CMS Issues Proposed Rule Impacting the Medicare Advantage and Prescription Drug Benefit Programs

On May 8, 2008, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule revising several regulations governing the Medicare Advantage (MA) and Prescription Drug Benefit (“Part D”) Programs.1 Many of these revisions clarify existing CMS policies or codify current subregulatory guidance, while others create new policies. CMS will be accepting comments on the Proposed Rule until 5 p.m. on July 15, 2008. This advisory identifies several key regulatory provisions added or modified by the Proposed Rule, including the revised requirements for special needs plans (SNPs), the new marketing guidelines for MA organizations and Part D plan sponsors, and the new requirement that all Part D sponsors (beginning in contract year 2010) use a “pass-through” model rather than a “lock-in” model for Part D drug cost calculations and reporting.

Provisions Affecting Only the MA Program

• **SNPs.** CMS proposes to require that MA organizations offering SNPs limit enrollment of non-special needs members to no more than 10 percent of new enrollees, and that 90 percent of new enrollees must be special needs individuals (as defined in regulation). CMS proposes to clarify that MA organizations must establish a process to verify that potential SNP enrollees meet the specific eligibility requirements, which vary depending on the type of SNP (dual eligible, chronic condition or institutionalized). CMS also proposes to require SNPs to develop a model of care tailored to the special needs population the plan serves. Further, CMS proposes to require SNPs serving dual eligibles to have, at minimum, a documented relationship with the relevant State Medicaid agency.

• **Medical Savings Accounts (MSA) Plans.** To facilitate transparency, CMS proposes to require all MSA plans to provide enrollees with information about the cost and quality of their services and, additionally, to inform CMS about how they intend to provide enrollees with this information.

Provisions Affecting Only the Part D Program

• **Passive Election for Full Benefit Dual Eligibles (FBDEs) Who Are Qualifying Covered Retirees.** CMS proposes to revise its regulations to establish a process under which FBDE individuals who CMS knows to be enrolled in qualifying employer group plans would be deemed to decline Part D coverage if, though notified of their options, they fail to indicate that they want such coverage.

---


---

This advisory is published by Alston & Bird LLP to provide a summary of significant developments to our clients and friends. It is intended to be informational and does not constitute legal advice regarding any specific situation. This material may also be considered attorney advertising under court rules of certain jurisdictions.
Late Enrollment Penalty (LEP). CMS proposes to clarify that prescription drug plans (PDPs) must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries, report this information to CMS, and notify beneficiaries of their LEP amounts (after CMS provides plans with this information) and of their ability to request reconsiderations of these amounts.

Part D Program Definitions. CMS proposes to clarify several existing definitions in the Part D regulations (such as “incurred costs,” “negotiated prices,” “actually paid,” “gross covered prescription drug costs,” and “allowable risk corridor costs”) and to add a new definition to these regulations for “administrative costs.” CMS also proposes to revise and add certain definitions related to the Retiree Drug Subsidy (RDS) Program to mirror the proposed changes to the definitions of these terms for purposes of the Part D Program.\(^2\) Significantly, many of these revised definitions create a policy that would require all Part D sponsors to use “pass-through” rather than “lock-in” pricing for reporting drug costs on the Prescription Drug Event (PDE) records and calculating beneficiary cost-sharing starting in 2010.

Limiting Copayments to a Part D Plan’s Negotiated Prices. CMS proposes to require Part D sponsors to provide enrollees with access to, or make available at the point-of-sale, the sponsors’ negotiated prices of covered Part D drugs when the applicable cost-shares are higher than the negotiated prices.

Timeline for Providing Written Explanation of Benefits (EOB). CMS proposes to require Part D sponsors to provide an EOB to the enrollee no later than the end of the month following the month in which the enrollee uses his or her Part D benefits.

Low Income Subsidy (LIS) Payments. CMS proposes to modify the regulation governing payments of low-income cost-sharing subsidies (LICS) to Part D plan sponsors to allow the agency to select an “alternative method” (from those currently in regulation) for making LICS payments. CMS also proposes to add a new regulatory provision codifying existing guidance that prohibits a Part D sponsor from imposing LICS amounts on LIS-eligible beneficiaries when, for instance, the sponsor’s negotiated prices are less than the LICS amounts.

Best Available Evidence Policy. CMS proposes to codify in regulation its policy requiring Part D plan sponsors to accept and use reliable documentation — referred to as “best available evidence” — to establish beneficiaries’ LIS eligibility status, and to communicate this information to the Secretary. CMS proposes to define “best available evidence” as documentation or information that is directly tied to authoritative sources, that confirms that an individual meets the LIS requirements and that is used to support a change in the individual’s LIS status.

Certification of Allowable Costs. CMS proposes to clarify that the certification of allowable costs for risk corridor and reinsurance information includes direct and indirect remuneration (DIR) that decreases the costs incurred by a Part D sponsor for a Part D drug.

---

\(^2\) The definitions of “negotiated prices,” “gross covered prescription drug costs,” and “allowable risk corridor costs”— as applied for purposes of the use of “pass-through” versus “lock-in” prices — are proposed to become effective for coverage year 2010. All other definition modifications, including those relating to the RDS Program, are proposed to become effective upon the effective date of the final rule.
• **Change of Ownership Provisions.** CMS proposes to clarify that plan sponsors may not sell or transfer individual beneficiaries or groups of beneficiaries who are enrolled in any of their plan benefit packages (PBPs). CMS views this proposed regulatory revision as a clarification of its current policy, which restricts a plan sponsor from selling “a line of business consisting solely of a set of beneficiaries without the accompanying transfer to the succeeding sponsor of the obligation to continue to provide the PBP services the beneficiaries have already elected.”

**Provisions Affecting Both the MA and Part D Programs**

• **Passive Enrollment Procedures.** CMS proposes new regulations providing that CMS may authorize plans to carry out passive enrollment procedures in situations involving immediate plan terminations or potential beneficiary harm from remaining enrolled in the beneficiary’s current MA plan or PDP.

• **Involuntary Disenrollment for Non-Payment of Premium.** CMS proposes to revise the MA and Part D regulations to prohibit plans from disenrolling individuals for failure to pay premiums if they either have requested the premium withhold option or are already in premium withhold status, since such individuals would not be at fault for any non-payments.

• **Disclosure of Plan Information.** CMS proposes to clarify that MA organizations and Part D sponsors are required to disclose detailed information (specified in regulation) about the plans they offer – both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

• **Retroactive Premium Collection and Beneficiary Repayment Options.** CMS proposes to expressly permit beneficiaries to prorate past due premiums over a period of monthly payments (i.e., at least the same period for which the premiums were due), except where a member’s willful refusal to pay caused the premium arrearage.

• **Prohibiting Improper Billing of Monthly Premiums.** CMS proposes to explicitly prohibit Part D sponsors and MA organizations from directly billing beneficiaries for premiums that the beneficiaries have requested be withheld from their Social Security payments. This proposal would protect beneficiaries when operational failures cause CMS payment delays for premiums collected by Social Security withholding.

• **Non-Renewal Notification Timelines.** CMS proposes changing the beneficiary and public notice requirement for non-renewals of MA plan or PDP contracts from at least 90 days to at least 60 days.

• **Reconsiderations.** CMS proposes changes to the reconsideration process for both programs. With respect to the MA Program, CMS proposes to allow an enrollee’s treating physician to request a standard plan reconsideration of a pre-service request on behalf of an enrollee, without having been appointed as the enrollee’s representative, and to require the physician to notify the enrollee of such requests. With respect to the Part D Program, CMS proposes to allow certain non-physician prescribers (termed “other prescribers”) to perform the same functions as prescribing physicians for purposes of coverage determinations and appeals. CMS also proposes to allow prescribing physicians and “other prescribers” to request standard redeterminations on behalf of enrollees.
• **Civil Monetary Penalties (CMPs).** CMS proposes to clarify that the agency may impose a CMP of not more than $25,000 for each enrollee covered under the organization’s contract that is adversely affected or substantially likely to be adversely affected by the organization’s deficiency (or deficiencies). This change would give CMS the option to assess CMPs at the level of each enrollee covered by the organization’s contract in addition to existing authority which enables CMS to levy CMPs at the “per contract” level.

• **Review and Distribution of Marketing Materials.** CMS proposes to eliminate “file and use” status based on an organization’s track record and, instead, to adopt a uniform policy of applying the file and use process either to marketing materials that use model language without substantive modification or to materials that are identified by CMS as not containing substantive content warranting CMS review.

• **Licensing of Marketing Representatives.** CMS proposes to codify existing guidance that requires MA organizations and Part D sponsors that conduct marketing through independent agents to use only State-licensed marketing representatives, if the State licenses such agents. In addition, CMS proposes to require MA organizations and Part D sponsors that market through independent agents to report to States that they are using such agents.

• **Marketing Resources.** CMS proposes to clarify that: (1) The prohibition on door-to-door solicitation includes other unsolicited instances of direct contact; (2) plans may not engage in sales activities, including the distribution or collection of plan applications, at educational events; and (3) sales activities are allowed only in common areas of health care settings, not in areas where patients intend primarily to receive health care services. CMS proposes to require organizations to: (1) Limit the types of promotional items offered to potential enrollees and the value of such items to a nominal amount; (2) refrain from cross-selling any non-healthcare-related products to prospective enrollees in any sales activities; (3) limit any appointment with a beneficiary involving marketing of healthcare-related products to the scope agreed to by the beneficiary; and (4) limit the use of names and/or logos of co-branded network providers on plan membership and marketing materials.

• **Broker and Agent Requirements.** CMS proposes to require each MA organization and Part D sponsor to: (1) Ensure that the commission and compensation (collectively termed “commission”) to an agent in the first year do not exceed the commission the agent would receive for selling or servicing the policy in all subsequent years; and (2) pay the same commissions for all its plans as well as for all plan product types offered by its parent organization.
If you have any questions or would like additional information, please contact your Alston & Bird attorney or a member of our Health Care Group.

Atlanta Office

Robert C. Lower
404.881.7455
bob.lower@alston.com

Donna P. Bergeson
404.881.7278
donna.bergeson@alston.com

Angela T. Burnette
404.881.7665
angie.burnette@alston.com

Gina G. Greenwood
404.881.4698
gina.greenwood@alston.com

D’Andrea J. Morning
404.881.7538
dandrea.morning@alston.com

Robert D. Stone
404.881.7270
robert.stone@alston.com

Jeffrey K. Hester
404.881.4254
jeff.hester@alston.com

Jack S. Schroder
404.881.7685
jack.schroder@alston.com

Michelle A. Williams
404.881.7594
michelle.williams@alston.com

Dawnmarie R. Matlock
404.881.4253
dawnmarie.matlock@alston.com

Washington Office

Jacqueline C. Baratian
202.756.3484
jacqueline.baratian@alston.com

Jennifer E. Bell
Senior Public Policy Advisor
202.756.3416
jennifer.bell@alston.com

Jennifer L. Butler
202.756.3326
jennifer.butler@alston.com

Tamara R. Carty
202.756.3489
tamara.carty@alston.com

Elinor A. Hiller
202.756.3401
elinor.hiller@alston.com

Peter M. Kazon
202.756.3334
peter.kazon@alston.com

Stephanie A. Kennan
Senior Public Policy Advisor
202.756.3159
stephanie.kennan@alston.com

Catherine A. Martin
202.756.3357
catherine.martin@alston.com

Mark Rayder
Senior Public Policy Advisor
202.756.3562
mark.rayder@alston.com

Julie K. Tibbets
202.756.3444
julie.tibbets@alston.com

Timothy P. Trysla
202.756.3420
tim.trysla@alston.com

Tiffani V. Williams
202.756.3412
tiffani.williams@alston.com

Marilyn Yager
Senior Public Policy Advisor
202.756.3341
marilyn.yager@alston.com

If you would like to receive future Health Care Advisories electronically, please forward your contact information including e-mail address to healthcare.advisory@alston.com. Be sure to put “subscribe” in the subject line.