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Health Law Advisory: CMS Finalizes Medicare Part D Negotiated Pricing Regulation and Additional Remaining Revisions to Medicare Advantage and Part D Programs

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Yesterday the Centers for Medicare & Medicaid Services (**CMS**) published in the Federal Register a final rule with comment period (**Final Rule**) that includes significant changes to the regulations governing the Medicare Prescription Drug benefit (**Part D**) and the Medicare Advantage (**MA**) program, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[1] Most importantly, the new regulations affect Special Needs Plans (**SNPs**), medical savings account plans, cost sharing for dual eligible enrollees in the MA program, Part D's prescription drug payment and novation processes, and the enrollment and appeals processes for both programs. The Final Rule also included interim final regulations governing certain aspects of the Retiree Drug Subsidy program (**RDS**).

The Final Rule becomes effective March 13, 2009, except for the regulations governing SNPs and certain definitions, which will become applicable on January 1, 2010. CMS will accept comments on the provisions concerning the new definitions relating to SNPs and those concerning negotiated prices and retained rebates under the RDS program until March 13, 2009.

Medicare Advantage Special Needs Plans and Medical Savings Accounts

New Definitions That Impact Institutional and Chronic-Condition SNPs

Congress passed the Medicare Improvements for Patients and Providers Act[2] (**MIPPA**) on July 15, 2008. Section 164 of MIPPA contains two new statutory definitions that relate to the eligibility for SNPs.

MIPPA defined, and the Final Rule codified, the requirements for an institutional SNP enrollee living in the community but requiring an institutional level of care (**LOC**), or an "**institutional-equivalent individual**." As of January 1, 2010, an institutional SNP must meet two new eligibility requirements in order to enroll an institutional-equivalent individual. First, the SNP must use a state assessment tool to determine institutional LOC. Second, the SNP must arrange to have the LOC assessment conducted by an entity other than the MA organization. This entity must be impartial and have the professional knowledge necessary to accurately identify institutional LOC criteria.

The Final Rule also codified the statutory requirements applicable to chronic-condition SNPs that enroll special needs individuals with a "**severe or disabling chronic condition**." As of January 1, 2010, in order to enroll such an individual, chronic-condition SNPs must determine that:

- the individual has 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
- requires specialized delivery systems across domains of care.

Ensuring SNPs Serve Primarily Special Needs Individuals

Current regulations permit SNPs to enroll non-special needs individuals so long as the SNP enrolls a "greater proportion of special needs individuals than occur nationally in the Medicare population."[3] However, in addition to codifying the definitions stated above, the Final Rule specified that all new SNP enrollees must be special needs individuals. CMS believes that change will underscore the need for SNPs to focus on providing care and services to their targeted population. Importantly, CMS clarified that SNPs may not disenroll a non-special needs individual already enrolled in the SNP.

Ensuring Eligibility to Elect an MA Plan for Special Needs Individuals

Under the new regulations, SNPs must establish a process, which must be approved by CMS, to verify that potential enrollees meet the SNP's eligibility requirements. Although CMS does not detail specific verification requirements in the Final Rule, the *Medicare Managed Care Manual* requires that SNPs promptly verify an individual's eligibility for the SNP, generally either before enrollment or no later than the end of the first month of enrollment.

Model of Care

Lastly, with respect to SNPs, the Final Rule requires that SNPs establish a model of care specific to the special needs population they are serving. SNPs must have networks of clinical expertise tailored to the special needs population of the plan, use 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. SNPs are required to coordinate the delivery of services and benefits through integrated systems of communication among plan personnel, providers, and beneficiaries.

Medical Savings Accounts

Under the Final Rule, all medical savings account (**MSA**) plans must report cost and quality information to enrollees and inform CMS how this information is reported to enrollees. CMS does not specify any requirements as to how plans are to disclose this information to enrollees, but rather encourages MSA plans to work with enrollees to develop such information.

Medicare Part D

Passive Election for Full Benefit Dual Eligible Individuals Who Are Qualifying Covered Retirees

For full benefit dual eligible individuals enrolled in a qualifying employer group plan, CMS established an exception to the normal auto-enrollment procedures. Such individuals with qualified retiree coverage **will not** be automatically enrolled in a Medicare Part D plan. Rather, CMS will send a notice informing them that they will be deemed to have declined such enrollment unless they affirmatively choose a plan or opt for auto-enrollment.

Part D Late Enrollment Penalty

The Final Rule codified Part D plan responsibilities with respect to the administration of the Late Enrollment Penalty (**LEP**). Part D plans must obtain information on prior creditable prescription drug coverage from all enrolled or enrolling beneficiaries and must report this information to CMS. Individuals who are determined to be subject to an LEP must have the opportunity to ask for a reconsideration of this determination. Individuals may provide CMS with additional information related to prior prescription drug coverage in support of a request for reconsideration of an LEP determination. Enrollees subject to an LEP do not have the right to further administrative review of CMS's reconsideration decision.

Benefits and Beneficiary Protections

The Final Rule amended certain definitions with respect to how drug costs are reported that may significantly impact certain relationships between Part D plan sponsors and pharmacy benefit managers (**PBMs**).

Negotiated Prices, Administrative Costs, Allowable Risk Corridor Costs, and Gross Prescription Drug Costs

As part of the proposed rule issued on May 16, 2008,[4] CMS proposed to amend the definition of **"negotiated prices**," **"administrative costs**," **"allowable risk corridor costs**," and **"gross prescription drug costs.**" The Final Rule implements these definitions as proposed, which will take effect on January 1, 2010.

CMS revised the definition of **"negotiated prices"** to require that Part D sponsors base beneficiary cost sharing and price reporting to CMS on the price ultimately received by the pharmacy or other dispensing provider, commonly referred to as "pass-through" pricing. Current regulations allow Part D sponsors that contract with a PBM to report to CMS the amount paid to the PBM (the lock-in price) or the amount the PBM paid to the pharmacy (the pass-through price). Under the lock-in approach, a Part D plan pays the PBM a set rate for a particular drug, and the PBM then negotiates with pharmacies to obtain the lowest possible price for the drug. The PBM retains any difference between the price paid by the plan to the PBM and the price paid by the PBM to the pharmacy. Current regulations allow this difference to be reported as drug costs.

The new definition of negotiated prices allows plans to continue to use lock-in pricing with their PBMs, but requires that plans report to CMS the price actually paid to the pharmacy as the negotiated price. Any difference between the price paid by the plan to the PBM and the price paid by the PBM to the pharmacy or other dispensing provider must be reported as an administrative cost. Additionally, Part D plans must use the pass-through price as the basis for determining beneficiary cost-sharing amounts.

The Final Rule also revised the definition of **"actually paid"** to clarify that, with respect to reporting drug costs, direct or indirect remuneration includes all 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. This requirement applies regardless of whether an intermediary contracting organization that negotiates the direct or indirect remuneration on behalf of the Part D plan retains all or a portion of the remuneration or passes the entire amount on to the Part D plan sponsor. CMS reasoned that although Part D plan sponsors may not directly receive remuneration from the manufacturer, sponsors still receive the amount indirectly through reduced administrative costs.

Further, beginning in 2010, CMS will define **"administrative costs"** as the Part D sponsor's costs other than those costs incurred to purchase or reimburse the purchase of Part D drugs under the Part D plan. 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 are to be reported as administrative costs.

To ensure consistency with changes to the definition of negotiated prices, the Final Rule similarly amended the definition of **"gross prescription drug costs"** to clarify that the amount received by the dispensing pharmacy or other dispensing provider, and not the amount paid by the Part D sponsor to the PBM, is the basis for determining the drug costs that must be reported to CMS. CMS also clarified that when a beneficiary is responsible for 100% of the cost for a covered Part D drug and obtains that drug at a network pharmacy for a price below the plan's negotiated price, the beneficiary's out-of-pocket incurred costs count toward both true out-of-pocket (**TrOOP**) costs and total drug spend.

Finally, CMS revised the definition of **"allowable risk corridor costs"** to make clear that the amount received by the dispensing pharmacy or other dispensing provider is the basis for determining the drug costs that must be reported to CMS.

Retiree Prescription Drug Programs

CMS made corresponding changes to the definition of **"actually paid**," **"administrative costs**," and **"gross covered retiree-plan related prescription drug costs"** under 42 C.F.R. § 423.882 as they apply to RDS plans. However, CMS deferred making any final decision with respect to the applicability of the Part D policy on negotiated price or treatment of retained rebate amounts to the RDS program. Instead, CMS invited comments on whether it has the statutory discretion to adopt a different policy for the RDS program than to the Part D program.

Incurred Costs

The Final Rule revised the definition of **"incurred costs"** to clarify that certain nominal co-payments assessed by manufacturer Patient Assistant Programs can be applied toward an enrollee's TrOOP balance or total drug spend. Unlike the previously discussed amended definitions, this definition becomes effective 60 days after the Final Rule is published in the Federal Register.

Limiting Co-payments to a Part D Plan's Negotiated Prices

CMS clarified that enrollees must have access to the Part D plan's negotiated prices when the covered Part D drug's cost share is more than the Part D sponsor's negotiated price. In other words, the enrollee is responsible for the lesser of the applicable cost-sharing amount or the Plan sponsor's negotiated price for that drug.

Low-Income Subsidy Provisions

The Final Rule made several revisions to the low-income subsidy provisions. First, with respect to low-income cost-sharing (**LICS**) payment adjustments, CMS revised the regulations to provide itself with the flexibility to make mid-year LICS payment adjustments or other modifications to the LICS interim payment methodology. Next, CMS established a **"lesser of"** policy and clarified that the LICS cost-sharing subsidy is not available when the individual's out-of-pocket costs under the plan benefit package are less than the subsidy amount. Finally, CMS codified its policy of requiring Part D plan sponsors to use the best available evidence to substantiate a beneficiary's eligibility for a reduction in premiums and/or cost-sharing amount in the case of individuals who indicate that they are eligible for the low-income subsidy.

Certification of Allowable Costs

CMS amended the regulations to clarify that the certification of allowable costs for risk corridor and reinsurance information includes direct and indirect remuneration that serves to decrease the costs incurred by a Part D sponsor for a Part D drug.

Change of Ownership

The Final Rule clarified that Part D plan sponsors may not sell or transfer individual beneficiaries or groups of beneficiaries enrolled in any of their plan benefit packages apart from the rights and obligations related to the plan benefit package.

Medicare Advantage and Medicare Part D

The Final Rule contained several provisions that are applicable to both MA and Part D plans.

Passive Enrollment Procedures

CMS codified its current practice of allowing certain individuals to enroll in a particular plan by taking no action. Plans may passively enroll certain individuals in limited situations, such as in the case of immediate plan terminations or if failure to elect enrollment into a plan would result in potential harm to beneficiaries. MA organizations and Part D sponsors must

notify affected beneficiaries of the passive enrollment action before the effective date of the enrollment or as soon as possible after the effective date if prior notification is not possible under the circumstances.

Involuntary Disenrollment for Nonpayment of Premium

The Final Rule prohibits MA and Part D plans from disenrolling individuals for failure to pay premiums if the enrollee has either requested the premium-withhold option, or if he or she is already in premium-withhold status. Plans may initiate involuntary disenrollment for failure to pay premium only after the plan has notified an individual in direct bill status of the proposed involuntary disenrollment and afforded the applicable grace period.

Retroactive Premium Collection and Beneficiary Repayment Option

CMS amended the MA and Part D regulations to allow MA and Part D plans to prorate past-due premiums over a period of monthly payments when the enrollee is without fault in creating the premium arrearage (*i.e.*, for reasons other than a member's willful refusal to pay the premium). The plan may not charge interest to enrollees on past-due premiums, but this provision does not preclude the plan from initiating involuntary disenrollment for failure to pay premium. To the extent the enrollee has not been previously notified of proposed involuntary disenrollment for non-payment of premium, the enrollee is "without fault."

Prohibiting Improper Billing of Monthly Premiums

The Final Rule prohibits double-billing an enrollee who has elected and whose premiums have been withheld from their Social Security payments.

Non-Renewal Notification Timelines

In the Final Rule, CMS reduced the timeline for required notice of non-renewal. MA and Part D plans now need only provide 60 rather than 90 days notice to enrollees and the public.

Reconsiderations

The Final Rule permits an MA enrollee's physician to request a standard plan reconsideration on the enrollee's behalf even if not appointed to serve as his or her representative. The treating physician may request a plan-level appeal on behalf of the enrollee for a preservice request, but cannot request a standard plan-level appeal for payment.

Similarly, a Part D enrollee's prescribing physician or other prescriber may request a standard reconsideration on the enrollee's behalf upon providing notice to the enrollee that he or she is acting on the enrollee's behalf.

Civil Money Penalties

The Final Rule allows CMS to impose a penalty of up to $25,000 for each enrollee covered under an MA or Part D contract who is adversely affected or substantially likely to be adversely affected by the organization's deficiency or deficiencies. CMS will consider factors such as the severity of the infraction, the evidence supporting the infraction, the amount of the harm to the enrollee, and the organization's past conduct when determining the amount of the penalty. The regulations do not provide for maximum penalties or caps associated with violations.

Conclusion

While many of the regulations implemented in the Final Rule simply codify policies that were already in place via CMS subregulatory guidance documents, there are several amendments that require MA and Part D plans to evaluate their current operations and to develop new policies and procedures.

First, the definitions for institutional-equivalent individual and severe disabling chronic condition created by MIPPA establish new requirements for institutional and chronic-condition SNPs. In preparation for the 2010 plan year, institutional and chronic-condition SNPs must develop policies and procedures to ensure that their plans adhere to the requirements that govern how to determine and confirm eligibility for their respective plans. Second, the amended definitions of negotiated prices, administrative costs, allowable risk corridor costs, and gross prescription drug costs significantly change how many Part D plans currently report drug costs, and will require Part D plans that contract with PBMs using lock-in pricing to renegotiate these contracts before 2010. Finally, the amended provisions governing civil money penalties of up to $25,000 for each enrollee covered under an MA or Part D contract who is adversely affected or substantially likely to be adversely affected by the organization's deficiency or deficiencies considerably increase the risk for MA and Part D organizations. Each MA and Part D organization must evaluate its oversight of its operations to mitigate the risk of being noncompliant with MA and Part D requirements.

Endnotes

[1] Pub. L. 108-173.

[2] Pub. L. 110-275.

[3] 42 C.F.R. § 422.4(a)(iv)(B).

[4] 73 Fed. Reg. 28556.

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