

OIG Interprets and Incorporates Statutory Exceptions to CMP Law

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As of January 6, 2017, final rules published by the United States Department of Health and Human Services Office of the Inspector General (the “OIG”) implementing certain exceptions to the Civil Monetary Penalty law (“CMP”) took effect. The CMP rules were published alongside final rules regarding safe harbors to the federal Anti-Kickback Statute (“AKS”), about which more can be learned in our earlier blog post [here](#). The final rule as published in the Federal Register is available [here](#).

As a refresher, the CMP, codified at [42 U.S.C. § 1320a-7a](#), prohibits inducements in the form of offering or transferring remuneration to beneficiaries of Medicare and State health care programs if the offeror knows or should know the inducement is likely to influence such beneficiary to order or receive a reimbursable service from a particular provider, practitioner, or supplier. It is important to note, and in fact the final rule goes out of its way to remind us, that activities potentially implicating the CMP and AKS may overlap, and meeting a CMP exception does not necessarily mean that AKS risk is mitigated.

The final rules amend the CMP’s definition of “remuneration,” codified at [42 C.F.R. § 1003.110](#), by interpreting and incorporating statutory exceptions. The exceptions interpreted and incorporated are: (i) copayment reductions for certain hospital outpatient department services; (ii) certain remuneration that poses a low risk of harm and promotes access to care; (iii) coupons, rebates, or other retailer reward programs that meet specified requirements; (iv) certain remuneration to financially needy individuals; and (v) copayment waivers for the first fill of generic drugs.

While all of the exceptions merit attention, this blog post specifically focuses on certain changes and clarifications to exceptions (ii), (iii), and (v), as listed above.

- Low risk of harm and promotes access to care: In the final rule, the OIG expanded its interpretation of “care” beyond “medically necessary health care items and services,” as it was in the proposed rules, to the broader “items and services payable under Medicare or State health care programs for beneficiaries who receive them” in

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recognition of the fact that nonclinical items and services can improve health.

Additionally, responding to various comments, the OIG pushed back multiple times on the idea that different standards should apply under this exception to different types of entities, such as risk-bearing providers and suppliers, ACOs, or pharmacy programs (though the OIG did recognize that the structure of arrangements with risk-bearing providers and suppliers and ACOs may make it easier for them to meet the same standards);

- Coupons, rebates, or other retailer reward programs meeting specified requirements: The OIG maintained its interpretation that a “retailer” is an entity that sells items directly to consumers and does not include individuals or entities that primarily provide services. The OIG clarified in comments that a pharmacy is considered a retailer whether it is a “big box” pharmacy or a smaller pharmacy, stating that, even if a smaller pharmacy provides services, it does not “primarily” provide services. In addition, entities such as a hospital system with a separate retail component (e.g., a pharmacy) may be considered a retailer with respect to a program specific to that retail component. The OIG also clarified that the concept of “other rewards” should be interpreted broadly, provided that it meets other requirements of this exception (i.e., it is a retailer reward, offered or transferred to the public on equal terms, and not tied to other reimbursable items or services). However, “other rewards” could not include a copayment waiver, as it fails to meet the requirement that the rewards not be tied to other reimbursable items or services; and
- Copayment waivers for the first fill of generic drugs: While otherwise finalizing this rule unchanged, OIG clarified that, because the final rule was published after the deadline for submission to CMS of benefit plan packages for coverage year 2017, the exception for copayment waivers would be applicable to coverage years beginning on or after January 1, 2018.

The final rule also adds “copayment” to the definition of “remuneration” for the sake of consistency with other proposed and finalized text and announces an increase in the limits for gifts of nominal value that do not require an exception under the CMP, from \$10 for an individual gift and \$50 annual aggregate per patient, to \$15 and \$75, respectively.