



## **Education and Outreach Arrangements Between Medicare-Endorsed Discount Drug Card Sponsors and their Network Pharmacies Under the Anti-Kickback Statute**

Under the Medicare Modernization Act, Medicare beneficiaries will be receiving important new benefits. Among these will be a discount drug card. The Centers for Medicare & Medicaid Services (CMS) has informed us that some discount drug card sponsors are seeking guidance about the application of the Office of Inspector General's (OIG's) fraud and abuse authorities to the sponsors' proposals to pay network pharmacies for certain education and outreach services (including enrollment assistance). While we cannot provide an advisory opinion with respect to any particular drug card sponsor's arrangement except through our advisory opinion process, given the importance of the new discount drug cards to Medicare beneficiaries and the expedited time frame for implementation of the program, we are offering the following general guidance. (While this guidance focuses on drug card sponsor payments to pharmacies, the same analytical framework would apply to similar payments to other individuals or entities.)

We understand that the proposed arrangements may take a variety of forms depending on the business models of individual drug card sponsors. In at least one circumstance, a drug card sponsor proposes paying pharmacies a fixed fee for every completed enrollment application submitted to the drug card sponsor. A substantial number of enrollees in the discount drug card program are expected to be eligible for up to \$630 in Medicare-funded transitional assistance subsidies. Payments that compensate pharmacies for submitting enrollment applications or for otherwise directing patients to a particular drug card may implicate the Federal criminal anti-kickback statute, section 1128B(b) of the Social Security Act. In light of the prominence of pharmacy benefits programs under the Medicare Modernization Act, we believe there is an increased need for scrutiny under the anti-kickback statute, and we intend to monitor the operation of drug card sponsor-funded education and outreach programs to determine whether they result in program or patient abuse.

As an initial matter, the OIG recognizes the critical importance of ensuring that all Medicare beneficiaries have access to complete, accurate, and impartial information regarding the Medicare discount drug card program and the specific choices available to them under the program. CMS plans to use a toll-free number and an internet website to facilitate informed decision-making by providing beneficiaries with objective, comparative information about the various drug cards. Notwithstanding these efforts, for

many beneficiaries, their pharmacy or pharmacist will be a natural point of inquiry about Medicare-endorsed drug cards.

The OIG supports any *bona fide* effort to educate beneficiaries about Medicare's discount drug card program and to assist beneficiaries in making informed choices based on full, accurate, and impartial information about their drug card options. The OIG's chief concern in this context is that financial incentives could distort or inhibit the flow of information to beneficiaries and, thereby, convert the education process into a mechanism for steering beneficiaries to a particular drug card without regard to the beneficiaries' best interests.

Since beneficiaries may rely on the educational and outreach information provided by sponsors in making their drug card choices, it is essential that the information be accurate. To protect beneficiaries, the OIG has the authority to impose a civil money penalty when a sponsor provides misleading information in educational or outreach material to a program enrollee or other person. 68 Fed. Reg. 69840, 69878 (Dec. 15, 2003).

From an anti-kickback statute perspective, our core concern is with the mechanisms used to finance education and outreach efforts. In our experience, payments tied directly or indirectly to the volume or value of business actually or potentially generated can result in the steering of patients based on the financial self-interest of the party receiving the payments rather than the patients' best interests.

To protect against fraud and abuse, including improper steering of patients, the Federal anti-kickback statute prohibits, in relevant part, the knowing and willful offer, payment, solicitation, or receipt of anything of value, directly or indirectly, overtly or covertly, in cash or in kind, in return for Federal health care program referrals or for arranging for or recommending the purchase or order of a good, item, or service payable, in whole or in part, by a Federal health care program. Under the anti-kickback statute, every arrangement is evaluated for compliance on a case-by-case basis taking into account the totality of facts and circumstances, including the intent of the parties.

Some education and outreach arrangements may qualify for "safe harbor" protection pursuant to the personal services contracts safe harbor at 42 C.F.R. § 1001.952(d). The safe harbor sets forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. As indicated in the regulations, the personal services contracts safe harbor would not protect any per-application, per-enrollment, or similarly structured fee. In addition, we think it worth noting that other industry sectors have addressed situations similar to the proposed education and outreach efforts by using neutral, independent third-parties (typically non-

profit charitable organizations) to marshal industry resources and promote objective access to care. Properly structured, these arrangements using neutral, independent third-parties pose little risk under the anti-kickback statute.

We recognize that pharmacies may incur additional costs associated with education and outreach efforts related to the drug card program. We believe that fair market value fees for services actually rendered can help to defray these costs so long as they are properly structured. However, payment made for services actually rendered that is conditioned in any manner upon the volume or value of referrals or other business generated, including submission of an application for a particular drug card as opposed to any card, is inherently suspect under the anti-kickback statute. Problematic payments include, without limitation, “success” fees, fees that disguise payments for the volume of business generated, and other kinds of fees or incentives intended to steer patients.

With respect to promotional arrangements, the OIG has identified several factors relevant to the anti-kickback analysis, including the identity of the party engaged in the promotional activity and the nature of the party’s relationship with the audience; the nature of the item or service being promoted; the demographics of the target audience; and the structure and form of the compensation paid for the activity; and the nature of the activity and the degree to which it may be coercive or perceived to be coercive. These factors are not indicative or necessarily probative of whether a practice, in fact, violates the anti-kickback statute. Rather, we consider these factors, as well as other relevant concerns, when assessing the level of risk presented by promotional activity.

In sum, we believe that payment arrangements between discount drug card sponsors and their network pharmacies in connection with education, outreach, and enrollment services may raise concerns under the anti-kickback statute. Drug card sponsors should review their arrangements with pharmacies carefully to ensure that payments are not being made improperly to influence pharmacies (directly or through their employees) to direct patients to a particular drug card.

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