Drug Manufacturer Coupons in Medicare Part D

Brand drug manufacturers use coupons to increase sales of their drugs among those with prescription drug coverage, by making them insensitive to the drug's cost. Because manufacturers are basically paying patients to use their products, which increases their revenues, manufacturer coupons are banned in federal health care programs (including Medicare Part D) as illegal kickbacks under the federal Anti-Kickback Statute (AKS).

What are manufacturer coupons? Drug manufacturers offer cost-sharing coupons ("copay coupons") to insured patients, regardless of their incomes, to reduce or eliminate their out-of-pocket costs for specific brand-name drugs. Coupons induce patients to take a more expensive brand drug instead of a generic or other less expensive brand alternative that would have lower cost sharing without the coupon.[1,2,3]

- Manufacturers use coupon programs to retain or increase market share for their brand-name drugs once more affordable generics are available.
- These coupons undercut formularies and lead to unnecessary spending on brand-name drugs.[4]

Why should manufacturer coupons remain banned in Medicare Part D during the COVID-19 public health emergency? Even a temporary lifting of the Anti-kickback Statute guidance banning the use of coupons in Medicare during the COVID-19 public health emergency would have long-term implications.[5]

- **Beneficiaries on less affordable drugs:** Coupons are intended to encourage prescribers and patients to start on a more expensive brand drug.[6] Once a patient is on the brand, they are not likely to switch. But most coupons are not permanent discounts and would leave a Medicare beneficiary worse off once they are stabilized on a medicine that may quickly become unaffordable for them.
- **Higher 2021 Part D premiums:** Prescription Drug Plan bids for 2020 did not anticipate the potential application of coupons, or of their associated greater use of more expensive brand drugs. Building these extra costs in at the same time as plans are having to account for COVID-19 unknowns may further exacerbate concerns about increased Part D premiums in 2021.
- **Part D regulatory uncertainty:** There are many Part D regulatory issues that would have to be addressed, which would add a major burden on CMS regulators at a time when they already are overextended due to the COVID-19 pandemic.

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[1] U.S. Department of Health and Human Services Office of Inspector General, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons" (September 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.
[2] Visante, "How Copay Coupons Could Raise Prescription Drug Costs By $32 Billion Over the Next Decade" (November 2011), https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-07-14-12-visante-copay-coupon-study.pdf.
[3] Coupons are any form of direct support offered by manufacturers to insured patients to reduce or eliminate out-of-pocket costs for prescription medicines. They include print coupons, electronic coupons, debit cards, and direct reimbursements. *See* HHS OIG, "Manufacturer Safeguards May Not Prevent Copayment Use for Part D Drugs" (September 2014), https://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf.
[4] Leemore Dafny, Christopher Ody, and Matt Schmitt, "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization." American Economic Journal: Economic Policy 9, no. 2 (May 2017): 91-123, https://doi.org/10.1257/pol.20150588. *See also* NBER Working Paper No. 22745 (October 2016), https://www.nber.org/papers/w22745.pdf.
[5] "While [] coupons provide an immediate financial benefit to beneficiaries, they ultimately can harm both Federal health care programs and their beneficiaries." *See* HHS OIG (September 2014).
[6] Research published in the *New England Journal of Medicine* found that 62% of manufacturer coupons were for brand-name medicines with lower-cost therapeutic alternatives *See* J.S. Ross and A.S Kesselheim, "Prescription-Drug Coupons—No Such Thing as a Free Lunch," New England Journal of Medicine 369 (September 2013):1188-1189.

- **Higher Medicare program costs:** With the Medicare trust fund estimated to run out in 2026[7]—a pace that could be quickened under different economic conditions[8]— the long-term costs to the Medicare program of this induced brand loyalty *after the COVID-19 pandemic* could be considerable.
    - Depending on how the coupon amount is treated for purposes of the true out-of-pocket costs (TrOOP), beneficiaries may advance more quickly through to catastrophic coverage—where the Medicare program pays 80% of total drug costs.
    - If the ban was not enforced, costs to the Part D program are estimated to increase by $2 billion for 2020 and $48 billion over the next 10-year period (2021-30).[9]
    - The Congressional Budget Office has estimated that Medicare pays an extra $76 each time a beneficiary chooses a brand over a generic in key therapeutic classes.[10]
- **A smaller generic marketplace:** The use of manufacturer coupons in Medicare Part D – a major insurer for prescription drugs – could undermine competition between generics and brands by reducing the market for generics and, thereby, the incentive for manufacturers to develop generics. [11]

What is the fiscal impact of manufacturer coupons?

- **A study published in the *American Economic Journal* estimates manufacturer coupons increased prescription drug spending by up to 4.6%,** with each 1% increase representing approximately $1.5 billion in higher drug spending annually.[12] Coupons increase total spending by $30 to $120 million per coupon-related drug per year (in 2010 dollars).
- **Coupons are, at their core, a marketing tool designed to increase sales.** For every $1 million in manufacturer coupon contributions, manufacturers reap an estimated $20+ million in profits.[13] Lifting the coupon ban in Medicare will only realize higher profits for manufacturers at a time when the U.S. economy is contracting.[14]

PCMA supports policies that help promote access to affordable prescription drug coverage during the COVID-19 pandemic, including for individuals at risk of losing coverage. In contrast to Medicare beneficiaries, who retain access to prescription drug coverage during this pandemic, 9.2 million workers were at risk of losing access to employer-provided health insurance in the past four weeks.[15] PCMA supports proposals that would maintain, expand, and stabilize health insurance coverage, including for individuals temporarily out of work as a result of the COVID-19 pandemic.

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[7] Board of Trustees, Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds, "2020 Annual Report" (April 22, 2020), https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.
[8] Daniel Di Martino, MarketWatch, "Opinion: Coronavirus may deal the final blow to Social Security and Medicare" (April 28, 2020), https://www.marketwatch.com/story/coronavirus-may-deal-the-final-blow-to-social-security-and-medicare-2020-04-28.
[9] Visante, "Drug Manufacturer Coupons Raise Costs in Medicare Part D, Hurting Vulnerable Beneficiaries" (May 2020).
[10] Congressional Budget Office, "Effects of Using Generic Drugs on Medicare's Prescription Drug Spending" (September 2010).
[11] "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 price." *See* HHS OIG (September 2014).
[12] Dafny et al. (2017).
[13] Ibid.
[14] Sylvan Lane, The Hill, "US economy contracts at 4.8 percent rate, most since Great Recession" (April 29, 2020), https://thehill.com/policy/finance/495196-us-economy-shrank-at-48-percent-annualized-rate-in-first-quarter-amid.
[15] Ben Zipperer and Josh Bivens, Economics Policy Institute, "9.2 million workers likely lost their employer-provided health insurance in the past four weeks," *Working Economics Blog* (April 16, 2020), https://www.epi.org/blog/9-2-million-workers-likely-lost-their-employer-provided-health-insurance-in-the-past-four-weeks/.