

# APhA REGULATORY SUMMARY

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## Centers for Medicare & Medicaid Services Proposed Rule on Revisions to the Medicare Advantage and Prescription Drug Benefit Programs

June 23, 2008

### Summary of Proposed Rule

On May 16, 2008, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule that contains new provisions related to special needs plans, medical savings accounts (MSA) plans, cost-sharing for dual eligible enrollees in the MA program, transparency, the prescription drug payment and negotiation prices processes in the Part D program, and the enrollment, appeals, and marketing processes for both programs. The changes are being proposed based on lessons learned since the initial year of the prescription drug program and the revised MA program.

Comments on the proposed rule are due July 15, 2008. The complete *Federal Register* proposed rule is available at: <http://edocket.access.gpo.gov/2008/pdf/08-1244.pdf>.

### Proposed Changes to Part 422: Medicare Advantage Program

#### *Special Needs Plans*

- Currently, Special Needs Plans (SNPs) serve: 1) institutionalized individuals, 2) individuals (dual eligibles) entitled to medical assistance under State Medicaid plans, and 3) other individuals with severe or disabling chronic conditions.
- Proposes to limit the number of non-special needs members to no more than 10% of new enrollees and that 90% of new enrollees must be special needs individuals; plans will be able to continue serving existing non-special needs members.
- Requires MA organizations (MAOs) to have a process, approved by CMS, to verify that potential SNP enrollees meet the dual eligible requirements. There are three means of meeting the verification requirement: 1) written documentation from beneficiary's former physician, 2) telephonic confirmation by the beneficiary's former physician, or 3) use of a verification tool followed by post-enrollment confirmation by any physician.
- SNPs are also required to verify enrollee's institutional status with the facility or appropriate State agency.
- Proposes that SNPs be required to develop a model of care specific to the special needs population they are serving.
- Proposes to add a new requirements that SNPs have networks with clinical expertise specific to the special needs population; use of performance measures to evaluate models of care; and be able to coordinate and deliver care targeted to the frail/disabled and those near the end-of-life based on appropriate protocols.
- Proposes to require that, within three years, MA organizations offering a SNP to serve dual eligibles must have, at a minimum, a documented relationship, such as a contract, memorandum of understanding (MOU), data exchange agreement, or some other agreed upon arrangement with the



State Medicaid agency for the State in which the dual eligible SNP is operating, in order to improve Medicare and Medicaid integration.

- Amends current regulations to require MA organizations, including SNPs, with dual eligible beneficiaries, to specify in their contracts with providers that enrollees would not be held liable for Medicare Parts A and B cost sharing when the State is liable for the cost sharing. Providers would either accept the MA plan payment in full or would bill the appropriate State agency (Medicaid). MA plans would be required to inform providers of the Medicare and Medicaid rules and benefits for dual eligible enrollees.

#### *MA Medical Savings Account (MSA) Transparency*

- Proposes to require MSA plans provide enrollees with information on the cost and quality of services as specified by CMS and provide information to CMS on how they would provide this information to enrollees. Proposes that requiring transparency on cost and quality information would permit enrollees to compare plan and provider costs and quality.

#### **Proposed Changes to part 423: Medicare Prescription Drug Benefit Program**

##### *Passive Election for Full Benefit Dual Eligible Individuals Who are Qualifying Covered Retirees*

- Proposes to establish a process under which Full Benefit Dual Eligibles (FBDE) who are enrolled in a qualifying employer group plan would be deemed to decline Part D coverage if, following a notice of their options, they do not indicate that they wish to receive it. As a result, these individuals would not be subject to default auto-enrollment. This option would be limited to only those employer group plans which receive an employer subsidy from CMS. No action by the beneficiary would be deemed as having declined enrollment in Medicare Part D to maintain coverage within their current qualified employer group plan.

##### *Part D Late Enrollment Penalty*

- Clarifies that Medicare Part D plan must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries.
- Proposes to require plans to report creditable coverage information, including the number of uncovered months from which the penalty will be calculated.
- Individuals determined to have a late enrollment penalty (LEP) have an opportunity to ask for a reconsideration of such determination. Beneficiaries would not have the right to further review of the reconsideration, but CMS would have the discretion to reopen, review, and revise a decision.

##### *Medicare Prescription Drug Benefit Program Definitions*

- Proposes to clarify CMS definitions related to what may be included in the drug costs that Part D sponsors use as the basis for calculating beneficiary cost sharing, use of pass-through costs versus locked-in costs on drug cost prices received at the pharmacy versus what the sponsor pays to a PBM, reporting drug costs to CMS for reinsurance reconciliations and risk sharing, and for submitting bids to CMS.
- Benefits and Beneficiary Protections:
  - “incurred costs”: amends current policy to allow nominal copayments assessed by manufacturer patient assistance programs (PAPs) to be applied toward an enrollee’s true out-of-pocket (TrOOP) balance or total drug spend.
  - “negotiated prices”: amends current definition to require that Part D sponsors base beneficiary cost sharing on the price ultimately received by the pharmacy or other dispensing provider. Specifically, the definition would state that negotiated prices are

prices that the Part D sponsor (or other intermediary contracting organization, such as a PBM) and the network dispensing pharmacy or other network dispensing provider will receive, in total, for a particular drug. The term would also be revised to include prices for covered Part D drugs negotiated between the Part D sponsor (or its intermediary contracting organizations) and other network dispensing providers.

- CMS indicates in the proposal that it intended “negotiated prices” to refer to the pass-through prices paid at the pharmacy and passed onto the beneficiary, not the locked-in prices that may be paid by a sponsor to the PBM, if the sponsor uses a PBM, that may be different than the prices paid at the pharmacy. Any PBM “spread” (net profit) should be included in a plan bid as an administrative cost, not as part of the drug cost.
- CMS anticipates that clarification would improve drug pricing transparency, better reflect the beneficiary TrOOP costs, and lower government subsidy payments for low-income cost sharing to Part D sponsors.
- CMS states that if locked-in prices continue to be used to calculate cost-sharing:
  - Beneficiaries would continue to advance more quickly through Part D coverage phases, incur higher cost sharing, and reach the coverage gap sooner;
  - Beneficiary would continue to experience confusion over actual drug prices;
  - Pharmacies would continue to have difficulties explaining drug prices to beneficiaries and in managing cash transfers to Part D sponsors; and
  - There would likely be an increase in drug spend cost shift from the government to beneficiaries in the form of higher out-of-pocket costs.
- **CMS is soliciting comments from chain and independent pharmacies on the extent to which this change will impact them, and particularly small independent pharmacies.**
- Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage
  - “actually paid”: codifies and clarifies previous guidance that direct or indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D sponsor has contracted for administrative services, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D sponsor. This definition applies regardless of the terms of the contract between the plan sponsor and any intermediary contracting organization. Similar amendments would be made to apply to the Retiree Drug Subsidy (RDS) program.
  - “administrative costs”: defined as the Part D sponsor’s costs other than those incurred to purchase or reimburse the purchase of Part D drugs under the Part D plan. Included in the definition are any costs incurred by Part D plans on drug claims that differ from the price charged by a dispensing entity for covered Part D drugs. Any net profit (or “risk premium” or “PBM spread”) retained by a PBM that is added to the prices paid to pharmacies and billed to a Part D sponsor would be considered an administrative cost and not a drug cost. Applies to the RDS program as well.
  - “gross covered prescription drug costs and allowable risk corridor costs”: would require plan sponsors to include the net profit or loss retained or incurred by the PBM as part of

lock-in pricing to be part of the administrative costs of the plan sponsor. This would require the amount ultimately received by the pharmacy (minus any other point-of-sale price concessions) to be used in calculating cost sharing for plan years 2010 and beyond. Specifically, CMS is proposing to require all plan sponsors report the amount ultimately received by the pharmacy or other dispensing provider, and that the amount ultimately received by the pharmacy or other dispensing provider (whether directly or indirectly) for the particular drug will be the basis for accumulating gross covered drug costs and reporting drug costs on the prescription Drug Event (PDE) records. CMS will consider comments on this proposed definition, as well the previously proposed rule (72 FR 29403-29423).

- “allowable risk corridor costs”: only based upon the amounts received directly by the pharmacy or other dispensing provider.
  - The amount received by the dispensing pharmacy or other dispensing provider (whether directly or through an intermediary contracting organization” is the basis for drug cost that must be reported to CMS, and not the amount paid by the Part D sponsor to the PBM.
  - Further amends the definition to ensure that when entities other than pharmacies dispense Part D drugs and receive payment for Part D drugs, these expenditures also are reflected in gross covered prescription drug costs and allowable reinsurance costs, as well as allowable risk corridor costs.
  - Amends definition of “gross covered prescription drug costs” to ensure that when a beneficiary is responsible for 100% of the cost for a covered part D drug, and the beneficiary obtains that covered Part D drug at a network pharmacy for a price below the plan’s negotiated price, the beneficiary’s out-of-pocket costs that are considered “incurred costs” for covered Part D drugs count toward both TrOOP and total drug spending.
- Payments to Sponsors of Retiree Prescription Drug Programs
    - Definitions under the Retiree Drug Subsidy (RDS) program mirror the changes noted above.

#### *Limiting Copayments to a Part D Plan’s Negotiated Price*

- Proposes to revise the requirements related to qualified prescription drug coverage to make clear that Part D sponsors must provide enrollees with access to, or make available at the point-of-sale, its negotiated prices of covered Part D drugs when the covered Part D drugs’ cost-share is more than the Part D sponsor’s negotiated price.

#### *Timeline for Providing Written Explanation of Plan Benefits*

- Proposes to require sponsors to provide an explanation of benefits (EOB) no later than the end of the month following the month in which an enrollee uses his or her Part D benefits.

#### *Low-Income Subsidy Provisions*

- Proposes to give CMS additional flexibility to make mid-year low-income cost-sharing subsidy (LICS) payment adjustments or other modifications to the LICS interim payment methodology.
- Codifies existing guidance and to clarify that the cost-sharing subsidy is not available when an individual’s out-of-pocket costs, under his or her Part D sponsor’s plan benefit package, are less than the amounts described in regulation.
- Part D sponsors must accept and use best available evidence (BAE) in those instances when this evidence, submitted by the beneficiary or another person the beneficiary’s behalf, substantiates that

the beneficiary's information in the CMS systems is not accurate. CMS plans to establish a feedback mechanism to the States to confirm the LIS corrections based on BAE and identify and address any problems in State to CMS reporting.

- Proposes to require Part D sponsors use BAE to substantiate a beneficiary's eligibility for a reduction in premiums or cost-sharing in the case of individuals who indicate they are eligible for the low-income subsidy.
- Part D sponsors would be required to accept and use BAE to correct the beneficiary's low-income subsidy data in the sponsor's system and, as applicable, document requests for CMS to correct the beneficiary's low-income subsidy data in the CMS system when the change has not occurred as a result of the routine reporting.
- BAE would be defined as documentation or information that is directly tied to authoritative sources, confirms that an individual meets the requirements for the low-income subsidy, and is used to support a change in an individual's low-income subsidy status. Examples of documentation currently include: Medicaid card, contact with the State Medicaid Agency, or State document confirming Medicaid status.

#### *Certification of Allowable Costs*

- Proposes to clarify that the certification of allowable costs for risk corridor and reinsurance information included direct and indirect remuneration that serves to decrease the costs incurred by a Part D sponsor for a Part D drug.

#### *Change of Ownership Provisions*

- Proposes to clarify that PDP sponsors may not sell or transfer individual beneficiaries or groups of beneficiaries enrolled in any of their plan benefit packages.

### **Proposed Changes to the MA and Prescription Drug Benefit Programs**

#### *Authorization of Automatic or Passive Enrollment Procedures*

- Sets forth in regulations 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 plan.
- Would require plans to notify all prospective enrollees of the passive enrollment prior to the effective date or as soon as possible thereafter.

#### *Involuntary Disenrollment for Nonpayment of Premium*

- Prohibits plans from disenrolling individuals for failure to pay premiums if they have either requested the premium withhold option or if they are already in premium withhold status.

#### *Disclosure of Plan Information*

- Proposes that plans must disclose plan information both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

#### *Retroactive Premium Collections and Beneficiary Repayment Options*

- Provides beneficiaries with the option of prorating past due premiums over a period of monthly payments

### *Prohibiting Improper Billing of Monthly Premiums*

- Prohibits plans from direct billing beneficiaries for premiums that the members have requested be withheld from the Social Security payments.

### *Non-Renewal Notification Timelines*

- Proposes to change the beneficiary and public notice requirement from at least 90 days to at least 60 days

### *Reconsiderations*

- Proposes to permit an enrollee's treating physician to request a standard plan reconsideration of a pre-service request on an enrollee's behalf without having been appointed by the enrollee as his or her representative.
- The physician must be able to demonstrate that he/she is treating the enrollee in question and would be required to notify the enrollee that he/she is taking this action.

### *Prescription Drug Benefit Program*

- Proposes to add a new definition for "other prescriber" to encompass health care professionals, other than physicians, with the requisite authority under State law or other applicable law to write prescriptions for Medicare beneficiaries.
- Proposes to allow physicians or other prescribers with the ability to request standard redeterminations on behalf of enrollees.

### *Civil Money Penalties*

- Proposes to clarify that CMS may impose a penalty 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.

### *Medicare Advantage and Prescription Drug Program marketing Requirements*

- Proposes to eliminate the file and use status based on an organization's track record, and apply a uniform policy to marketing materials that either use model language without substantive modification, or materials that are identified by CMS as not containing substantive content warranting CMS review.

### *Licensing of Marketing Representatives and Confirmation of Marketing Resources*

- Proposes to codify existing requirement that MA organizations and Part D sponsors utilize only state-licensed marketing representatives to do marketing where they use independent agents in the States that license such agents. Would also require plans to report to States that they are using such agents.
- Proposes to clarify several standards for MA and PDP organization marketing, including prohibition on door-to-door solicitation and outbound calling.
- Plans would not be permitted to engage in sales activities, including the distribution or collection of plan applications, at educational events. Sales activities would only be permitted in common areas of health care settings and would be prohibited in areas where patients primarily intend to receive health care services.
- Proposes to limit the types of promotional items offered to potential enrollees, and may not provide meals.
- Proposes to prohibit cross-selling of non-health care-related products.

- Proposes to limit the use of names and/or logos of co-branded network providers on plan membership and marketing materials.

*Broker and Agent Requirements*

- CMS intends to establish guidelines for agent compensation.
- Proposes to require that agents are trained on Medicare rules, regulations and compliance-related information on plan products they intend to sell. In addition, agents would be required to pass a written test.
- Would require plans to comply with State requests for information about the performance of licensed agents or brokers. CMS will establish and maintain a Memorandum of Understanding (MOU) with States to share compliance and oversight information.