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New Exceptions to Federal Anti-Inducement Law Create Opportunities for Health Care Providers

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Significant attention has been focused on provisions of the recently enacted Patient Protection and Affordable Care Act, H.R. 3590 ("PPACA") that expand the definition of fraud and abuse and enhance the government's ability to prosecute health care providers.

Less attention has been given to provisions of the PPACA that offer greater flexibility to providers for "certain charitable and other innocuous programs" under the beneficiary anti-inducement provisions of the federal Civil Monetary Penalties Law ("CMPL"). These changes clarify some of the regulatory uncertainty surrounding certain types of patient incentive programs and create opportunities for expanding those programs without running the risk of violating the CMPL.

Anti-Inducement Prohibitions Under the CMPL and the Anti-Kickback Statute ("AKS")

The offer or provision of items or services for free or below fair market value ("FMV") to federal health care program beneficiaries potentially implicates both the CMPL and the federal Anti-Kickback Statute ("AKS"). The CMPL makes it illegal for any person to offer or transfer remuneration to any individual covered by a federal health care program "that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part . . ." under such program. 42 U.S.C. § 1320a-7a(a)(5). Remuneration includes, among other things, waivers of copayments and deductible amounts and transfers of items or services for free or for other than FMV. 42 U.S.C. § 1320a-7a(i)(6). A violation of the CMPL is punishable by civil monetary penalties as well as exclusion from federal health care programs.

The AKS makes it illegal for, among other things, any person to knowingly and willfully offer or pay anything of value, in cash or in kind, in return for the purchase of an item or service covered by a

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federal health care program such as Medicare or Medicaid. 42 U.S.C. § 1320a-7b. Violations of the AKS may be punishable as a felony, through exclusion from participation in federal health care programs or by the imposition of civil monetary penalties of up to three times the amount of the illegal kickback.

Existing CMPL Exceptions

Prior to enactment of the PPACA, there were a limited number of exceptions to the inducement prohibition under the CMPL set forth in the statute or in regulations issued by the U.S. Department of Health and Human Services ("DHHS") Office of Inspector General ("OIG"):

Gifts of nominal value. The OIG has interpreted the statute to permit the offering of inexpensive gifts (other than cash or cash equivalents) or services to a beneficiary so long as the gift has a retail value of no more than \$10 to an individual patient, and no more than \$50 in the aggregate annually per patient.

Properly disclosed health plan differentials in copayments or deductibles. This exception permits health plan incentives that are part of a benefit plan design, such as lower plan copayments for using generic drugs.

Need-based cost-sharing waivers. Beneficiary cost-sharing amounts can be waived if they are unadvertised and based on an individualized determination of financial need or exhaustion of reasonable collection efforts.

Preventive care incentives. This exception permits incentives to promote the delivery of preventive care. Such incentives may not be in the form of cash or cash equivalents and must be proportionate to the value of the preventive care provided.

Waivers of hospital outpatient co-pays in excess of minimum co-pay amounts.

Anti-kickback safe harbor. Any practice permitted under an AKS safe harbor is allowed under the CMPL.

While health care providers and plans have been assured that they would not be subject to prosecution for business practices meeting all the requirements of an exception, they have faced some risk for arrangements that are seemingly innocuous but do not fit precisely within an exception. The OIG's advisory opinions provided some insight into the OIG's position on such borderline arrangements but were limited to the specific facts addressed in each opinion.

New Anti-Inducement Exceptions

Section 6402(d) of the PPACA creates new CMPL exceptions for certain “charitable and innocuous” arrangements. Unless otherwise specified, the new exceptions are effective as of March 23, 2010, the date of enactment of the PPACA.

Transfer of coupons or rebates from a retailer. This exception permits the offer of items or services for free or less than FMV if: i) the items or services consist of coupons, rebates, or other rewards from a retailer; ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and iii) the offer is not tied to the provision of other items or services reimbursable by Medicare or by a State health care program. This exception would appear to permit, for example, a retail pharmacy to offer a coupon for an over-the-counter drug or a free 10-day supply of a prescription drug, as long as the coupon is offered to all customers and redemption of the coupon is not conditioned on the purchase of any items covered by a federal health care program.

Items or services for individuals determined to be in financial need. This exception goes beyond the existing one for need-based cost-sharing waivers. It protects the offer or provision of free or below FMV items or services if i) the items or services are not offered as part of any advertisement or solicitation; ii) the items or services are not tied to the provision of other services reimbursable by Medicare or a State health care program; iii) there is a reasonable connection between the items or services and the individual’s medical care; and iv) the items or services are provided after a good faith determination of individualized financial need. For example, this exception might permit a home health agency or durable medical equipment supplier to offer a free home safety assessment to Medicare beneficiaries if the assessment were not advertised and offered only to financially needy individuals.

Waiver of co-pays for covered Part D generic drugs. This exception, which will be effective on a date specified by the Secretary of DHHS (but no earlier than January 1, 2011), will permit Medicare Prescription Drug Plan sponsors and Medicare Advantage (“MA”) organizations offering Part D and MA-PD plans to waive co-pays for the first fill of generic drugs covered under Part D. For example, when a brand drug comes off patent, a plan sponsor may want to encourage members to switch from the brand to a lower-cost generic by offering to waive co-pays of the first fill of the generic during a time-limited period. The exception allows plan sponsors to offer such promotions without incorporating the co-pay

waiver into the plan's filed benefit design.

Additional regulatory exceptions. The PPACA further authorizes the Secretary of DHHS to add exceptions for remuneration that "promotes access to care" and "poses a low risk of harm to patients and Federal health care programs." The parameters and effective date of such additional exceptions, which must be defined under regulation, remain unclear.

Notably, the legislation does not establish parallel safe harbors under the AKS. While any activities protected under the AKS safe harbors are permitted under the CMPL, the converse is not true. However, it is generally assumed that, absent unusual circumstances, arrangements that fit within a CMPL exception will not be prosecuted under the AKS. Therefore, while there is still no absolute certainty about the compliance of the types of arrangements described above with the AKS, most health care organizations are likely to feel comfortable implementing arrangements that satisfy one of the new CMPL exceptions.

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