

## PHARMACY FRAUD AND ABUSE: OPERATIONALIZING THE NEW OIG FINAL RULE IN AN INTEGRATED CARE ENVIRONMENT

The role of pharmacists and pharmacies as integral cogs in the patient care continuum continues to grow, thanks in no small part to incentives encouraging integrated and coordinated care designed to enable improved outcomes at lower cost. From Medicare bundled payment initiatives that include drug costs to third party payor reimbursement reductions driven by pharmacy benefit manager ("PBM") consolidation, the role that pharmacies play in achieving efficiencies in the patient care continuum has never been more prominent. This challenging environment has led many pharmacies to implement creative programs that, in many cases, can implicate what are commonly referred to as "Fraud and Abuse" laws including the federal Anti-Kickback Statute ("AKS") and Civil Monetary Penalties law ("CMP"). Failing to comply with these laws can result in significant civil and, in certain circumstances, criminal penalties. As more and more drugs in the pipeline move to oral administration routes, these issues will only increase in prominence.

On December 7, 2016, the Department of Health and Human Services Office of Inspector General ("OIG") released a final rule ("Final Rule") implementing and updating regulations and providing additional background regarding new AKS safe harbors and CMP beneficiary inducement exceptions that implicate many current pharmacy activities and practice models. We previously provided high-level overviews of these new [AKS safe harbors](#) and the new [CMP exceptions](#) outlined in the Final Rule. Here, we provide a more detailed discussion of those Final Rule provisions as they relate specifically to pharmacy stakeholders and their related entities.

We first address the AKS safe harbors governing the inducement of referrals (i.e., cost-sharing waivers, Medicare coverage gap discount programs, free or subsidized transportation services and referral service programs). Then, we address the CMP exceptions governing beneficiary inducements (i.e., first-fill generic cost sharing waivers for Part D beneficiaries and retailer rewards programs).

### AKS SAFE HARBORS

The AKS makes it a criminal offense to knowingly and willfully offer or receive remuneration in an effort to induce or reward referrals of items or services reimbursable by federal health care programs. However, conduct that meets all elements of an AKS safe harbor is not subject to sanctions under the AKS. The Final Rule creates five new AKS safe harbors and makes a technical correction to an existing safe harbor for referral services. Below, we discuss three of the new AKS safe harbors and a technical correction to the referral safe harbor that will likely have the most significant impact on pharmacy operations.

*Pharmacy Cost-Sharing Waivers.* *OIG updated the Waiver of Beneficiary Copayment, Coinsurance and Deductible Amounts Safe Harbor<sup>1</sup> to provide for protection to pharmacies for waiving financially needy beneficiaries' coinsurance, copayment or deductible payments for drugs that are covered under a federal health care program. Notably, OIG notes that this includes Parts D and B and, further, that the safe harbor does not protect waivers by physicians for copayments due for Part B drugs.*

In implementing these waivers in the pharmacy setting, an ounce of prevention is definitely worth a pound of cure. For example, in order to meet all of the elements of the safe harbor to ensure protection, a pharmacy should consider all sources of payment. These sources include more than simply those available from the patient at the point of sale. Among others, they might include bundled payments from a particular Medicare demonstration program or a patient assistance program ("PAP").

Nevertheless, it is clear that the expansion of this safe harbor presents new opportunities for pharmacies seeking to assist financially needy patients. As a result, pharmacies should carefully evaluate and establish policies and procedures that affirmatively comply with the expanded safe harbor elements. In evaluating or establishing such policies, pharmacies should consider:

- Developing financial aid policies which establish patient financial aid eligibility thresholds. In the institutional pharmacy setting (e.g., hospital pharmacies), pharmacies should be careful to ensure that these policies do not conflict with established system policies which themselves likely govern financial assistance eligibility and/or cost-sharing standards. Among other standards (e.g., tax-exemption standards, Federally Qualified Health Center sliding fee schedule requirements), pharmacies should review other applicable guidance, including previous OIG guidance on financial need.<sup>2</sup>

- Reviewing OIG's guidance regarding routine waivers of cost-sharing obligations to establish appropriate protocols for waivers.<sup>3</sup>
- Reviewing applicable state law for any prohibitions on cost-sharing and waivers, including any prohibition that may exist in the state's anti-kickback, pharmacy and/or insurance statutes or regulations.

Medicare Coverage Gap Discount Programs. The Medicare Coverage Gap Discount Program discounts Part D covered drugs for beneficiaries while they are in the Part D coverage gap or "donut hole." The new AKS safe harbor established in the Final Rule protects and more clearly allows for drug manufacturer discounts on drugs to be offered at the point of sale to beneficiaries in the Medicare Coverage Gap Discount Program, provided manufacturers comply with the safe harbor elements. This development promises to expand the scope of PAPs accessed at the point of sale, the use of which are subject to a series of OIG advisory opinions and are often funded directly or indirectly by manufacturers.

More specifically, to safeguard these drug discounts and to give better guidance to providers, the safe harbor allows for discounts provided to "applicable beneficiaries" for "applicable drugs" of a manufacturer. An applicable beneficiary is a Part D enrollee that does not receive income-related subsidies under the Social Security Act, has reached or exceeded their initial coverage limit and has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold. An applicable drug must be an FDA-approved drug or biologic and be available to the beneficiary through the beneficiary's Medicare prescription drug plan.

Provided that a manufacturer participates in and complies in all material respects with the requirements of the Medicare Coverage Gap Discount Program Safe Harbor, the discounts offered to beneficiaries on applicable drugs will be permissible and not viewed as in violation of the AKS. Notably, in the Final Rule, OIG relaxed its earlier proposal that drug manufacturers must be in "full" compliance with all requirements of the Medicare Coverage Gap Discount Program to receive the full benefits of the safe harbor. Rather, OIG noted that minor, technical or temporary noncompliance with program requirements should not preclude safe harbor protection. Willful noncompliance, however, would still implicate the law.

In adjudicating Part D drugs at the point of sale, pharmacies should be aware of the types of discounts that beneficiaries may receive under the Medicare Coverage Gap Discount Program and make note of how discounts may impact operations in billing or other areas of recordkeeping. Pharmacies should further ensure that any contracts with manufacturers or PAPs contemplate adherence to the safe harbor requirements.

Free or Subsidized Local Transportation Services. The new Local Transportation Safe Harbor<sup>4</sup> protects the provision of local or shuttle transportation (excluding ambulance, luxury and air transportation) provided to existing patients by "eligible entities" for the purpose of obtaining medically necessary services. OIG defines an eligible entity as any individual or entity, except individuals or entities (or family members or others acting on their behalf) that primarily supply health care items (including, but not limited to, durable medical equipment ("DME") suppliers or pharmaceutical companies).

It is important to focus on the fact that the Final Rule commentary specifically details OIG's position regarding the provision of such transportation by pharmacies as follows.

- Standalone/Retail Pharmacies. OIG states in the Final Rule that "[p]harmacies... primarily provide items and thus would be excluded from the definition" and that OIG excluded suppliers of items (including pharmacies) since they "generally do not play a role in ensuring that patients have access to other providers and suppliers." In response to comments disputing OIG's perception of the role that pharmacies play in the patient care continuum, OIG notes that it believes allowing suppliers such as pharmacies that "primarily supply health care items to offer transportation to patients presents a heightened risk of using such transportation to generate referrals, potentially in a way that increases costs to patients and Federal health care programs." As a result, standalone and retail pharmacies are likely ineligible for protection under the safe harbor.
- Institutional Pharmacies. Institutional pharmacies should be careful to consider the Fraud and Abuse implications of any transportation programs. While OIG did clarify that entities that primarily provide services but also provide items are still eligible for protection under this safe harbor, whether or not an institutional pharmacy is part of an entity is a fact-specific analysis that depends in part on corporate structure and licensure/enrollment status. A hospital with an on-site pharmacy, for example, might, in certain circumstances, be able to offer transportation to its established patients to its own location for items or services provided by the entity (such as obtaining items at

the hospital's on-site pharmacy). In other circumstances, restrictions could apply.

Each pharmacy should review the safe harbor and OIG's accompanying commentary to assess whether it meets the criteria of an "eligible entity" under the safe harbor. If the pharmacy is an eligible entity, then the pharmacy should coordinate with its accompanying institution on the provision of any free or discounted transportation services to its existing patients. Similar to pharmacy cost-sharing waivers, such pharmacies will need to consider developing financial aid policies that both establish patient financial aid eligibility requirements and align/coordinate with established system policies addressing financial aid eligibility.

*Technical Correction to the Referral Services Safe Harbor.* OIG included a technical correction to the Referral Services Safe Harbor<sup>5</sup> to clarify that the payment for referral services cannot take into account business generated for which payment is available from a federal health care program. OIG indicated it had inadvertently updated the language in previous issuances to refer to all business generated between the parties. To be clear, though, pharmacies and other interested parties should carefully consider the structure of any referral arrangements for compliance with all state and federal laws, which may or may not permit certain arrangements with non-government payors.

Regarding pharmacies in particular, collaborations with manufacturers to offer PAPs that include "hub transfers" or "warm transfers" of patients to a manufacturer's PAPs should evaluate such arrangements for compliance under the Referral Services Safe Harbor. Pharmacies and manufacturers could each be deemed a potential referral source for the other, and any arrangement that might be viewed as under the rubric of a referral arrangement could implicate AKS restrictions. While OIG has historically approved of PAPs, arrangements between pharmacies and manufacturers for patient transfers to the manufacturer's PAPs often include a fair market value fee for the cost of the services provided. As a result, these arrangements should be structured to comply with the Referral Services Safe Harbor to mitigate the risk that such patient transfers from pharmacies to manufacturers are viewed as inappropriate by OIG.

## **NEW CMP EXCEPTIONS**

The CMP provides for penalties against anyone who offers or transfers remuneration to a Medicare or Medicaid beneficiary that the provider knows or should know is likely to influence the beneficiary's selection of a provider or supplier of any item or service that will be paid, in whole or in part, by federal health care programs. The Final Rule implements four new exceptions to the CMP established by the ACA. We discuss below two of the CMP exceptions of particular interest to pharmacy stakeholders.

*Cost-Sharing Waivers for the First Fill of a Generic Drug for Medicare Part D Beneficiaries.* OIG finalized a statutory exception to the definition of "remuneration" under the CMP by establishing that a waiver of copayments owed by certain beneficiaries for the first fill of certain prescription drugs does not constitute remuneration to a beneficiary.<sup>6</sup> Specifically, under the exception, Part D Plan sponsors and Medicare Advantage Organizations offering MA-PD plans ("Plans") may waive enrollee copayments for the first fill of a covered Part D generic drug starting in coverage year 2018 without violating the CMP.

Plans intending to offer copayment waivers under the exception must disclose the incentives to CMS in their benefit design package. Because OIG does not have a role in setting Plan reimbursement to pharmacies, Plans are free to negotiate reimbursement terms with their network pharmacy providers. As a result, pharmacies should assess the financial and administrative terms offered by Plans with regard to copayment waivers and confirm that the agreement language appropriately apportions responsibility regarding compliance with these CMP exception terms.

*Retailer Rewards Programs.* Next, OIG provided welcome additional guidance to retail pharmacies operating or otherwise affected by store rewards programs when it finalized an exception to the CMP permitting certain programs offered by retailers.

Under this exception, a "retailer" may offer items or services to federal health care program beneficiaries for free or less than fair market value if: (i) the rewards consist of coupons, rebates or other rewards from the retailer; (ii) the rewards are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (iii) the offer or transfer of the rewards is not tied to the provision of other items or services reimbursed in whole or in part by federal health care programs.<sup>7</sup>

OIG defines a "retailer" as an entity that sells items directly to consumers. As a result, rewards programs offered by pharmacy stakeholders that sell consumer items - including retail, independent and community pharmacies, hospital convenience stores and hospital retail pharmacies - will qualify for the retailer rewards exception provided the other criteria are met. Entities that primarily provide services (such as physicians and hospitals) and entities that do not sell items directly to consumers (such as pharmaceutical manufacturers and PBMs) are

not considered retailers, and are therefore ineligible for the retailer rewards exception.

The exception permits retailers to offer free or reduced-priced items or services as rewards to customers, provided the reward is offered to everyone regardless of health insurance status, is not conditioned on the purchase of goods or services reimbursed by federal health care programs and is not itself an item or service reimbursed by federal health care programs. OIG notes that permissible rewards might include a pharmacy offering gasoline discounts, frequent flyer miles, free toys or educational items, grocery coupons or gift cards that can be used on anything in the pharmacy's store.

OIG further notes that examples of impermissible rewards include prescription copayment waivers or discounts, coupons or rewards offered only when a patient transfers or fills a prescription at a pharmacy and discounts offered on prescriptions or medical devices. Moreover, a pharmacy may not have a rewards program that offers more rewards or credit to a customer that spends money on prescription copayments compared to other store items (e.g., when a customer earns two points for each dollar spent on a prescription copayments but one point for a dollar spent elsewhere in the store).

The retailer rewards exception to the CMP offers pharmacies increased flexibility and additional options to offer incentives and rewards to patients. Nevertheless, while OIG notes that it does not intend to "prohibit a retailer from having an enrollment process," OIG does not detail what a permissible rewards program enrollment process may or may not include. As such, retailers should carefully consider the enrollment criteria associated with any rewards program, including any OIG advisory opinions that might be released subsequent to the Final Rule.

## **PRACTICAL TAKEAWAYS**

The Final Rule offers much needed clarification in a variety of areas that directly impact retail and institutional pharmacy operations in the patient care continuum as the role of these pharmacies increases. The Final Rule also serves to highlight the AKS and CMP risks associated with pharmacy operations where such risks have traditionally been a significant focus for institutional providers like hospitals and physician group practices. Going forward, pharmacies will want to revisit their policies and procedures to ensure compliance with the Final Rule while simultaneously assessing whether new opportunities might exist to share in savings and expand access to care by functioning more as a care coordination partner than as a standalone point of contact for patients.

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<sup>1</sup> 42 C.F.R. § 1001.952(k)(3).

<sup>2</sup> 65 FR 24400 (Apr. 26, 2000), available [here](#).

<sup>3</sup> Special Fraud Alert, 59 FR 65372 (Dec. 19, 1994), available [here](#).

<sup>4</sup> 42 C.F.R. § 1001.952(bb)

<sup>5</sup> 42 C.F.R. § 1001.952(f).

<sup>6</sup> 42 C.F.R. § 1003.110.

<sup>7</sup> 42 C.F.R. § 1003.110(7).

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