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**To: Clients and Friends**  
**From: John Gorman and Jean LeMasurier**  
**Date: January 16, 2009**  
**Re: Summary of the Final and Proposed Regulations Impacting Medicare Advantage, Part D and RDS Programs (Including Negotiated Pricing)**

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On January 12, 2009, CMS issued final regulation CMS-4131-FC, “**Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions**”. This regulation finalizes a number of provisions from the May 16, 2008 proposed regulation impacting the Medicare Advantage, Prescription Drug and the Retiree Drug Subsidy programs. Regulations to implement related provisions from the Medicare Improvements for Patients and Providers Act (MIPPA) are also included.

Comments are requested on the new definitions of Special Needs Plans (SNPs) and proposals for treatment of negotiated prices in the Retiree Drug Subsidy (RDS) program. Most of the provisions in the regulations go into effect 60 days after publication. The provisions on “negotiated prices” for Part D plans and the SNP definitions and cost sharing requirements are effective January 1, 2010.

A full-text version can be found at:  
<http://www.gormanhealthgroup.com/download/FedRegCMS-2008-0056-0133.pdf>.

In addition, CMS issued CMS-4131-P2, “**Medicare Program; Prescription Drug Benefit Program: Payments to Sponsors of Retiree Prescription Drug Plans**”. This proposed regulation seeks comments on whether and how CMS should expand the interpretation of the employer waiver authority to “waiver or modify” statutory requirements related to the RDS program to facilitate the offering of a prescription drug plan to Medicare retirees. The regulation specifically seeks to determine whether the RDS waiver should be used to exclude the RDS program from the requirement to report pass-through prices and to report rebates and other price concessions retained by the PBM or other intermediary entity.

A PDF file version can be found at:  
<http://www.gormanhealthgroup.com/download/FedRegCMS-2008-0056-0132.pdf>.

## Summary of the Changes

The final regulation includes a summary of comments on the May proposed rule. In the majority of provisions, CMS adopted the policy in the proposed rule, unless it was superseded by provisions in MIPPA. The following includes some of the significant changes in the final rule:

- Modifies the SNP provision in the proposed rule (which allowed 90 percent of enrollees to meet the eligibility requirement) and adopted the MIPPA provisions requiring 100 percent of enrollees to meet the eligibility requirements
- Includes the MIPPA SNP definitions and added the MIPPA care management requirements
- Retains the policy in the proposed rule that limits the amount of cost sharing for duals for all Medicare plans (MIPPA was limited to Dual-SNPs)
- Defers policy on negotiated pries and retained rebates in the RDS program for further comment and rulemaking
- Expands the LICS payment adjustment provision to allow additional methods than mid-year payment adjustments in response to an OIG audit
- Requires best available evidence to determine low income subsidy eligibility be tied directly to the state or SSA systems and requires Part D plans to respond to requests from beneficiaries following the CMS process

**Special Needs Plans (SNPs)** -The regulation adds the new statutory definitions of SNPs that were included in MIPPA and finalizes other provisions from the final rule:

- **Institutional-Equivalent Individual** - As of January 1, 2010, new Institutional SNP enrollees who live in the community are required to be assessed by an entity other than the SNP using a State assessment tool. The preamble references a recently published survey to assist plans identify state tools and allows plans in states without tools to use the state's level of care methodology.
- **Severe or Disabling Chronic Conditions** - As of January 1, 2010, the eligibility definition is amended to require one or more co-morbid and medically complex chronic conditions that are substantially disabling or life threatening, has a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care. The preamble states that CMS will issue separate guidance to implement the MIPPA provision that requires the Secretary to convene a panel of clinical advisors to determine the conditions that meet the definition of severe and disabling chronic conditions.
- **Exclusive SNP Enrollment** – Effective January 1, 2010 the regulation modifies the definition of a SNP to require that all new SNP enrollees must be special needs individuals. This change will end the “disproportionate share” SNP policy that was allowed under the MMA and supersede the 90 percent methodology that was included in the May 2008 proposed rule. The preamble clarifies that current members who do not meet the definitions may not be disenrolled.

- **Eligibility Verification** - The final rule includes the requirement that SNPs must establish a process approved by CMS to verify that potential SNP enrollees meet the SNP's specific eligibility requirements. The preamble states that while verification generally will be either before enrollment or no later than the end of the first month of enrollment, CMS will continue to validate alternative proposals presented by plans.
- **Models of Care** - The regulation includes a new requirement for models of care to address the MIPPA clarification for effective care management. The new requirement is that model of care plans must: target one of the three SNP populations; have appropriate staff trained on the model of care to coordinate and/or deliver all services and benefits; coordinate the delivery of care across all health care settings, providers of services and services to assure continuity; coordinate the delivery of services that meet the needs of the most vulnerable beneficiaries including frail/disabled and beneficiaries near the end of life; and coordinate communication among plan personnel, providers and beneficiaries.

**Late Enrollment Penalty (LEP)** - Codifies current policy on plan responsibilities for LEP. For example, plans must obtain information on prior creditable coverage for all enrollees and report to CMS; the plan would then communicate the penalty to beneficiaries and their right for a reconsideration of the LEP penalty.

**MA Cost Sharing** – Effective January 1, 2010, All Medicare Advantage plans with Dual Eligible enrollment (including SNPs) must specify in their provider contracts that enrollees will not be held liable for Medicare Parts A and B cost sharing when the state is liable for this cost-sharing. Plans must also inform providers of the Medicare and Medicaid benefits and rules for enrollees.

The plan's cost sharing cannot exceed the amount that would have been permitted under Medicaid. Further, provider contracts must require the provider to accept the MA plan payment as payment in full or bill the appropriate State source. The preamble notes that this regulation is consistent with the proposed rule and goes beyond the MIPPA requirements which were limited to DE-SNPs because all duals need these protections.

**MA Medicare Savings Accounts (MSA) Transparency** – The final rule extends to regular MSAs the requirement to provide enrollees with information on cost and quality of services to the extent available and requires plans to submit their proposed approach to CMS for approval.

**Passive Election of Full Benefit DEs in Employer Group Plans** – The final rule includes the proposed provision to add a new process that would deem a full benefit DE retiree to decline Part D coverage following a notice of their options, thus avoiding a default auto-assignment to a Part D plan. This would apply to retirees whose employer receives the Retiree Drug Subsidy.

CMS has discretionary retroactive enrollment authority if the retiree subsequently chooses to enroll in a Part D plan rather than remaining in the employer plan.

**Part D Late Enrollment Penalty (LEP)** – The final rule adopts the proposal to codify current policy on plan responsibilities for LEP without modification. For example, plans must obtain information on prior creditable coverage for all enrollees and report to CMS and plans would report the CMS calculated penalty to beneficiaries. The preamble mentions several process improvements that have recently been adopted e.g. simplified documentation of creditable coverage for beneficiaries who change plans and allowing beneficiary telephonic attestations. The final rule also codifies the beneficiary right to and process for a reconsideration of the LEP penalty.

**Manufacturer Patient Assistance Program Copayments** – The final rule adopts the proposal to allow nominal copayments assessed by manufacturer Patient Assistance Programs to be included in “incurred costs” provided they are paid out of pocket and supported by beneficiary documentation. As a result, these copayments will count towards TrOOP balances (gross covered prescription drug costs and allowable reinsurance costs). In the preamble, CMS said they will consider developing a model form to simplify beneficiary reporting of these copayment amounts.

**Negotiated Prices** – The final rule adopts the provision in the proposed rule to amend the definition of negotiated prices effective January 1, 2010. Under the provision, base beneficiary cost sharing, total drug spend and cost reporting to the government will be based on the price ultimately received by the pharmacy (including mail order pharmacies) or other dispensing provider (i.e. the “pass-through price”). If a plan uses “lock-in” pricing, any differential between the price paid to the pharmacy and the price paid to the PBM or other intermediary contracting organization will be treated as an administrative cost rather than a drug cost under Part D. “Other network dispensing providers” will be added to the definition effective on enactment the regulation.

The preamble states that CMS will allow plans the option of paying administrative fees to intermediaries (i.e. the lock-in price) if they believe there will be better management of drug expenses and thus, lower costs. The preamble explains that this policy will result in lower costs for most beneficiaries who are enrolled in plans that use lock-in pricing because it will assure that administrative fees paid to intermediary contracting organizations (e.g. PBM spread or risk premium) will not be used to advance the beneficiary through the phases of the Part D benefit causing many beneficiaries to reach the coverage gap earlier.

Also these administrative fees will not be used to overstate low income subsidies and reinsurance subsidy payments paid by the government. The preamble agrees that the new policy could increase the bids of plans that use lock-in pricing, thus increasing beneficiary premiums overall, but that it will reduce cost sharing for all beneficiaries and especially beneficiaries who are high utilizers.

The preamble states that pharmacies supported the policy in the proposed rule and that CMS will monitor prices charged by plans that own their own pharmacies as part of the bid process. The preamble also discusses that Part D plan sponsors are not required to pass through rebates and price concessions at the point of sale.

Conforming regulatory changes are made to the definitions of:

- “Actually Paid” – The final rule modifies the language in the proposed rule to delete the phrase “administrative services” since this language could be interpreted as applying to organizations that provide administrative services such as audits or utilization management, which was not intended.
- “Administrative Costs” – New Definition
- “Gross Covered Drug Costs”
- “Allowable Reinsurance Costs”
- “Allowable Risk Corridor Costs”
- “Certification of Allowable Costs”

**Retiree Drug Subsidy (RDS) Program** - The proposed rule modified provisions to make the RDS program consistent with the Part D program, including the reporting of negotiated prices (“pass-through prices”) and treatment of risk payments to a PBM or other intermediary organization as administrative costs. Commenter opposed these changes in the RDS program citing concerns that employers (especially large employers that usually use lock-in pricing) would leave the RDS program and shift their retirees to Part D or drop retiree health care coverage.

In response, CMS is assessing whether there is statutory authority to adopt a different policy for the RDS program and CMS is requesting comments on whether and how to apply the Part D negotiated price policy to the RDS program. The preamble to the final rule presents three legal theories for keeping the current RDS option of reporting lock-in or pass-through pricing.

- Interpretation of Actually Paid – The theory would exclude any difference between lock-in and pass-through pricing, thus permitting either method to be used. Under this theory, the amount paid to a PBM or intermediary entity that includes ingredient an dispensing costs and management costs would be treated as “costs that are actually paid... by the sponsor.” This theory would not read the phrase “for the portion or the retiree’s gross covered retiree plan-related prescription drug costs,” which specifically excludes administrative costs.
- Prohibition on Interference with RDS Benefit Design – The theory would conclude that requiring the use of pass-through pricing would allow CMS to interfere with the benefit design of RDS coverage which is prohibited by statute. This theory would treat contractual arrangements between an RDS plan sponsor and a PBM as a “benefit design” and treat reporting of benefits as a mandated benefit design.

- Change the Interpretation of Waiver Authority – Use the employer waiver authority in section 1860D-22(b) to modify requirements of the RDS program. Since this change would require notice and rulemaking, CMS has issued CMS-4131-P2 requesting comments on this change. While this waiver authority is included in the RDS section of the law, it has been interpreted to only apply to MA and PDP plans.

In the preamble, CMS states that it shares the concerns of commenters who believe the purpose of the RDS program is to allow sponsors flexibility to maintain their plan designs. As a result CMS is deferring changes to the RDS program until further comments are analyzed. CMS also believes that the policy on retained rebates by PBMs and intermediary organizations is linked to the policy on negotiated prices and requests comments on whether the three legal theories provide CMS with the discretion to adopt a different policy for RDS than for Part D on retained rebates.

The final rule includes the following RDS changes to make the program consistent with Part D:

- Adding a definitions of “actually paid” and “administrative costs” that are not affected by the negotiated price issue described above
- Revising the definition of “allowable retiree costs” and “gross covered retiree plan-related prescription drug costs, or gross retire costs” (e.g. adding the term “intermediary contracting organization” which pays pharmacies or other drug dispensers or negotiates rebates)

**Limiting Co-pays to a Part D Plans’ Negotiated Price** - The final rule codifies current policy that requires the Part D plan sponsor to charge the beneficiary the lower of the cost sharing amount or the negotiated price throughout the Part D benefit. Negotiated prices must be provided even if no benefits are payable because of the application of the deductible and 100% coinsurance following satisfaction of the initial coverage limit.

**Timeline for Written EOBs** - The rule requires that the EOB be provided no later than the end of the month following the month in which an enrollee uses a Part D benefit, as included in the proposed rule.

### **Low Income Subsidy Provisions**

- **Low Income Cost Sharing (LICS) and Payment Adjustments** - This rule modifies the LICS payment methodology to permit mid-year payment adjustments. By adding the phrase “or by an alternative method that CMS determines” to the regulation text, CMS is responding to an OIG finding that the current method that uses estimates as part of the bid process may result in excessive LICS payments. In the preamble, CMS indicates it will seek stakeholder input to any alternative methods CMS might use.

- **Lesser of Policy for LIS Individuals** - The rule codifies existing policy that requires that Part D sponsors charge low income beneficiaries the lesser of the PBP prescribed cost sharing or the negotiated rate for the drug or the LIS amount in statute. Also the rule provides that the beneficiary should not be charged more than the plan's actual deductible.
- **Best Available Evidence (BAE)** - The final rule also modifies the definition of BAE to require that BAE documentation must be tied directly to the State or SSA systems. The final rule specifically requires Part D plans to use the CMS developed BAE process described in guidance to establish the appropriate cost sharing for low income beneficiaries whose information in CMS systems is not correct. The final regulation was further modified to include a requirement that Part D plans respond to requests from beneficiaries or others on their behalf in securing BAE following the CMS process (currently by referring the request to the CMS regional office). The preamble indicates that CMS will issue policy on correcting LIS status in CMS systems through operational guidance. The preamble also includes an amended list of BAE which includes SSA letters showing a beneficiary receives SSI (this item was inadvertently not included in the preamble of the proposed rule).

**Certification of Part D Allowable Costs** - The final regulation clarifies that the required certification of allowable costs for risk corridor and reinsurance information includes direct and indirect remuneration that decreases costs incurred for the Part D drug benefit. In the preamble, CMS indicates that they may refer cases to Federal law enforcement where they identify misrepresentations or omissions in the information provided to determine allowable costs.

**Change of Ownership** - This rule clarifies that PDP sponsors may not sell or transfer individual beneficiaries or groups of beneficiaries enrolled in any of their plan benefit packages. The language in the final rule has been modified to clarify that CMS would recognize the sale of one or more plan benefit packages (PBPs) as a line of business rather than requiring a sponsor to sell all PBPs under a contract. The preamble clarifies that this provision will not impact CMS policies concerning cross-walking, auto-enrollment or reassignment of beneficiaries.

**Automatic or Passive Enrollment Procedures** - The regulation would codify the current passive enrollment policies for MA and Part D plans in situations involving immediate plan terminations or potential beneficiary harm. The passive enrollment procedures include a beneficiary notification by the receiving plan prior to the enrollment effective date (or if impractical, as soon as possible) and provision of a special election period. In the preamble, CMS indicates that most commenters objected to a passive enrollment policy which allows CMS to enroll a MA enrollee from a terminating plan into another MA plan; however CMS does not agree and retains the current policy in the final rule.

**Involuntary Disenrollment for Nonpayment of Premiums** - The regulation would limit the MA and PDP plan option to disenroll beneficiaries for failure to pay premiums only if they pay premiums directly to the plan. Beneficiaries who have elected the Social Security withhold premium option could not be disenrolled.

**Retroactive Premium Collections** – The final rule includes the proposed new policy to allow beneficiaries that have retroactive MA or Part D premium obligations for reasons other than willful refusal to pay (e.g. systems errors where the enrollee is without fault) to choose a lump sum or to prorate past due premiums over a period of monthly payments consistent with the period of premium arrearage. The language in the final rule is modified to also permit other mutually acceptable means of repayment of past-due premiums.

**Prohibiting Improper Billing of Monthly Premiums** – The final rule includes the new regulatory provision to prohibit MA and Part D plans from direct billing enrollees when premium withholding was selected, and clarifies that the prohibition applies to premiums that the beneficiary has already paid through premium billing.

**Non-Renewal Notification Timelines** - The final regulation includes the proposal to change the MA and PDP notification timelines to “at least 60 days” to allow the completion of an appeal when CMS decides to non-renew a contract.

**Reconsiderations** – For MA plans, the rule would permit an enrollee’s treating physician to request a standard plan reconsideration of a pre-service request on an enrollee’s behalf without appointment as his or her representative. The physician would be required to notify the enrollee that he or she is taking this action.

For PDPs, the final rule will modify the definitions in Subpart M to add “other prescribers” to allow non-physician prescribers to perform the coverage determination and appeals processes. The rule also allows prescribing physicians and other prescribers to request a plan redetermination upon notice to the enrollee.

**Civil Money Penalties (CMPs)** - The final rule retains the proposed requirement that CMS may impose a penalty of not more than \$25,000 for each enrollee that is adversely affected (or substantially likely to be adversely affected) by an MA or PDP plans deficiency. The preamble states that CMS did not receive substantive comments on alternative approaches or monetary ranges for CMPs. However, CMS reserves the right to issue guidance on the range of penalties or caps associated with violations.

A full-text version of CMS-4131-FC can be found at:

<http://www.gormanhealthgroup.com/download/FedRegCMS-2008-0056-0133.pdf>

A PDF version of CMS-4131-P2 can be found at:

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