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MATTHEW BENDER

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OIG Releases New Proposals on Anti-kickback Statute Safe Harbors, Exceptions to the CMP Law and the Gainsharing Prohibition

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Recently, the Department of Health and Human Services Office of Inspector General published a long-awaited proposed rule for implementing amendments to safe harbors under the anti-kickback statute and exceptions to the civil monetary penalty law. The authors of this article discuss the proposals.

The Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") recently published a long-awaited proposed rule[1] for implementing amendments to safe harbors under the anti-kickback statute and exceptions to the civil monetary penalty ("CMP") law. The proposed rule codifies statutory changes stemming from the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") of 2003, as well as those enacted as part of the Patient Protection and Affordable Care Act ("ACA"), and adds certain other safe harbors under the OIG's general statutory authority to establish and modify safe harbors. The OIG accepted comments on its proposals through December 2, 2014.

The proposed rule addresses modifications to the anti-kickback statute regulatory safe harbors at 42 C.F.R. § 1001.952 and the regulatory provisions regarding the CMP law's beneficiary inducement and gainsharing prohibitions. Below is a summary of each of the various proposals.

AMENDMENTS TO THE FEDERAL ANTI-KICKBACK STATUTE'S REGULATORY SAFE HARBORS

Section 1128B(b) of the Social Security Act calls for criminal penalties for knowingly and willfully offering, paying, soliciting or receiving remuneration in order to induce or reward referrals of items or services that are reimbursable under federal health care programs. Because of the breadth of this prohibition, Congress tasked the OIG with developing and promulgating regulatory safe

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[1] http://www.gpo.gov/fdsys/pkg/FR-2014-10-03/pdf/2014-23182.pdf.

harbors specifying certain practices that would not be treated as criminal under the anti-kickback statute.

In the proposed rule, the OIG makes one technical correction to the existing safe harbor for referral services, and identifies several new payment practices to incorporate in safe harbors under 42 C.F.R. § 1001.952, believing that these safe harbors will "protect beneficial arrangements that enhance the efficient and effective delivery of health care and promote the best interests of patients, while also protecting the Federal health care programs and beneficiaries from undue risk of harm associated with referral payments."

1. *Referral services*—To clear up a perceived ambiguity, the OIG proposes to amend the safe harbor for referral services at 42 C.F.R. § 1001.952(f) to make clear that the safe harbor will not protect payments that participants make to a referral service if those payments are based on the volume or value of referrals to, or business otherwise generated by, either party for the other party.
2. *Part D cost-sharing waivers by pharmacies*—The MMA added a new statutory safe harbor protecting reductions by pharmacies of any cost-sharing imposed under the Medicare Part D prescription drug program, as long as certain conditions are met. Consistent with the statute, the OIG proposes to codify this exception at 42 C.F.R. § 1001.952(k)(3) to protect pharmacies waiving Part D cost-sharing if: (i) the waiver or reduction is not advertised or part of a solicitation; (ii) the pharmacy does not routinely waive the cost-sharing; and (iii) before waiving the cost-sharing, the pharmacy either determines in good faith that the beneficiary has a financial need or the pharmacy fails to collect the cost-sharing amount after making a reasonable effort to do so. Under this proposal, pharmacies would only need to satisfy the first condition (i.e., the prohibition on advertisements and solicitations) when waiving the cost-sharing for individuals eligible for Part D low-income subsidies.
3. *Cost-sharing waivers for ambulance services*—OIG proposes to establish a new safe harbor at 42 C.F.R. § 1001.952(k)(4) to protect reductions or waivers of Medicare coinsurance or deductible amounts owed for emergency ambulance services to an ambulance supplier owned and operated by a state (or political subdivision of a state). OIG notes that it is proposing this exception in light of the continued requests for advisory opinions on these arrangements that it has received. OIG seeks comments on the proposed conditions of this safe harbor, as well as whether it should expand the safe harbor to protect waivers of cost-sharing for ambulance services owed under other federal health

care programs (e.g., Medicaid).

4. *Federally Qualified Health Centers ("FQHCs") and Medicare Advantage ("MA") Organizations*—The MMA added a new statutory safe harbor protecting remuneration between an FQHC and an MA organization pursuant to a written agreement. OIG proposes to codify this safe harbor at 42 C.F.R. 1001.952(z).

5. *Discounts to beneficiaries under the Medicare Coverage Gap Discount Program*—The ACA established the Medicare Coverage Gap Discount Program, which requires manufacturers to provide certain discounts on drugs to Medicare Part D beneficiaries who are subject to the Part D coverage gap (commonly referred to as the "doughnut hole"). The ACA also amended the anti-kickback statute to add a self-implementing exception protecting the manufacturer discounts provided under the Program. The OIG proposes to codify this statutory exception under the existing safe harbor regulation at 42 C.F.R. § 1001.952(aa) to protect manufacturer discounts furnished to beneficiaries under the Medicare Coverage Gap Discount Program, as long as the manufacturer participates in, and is in full compliance with, the program's requirements.

6. *Local transportation arrangements*—Pursuant to its authority to develop and promulgate new safe harbors, the OIG proposes to add a new safe harbor at 42 C.F.R. § 1001.952(bb) that would protect free or discounted local transportation services provided to federal health care program beneficiaries who are "established patients" for purposes of helping them to obtain "medically necessary items and services." The OIG is proposing a number of conditions on entities seeking protection under this safe harbor, such as (i) limiting the types of entities that can qualify for the safe harbor to those that provide services, not items; (ii) imposing geographic limits (25 miles); and (iii) placing limits on marketing and advertising of services. The OIG says it is considering further limiting the types of entities eligible to provide local transportation services, and whether more stringent safeguards are needed for certain types of entities, such as home health entities, to prevent abuse. The OIG invites comments on numerous aspects of the proposal, including whether the exception should be limited to arrangements that provide transportation for specific medical purposes, or whether it should be expanded to allow transportation for other health-related services such as applying for government benefits, obtaining counseling or social services, or visiting food banks.

AMENDMENTS TO THE CIVIL MONETARY PENALTY LAW—BENEFICIARY INDUCEMENTS PROHIBITION

Section 1128A(a)(5) of the Social Security Act—the "beneficiary inducements" prohibition—authorizes HHS to impose civil monetary penalties on persons or entities who offer "remuneration" to Medicare or state health care program beneficiaries where such remuneration is likely to influence the beneficiary to order or receive an item or service from a particular provider, practitioner or supplier. The ACA amended the definition of "remuneration" for purposes of the beneficiary inducements CMP by adding four new exceptions protecting arrangements that offer beneficiaries with incentives to engage in wellness or treatment regimens or that improve access to care.

1. *Arrangements that "promote access and pose a low risk of harm to patients and Federal health care programs"*—The OIG does not propose regulatory text for this exception, but rather solicits proposals for the language, including specific examples of the types of remuneration to beneficiaries that should fall within the exception. To guide comments, the OIG says it is proposing to interpret "promotes access to care" to mean that the remuneration provided improves a beneficiary's ability to obtain medically necessary health care items and services, and requests comment on the scope of its interpretation (i.e., whether it should be broadened beyond "medically necessary" items and services). OIG proposes to interpret "low risk of harm" as meaning that the remuneration is unlikely to interfere with clinical decision-making, is unlikely to increase costs to federal health care programs or beneficiaries and does not raise safety or quality concerns. The OIG also offers examples of the types of arrangements it would consider as falling under this new exception. For instance, OIG believes that giving items that are necessary for patients to record and report health data, such as blood pressure cuffs or scales, to patients who can benefit from such monitoring, can promote access to care and poses a low risk of harm as long as receipt is not conditioned on the patient obtaining other items or services. By contrast, the OIG says that rewards or incentive programs offered by providers to patients for compliance with treatment regimens may actually be marketing activities that pose a risk of abuse where the rewards could influence recipients to seek out unnecessary or poor quality care.
2. *Coupons, rebates or other retailer reward programs*—The OIG proposes to codify the ACA amendment protecting the offer or transfer of certain coupons, rebates or other rewards from a retailer to a federal health care program beneficiary where (i) the items or services are

offered on equal terms available to the general public; and (ii) the offer is not tied to the provision of other items or services reimbursable under Medicare or a state health care program. The OIG said it does not consider entities that primarily provide services, such as hospitals or physicians, as "retailers," but requests comments on whether other entities that sell items that require prescriptions, such as medical equipment stores, should fall under the exception.

3. *Arrangements that involve the "offer or transfer of items or services for free or at less than fair market value" based on financial need*—The OIG proposes to codify the ACA's amendment to the definition of "remuneration" to exclude the offer or transfer of "items or services" for free or less than fair market value where (i) the items or services are not offered as part of any advertisement or solicitation; (ii) the offer is not tied to the provision of other items or services reimbursed by Medicare or a state health care program; (iii) there is a reasonable connection between the items or services and the medical care of the individual; and (iv) the person providing the items or services has made a good faith determination that the recipient is in financial need. The OIG offered certain examples of arrangements that could fall within this exception, such as the distribution of protective helmets and safety gear to hemophiliac children, distribution of pagers to alert patients with chronic medical conditions to take their drugs, provision of free blood pressure checks to hypertensive patients and distribution of free nutritional supplements to malnourished patients with end-stage renal disease. By contrast, the OIG states that the provision of free lodging or transportation would not fall under this exception because those arrangements are tied directly to the provision of other items and services (however, these arrangements could still be exempted from the CMP law as arrangements that promote access to care). The OIG is seeking comments on what it means for remuneration to be "reasonably connected" to a patient's medical care, and what constitutes a "good faith determination" of financial need.

4. *Copayment waivers for first-fill generic drugs*—The OIG proposes to implement the statutory exception to the definition of "remuneration" for waivers by Part D plans of any copayments owed by enrollees for their first fill of a generic drug. To ensure consistency with current Centers for Medicare and Medicaid Services ("CMS") practices and transparency to beneficiaries in plan selection, the OIG would require Part D plan sponsors who wish to offer these waivers to disclose them in their benefit plan submissions to CMS. This exception would

become effective for Part D coverage years beginning after the publication of the final rule. However, in the interim, the OIG notes that it will not exercise its enforcement authority against Part D plans offering generic first-fill copayment waivers if such plans comply with CMS requirements.

The OIG is also proposing to codify an exception added to the CMP statute by the Balanced Budget Act of 1997 protecting copayment reductions for covered outpatient services. The proposed regulatory language mirrors the statutory provision.

AMENDMENTS TO THE CIVIL MONETARY PENALTY LAW—GAINSHARING PROHIBITION

Section 1128A(b)(1) of the Social Security Act—the "gainsharing" prohibition—authorizes HHS to impose civil monetary penalties on hospitals for knowingly making a payment to a physician as an inducement to reduce or limit "services" provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician. The OIG has never codified the gainsharing CMP in regulation. The breadth of the prohibition, which extends to any type of incentive that would encourage physicians to reduce or limit any type of services to their patients (not just those that are medically necessary) has made it difficult to enforce, and the OIG has never actually pursued any gainsharing CMP case. In fact, the OIG has approved of 16 gainsharing arrangements through the advisory opinion process.

OIG is proposing to codify the gainsharing CMP at 42 C.F.R. §§ 1003.700–.720. It is also seeking comment on a regulatory definition of what it means to "reduce or limit services." In considering such a definition, the OIG acknowledges that gainsharing arrangements can be beneficial and pose low risk to beneficiaries where certain safeguards are in place, and that the health care landscape has evolved to a point where there are effective ways of measuring quality and outcomes and ensuring accountability. Because the OIG cannot amend the statutory gainsharing CMP language to narrow the prohibition to only those arrangements that limit "medically necessary services," it is attempting to narrow its interpretation of what it means to "reduce or limit services," recognizing that due to the increased use of objective quality metrics, a change in practice (i) does not always constitute a limitation or reduction of services, and (ii) may in fact constitute an improvement in patient care or a reduction in cost without reducing patient care or diminishing its quality.

The desire to provide additional flexibility and clarity around gainsharing arrangements is likely also being driven by the government's increased focus on incentivizing delivery systems to reduce costs and improve quality, such as

through shared savings and value-based purchasing models. Many in the health care industry have expressed concern that the efforts to achieve the goals of better quality and lower costs are inconsistent with some of the restrictions in the health care anti-fraud measures, and, specifically, the gainsharing prohibition. In proposing to codify the gainsharing CMP, OIG notes the benefits that these value-based programs can offer, suggesting a desire to provide additional flexibility to providers seeking to implement new models and deliver high-value care.