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CLIENT ALERT

CMS Part D Guidance on LTC Pharmacy Rebates Creates Confusion

February 1, 2006

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The Centers for Medicare & Medicaid Services (CMS) recently issued guidance in which it expressed “significant concerns” about access/performance rebates paid by pharmaceutical manufacturers to long-term care (LTC) pharmacies that participate in Medicare Part D plan LTC pharmacy networks. This guidance creates confusion given CMS' prior remarks on rebates received by independent PBMs participating in the Part D program.

In an answer to a question posted on its website, CMS implied that LTC pharmacy rebates might increase program and beneficiary costs and create fraud and abuse concerns in the Part D context. CMS stated that such LTC pharmacy rebates should at minimum be fully disclosed to the Part D plan sponsor, who would then have to account for this benefit in the plan's bid and would have to net out the price concessions for purposes of allowable reinsurance and risk corridor costs. CMS argued that when the Medicare program pays for 100% of the costs of the drug benefit, as is the case for most institutionalized beneficiaries, the benefit of the LTC pharmacy rebate should accrue to the government. As regards purported fraud and abuse concerns, the statement did not acknowledge the possible application of the anti-kickback law discount safe harbor to rebates paid to the LTC pharmacies.

CMS' reasoning is arguably in tension with its earlier guidance regarding manufacturer rebates paid to pharmacy benefit managers (PBMs). Specifically, CMS recognized that where a PBM serves as an independent subcontractor to a Part D sponsor, and is not acting as the sponsor's negotiating agent, “the PBM may not necessarily pass through 100% of rebates it receives” to the sponsor. CMS acknowledged that, in this instance, the PBM's retention of manufacturer rebates would be subject to negotiations with the Part D sponsor.

The difference in CMS' reasoning with respect to the LTC and PBM guidance is unclear. In each instance, the Part D sponsor presumably enters into arms-length negotiations with its subcontractor based on certain assumptions regarding rebates that the subcontractor may, or may not, be receiving. The parties may decide, for example, to negotiate for all rebates to be passed through to the sponsor, or they may negotiate an arrangement which permits the LTC pharmacy to retain some or all of the rebates it receives, in exchange for lower rates of payment from the health plan on covered prescription drugs

CMS' guidance on LTC pharmacy rebates, now unsettles these expectations after negotiations have been completed. If the agency maintains its position, it might be appropriate, at a minimum, to permit parties sufficient time to adjust to the guidance, *e.g.*, by stating that any rebates must be passed through effective as of the 2007 plan year. As it stands, the industry may see LTC pharmacies demand renegotiation of rates with plan sponsors if they are, in fact, expected to turn over any rebates received to the plans.

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