Summary of Title I MMA Regulations

Title I, Subpart A – General Provisions

Amy Posner

Basis and Scope

Section 423.1 did not change from the proposed rules. It simply lists the sections of the Social Security Act Amendments that create the Medicare Part D prescription drug payment program. § 423.1; FR 4527.

Definitions

The final rule added definitions for the following terms: cost plan, eligible fallback entity, group health plan, monthly beneficiary premium, PACE Plan, PACE organization, Part D plan, and Part D plan sponsor. § 423.4; FR 4527. A Part D plan now refers to both regional PDPs and MA-PDs (regional or local). The proposed regulation had created some confusion over whether certain requirements were applicable to both types of plans or only one of them. *Id.* Thus, when the terms PDP and MA-PD appear in the Title I regulations, CMS is generally (but not uniformly) differentiating the requirements that apply to each type of plan. Other definitions were moved to other Title I Subparts (*e.g.*, fallback plan, group health plan, full-benefit dual eligible, MA plan). The definition of State Pharmaceutical Assistance Program (SPAP) was removed. *See id.* The terminology regarding sponsors and plans was standardized throughout the final rule. FR 4201.

The definition of "service area" was altered to tie it to the concept of meeting access standards. The preamble notes that a consequence of this definitional change is that incarcerated individuals or beneficiaries living abroad cannot be within the boundaries of any PDP region or MA-PD service area because they would not have access to the plan's pharmacy network and, therefore, will not be assessed a late penalty if they subsequently enroll in Part D. CMS notes in the preamble that it will provide guidance on methods for demonstrating "actuarial equivalence," which is important in several different contexts of Part D, at a later date. FR 4199. CMS stated it will provide details on its authority to waive the service area requirement for employer-sponsored group prescription drug plans in further guidance. FR 4200.

Cost-Sharing in Beneficiary Education and Enrollment-Related Costs.

Section 423.6 did not change from the proposed rule. It implements user fees which will be used to defray the costs of beneficiary education. § 423.6; FR 4200.

Title I, Subpart B – Eligibility and Enrollment

Barbara Ryland

CMS made substantial revisions to the proposed rules governing eligibility and enrollment in a Part D benefit plan.

Eligibility

Under § 423.30, CMS has clarified that an individual is eligible for Part D if he or she is entitled to Medicare benefits under Part A or enrolled in Medicare Part B, and lives in the service area of a Part D plan. In addition, an individual may not be enrolled in another Part D plan.

CMS clarifies the effect of retroactive Part A or Part B determinations on Part D eligibility. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement to Part A or enrollment in Part B is provided.

As provided in the statute, the rule now clearly states that a Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan.

CMS also clarifies the options of enrollees in PACE or Medicare Cost Contract Plans. A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan. A Part D eligible individual enrolled in a cost-based HMO or CMP can elect prescription drug coverage either under the cost plan, but is also eligible to enroll in a PDP if the individual does not elect to receive coverage under the cost-based plan.

Enrollment

CMS eliminated what appeared to be duplicative provisions, and the enrollment process other than for auto-enrollment is now specified in § 423.32.

In spite of regulatory language stating that the enrollment must be completed by the individual, in comments (FR 4203-04) CMS indicated that it would abide by state laws that authorize decision making by personal representatives. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

Auto-Enrollment

As stated above, the final rule now sets out the auto-enrollment process for dual eligibles separately, in § 423.34.

Auto-enrollment only applies to full-benefit dual eligible individuals who fail to enroll in a Part D plan but are eligible for Part D. CMS will automatically enroll such full-benefit dual eligible individuals into a PDP offering basic prescription drug coverage that has a monthly beneficiary premium that does not exceed the low-income premium subsidy amount. In the event that there is more than one plan that satisfies this requirement, enrollment will be done on a random basis. Auto-enrollment also applies to individuals enrolled in an MSA plan or an MA Private Fee For Service (PFFS) plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage.

Notwithstanding the auto-enrollment process, the beneficiary may decline enrollment in Part D. In addition, CMS plans to conduct a special enrollment process specifically to permit enrollees who have been auto-enrolled to disenroll from the selected plan and elect to enroll in another Part D plan (§ 423.38).

Disenrollment Process

The voluntary disenrollment process has also been restated, at § 423.36. An individual may disenroll from a PDP during the annual or special enrollment periods specified in § 423.38 simply by enrolling in a different PDP plan, or submitting a disenrollment request in any manner approved by CMS. A separate rule has been established for involuntary disenrollment by the PDP.

Enrollment Periods

Rules setting out initial, annual, and special enrollment periods are specified in § 423.38 and remain largely unchanged from the proposed rule. CMS has clarified that in the case of an individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date will have an initial enrollment for the Part D benefit beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

Effective Date

Rules governing the effective date of enrollment are set out at § 423.40 and have not been materially changed, except that CMS has provided specific effective dates for the auto-enrollment process within the framework of the rules governing auto-enrollment.

Coordination of the Enrollment Process Through PDPs

Proposed § 423.42 has been deleted from the rule because it was considered potentially confusing in light of other rules governing the enrollment process. As stated above, the enrollment process, including a PDP's responsibility to process enrollment applications in its plan, is now set forth in § 423.32.

Involuntary Disenrollment by the PDP

The rule governing involuntary disenrollment by the PDP is set forth at § 423.44. Material changes to the rule provide for greater CMS scrutiny for disenrollment due to disruptive behavior of the enrollee.

With regard to involuntary disenrollment due to disruptive behavior, the final rule now defines what behavior is considered to be disruptive: While a PDP enrollee is considered to be disruptive if his or her behavior *substantially* impairs the plan's ability to arrange or provide for services to the individual or other plan members, an enrollee cannot be considered disruptive if the behavior is

related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

Further, the rule now permits a PDP to disenroll an individual whose behavior is disruptive only after the PDP sponsor meets notice and procedural requirements set forth in the rule, and only after CMS has reviewed and approved the request.

The PDP sponsor must make a serious effort to resolve the problem, including providing reasonable accommodations for individuals with mental or cognitive conditions and developmental disabilities. The PDP sponsor must also inform the individual of the right to use the PDP's grievance procedures.

The PDP sponsor must document the enrollee's behavior, as well as its own efforts to resolve any problems, and any extenuating circumstances, which must be submitted to CMS by the sponsor, along with any documentation received by the individual.

CMS will review the information submitted by the PDP sponsor and any information submitted by the individual to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS may approve or deny the request for disenrollment, including imposing conditions on future enrollment, within 20 working days. CMS will utilize staff with appropriate clinical or medical expertise in reviewing the case before it makes a final decision, and may require the PDP to make accommodations for the individual's behavior.

CMS reserves the right to deny a request from a fallback prescription drug plan as defined to disenroll an individual for disruptive behavior.

Late Enrollment Penalty

The final rule, § 423.46, is materially unchanged from the proposed rule.

Information about Part D

The final rule, § 423.48, is materially unchanged from the proposed rule.

Approval of Marketing Materials and Enrollment Forms

The final rule made certain changes to the proposed rule at § 423.50.

The final rule provides for additional circumstances under which CMS's review of marketing materials is not required. Review is not necessary if, prior to distribution, the Part D sponsor submits and certifies that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

Subsection (f) (v) limits a PDP sponsor's use of providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

The final rule, at § 423.56, adds several types of coverage to the definition of potentially creditable prescription drug coverage. In addition to the entities previously listed in the proposed rule, the following are now considered to be creditable under subsection (b) of the final rule:

- Coverage under State Pharmaceutical Assistance Programs (SPAP) as defined at § 423.454.
- Coverage provided by a PACE organization.
- Coverage provided by a cost-based HMO or CMP under part 417 of 42 CFR.
- Coverage provided through a State High-Risk Pool as defined under § 146.113(a)(1)(vii).
- Other coverage as the Secretary may determine appropriate.

The disclosure requirements have also been modified under subsection (c), (d), and (e) to clarify that, with the exception of PDPs and MA-PD plans and PACE or cost-based HMOs or CMPs that provide qualified prescription drug coverage, all other entities listed under paragraph (b) must provide notice to an enrollee and to CMS as to whether coverage is creditable.

Entities that provide non-creditable coverage must also disclose additional information to enrollees, specifically, that there are limitations on the periods in a year in which the individual may enroll in a Part D plan; and that the individual may be subject to a late enrollment penalty.

The notice must be sent as follows, under subsection (f):

- Prior to an individual's initial enrollment period for Part D;
- Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;
- Prior to the commencement of the Annual Coordinated Election Period that begins on November 15 of each year; and
- Upon request by the individual.

Title I, Subpart C – Voluntary Prescription Benefits and Beneficiary Protections

David C. Hammond

Introduction

Subpart C is among the lengthiest and most complex of the Title I regulations. It deals with a wide array of related subjects, including the definition of Part D coverage and its relationship with other types of drug coverage, the calculation of "incurred costs" for the purpose of "True Out-of-Pocket"(TrOOP) cost computations, the disclosure of negotiated drug pricing, access standards, and a number of other subjects.

Overview and Definitions

The proposed rule sets forth definitions used in the regulation, many of which define the scope of the benefits. Section 423.100 of the final rule continued these definitions in large part, but provided additional guidance, particularly regarding the definition of a "Part D drug" and "dispensing fees." Some of the key points are discussed below:

Part D Drugs

The definition of Part D drugs in the final regulation, § 423.100, did not materially change, including the requirement that a Part D drug must have a "medically accepted indication." CMS clarified in the preamble that pharmacists will not be required to contact each physician to verify whether a prescription is being used for other than a medically accepted indication. FR 4229. Although certain "lifestyle" drugs are within the definition of Part D drugs, CMS indicated in the preamble that Part D plans can establish utilization management processes as long as they do not discourage enrollment in Part D plans. FR 4230.

CMS acknowledged in the preamble that some drugs could qualify for payment under Part B in some circumstances and Part D in others, depending on how the drug is dispensed or administered (under the Act and the final regulations, Part A and Part B drugs are not covered under Part D). CMS further acknowledged the complexity of making these distinctions, and intends to provide separate guidance to Part D plans on the relation between Part B and Part D coverage. FR 4233. In the meantime, CMS advised in the preamble that Part D plans could establish utilization management strategies, including prior authorization, to identify potential Part B drug coverage overlap and to verify appropriate coverage. Adding to the complexity, CMS stated that Part B plans will have to ensure that they exclude drugs that are deemed to be Part B drugs under a specific region's local medical review policy, highlighting the potential for regional differences in the application of the definition of Part D drugs. *Id.*

Dispensing fees

CMS defined the term "dispensing fees" in § 423.100 consistent with Option 1 in the proposed rule. FR 4234-36. As defined, the term means, in part, those costs related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. CMS rejected suggestions to include fees associated with *administering* a drug, which was a significant issue for providers of home infusion therapy. Enrollees requiring home infusion will have to pay for extra supplies, equipment, and professional services out-of-pocket or through supplemental coverage.

Standard Prescription Drug Coverage

The final regulation did not change the criteria for standard prescription drug coverage set forth in § 423.104(e), which largely repeated the statutory criteria, but CMS stated in the preamble that Part D plans will determine the amount of cost-sharing based on brands, generics, or other classifications of drugs. FR 4237. In addition, CMS stated in the preamble that it will later provide Part D sponsors details regarding the sources of data and how the annual percentage increase in different cost-sharing and coverage limits will be determined. FR 4238.

Incurred Costs (also referred to as TrOOP)

The final rule did not make any significant changes to the draft regulation's definition of "incurred costs," which is used to define the type of costs that can be included in an enrollee's spending towards the annual out-of-pocket limit. FR 4238.

In the final definition of "incurred costs," CMS split the definition of the terms "insurance" and "or otherwise." Under the MMA, any payment of a Part D drug by "insurance or otherwise" cannot be counted toward the enrollee's incurred costs. In the final rule, the term "or otherwise" means any government program that receives federal funding, in whole or in part, except for "some Federal administrative funding or incidental Federal monies," which CMS did not define. FR 4240-41. Because AIDs Drug Assistance Program (ADAPs) receive federal funding, they are included in the definition of "or otherwise." CMS encouraged states in the preamble to restructure programs to meet the requirements of State Pharmacy Assistance Programs (SPAPs), because only state funds are used in those programs and, therefore, such benefits can count towards an enrollee's incurred costs. FR 4241.

Final § 423.100 added the term "personal health savings vehicles" to ensure that payments from health savings accounts (HSAs), flexible spending accounts (FSAs), and medical savings accounts (MSAs) can count toward a enrollee's incurred costs. In contrast, because health reimbursement accounts (HRAs) are solely employer-funded, such payments do not count toward incurred costs. FR 4241-42.

CMS clarified in the preamble that any higher cost-sharing associated with purchasing a drug from a retail pharmacy rather than a mail order pharmacy for 90-day supplies of a Part D drug will be included in incurred costs. FR 4245.

CMS clarified in the preamble that payments made on behalf of a Part D enrollee by a pharmaceutical manufacturer's patient assistance program will count towards the enrollee's incurred costs, but such programs must comply with all applicable Federal fraud and abuse laws. FR 4239.

CMS clarified in the preamble that waivers or reduced cost-sharing obligations under the MMA's new pharmacy waiver safe harbor can be counted towards an enrollee's incurred costs. FR 4240.

Negotiated Prices

While proposed § 423.104(h) was not changed, CMS clarified in the preamble that Part D sponsors may pass on to enrollees some, but not necessarily all, of the price concessions received from manufacturers. FR 4244.

The preamble states that enrollees must have uniform access to negotiated prices from the same pharmacy regardless of the deductible, initial coverage limit, out-of-pocket threshold, or amounts in excess of these thresholds. *Id.* The preamble further observed that Part D plans must report in their Part D plan bids all aggregate negotiated

price concessions data and not just the proportion passed through to beneficiaries. FR 4245.

CMS noted in the preamble that Part D plans will be required to break out any fair market value of administrative fees paid by pharmaceutical manufacturers when reporting price concessions, subsidies, rebates, or discounts. § 423.104(g)(3). CMS will specify in future operational guidance the format and frequency of these reports, as well as what constitutes direct or indirect subsidies, remunerations, rebates, and discounts. FR 4246.

CMS concedes that it cannot regulate whether or not Part D plans and pharmaceutical manufacturers can negotiate simultaneously for commercial and Part D drug prices, the former of which is not exempt from Medicaid "best price" calculations. *But see* CMS's observation in the preamble to Title I, Subpart B, that disclosure of commercial pricing arrangements will be required in such circumstances. FR 4308.

Establishment of Prescription Drug Plan Service Areas

Final § 423.112 is not materially different from the proposed rule, which outlines how CMS establishes the Prescription Drug Plan (PDP) regions. CMS responded to comments regarding the lack of specificity regarding PDP regions by conducting extensive outreach programs to obtain public input prior to the final rule, and announced on December 6, 2004, the establishment of 26 MA regions and 34 PDP regions. FR 4246-47. In response to a number of comments, CMS noted in the preamble that it did not have the authority either to call for a national PDP or to require visitor/traveler (snowbird) coverage. FR 4248-49.

Access to Covered Part D Drugs

Assuring Pharmacy Access

In final § 423.120(a)(1), CMS revised the proposed rule to prohibit Part D plans or regional MA-PD plans operating in a multi-region or national service area to meet the access standards by applying them across the entire geographic area serviced by the plan; instead, such plans must meet the standards in each State of its multi-region or national service area. FR 4248.

Applicability of Some Non-Retail Pharmacies to Standards for Convenient Access

CMS revised proposed § 423.120(a)(2) to allow Part D plans to count certain non-retail pharmacies – specifically, I/T/U, FQHC, and RHC pharmacies – toward the pharmacy access requirements in § 423.120(a)(1).

Access to Home Infusion

The final regulation adds a provision at § 423.120(a)(4) requiring Part D plans to demonstrate they provide adequate access to home infusion pharmacies. FR 4250.

Access to Long-Term Care Pharmacies

The final regulation adds a provision requiring Part D plans to allow any willing long-term care pharmacy to contract with the plan based on standard terms and conditions developed by the plan and reviewed by CMS for reasonableness. § 423.120(a)(5). Additional detail will be issued in future operational guidance. FR 4252.

Access to I/T/U Pharmacies

The final rule adds a provision at § 423.120(a)(6) requiring a Part D plan to demonstrate that it has contracts with a sufficient number of I/T/U pharmacies to ensure convenient access for American Indian/American Native enrollees within the service area. The plan must develop a model special addendum containing standard terms and conditions reflecting the special circumstances of Indian Tribes, Tribal Organizations, and Urban Indian organizations ("I/T/U"), including the limited stocking of drugs and its ability to obtain discounts under the FSS and 340B program. CMS will review such plans for reasonableness. FR 4252-53.

Pharmacy Network Contracting Requirements

CMS clarified in the preamble that State "any willing pharmacist" laws are preempted by the MMA to the extent they apply to Part D business. FR 4253. New § 423.120(a)(9) will allow Part D plans to have two classes of network pharmacies, one of which could be deemed

"preferred" in order to deal with some of the difficulties associated with the "any willing pharmacy" requirement of the MMA. FR 4254.

Level Playing Field Between Mail-Order and Network Pharmacies

Although rephrased in final § 423.120(a)(10), Part D plans must permit enrollees to receive extended supplies of covered Part D drugs (*e.g.*, 90-day supplies) through a network retail pharmacy and not limit such access to only a network mail order pharmacy. A higher cost-sharing, however, may be applied if an enrollee obtains such quantities of the Part D drug from a network retail pharmacy. FR 4254.

Formulary Requirements

The proposed rule would have required Part D plans to use Pharmacy & Therapeutic (P&T) committees that include at least one practicing physician and one practicing pharmacist that are free of any conflicts from Part D sponsors and plans and from pharmaceutical manufacturers. While final § 423.120(b)(1) continues this requirement, CMS clarifies in the preamble that the P&T committee is in an advisory role only, and that conflicts of interest would include any direct or indirect investment in a Part D plan or pharmaceutical manufacturer that would benefit from decisions regarding plan formularies. FR 4255-56.

CMS notes in the preamble that P&T committee members *could* have certain non-employee relationships with pharmaceutical manufacturers (*e.g.*, consulting, advisory, or research relationships), provided those relationships do not constitute significant sources of their income and they do not otherwise have any conflicts of interest that could compromise their independence. FR 4256.

The proposed rule would require the P&T committee to base clinical decisions on the strength of scientific evidence and therapeutic advantages in terms of safety and efficacy, among other factors. Final § 423.120(b)(1)(iv) continued this requirement and CMS stated in the preamble that it will be issuing guidance to make clear that to the extent a Part D plan and its P&T committee considers costs in its decisions, it should take into account *total health care costs* rather than just drug costs. FR 4257.

Plan Formularies

Proposed § 423.120(b)(2) required the inclusion of at least two Part D drugs in each therapeutic category and class in a Part D plan's formulary, unless only one such drug exists. Final § 423.120(b)(2) follows this requirement, but will allow plans to request exemptions from this "two drug" minimum requirement when there are only two drugs in a category or class and one drug is clinically superior to the other drug.

CMS clarified in the preamble that the "two drug" minimum requirement must be accomplished using two chemically distinct drugs rather than two dosage forms or strengths of the same drug, or a brand-name and a generic equivalent. FR 4259-60.

Final § 423.120(b)(2)(iii) adds a requirement that plans include adequate access to the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

Final § 423.120(b)(3) incorporates an added requirement for Part D plans to have an appropriate transition process for new enrollees switching to a new Part D drug under that plan's formulary. The transition process must be consistent with written policy guidelines and other CMS instructions.

Proposed § 423.120(b)(5) contained a 30-day prior written notice period before removing a drug from a formulary or making any changes to the cost-sharing tiers. The final regulation requires Part D plans to either give at least 60-day prior written notice and/or allow enrollees to obtain a 60-day supply of the Part D drug under the same terms as previously allowed, along with providing the written notice of the change when the 60-day supply is obtained. *Id.*

Final § 423.120(b)(5)(ii) adds a detailed list of the information Part D plans must include in prior written notices of a change in the formulary, including what is being changed, the reason for the change, alternative drugs, and the means for an enrollee to obtain a coverage determination or exception to the formulary.

Consistent with changing the notice period from 30 days to 60 days in connection with changes to a plan's

Part D formulary, the final rule prohibits changes in the formulary or cost-sharing tiers for 60 days starting from the beginning of the annual election period (the proposed rule had a 30-day requirement). § 423.120(b)(6).

Special Rules for Out-of-Network Access to Covered Part D Drugs at Out-of-Network Pharmacies

Proposed § 423.124 would have required Part D plans to ensure that enrollees have adequate access to Part D drugs from out-of-network pharmacies when an enrollee cannot reasonably be expected to obtain such drugs at a network pharmacy. The final rule retains and expands this requirement to ensure that enrollees have such access when they do not obtain such drugs at an out-of-network pharmacy on a routine basis, and to ensure adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office. The final § 423.124 also adds a requirement for Part D plans to establish reasonable rules to limit out-of-network access to Part D drugs.

Dissemination of Part D Plan Information

Proposed § 423.128 required Part D plans to provide enrollees with information regarding the service area, benefits, cost-sharing, formulary, access, out-of-network coverage, grievance and appeals, quality assurance policies and procedures, and other information. Final § 423.128 retains these provisions, but adds a requirement that plans provide a list of the drugs in the formulary and a description of the process for obtaining an exception to the formulary or tiered cost-sharing structure. § 423.128(b)(4).

Public Disclosure of Pharmaceutical Prices for Equivalent Drugs

Final § 423.132 retains the requirement for pharmacies that dispense Part D drugs to inform enrollees of any less expensive generic version of the drug (including the price differential) at the time the drug is dispensed, at the point of sale or, in the case of mail order, at the time of delivery. The final rule also retains the ability to obtain waivers from this public disclosure requirement for a MA private fee-for-service plan under certain conditions, and for out-of-network and I/T/U pharmacies, as well as for network pharmacies located in U.S. territories.

Privacy, Confidentiality, and Accuracy of Enrollee Records

Proposed § 423.136 required Part D sponsors to meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations. The proposed rule accomplished this requirement by incorporating by reference the relevant Code of Federal Regulation section applicable to MA organizations. Final § 423.136 drops the incorporation by reference and lists these requirements, including abiding by all Federal and State laws regarding confidentiality and disclosure of medical records, establishing procedures to safeguard the privacy of such information, and maintaining records and information in a timely and accurate manner, among other things. The preamble comments that Part D plans are covered entities under the HIPPA Privacy Rule. FR 4276.

Title I, Subpart D – Cost Control and Quality Improvement for Prescription Drug Benefit Plans

David C. Hammond

Scope

The final regulations introduced a number of minor changes to this section, which lists the type of cost and quality control programs Part D plans must implement. § 423.150; FR 4540.

Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMP)

General Rule

The final regulation did not substantively change this section, which provides an overview of the various cost and quality programs. § 423.153(a); FR 4540. CMS indicated in the preamble, however, that it intends to implement a plan for utilizing Medicare prescription drug data to improve the evidence on risk, benefits, and overall costs of drug therapies for chronically ill and other Medicare beneficiaries. FR 4277. CMS indicated that such a plan will be developed through a public process and implemented

in a manner that preserves the confidentiality of beneficiary information. FR 4277.

Drug Utilization Management

The proposed rule would have required a Part D sponsor to establish a reasonable and appropriate drug utilization management program that includes incentives to reduce costs and policies and procedures to help prevent over- and under-utilization of Part D drugs. The final rule continues these requirements, but adds a requirement to provide CMS with information concerning the procedures and performance of its drug utilization management program in accordance with CMS guidelines to be issued in the future. § 423.153(b); FR 4540.

Quality Assurance

The final regulation expanded the elements of a Part D sponsor's quality assurance program designed to reduce medication errors, adverse drug interactions and improve medication use. § 423.153(c); FR 4540. Rather than specifying that the Part D sponsor had to meet Medicaid standards in OBRA 1990 (codified in § 456.705), CMS decided to rely on State standards by adding a requirement that a Part D sponsor make a representation that its network providers are required to comply with minimum standards for pharmacy practice as established by the States. § 423.153(c)(1); FR 4278. The final rule also added more elements of a quality assurance program, including requiring a concurrent drug utilization review, a retrospective drug utilization review, and internal medication error identification and reduction systems. CMS also added a requirement for Part D plans to provide it with information regarding its quality assurance program. § 423.153(c)(2)-(5); FR 4540.

Medication Therapy Management Programs (MTMP) and Coordination with Care Management Plans

The final rule did not make any substantive changes to these subsections, which require a medication therapy management program targeted at Part D enrollees ("targeted beneficiaries") that have multiple chronic diseases, are taking multiple covered Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level to be set by CMS. These provisions also require coordination with care management plans under Section 1807 of the MMA. § 423.153(d)(1)-(4); FR 4540.

CMS stated in the preamble that there are insufficient industry standards regarding standards and performance measures for MTMPs and therefore adopted a flexible approach that does not specify the elements of such programs. FR 4280.

Considerations in Pharmacy Fees

Final § 423.153(d)(5) requires Part D sponsors to describe in their applications how they take into account fees to be paid to pharmacists or others providing MTMP services and to disclose, upon request by CMS, the amount of management and dispensing fees and the portion paid for MTMP services.

CMS stated in the preamble, but does not so state in the regulations, that the cost of the MTMP services to targeted beneficiaries must be treated as an administrative fee and incorporated into a plan's bid, rather than a fee to targeted beneficiaries. However, plans can offer and charge non-targeted beneficiaries for MTMP services, but the plans must notify such beneficiaries that such services are not a Part D covered benefit and that they will be 100 percent responsible for the cost. FR 4281.

MTMP Reporting

Final § 423.153(d)(6) also adopts certain reporting requirements for MTMPs, including requiring Part D plans to provide CMS with information regarding procedures and performance of the MTMPs pursuant to future CMS guidelines.

Exemption for Private Fee-for-Service MA Plans Offering Qualified Prescription Drug Coverage

The final rule continues to exempt fee-for-service MA plans offering qualified prescription drug coverage from the requirement to provide drug utilization management and to establish MTMPs. § 423.153(e).

Consumer Satisfaction Surveys

Final § 423.156 continues to provide that CMS will conduct consumer satisfaction surveys of Part D plan enrollees.

Electronic Prescription Program

The final rule does not make any substantive change to this subsection, which requires Part D sponsors to support and comply with electronic prescription standards to be developed by CMS. § 423.159(a); FR 4541. CMS plans to issue another proposed rule regarding these standards. FR 4284.

Final § 423.159(d) also continues to allow a MA organization, but not a Part D plan, to offer a separate or differential payment to physicians that participate in the electronic prescription program. In the preamble, CMS agreed that MA plans could also offer such incentive payments to pharmacies and pharmacists through individual plan contracts. FR 4284. The final rule cautions, however, that such payments to physicians, pharmacies, and pharmacists must be in compliance with applicable Federal and State fraud and abuse laws. *Id.*

Quality Improvement Organization Activities

The final rule does not make any substantive change to this subsection, which requires Quality Improvement Organizations (QIOs) to offer providers, practitioners, MA organizations, and Part D sponsors quality improvement assistance pertaining to health care services. § 423.162(a); FR 4541. All information collected by QIOs in performing such services will be treated as confidential by including the QIOs in the definition of "health care facility," which are subject to confidentiality requirements under Part 480. § 423.159(b); FR 4541.

CMS stated in the preamble that decisions concerning which medications are on a Part D plan's formulary and the number of rejected claims are administrative decisions by the plan and fall outside the quality review functions of the QIO. FR 4286.

Compliance Deemed on the Basis of Accreditation

Final § 423.165(a)-(b) does not make any substantive change to this subsection, which allows accredited PDP sponsors and MA organizations to be *deemed to meet* the requirements relating to access to covered drugs, drug utilization management programs, quality assurance measurements and systems, MTMPs, programs to control fraud, abuse, and waste, and privacy requirements. This subsection also specifies the effective date of such deemed compliance, and requires deemed entities to submit to CMS surveys and allow its accreditation organization to release to CMS a copy of its most recent accreditation survey and related information.

CMS can remove the deemed status, in whole or in part, if CMS determines that the Part D sponsor does not meet the Medicare requirements for which the deemed status was granted, CMS withdraws its approval of the accreditation organization, or the entity does not comply with CMS surveys or request for accreditation surveys and related information. § 423.165(e); FR 4541-42.

Accreditation Organizations and Procedures for Approval of Accreditation as a Basis For Deeming Compliance

The final regulation does not make any substantive changes to these subsections, which set forth the conditions, requirements and procedures for CMS's approval of an accrediting organization. § 423.168 and § 423.171; FR 4542-43. These include applying standards at least as stringent as Medicare requirements for the standard or standards in question, avoiding conflicts of interest, and having a broad and balanced representation. § 423.168(a)(1) and (3); FR 4542. The final rule also identifies the type of reports an accrediting organization must submit to CMS regarding is activities, and outlines the criteria and procedures for oversight and for withdrawing approval of an accrediting organization. § 423.171; FR 4543.

The final rule identifies in detail the type of information and materials to be submitted to CMS when requesting approval to be an accreditation organization. CMS will notify applicants within 210 days of receiving a completed application regarding its decision. Request for reconsideration is available in case of a denial.

CMS stated in the preamble that it recognizes that accrediting organizations will not be in place before the due date for 2006 bids and contract applications, and will allow applicants for the first year to determine on their own that they meet all of the CMS standards. CMS also commented that it does not believe that any current accrediting organization meets its standards, and further noted that it was several years before accrediting organizations were accredited under the MA program. FR 4288.

Title I, Subpart F – Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

David O'Brien

Subpart F sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans. It also explains the calculation of the national average bid amount and determination of enrollee premiums.

Submission of Bids and Related Information

Submission Deadline

Final § 423.265 is unchanged from the proposed rule. Each potential Part D sponsor must submit a bid no later than the first Monday in June that contains the information set forth in this section for each Part D plan it intends to offer during the subsequent calendar year. § 423.265(b).

Information Required in the Bid

Each bid must "reflect" a uniform benefit package, premium, all applicable cost sharing for all enrollees along with the applicant's estimate of its average revenue requirements to provide the drug coverage. The bid must include only the costs for which the plan is responsible. It will not include costs paid by the enrollees.

Actuarial Requirement

The bid must be prepared in accordance with CMS actuarial guidelines and the actuarial valuation must be certified. § 423.265(d)(2).

Specific Bid Requirements

Final § 423.265(c) describes in some detail particular information that must be included in the bid. This includes a description of the coverage, the bases for actuarial value estimates, the profit, the service area, the level of risk and an estimate of the plan's average risk score.

Special Rule for PDP Sponsors

Bids of potential PDP sponsors may include a uniform modification of the amount of risks assumed related to increases and decreases of federal percentages in risk corridors. § 423.265(e). This special PDP rule does not apply to MA and PACE organizations or to cost based HMOs and CMPs. *Id.* Fallback prescription drug plan bids are not subject to § 423.265 requirements. § 423.265(f).

The final rule eliminated language that elaborated on the inapplicability of its requirements to fallback prescription drug plans. It added a requirement that the bid include supplemental coverage information. § 423.265(c)(1).

Review and Negotiation of Bid and Approval of Plans Submitted by Potential Part D Sponsors

This section specifies that in addition to its general negotiating authority, CMS also has authority similar to that of OPM for FEHBP health plans. § 423.272(a). It sets forth factors that CMS considers when it reviews bids. CMS will approve bids *only* if the actuarial bases equitably reflect the plan's revenue requirements. CMS will *not* approve a bid whose design and benefits, including drug formulary, are likely to discourage enrollment. § 423.272(b)(2).

There is no limit on the number of full risk plans that CMS will approve, and it will give priority to those limited risk plans that bear the highest risk. § 423.272(c). Fee for service plans are exempted during the bid approval process from the revenue requirements, from disclosure of

negotiated prices, and from the disclosure of the availability of generic drugs if the plan provides drug coverage under the circumstances indicated. § 423.272(d).

A special rule applies to plans with standardized bids that are sufficiently below the national average monthly bid to result in a negative premium. In such instances, a reduction in the supplemental premium or an enhanced alternative benefit equal in value to the negative premium would be required. § 423.272(e). This special rule is a *change* from the proposed rule. FR 4301.

National Average Monthly Bid Amount

Section 423.279 provides for CMS's computation of a national average monthly bid amount based upon a weighted average in order to calculate the base beneficiary premium. It explains how the weighted average will be calculated. § 423.279(b). It also provides for an adjustment in the national average monthly bid amount in order to take into account differences in prices for Part D drugs among PDP regions once an appropriate methodology for doing so is developed. § 423.279(c).

Rules Regarding Premiums

The monthly beneficiary premium of a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. § 423.286. The monthly beneficiary premium is the base beneficiary premium adjusted as otherwise explained in this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties. The base beneficiary premium is equal to the product of the beneficiary premium percentage as specified in this section and the national average monthly bid amount.

The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(c) rather than this section.

The final rule now provides that the beneficiary premium is zero where the amount of the adjusted national average monthly bid exceeds the standardized bid by an amount greater than the base beneficiary premium thereby resulting in a negative premium. The excess is applied to the supplemental Part D benefits. § 423.286.

The final rule also subjects enrollees in fallback prescription drug plans to late enrollment penalties even though this rule does not otherwise apply to fallback plans. The final rule's reduction or elimination of premiums for subsidy eligible individuals also applies to fallback plans.

Collection of Monthly Beneficiary Premium.

Part D sponsors must charge enrollees a consolidated monthly premium equal to the sum of the Part D monthly premium for basic prescription drug coverage and, where applicable, the premium for supplemental coverage. § 423.293(a). The Part D sponsors must allow the enrollees to pay the premiums using any of the methods listed in § 422.262(f). The rule also provides for the crediting and collection of late enrollment penalties. § 423.293(c). Once again it does not apply to fallback plans. § 423.293(d).

Title I, Subpart G – Payments to Part D Sponsors for Qualified Prescription Drug Coverage

Barbara Ryland

Introduction

Subpart G of Title I sets forth rules for the calculation and payment of the various types of payments and subsidies that Part D plans will receive under the MMA. These are the direct subsidy amount plus enrollee premiums (which CMS sometimes refers to collectively as the "prepayment" amount for the risk assumed by the PDP); the reinsurance subsidies for Part D plans; payment adjustments as a result of the application of risk corridors and risk-sharing; and retroactive adjustments and reconciliations to actual enrollment and interim payments. In addition, PDP sponsors and MA organizations will receive payments to cover certain premium, cost-sharing, and extended coverage subsidies for low-income subsidy-eligible individuals. CMS clarified that none of the provisions of Subpart G (including budget neutrality) apply to fallback plans. § 423.301.

Required Data

The general provisions regarding the provision of information are found in § 423.322. As it did in the proposed rule, CMS emphasized the importance of providing data to document the various payments and payment adjustment processes that are provided for Part D plans.

With respect to the risk adjustment process, CMS will require the submission of 100 percent of drug claims in order to develop and calibrate the weights for the model of the new benefit. Consequently, PDP sponsors and MA organizations offering MA-PD plans will be required to submit 100 percent of prescription drug claims for Part D enrollees for the coverage year. Risk adjustment will require the submission of prescription drug agent identifying information, such as NDC codes and quantity, in order to allow the standardized pricing of benefits in the model. However, CMS plans to use a standardized pricing in the model and therefore will not require cost data on each prescription for purposes of risk adjustment. FR 4307.

With respect to the reinsurance subsidy payment process, CMS will require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs. All claims for enrollees with expenses in excess of the out-of-pocket limit will be necessary to verify that the costs are allowable because the totality and order in which the claims are incurred will define which claims will be eligible for reinsurance payments. FR 4307.

For the risk sharing process, CMS will require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs. The plan will need to segregate costs attributable to supplemental benefits from those attributable to basic benefits since supplemental benefit costs are not subject to the risk corridor provisions. FR 4307.

CMS will require at least a statistically valid random sample of all Part D drug claims to support the program audit process. However, a routine audit will be unlikely to require additional submissions from the plan, because CMS will be able to draw a sample from the claims data that has been submitted to support the payment processes. FR 4307.

CMS agreed with numerous commenters that data submissions should be based on an established standardized format, and will require data submissions in the NCPDP format. The data require will be from both incoming claims and the remittances to those claims. However, not all paid amounts that need to be reported are contained within the NCPDP format (for example, the low income cost sharing subsidy). Therefore, plans will still be responsible for calculating and retaining those amounts while calculating appropriate payments and cost-sharing for each claim. FR 4308. CMS will require data related to drug claims be submitted no less frequently than monthly. Further details on data submission will be issued in separate guidance. *Id.*

Allowable Costs

In determining allowable costs for the purposes of both reinsurance and risk sharing, CMS requires Part D plans to factor in the receipt of discounts, rebates, chargebacks, or any similar payment that reduces the overall cost of providing covered Part D prescription drugs. In the proposed rule, CMS referred to "average percentage rebates," (*see* § 423.308, defining "actually paid") but now acknowledges that such a calculation would "represent only a rough estimate on the part of a Part D plan." FR 4308. CMS will now require Part D plans to report aggregate rebates at the product level (as opposed to at the beneficiary or claim level) on a quarterly basis. Additional guidance will be released subsequent to publication of the final rule that specifically deals with rebate accounting rules. *Id.*

In addition, CMS expects Part D plans to report "all rebate dollars with no allowance for separate administration fees." *Id.* CMS advises Part D plan sponsors that seek to limit CMS's access to rebate information to Part D business only "to seek out separate contracts with manufacturers for their Part D and other lines of business." *Id.*

In response to a comment that administrative fees should not be included in the assessment of rebate fees, CMS stated that it disagreed with the commenter, and that such accounting would be incompatible with the need to report all price concessions for purposes of determining allowable reinsurance and risk corridor costs. FR 4308-09.

CMS reiterated its comments from the preamble to the proposed rule, that to the extent the administrative fees paid to Part D plans are above the fair market value of the services rendered, the differential would be considered a price concession. "In sum, as fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not masked as administrative fees, and therefore, we continue to believe that administrative fees are important in determining the reinsurance and risk-sharing payments." FR 4309.

When asked for clarification on how the fair market value of administrative fees is to be determined, CMS stated that the fair market value of fees paid to a Part D plan would be evaluated in relation to the values reported by other Part D plans. "The fair market value will be the average or normal value of administrative fees within this market." FR 4309. CMS also stated that this methodology may not be exclusive, and that if administrative fees paid to all plans were found to be improperly inflated, CMS would devise an alternative methodology. *Id*.

CMS also took the opportunity in the final rule to interpret allowable costs in the context of repackaged drugs. AWP may not be published for some classes of products that are repackaged for a specific buyer, such as a mail-order pharmacy or a pharmacy chain. In addition, CMS noted that if a pharmacy benefit manager or managed care organization owns a pharmacy and refers members to that facility, it essentially purchases product from itself. In both of these cases, CMS is concerned that sponsors exercise due care to ensure that the prescription ingredient cost accurately reflect the product that the facility purchased. "Any repricing or restatement of price of a pharmaceutical product is subject to audit, and potentially constitutes fraudulent behavior if the repricing or price restatement is done with the intent of increasing the profits of that sponsor or mail order facility by increasing the reimbursement due by the Federal government." FR 4308.

Finally, CMS noted that it did not have the authority to require an attestation of the accuracy of data submitted by Part D plans, and therefore would not require such an attestation. FR 4309.

Coverage Year

CMS adhered to its definition of "coverage year," § 423.308, as proposed, and has adopted applicable time frames for the submission of final data in order to promote the finality of the reconciliation and adjustment process. It has established an ambitious goal of calculating risk sharing as soon as six months after the close of the payment year. As a result of its goal of speedy reconciliation, drug claims paid past the close of the 3-month period will not be considered part of that coverage year (or the next), and will not be used to calculate that year's payments or in reconciling risk adjustment payments for the year. However, the 3-month close-out window would not limit the liability of the plan or its claims processing contractor for reimbursing any lagging claims. Further, even though CMS is closing the year for claims purposes after 3 months, the plan must account for and report all rebates that occur throughout the coverage year and send all data within 6 months after the end of the coverage year. FR 4309.

CMS acknowledged that the 3 month period is significantly less than the fee-for-service Medicare medical claims standard of 18 months, but it justified the shorter period as being warranted due to the highly automated and point of sale nature of prescription drug claim processing. FR 4309.

Determination of Payment

Direct Subsidy

CMS made one significant change to the payment of direct subsidies. Specifically, as outlined in detail in subpart F of the final rule, if the standardized bid amount is less than the national average monthly bid by an amount so great that it is in excess of the base beneficiary premium, the direct subsidy payment will be increased by the amount of the negative premium. § 423.329(a).

Risk Adjustment

CMS will develop and publish its risk adjustment methodology in the 45-day notice for the announcement of the 2006 Medicare Advantage rates. FR 4310.

The risk adjustment methodology will initially be based on the relationship of prescription drug utilization

within the entire Medicare population to medical diagnoses, and will be applied at the individual beneficiary level. CMS will use claims data linked to the Medicare beneficiary HIC# in order to develop the model. While the Part D risk adjustment model will initially use demographics and diagnoses, it will be refined as Part D program data becomes available, which will be incorporated to enhance the predictive power of the model. FR 4310.

In response to comments, CMS stated that its risk adjustment model would not use drugs as a marker of disease even though there is research indicating that this may be a valid approach. Instead, CMS will use diseases to predict drug spending. It directed interested parties to several web sites for additional information on the risk adjustment process. (See www.cms.hhs.gov/pdps/riskad.zip; and www.cms.hhs.gov/review/default.asp.) FR 4311.

Specific comments raised concern about the risk adjustment process for beneficiaries receiving the low income subsidy. CMS noted that its goal is to accurately adjust risk for all classes of beneficiaries, but is particularly concerned that risk adjustment not discourage plans from enrolling low income individuals. CMS plans to calibrate the risk adjustment model on a sample of beneficiaries that includes low income beneficiaries. It expects to conduct the adjustment process in analogous fashion to what it currently does to deal with beneficiaries in long term care institutions enrolled in Part C plans. FR 4310-11.

In addition, comments noted that the utilization of low income beneficiaries could exceed estimates based on prior utilization as a result of the "induced demand" that will likely result because such beneficiaries might have been less able to fulfill their drug needs prior to enrolling in Part D. CMS stated that it is confident that it can address this issue based on Federal Employee Health Benefit Program and State Medicaid program data. FR 4310-11.

Budget Neutrality

CMS received no comments on its methodology for determining budget neutrality, and did not change the proposed rule. The Part D risk adjustment system will be based only on Part D enrollees, since there is no group of beneficiaries outside the system like there is under Part C. Thus, the only requirement for budget neutrality in CMS's view is that total payments with and without risk adjustment should always be equal. FR 4311.

Reinsurance

Interim Monthly Payments. As CMS indicated in the proposed regulations, it will make payments to plans on an incurred basis to assist the ongoing cash flow of PDP sponsors and MA organizations. § 423.329(c)(2)(i). The initial methodology will entail making monthly prospective payments of estimated allowable reinsurance costs submitted with the bid, which will be established and calculated at the plan level so that reinsurance estimates reflect individual plan risk and the impact of plan supplemental benefits (if any) on when catastrophic benefits and reinsurance payments are triggered. FR 4312.

Delayed Attachment Point as a Result of Enhanced Benefits. CMS agreed with comments that the impact of the so-called delayed reinsurance attachment point that results from the provision of supplemental benefits could be a strong disincentive for plans to offer enhanced coverage, and noted that plan sponsors would have to take that into account when designing a benefit. However, it also reiterated that the definition of reinsurance costs under section 1860D-15(b)(2) of the Act does not permit claims for supplemental benefits to count toward allowable reinsurance costs. CMS stated, however, that it intends to conduct a reinsurance demonstration that represents an alternative payment approach, which will be the subject of separate guidance issued in the near future. § 423.343(d)(1); FR 4312.

Induced Utilization. CMS received comments on what it calls "induced utilization," or the additional utilization that occurs when the availability of supplemental benefits increases the level of total drug spending. CMS explains this phenomenon as follows:

> Assuming 2 identical groups of enrollees for utilization, one enrolled in enhanced alternative coverage and one in defined standard coverage, the total allowable reinsurance costs for the group with standard coverage would be greater than for the group with enhanced alternative coverage. Thus,

one might hold that the differences in benefit packages are accounted for without the need for further adjustment. *If one would examine average total spending for both groups, however, one would find that the average spending under enhanced alternative coverage would be greater than the average under defined standard coverage because of the impact of the insurance effect (or "moral hazard", that is, the tendency of increased coverage resulting in increased utilization due to decreased financial stake in the costs associated with utilization)*. All other things being equal, this higher total spending would result in higher allowable reinsurance costs than would otherwise occur if the total spending under enhanced alternative coverage were comparable to that under standard coverage. FR 4312 (emphasis added.)

CMS did not change the proposed definition of allowable reinsurance costs at § 423.308. However, in response to comments that the issue was very complex, and that it needed further study and follow up, and will continue to require that allowable reinsurance costs be adjusted to reflect the impact of induced utilization, CMS stated that additional guidelines will be provided to plans on estimating induced utilization. *Id.*

Low Income Subsidies

CMS will also make interim estimated payments to account for the impact of low income cost sharing subsidies, on a monthly prospective basis based on estimates of low-income cost sharing submitted and negotiated with each plan's approved bid. § 423.329(d). CMS also noted that in cases where the low income subsidy amount is less that the plan's premium, any low-income beneficiary enrolling in the plan is responsible for making up the difference between the low-income premium subsidy and the plan's premium. FR 4313.

CMS also noted that the same process can be used by Part D plans that is currently used by Part C plans whereby state pharmaceutical assistance programs (SPAPs) would be able to supplement the premium subsidy so that their beneficiaries do not have to pay first and be reimbursed by the SPAP. Further information on these standards will be issued in separate guidance. FR 4313-14.

Risk Sharing Adjustment

The final regulation clarifies that the risk corridor calculation and risk sharing methodology is inapplicable to MA-PD plans. § 423.336(a)(ii)(2). Further, MA-PD plans cannot request a modification of the risk assumed under the plan. § 423.336(a)(iii).

Retroactive Adjustments and Reconciliation

General. The final rule on reconciliation clarifies that the processes outlined in Title I are applicable only to Part D plans, and not to MA-PD plans. The rule is largely unchanged, though it has deleted references to the specific information that will be required, and provides instead that any information that CMS requires must be provided. § 423.343(c) and (d).

Lack of Documentation. CMS reiterates its pronouncement in the proposed regulations that if an entity does not submit sufficient documentation to reconcile payments, CMS will reconcile by recovering payments for which the entity lacked documentation. "For example, if we make interim payments during the year for the low-income subsidy, but at the end of the year, the PDP sponsor or MA organization cannot provide documentation demonstrating the amounts of beneficiary cost-sharing, the reconciliation process would involve recouping the interim payments for such subsidy." FR 4316.

From CMS's perspective, the most important issue related to documentation is that which affects the determination of risk corridor costs, where the organization or sponsor would potentially owe the government money. Under the final rule, CMS will assume that the sponsor's or organization's adjusted allowable risk corridor costs are 50 percent of the target amount, since CMS acknowledges that it would be unlikely for any organization or sponsor to have costs lower than 50 percent of their total payments. § 423.343(d)(2); FR 4316.

Reopening

Reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when there is fraud or similar fault. CMS will have the authority to initiate a reopening on its own, and will reopen upon the request of

a sponsor only at its discretion. The rule now provides that a decision not to reopen is final and is not subject to review. § 423.346(d).

Appeals

CMS has added a new provision, § 423.350, to establish a payment appeals process whereby payment determinations involving the following may be subject to appeals:

- the reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b);
- the reconciled reinsurance payments under § 423.343(c);
- the reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or
- the final risk-sharing payments made under § 423.336. We wish to clarify that the payment appeals process only applies to perceived errors in the application of the payment methodology described in this subpart and subsequent CMS guidelines.

CMS will not permit plans to use the appeals process to submit new payment information after the established deadline. FR 4317.

Title I, Subpart I – Organization Compliance with State Law and Preemption by Federal Law

Kenneth M. Bruntel

General Requirements for PDP Sponsors

Final § 423.401 is essentially unchanged from the draft regulation. FR 4317. The regulation restates the MMA requirement that a PDP sponsor be licensed under state law as a risk bearing entity eligible to offer health insurance or health coverage in each state it offers a Part D plan. The proposed and final regulation provides that a PDP sponsor (a) meet State solvency requirements, (b) assume financial risk for unsubsidized coverage, and (b) can obtain reinsurance.

Authorized Waivers

The MMA authorized CMS to waive state licensing and solvency requirements so long as a PDP sponsor meets such requirements in at least one state in which it offers a Part D plan. Final § 423.410 has been revised to clarify how CMS will handle such waivers. In addition to issuing waivers to plans with pending licensure applications who can establish they meet a state's licensing requirements, CMS can grant waivers if a state has failed to act on a licensing application within 90 days of filing or a state has denied a license for what CMS deems to be discriminatory reasons. § 423.410(b). Other circumstances that could result in waivers remain unchanged from the proposed regulation. In response to comments, CMS modified § 423.410(b)(3) to permit waivers if a state denies licensure for reasons not required by Federal law. An example provided by CMS in the preamble was a State requirement that a PDP sponsor be a non-profit entity. FR 4318. Waivers under § 422.410(b) are normally for 36 months, but can be longer if there is no other PDP sponsor in the State. §§ 423.410(e)(1) and (e)(3).

Standards for temporary waivers for a plan year are at § 423.415 of the final regulations, rather than, as proposed, in § 423.410(b).

Solvency Standards Established by CMS

Final § 423.420 is unchanged from the proposed rule on solvency standards for unlicensed plans. The preamble indicates that such standards, which were required by the statute to be issued by January 1, 2005, are under review at CMS and will be published in the "near future." FR 4319.

Federal Preemption of State Law

Final § 423.440(a) is substantively unchanged from the proposed rule despite some comments seeking a more expansive statement of preemption. FR 4319.

Prohibition of Premium Taxes

CMS clarified its rule prohibiting premium taxes by adding in final § 423.440(b) that the prohibition extends to any taxes on "the direct subsidy, reinsurance payments, and risk corridor payments" provided under Part D.

Title I, Subpart J – Coordination of Part D Plans With Other Prescription Drug Coverage

Jenny Kim

Scope

The final rule established certain waivers for MA-PD plans, cost plans, and PACE organizations. § 423.452; FR 4552.

Definitions

The final rule moved the definition of "Part D plan" to § 423.4 and expanded the definition to include cost plans and PACE organizations offering qualified prescription drug coverage. Similarly, the definition of "Part D sponsor" was revised to include cost plans and PACE organizations offering qualified prescription coverage. § 423.4; FR 4527.

The final rule revised the definition of "employer-sponsored group prescription drug plan" to mean "prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in § 423.882) approved by CMS as a prescription drug plan." § 423.454; FR 4552.

The final rule did not significantly change the definition of "State Pharmaceutical Assistance Program (SPAP)." § 423.454; FR 4552. CMS interpreted the non-discrimination language in section 1860D-23(b)(2) of the Act and § 423.464(e)(1)(ii) of its final rule to mean that SPAPs, if they offer premium assistance or supplemental assistance for Part D cost sharing, must not only offer equal assistance to beneficiaries enrolled in all Part D plans available in the State, but also may not steer beneficiaries to one plan or another through benefit design or otherwise. If a State auto-enrolls beneficiaries into a plan, the State program will no longer meet the statutory definition of SPAP under section 1860D-23(b) of the Act. Thus, this will jeopardize the program's special status with respect to true out-of-pocket (TrOOP) costs. The nondiscrimination requirement also bars SPAPs from recommending Part D plans based on the SPAP's financial interest in minimizing the cost of providing benefits under SPAPs that supplement the benefits available under Part D coverage. CMS's outreach to SPAPs will also include guidance on various educational, outreach, and assistance activities SPAPs may undertake in a manner that will not discriminate among Part D plans.

Additionally, CMS believed that a hybrid SPAP with multiple components, some of which meet the definition of SPAP, and some of which do not, did not necessarily render an entire SPAP "unqualified" under its definition. FR 4321. CMS did not see any reason why the existence of both qualified and non-qualified components of a SPAP would interfere with its ability to count the spending of a qualified SPAP toward TrOOP, as long as operations and funding are appropriately segregated. FR 4321.

CMS clarified the definition of SPAP to exclude any program under which program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding. § 423.464(e)(1); FR 4553. Although the statutory definition of SPAP does not address program funding sources, CMS believed that a State program may still be considered a SPAP if some or all of its program funding is from private sources (*i.e.*, charities or independent foundations). CMS also clarified that the exclusion of Federal program funding does not exclude some Federal administrative funding or incidental Federal monies (*i.e.*, Federal grants to SPAPs provided for in section 1860D-23(d) of the Act). FR 4320-22. Furthermore, based on the Webster's II dictionary definition, CMS interpreted the word "assistance" to mean financial help or aid provided to any individual in need of such support – specifically individuals in financial need, the aged, or those with certain medical conditions. FR 4321-22.

Pharmacy Plus programs may continue with Federal match after January 1, 2006, provided that any State that operates a Pharmacy Plus demonstration program determines whether it is feasible to continue that Pharmacy Plus program by submitting a revised budget neutrality calculation for the demonstration. FR 4322.

Application of Part D Rules to Certain Part D Plans on and after January 1, 2006

The final rule adopted the proposed rule without significant changes. § 423.458; FR 4552-53. These provisions cover the application of Part D rules to MA-PD plans, as well as waivers of Part D requirements for MA-PD plans, cost plans, employer-sponsored group prescription drug plans, and PACE organizations. FR 4322. Thus, Part D requirements not related to the provision of drug coverage (*i.e.*, licensing requirements) do not apply to MA-PD plans. Additionally, Part D provisions would be waived to the extent that CMS determined that they duplicate, or conflict with, provisions under Part C, or as necessary in order to improve coordination of Part D benefits with the Part C program and/or to ensure that Part C benefits continue to be effectively delivered under § 423.458(b) of the final rule. FR 4322.

The final rule adopted the provision regarding waivers of Part D requirements for PACE organizations set forth in § 423.458(d) of the proposed rule. PACE organizations will not be deemed MA-PD local plans, but will be treated in a manner that is similar to MA-PD local plans for Part D requirements applicable to the offering of qualified prescription drug coverage. § 423.458(d); FR 4552-53. Subpart T of Title I of the final rule provides additional information.

Waivers of Part D requirements for employer-sponsored group prescription drug plans are the same as in the proposed rule. § 423.458(c); FR 4552. Details on employer-sponsored group prescription drug plan waivers that CMS will and will not consider will be included in separate guidance. FR 4323. Additional waiver requests will be addressed on a "flow basis," *i.e.*, they will be addressed as waiver requests are received. FR 4323. Although CMS believes that section 1860D-21(e) of the Act extended waiver authority to cost plans, it concludes that the provisions of Parts C and D that do not relate to the offering of qualified prescription drug coverage by cost plans (including the employer waiver authority under section 1857(i) of the Act) cannot be waived for benefits offered by a cost plan other than qualified prescription drug coverage. FR 4323.

Medicare Secondary Payer Procedures

The final rule adopted the proposed rule without significant changes. § 423.462; FR 4553. Medicare Secondary Payer (MSP) provisions under section 1860D-12(g) of the Act are extended to cost plans for offering of qualified prescription drug coverage under the plans. FR 4323. However, MSP and preemption provisions of both Parts C and D would not apply to benefits offered under a cost plan for other than qualified prescription drug coverage. CMS does not interpret these statutory provisions as permitting CMS to apply these provisions to Parts A and B benefits offered by cost plans. FR 4323. Cost plans are still subject to MSP and state law preemption provisions under § 411.172 for their Parts A and B benefits. FR 4323-24.

Coordination of Benefits With Other Providers of Prescription Drug Coverage

The final rule adopted the coordination of benefit provisions set forth in § 423.464 of the proposed rule with one addition (§ 423.464(f)(4)) and minor language changes. § 423.464; FR 4553. CMS will establish procedures and coordination requirements for Part D plans no later than July 1, 2005, to ensure effective coordination. FR 4324. In addition, as specified at section 1860D-24(a) of the Act, CMS will apply the requirements for coordination of benefits with SPAPs to Part D plans when they coordinate with entities providing other prescription drug coverage, including Medicaid insurers, group health plans, Federal Employees Health Benefits Program (FEHBP), military coverage, and other coverage that CMS specifies. § 423.464(f)(1); FR 4553.

Although commenters expressed concern that confidential negotiated pricing might be released due to the requirement that Part D plans collect information on incurred costs for purposes of tracking TrOOP expenditures, CMS clarified that it did not expect that SPAPs will need to report paid claims data. FR 4324-25. TrOOP calculations will work by counting all amounts not paid by the Part D plan, unless such amounts are paid through group health plans, insurance or otherwise, or third party payment arrangements. FR 4325.

CMS will issue further guidance regarding the method that it will use for assessing user fees on Part D plans in separate guidance. FR 4325. However, it expects that it will charge a user fee of no more than $1 per beneficiary per year to Part D plans, and perhaps, charge considerably less. FR 4325. Additionally, Part D plans may charge user fees to SPAPs and entities providing other prescription drug coverage but only for costs that are related to coordination of benefits between Part D plans and SPAPs or entities providing other prescription drug coverage. FR 4326.

Regarding coordination with SPAPs, although CMS does not have the authority to require data exchanges between Part D plans and states, it strongly encourages Part D plans to exchange data on shared enrollees with State Medicaid plans, provided such disclosure is consistent with the HIPAA Privacy Rule provisions for the sharing of protected health information with another covered entity. § 423.464(e); FR 4326-27, 4553.

Regarding coordination with other prescription drug coverage, the final rule added to the definition section the Indian Health Service, federally qualified health centers, and rural health centers. § 423.464(f)(1)(v)-(vii); FR 4553. Commenters requested that CMS clarify that States are prohibited from requiring pharmaceutical manufacturers to pay rebates on drugs delivered to beneficiaries through Part D plans. § 423.464(f); FR 4553. However, given that Medicaid rebate program does not apply to SPAPs, CMS did not believe that it had the authority under the Act to regulate or to impose prohibitions on drug rebates or drug pricing negotiations between SPAPs and manufacturers. FR 4327.

For coordination of benefits generally, while CMS conceded that it could eventually adopt automatic cross-over procedures, it did not believe that commenters provided a compelling rationale for automatically covering drugs under Part D that are denied coverage under Part B because a beneficiary fills the prescription at the wrong pharmacy. FR 4327-28. As for vaccine administration, in the short-term, CMS decided that a two-step approach is the most appropriate policy. FR 4328. A Part D enrollee may self-pay the physician for the vaccine cost and submit a paper claim for reimbursement to the Part D plan. FR 4328.

For collection of data on third party coverage, CMS noted the Act does not give CMS an enforcement mechanism to impose mandatory reporting by third-party payers. In separate guidance, CMS will require beneficiaries enrolling in or enrolled in a Part D plan to provide third-party coverage information. § 423.32(b)(ii); FR 4528. Part D enrollees must also consent to the release of such information collected or obtained from other sources – otherwise, failure to provide this information could be cause of termination of Part D coverage. FR 4329. In the event that a beneficiary does not disclose alternative coverage payments to the Part D plan, CMS modified § 423.464(f)(2) in the final rule and added paragraph (f)(4) to give the Part D plan authority to recover any payments made in error on the basis of incorrect assumptions about the level of TrOOP expenditures. §§ 423.464(f)(2), (f)(4); FR 4553. The plan may recover these payments directly from the beneficiary on whose behalf the payments were made. §§ 423.464(f)(2), (f)(4); FR 4553, 4329.

Despite overwhelming commenter support for the option of having CMS procure a TrOOP facilitation contractor to establish a single point of contact between primary and secondary payers, CMS decided that PDP and MA-PDs will be responsible for calculating TrOOP costs for all individuals enrolled in their plan. FR 4329. CMS will continue to work with industry on a solution to facilitate the TrOOP tracking process. FR 4330. CMS will issue a final decision on how to best address TrOOP process challenges well before the July 1, 2005 statutory deadline. FR 4330. Part D plans will always ultimately be responsible for correctly calculating TrOOP for their Part D enrollees. FR 4330. If enrollees fail to provide information about other prescription drug coverage to their Part D plans, and the Part D plan later discovers that payments were made by a third-party payer, it must recalculate TrOOP and, if necessary, recover overpayments. FR 4330.

Title I, Subpart K – Application Procedures and Contracts with Part D Plan Sponsors

Lloyd M. Weinerman

Record Retention Requirements

The proposed rule contained a 6-year period for which records needed to be retained. The final rule substantially increased the time period to ten years from the end of the final contract period or the completion of a Government audit, whichever is later. CMS states that this increase from a six-year to a ten-year period was made in order to conform to the statute of limitations for discovery of violations under the False Claims Act. § 423.505(d); FR 4556.

Compliance with Laws and Regulations

The proposed rule required a Plan D sponsor to comply with "all applicable laws and regulations" but did not define what those laws and regulations might be. The final rule clarifies that the laws and regulations CMS has in mind are those that are designed to prevent fraud, waste, and abuse. Examples of such laws are Federal criminal law, the False Claims Act, and the federal healthcare Anti-kickback Act. § 423.505(h)(1); FR 4557-58.

CMS neglected to make a conforming change to the requirements for a sponsor's subcontracts or arrangements with related entities. The final rule continues to require a Part D sponsor to require a related entity, contractor, or subcontractor to comply with "all applicable Federal laws." § 423.505(i)(4)(iv); FR 4558.

Self-Reporting

The proposed rule contained an explicit requirement that Part D plan sponsors must self-report to CMS any suspected violations of law, regulation, or other wrongdoing. The final rule eliminates this explicit reporting requirement. However, the final rule makes it clear that CMS expects a sponsor's compliance plan to contain, as one of its critical features, a requirement for reporting violations to the appropriate authorities in the event there is suspected fraud or misconduct. § 423.504(b)(4)(vi)(H); FR 4555.

Incomplete Contract Application

The proposed rule indicated that CMS would allow an applicant for a contract up to ten days to submit missing information in order for its application to be evaluated. The final rule states that missing information should be submitted within two days of receiving CMS's request. While the preamble to the final rule states that the two-day period is a guide, and an applicant continues to have a ten-day period to submit missing information, CMS maintains that it could issue an intent to deny the application if an applicant doesn't conform to the new two-day limitation. FR 4333; § 423.503(c)(2)(ii); FR 4555.

Compliance Program

The requirements for an effective compliance plan have been moved from Subpart D to Subpart K in the final rule. The final rule requires that as a condition for receiving a contract, a Part D sponsor must have a fraud and abuse compliance plan that, according to the preamble is similar to the plan that the Office of Personnel Management requires its FEHBP plans to have. FR 4338; § 423.504(b)(4)(vi)(H); FR 4555.

Frequency of CMS Audit

The proposed rule provided that CMS would audit one-third of the contracted plans each year. Despite receiving comments suggesting that plans be audited each and every year, the final rule retained the provision that only one-third of the plans would need to be audited each year. § 423.504(d)(1); FR 4556.

Title I, Subpart L – Effect of Change of Ownership or Leasing of Facilities During the Term of Contract

Kenneth M. Bruntel

The final regulations are essentially unchanged from the proposed regulations. These regulations largely mirror those for Medicare+Choice Organizations. A PDP sponsor must give CMS prior notice of a change of ownership (CHOW) (including asset transfers). § 423.551(c). CMS can approve the transfer of the PDP contract through a novation process. § 453.552. CMS had specifically requested comments on several aspects of the proposed rule, but determined not to change its proposed rule despite the comments it received. FR 4341-2.

Title I, Subpart M – Grievances, Coverage Determinations, and Appeals

Jody Goodman

Introduction

The final rule replaces all "PDP sponsor" references in Part M with "Part D plan sponsor," which is defined in § 423.4 as PDP sponsors (including fallback entities), MA organizations offering MA-PD plans, PACE plans offering qualified prescription drug coverage, and cost-based HMOs and CMPs. FR 4343.

General Provisions

In general, plans are responsible for establishing and maintaining procedures for grievances, coverage determinations, and appeals. Enrollees must receive written information about the procedures. FR 4343.

CMS added to § 423.612(b) that the time and place for a hearing before an ALJ will be set in accordance with § 405.1020. § 423.562; FR 4343.

CMS deleted the proposed provision that would have prohibited an enrollee's appeal rights when he or she has no further liability to pay for prescription drugs through a Part D plan so as not to preclude SPAPs or other secondary payors from filing appeals with Part D plans on behalf of enrollees. § 423.560; FR 4343-44.

Grievance Procedures

Part D Grievance procedures are modeled after the MA grievance procedures. The same grievance requirements (who may file a grievance, filing procedures, and record-keeping procedures) that are applicable under MA are applicable under Part D. § 423.564; FR 4344.

Coverage Determinations

In general, the MMA requires that a plan's procedures meet the same requirements as the procedures that apply to MA organizations. § 423.572; FR 4345. One difference between the new regulations and the MA rules is that enrollees may request exceptions to a plan's formulary and tiered cost-sharing structure. These "exception requests" are treated as requests for coverage determinations. §§ 423.566-423.630; FR 4346.

CMS agreed with commenters that the adjudication timeframes for making decisions with respect to an enrollee's access to drugs were too long. CMS used the NAIC Model Act as a benchmark. The new rule requires that plans make determinations within 72 hours of receipt of the request for standard coverage determinations and seven days for standard redeterminations. For expedited requests, a plan will have 24 hours for expedited coverage determinations, and 72 hours for redeterminations. FR 4346-47. Plans are required automatically to provide an expedited determination or redetermination when the prescribing physician indicates that the standard timeframe "would seriously jeopardize the life or health of the enrollee." FR 4351.

CMS has amended § 423.566(b)(3) and (4) "to state that a decision concerning an exceptions request under § 423.578(a) or . . . § 423.578(b), is a coverage determination." § 423.566(b); FR 4349.

Plans must require that their network pharmacies notify enrollees of their right to receive a detailed written notice from the Part D plan sponsor regarding the enrollee's prescription drug coverage, including information about the exceptions process. Pharmacies may post these notices or distribute them. § 423.562(a)(3); FR 4349.

The proposed rules provided that a plan's failure to make an adjudication within the requisite timeframe constituted an adverse determination that could be appealed. In light of comments received, CMS concluded that this would provide a disincentive to plans to make timely determinations. The new policy under Part D is that, if a plan fails to make a timely determination, the enrollee's request is automatically forwarded to the IRE. The request must be forwarded to the IRE within 24 hours of the expiration of the adjudication timeframe. § 423.578(c)(2); FR 4350-51.

Formulary Exceptions Procedures

An enrollee may request an exception to a plan's tiered cost-sharing structure, and a plan must have a process in place to handle such requests. § 423.578; FR 4352.

In the interests of providing some consistency regarding exceptions criteria, plans must grant exceptions when the plan determines that a lower-cost drug would not be as effective for the enrollee as the requested drug, would have adverse effects for the enrollee, or both. § 423.578; FR 4352-53.

When an enrollee is receiving medication that is affected by a mid-year change in the tiering structure, plans must ensure that the enrollee is "able to receive a medically necessary drug at a given cost-sharing amount when a tiering exception is granted." Regulatory language has been added to require that off-formulary and tiering exceptions are based upon the medical needs of the enrollee. § 423.578; FR 4353.

CMS has added language to reflect that exception criteria should be designed to grant exceptions when a plan determines that an off-formulary drug is medically appropriate for an enrollee, and that the drug would have been covered had it not been off-formulary. § 423.578; FR 4355.

In order to clarify who may make safety determinations, CMS says that plans may discontinue coverage of medications for safety reasons. Plans must include in their exceptions procedures for non-formulary drugs a process for comparing medical and scientific evidence on a drug's safety and effectiveness. § 423.578; FR 4356.

CMS agrees that it should not add an exceptions criterion that would require an enrollee to try a preferred drug and experience adverse effects before being permitted to use a previously-used drug that has been removed from the formulary or is no longer designated as the "preferred" drug. However, plans are free to establish such a requirement in their exceptions process. § 423.578; FR 4356.

One of the safeguards (along with continued coverage during exceptions request process and reduced timeframes for determinations) implemented by CMS to ensure that the exceptions process is fair and efficient for enrollees is to prohibit plans from assigning drugs approved under an exceptions process to a special formulary tier, co-payment, or other cost-sharing requirement. § 423.578; FR 4357.

Appeals

Redeterminations

If a plan's coverage determination is unfavorable to an enrollee, the enrollee may request (orally or in writing) a redetermination. §§ 423.580-423.590.

CMS has not defined "good cause" for extending the timeframe for filing a redetermination request, but provided examples of good cause, such as: (1) the enrollee was prevented by serious illness from contracting the plan; (2) the enrollee had a death or serious illness in his or her family; and (3) important records were destroyed by fire or accident. § 423.582(c); FR 4358.

Independent Review Entity (IRE) Reconsideration

Section 423.600 proposed that an enrollee who was dissatisfied with a plan's redetermination could file a written request for reconsideration by the IRE; the IRE

would be required to solicit input from the prescribing physician. A physician who requested a non-formulary drug would have to indicate that all covered Part D drugs on any tier of the formulary for treatment of the condition in question would not be as effective for the patient, would have adverse effects, or both. CMS added subsection (e) to 423.600, requiring that reconsiderations be made by a physician with expertise in the area of medicine applicable to the treatment at issue, when the reconsideration involves a denial of coverage based on medical necessity. § 423.600; FR 4359.

The IRE's review is not limited to whether a plan applied its exceptions criteria correctly. The IRE also reviews whether a drug is medically necessary. § 423.600; FR 4359.

Effectuation of Reconsideration Determinations

CMS determined that, like adjudication timeframes, the timeframes for effectuation of reversals were too long. As a result, the effectuation timeframes are as follows:

For appeals involving non-payment issues:

- 72 hours (expedited) and seven days (standard) from the date the plan receives the request for redetermination if the plan is reversing its previous determination; or
- No later than 24 hours (expedited) or 72 hours (standard) from the date the plan receives notice of a reversal by the IRE, ALJ, MAC, or federal court.

For payment issues:

- The plan must authorize payment within seven calendar days from the date it receives the request for redetermination, and make payment within 30 days from the date it receives the request for redetermination, if the plan is reversing its previous determination; or
- The plan must authorize payment for the benefit within 72 hours and make payment no later than 30 days from the date it receives notice reversing the coverage determination by the IRE, ALJ, MAC, or federal court.

§§ 423.636, 423.638; FR 4361.

Federal Preemption of Grievances and Appeals

CMS sought a uniform set of grievance standards, and consistency between the Part D drug program under Title I and the MA program under Title II. Section 423.564 implements for Part D grievances the guidelines proposed in January 2001 for Medicare+Choice organizations. Part D provisions do preempt state appeals requirements. "[E]nrollees will still have access to various State remedies available in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD plan." § 423.564; FR 4362.

Employer Sponsored Prescription Drug Programs and Appeals

Some employers may establish group plans that are governed by Part 423 as well as ERISA and State law. CMS consulted with the Department of Labor to streamline the process and to avoid parallel appeals proceedings. CMS added § 423.562(d), which gives ERISA plans the option of electing a Part D process instead of the procedures under CFR 2560.503-1 for claims involving supplemental benefits provided by contract with a Part D plan. DOL must pass regulations before this provision can take effect. § 423.562; FR 4363.

Miscellaneous

CMS declined to reimburse physicians for administrative activities related to the grievance and appeals process, but to reduce this burden, CMS eliminated the requirement that physicians' supporting statements be in writing. FR 4363.

In response to commenters' concerns about notice to enrollees concerning the grievance and appeal process, § 423.568(g) requires plans to include specific information in denial notices, including the reason for the denial, the right to appeal, and information about the appeals process. Denial notices must be easily readable and understandable, and will be available in alternative formats.

Redetermination notices also require detailed written notice to enrollees. § 423.590(g); FR 4364.

CMS agreed with commenters that enrollees should have access to assistance with the appeals process. CMS rejected the viability of paying for consumer advocates, but stated that there are adequate mechanisms in place to provide assistance, including the Medicare Ombudsman.

Title I, Subpart N – Medicare Contract Determinations and Appeals

David W. O'Brien

In response to comments, CMS decided against amending this regulation to explicitly state that Subpart N only applied to PDP sponsors and not to MA plans since MA organizations will, by definition, be subject to appeals procedures in part 422 and not Part 423. CMS did clarify that, with the exception of the termination of a fallback contract, fallback plans are not subject to the procedures of subpart N. FR 4365.

Contract determinations

Section 423.641 provides for reviews of determinations that an entity is not qualified to enter a contract, that a contract renewal is not authorized and that a contract should be terminated. The subpart's application to fallback entities is limited to review of contract terminations.

Notice

Notice of contract determinations must be in writing, specify its reason and inform the PDP sponsor of its right to request reconsideration. § 423.641. Notice of termination must be provided 90 days in advance of the termination unless the termination is based upon fraud or severe financial difficulty. Determinations not to renew must be mailed by May 1 of the current contract year. § 423.641(d).

Finality

A contract determination is final unless it is reconsidered, or a request for hearing is filed or the reconsideration is reopened. § 423.643(a) and (b).

Reconsiderations

CMS will reconsider a contract determination if an authorized official of the PDP sponsor or contract applicant files a written request with CMS within 15 days of the determination. § 423.645(b). Both CMS and the entity seeking reconsideration are given a reasonable opportunity to present documents or written statements that are relevant to the issues under reconsideration. § 423.646. A reconsidered determination is a *new* determination that affirms, reverses or modifies the initial determination. § 423.647(b). Favorable reconsiderations must be made by July 15 in order to be effective on January of the following year. § 423.647(c); FR 4365. Notice of the reconsideration decision must be in writing and contain findings regarding the qualifications of the appealing entity to enter into or remain under a Part D contract with CMS, state specific reasons for the decision and inform the appealing entity of its right to a hearing if it is dissatisfied with the decision. § 423.648. A reconsidered determination is *final* unless a timely request for hearing is filed. § 423.649.

Hearings

Contract applicants who are determined in a reconsidered determination not to be qualified to enter into a Part D contract, and PDP sponsors whose contracts are terminated or not renewed through a contract determination, are entitled to a hearing. For contract determinations of termination and non-renewal, it is not necessary to go through the reconsideration process. A request for hearing can be made directly to any CMS office. § 423.651(a).

A request for a hearing must be made in writing by an authorized official of the appealing entity and filed with CMS within 15 days "after the date of the reconsidered determination." § 423.651(b). The quoted language is inconsistent with the subpart's provisions on those entitled to a hearing. As noted, entities aggrieved by a contract determination to terminate or not renew are entitled to a hearing. Such a contract determination will usually not be

a "reconsidered determination." The time for filing a request for a hearing should run from that initial contract determination.

Parties to a hearing may include parties beyond those immediately aggrieved by the contract determination. They may include interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing. Presumably, this could include competitors and perhaps even enrollees.

Stays

CMS will postpone contract termination or non-renewal until after the hearing officer's decision or the Administrator's review where such review is sought if CMS finds that contract extension is consistent with the purpose of this part, *i.e.*, the rules and regulations pertaining to the Voluntary Medicare Prescription Drug Benefit, and CMS and the appealing party agree to do this. § 423.652(a) and (b). This stay will not apply to terminations for fraud and severe financial difficulty. § 423.652(c).

Conduct of Hearings

Hearings will be conducted by a hearing officer designated by CMS. The hearing officer need not be an ALJ. § 423.653. A hearing must occur within 30 days from receipt of the request for hearing unless postponement is sought and the hearing officer is required to send written notice to the parties of its time and place. § 423.655(a).

Prehearing discovery is permitted upon request made anytime before the beginning of the hearing. § 423.661. The scope of discovery is not specified although the regulation only refers to the inspection of documents. The hearing is open to the public. Parties to the hearing may offer documents and call and cross-examine witnesses. Evidence inadmissible under court rules may be admitted at a hearing. § 423.659. A transcribed record of the hearing will be made and is available to the parties. § 423.663(a)

The hearing officer will make a written decision as soon as practical and it will contain separately numbered findings of fact and conclusions of law. § 423.665(a). The decision is final unless it is reversed or modified after review by the Administrator or reopened and revised. § 423.665(e).

Administrator Review

A PDP sponsor may request the Administrator's review of a hearing officer's upholding of a contract termination decision within 15 days of the decision. § 423.666(a). The PDP sponsor may submit written argument to the Administrator and the Administrator will decide whether the termination must be upheld, reversed or modified after consideration of those arguments and review of the hearing record and the hearing officer's decision. The Administrator's decision is final and binding unless reopened and revised. § 423.667.

Reopening

CMS may reopen an initial or reconsidered determination upon its own motion within a year of the date of the notice of the determination. § 423.668(a). A hearing officer or the Administrator may also reopen and revise their respective decisions within one year of the date of the notice of those decisions. § 423.668(b). Revisions are binding unless a party files a request for a hearing on the revision. § 423.669.

Title I, Subpart O – Intermediate Sanctions

Ben Butler

CMS received relatively few comments regarding intermediate sanctions under Title I and, as a result, made few changes to the final regulations. Among them, CMS clarified its authority to impose more than one sanction at a time. § 423.752; FR 4366. Despite commenters' requests that CMS "publicize" sanctions imposed on Plan D sponsors, CMS declined, stating that such publication would not only be unnecessary, but also "unfair" to sanctioned organizations that "have later become solid examples of compliant contract administration." FR 4367.

Title I, Subpart P – Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Robyn Whipple Diaz

Subpart P addresses assistance provided to individuals with limited means, and provides details on the transition of dual eligibles from Medicaid to Medicare for purposes of prescription drug coverage.

Definition of Full Benefit Dual Eligible Individuals

Several significant changes were made with regard to the definition of full benefit dual eligible individuals. First, the definition was narrowed to exclude individuals enrolled in section 1115 demonstration programs that provide pharmacy-only benefits.[1] § 423.772; FR 4572. *See also* FR 4371. Moreover, a commenter expressed concern that the definition of full benefit dual eligible individuals set forth in the proposed rule would create a technical conflict with the auto enrollment provisions for those who failed to enroll in a prescription drug plan ("PDP") or Medicare Advantage PDP ("MA-PD") plan. CMS stated that it did not have the authority to change the definition of full benefit dual eligible found in § 423.772, as the definition "reflects the statutory definition of that term found at section 1935(c)(6) of the Act." FR 4370-71. In order to avoid thwarting Congress' intended policy with respect to the auto-enrollment process, however, CMS set forth a definition of full benefit dual eligible individuals specifically for the purpose of implementing the auto-enrollment process. *Id*. For this purpose, they are defined as "Part D eligible individuals who meet statutory conditions but are not enrolled in a Part D plan." FR 4370-71.

Requirements for Eligibility

CMS will not require States to inform beneficiaries that they have been deemed full-subsidy eligibles.[2] Instead, CMS will send notices to those who are deemed eligible, informing them they need not apply for subsidies. FR 4376 states, in this regard, that CMS' goal "is to begin sending notices to individuals deemed to be subsidy eligible in the Spring of 2005, before the start of taking applications for individuals who are not deemed eligible for the low-income subsidy." CMS "will ensure that the notices clarify that individuals deemed eligible for a full subsidy need not apply to receive the subsidy." Individuals treated as full-subsidy eligible will be deemed eligible for up to one year. *Id*. Medicare beneficiaries who become eligible for Medicaid after spending down their resources "will be notified that they are eligible for a full subsidy under Part D for up to one year without interruption. If the individuals periodically go off Medicaid because they have to meet a new spenddown budget, they will still be 'deemed' full subsidy eligible individuals for the remaining period of subsidy eligibility." FR 4376.

Despite requests for CMS to implement a presumptive eligibility process for individuals not deemed to be subsidy eligible, CMS has declined to institute such a process. FR 4379. CMS noted that it acknowledges the need for applications to be submitted and eligibility determinations to be made as quickly as possible. CMS will work with the States and SSA to encourage individuals to apply for the subsidy and "pre-qualify" before enrolling in a Part D plan. *Id*.

Eligibility Determinations

The final rule requires SSA and State Medicaid programs to make low-income subsidy eligibility determinations. § 423.774(a); FR 4573. Despite the requirement that States ensure their ability to make eligibility determinations upon request, CMS encourages States to: (1) use the SSA application as their default for processing subsidy applications; (2) assist individuals with the SSA application process; and (3) submit SSA applications on applicants' behalf. FR 4381.

Premium Subsidy

Sliding scales applied to "other low-income subsidy eligible individuals" are discussed at § 423.780. Other low-income subsidy eligible individuals (1) have incomes less than 150% of the FPL and (2) limited resources (the resources of the individual's spouse are taken into account). § 423.773(d); FR 4573. The proposed rule suggested a sliding scale premium calculation broken down into 5 percent increments; CMS requested comments on that proposal. *See* FR 4386. The sliding scale premium will be adopted as set forth at 423.780(d).[3] FR 4574.

In response to requests for clarification regarding how CMS will arrive at a weighted average used to calculate the premium subsidy amount for a given region, regulatory language regarding low-income benchmark premiums was added at § 423.780(b)(2); FR 4574. *See also* FR 4386.

Administration of Subsidy Program

The final rule clarified that Part D plans will be required to reimburse subsidy eligible individuals for out-of-pocket expenses incurred after the effective date upon which the individual became subsidy eligible. § 423.800; FR 4575. *See also* FR 4390. Part D plans will also be required to reimburse charities or other programs for premiums and cost-sharing amounts paid on behalf of eligible individuals after the effective date of subsidy eligibility. § 423.800; FR 4575. *See also* FR 4391.

Footnotes

1 Under the proposed and final rules, individuals covered under Pharmacy Plus program demonstrations are excluded from this definition.

2 A full subsidy eligible individual is a subsidy eligible individual who (1) has income below 135% of the federal poverty level ("FPL"), and (2) limited resources (the resources of the individual's spouse are taken into account). § 423.773(b); FR 4573. An individual is automatically treated as full subsidy eligible if he/she is (1) full benefit dual eligible; (2) a recipient of Supplemental Security Income ("SSI") benefits; or (3) eligible for Medicaid as a qualified Medicare beneficiary ("QMB"), specified low-income Medicare beneficiary (SLMBs) or qualifying individual (QIs). § 423.773(c)(1); FR 4573. A subsidy eligible individual is Part D eligible and is enrolled in a PDP or MA-PD plan and (1) has income below 150 percent of the federal poverty level applicable to the individual's family size and (2) has resources at or below the resource thresholds. § 423.773(a); FR 4573.

3 "Beneficiaries with incomes at 135 percent of the FPL will receive a 100 percent premium subsidy; beneficiaries with income greater than 135 percent but at or below 140 percent of the Federal poverty level will receive a 75 percent premium subsidy; beneficiaries with incomes greater than 140 percent but at or below 145 percent receive a 50 percent premium subsidy; and beneficiaries with incomes greater than 145 percent but below 150 percent of Federal poverty level will receive a 25 percent premium subsidy." FR 4386.

Title I, Subpart Q – Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

Ben Butler

CMS included some modifications and clarifications with respect to fallback PDPs, but deferred other issues (such as details on payment methodologies) to future publications that are to provide guidance on fallback plan solicitations. FR 4400. Among the key provisions, CMS clarified that an MA organization may offer both an MA-PD plan and a fallback plan in the same region. § 423.855; FR 4391. CMS also clarified that fallback PDPs are a form of PDPs and, thus, are subject to the same requirements (unless otherwise inapplicable, *e.g.*, reinsurance payments). § 423.855; FR 4393-94.

The definitions section within subpart Q has been modified to reflect that fallback PDPs may offer either defined or actuarially standard benefits. § 423.855; FR 4393. As a related matter, CMS has added a definition of actual costs. *Id.*

With respect to the number of fallback contracts to be awarded, CMS indicates in the Preamble that it "plan[s] to award as many contracts as needed to provide potential fallback services[, but] still plan to have only a very limited number." FR 4395. In the preamble, CMS also clarifies that contracting restrictions apply to fallback PDPs that have actually "offered" coverage, thus, if a fallback plan was not activated through year 3 of a fallback contract, the entity could be eligible to bid on a risk plan for year 4. FR 4392.

The fallback solicitation process will take place after the risk plan solicitation process. § 423.863; FR 4396. Regarding solicitations, CMS clarifies the relationship between fallback plans and the Federal Acquisition Regulations (FAR). CMS indicates that "unlike both risk and MA contracts, we will enter into fallback contracts using the Federal acquisition rules on a timetable to ensure that the contracts are in place on time," although the contracts themselves "will not look like typical 'FAR contracts.'" *Id.*

On the subject of performance targets for fallback plans, CMS indicates that it will incorporate the average wholesale price (AWP) as a price reference point, "despite its frequent fluctuations and inherent vulnerability to manipulation." § 423.871; FR 4398.

Finally, CMS clarifies its authority "to require that premiums be collected by fallback plans, and to deduct such amounts from payments due to fallback plans" with respect to certain individuals. § 423.867; FR 4399.

Title I, Subpart R – Payments to Sponsors of Retiree Prescription Drug Plans

William J. Flanagan

Final §§ 423.880 – 423.894 apply only to those plans with respect to which employers intend to seek the new government subsidy payment provided in Subpart R. This portion of the regulations does not apply to employer-sponsored enhanced benefit or "wrap-around" programs for retirees who have elected Part D prescription drug coverage. This portion of the regulations also does not apply to those situations in which an employer wishes to have its plan qualified as a stand alone prescription drug plan or to a Medicare Advantage Organization that provides Part D benefits. § 423.880; FR 4400-401.

Definitions

Section 423.882 sets forth definitions of terms used in this Subpart. Key provisions include:

Qualifying Covered Retiree

Subsidy payments may be received only with respect to a qualifying covered retiree. Determination of whether a plan participant is a qualifying covered retiree is subject to a three-prong test. The individual must be: (1) a retiree or dependent; (2) who is covered by a "qualifying retiree prescription drug plan;" and (3) who is not enrolled in Medicare Part D. If the person covered by the plan is not a retiree, the status of his or her dependents, and the issue of whether they are themselves eligible for Part D coverage, will not affect this determination. § 423.882; FR 4402-403.

Gross Covered Retiree Prescription Drug Costs

This term excludes administrative costs but is not limited solely to Part D formulary drugs. Further, it can include costs paid by the retiree, as well as costs directly related to dispensing covered drugs. § 423.882; FR 4403.

Allowable Retiree Costs

The actual drug subsidy paid pursuant to this Subpart is calculated with respect to allowable retiree costs. This amount is determined within annual threshold and cap amounts ($250 – $5000 for 2006). It can include amounts paid by both employer and employee but excludes drug company or insurance discounts, rebates, etc. This figure must reflect the actual cost of providing prescription benefits, not merely, for example, the premium paid to an insurer under an insured arrangements. In the case of an insured arrangement, the amount of premiums paid may be used as the basis for requesting monthly, quarterly or interim annual payments, subject to end of the year reconciliation. § 423.882; FR 4403-404.

Sponsor

Both private and governmental plans are included in this subsidy program. Where a plan is maintained jointly by a union and an employer, whichever entity is the primary source of financing for the plan is viewed as the sponsor eligible to receive subsidy payments. In all other cases, this term is to be interpreted consistent with the definition of the term "sponsor" in ERISA § 3(16)(B). § 423.882; FR 4404-405.

Group Health Plan

The regulations adopt the COBRA definition of this term, 26 C.F.R. § 54.4980B-2, Q -6. It should be noted that for the purposes of these regulations, this term includes HRA's and FSA's, but not HSA's or Archer MSA's. § 423.882; FR 4401-402.

Benefit Option

This term includes any benefit design, category of benefits or cost-sharing arrangement within a group health plan. It is intended to allow sponsor flexibility in determining whether to treat benefit options separately as group health plans or collectively as a single plan for the purposes of this regulation. § 423.882; FR 4405.

Requirements for Qualified Retiree Prescription Drug Plan

An employee-based plan will qualify for the subsidy only if it meets the requirements of this section. An initial issue faced by sponsors seeking this subsidy will be the availability of the information needed to support an application for the payment. § 423.884(b) and (c)(2); FR 4405-406. Most of the data required by this section is "protected health information" ("PHI") under HIPAA. CMS believes it can be provided pursuant to the "required by law" exception to HIPAA privacy rules, 45 C.F.R. § 164.512(a). *Id.* In order to receive the subsidy, each Sponsor must annually file an "actuarial attestation" that retiree prescription drug coverage provided under the plan is "actuarially equivalent" to that offered under Part D. § 423.884(a)(1), (d); FR 4406-407. Actuarial equivalency is determined pursuant to a two-prong test. The plan must meet both the "Gross Value Test" and the "Net Value Test" in order to be deemed as actuarially equivalent to Part D prescription drug coverage. § 423.884(d)(i)-(ii); FR 4407-408.

Gross Value Test

The expected amount of retiree claims paid under retiree plan must equal or exceed the expected amount paid under the Medicare Part D benefit. § 423.884(d)(5)(ii)(A); FR 4408.

Net Value Test

This prong again compares the value of benefits under the private plan with Medicare Part D coverage, but takes into account amounts of premiums, etc. paid by the retiree and the impact of private plans supplemental standard coverage under Part D. § 423.884(d)(5)(ii)(B); FR 4408-409.

(a) CMS has indicated that additional guidance will be forthcoming on these calculations. FR 4409.

(b) The regulation contains special rules for making these calculations for plans with multiple benefit designs, cost-sharing arrangements, and plans with integrated prescription and non-prescription premiums. § 423.884(d)(5)(iii); FR 4409-410.

Timing of Subsidy Applications

For 2006 subsidies, a Sponsor must file its application for a subsidy by September 30, 2005. Thereafter, annual applications are required 90 days prior to the close of the plan year for which the subsidy is sought. § 423.884(b)(5); FR 4410-411.

The Retiree Drug Subsidy Amount available under Subpart R is 28% of allowable retiree costs per qualifying covered retiree. The payment is made to the plan Sponsor (even when the plan is insured) and all payments are tax exempt. These regulations place no restriction on the Sponsor's use of subsidy payments, nor do they require that the payments be used for the benefit of the plan or its participants and beneficiaries (although HHS does not rule out the possibility that other laws may impose such restrictions). The subsidy is subject to cost thresholds and cost limits set annually under Part D. For 2006, this range is $250 - $5000. § 423.886; FR 4413.

Payment Options

A Sponsor has several options for the way in which it receives subsidy payments. A Sponsor may elect monthly, quarterly, interim annual or final annual payments, as determined on a plan (as opposed to a calendar) year basis. There is a required annual reconciliation within 15 months after the end of the plan year for any estimated information submitted in support of application for monthly, quarterly or interim annual payments. Records in support of a subsidy application must be maintained for a period of six years. § 423.888; FR 4414-416.

Appeals

The regulations provide for an informal appeals procedure covering only determinations regarding the amount of the subsidy payment, actuarial equivalency, whether an enrollee is a "qualifying covered retiree," and any other similar determinations regarding eligibility or the amount of the subsidy. Appeals rights are available only to the Sponsor of a plan seeking a subsidy. § 423.890; FR 4416-417.

Change of Ownership of Sponsors

Section 423.892 outlines those types of transactions that will result in a change of ownership of the sponsor applying for or receiving a subsidy. These are identical to the change in ownership provisions of § 423.551 of the regulations (discussed above). Sixty days advance notice to CMS is required if a sponsor wishes to receive (or continue to receive) subsidy payments pursuant to an existing Sponsor agreement. § 423.892; FR 4417.

Miscellaneous

A Sponsor seeking reimbursement under these rules cannot prevent any of its employees or retirees from enrolling in Medicare Part D. The Sponsor can, among other things, exclude Medicare Part D enrollees from participation in an actuarially equivalent plan, and can amend its plan to increase benefit flexibility, to provide wrap-around coverage or to become a free-standing Prescription Drug Plan or a Medicare Advantage Organization. § 423.894; FR 4417.

Title I, Subpart S – Special Rules for States – Eligibility Determinations for Low-Income Subsidies

Robyn Whipple Diaz

Definitions

The final regulations provide clarification on the process to be used to establish the actuarial value of capitated prescription drug benefits. The additional detail is "based on feedback obtained from State workgroups addressing this issue." FR 4424. The final regulation states that actuarial value "will be established using data determined by the Secretary to be the best available data among the following options: (1) State rate setting documentation for drug costs to the full dual eligible population; (2) State encounter and enrollment record databases including cost data; and (3) State managed care plan-specific financial cost data; and (4) other appropriate data." § 423.902; FR 4582.

The definition of full benefit dual eligible individual has been changed (as also noted in Subpart P, § 423.772) to exclude individuals under Pharmacy Plus demonstrations and individuals under a section 1115 demonstration that provides pharmacy only benefits to a portion if its demonstration population. § 423.902; FR 4582.

The method to be used for calculating phased-down state contribution payments has also changed. The contribution will now be calculated as "1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals, (1) multiplied by the State medical assistance percentage; (2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor; (3) multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and (4) multiplied by the phased-down State contribution factor." § 423.09; FR 4583.

Eligibility Determinations for Low-Income Subsidies

The requirement that States notify deemed subsidy eligible individuals of their eligibility was removed. § 423.904(c); FR 4583. Instead, CMS will send notices to those who are deemed eligible, informing them they need not apply for subsidies. FR 4418.

General Payment Provisions

The final rule clarifies that full-benefit dual eligible individuals will be deemed eligible for Part D low-income subsidies and assigned to a PDP. FR 4420. These individuals will be given the option to disenroll. This process is intended to ensure that "there will be no breaks in coverage between Medicaid and the implementation of Medicare Part D in January 2006 for this population." *Id*.

Treatment of Territories

No significant changes were made to § 423.907.

State Contribution Requirements

The start date and ongoing due dates for the phased-down State contribution payments are set forth at § 423.910(b)(2); FR 4584-85. Payments must begin in January 2006, and will be required monthly thereafter. The method of State payment is also clarified in § 423.910(b)(2). CMS explained that it "is our intent ... to mirror the payment process for the [Parts A and B premium] buy-in process .... This process includes funds transfers, with a provision that any late payments will be offset against the Medicaid grant with appropriate interest accrual. In this case, the Medicaid offset would be transferred to the Medicare Prescription Drug Account to complete the transaction." FR 4424.

Title I, Subpart T – Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

Dan Swanson

Definition of Outpatient Prescription Drugs for Purposes of Physician Self-Referral

Proposed § 411.351 suggested amending the definition of "outpatient prescription drugs" in the physician self-referral statute in order to include the additional outpatient drugs covered under the new Medicare Part D benefit. The purpose of this amendment was to make the self-referral prohibition apply to physician referrals for outpatient prescription drugs. This proposed rule was finalized without change. FR 4424.

Cost-Based HMOs and CMPs Offering Part D Coverage

Final § 417.440(b) was amended to specify that a cost-based HMO or competitive medical plan (CMP) may offer qualified prescription drug coverage under Part D, and that the enrollee is entitled to benefits under Part D. FR 4425.

The final rule provides that cost-based HMOs and CMPs may offer qualified prescription drug coverage to Part D eligible enrollees only as an optional supplement benefit rather than as a basic benefit. This amendment of the proposed rule is in keeping with CMS's reading of § 1876(c)(2)(A)(ii)(I) of the Act which provides that cost-based HMOs and CMPs may only offer non-Part A/B Medicare benefits as optional supplemental benefits. The proposed rule was also changed to amend § 417.440(b)(2) by adding subpart (iii), which provides that the HMO/CMP may not set health status standards for those enrollees whom it accepts for those optional supplemental services. FR 4424-25.

Also, the proposed rule suggested adding a new § 417.534(c), specifying to the extent that a cost HMO or CMP chooses to participate in the Part D program by offering qualified prescription drug coverage to its members, any costs associated with the offering of Part D benefits may not be claimed on its Medicare cost report. This provision was finalized as proposed. FR 4425.

PACE Organizations Offering Part D Coverage

CMS is of the view that Congress did not intend for the MMA to alter the way in which PACE services, including outpatient prescription drugs, are currently being provided. Therefore, CMS proposed § 423.458(d), which waived any provision of this part as applied to a PACE Organization that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to PACE organizations under Sections 1894 and 1934 of the Act or as may be necessary in order to improve coordination of this Part with the benefits offered by PACE organizations. *See* 69 FR 46832. CMS also proposed waiving the applicability of numerous provisions to PACE, and requested comments regarding the appropriateness of these waivers.

The final rule adopted § 423.458(d) as proposed, FR 4452, but CMS announced in the final rule that CMS has only chosen to finalize their proposed waiver for PACE organizations of § 423.265(b), which would have required PACE organizations planning to offer Part D prescription drug plans to submit bids and supplemental information no later than the first Monday in June of each year. *See* 70 FR 4427. CMS stated that it will issue further guidance at a later date that will list additional Part D provisions that CMS will waive for PACE organizations. FR 4427. In issuing such guidance, CMS will take into consideration all of the comments it received regarding waivers. *See* discussion of PACE organizations in final rule at FR 4426-434.

Definition of Medicare Supplemental Policy and Model Disclosure Notices

Section 1882(v) of the Act required CMS to establish standards for the disclosure notice that Medigap issuers must provide to policyholders of Medigap RX policies. In draft § 403.205(c), CMS proposed a model disclosure notice with basic language that would be required to be included in all such disclosure notices sent by Medigap issuers for policies that do not provide creditable coverage. CMS received numerous comments on the proposed model disclosure notice. However, because CMS determined that the format and comment of the notice could be improved based on information gathered through consumer testing, CMS now plans to publish the final disclosure notice separately from the final rule. CMS also plans to publish separately a model disclosure notice for policies that do provide creditable coverage. FR 4434.

The draft regulation also proposed revising the definition of a Medigap (*i.e.*, Medicare Supplemental) policy at § 403.205(c) to clarify several things: (1) that a rider to a Medigap policy is not a separate insurance product, but rather is incorporated into, and becomes an integral part of, the policy; and (2) that stand-alone, limited benefit drug policies will be considered Medigap policies once the Part D drug benefit is implemented, but only if the coverage provided by the policy is primarily designed to supplement Medicare, or if the policy is primarily marketed and sold to Medicare beneficiaries. FR 4435-436. The final rule adopted the proposed rule's revised definition. FR 4525; *see* discussion at FR 4436.