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CMS Issues Proposed Regulations Intended to Offer New Protections for Medicare Beneficiaries in Medicare Advantage and Prescription Drug Programs

Wendy L. Krasner, 202.585.6548
William Connelly, 202.585.6552

On May 8, 2008, the Centers for Medicare & Medicaid Services (CMS) issued proposed regulations intended to enhance protections for beneficiaries who are enrolled in Medicare Advantage (MA) organizations (MAOs) and Medicare prescription drug plans (Part D plans). According to CMS's press release, its actions "will strengthen marketing standards and extend additional protections to all beneficiaries including those receiving the low-income subsidy (LIS) and beneficiaries enrolled in special needs plans." The proposed rule also covers a wide range of other provisions of interest to various Part D stakeholders. A copy of the proposed regulation, which is scheduled for publication in the May 16 *Federal Register*, is available on CMS' website. Comments must be submitted to CMS by **July 15, 2008**.

The proposed rule would incorporate into regulation a number of requirements that CMS previously imposed through operational guidance. It also would introduce several new MA and Part D plan requirements largely aimed at beneficiary protection. While the marketing standards are the focus of the proposed rules, there are several other substantive proposals, as discussed below.

Marketing Standards

The proposed rule contains plan marketing standards that would:

- Prohibit cold-calling and expand the current prohibition

NEWSLETTER EDITORS

Helen Pfister
Partner
hpfister@manatt.com
212.830.7277

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on door-to-door solicitation to cover other unsolicited circumstances. Any appointment with a beneficiary to market healthcare-related products would have to be limited to the product types the beneficiary agreed to in advance. Cross-selling of non-healthcare-related products to a prospective MA or Part D enrollee would also be prohibited.

- Prohibit sales activities at educational events such as health information fairs and community meetings, or in areas such as waiting rooms where patients primarily intend to receive healthcare-related services, as well as limit the value and type of promotional items offered to potential enrollees.

- Require that MAOs and Part D plans that use independent agents to market MA and Part D plans use State-licensed agents for such marketing, and require that MAOs report to States, in a manner consistent with State appointment laws, that they are using those agents.

- Require MAOs to establish commission structures for sales agents and brokers that are level across all years and across all MA plan product types (for example, HMOs, PPOs, and private fee-for-service plans). Commission structures for Part D plans would have to be level across plans as well. The ban on incentives for sales agents to move beneficiaries would help create market stability so they can earn greater commissions.

♦ These proposals, which many view as an effort to stave off congressional efforts to further legislate in this arena, would increase CMS oversight over Part C and D marketing.

Low Income and Beneficiary Liability Standards

The proposed rule contains provisions to streamline eligibility determinations for extra help and limit beneficiary liability that would:

- Codify earlier guidance to plan sponsors about using "best available evidence" (BAE) to determine an enrollee's eligibility for extra help through the LIS program. Recognizing that the monthly files from the States and the Social Security Administration that Medicare uses to establish LIS eligibility sometimes do not reflect an applicant's current eligibility status, the regulation would require Part D sponsors to use the CMS-developed BAE process to establish the appropriate cost-sharing for low-income beneficiaries whose information in CMS systems is not correct or up-to-date.

- Establish other premium and cost-sharing protections related to the Social Security premium withholding and point-of-sale drug prices.

♦ These proposals would help protect low-income beneficiaries from unnecessary cost-sharing charges at pharmacy counters.

Special Needs Plan Standards

The rule also proposes new protections for beneficiaries enrolled in special needs plans (SNPs), which would:

- Require that 90 percent of new enrollees in SNPs be special needs individuals, to ensure that SNPs focus on the population for which these MA plans are designed.

- More clearly establish and clarify delivery of care standards for SNPs.

- Prohibit beneficiaries from being billed for cost-sharing that is not their responsibility.

- For SNPs for beneficiaries who are eligible for both Medicare and Medicaid, the rule would establish standards designed to ensure that those beneficiaries are able to access essential services that are available through Medicaid in addition to those benefits available through the SNP.

♦ These proposals will help ensure that when the moratorium on new SNPs is lifted for the 2010 contract year, better-articulated SNP standards will be in place. It will also encourage better coordination of Medicare and Medicaid benefits within SNPs.

Plan Penalties

The rule would provide CMS more leeway in calculating civil monetary penalties against MAOs or Part D plans that violate Medicare rules in ways that adversely affect beneficiaries. Under the proposal, CMS would have greater flexibility in determining penalty amounts and would have clear authority to levy a penalty of up to $25,000 for each enrollee affected, or likely to be affected, by the violation.

♦ This proposal would give CMS more leverage in how it penalizes MAOs and Part D plans.

Reporting of Drug Costs

CMS proposes to require that, for purposes of calculating beneficiary cost-sharing, reinsurance subsidies, and risk corridor payments, Part D sponsors report drug costs based on the amount a pharmacy receives for a drug, rather than what the Part D sponsor pays for the drug.

- This long-standing issue has been controversial because it affects whether Part D sponsors and PBMs will choose to contract using a "pass-through" or "lock-in" methodology.
    - Under the "pass-through" methodology, the drug prices that Part D sponsors pay to PBMs are based on the amount that PBMs actually pay to the dispensing pharmacy.
    - Under the "lock-in" methodology, Part D sponsors and PBMs negotiate drug prices in advance, and PBMs assume risk for price variability.
- CMS does not propose to mandate either "pass-through" or "lock-in" contracts between Part D sponsors and PBMs, but proposes to calculate cost-sharing, reinsurance subsidies, and risk corridor payments as if all PBMs and sponsors have "pass-through" contracts.
- CMS also proposes to adopt the same policy under the retiree drug subsidy program.
- By basing the amount of reinsurance subsidies and risk corridor payments on "pass-through" drug prices, CMS may discourage "lock-in" contracting.
- These changes would be effective for contract year 2010.

♦ Some in the industry have argued that implementation of this policy would remove incentives for PBMs to push for price concessions and rebates from drug manufacturers because any savings would be passed through to plan sponsors.

Other Provisions

PAPs

CMS proposes to revise the definition of "incurred costs" to include nominal copayments assessed by PAPs, which count toward TrOOP. CMS previously clarified that these nominal copayments count toward TrOOP and updated Chapter 14 (Coordination of Benefits) of the

Prescription Drug Benefit Manual to include language to this effect. CMS is merely updating the definition of "incurred costs" at Section 423.100 to be consistent.

Part D Late Enrollment Penalty

The proposed rule would allow individuals who are determined to have a late enrollment penalty the opportunity to seek a reconsideration of this determination and it provides CMS with additional discretion to review any such determination.

Limiting Copayments to Part D Plan's Negotiated Price

CMS proposes to revise its policy to make clear that Part D sponsors must charge the beneficiary the lesser of the cost-sharing amount or the negotiated price. Thus, for example, a beneficiary who is subject to a $5 copayment cannot be required to pay more than the negotiated price of the covered Part D drug, if the negotiated price is less than $5.

Effective Dates

Other than for the proposed rule on reporting of drug costs, which would be effective for 2010, the effective date of these changes remains unclear. CMS has stated that it hopes to issue the final rule by late October, so that it will be effective for the 2009 benefit year. Rules typically take effect 60 days after final publication, so CMS has until November 1, 2008, to issue the final rule for a 2009 effective date. However, most marketing takes place during the annual open enrollment in November and December, so it remains unclear whether these provisions could be in effect for the upcoming marketing season.

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FOR ADDITIONAL INFORMATION ON THIS ISSUE, CONTACT:

Wendy L. Krasner Ms. Krasner has extensive expertise in federal healthcare programs in areas including Medicare coverage, pharmaceutical reimbursement, and Medicare and Medicaid managed care arrangements. In particular she has a unique expertise with regard to the legal, regulatory and policy implications of the new prescription drug benefit now offered under Medicare and how the new benefit interacts with the many other facets of our healthcare system.

William Connelly Mr. Connelly advises health care providers, health plans, pharmacy benefit management companies, and pharmaceutical manufacturers on regulatory, transactional, and compliance issues. His practice focuses on federal healthcare programs -- including Medicare managed care, Medicare Part D, and compliance with the federal anti-kickback statute. Mr. Connelly also has experience with state regulation of pharmacies and health plan contracting.