

January 27, 2005

## Overview of Final Rule Implementing Medicare Part D Prescription Drug Benefit

On January 21, 2005, the Centers for Medicare and Medicaid Services ("CMS") released its final rule to implement the Medicare Prescription Drug Benefit authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). The rule is expected to be published in the Federal Register by January 28, 2005.

The final rule and its preamble incorporate or reference several other policy and administrative decisions that are key to the implementation of the new benefit, such as the establishment by CMS of Prescription Drug Plan and Medicare Advantage Plan regions; the issuance of final formulary guidance by the United States Pharmacopoeia ("USP"); CMS's proposed solicitation for entities seeking Prescription Drug Plan contracts; and the agency's approach to the automatic enrollment of "dual-eligibles" (i.e. individuals with coverage under both the Medicare and Medicaid programs).

The final rule contains no major surprises. Throughout the myriad details included in the massive final rule and preamble, CMS generally maintains its stated underlying policy objectives of promoting a competitive marketplace by providing substantial flexibility to Part D plan sponsors while establishing procedural safeguards and retaining significant agency review authority to assure access by Medicare beneficiaries to needed medications. In addition, the final rule provides substantial flexibility to employer and other sponsors of retiree drug coverage to adopt various strategies to achieve savings as a result of the new Medicare prescription drug benefit.

The economic impact of the Medicare Part D prescription drug benefit is significant. CMS estimates that, in 2006, 39 million beneficiaries will receive Part D or at least equivalent prescription drug benefits through Part D plan sponsors or through employer- or union-sponsored retiree drug coverage that qualifies for the Medicare retiree drug subsidy. Moreover, federal gross spending on the Medicare Part D program is projected to exceed \$69 billion in 2006.

With the publication of this final rule and the ongoing flow of administrative guidance being issued by CMS, the stage is set for the solicitation/approval of Part D plan sponsors, the review/approval of formularies, benefits and premium bids, and outreach to beneficiaries to educate them about their options. The key dates in this process are:

- Part D Plan Process (2005)
 

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|---------------------------------------------------|----------------|
| -Letters of Intent from Potential Plan Sponsors   | Early February |
| -Formal Applications from Potential Plan Sponsors | Late March     |
| -Submission of Proposed Formularies               | April 18       |
| -Submission of Bids on Premium/Benefits           | June 6         |
| -Contract execution                               | September 2    |

- Employer Filing for Retiree Drug Subsidy September
- Part D Enrollment Begins November 15
- Part D Benefits Effective January 1, 2006

In summary, the key elements of the MMA and the final rule are as follows:

- **Program Structure and Benefits** - Beginning January 1, 2006, Medicare beneficiaries will have access to a standard drug benefit or actuarially equivalent variations thereof, and may have access to supplementary drug benefits provided by Part D plan sponsors. The Part D benefits are available through private entities that enter into contracts with CMS as Prescription Drug Plans ("PDPs") or Medicare Advantage Prescription Drug Plans ("MA-PDs"). PDPs will provide Part D drug benefits only. MA-PDs will provide a comprehensive set of benefits, including Medicare-covered hospital (Part A) and medical (Part B) services, Part D drug benefits and, at plan option, supplemental benefits.

The program is structured on a regional basis. CMS has designated 34 geographic areas as PDP regions. Medicare Advantage plans can be established on a local (county) basis or on a regional basis for Medicare Advantage Preferred Provider Organization plans (MA-PPO). CMS has designated 26 geographic areas as MA-PPO regions.

For 2006, the standard Part D drug benefit consists of:

- A \$250 deductible;
- After the deductible is met, 75% coverage for drug costs up to an initial coverage limit of \$2,250;
- After the initial coverage limit is met, a gap in coverage ("donut hole") in which the beneficiary pays 100% of drug costs; and
- A catastrophic benefit that pays about 95% of drug costs after the beneficiary has at least \$3600 in "true out-of-pocket" ("TrOOP") expenses.

A Part D plan may provide (with CMS approval) alternative benefit designs, such as incentive formulary plans with multi-tiered cost-sharing, that are actuarially equivalent to the standard design. While a plan must offer standard or equivalent coverage, it may also offer an enhanced benefit package for an additional beneficiary premium.

Beneficiaries electing Medicare Part D coverage will pay a monthly premium that will vary based on the plan they select. CMS estimates that the average monthly premium in 2006 for standard coverage will be about \$37.

Low-income beneficiaries (i.e., those with limited savings and incomes below 150% of the federal poverty level) will face lower or no premiums, significantly reduced cost-sharing and no "donut hole" gap in coverage.

- **Covered Drugs** - Under the final rule, the term “Part D drugs” refers to the full universe of drugs that meet the standards for coverage. The term “Covered Part D drug” refers to a drug within this universe that is either included in a Part D plan’s formulary or, as a result of a beneficiary appeal, the plan has determined to cover for that beneficiary despite its non-formulary status.
  - To meet the standards for coverage, a Part D drug must be available only by prescription, approved by the Food and Drug Administration (“FDA”), used and sold in the United States, and used for a medically accepted indication. This includes prescription drugs, biologics, insulin and vaccines, and excludes products that may be excluded under Medicaid (except for smoking cessation products that otherwise meet the standards). A drug will not be covered under Part D if coverage for the drug is available to the beneficiary under Part A or B of Medicare.
  - The final rule clarifies CMS policy that off-label uses of drugs may be covered under Part D, provided that the drug is used for a medically accepted indication. Contrary to suggestions in the proposed rule, the final rule does not impose on prescribers a federal documentation requirement relating to off-label uses.
  - The final rule confirms the policy that only prescription drugs may be Part D drugs. While the rule does not explicitly address whether Part D plan sponsors could pay for certain over-the-counter medications and include such costs in the administrative expenses that are built into their premium structures -- a concept supported in previous oral comments by a CMS official -- the rule appears to preclude this strategy.
- **Flexibility for Part D Plan Sponsors** - Consistent with CMS’s policy goal of maximizing beneficiary choice among full-risk PDP and MA-PD plans, the final rule provides substantial, but not unlimited, flexibility for plans to establish formularies, plan designs, pharmacy networks and cost management programs.
  - The final rule incorporates the USP guidelines establishing model formulary categories and classes. CMS indicates, however, that it will review the content of all plan formularies (regardless of whether they comply with the USP guidelines), as well as plan benefit design and cost management programs, to determine whether any of these features would have the effect of discriminating against certain classes of beneficiaries.
  - CMS does not indicate in the final rule whether it will adopt the USP’s recommended formulary review strategy of requesting plan justification in cases where a drug on USP’s list of “key drug types” is not included in the plan’s formulary. However, such an approach is consistent with the overall review framework CMS has established for formulary content.
  - While the final rule maintains the policy that Part D plans must generally include at least two different drugs in each therapeutic category and class, it provides an exception. Only one drug would be required in any category or class containing only two Part D drugs if one of those drugs is clinically superior to the other. CMS also clarifies that the two-drug-minimum rule does not require plans to include all strengths and dosages of each drug.
  - The final rule gives Part D plan sponsors the discretion to establish a policy for assigning to a cost-sharing tier any non-formulary Part D drug that is covered for a specific

beneficiary upon appeal. Moreover, since non-formulary drugs, even if covered as a result of an appeal, are still not considered formulary drugs under the final rule, a beneficiary would not be able to request an exception in order to move that drug to a more favorable cost-sharing tier. For example, a plan could specify that any non-formulary drug covered as a result of an appeal would be paid as if it were a “non-preferred formulary drug,” and this status would not be subject to further appeal.

- The final rule specifies numerous requirements relating to the composition and functions of plan Pharmacy and Therapeutics (“P & T”) committees. Responding to concerns expressed by potential Part D plan sponsors, CMS clarifies in the final rule that P & T committees will have binding authority on clinical matters only. Decisions on plan design (e.g., cost sharing tiers) and financial matters will be the responsibility of plan management. In addition, the final rule includes a new requirement that relates to conflicts of interest for independent members of the P & T committee. Under the final rule, a plan P & T committee must include at least one practicing pharmacist and one practicing physician, both of whom are free of conflicts of interest in relation to the Part D plan sponsor AND pharmaceutical manufacturers.
- With respect to pharmacy networks, the final rule specifies that compliance with the pharmacy access standards (90 percent of beneficiaries on average live within 2 miles (urban areas) or 5 miles (suburban areas) and 70 percent of beneficiaries in rural areas live within 15 miles of a network pharmacy) will be calculated on a statewide basis, even if the PDP or MA-PD region is larger than a state. The final rule retains the “any willing pharmacy” requirement, i.e., the requirement that a plan allow any pharmacy meeting the plan’s contract terms and conditions to be included in its network. The rule establishes some related new requirements for plans, but also underscores the range of flexibility granted to plans. Thus, a plan must have a standard set of pharmacy contract terms and conditions applicable to any pharmacy (variations in terms/conditions are permitted by type of pharmacy), but CMS indicates that the plan may negotiate different terms with specific pharmacies. The final rule also clarifies that pharmacies other than retail pharmacies, such as mail order pharmacies and long-term care pharmacies, also can participate in a Part D plan network as a “willing pharmacy.” However, CMS will allow plans to make benefit design distinctions (such as differential cost-sharing) between “preferred” pharmacies and those “non-preferred” pharmacies that participate in the network as a result of the “any willing pharmacy” provision. In determining whether the pharmacy access standards are met, CMS will permit a plan to include both preferred and non-preferred pharmacies in the calculation.
- The final rule also provides increased marketing flexibility for Part D plan sponsors. Unlike drug card sponsors under the Medicare Prescription Drug Discount Card program, Part D plan sponsors will be allowed to engage in telemarketing activities. CMS is also reviewing the appropriate role of drug card sponsors in the transition from the drug card program to the Part D drug benefit. Based on that review, CMS may allow PDP plan sponsors currently offering a drug card to use drug card enrollee information to market their Part D plans. This issue will be addressed in further guidance. If adopted, such a policy would have major implications for the Part D plan competitive market.
- **CMS Bid Review** - CMS will review the premium and benefit bids submitted by Part D plan sponsors to assure that they are reasonable. While CMS reserves the right to engage in

detailed bid negotiations with plan sponsors, its preferred approach under the final rule is an actuarial review that focuses on the validity of the plan's cost and utilization assumptions and its administrative costs. CMS believes that the competitive market will drive plan sponsors to submit reasonably priced bids, but is prepared to request detailed justification of bid elements, if necessary.

- **Negotiated Drug Prices and Part D Plan Rebate Reporting** - CMS clarifies in the preamble to the final rule that, while a Part D plan sponsor with a risk contract must pass through in its negotiated prices some portion of the price concessions it obtains from pharmacies and manufacturers, the sponsor retains discretion to decide what portion of such concessions to pass through. The negotiated price of a drug will be the basis on which plan coinsurance will be calculated when a beneficiary is in benefit status and will be the price paid by a beneficiary in deductible or "donut hole" status. Similarly, a plan can decide how much of these price concessions will be passed through to the Medicare program and beneficiaries in the form of lower premiums or other costs. In contrast, fallback PDPs, which are not risk plans, must pass through the full amount of any price concessions in the negotiated prices or in premium or other savings.
  - While a plan has discretion in the amount of price concessions it may retain, it will be required to report all price concessions to CMS. In the final rule, CMS defines the concept of reporting "aggregate rebates" to include reporting rebates at the product level. This is a major change from the proposed rule.
- **Medication Therapy Management Programs ("MTMPs")** - Part D plans will be required to have MTMPs that focus on improving the quality of pharmaceutical care. CMS decided that the lack of industry norms precluded the specification of detailed standards on the design, operation and financing of these programs. A plan will have substantial discretion to design programs that meet its needs, and CMS will not intervene in any payment disputes between a plan and practitioners that it may choose to contract with for counseling and other MTMP services.
- **Patient Assistance** - In the preamble, CMS underscores the distinctions between the current Medicare Prescription Drug Discount Card program and the Part D prescription drug benefit that will begin in 2006 as they relate to targeting private sector assistance to low-income beneficiaries. Under the discount card program, a number of card sponsors entered into arrangements with drug manufacturers to provide special discounts to low income beneficiaries who had exhausted the \$600 Medicare transitional assistance provided under that program. Such targeted arrangements are not permitted under the Part D prescription drug plans because benefits (except for MMA-required benefit improvements for low income beneficiaries) and negotiated prices must be uniform for all beneficiaries who may enroll in the plan.
  - In the preamble, CMS states that any payments by drug manufacturer patient assistance programs that serve to reduce the cost-sharing responsibility of lower income beneficiaries may be considered TrOOP expenses that count toward the \$3,600 threshold for the catastrophic benefit if the program was not otherwise a health insurance or other benefit plan. Such programs would not need to be "bona fide charities" but would need to comply with the anti-kickback restrictions.

- **States** - Medicare Part D will have major effects on State Medicaid programs, State Pharmaceutical Assistance Programs (“SPAPs”), and State employee retiree benefit plans.
  - Medicaid - Effective January 1, 2006, the responsibility for providing drug benefits for over 6 million dual eligibles shifts from State Medicaid programs to Medicare Part D plans. While a State will no longer be providing the benefits, it will be responsible for reimbursing the Federal Government for a share of its costs under a statutorily defined formula (commonly referred to as the dual eligible “clawback” formula). In response to concerns about the potential negative effects on dual-eligible beneficiaries of the transition of drug benefit responsibilities from Medicaid to Medicare Part D, CMS adopted two new policies in the final rule:
    - 1.) Automatic Enrollment - CMS will not wait until the end of the initial Part D enrollment period (May 2006), but will “auto-enroll” any dual-eligible who hasn’t chosen a Part D plan by December 31, 2005.
    - 2.) Transition Policy - All Part D plans will be required to have transition policies (subject to CMS review/approval) that specify how they will meet the drug regimen needs of dual eligibles and other vulnerable populations during the initial period of their enrollment.
  - SPAPs - The Medicare Part D drug benefit, which is a primary payer, will enable SPAPs to achieve savings. States may modify their SPAPs to enable them to act as a secondary or supplemental payer, providing eligible State residents coverage of Part D cost-sharing or drugs not covered by the Part D plan. The MMA provides favorable treatment of SPAP payments of Part D cost-sharing amounts in that such payments would be counted as TrOOP expenses of the beneficiary for purposes of determining eligibility for the Part D catastrophic benefit. Although it received numerous comments to the contrary, CMS maintains in the final rule its proposed policy that, to qualify for this favorable treatment, the SPAP cannot endorse one or more Part D plans for SPAP enrollees.
  - State Retiree Drug Plans - State retiree drug plans will have virtually the same options for obtaining savings resulting from Medicare Part D as private employer/union sponsored plans. While governmental entities generally are not eligible for PDP or MA-PD contracts, CMS notes its belief that it can waive this prohibition for States that seek to sponsor Part D plans on behalf of their retirees. State plans can also qualify for the Medicare retiree drug subsidy (with an estimated value of \$668 annually per qualified beneficiary) or they can become secondary payers (with estimated savings of \$900 annually per qualified beneficiary).
- **Employers** - The final rule provides employer and union sponsors of retiree drug plans with numerous options to achieve savings as a result of the Medicare Part D benefit. CMS estimates that, in 2006, of the 11.4 million beneficiaries projected to have retiree drug coverage absent the law change, about 9.8 million will receive benefits at least equivalent to Part D benefits through an employer/union-sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. The rest will be enrolled in Medicare Part D plans, and most of these beneficiaries will receive enhanced benefits or wraparound coverage through their former employer or union.

- For sponsors interested in the Medicare retiree drug subsidy, the final rule provides substantial flexibility in actuarial equivalence, plan definition, qualifying covered retirees, payment methodologies, and reporting requirements. The final rule establishes a “two-prong” test that would be used in determining whether the retiree drug plan provides benefits that are at least actuarially equivalent to the standard Medicare Part D benefit. The first prong evaluates the overall value of the benefit design, without regard to the source of funding. The second prong tests the employer’s contribution to financing drug benefits by subtracting beneficiary premiums and other contributions from the overall value and comparing this to the comparable value for Medicare Part D. This test is intended to prevent “windfalls” to certain retiree drug plans (e.g., those that provide “access only” benefits with no plan contribution to the premium) and was a policy largely supported by the employee benefits community.
- **Fallback Plans** - The MMA provides that non-risk fallback plans be established in any geographic area that has less than two choices of Part D plans for beneficiaries, one of which must be a PDP. In the preamble to the final rule, CMS reiterates its goal that sufficient risk plans be available to avoid the triggering of fallback plans in any area. CMS will allow a fallback plan to provide either the standard Part D benefit or an actuarially equivalent benefit. (The proposed rule precluded the offering of the standard benefit.)
- **Additional Regulations/Guidance to be Issued** - CMS plans to issue proposed rules governing electronic prescribing “shortly” and will also provide sub-regulatory guidance on several aspects of Medicare Part D, including the determination of actuarial equivalence, the cost thresholds to be used to target beneficiaries for MTMPs, the risk adjustment methodology, and waivers for employer-sponsored prescription drug plans.

This memorandum is intended to provide a high-level overview of the final rule. We will be distributing additional memoranda that will delve more deeply into areas of the rule of greatest interest to our clients.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please call the following members of our life sciences group:

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