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Client Alert

FDA & Life Sciences Practice Group

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OIG Issues Final Rule Expanding Anti-Kickback Statute Safe Harbors and Revising Civil Monetary Penalty Regulations

On December 7, 2016, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) published a final rule[i] to amend the Anti-Kickback Statute (AKS or Statute) by adding new safe harbors. The Final Rule also revises the definition of "remuneration" in the civil monetary penalty (CMP) rule. The Final Rule becomes effective on January 6, 2017.

This client alert summarizes changes that are likely to have the greatest potential impact on the health care and life science industries generally. However, the Final Rule will likely be of most significance to providers, including hospitals, pharmacies, and public ambulance services, and of lesser importance to manufacturers (which are explicitly excluded from utilizing many of the new and revised protections).

KEY PROVISIONS

REVISIONS TO ANTI-KICKBACK STATUTE SAFE HARBORS

Because the AKS is broadly written and implicated by many types of common arrangements, Congress created statutory exceptions, and OIG has promulgated regulatory safe harbors to protect certain activities that do not pose a risk of harm to federal health care programs. An arrangement that fits squarely into one or more of these exceptions or safe harbors is immune from prosecution. The Final Rule revises and/or expands two existing safe harbors and creates three entirely new safe harbors.

- ***New* local transportation services safe harbor.** The Final Rule creates a safe harbor protecting free or discounted local transportation services provided by a health care provider or supplier to federal health care program beneficiaries to receive medically necessary items or services. Note, however, that free transportation provided by individuals or entities that primarily supply health care items (as opposed to medical services), such as pharmacies, durable medical equipment suppliers, and pharmaceutical and device

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manufacturers, would not be protected. The safe harbor generally applies to transportation services within 25 miles of the health care provider or supplier (50 miles if the patient resides in a rural area) that are not marketed or advertised.

- ***New and revised* safe harbor for waiver of beneficiary copayment, coinsurance and deductible amounts.** The Final Rule expands the scope of the safe harbor for cost-sharing waivers offered by health care providers, to include all federal health care programs. The safe harbor previously applied only to Medicare and state health care program beneficiaries. The Final Rule also revises the definition of cost-sharing to include coinsurance in addition to copayment and deductibles. The changes will potentially allow health care providers (but not manufacturers) to offer these cost-saving programs to a larger segment of their patient population.

  - ***New* safe harbor for cost-sharing waivers by pharmacies.** Within the existing safe harbor for waiver of beneficiary copayment, coinsurance, and deductible amounts , the Final Rule creates a new provision allowing pharmacies to waive or reduce the cost-sharing obligation of a federal health care beneficiary, provided the pharmacy does not advertise the waiver, does not routinely waive the cost-sharing obligation, and determines in good faith that the beneficiary is in financial need. The new safe harbor would not allow, however, for the waiver or reduction to be subsidized by a manufacturer, such as through a copay card or coupon.

  - ***New* safe harbor for cost-sharing waivers for emergency ambulance services.** Also within the existing safe harbor for waiver of beneficiary copayment, coinsurance, and deductible amounts , the Final Rule creates protection for government-owned and operated ambulance providers to waive cost-sharing obligations owed for emergency ambulance services when the waiver is offered on a uniform basis and the ambulance provider does not claim the amount waived as bad debt under a federal health care program or otherwise shift the burden to a federal health care program.

- ***New* Medicare Coverage Gap Discount Program safe harbor.** The Medicare Coverage Gap Discount Program allows prescription drug manufacturers to enter into an agreement with HHS to provide discounts to certain beneficiaries when they are in the coverage gap or "donut hole." The Final Rule protects discounts for "applicable drugs" furnished to an "applicable beneficiary" when the manufacturer of the drug in question participates in, and is in compliance with, the Medicare Coverage Gap Discount Program.[ii] The Final Rule defines both "applicable drugs"[iii] and "applicable beneficiary"[iv] by statutory reference to definitions in the codified provisions of the ACA.

- ***New* Federally Qualified Health Centers and Medicare Advantage organizations safe harbor.** The Final Rule creates a new safe harbor that protects any remuneration between a federally qualified health center and a Medicare Advantage organization (a health plan such as health maintenance organization, preferred provider organization, or provider-sponsored organization) made pursuant to a written agreement.

- **Technical correction to the safe harbor for referral services.** The Final Rule makes a technical correction to the safe harbor for referral services to revert back to the language in the 1999 Final Rule, which states remuneration paid to the referral source must not be based on the volume or value of any referrals to or "business otherwise generated by either party *for the other party*"[v] (emphasis added).

REVISIONS TO CIVIL MONETARY PENALTY RULES

The Final Rule also revises the definition of "remuneration" under the CMP rules. The CMP rules, which implement the beneficiary inducement prohibition of the CMP statute, prohibit the offer or transfer of remuneration to Medicare and state health care program beneficiaries to influence those beneficiaries to obtain reimbursable services from a particular provider, practitioner, or supplier. (Note that the definition of remuneration under the CMP authorities is distinct from the AKS.) "Remuneration" under the CMP rules now includes coinsurance, in addition to copayment and deductible amounts, and is consistent with the definition of remuneration under the CMP statute. The Final Rule also incorporates statutory exemptions for:

- **Coupons, rebates, or other retailer reward programs.** Coupons, rebates, or other retailer reward programs from a retailer when the offer is given to the general public on equal terms regardless of health insurance status and is not tied to the provision of other items or services. A retailer is an individual or entity that sell items directly to consumers such as independent or small pharmacies, and online retailers. However, the term retailer excludes individuals or entities that primarily provide services such as hospitals or physicians.

- **Items or services to financially needy individuals.** Items or services that are reasonably connected to an individual's medical care may be offered by a health care provider, practitioner, or supplier for free or less than fair market value if they are not advertised or solicited, not tied to other items or services reimbursed by Medicare or an applicable state health care program, and the person providing the items or services makes a good faith determination that the individual is in financial need. This exception does not generally apply to free or discounted products furnished by manufacturers, including OIG's previous guidance[vi] on patient assistance programs that furnish free drugs to beneficiaries enrolled in Medicare Part D plans.

- **Remuneration that poses a low risk of harm and promotes access to care.** Items or services that promote access to care and pose a low risk of harm to patients and federal health care programs are excluded from the definition of "remuneration." Access to care means supporting or helping patients to access items and services payable by Medicare or Medicaid, or make the availability of items and services payable by Medicare or Medicaid more convenient than they otherwise would be. The definition encompasses providing the tools patients need to remove barriers to accessing necessary care such as providing child care while the patient obtains treatment. However, the definition excludes providing patients cash or cash equivalent items, or providing rewards for accessing care. An arrangement poses a low risk of harm where the remuneration is: (1) unlikely to interfere with clinical decision making, (2) unlikely to increase costs of care through overutilization or inappropriate utilization, and (3) unlikely to raise patient safety or quality-of-care concerns.

- **Copayment waivers for first fill of generic drugs.** Beginning on or after January 1, 2018, a Part D Plan sponsor may provide plan enrollees a waiver of the copayment for the first fill of a covered generic drug. The Part D Plan sponsor must include the waiver in the plan's benefit design package submitted to CMS.

- **Copayment reduction for certain hospital outpatient department (OPD) services.** The Final Rule makes a technical change to the regulation to coincide with the current statutory reference to the definition of covered outpatient department services.

In addition to the exceptions highlighted above, the Final Rule adjusts OIG's interpretation of nominal value under the CMP statute to mean $15 for an individual gift and $75 in the aggregate annually per patient, which are increases from the prior definitions of $10 per instance and $50 per year.

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King & Spalding has extensive experience with the AKS, as well as its implementing regulations and Safe Harbors, and CMP Statute and regulations. Our team would be pleased to assist in helping health care and life sciences entities understand the implications of the Final Rule as it applies to any specific practices or business arrangements, as well as in connection with updates to internal policies, procedures, and personnel training. We are also available to prepare briefing materials for corporate leadership.

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[i] 81 Fed. Reg. 88368 (December 7, 2016).

[ii] In order to participate in the Discount Program, manufacturers must sign an agreement with CMS to provide the discount on all of its applicable drugs (i.e. prescription drugs approved or licensed under new drug applications or biologic license applications). Beginning in 2011, only those applicable drugs that are covered under a signed manufacturer agreement with CMS can be covered under Part D.

[iii] Applicable drug means a covered part D drug that is approved or licensed by the FDA and for which the applicable beneficiary's Part D Plan or MA-PD plan would provide benefits for. 42 U.S.C. § 1395w-114A(g)(2).

[iv] Applicable beneficiary means an individual who, on the date of dispensing an applicable drug a covered part D drug, is enrolled in a prescription drug plan or an MA–PD plan; is not enrolled in a qualified retiree prescription drug plan; is not entitled to an income-related subsidy; and (D) who has not exceed curtain coverage limits or out-of-pocket thresholds. 42 U.S.C. § 1395w-114A(g)(1).

[v] 64 Fed. Reg. 63,518, 63,526 (November 19, 1999).

[vi] 70 Fed. Reg. 70,623, 70,623 (November 22, 2005).