

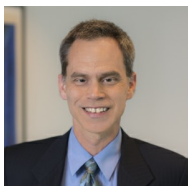
A new anti-kickback safe harbor that takes effect January 6, 2017, will allow pharmacies to waive or reduce copayment, coinsurance, and deductible (cost-sharing) obligations of financially needy Medicare and Medicaid beneficiaries without triggering potential exposure under the federal anti-kickback statute.

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) recently issued a final rule establishing new anti-kickback safe harbors for certain (i) waivers and reductions by pharmacies or ambulance providers of patient cost-sharing obligations, (ii) remuneration between Medicare Advantage organizations and federally qualified health centers (FQHCs), (iii) Medicare coverage gap drug discounts, and (iv) free or discounted local transportation.

The new safe harbor for pharmacy cost-sharing waivers will protect pharmacy waivers or reductions of a Federal health care program beneficiary's cost-sharing obligations on an unadvertised, non-routine basis after either an individualized determination of financial need or reasonable collection efforts. With respect to a Part D subsidy-eligible individual, a pharmacy can fit into the safe harbor without making an individualized determination or reasonable collection efforts. The safe harbor will not extend to any waiver or reduction that is offered as part of an advertisement or solicitation.

In its commentary, the OIG declined to impose specific guidelines for determining financial need, but emphasized that financial need must be determined on a good faith, individualized basis by uniformly applying reasonable guidelines in accordance with objective criteria appropriate for the geographic area. Furthermore, the OIG expects pharmacies to follow written policies and to take reasonable steps to verify an individual's financial resources before waiving or reducing the individual's cost-sharing obligations.

To learn more about the new anti-kickback safe harbors, contact the attorney listed below.



RICK HINDMAND

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