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A Busy Start to 2009: A Summary of Recently Issued CMS Rules

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Introduction

January was a busy month for the Centers for Medicare & Medicaid Services (CMS). In the first three weeks of January 2009, CMS issued three rules concerning the Medicare Advantage (MA) and Part D programs. On January 12, CMS issued a rule containing a final regulation with comment period concerning several important aspects of the MA and Part D programs, and an interim final regulation governing certain aspects of the Retiree Drug Subsidy (RDS) Program and new definitions relating to Special Needs Plans (Final MA/PD Rule).[1] The same day CMS also issued a proposed rule on waiving or modifying statutory requirements pertaining to the RDS Program (RDS Rule).[2] And on January 16, CMS issued an interim final rule with comment period concerning the definition of a covered Part D drug and new requirements that apply to Part D formularies (Part D Formulary Rule).[3]

Below is a summary of the Final MA/PD Rule, RDS Rule, and Part D Formulary Rule. Following a brief review of the background to these rules, we provide a summary of changes that apply to Special Needs Plans (SNPs) and Medical Savings Accounts (MSAs) and review the requirements specific to Part D sponsors, before concluding with

[1] 74 Fed. Reg. 1493 (Jan. 12, 2009).
[2] 74 Fed. Reg. 1550 (Jan. 12, 2009).
[3] 74 Fed. Reg. 2881 (Jan. 16, 2009).

a summary of changes applicable to both Medicare Advantage Organizations (MAOs) and Part D sponsors.

Background

Over the last eight months both Congress and CMS proposed, and in some cases enacted or implemented, important operational changes to the MA and Part D programs. On May 16, 2008, CMS published a proposed rule that addressed many important aspects of the MA, Part D, and RDS programs (May Proposed Rule).[4] CMS explained in the preamble that "[a]s we have gained more experience with the MA program and the prescription drug benefit program, we are proposing to revise areas of both programs."[5] Shortly thereafter, Congress passed the Medicare Improvements for Patients and Providers Act (MIPAA)[6] over a presidential veto. MIPPA addressed several of the same issues as the May Rule—in some instances MIPAA requirements paralleled the May Proposed Rule, and other times "they complemented or superseded them."[7]

CMS subsequently published rules to implement MIPPA and modify the May Rule as appropriate. On September 18, 2008, CMS issued a final rule (Marketing Rule)[8] and an interim final rule with comment period (SNP Rule).[9] The Marketing Rule addressed MAO and Part D sponsor marketing practices, and the SNP Rule addressed a broader range of issues, including several new requirements for SNPs. Subsequently, on November 14, 2008, CMS issued an interim final rule with comment period modifying the earlier Marketing Rule.[10] CMS most recently issued this Final MA/PD Rule to respond to comments on the May Proposed Rule and finalize provisions that were not previously addressed.

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[4] 73 Fed. Reg. 28555 (May 16, 2008).
[5] 73 Fed. Reg. at 28557.
[6] Pub. L. No. 110-275.
[7] 74 Fed. Reg. at 1495.
[8] 73 Fed. Reg. 54208 (Sept. 18, 2008).
[9] 73 Fed. Reg. 54226 (Sept. 18, 2008).
[10] 73 Fed. Reg 67406 (Nov. 14, 2008).

Special Needs Plans

Congress first authorized the establishment of SNPs under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[11] MAOs that offer SNPs may target specific Medicare populations: (1) beneficiaries that continuously reside or are expected to continuously reside for ninety days or longer in a long term care facility, or are eligible for an institutional level of care (Institutional SNPs or I-SNPs); (2) dual eligible beneficiaries (Dual SNPs or D-SNPs); and (3) beneficiaries with severe or disabling conditions (Chronic Condition SNPs or C-SNPs).

The last several years have seen an explosion in SNPs and in Medicare beneficiaries enrolling in these plans.[12] With this growth has come increased scrutiny—by Congress, CMS, and advocacy groups. The May Proposed Rule, SNP Rule, MIPPA, and these Final MA/PD Rules all seek to ensure that SNPs are indeed "special." Since the authority to offer SNPs currently is set to expire December 31, 2010, MAOs that offer SNPs should view these requirements not only as a compliance obligation, but also as an opportunity to prove to Congress, CMS, and all stakeholders that SNPs provide valuable services to the frail and vulnerable populations that they serve.

Ensuring SNPs Serve Special Needs Individuals

Effective January 1, 2010, MIPPA requires SNPs to exclusively enroll special needs individuals—that is, beneficiaries who have the condition or qualification that the SNP targets. The Final MA/PD Rule similarly requires that MAOs offering SNPs exclusively enroll special needs individuals, although this limitation is effective March 13, 2009, under the Final MA/PD Final Rule.[13]

Under the original rules issued by CMS after the MMA, SNPs may either exclusively serve individuals with special needs or disproportionately serve special needs individuals.[14] A disproportionate SNP is required to enroll a greater proportion of special

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[11] Pub. L. No. 108-173.
[12] As of January 2009: 698 SNPs and 1,300,923 SNP enrollees. *See* CMS Special Needs Plan Comprehensive Report, January 2009.
[13] 74 Fed. Reg. at 1496-1497 and 1541 (to be codified at 42 C.F.R. § 422(a)(1)(iv)).
[14] 42 C.F.R. § 422.4(a)(iv)(B).

needs individuals than what would occur nationally in the Medicare population. CMS explained in the May Proposed Rule that it expected non-special needs beneficiaries to be primarily spouses and children of individuals who have the special needs condition.[15] CMS found that a large number of dual-eligible SNPs may have enrolled between 25% and 40% of non-special needs beneficiaries.[16] In the preamble to the May Proposed Rule, CMS explained its concern that disproportionate SNPs cannot focus appropriately on special needs enrollees because of the non-special needs membership. CMS proposed that non-special needs beneficiaries should account for no more than 10% of the membership.[17] The Medicare Payment Advisory Commission (MedPAC) also criticized the nature of disproportionate SNPs and recommended that 95% of their enrollees have a special need.[18] As noted above, Congress decided to take a more aggressive stance and require all Medicare beneficiaries to have a qualifying special needs condition.

This rule modifies the May Proposed Rule to comport with MIPPA and will require all beneficiaries to have a special need. While all new enrollees must have a special need, CMS stated in the preamble that a SNP may not disenroll a non-special needs beneficiary who was otherwise appropriately enrolled into a disproportionate SNP.[19] Given this issue's importance, we should expect additional guidance from CMS.

Ensuring Beneficiary Eligibility

Beginning March 13, 2009, since all beneficiaries will be required to have a qualifying special needs condition, verifying eligibility will become all the more important. The Final MA/PD Rule requires that SNPs employ a process approved by CMS to verify eligibility of beneficiaries.[20] While CMS currently provides guidance on verification requirements

[15] 73 Fed. Reg. at 28557.
[16] 73 Fed. Reg. at 28558.
[17] *Id.*
[18] MedPAC, *Report to the Congress: Medicare Payment Policy (March 2008)*, p. 240.
[19] 74 Fed. Reg. at 1496.
[20] 74 Fed. Reg. at 1497-1498 and 1541 (to be codified at 42 C.F.R. § 422.52(f)).

in Chapter 2 of the Medicare Managed Care Manual, CMS decided to set forth in its regulation its specific authority to establish verification requirements.[21]

There are unique operational challenges for all three types of SNPs: C-SNPs, D-SNPs, and I-SNPs. The industry generally has found and CMS has acknowledged that the greatest challenge has been verifying beneficiary's chronic conditions for C-SNPs. CMS has provided C-SNPs with several alternatives, including the use of a pre-enrollment qualification assessment tool followed by post-enrollment verification. These options may be inadequate. In an October 2008 memorandum (C-SNP Memo), CMS acknowledged the challenge in confirming eligibility through a provider's office: "[w]e have heard from some organizations that occasionally a provider or the provider's office is unwilling or unable to provide the requested confirmation of an individual's special needs status on a timely basis."[22] In that memo and in the preamble to the Final MA/PD Rule, CMS indicates that it is willing to accept alternative proposals presented by C-SNPs to verify eligibility. CMS provided in the C-SNP Memo a list of required elements that must be included in the proposal.[23]

Model of Care

One of the main ways SNPs provide value is by developing and implementing a robust model of care. The Final MA/PD Rule requires that SNPs implement a specific model of care.[24] MIPPA also includes specific model of care requirements. CMS' requirements are intended to complement MIPPA; the model of care requirements should be read together. In the preamble to the Final MA/PD Rule, CMS explained that, "[w]e believe that combination of MIPPA's statutory elements and our regulatory prescriptions for the SNP model of care establishes the standardized architecture for effective care

[21] *See* Medicare Managed Care Manual, Ch. 2 § 20.11.
[22] Memorandum from Teresa DeCaro, Acting Director Medicare Drug & Health Plan Contract Administration Group, and Anthony Culotta, Director Medicare Enrollment & Appeals Group to All Medicare Advantage Organizations (Oct. 21, 2008) (on file with author).
[23] *Id.*
[24] 74 Fed. Reg. at 1498-1499 and 1541 (to be codified at 42 C.F.R. § 422.101(f)).

management, yet gives plans the flexibility to meet the identified needs of their target population."[25]

Section 164 of MIPPA requires that SNPs:

- Have an evidenced-based model of care with appropriate networks of providers and specialists;
- Conduct an initial assessment and an annual reassessment of the member's physical, psychosocial, and functional needs;
- Develop a plan in consultation with the member (as feasible) that identifies goals and objectives; and
- Use an interdisciplinary team in the management of care.[26]

The Final MA/PD Rule also requires MA organizations offering SNPs to implement a model of care to assure an effective management structure:

- Target one of the three SNP populations;
- Have appropriate staff trained on the SNP model of care to coordinate and/or deliver all services and benefits;
- Coordinate the delivery of care across healthcare settings, providers, and services to assure continuity of care;
- Coordinate the delivery of specialized benefits and services that meet the needs of the most vulnerable members, including frail/disabled and members near the end of life; and
- Coordinate communication among plan personnel, providers, and members.[27]

The 2010 Draft Call Letter provided that all MAOs wishing to offer SNPs in 2010 must submit information on their model of care for the 2010 contract year. CMS will audit MAOs for compliance with the model of care requirements.

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[25] 74 Fed. Reg. at 1498.
[26] 42 U.S.C. § 1395w-28(f)(5).
[27] 74 Fed. Reg. at 1541 (to be codified at 42 C.F.R. § 422.101(f)(2)).

Responsibility for Cost-Sharing

Providers often receive two payments for dual eligible beneficiaries. The first is the MAO's primary payment for Medicare services, and the second is the State Medicaid Agency's payment of the Medicare cost-sharing (copayment or coinsurance). At times, the dual payment stream creates operational difficulties, and dual eligible beneficiaries may be incorrectly billed by healthcare providers for the Medicare cost-sharing. Congress addressed this issue in Section 165 of MIPPA. Effective January 1, 2010, a D-SNP cannot impose "cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX [Medicaid] if the individual were not enrolled in such plan."[28]

The Final MA/PD Rule expands the scope of MIPPA: it will apply to all MA plans that enroll dual eligible beneficiaries. MAOs with dual eligible enrollees must specify in provider contracts that such members will not be held liable for Medicare Part A and B cost sharing when the state is responsible for those amounts. The contract must state that providers will (1) accept the MA plan payment as payment in full or (2) bill the appropriate state source.[29] The MAO must also inform providers of Medicare and Medicaid benefits and eligibility rules.[30] Given the large number of dual eligible beneficiaries, this requirement will likely apply to most MAOs. MAOs must have contracts in place by January 1, 2010.

Definitions

CMS has added two new definitions; "institutional-equivalent individual" and "severe or disabling chronic condition" to comport with MIPPA.[31] Since these definitions were not included in the May Proposed Rule, they are being added in the interim final regulations as part of the Final MA/PD Rule.

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[28] 42 U.S.C. § 1395w-22(a)(7).
[29] 42 Fed. Reg. at 1542 (to be codified at 42 C.F.R. § 422.504(g)(1)(iii)).
[30] *Id.*
[31] 74 Fed. Reg. at 1495-1496 and 1540 (to be codified at 42 C.F.R. § 422.2).

Unlike with the earlier SNP rules, these definitions are interim final regulations. CMS will consider comments on the proposed definitions that are provided no later than March 13, 2009.

Medical Savings Account Transparency

The Final MA/PD Rule requires all MAOs offering MSAs to provide members with available information on the cost and quality of services in their service area.[32] MAOs must submit to CMS for approval a proposed approach to providing the cost and quality information.[33] This section of the Final MA/PD Rule is effective March 13, 2009.

MSAs are a type of MA plan with a high deductible and a savings account feature. The plan covers Medicare covered services once the high deductible is met. In addition, moneys are placed in a savings account to cover healthcare costs until the deductible is met.[34] As of January 2009, CMS reported 1,357 beneficiaries enrolled in MSAs.[35]

CMS explains in the preamble to the May Proposed Rule that it seeks to "implement a basic tenet of high-deductible health plans, the availability of useful cost and quality information to support consumer shopping."[36] A key component to the success of MSAs is consumer information and empowerment. Information on cost and quality permits beneficiaries to best manage their medical care and corresponding costs. CMS did not mandate any specific reports or other data, but rather required that the MAO file its plans with CMS for approval. In the preamble to the Final MA/PD Rule, CMS explains that it expects MAOs to provide the same level of information on cost and quality of services that it provides to its commercial enrollees.[37]

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[32] 74 Fed. Reg. at 1500-1501, 1541 (to be codified at 42 C.F.R. § 422.103(e)).
[33] *Id.*
[34] 73 Fed. Reg. at. 28560.
[35] CMS Monthly Contract Summary Report-January 2009, *available at:* www.cms.hhs.gov/MCRAdvPartDEnrolData/MCESR/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS1219315&intNumPerPage=10.
[36] 73 Fed. Reg. at 28561.
[37] 74 Fed. Reg. at 1500.

Changes to the Medicare Prescription Drug Program

Many of the provisions in the Final MA/PD Rule released by CMS on January 12, 2009, represent codifications and clarifications of current guidance on Best Available Evidence, the low-income subsidy program, and the Late Enrollment Penalty. The new regulations also include a number of additions and revisions that affect pricing and drug cost reporting.

Part D Payment and Pricing Policies and Cost Reporting

Negotiated Prices

CMS made two revisions to the definition of "negotiated prices," each with different effective dates. The most significant change, which goes into effect for contract year 2010, requires Part D sponsors to use pass-through pricing to determine beneficiary cost-sharing and for drug cost reporting. The pass-through price is the price ultimately received by the pharmacy or other dispensing provider for covered Part D drugs. Many plans currently use lock-in pricing, whereby the plan pays the PBM a set amount for a particular drug, and the PBM negotiates with pharmacies to obtain the best price.

Since Part D sponsors may contract with providers other than pharmacies to dispense Part D drugs, CMS also expanded the term "negotiated prices" to include prices for Part D drugs negotiated between the Part D sponsor and *all* network dispensing providers, rather than just network pharmacies. This aspect of the definition goes into effect on the effective date of the Final MA/PD Rule, March 13, 2009.

In a related provision at § 423.104, CMS clarified that Part D sponsors must make Part D drugs available to enrollees at the negotiated price when the negotiated price is less than the plan cost-share.

CMS stressed in the preamble of the Final MA/PD Rule that plans are free to use either pass-through or lock-in pricing in their pharmacy benefits manager (PBM) contracts. In fact, CMS expects plans to continue using lock-in to the extent that they are able to obtain better discounts or reduced total drug costs. However, beginning with contract year 2010, the difference between the amount paid to the PBM and the amount the

PBM pays to the pharmacy or other dispensing provider must be categorized as an administrative cost, as defined in the Final MA/PD Rule and described below.

Administrative Costs

Consistent with the changes to “negotiated prices,” CMS added a definition for the term “administrative costs” in Subpart G—Payments to Part D Plan Sponsor for Qualified Prescription Drug Coverage. This definition clarifies that any costs other than those incurred to purchase or reimburse for the purchase of Part D drugs are considered administrative, including any difference in the price paid to a PBM and the price the PBM pays the dispensing provider. Like the revised definition of “negotiated prices,” the definition of “administrative costs” is effective for the 2010 contract year.

Allowable Risk Corridor Costs, Gross Covered Prescription Drug Costs, and Target Amount

CMS revised the definitions of Allowable Risk Corridor Costs, Gross Covered Prescription Drug Costs, and Target Amount to establish that when reporting drug costs to CMS, Part D sponsors must use the amount received by the dispensing pharmacy or other dispensing provider, rather than the amount paid by the Part D sponsor to the PBM or other intermediary contracting organization. Again, these changes are designed to ensure that administrative costs—such as the difference in price paid to a PBM and the price paid by the PBM to the dispensing provider—will not be a factor when determining the amount of the Medicare Program’s reinsurance and risk sharing payments to Part D sponsors.

CMS adopted this pricing policy for several reasons. CMS believes that overall, lock-in pricing results in higher negotiated prices than pass-through pricing, leading to a potential shifting of costs from the Part D sponsor to beneficiaries and the government. For plans that impose coinsurance, beneficiaries pay a percentage of the negotiated price. And for plans that impose copayments, the copayment amounts are tied to actuarial equivalence requirements based on negotiated prices. When negotiated prices are higher, beneficiaries move through the phases of the Part D benefit more quickly, making them more likely to reach the coverage gap during the plan year. Ultimately, more beneficiaries may reach the catastrophic coverage limit when lower cost-sharing

and reinsurance subsidies kick in. Higher negotiated prices also lead to higher allowable drug costs, upon which the reinsurance subsidy is based. Continuing to allow lock-in pricing also could lead to CMS sharing risk with Part D sponsors (through the reinsurance subsidy) on amounts that include administrative costs. The use of pass-through pricing separates the point-of-sale drug price from any administrative costs paid by the plan to its PBM.

The pass-through pricing policy also will lead to greater transparency. Because cost reporting will be based on the point-of-sale price, both CMS and Part D sponsors will be aware of actual Part D drug costs. In addition, plans continuing to contract with PBMs using the lock-in method will be more aware of their administrative fees.

Actually Paid

CMS revised the definition of "actually paid" to codify existing guidance regarding direct or indirect remuneration (DIR). CMS intends for rebates, price concessions, and other forms of DIR to be treated as part of the true drug cost. Under the revised definition, discounts, rebates, grants, and other price concessions or similar benefits are counted as DIR, regardless of whether the concessions and benefits are retained in whole or in part by an intermediary contracting organization, (e.g., a PBM) or passed onto the Part D Sponsor.

CMS made one change to the revised definition presented in the May Proposed Rule in order to clarify the meaning of "intermediary contracting organization." As originally drafted, the definition could be construed to encompass any entity with which the Part D Sponsor contracts for administrative services. CMS clarified that for purposes of this rule, an intermediary contracting organization is any entity that contracts with a plan sponsor to:

(a) Pay pharmacies and other dispensers (regardless of whether the intermediary negotiates on behalf of the Part D Sponsor or on its own behalf); and/or

(b) Negotiate rebates or price concessions with manufacturers (either on behalf of the Part D Sponsor or on its own behalf).

Incurred Costs and Gross Covered Prescription Drug Costs

CMS revised the definition of “incurred costs” to require Part D sponsors to apply copayments assessed by manufacturer Pharmacy Assistant Programs (PAPs) toward true out-of-pocket expenses (TrOOP) and total drug spend, consistent with current policy. Part D plan enrollees must submit appropriate documentation to the Part D sponsor in order for the copayments to be applied. Because of the additional burden this may place on Part D plan enrollees, CMS is considering issuing a model form that beneficiaries can use to notify Sponsors of copayments paid under a PAP. Consistent with the definition of “incurred costs,” CMS also revised the definition of “gross covered prescription drug costs” to ensure that PAP copayments are included.

Pricing Policies in the Retiree Drug Subsidy Program

In the May Proposed Rule, CMS proposed adopting the same pass-through pricing and retained rebates policies to the RDS program as it has for the Part D program. After receiving comments expressing concern about the potential impact these policies might have on retiree group health coverage, CMS, through the Final MA/PD Rule, decided to defer finalizing the proposed changes and to re-open the comment period with respect to these provisions. By doing so, CMS preserved the status quo for the RDS program regarding negotiated prices and retained rebates.

The May Proposed Rule would have added a definition of “actually paid” consistent with the definition adopted in the final Part D regulations. Language in this definition would have provided that DIR includes discounts, rebates, coupons, goods in kind, etc. whether retained in whole or in part by an intermediary or passed on to the Sponsor (retained rebate policy). CMS also proposed to add a definition of “negotiated prices” that would mirror the definition finalized in the Part D regulations. That is, it would require the use of pass-through prices for reporting, rather than the lock-in prices.

During the reopened comment period, CMS invites comments on three legal theories under which it could be argued that CMS has the discretion to adopt different cost-reporting policies for RDS than those adopted for Part D.

Legal Theories

—Interpretation of “Actually Paid”—

CMS could interpret “actually paid” to exclude the difference between the pass-through price and the lock-in price. This would allow Retiree Prescription Drug Plan Sponsors to use either method to report allowable costs upon which the subsidy is calculated. CMS points out a potential problem with this theory: the use of lock-in pricing to calculate drug costs could lead to the inclusion of administrative costs in gross retiree plan-related prescription drug costs. The definition of this term in the RDS regulations explicitly excludes administrative costs.

—Interference with Employer Group retiree plan benefit design—

The RDS program contains provisions prohibiting CMS from interfering in the benefit design of retiree drug coverage. Under the second legal theory proposed by CMS, requiring Sponsors to use pass-through pricing to report drug costs could be construed as interfering in an RDS Sponsor’s benefit design. As CMS points out, however, there is some question as to whether the contractual arrangement between the RDS Sponsor and PBM can be construed as a “benefit design,” and, even if it is, whether requiring Sponsors to report the pass-through price interferes with that relationship.

—Interpretation of Waiver Authority—

CMS has the authority to waive or modify statutory requirements in order to give employers flexibility in their benefit designs. Historically, CMS has interpreted its waiver authority as applying only to the Part D program. CMS suggests it could change its interpretation of this authority to apply to the RDS program. To do so, CMS would need to revise current regulations. Concurrent with the Final MA/PD Rule, CMS published a notice of proposed rule making (RDS Rule) and is

soliciting comments on this proposed change to its interpretation of the waiver provision.

Comments on the RDS Rule and on the three legal theories described in the RDS section of the Final MA/PD Rule are due March 13, 2009.

The remainder of the RDS changes proposed in the May Proposed Rule are adopted in the Final MA/PD Rule. Specifically, CMS adopted the proposed definitions of “actually paid,” “administrative” costs,” and “gross retiree plan-related prescription drug cost,” “or gross retiree costs,” minus the portions of these definitions related to negotiated prices and retained rebates. CMS also adopted the definition of “allowable retiree costs” as proposed.

Auto-Assignment Process Change

Under current CMS rules, full benefit dual eligible beneficiaries are automatically assigned to a Part D plan by CMS when they become dually eligible, unless they have already selected a Part D plan. In the Final MA/PD Rule, CMS established an exception to these auto-assignment procedures for full benefit dual eligible individuals who are enrolled in a qualifying employer group plan. A qualifying employer group plan is one that has been approved to receive the RDS.

Instead of being auto-assigned, full benefit dual eligible beneficiaries covered under a qualifying employer group plan will need to affirmatively choose to enroll in a Part D plan. If they do not, CMS will consider them to have declined such enrollment. Coverage for full benefit dual eligible beneficiaries who declined enrollment when first becoming dually eligible and then later elected to enroll in a Part D plan will usually be prospective; CMS will generally not make such later enrollment retroactive to the date of dual eligibility. However, CMS will consider retroactivity on a case-by-case basis under certain circumstances; CMS says it will issue guidance clarifying situations in which retroactivity may be appropriate.

Late Enrollment Penalty

The Final MA/PD Rule provides clarification regarding the role of Part D sponsors in the Late Enrollment Penalty (LEP) redetermination process. Plan responsibilities are

already outlined in existing guidance, specifically Chapters 4 and 19 of the Medicare Prescription Drug Benefit Manual.

If CMS systems show a gap in coverage, Part D sponsors must obtain creditable coverage information directly from the beneficiary. CMS systems only reflect information on Part D coverage and coverage through an RDS-qualified employer group health plan; the beneficiary may have had other sources of creditable coverage. Part D sponsors who identify a true gap in creditable coverage must then report the number of uncovered months to CMS, which will calculate the penalty and report it back to the Part D sponsor. The Part D sponsor will then notify the beneficiary of the LEP determination and provide information on the redetermination process.

Under the MMA, beneficiaries may request a redetermination of the LEP if they believe that they were not adequately informed that existing coverage was not creditable. In the final regulations, CMS extends the redetermination process to all beneficiaries determined to have an LEP. The regulations also provide that CMS' redetermination decision (or that of the independent review entity) is final; beneficiaries do not have the right to further administrative review. However, CMS has the discretion to reopen, review, and revise their decisions.

Low-Income Subsidy Provisions

Recouping excessive LICS payment

CMS uses estimates provided as part of the annual bidding process to make prospective payments of the low-income cost-sharing subsidy (LICS). The current regulation at § 423.329(d)(2)(i) requires CMS to establish a payment method for making interim LICS payments based on estimates provided as part of the annual bidding process. CMS makes prospective payments based on these estimates, resulting in overpayments when the estimates are too high. The language in the current regulation restricts CMS' ability to recover excessive LICS payments until the year-end reconciliation. The final regulation adds language to this section that gives CMS greater flexibility in devising the method for making interim LICS payments, including the ability to make mid-year adjustments or other modifications. CMS did not provide specifics on the methodology that they might use for mid-year LICS adjustments.

Lesser of Policy

In a codification of existing guidance, the Final Regulations specify that the low-income cost-sharing subsidy is not available for a Part D drug when the cost-sharing under the enrollee's benefit plan is less than the statutory low-income subsidy cost-sharing. That is, the low-income subsidy cost-sharing amounts are maximum, not minimum amounts. Beneficiaries receiving the low-income subsidy can be charged no more than the low-income subsidy cost-sharing. If the plan's benefit package provides a lower cost-sharing amount, the LIS beneficiary is entitled to that cost-sharing amount.

Using Best Available Evidence to Determine Low Income Subsidy Eligibility Status

In the final regulations, CMS codified the existing policy guidance found in their June 27, 2007 memo titled "Part D Guidance – Low-Income Subsidy (LIS) Status Corrections Based on Best Available Evidence."[38] Specifically, Part D sponsors must use Best Available Evidence (BAE) to verify a beneficiary's eligibility for reduced premiums and/or cost-sharing when the beneficiary indicates he or she is eligible for the low-income subsidy. When BAE confirms that a beneficiary is qualified, the Sponsor must correct the beneficiary's LIS status in its own system, *and* send a request (which must be documented) to CMS for correction of the beneficiary's status in either CMS' or the Social Security Administration's (SSA) systems.

CMS revised the definition of Best Available Evidence to indicate that BAE documentation or other information must be tied to directly to the state or SSA systems. In the comments section, CMS provided a list of the types of BAE that Sponsors must accept.

[38] *Available at:* www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/Final%20Sponsor%20Guidance%20on%20BAE%20062707.zip.

Other changes in the Final MA/PD Rule

The following additional revisions were adopted in the Final MA/PD Rule as proposed:

> —The timeframe for providing the written explanation of plan benefits (EOB) is extended to the end of the month following the month in which the beneficiary used his/her benefit. (§ 423.128)
>
> —Certification of allowable costs for risk corridor and reinsurance information includes direct and indirect remuneration that reduces a Part D sponsor's costs for Part D drugs. (§ 423.505(k)(5))
>
> —PDP sponsors are not permitted to sell or transfer individual beneficiaries or groups of beneficiaries enrolled in any of their plan benefit packages. Any such sale or transfer must be accompanied by a transfer of the rights and obligations related to the pharmacy benefits package. (§ 423.551(g))

Changes to the Medicare Advantage and Prescription Drug Programs

Authorization of Automatic or Passive Enrollment

Passive enrollment is when a Medicare beneficiary is notified that he or she can make an enrollment election into an MA or Part D plan by taking no action. The Final MA/PD Rule provides that CMS may implement passive enrollment into an alternate plan in the event of immediate termination of an MA or Part D plan, or other situations in which CMS determines that a beneficiary remaining enrolled in the plan poses potential harm.[39] The enrollee will be deemed to have elected the new plan unless the beneficiary declines enrollment in the plan or requests enrollment in another plan. The new MA or Part D plan must provide notice that describes the costs and benefits of the new plan, and clearly explains the beneficiary's ability to decline the enrollment or choose another plan. The beneficiary also is eligible for a special election period (SEP) that begins when the beneficiary is notified of the passive enrollment and extends for

[39] 74 Fed. Reg. at 1524-1526, 1541 (to be codified at 42 C.F.R. § 422.60) (MA), and 1543 (to be codified at 42 C.F.R. § 423.32) (Part D).

two additional months.[40] The SEP may be extended at CMS' discretion.[41] This section of the Final MA/PD Rule is effective March 13, 2009.

In the May Proposed Rule, CMS sought to incorporate its existing passive enrollment policy into regulations.[42] Under the Final MA/PD Rule, in rare circumstances, such as an MAO or Part D sponsor's insolvency or a significant compliance issues, CMS may passively enroll beneficiaries into an alternative MA or Part D plan.[43] As an example, after MD Medicare Choice fell into financial distress, the company's beneficiaries were passively enrolled in a Humana MA plan.[44] As a result of increased economic challenges, CMS may be required to use this option more frequently in the future.

Involuntary Disenrollment for Nonpayment of Premium

Beneficiaries can have monies withheld from their Social Security benefit to pay for MA or Part D plan premiums.[45] The interface and exchange of information between CMS and the Social Security Administration can be challenging.[46] CMS is working closely with the Social Security Administration to "refine the premium withhold process in order to ensure a more timely and equitable outcome for all."[47]

To protect beneficiaries from disenrollment when the nonpayment of premium is not the beneficiary's fault, this section of the Final MA/PD Rule provides that an MAO or Part D sponsor shall not disenroll a member for failure to pay premiums if he or she had the premium withheld, or is in premium withhold status.[48] Rather, MAOs or Part D sponsors may initiate disenrollment for failure to pay premiums only if the beneficiary is in "direct

[40] 74 Fed. Reg. at 1526.
[41] *Id.*
[42] 73 Fed. Reg. at 28576-28577, 28592-28593 (to be codified at 42 C.F.R. § 422.60) (MA) and 28596 (to be codified at 42 C.F.R. § 423.32) (Part D).
[43] *Id.*
[44] A copy of the CMS beneficiary communication is *available at:* www.cms.hhs.gov/HealthPlansGenInfo/Downloads/MDMCbeneltr092908.pdf (Last visited on Jan. 30, 2009).
[45] 42 C.F.R. §§ 422.262(f) (MA) and 423.293 (Part D).
[46] *See e.g.*, United States Government Accountability Office, *Schedule and Timing Issues Complicate Withholding Premiums for Medicare Parts C and D from Social Security Payments*, July 15, 2008.
[47] 74 Fed. Reg. at 1526.
[48] 74 Fed. Reg. at 1526-1528, 1541 (to be codified at 42 C.F.R. § 422.74) (MA) and 1543 (codified at 42 C.F.R. § 423.44) (Part D)).

bill" status—meaning that the beneficiary pays the MAO or Part D sponsor directly for the premium, and the beneficiary has been notified of the premium owed. This section of the Final MA/PD Rule is effective March 13, 2009.

For MA plans, the beneficiary must be provided a grace period while it makes reasonable efforts to collect unpaid premium amounts.[49] And for Part D plans, the plan must make reasonable efforts to collect unpaid premiums before disenrollment, as provided in 42 C.F.R. § 423.44(d)(1)(i). CMS explained in the May Proposed Rule that "we believe that such disenrollments [for failure to pay premiums] should be an option only in cases where individuals pay their required premiums directly to the plan, as opposed to individuals who have chosen to have their premiums automatically withheld from their Social Security benefits."[50]

Retroactive Premium Collections and Beneficiary Repayment Options

The Final MA/PD Rule protects enrollees from a MAO or Part D sponsor demanding lump-sum collection payment of past premiums due by an enrollee. This provision provides that if the enrollee is "without fault," the MAO or Part D sponsor may collect past premiums due by any of the following options, at the enrollee's discretion: (1) Lump sum payment; (2) Payment by equal monthly installments equal to the period of time that premiums were due; or (3) Other mutually agreed upon arrangements.[51] "Without fault" is not defined by CMS, although the May Proposed Rule provides that "[w]e believe it would be consistent with these provisions to provide beneficiaries with the option of prorating due premiums over a period of monthly payments when the reason for the premium arrearage is other than a member's willful refusal to remit the premium."[52] In the Final MA/PD Rule, CMS provides an example of "without fault"—an enrollee who has not been previously notified of a proposed involuntary disenrollment

[49] 42 C.F.R. § 422.74(d)(1)(i).
[50] 73 Fed. Reg. at 28577.
[51] 73 Fed. Reg. at 1528-1529, 1541-1542 (to be codified at 42 C.F.R. § 422.262(h)) (MA) and 1544 (to be codified at 42 C.F.R. § 423.293(a)) (Part D).
[52] 73 Fed. Reg. 28578.

for nonpayment of premium.[53] This section of the Final MA/PD Rule is effective March 13, 2009.

Prohibiting Improper Billing of Monthly Premium

Under the Final MA/PD Rule, a MAO or Part D sponsor may not bill an enrollee for premiums that he or she has already paid through premium withhold.[54] This is a change from the May Proposed Rule that prohibited MAOs and Part D sponsors from billing enrollees for premiums if they submitted a request for premium withhold or already paid through the withhold. CMS made this change to address the concern that enrollees could request premium withhold to avoid premium liability. This section of the Final MA/PD Rule is effective March 13, 2009.

Non-Renewal Notification Timelines

The Final MA/PD Rule changes from ninety to sixty days the period of time for MAOs and Part D sponsors to notify enrollees and the public of a non-renewing plan.[55] This change provides CMS with more time to conclude the contract non-renewal process, including any administrative appeals. While this section of the Final MA/PD Rule shortens the notification period, CMS believes that a "60-day notice is sufficient for beneficiaries to make choices."[56] This section of the Final MA/PD Rule is effective March 13, 2009.

Reconsiderations

This section of the Final MA/PD Rule expands the right of physicians to file a standard plan reconsideration of a pre-service request without having to be appointed by the enrollee.[57] Under the existing regulations, a physician, whether the enrollee's treating physician or not, may request an expedited plan reconsideration on behalf of the

[53] 74 Fed. Reg. at 1528.
[54] 74 Fed. Reg. at 1529-1530, 1541-1542 (to be codified at 42 C.F.R. § 422.262) (MA) and 1544 (to be codified at 42 C.F.R. § 423.293) (Part D).
[55] 74 Fed. Reg. at 1530, 1542 (to be codified at 42 C.F.R. § 422.506) (MA) and 1545 (to be codified at 42 C.F.R. § 423.507) (Part D).
[56] 74 Fed. Reg. at 1530.
[57] 74 Fed. Reg. at 1530-1532, 1542 (to be codified at 42 C.F.R. §§ 422.578 and .582) (MA) and 1546-1547 (to be codified at 42 C.F.R. §§ 423.560 and .580) (Part D).

enrollee without having been appointed as the enrollee's authorized representative. To request a standard pre-service plan reconsideration, a physician must be appointed as the enrollee's representative or be authorized to act on behalf of the enrollee under state law. The physician must demonstrate that he or she is the treating physician and must notify the enrollee that the reconsideration has been filed.

This change will provide additional flexibility for physicians to file standard plan reconsiderations. In the preamble to the May Proposed Rule, CMS explained that "[w]e believe that an enrollee's treating physician already has been selected by the enrollee and occupies a position of trust. We also believe that as a treating physician, he or she is in a good position to know whether a request for plan reconsideration is warranted, and in the enrollee's interests."[58] For any appeal beyond the plan level, the physician must be appointed or otherwise authorized under state law.

In addition, the Final MA/PD Rule adds a new definition of "other prescriber" that includes non-physician healthcare professionals that have authority under state law or other law to write prescriptions.[59] "Other prescriber" will often include nurse practitioners and physician assistants. This new definition better seeks to expand the scope of professionals that are allowed to request coverage determinations and appeals.[60] This Rule also provides that prescribing physicians and other prescribers may request standard rederminations on behalf of a Part D enrollee.[61] This section of the Final MA/PD Rule is effective March 13, 2009.

Civil Money Penalties

CMS may impose civil money penalties (CMPs) on MAOs and Part D sponsors for failing to comply with regulatory requirements. CMS may impose CMPs of up to $25,000 per determination of a regulatory violation. CMS modified the CMP regulations to permit imposition of no more than $25,000 *for each enrollee* covered under the MAO, or under the Part D sponsor's contract that is adversely affected or substantially likely to

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[58] 73 Fed. Reg. at 28579.
[59] 74 Fed. Reg. at 1531-1532 and 1546 (to be codified at 42 C.F.R. § 423.566(c)(3)).
[60] 74 Fed. Reg. at 1531.
[61] 74 Fed. Reg. at 1532 and 1547 (to be codified at 42 C.F.R. § 423.582).

be adversely affected by the Organization's noncompliance.[62] This section of the Final MA/PD Rule is effective March 13, 2009.

Part D Formulary Rule

On January 16, 2009, CMS released an interim final rule with comment period, amending the Medicare Part D regulations to reflect certain MIPAA provisions. MIPPA changed the definition of "medically accepted indication" and added new requirements for Part D formularies. The interim final regulations are effective January 16, 2009. Comments are due March 17, 2009.

Medically Accepted Indications

Consistent with new statutory requirements, CMS amended the definition of a Part D drug at § 423.100 to incorporate MIPPA's new definition of "medically accepted indications" for anticancer drugs. Under MIPPA, "medically accepted indications" for Part D anticancer drugs has the same meaning as it does in Medicare Part B. Part D sponsors must continue using the definition of "medically accepted indications," as used in the Medicaid rebate statute for all other Part D drugs. In addition, the list of compendia used to identify medically accepted off-label indications will be revised.

Access to covered Part D drugs (six classes of clinical concern)

MIPPA requires CMS to identify certain categories or classes of drugs for which:

- Restricted access would have major or life threatening clinical consequences; and
- Access to multiple drugs within the category or class is necessary because of their unique clinical actions and pharmacological effects.

Part D sponsors must include in their formularies (beginning in 2010) all Part D drugs in the categories and classes of drugs identified by CMS as meeting MIPPA criteria. However, CMS has concluded that it cannot complete the evaluation necessary in time to identify such categories for the 2010 contract year. Instead, CMS is retaining the

[62] 74 Fed. Reg. at 1533-1535, 1542-1543 (to be codified at 42 C.F.R. § 422.760(b)(2)) (MA) and 1548 (to be codified at 42 C.F.R. § 423.760(b)(2)) (Part D).

existing six classes of clinical concern (described in Chapter 6 of the Medicare Prescription Drug Program Manual, at section 30.2.5).

For contract years 2011 and beyond, CMS intends to issue modifications to the protected categories and classes, consistent with the MIPPA criteria, through notice-and-comment rulemaking. CMS will implement an identification and validation process prior to establishing the protected categories and classes under the new MIPPA authority.

CMS issued an interim final rule rather than a notice of proposed rule-making because its provisions serve merely to reflect in the Code of Federal Regulations changes in the statute made by MIPPA.

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