



## Medicare Prescription Drug Benefit

### CMS' Proposed Rule to Implement the Prescription Drug Benefit

On August 3, 2004, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule to implement the new Medicare prescription drug benefit. The drug benefit was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The MMA dramatically changes the Medicare program by creating a temporary discount card program, revising the reimbursement system for durable medical equipment and Medicare Part B drugs, altering payments to physicians, hospitals, and skilled nursing facilities, and most significantly, by adding a prescription drug benefit.

The proposed rule implements only the section of the MMA that creates a prescription drug benefit for Medicare beneficiaries. Regulations to implement other sections of the Medicare law will be released separately.

The prescription drug benefit is obviously important because it increases access – especially for low-income beneficiaries – to affordable medications. The benefit is also important because of the changes it will bring to pharmacy practice – including payment for pharmacists to provide medication therapy management services (MTMS).

Following is a summary outlining the key components of the proposed rule.  
*This document is a work in progress and is subject to change.*

Please note that the regulation is not finalized. CMS is soliciting comments on the proposed regulation. Comments must be submitted by **October 4, 2004**. CMS will review the comments and then issue a final rule. Pharmacists and student pharmacists are strongly encouraged to submit comments to CMS. Comments may be submitted electronically at <http://www.cms.hhs.gov/regulations/ecomments>; or via mail to:

Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
Attention: CMS-4068-P  
Baltimore, MD 21244-8014

All comments must reference “CMS-4068-P”.

A copy of the rule is available on the CMS website at [www.cms.gov/medicarereform](http://www.cms.gov/medicarereform).

## Medicare Prescription Drug Benefit

### GENERAL OVERVIEW

#### **Medicare Part D**

The existing Medicare program consists of Part A (hospital insurance), Part B (medical insurance), and Part C (Medicare managed care plans). The MMA adds Part D – a prescription drug benefit – to the Medicare program. Part D is an optional benefit generally available to beneficiaries for an additional cost.

#### **Enrollment**

Prescription drug coverage will be available through private prescription drug plans (PDPs), which will offer only prescription drug coverage, and Medicare Advantage prescription drug plans (MA-PDs), which will offer drug coverage that is integrated with the health coverage provided by the managed care plan.

Medicare beneficiaries who are enrolled in a Medicare Advantage plan that offers qualified prescription drug coverage must obtain their Part D coverage through the MA-PD. Medicare beneficiaries who are not enrolled in a Medicare Advantage plan, or are enrolled in a Medicare Advantage plan that does not provide qualified drug coverage, may select and enroll in a PDP.

Beneficiaries will have at least two prescription drug plans to choose from – at least one of which must be a PDP. Plan sponsors must provide beneficiaries with a plan description that they can use to compare and select a prescription drug plan. The plan description, as well as all marketing materials, must be approved by CMS in advance.

CMS is considering publishing negotiated drug prices offered by PDP and MA-PD plans on the CMS Medicare website. This would allow beneficiaries, similar to with the Medicare-approved prescription drug discount card program; to compare negotiated drug prices when selecting a plan.

Beneficiaries can begin enrolling in a prescription drug plan on November 15, 2005. Beneficiaries that do not enroll in a Part D plan during their initial enrollment period, or within 63 days of losing another form of drug coverage, must pay a late enrollment fee.

#### **Full Benefit Dual Eligibles**

The rule contains special enrollment requirements for Full Benefit Dual Eligibles. Full Benefit Dual Eligibles are Medicare beneficiaries who are also eligible for full benefits under their State Medicaid program.

Full Benefit Dual Eligibles that fail to enroll in a PDP or MA-PD during their initial enrollment period or during a special enrollment period, will be automatically enrolled into a PDP plan. Or, if the beneficiary is currently enrolled in a MA plan without qualified

prescription coverage, the beneficiary will be enrolled into a MA-PD plan offered by the same Medicare Advantage organization.

### **Coverage**

PDP and MA-PD plans are required to provide at least “standard prescription drug coverage.” Standard prescription drug coverage consists of prescription drug coverage subject to:

- An annual deductible of \$250 (in 2006)
- 25% coinsurance
- Initial coverage limit of \$2,250 (in 2006)
- Catastrophic coverage after \$3,600 in out-of-pocket expenses (under catastrophic coverage a beneficiary pays the greater of 5% coinsurance or a copayment of \$2 for a generic drug or a preferred multiple source drug and \$5 for any other drug)

Plans can offer enhanced coverage beyond the standard prescription drug coverage. Plan sponsors may only offer enhanced coverage if the sponsor also offers another plan that provides basic prescription drug coverage in the same service area.

### **Covered Drugs**

Part D Covered Drugs include prescription drugs, biological products, certain vaccines, insulin, and medical supplies associated with the injection of insulin (syringes, needles, alcohol swabs, and gauze).

Part D will not cover drugs used for:

- Anorexia, weight loss, or weight gain
- Fertility promotion
- Hair growth
- Symptomatic relief of cough and colds
- Prescription vitamins and mineral products (except prenatal vitamins and fluoride preparation)
- Nonprescription drugs
- Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale
- Barbiturates
- Benzodiazepines
- Any drug covered by Medicare Part A or B

### **Negotiated Prices**

PDPs and MA-PDs must offer beneficiaries negotiated prices on covered Part D drugs. Negotiated prices have to take into account discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, and include any applicable dispensing fees. Plans must disclose to CMS all aggregate negotiated price concessions they obtain from manufacturers and pass through to the Medicare program in the form of lower subsidies, or to beneficiaries as lower monthly premiums or lower drug prices.

## PHARMACY SPECIFIC ISSUES

### **Dispensing Fee**

CMS does not set an amount or propose a specific definition for a pharmacy “dispensing fee”. Instead the proposed rule offers three options for the definition.

- Option 1: The dispensing fee would only include activities related to the transfer of the possession of the drug from the pharmacy to the beneficiary including charges associated with mixing drugs, delivery, and overhead. The dispensing fee would not include any activities beyond the point of sale.
- Option 2: The dispensing fee would include activities in option 1, and amounts for any supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered. (Limited to home infusion therapy).
- Option 3: The dispensing fee would include activities in option 2, and activities associated with ensuring proper ongoing administration of the drugs such as professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist. (Limited to home infusion therapy).

#### *CMS Questions for Pharmacy*

*CMS prefers option 1. It limits the dispensing fee to the transfer of the product, not fees associated with administering the drug. CMS is concerned that including any fees for administration or services such as quality assurance or MTMS might result in beneficiaries being billed twice for those services if they have already been included in the cost of the premium. CMS seeks comment on the appropriate definition.*

### **Pharmacy Access Standards**

PDPs and MA-PDs are required to secure the participation of a sufficient number of pharmacies (not including mail order) in their pharmacy networks to ensure convenient beneficiary access. Plan sponsors must meet the Department of Defense TRICARE Retail Pharmacy access standards:

- Urban Areas: At least 90% of beneficiaries in the plan’s service area, on average, live within 2 miles of a participating retail pharmacy.
- Suburban Areas: At least 90% of beneficiaries in the plan’s service area, on average, live within 5 miles of a participating retail pharmacy.
- Rural Areas: At least 70% of beneficiaries in the plan’s service area, on average, live within 15 miles of a participating retail pharmacy.

The plan sponsor must meet the TRICARE standards across the region in which it operates. If a sponsor operates in multiple regions, it must meet the standard within each region.

Plan sponsors are encouraged to secure participation of non-retail pharmacies in their pharmacy network such as hospital pharmacies, clinic pharmacies, mail order, etc. However, only retail pharmacies can be counted toward the pharmacy access

requirements. Plans can also contract with pharmacies outside their service area, but they do not count toward meeting the pharmacy access standard.

MA-PD plan sponsors may obtain a waiver for the pharmacy access standards, if they provide access through pharmacies owned and operated by the managed care organization that provide comparable access to the plan's beneficiaries.

*CMS Questions for Pharmacy*

*CMS seeks comments on "permissible ways" to assure beneficiaries' access to federally qualified health centers (FQHCs) and rural pharmacies.*

**Any Willing Provider**

PDP and MA-PD plan sponsors are required to permit any pharmacy willing to accept the plan's terms and conditions to participate in the plan's pharmacy network.

Under the proposed rule, plans are not required to offer a uniform contract to each pharmacy within the plan's pharmacy network. Plans can modify their contract terms.

Plans may also make distinctions between pharmacies in their network. Plans may designate "preferred" and "non-preferred" pharmacies. The plan could reduce a beneficiary's cost-sharing at preferred pharmacies. CMS is aware that allowing plans to make this distinction could result in plans using non-preferred pharmacies to discourage certain beneficiaries (such as those in rural areas) from enrolling in the plan. CMS will examine the plan's design as part of the bid review process to "preclude the approval of bids submitted by plans that attempt to use strategies such as that outlined above to limit enrollment in portions of their service areas that are more difficult or costly to serve."

*CMS Questions for Pharmacy*

*CMS seeks comments on whether, in order to guarantee that any pharmacy willing to meet a PDP's or MA-PD's contracting terms could participate in the plan's pharmacy network, it should require plan sponsors to make available to all pharmacies a standard contract for participation in the plan's pharmacy network. If CMS were to require a standard contract be made available, it would not forbid plans from negotiating different terms and conditions with a subset of pharmacies.*

**Level Playing Field**

Under the MMA, plans must allow beneficiaries to obtain their benefits at a network community pharmacy instead of a mail order pharmacy, if they so choose. The benefits could include an extended supply of medications (such as a 90-day supply) which is typically available only through a mail order pharmacy. However, under the rule, plans can charge more when beneficiaries obtain an extended supply of medications at a retail pharmacy instead of a mail order pharmacy. Beneficiaries are responsible for any

difference between the network retail pharmacy's and the network mail order pharmacy's negotiated price for that drug.

### **Formulary Requirements**

PDP and MD-PD plans are allowed to use a drug formulary. Plans must use a pharmaceutical and therapeutic (P&T) committee to develop and review the formulary. The majority of the P&T committee must be comprised of practicing physicians and/or pharmacists. In addition, at least one practicing pharmacist and one practicing physician member have to be experts in the care of elderly and disabled individuals. At least one pharmacist and one physician member must also be independent and free of conflict of interest with respect to the sponsor, plan, and pharmaceutical manufacturers.

The U.S. Pharmacopeia (USP) has been asked to develop a model set of guidelines that consist of a list of drug categories and classes that plan sponsors may use to develop their formularies. The USP model guidelines will simply serve as guidelines; plan sponsors will have the flexibility to develop their own classification schemes.

In general, formularies are required to include at least two drugs within each therapeutic category and class of covered Part D drugs. The drugs included in each therapeutic class or category must include a variety of strengths and doses.

Plans may develop a formulary using strategies to minimize costs for beneficiaries and the Medicare program. These strategies could include financial incentives to encourage use of generics, tiered cost-sharing and other mechanisms that create strong incentives for manufacturers to negotiate favorable prices for covered Part D drugs, prior authorization procedures, therapeutic interchange, step therapy, and use of mail order.

If a plan uses a tiered cost-sharing structure, the plan must establish an exceptions process. Under the exceptions process, a nonpreferred drug could be covered as if it were a preferred drug if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual.

When a plan removes a drug from its formulary or makes any change in the preferred or tiered cost-sharing status of a drug, the plan must provide CMS, affected enrollees, authorized prescribers, pharmacists, and pharmacies at least 30 days notice prior to the change taking effect.

### **Inform Beneficiaries About Generics**

Plans must ensure that pharmacies inform beneficiaries of any price differential between a covered Part D drug and the lowest priced generic version of that drug that is available under the plan at the pharmacy. Pharmacists must provide this information at the time the beneficiary purchases the drug, or in the case of drugs purchased from mail order pharmacies, at the time of delivery.

## USE OF STANDARDIZED TECHNOLOGY

### **Standard ID Card**

Plan sponsors must issue beneficiaries a standard identification card. CMS intends to base the card standards on the National Council for Prescription Drug Program's (NCPDP) Pharmacy ID Card Standard.

### **Electronic Prescribing Program**

Plan sponsors must have the capacity to support and must comply with electronic prescribing standards relating to covered drugs, for eligible individuals, developed by CMS, once final standards are effective. Final electronic prescribing standards must be published by April 1, 2008. There is no requirement that prescriptions be transmitted electronically; however, plans must be able to support e-prescribing by prescribers who choose to use it.

E-prescribing will not be limited to a physician sending a prescription to a pharmacy. E-prescribing is also intended to ensure that pharmacies receive electronic information on the drugs included in the plan's formulary, any tiering of the formulary, the patient's medical history, the possibility of adverse drug interactions, and the availability of lower-priced, alternative prescriptions.

#### *CMS Questions for Pharmacy*

*CMS solicits comments on additional steps to spur adoption of electronic prescribing, overcome implementation challenges, and improve Medicare operations. For example, the MMA allows MA-PD sponsors to provide payment to a participating physician who prescribes drugs in accordance with the electronic prescription standards. CMS also solicits comments on how to promote the use of electronic prescribing by providers, health plans and pharmacies, and other entities involved in the provision and payment of health care to Medicare beneficiaries. What incentives could be used to spur more widespread adoption?*

## COST CONTROL AND QUALITY IMPROVEMENT

PDP and MA-PD sponsors are required to establish a cost-effective drug utilization program, a quality assurance program, a medication therapy management program (MTMP), and a program to control fraud, abuse, and waste. (Private fee-for-service MA plans that offer prescription drug coverage will be exempt from the requirement to establish a drug utilization management program and a medication therapy management program. These plans would be required to establish a quality assurance program and a program to control fraud, abuse, and waste.)

### **Cost-Effective Drug Utilization Management**

The program would include incentives to reduce costs when medically appropriate, such as the use of different dispensing fees to encourage the use of multiple source drugs, prior authorization, step therapy, tiered cost-sharing, and other utilization tools.

PDP sponsors and MA Organizations must inform enrollees of program requirements and procedures in order to prevent unintended interruption in drug therapy (such as procedures to refill a prescription if special circumstances require an early refill).

#### *CMS Questions for Pharmacy*

*CMS solicits comments on whether there are industry standards for cost effective drug utilization management and whether CMS should adopt any of these standards for PDPs and MA-PDs.*

*CMS is also considering adding a requirement to the final rule that these tools should be under the direction of a P&T Committee to ensure the appropriate balance between clinical efficacy and cost effectiveness. CMS is also considering requiring the direct involvement of the P&T Committee with other areas of quality assurance and medication therapy management. CMS seeks comments on these areas.*

### **Quality Assurance**

PDP sponsors and MA organizations must have a quality assurance (QA) plan that includes measures and systems to 1) reduce medication errors, 2) reduce adverse drug interactions, and 3) improve medication use. QA programs must include requirements for DUR, patient counseling, and patient information record keeping. Plan sponsors will also be required to have systems and measures established to ensure that network pharmacy providers are complying with their QA requirements.

Desirable elements for QA systems include:

- Electronic prescribing
- Clinical decision support systems
- Educational interventions (which could be provided by QIOs or rely on other mechanisms)
- Bar codes
- Adverse event reporting systems
- Provider and patient education

In the future, CMS may require quality reporting that includes error rates. This information could be used by CMS and beneficiaries to evaluate plans.

#### *CMS Questions for Pharmacy*

*CMS solicits comments on how it can evaluate plans based on the types of QA measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could best be provided to beneficiaries to assist them in making their choice among plans.*

### **Medication Therapy Management Program**

PDPs and MA-PDs must establish a medication therapy management program (MTMP). The purpose of the MTMP is to provide services that will optimize therapeutic outcomes for targeted beneficiaries. Specific services to be provided under a MTMP would be distinct from those required for dispensing medication. MTM services (MTMS) would be reimbursable when adopted by a plan and only when provided to targeted beneficiaries.

#### **Targeted Beneficiaries**

Targeted beneficiaries include individuals with multiple chronic diseases, who are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level. CMS has the authority to set the level of annual costs that must be incurred by a beneficiary to qualify for MTMS; however, CMS prefers to delegate the determination of “high annual costs” to the drug plan sponsor.

#### **MTMP Services**

MTMPs may include elements designed to promote:

- Enhanced enrollee understanding – through beneficiary education counseling, and other means – that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with medications
- Increased enrollee adherence to prescription medication regimens (for example through refill reminders, special packaging, and other compliance programs and other appropriate means)
- Detection of adverse events and patterns of overuse and underuse of prescription drugs

In addition to those services mentioned in the MMA, services could include, but not be limited to:

- Performing patient health status assessments
- Formulating prescription drug treatment plans
- Managing high cost “specialty” medications
- Evaluating and monitoring patient response to drug therapy
- Providing education and training
- Coordinating medication therapy with other care management services
- Participating in State-approved collaborative drug therapy management

These services could be offered as components of more coordinated disease management program, but CMS does not expect provision of these services to be limited to such programs.

CMS envisions MTMPs potentially spanning a range of services, from simple to complex. In addition to MTMPs providing for different types of services, CMS also anticipates the need for different levels of service based on the individual requirements of the targeted beneficiaries. “For example, one beneficiary may require only a 15 minute phone consultation, while another would be better served by a one-hour in-

person visit with the pharmacist.” The level of service should be determined by time and resources required to accommodate the specific needs of the individual beneficiary. MTMPs would include policies and procedures for ensuring targeted beneficiary access to the appropriate types and levels of service offered by the particular PDP or MA-PD plan.

Within this broad framework, CMS believes plan sponsors can customize their MTMPs and that a competitive market supported by useful information on MTMP services will provide the best mechanism for establishing optimal MTMPs. CMS may require plans to demonstrate the types of services, levels of service, and quality outcomes associated with their MTMPs to further aid beneficiaries with choosing the plan that will best meet their needs.

A MTMP, as adopted by a plan, would have to be developed in cooperation with licensed practicing pharmacists and physicians.

CMS considers MTMPs to be administrative activities similar to QA, DUR, or fraud, abuse and waste control measures. Therefore, MTMP services would not involve direct beneficiary cost-sharing and Part D enrollees would not be required to pay separate fees for these services, although the cost could be reflected in the premium rate. The cost of a MTMP is considered an administrative cost incident to appropriate drug therapy and therefore, not an additional benefit.

CMS plans to conduct more research and seek comments before establishing requirements for MTMPs.

#### MTMS Providers

CMS believes that pharmacists will be the primary providers of MTMS; however, MTMPs could also include other qualified health care professionals as providers of services. The individual needs of the targeted beneficiary should determine the appropriate provider and setting for MTMP services. For example, consultant pharmacists will likely provide services to beneficiaries in long-term care facilities; retail pharmacists could provide those same services to ambulatory beneficiaries.

CMS believes that “beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the best provider for MTMP services... While population based QA and cost control measures might adequately be served by impersonal telephone services, CMS believes that telephone services are only one mode of providing MTMS. Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships.”

#### MTMS Fees

In establishing fees for pharmacists and others providing MTMP services, the plan must take into account the resources and time associated with implementing the MTMP. Plans must describe, as part of their application, their plan to consider the resources used and the time required to implement MTMP in establishing fees. Plans must, upon

request, disclose to CMS the management and dispensing fees and the portion paid for MTMS services to pharmacists and other providers. If CMS receives complaints that a plan is not paying pharmacists or others in accordance with the fees discussed in the application, CMS will investigate.

CMS does not set a certain amount plans must pay pharmacists or other providers to provide MTMP services. CMS does not believe it has the authority to do so. CMS does state that it believes that MTMS fees are separate and distinct from dispensing fees.

While the MMA states that PDP sponsors must disclose to the Secretary the amount of “any such management or dispensing fees”, it merely governs disclosure and does not require that MTMP be included in the dispensing fee (and the Act distinguishes management fees from dispensing fees that are part of individual prescriptions). Therefore, CMS includes the costs associated with MTMPs, including these management fees, as part of the general administrative overhead costs in the plan bid. For purposes of evaluating the administrative component of a PDP’s bid, CMS will ask a plan sponsor to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services. CMS would be prohibited from disclosing the specific fees in a manner that links the fees to the particular pharmacy or other provider, except in certain cases.

#### *CMS Questions for Pharmacy*

*CMS acknowledges that it does not have extensive experience requiring reimbursement for MTMPs. CMS solicits comments on what requirements and/or guidelines for MTMPs should be included in the regulation.*

*CMS is interested in current MTMP best practices, essential components of MTMPs, and which QA requirements, if any, should be included in MTMPs. Also, what measures and information on effective MTMP services that could be publicized and used by beneficiaries who wish to use these services? What are the most effective steps to make valuable, proven MTMP services available to beneficiaries to improve health care quality and reduce costs?*

*With regard to “targeted beneficiaries” CMS seeks comments on how to define “multiple chronic diseases” and “multiple covered Part D drugs” for the purpose of determining which enrollees will qualify for MTMS, or whether such determinations are best left to the plans as part of their benefit design. CMS also requests comments on its proposal to allow plans to determine the level of annual costs a beneficiary must meet before qualifying for MTMS. CMS seeks comments on what guidance its can provide to plans to ensure these services are targeted in the most efficient manner and to the most appropriate beneficiaries.*

*CMS solicits comments on how MTMP services provided through the new Chronic Care Improvement Program can be effectively coordinated with MTMP services provided by PDPs. The CCIP is only available to beneficiaries with multiple chronic conditions that are in the original fee-for-service Medicare program. CMS is concerned with these beneficiaries receiving duplicative services.*

### **Fraud, Abuse, and Waste**

Plans must provide a program to control fraud, abuse, and waste. Fraud, abuse, and waste control efforts should apply not only to the plans, but also to the PBMs, pharmacies, physicians, and others the plan deals with. Plan can develop and utilize methods such as data analysis, record audit of PBMS, pharmacies, physicians, and other providers, DUR, and methods to consider and resolve disputes related to pharmacies', physicians', and other providers' dissatisfaction to ensure the integrity of all entities.

CMS is concerned with the inappropriate switching of prescriptions by a plan without consulting a prescribing physician. While switching from brand to generic may be appropriate, switching from one brand to another, may not be without consultation.

### **Quality Improvement Organization Activities**

Under the MMA, Quality Improvement Organizations (QIO) are required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. CMS will issue guidance on how QIOs can provide this assistance and will coordinate the activities of the QIOs with the quality related activities of other parties.

To fulfill this responsibility, QIOs will need access to data from the transactions between pharmacies and PDP and MA-PD plans. The data would be extracted from the claims data submitted to CMS. CMS anticipates aggregating the data and then distributing it to QIOs to fulfill their requirements for quality improvement as specified in their contracts and in response to requests. Any information collected by QIOs would fall under confidentiality provisions.

### **Accreditation**

A plan may be deemed to meet the requirements that relate to access to covered Part D drugs, quality assurance, DUR, MTM, and a program to control fraud, abuse, and waster; and confidentiality and accuracy of enrollee records, if it is accredited and periodically reaccredited by a private national accrediting organization. The accrediting organization must use a process and standards that meet CMS requirements.

## **BID SUBMISSION**

To provide a Part D benefit, PDP and MA-PD plans must submit a bid to CMS for each plan it intends to offer. Bids are due no later than the first Monday in June for each plan to be offered in the subsequent calendar year.

**Bid Content**

The bid must contain at a minimum:

- Information about the prescription drug coverage (structure of the benefit, deductibles, coinsurance, coverage limits at which coinsurance changes, out-of-pocket thresholds, the plan's formulary, and any documents that will be provided to beneficiaries)
- The actuarial value of the coverage
- The portion of the bid attributable to basic benefits
- The portion of the bid attributable to supplemental benefits, if applicable
- The actuarial basis for the portion of the bid attributable to basic coverage and to supplemental benefits
- The assumptions regarding reinsurance subsidy payments
- The assumptions regarding administrative expenses
- The plan's service area and the plan's network of pharmacies serving that area
- For PDP sponsors, the level of risk assumed in the bid

CMS will provide more detailed information about the bidding process in a separate document.

CMS will review the bids and may negotiate with applicants on administrative costs, aggregate costs, benefit structure, and plan management if CMS is dissatisfied with some or all of the bid submissions.

**Private Sector Price Negotiation**

CMS anticipates that most price negotiations including discounts, rebates, or other direct or indirect subsidies or remunerations would take place between plan sponsors and pharmacies and pharmaceutical manufacturers. According to the rule, CMS cannot interfere with negotiations between pharmaceutical manufacturers and pharmacies or PDP sponsors, or require a particular formulary or pricing structure.

CMS expects negotiations will not only include price levels for drugs, but also prohibitions on substitutions of drugs if the net result would be higher costs for patients or the plans.

CMS believes that private negotiations between sponsors and drug manufacturers will achieve comparable or better savings than direct negotiations between the government and manufacturers.

**Monthly Beneficiary Premium**

Beneficiaries may pay their monthly beneficiary premium by having the amount withheld from his/her social security check or by paying the premium directly to the plan sponsor through an electronic funds transfer.

## COMPLIANCE WITH STATE LAW

In general, the standards established by the MMA and the implementing regulations supersede any State law. With the exceptions of State licensing laws and State laws related to plan solvency, State laws do not apply to prescription drug plans and PDP sponsors.

## COORDINATION WITH OTHER PRESCRIPTION DRUG COVERAGE

A PDP and MA-PD must permit State Pharmaceutical Assistance Programs (SPAPs) and other drug plans (Medicaid, group health plans, FEHBP, military coverage) to coordinate plans. PDP and MA-PD plans may impose fees related to the cost of coordination with SPAPs and other drug plans. CMS may impose user fees for the transmittal of information necessary for benefit coordination related to third party reimbursement (other than by a SPAP) of Part D enrollees' costs for covered Part D drugs.

### **State Pharmaceutical Assistance Program**

For purposes of this regulation, a SPAP is a state program that:

- Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of a Part D eligible individual
- Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls
- Meets the benefit coordination requirements specified in this part
- Does not change or affect the primary status of a Part D plan

SPAPs do not include programs such as Medicaid, Section 1115 Demonstration programs, or other programs that are mainly funded by the Federal government.

SPAPs are not required to coordinate or provide any financial assistance with respect to a Part D plan. SPAPs that choose to coordinate with a Part D plan can pay beneficiary premiums for Part D coverage, provide a lump sum per capita payment for enrollee coverage through Part D plans, coordinate on a claim-specific basis when a Part D plan pays first and the SPAP is the secondary payor, etc. (Payments for beneficiary cost-sharing made by SPAPs may be counted toward a beneficiary's total out-of-pocket costs.)

SPAPs and Part D plans that coordinate benefits may have a single card that beneficiaries can use to access both Part D and SPAP benefits. The cards may contain a symbol or logo indicating that a connection between the two programs exists.

### **PACE Plans**

The Program of All Inclusive Care for the Elderly (PACE) is a managed care benefit for the frail elderly provided by a not-for-profit or public entity that features a comprehensive medical and social service delivery system. A PACE program may elect to provide Part D prescription drug coverage to its Part D eligible beneficiaries. The payor for PACE enrollees would shift from Medicaid to Medicare for full benefit dual eligibles and in part from the beneficiary to Medicare for partial benefit dual eligibles who elect to enroll in Part D.

Because of the unique operation of PACE programs, CMS believes that PACE programs would be unable to provide a Part D benefit and meet all the requirements in this regulation. CMS is considering a special rule for PACE organizations that would automatically allow them to waive several of the program requirements.

### **Employer Retiree Coverage**

Employers that offer retirees a prescription drug benefit that is at least actuarially equivalent to the standard prescription drug coverage under Part D are eligible for a special Federal subsidy for each individual enrolled in the employer's retiree health coverage who is eligible for Part D but elects not to enroll in Part D. The subsidy is intended to discourage employers from dropping retiree drug coverage programs.

### **Coordination of Benefits**

#### *Coordination of Benefits System*

CMS must establish procedures and requirements to ensure effective coordination by July 1, 2005. The system must allow enrollment file sharing, claims processing and payment, tracking of out-of-pocket expenses, and other processes CMS identifies.

CMS envisions a system of information sharing between Medicare, Part D plans, SPAPs, group health plans, insurers, and other third-party arrangements. CMS' goal is that the design and implementation of the coordination of benefits system will enable pharmacies to obtain information about secondary insurers as well as the correct billing order. Ideally CMS anticipates that pharmacists would query the system and be provided with information they can use to bill all the insurers involved in the correct order as well as calculating the correct beneficiary copayment at the point of service. CMS acknowledges that coordinating insurance coverage at the point of sale is a technical communications challenge.

#### *Coordination of Part B Products*

CMS wants to ensure that beneficiaries with Medicare Parts A and B do not lose Medicare coverage otherwise available to them due to difficulties in the coordination of benefits process. For example, pharmacy-dispensed drugs covered by Part B (DME drugs, immunosuppressive drugs, and oral anti-cancer drugs) are not reimbursed unless the pharmacy has a Medicare supplier number; therefore a beneficiary could lose Part B coverage by filling a prescription at the wrong pharmacy. To reduce this risk, CMS is proposing to:

- Encourage Part D plans to enroll pharmacies with Medicare supplier numbers in their networks.
- Encourage Part D plans to inform beneficiaries whether their network pharmacies have a Medicare supplier number, and explain why this is important when filling prescriptions for drugs potentially covered by Part B.
- Develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collected from beneficiaries enrolled in Part B for Part B drugs unless they first notify the beneficiary that Medicare will likely deny the claim.

For drugs potentially covered by Part B that are dispensed by a pharmacy that is a Medicare supplier, CMS is considering the development of a system that would require the pharmacy to submit the claim to the appropriate Part B carrier. If the carrier denies the claim, the carrier must automatically submit the claim to the PDP through which the beneficiary has Part D coverage.

#### *CMS Questions for Pharmacy*

*CMS solicits comments on whether a drug denied Part B coverage because the supplier does not have a Medicare supplier number should become a covered Part D drug with the claim processed under Part D. CMS would like comments on the likelihood of this occurrence and on alternative means of addressing such circumstances.*

*CMS also seeks comments on whether a drug denied Part B coverage for any other reason should become a covered Part D drug.*

## LOW INCOME BENEFICIARIES & THE STATE'S ROLE

### **Premium and Cost-Sharing Subsidies**

The MMA establishes a program to provide subsidies for assistance with premium and cost-sharing amounts for beneficiaries with low income and resources. Depending upon income level and resources, beneficiaries may qualify as full subsidy eligible individuals or other low income subsidy individuals.

Full subsidy eligible individuals must:

- Live in one of the 50 states or Washington, DC
- Have countable income below 135% of the federal poverty level
- Have resources that do not exceed three times the resources limit for Supplemental Security Income (For 2006, \$6,000 if single, \$9,000 if married)

Individuals that are eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State plan are also treated as full subsidy eligible individuals.

Other low income subsidy individuals must:

- Live in one of the 50 states or Washington, DC
- Have countable income below 150% of the federal poverty level
- Have resources that do not exceed \$10,000 if single, \$20,000 if married in 2006

Full subsidy eligible individuals are entitled to:

- A premium subsidy equal to 100% of the “premium subsidy amount” which is equal to the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in the beneficiary’s region
- An additional premium subject to 80% of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100% of the penalty thereafter (Only applies to full subsidy eligible individuals who are subject to the late enrollment penalty)
- Elimination of the annual deductible
- Reduction in coinsurance for all covered Part D drugs
- Elimination of all co-payments for covered Part D drugs once the out-of-pocket limit has been reached

Other low income subsidy individuals are entitled to:

- A premium subsidy based on a sliding scale ranging from 100% for individuals with incomes below 135% of the federal poverty level to 0% for individuals with incomes at 150% of the federal poverty level
- A reduction in the annual deductible from \$250 to \$50 in 2006
- 15% coinsurance for all covered Part D drugs after the initial coverage limit has been passed (\$2,250 in 2006), up to the out-of-pocket limit (\$3,600 in 2006)
- Reduction in co-payments for all covered Part D drugs once the out-of-pocket limit has been reached

CMS will establish a process to inform plan sponsors that an individual is eligible for a subsidy.

Under the proposed rule, States would be required to make the initial eligibility determinations for premium and cost sharing subsidies. The determinations would be based on applications filed with the States. States would be required to begin accepting application forms for the low-income subsidy no later than July 1, 2005. States would also be required to provide CMS with information such as income levels for partial subsidy eligible individuals. This information would allow plans to determine the amount of the sliding scale premium subsidy these individuals would receive. States could receive the regular Federal match for administrative costs in determining subsidy eligibility.

### **State Contributions to Drug Benefit Costs Assumed by Medicare**

Under the MMA, the Medicare program will subsidize prescription drug costs for dual eligibles – those individuals that are eligible for both the Federal Medicare program and the State-based Medicaid program. However, States will be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a

portion of the Medicare drug expenditures for these individuals. The payments would be made in a manner similar to the mechanism through which States pay Medicare Part B premiums on behalf of low-income individuals who are eligible for both Medicare and Medicaid, except that those payments will be deposited into the Medicare Prescription Drug Account.

The amount each State must pay is determined by a multi-step calculation process. (See Sections 423.908 through 423.910 of the rule for specifics). The contribution is the product of the projected monthly per capita drug payment, the total number of full benefit dual eligible individuals for the State in the applicable month, and the applicable ten year phased down factor for the year. (See Table below)

Failure by a State to pay the State contribution amounts would result in interest accruing on those payments. CMS would immediately offset unpaid amounts and accrued interest against Federal Medicaid matching payments due to the State.

States would only make contributions on behalf of Medicare beneficiaries who would otherwise be eligible for outpatient prescription drug benefits under Medicaid.

CMS must notify States by October 15<sup>th</sup> each year of the projected monthly per capita drug payment calculation for the next calendar year.

#### Annual Phased-Down Percentage of State Contributions to Medicare Part D Benefit

Year	State Percentage	Year	State Percentage
2006	90	2011	81 2/3
2007	88 1/3	2012	80
2008	86 2/3	2013	78 1/3
2009	85	2014	76 1/3
2010	83 1/3	2015 and beyond	75

## PHYSICIAN SELF-REFERRAL PROHIBITION

### Physician Self-Referral Prohibition

CMS proposes to amend the physician self-referral rule (also known as the Stark law) to include outpatient prescription drugs covered under the Part D benefit. CMS believes that referrals for Part D drugs are subject to the same risk of overutilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs.

#### *CMS Questions for Pharmacy*

*CMS solicits comments on the addition of "outpatient prescription drugs" to the Physician Self-Referral Rule.*

## IMPACT ANALYSIS

CMS is required to examine the impact of this proposed rule including its costs and benefits – particularly the impact on small entities such as small pharmacies.

### **Enrollment Estimates**

CMS estimates that in 2006, 41 million beneficiaries will receive prescription drug coverage through a Part D plan or an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. By 2010, CMS estimates 45 million beneficiaries will be receiving such coverage.

CMS estimates that 10.9 million beneficiaries will enroll in the Medicare Part D low-income subsidy program in 2006.

CMS believes that the creation of the Part D benefit will help beneficiaries by enhancing the Medicare benefit package, increasing access to subsidized prescription drug coverage, improving compliance with treatment regimens, and improving health and reduction of adverse events. CMS, however, states that it cannot determine the effect that increasing prescription drug spending will have on the overall Medicare program. “At this time, there have not been studies that found evidence that expansion of drug coverage across a large population, as will occur under the Medicare drug benefit, yields aggregate health care cost savings.”

### **Impact on States**

States will incur direct costs as a result of the proposed rule; however, CMS believes States will achieve a net savings since Medicare will be paying for prescription drug costs previously funded under Medicaid, SPAPs, and state sponsored retiree health insurance.

CMS estimates that the payments States must make to the Federal government to defray a portion of the Medicare costs will be \$8.5 billion in 2006. The payments are estimated to reach \$11.1 billion by 2010.

States will also incur costs associated with assisting in eligibility determinations for the Medicare Part D low-income subsidies. Federal matching funds will be available to assist in paying for these administrative costs.

States will also need to provide disclosure notices to Medicare beneficiaries who receive drug coverage through State Medicaid program, State Pharmacy Plus Programs, and SPAPs.

Overall, CMS estimates that States will save \$65 billion between 2006 and 2010 due to the shift of some low-income beneficiaries, state retirees, and SPAP participants to the Medicare program. The savings will be partially offset by approximately \$57 billion in

State costs related to the Part D benefit. This results in a net savings for States of \$8.2 billion during that 5 year period.

### **Impact on Pharmacy**

“While the Medicare prescription drug benefit is expected to have several effects on pharmacy revenue, both positive and negative, our estimate is that the impact on the overall pharmacy industry, including small pharmacies, will be positive.” CMS further emphasizes that any effect on pharmacies “is really a result of the statutorily-created Medicare prescription drug benefit, and not this rule-making.”

CMS estimates that pharmacy revenue will increase between 1.7% and 3% because of increased drug utilization (especially among beneficiaries who previously had no drug coverage). This estimate takes into account the fact that former cash-paying customers may now obtain pharmacy discounts through the Part D benefit and a possible increase in mail order pharmacy. The estimate does not include potential sources of additional revenue such as payment for MTMS and increased sales of other products due to increased pharmacy traffic.

CMS predicts pharmacies will experience a reduction in revenue due to the movement of dual-eligibles from Medicaid to Medicare since private sector insurers typically pay lower reimbursement rates than State Medicare programs. CMS estimates that the reduction could be as much as 1.1%.

Overall, CMS estimates a net increase in total prescription drug spending at community pharmacies of between 0.6% and 1.9%.

### **Impact on Insurers and PBMs**

While the proposed rule provides a somewhat detailed discussion on the rule’s impact on states and pharmacies, the rule does not provide much detailed information on the rule’s impact on insurers and PBMs. The rule does state that CMS expects the Part D program to increase drug utilization which will in turn be favorable to insurers and PBMs. CMS also predicts that PBM business will expand because many PDPs and MA-PDs will use PBMs to manage their prescription drug benefit. However, the rule does not provide any predictions on increased revenue or expenses.

Simply, the rule states “While the statutorily-created Part D and Medicare Advantage programs will be largely favorable to PBMs, this proposed rule as such will have little or no direct effect on the PBM industry, and certainly not a significantly adverse effect on a substantial number of small entity PBMs.