that administers a number of disease-specific medication assistance funds—including one for multiple myeloma—designed to help patients pay their pharmaceutical bills. Today, Holt, 70, pays nothing for Revlimid.

 [Stop Rx Greed Cut Drug Prices Now](https://action.aarp.org/site/Advocacy.jsessionid=00000000.app262b?cmd=display&page=UserAction&id=7577&pagename=homepage&NONCE_TOKEN=D9F9634417BEF95EE2E)

([https://action.aarp.org/site/Advocacy.jsessionid=00000000.app262b?](https://action.aarp.org/site/Advocacy.jsessionid=00000000.app262b?cmd=display&page=UserAction&id=7577&pagename=homepage&NONCE_TOKEN=D9F9634417BEF95EE2E)

[cmd=display&page=UserAction&id=7577&pagename=homepage&NONCE_TOKEN=D9F9634417BEF95EE2E](https://action.aarp.org/site/Advocacy.jsessionid=00000000.app262b?cmd=display&page=UserAction&id=7577&pagename=homepage&NONCE_TOKEN=D9F9634417BEF95EE2E)

Sounds wonderful, yes? But it's not so simple. Medicare — that is, taxpayers — still must pay the remainder of the drug's more than \$250,000 annual tab. Experts say the seemingly generous charitable aid that Holt receives is actually intended to reduce public pressure for drugmakers to lower their prices. It helps Holt and others like her, but at the cost of the nation's rising health care budget. "It's really just a racket," she says.

The same can be said for other discounts and help for consumers funded by pharmaceutical companies — for example, manufacturers' coupons for brand-name drugs with high sticker prices. While these can make brand-name drugs cheaper than generic equivalents for the patient, the health insurance company receives no such assistance, resulting in higher premiums and more cost-sharing for all its customers. In fact, a 2017 paper published in the *American Economic Journal* found that coupons increased spending on brand-name offerings by 60 percent.

 [pie chart showing profits made my drugmakers](#)

AARP/HEALTH AFFAIRS, JULY 2018

Sticking to expensive drugs

Adding insult to injury: A 2013 study in the *New England Journal of Medicine* found that when a coupon-based discount ends — and it almost always does — consumers often stick with the brand-name drug, rather than switch to a less expensive alternative. The reason is understandable: Patients are hesitant to experiment with a medication protocol that works for them. The coupons end up functioning like those for laundry detergent or cereal: They create brand awareness and loyalty, thus fueling sales. "These coupons inflate costs for everyone," says Jon Conradi, a spokesman for the Campaign for Sustainable Rx Pricing, an advocacy group. "Policy makers and patients shouldn't confuse an advertising play for any kind of solution to the crisis of rising prescription drug costs."

Charitable aid that manufacturers provide — not the same as the coupons — isn't a fix, either. Some pharmaceutical companies operate income-based discount programs, but these are voluntary efforts. Drug companies supply nearly all the money for disease-specific funds, like the one that helped Holt, but the demand from patients far exceeds the available cash.

More on Prescription Drug Prices

- [AARP is fighting for lower prescription drug prices \(/politics-society/advocacy/prescription-drugs/\)](#)