

OIG Anti-Kickback Safe Harbors Law Revision: Fact Sheet for Pharmacies

On December 7th, 2016, the Office of Inspector General (OIG) of the Department of Health and Human Services published a final rule to update existing and add new safe harbor regulations to apply protections and further facilitate federal health care program beneficiaries' access to care (Unless otherwise stated, federal health care programs include, but are not limited to: Medicare, Medicaid, and TRICARE but excludes the Federal Employees Health Benefits Program). The regulation is applicable to pharmacy and affects pharmacies who serve various federal health care program beneficiaries. The Final Rule went into effect January 6th, 2017 but some provisions may not take effect until 2018.

Frequently Asked Questions

Q: Can pharmacies waive or reduce a Medicare Part D beneficiary's co-pay?

- A: A pharmacy may waive or reduce a federal health care program beneficiary's co-pay if all the following requirements are met:
1. The waiver or reduction is **not advertised** or part of a solicitation
 2. The pharmacy does **not routinely** waive or reduce the cost-sharing obligation for that beneficiary; and
 3. Before waiving a co-pay, the pharmacy fails to collect the cost-sharing amount after reasonable effort or determines in good faith that the beneficiary has a financial need
 - If the waiver or reduction is made on behalf of a subsidy-eligible beneficiary, then only the first criterion is applicable because these individuals already satisfy financial need and eligibility criteria for purposes of subsidy of their Part D premiums

Q: What are the pharmacies' responsibilities and liabilities for reporting the waiver since contracts say co-pays cannot be waived and are subject to fraud, waste, and abuse claims if the patients' true out-of-pocket is reported incorrectly via their transmitted claim?

- A: Pharmacies should work with contracting organizations and their significant Medicare Part D plan payors to confirm the situations in which co-pays can be waived and not be considered in violation of contract terms and breach of contract. In addition, pharmacies should document evidence that all the co-pay waiver requirements are met including financial need or hardship.

*Q: In **2018**, can MEDICARE PART D PLAN SPONSORS waive co-pays for first fills for Medicare Part D recipients?*

A: **Beginning January 1, 2018**, Medicare Part D plan sponsors and Medicare Advantage plans may choose to waive the co-pay for the first fill of a covered generic drug if the sponsor discloses such waivers in its benefit design packet submitted to the Centers for Medicare & Medicaid Services.

This applies to Medicare Part D and Medicare Advantage plans only and does not become effective until January 1, 2018.

Q: Can pharmacies offer rewards programs to federal health care program beneficiaries?

A: The final rule allows for the transfer of items or services for free or less than fair market value for beneficiaries of all federal health care plans if all the following requirements are met:

1. The items or services consist of coupons, rebates, or other rewards from a retailer such as coupons to transfer prescriptions, gasoline, or store merchandise.
2. The items or services are offered or transferred on equal terms available to the public (all pharmacy customers), regardless of health insurance status; and
3. The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by a federal health care program including Medicare and Medicaid.

Q: Are there any limits to the rewards that can be offered?

A: There is no monetary value limit to the rewards that can be offered. However, the OIG also concurrently updated its 2010 policy statement on gifts of nominal value. Adjusted for inflation, gifts other than cash or cash equivalents such as store merchandise valued at no more than \$15 per item or \$75 aggregated annually are now permitted (an increase from \$10 and \$50 respectively). Therefore, items or services obtained through a pharmacy rewards program are not limited by the OIG's gift policy and gifts permitted outside of a rewards program are subject to the monetary value limits previously stated.