

Health Care Alert

## Proposed Rule Issued by OIG Realigns Its Enforcement Views with Health Care Reform Goals

10.09.2014

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Fridays never seem to be slow in the health care regulatory world. On Friday, October 3rd, the [HHS Office of the Inspector General](#) (OIG) issued a highly anticipated [proposed rule](#) (the Proposed Rule) that provides amendments to the Anti-Kickback Statute's regulatory safe harbors (AKS Safe Harbors) and adds protections for increasingly common payment practices and business arrangements under the Civil Monetary Penalty Law (CMP). These amendments and updates to the AKS and CMP regulations attempt to clarify the OIG's enforcement position in light of changes due to health reforms, to streamline the OIG's advisory opinion workload, and to implement long-existing mandates enacted in statutes.

### New and Modified AKS Safe Harbors

The OIG's Proposed Rule with respect to the AKS Safe Harbors makes additions and modifications related to the following five business practices and arrangements:

1. **Referral Services.** As a "technical correction," the proposed AKS Safe Harbor will revert to the language of the 1999 final rule, which prohibited payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, "either party for the other party," rather than "business generated by either party for the referral service." Thus, the nexus for negating this AKS Safe Harbor's protection is generating a direct benefit to another participant in the referral service, rather than the referral service itself.
2. **Low-Risk Cost-Sharing Waivers.** The OIG proposes additional provisions to protect certain "cost-sharing waivers that pose a low risk of harm" to allow for Part D cost-sharing waivers by pharmacies (the Part D Waiver) and for emergency ambulance services (the Ambulance Waiver).
  - o **Part D Safe Harbor** – The Part D Waiver implements the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) addition of subparagraph (G) to [Section 1128B\(b\)\(3\)](#) of the Social Security Act (the Act). In the proposed new 42 C.F.R. § 1001.952(k)(3), a pharmacy that waives Part D cost-sharing amounts for patients must meet the following three criteria to receive protection:
    - The waiver or reduction is not advertised or part of a solicitation;
    - The pharmacy does not engage in routine waiver of cost-sharing amounts;
    - The pharmacy determines "in good faith that the beneficiary has a financial need or fails to collect the cost-sharing amount after making a reasonable effort to do so."

The pharmacy must only meet the first criterion if it waives cost-sharing amounts for a Part D beneficiary eligible for subsidies under Section 1860D-14(a)(3) of the Act.



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- **Ambulance Safe Harbor** – The OIG’s proposed new Ambulance Safe Harbor is an attempt to reduce the amount of “advisory opinion requests concerning the reduction or waiver of coinsurance or deductible amounts owed for emergency ambulance services to an ambulance supplier that is owned and operated by a State or a political subdivision [thereof].” Seven out of the last 26 advisory opinions issued in 2013-2014 dealt with these arrangements. In its proposed new 42 C.F.R. § 1001.952(k)(4), the OIG sets out ownership, contracting, and Medicare Part B participation requirements, as well as criteria regarding the extent to which the state or political entity may pay for such emergency ambulance services. The state must implement the cost-sharing uniformly for all patients and may not claim these amounts as bad debt for payment purposes under Medicare or a state health care program or otherwise shift these costs to public or private payers. The OIG is also seeking comment on whether other Federal health care program cost-sharing waivers should be included in this new AKS Safe Harbor.

3. **Federally Qualified Health Centers (FQHCs) and Medicare Advantage Organizations (MAOs).** The Proposed Rule also implements Section 237 of the MMA, which imposes an “anti-swapping” prohibition that requires agreements between MAOs and FQHCs to mandate that the MAO pay the FQHC “no less than the level and amount of payment that the plan would make for the same services if the services were furnished by another type of entity.” The Proposed Rule also incorporates the AKS statutory exception at Section 1128(B)(b)(3)(H) of the Act that allows Medicare Advantage (MA) beneficiaries to receive services at a FQHC that has a written agreement with the beneficiary’s MA Plan into a new 42 C.F.R. § 1001.952(z).
4. **Medicare Coverage Gap Discount Program.** The Proposed Rule implements the new exception to the AKS from the Medicare Coverage Gap Discount Program (Discount Program) established by Section 3301 of the Affordable Care Act (ACA) in new proposed 42 C.F.R. S 1001.952(aa). The new exception defines “applicable drugs” and “applicable beneficiaries” to which the AKS Safe Harbors would apply.
5. **Transportation Waivers.** The OIG proposes an AKS Safe Harbor “for free or discounted local transportation made available to established patients . . . to obtain medically necessary items and services.” The Proposed Rule solicits comments on the proposed criteria for this AKS Safe Harbor, including those regarding the advertisement and referral of such transportation services, permissible modes of transportation, the types of patients to whom such services are offered, and the maintenance of beneficiary eligibility criteria regarding service areas and financial need.

## Beneficiary Inducement Amendments

The beneficiary inducement provisions of the [CMP](#) prohibit any person from offering inducements to Medicare or Medicaid beneficiaries that the offeror knows or should know are likely to influence the selection of particular providers, practitioners, or suppliers. The Proposed Rule would amend the definition of “remuneration” in the [CMP regulations](#) by codifying certain statutory exceptions:

1. **Copayment Reductions for Certain Hospital Outpatient Department (OPD) Services.** As part of the [Balanced Budget Act](#) of 1997 (BBA), Congress exempted from prosecution under the CMP arrangements involving a reduction in the copayment amount for hospital covered OPD services. The OIG proposes to adopt language identical to the statutory exception language.
2. **Remuneration that Promotes Access to Care and Poses a Low Risk of Harm.** As part of the [Affordable Care Act](#) (ACA), Congress enacted an exception that permits any remuneration that “promotes access to care and poses a low risk of harm to patients and Federal health care programs.” Although the Proposed Rule does not contain any regulatory text implementing this exception, the OIG does propose specific definitions for “promotes access to care” and “low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs.” The

OIG proposes that the phrase “promotes access to care” be defined to mean that “the remuneration provided improves a particular beneficiary’s ability to obtain medically necessary health care items and services.” The OIG further proposes that the phrase “low risk of harm” mean that the remuneration (1) “is unlikely to interfere with, or skew, clinical decision-making,” (2) “is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization,” and (3) “does not raise patient-safety or quality-of-care concerns.” The OIG is explicitly soliciting comments on the potential expansion of both of these definitions to cover more types of remuneration that could be beneficial to patients and decrease costs of providing health care services to beneficiaries. Of note, the Proposed Rule expressly reiterates the OIG’s long-standing concern that rewards offered by providers or suppliers to patients who comply with a treatment regimen pose a risk of abuse when the rewards are likely to influence the recipients to order or receive items or services from a particular source. But the OIG also recognizes that such programs can promote health and wellness as well as encourage patients to engage in arrangements that lower health care costs. To that end, the OIG is soliciting comments on whether incentives for compliance with treatment regimens should be explicitly permitted under this exception and, if so, what limitations or safeguards should be put in place.

3. **Coupons, Rebates, and Other Retailer Reward Programs.** The OIG also proposes to codify the ACA exception permitting retailers to offer or transfer coupons, rebates, or other rewards (including store merchandise, gasoline, or frequent flyer miles) for free or less than fair market value if the items or services are available on equal terms to the general public and are not tied to the provision of other items or services reimbursed in whole or in part by Medicare or Medicaid. The OIG notes that “this new exception should increase retailers’ willingness to include Federal health care program beneficiaries in their reward programs in appropriate circumstances,” but the OIG offers somewhat confusing guidance on what the appropriate circumstances would be. For example, the OIG states that “a drugstore program that offered a \$20 coupon to customers, including Medicare beneficiaries, who transferred their prescriptions to the drugstore would not meet the [exception] because the \$20 coupon would be tied to the drugstore’s getting the recipients’ Medicare Part D prescription drug business.” However, “a program that awarded a \$20 coupon once a customer spent \$1,000 out-of-pocket in the store — even if a portion of that \$1,000 included copayments for prescription drugs — would likely meet the [exception].” Although the Proposed Rule explicitly excludes from protection reward programs in which the rewards themselves are items or services reimbursed in whole or in part by a Federal health care program, the example provided by the OIG indicates that rewards can be redeemed on customer’s out-of-pocket costs for federally reimbursable items as long as the rewards can also be redeemed for anything else purchased in the store.
4. **Financial-Need-Based Exception.** The third ACA exception that would be codified in the Proposed Rule permits the offer or transfer of items or services for free or less than fair market value if there is a good faith determination of the individual’s financial need, the items or services are not advertised, the offer is not tied to the provision of other items or services reimbursed by Medicare or Medicaid, and there is a “reasonable connection” between the items or services being offered and the medical needs of the individual. The OIG notes that a “reasonable connection exists from a medical perspective when the items or services would benefit or advance identifiable medical care or treatment that the individual patient is receiving.” The OIG is soliciting comments on the boundaries of a “reasonable connection” for purposes of this exception.
5. **Waivers of Cost-Sharing for the First Fill of a Generic Drug.** The final ACA exception permits Part D and MA-PD plan sponsors to waive enrollee copayments for the first fill of a generic covered Part D drug. The OIG proposes to rely on the definition of “generic drug” set forth in the Part D regulations. Additionally, the Proposed Rule would require sponsors to disclose this incentive program in their benefit plan package submissions to CMS.

Nearly 20 years after it abandoned its last attempt at formal rulemaking in December 1994 ([1994 Proposal](#)) and over 15 years after publishing the [Special Advisory Bulletin](#) on “Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries” in 1999 as a stopgap, OIG attempts to address a long-standing dilemma regarding the Gainsharing CMP in the Proposed Rule. Given that the Gainsharing CMP is a self-implementing law that explicitly “prohibits hospitals and critical access hospitals from knowingly paying a physician to induce the physician to reduce or limit services to Medicare or Medicaid beneficiaries who are under the physician’s direct care,” the OIG has no authority to create an exception to the Gainsharing CMP, even to limit the prohibition to limiting services that are not “medically necessary.” However, the OIG seeks comments on its proposal to narrow its interpretation of “reduce or limit services” to better align the statute with current health care reform goals. The OIG is particularly interested in comments on the following four aspects that would inform whether it should issue definitions of this key phrase of the statute:

1. Whether the prohibition of payments to reduce or limit services requires the OIG to also prohibit the reduction or limit of items used in providing such services;
2. Whether a hospital’s decision to standardize certain items or rely on clinical protocols based on objective quality metrics amounts to reducing or limiting care for patients;
3. Whether permissible standardizing of such items or processes should require hospitals to “establish certain thresholds based on historical experience or other clinical protocols, beyond which participating physicians could not share in cost savings;” and
4. Whether the OIG should include a requirement that the parties participating in a gainsharing arrangement disclose it to patients as a *per se* criteria that the arrangement is for legitimate purposes allowed by the statute.

The OIG is also proposing to add a definition of “hospital” to proposed section 42 C.F.R. § 1003.110 (which is currently § 1003.101). Otherwise, the proposed rule mostly reflects the same language as used in the 1994 Proposal, which essentially codifies the statute.

Although Congress has not amended the statute since its enactment, the OIG now acknowledges that “[h]ealth care payment and delivery systems are changing, with greater emphasis on accountability for providing high quality care at lower costs,” which is evidenced by Congress’s authorization of programs that essentially endorse gainsharing as a mechanism to lower health care costs (e.g., the [Medicare Shared Savings Program](#) and the [Medicare Hospital Gainsharing Demonstration](#)). But given that the OIG has never pursued a Gainsharing CMP case and has, in fact, approved 16 gainsharing arrangements through its [advisory opinions](#), the proposed reinterpretation of the Gainsharing CMP language is long in coming. Unfortunately, the OIG is continuing to rely heavily on the 1994 Proposal as a starting point for the Proposed Rule, which shows that the OIG’s position on gainsharing arrangements has not evolved significantly. Rather than only requesting stakeholder input to inform its future enforcement approach, the OIG could have been more helpful by proposing actual regulation text. Thus, stakeholders should consider focusing their comments on whether the Proposed Rule on gainsharing provides sufficient clarity for practical implementation.

## Conclusion

The OIG is accepting comments on the Proposed Rule until December 2, 2014. This proposed rulemaking represents an attempt by the OIG to adapt its fraud and abuse enforcement position in light of broader health care reform initiatives and demonstrates how difficult it is to balance the broad prohibitions in the law with actual business practices and the particular needs of patients. Health care providers and industry stakeholders involved in creating patient incentive programs, care coordination arrangements, or gainsharing arrangements with hospitals should be especially interested in providing comments to the Proposed Rule and may have an invaluable opportunity to influence the outcome of this rulemaking.

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**If you have any questions about this topic, please contact the author(s) or your principal Mintz Levin attorney.**

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4340-1014-NAT-HL