

**Key Provisions of the  
CMS Medicare Drug Benefit Proposed Rule  
August 2004**

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Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”)<sup>1</sup> provides for the addition of an outpatient prescription drug benefit to the Medicare program. This new optional Medicare Part D coverage will be available to Medicare beneficiaries beginning January 1, 2006.

The Centers for Medicare and Medicaid Services (“CMS”) has published a proposed rule to create regulations at 42 C.F.R. Parts 403, 411, 417, and 423, which will implement the new prescription drug benefit.<sup>2</sup> CMS will accept comments on the proposed rule through October 4, 2004. Although the proposed rule applies most directly to potential sponsors of prescription drug plans (“PDPs”) and to Medicare Advantage (“MA”) organizations that will offer prescription drug benefits (“MA-PDs”), the drug benefit will have a significant impact on pharmaceutical manufacturers. This memorandum addresses those provisions of the proposed rule that may be of greatest interest to industry clients<sup>3</sup> The sections of the memo are organized as follows:

- I. Plan requirements most directly affecting manufacturers.
- II. CMS’s proposed bid review process and its potential for interference with the negotiations between plan sponsors and pharmaceutical manufacturers.
- III. Provisions related to fallback plans and their potential implications for pharmaceutical manufacturers.
- IV. Coordination of existing drug coverage in Medicare Parts A and B with the new drug benefit in Part D.

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<sup>1</sup> Public Law 108-173.

<sup>2</sup> 69 Fed. Reg. 46632 (Aug. 3, 2004).

<sup>3</sup> This memorandum does not discuss in detail the MMA or other provisions of the proposed rule that may be of lesser interest to our industry clients (*e.g.*, the requirements that plans have the capacity to support electronic prescription programs and for disclosure to beneficiaries of pricing information for generic versions of covered Part D drugs). Please see our memorandum of November 26, 2003 (available on our website, <http://www.cov.com/publications/index.html>) for a more detailed discussion of the prescription drug provisions of the MMA.

- V. Proposed treatment of rebates paid by manufacturers.
- VI. Treatment of manufacturers' patient assistance programs.
- VII. Topics upon which industry clients might consider submitting comments to CMS.

## I. Plan Requirements

### A. Types of Drug Coverage

“Defined standard coverage” under Medicare Part D is “subject to an annual deductible [which will be \$250 in the year 2006]; 25 percent coinsurance . . . up to an initial coverage limit [\$2,250 in 2006]; and catastrophic coverage after an individual incurs out-of-pocket expenses above a certain threshold [\$3,600 in 2006].”<sup>4</sup> A beneficiary who has reached this true out-of-pocket (“TrOOP”) threshold is responsible for cost-sharing “equal to the greater of: (1) 5 percent coinsurance, or (2) a copayment of \$2 for a generic drug or a preferred multiple source drug and \$5 for any other drug . . . .”<sup>5</sup>

The MMA allows plans to offer “actuarially equivalent” plan designs as well as supplemental benefits. CMS proposes to allow plan sponsors offering actuarially equivalent standard coverage “to substitute cost-sharing requirements (including tiered structures tied to plan formularies or particular pharmacies in a plan’s network) for costs above the annual deductible and up to the initial coverage limit,” as long as the cost-sharing requirements are actuarially equivalent to an average expected coinsurance of 25 percent.<sup>6</sup> Plan sponsors also may create cost-sharing responsibilities above the catastrophic coverage limit that are actuarially equivalent to the expected cost-sharing under defined standard coverage plans. CMS proposes to allow plan sponsors offering “basic alternative coverage” to decrease the deductible while increasing the cost-sharing below the initial coverage limit, provided such designs meet a number of actuarial equivalence and other tests.

CMS recognizes that private plans routinely use tiered cost-sharing for cost and utilization containment purposes and proposes to allow PDP sponsors and MA-PDP organizations the same option.

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<sup>4</sup> Proposed 42 C.F.R. § 423.104(e); 69 Fed. Reg. at 46649.

<sup>5</sup> 69 Fed. Reg. at 46649.

<sup>6</sup> *Id.* at 46652.

## B. Plan Formularies

As required by the MMA, CMS has requested that the U.S. Pharmacopoeia (“USP”) develop model formulary guidelines, including lists of drug categories and classes.<sup>7</sup> Plan sponsors will have the flexibility to develop their own formulary classifications, as well. CMS, however, will evaluate any formulary with classifications that differ from the USP guidelines to ensure that such formulary does not discriminate against particular classes of beneficiaries. CMS has invited comments regarding the standards it could use to determine whether a particular formulary discriminates against a class of eligible beneficiaries.

CMS interprets the MMA to require the inclusion of two or more drugs in all therapeutic categories and classes, unless only one drug is appropriate for a particular therapeutic category.<sup>8</sup> To the extent possible, drugs in each category must represent a variety of strengths and doses. CMS also expects that plan formularies will contain an expansive list of generic drugs. Furthermore, CMS requests comment on whether special requirements are necessary to ensure that vulnerable populations such as HIV-positive beneficiaries and beneficiaries in long-term care facilities have access to the necessary range of drugs.<sup>9</sup>

CMS expects that the USP model formulary will contain at least one drug with an approved indication for each category. Nonetheless, prescribers would be permitted to prescribe a drug for an off-label indication. CMS “strongly encourages” prescribers to document and justify these off-label prescriptions in their patients’ clinical records.<sup>10</sup> Plan sponsors would also be permitted to designate drugs to particular categories based upon off-label uses, provided that FDA has not deemed the drugs to be unsafe for such uses.

Plans may remove a drug from the formulary or change a drug’s preferred or cost-sharing status upon 30 days’ notice to CMS, affected enrollees (i.e., those currently taking the drug), authorized prescribers, pharmacists, and pharmacies.<sup>11</sup> Plan sponsors may not remove or change the status of formulary drugs during the period

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<sup>7</sup> USP is expected to issue a draft of its model formulary in mid-August, 2004, and to finalize its guidelines by the end of 2004.

<sup>8</sup> *Proposed* 42 C.F.R. § 423.120(b)(2).

<sup>9</sup> For instance, CMS notes that long-term care pharmacies often use open formularies. CMS seeks comment on both the special populations that need protection, and the special treatment necessary for these populations. 69 Fed. Reg. at 46661.

<sup>10</sup> *Id.* at 46660.

<sup>11</sup> *Id.* at 46661. Plans may not, however, change formulary categories or classes during the year, except as permitted to account for new therapeutic uses and newly approved drugs.

between the beginning of the annual coordinated election period and 30 days subsequent to the beginning of the contract year.<sup>12</sup>

If a plan sponsor chooses to utilize a formulary, a pharmaceutical and therapeutic (“P&T”) committee must be involved in formulary development and review.<sup>13</sup> CMS expects that P&T committees will participate in the design of formulary tiers and clinical programs such as prior authorization, step therapy, and generics programs. CMS also expects that the decisions of the P&T committee would be binding upon the plan, although the agency invites comments on this interpretation. P&T committees may consider pharmacoeconomic studies in making clinical decisions, but CMS expects committees to balance cost considerations with clinical considerations.

The majority of P&T committee members must be practicing pharmacists or physicians, and CMS asks plan sponsors to seek members from diverse specialties. At least one pharmacist and one physician on the committee must possess expertise in the field of elderly and disabled care.

At least one pharmacist and one physician member of the P&T committee “must have no stake, financial or otherwise, in formulary determinations.”<sup>14</sup> These members must be independent of plans, plan sponsors, and pharmaceutical manufacturers. CMS also is considering a requirement that more than one pharmacist and one physician on a P&T committee qualify as independent and free of conflict, and has invited comment on this proposal.

### C. Cost Effective Drug Utilization Management

Each plan must create a cost effective drug utilization management program, which will include incentives to reduce costs when medically appropriate.<sup>15</sup> As an example, CMS suggests that plans may utilize different dispensing fees to encourage the use of multiple source drugs.<sup>16</sup> Other potential tools include prior authorization, step therapy, and tiered cost-sharing. For further guidance in developing these programs, plans may look to industry standards and other tools currently used by commercial and

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<sup>12</sup> Proposed 42 C.F.R. § 423.120(b)(6).

<sup>13</sup> *Id.* § 423.120(b)(1).

<sup>14</sup> 69 Fed. Reg. at 46659. The proposed regulation appears to require that the independent members of the P&T committee have expertise in the area of elderly and disabled care. Proposed 42 C.F.R. § 423.120(b)(1)(ii).

<sup>15</sup> Proposed 42 C.F.R. § 423.153(a); 69 Fed. Reg. at 46666-71.

<sup>16</sup> 69 Fed. Reg. at 46666-67. This would not be the same as “switching” one branded drug product with another similar branded drug product. CMS emphasizes that “switching,” or “therapeutic substitution,” would always require prescriber notification and approval.

State programs to manage pharmacy benefit costs. CMS also is considering a requirement that a P&T committee oversee such drug utilization management programs. CMS queries whether a P&T committee could ensure an appropriate balance between clinical efficacy and cost effectiveness if it also is directly involved with cost containment, quality assurance, and medication therapy management. Industry clients may wish to comment on this question.

#### **D. Quality Assurance**

Plans must develop quality assurance programs that include measures and systems for reducing medication errors, reducing adverse drug interactions, and improving medication use.<sup>17</sup> Quality assurance programs must include drug utilization review, patient counseling, and patient information record-keeping. CMS believes that plans should comply generally with existing Medicaid prescription drug quality standards, but requests comment on whether the Medicaid standards are appropriate for the Part D benefit.<sup>18</sup>

#### **E. Medication Therapy Management Programs (MTMPs)**

The MMA requires all plans to establish a MTMP. Plans can provide a broad range of services through a MTMP to optimize outcomes for targeted beneficiaries.<sup>19</sup> Examples of MTMP services include education and counseling programs, medication regimen compliance measures, and patient status assessments. MTMP services would be distinct from those services required for dispensing medication. Because CMS considers MTMPs to be administrative activities incident to appropriate drug therapy, enrollees will not be required to pay cost-sharing or other fees for the services.

Targeted beneficiaries are plan enrollees who have multiple chronic diseases, are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a specific level determined by CMS. Although the MMA directs CMS to set the level of annual costs a beneficiary must incur to qualify for MTMP services, CMS prefers to delegate this function to the drug plans, reasoning that the plans have better information with which to evaluate their beneficiaries. CMS recognizes that the delegation of its authority might create legal and policy issues, and accordingly has requested comments on the proposed delegation, on the suggested threshold level, and on plans' suggested methods for determining the costs that enrollees are likely to incur.

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<sup>17</sup> *Id.* at 46667.

<sup>18</sup> *Id.*; *see also proposed* 42 C.F.R. § 456.705.

<sup>19</sup> 69 Fed. Reg. at 46668-70.

## F. Medical Necessity and Appeals

The MMA requires PDP sponsors to follow particular procedures with regard to grievances, coverage determinations, and appeals.

**Grievance Procedures.** PDP sponsors must establish procedures to ensure that enrollee grievances are heard and resolved in a timely manner.<sup>20</sup> The regulations provide only general outlines of the types of procedures that each PDP sponsor must establish.

**Coverage Determinations.** PDP sponsors must establish procedures for making coverage determinations and redeterminations. A plan makes a coverage determination when it fails to pay for a covered Part D drug that the enrollee believes may be furnished by the PDP.<sup>21</sup> The failure to provide a coverage determination in a timely manner also is a coverage determination, as are cost-sharing decisions and decisions on whether a drug is a preferred drug for an enrollee. The coverage determination and redetermination requirements for PDP sponsors are essentially the same as those for the MA program.<sup>22</sup>

**Exceptions.** The proposed rule would implement the MMA requirement that PDP sponsors establish a process for granting exceptions to the formulary and to the tiers in the formulary.<sup>23</sup> A patient may qualify for an exception only if, at a minimum, the physician determines that a preferred drug would not be as effective for the patient as a nonpreferred drug, would have adverse effects for the individual, or both. The PDP can require the physician to certify this finding in writing.

CMS proposes to include provisions to protect enrollees in certain circumstances. Once a sponsor approves an exception, for instance, CMS specifies that the enrollee is entitled to refills of the drug as long as a physician prescribes it and the drug is safe and effective for the enrollee's condition. Furthermore, PDP sponsors may not assign drugs covered under an exception to a special formulary tier, co-payment, or other cost-sharing requirement. Instead, the sponsor must use reasonable criteria in determining the co-payment or other cost-sharing for those drugs.

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<sup>20</sup> *Proposed* 42 C.F.R. § 423.564. A “grievance” includes any complaint or dispute, other than a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor’s operations, activities, or behavior, regardless of whether remedial action is requested. Grievances may include complaints about the timeliness of the filling of a prescription and about the accuracy of a prescription.

<sup>21</sup> CMS considers that a covered Part D drug is likely to be medically necessary if it is prescribed to a covered individual. 69 Fed. Reg. at 46662.

<sup>22</sup> *Proposed* 42 C.F.R. § 423.566.

<sup>23</sup> *Id.* § 423.578. These requirements apply only if the plan uses a formulary and/or tiers. The requirements are essentially the same as those for the MA program.

*Exceptions to Formulary.* PDP sponsors must allow plan enrollees, their authorized representatives, and physicians to request coverage of covered Part D drugs not on the formulary, continued coverage of drugs that the sponsor has removed from its formulary, and exceptions to step therapy requirements and dosing limitations.<sup>24</sup> The PDP sponsor must describe the criteria that it will use to evaluate the physician's determination of need, clarify its evaluation of the relative safety and efficacy of the requested drug, and describe the cost-sharing that will apply if the exception is approved. If the sponsor removes a drug from the formulary, the sponsor must continue to cover the drug for up to one month, until reaching a decision on the enrollee's exception request.

*Exceptions to Tiering.* PDP sponsors may impose additional criteria for exceptions to the tier structure. For instance, PDP sponsors may require a stronger physician certification that includes the enrollee's patient history, or may require the enrollee to try the preferred drug before requesting an exception, absent medical contraindications.

The PDP sponsor must describe the process that it will use to evaluate the physician's determination of need. The sponsor must consider the cost of the preferred and nonpreferred drugs, whether the formulary includes a therapeutic equivalent to the requested drug, and the number of formulary drugs in the same class and category as the requested drug. The sponsor must describe the enrollee's cost-sharing obligations for drugs provided under an exception.

*Appeals.* Plan enrollees can request redeterminations of unfavorable coverage determinations and of denials of tiering exception or formulary exception requests. The proposed regulations would impose specific requirements regarding request handling, timeframes for responding to requests, and follow-up.<sup>25</sup>

If the sponsor's redetermination affirms its original decision, the enrollee then may request reconsideration by the independent review entity ("IRE").<sup>26</sup> Unlike in the MA program, the appeal request will not be automatically forwarded to the IRE. The IRE will review whether the sponsor properly applied its exceptions criteria. The IRE has no authority with regard to the formulary or exceptions criteria. The IRE finding would be binding on all parties under the proposed rule, unless the enrollee requests a hearing by an administrative law judge.

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<sup>24</sup> After the first year of the program, CMS will examine the history of formulary appeals to determine whether a plan's formulary requires modification. 69 Fed. Reg. at 46681.

<sup>25</sup> *Proposed* 42 C.F.R. §§ 423.580 - .590.

<sup>26</sup> *Id.* §§ 423.600 - .604.

## II. Interaction of Statutory Non-Interference Provisions and CMS's Proposed Bid Review Process

The MMA prohibits CMS from interfering with negotiations among drug manufacturers, pharmacies, and PDP sponsors or MA-PDP organizations,<sup>27</sup> or requiring a particular formulary or pricing structure.<sup>28</sup> CMS, is, however, proposing that it take a very active role in negotiating premium bids from PDP sponsors and MA-PD organizations, based on evaluations of the sponsor's effectiveness in obtaining drug price concessions. The MMA requires CMS, in evaluating bids, to use the Federal Employees Health Benefits Program ("FEHBP") standard that the plan bid "reasonably and equitably reflects the costs of benefits provided."<sup>29</sup> CMS is proposing to use this authority aggressively to compare plan bids to industry standards and other comparable bids. In addition to looking at the aggregate price of the bid, CMS wants to know the final drug price levels implicit in the bid. The agency may request information about rebates and discounts from the sponsor "in order to ensure that they are negotiating as vigorously as possible."<sup>30</sup> This process has the potential to create a high degree of uncertainty for PDP sponsors and MA-PD organizations. Industry clients may wish to consider commenting on whether such intensive review would indirectly influence the price negotiations between manufacturers and plans.

## III. Fallback Plans and Cost Containment

Under the MMA, non-risk-bearing fallback plans may be established in areas where beneficiaries do not have a choice of at least two qualifying drug plans (including at least one PDP). Fallback plan sponsors would be paid on a cost basis, and thus would have a lesser incentive to negotiate prices with pharmaceutical manufacturers than would sponsors of risk-bearing plans. CMS also must pay to fallback plans management fees tied to performance measures. CMS plans to use these payments to create incentives for fallback plan sponsors to contain costs and provide the lowest possible prices for beneficiaries and the Medicare program.<sup>31</sup>

CMS is contemplating tying performance incentive payments to the plan's ability to maintain a certain average discount relative to the average wholesale price. The agency also is considering other targets such as the "average cost per prescription, average anticipated (or guaranteed) rebate per prescription, average dispensing fee per

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<sup>27</sup> Social Security Act § 1860d-11(i)(1).

<sup>28</sup> See 69 Fed. Reg. at 46681.

<sup>29</sup> *Id.* citing 5 U.S.C. § 8902(i).

<sup>30</sup> *Id.* at 46682.

<sup>31</sup> *Id.* at 46734.

(type of) prescription, or average administrative fee per prescription.”<sup>32</sup> CMS invites comments identifying targets that may be less susceptible to manipulation than the average wholesale price, such as the average sales price or the prior year’s negotiated and delivered prices, as well as alternative methodologies that would promote competitive pricing.

Under the MMA, fallback plans must provide standard coverage. CMS is proposing that fallback plans be required to provide only actuarially equivalent cost-sharing alternatives to the standard benefit. Thus, in areas where there is minimal effective competition among plans, the fallback plans would be expected to have incentive formulary designs with tiered cost-sharing. As a result, beneficiaries in fallback plan regions may have decreased ability to obtain coverage for non-formulary drug products. Industry clients may want to consider recommending that CMS reconsider this proposal.

#### **IV. Coordination of Parts A, B, and D**

The proposed definition of covered Part D drug would “exclude any drug for which, as prescribed and dispensed or administered to an individual, payment would be available under Parts A or B of Medicare for that individual (even though a deductible may apply).”<sup>33</sup> CMS interprets the MMA to mean that if Medicare Part A or B could cover a drug that would otherwise qualify as a Part D drug, the drug will not be covered under Part D. For example, if a beneficiary is eligible for Part A or B coverage but has declined to enroll in such coverage, Part D will not cover the drugs that Part A or B would have covered if the beneficiary had enrolled.

A covered Part D drug may qualify for payment under Part B in some situations, depending on its method of dispensing or administration. For example, certain drugs may be covered by Part B if they are administered via a physician’s injection, but covered by Part D if they are dispensed as tablets or capsules for home administration. CMS interprets “dispensation or administration” to include the setting, personnel, and method involved, as well as the route of administration. Drugs that are not covered by Part B for reasons of medical necessity also will not be covered by Part D.

A primary goal of Part D coverage is to cover the gaps created by Part B. CMS “intend[s] to ensure that the Part D benefit ‘wraps around’ Part B drug benefits to the greatest extent possible.”<sup>34</sup> For example, Part D would cover immunosuppressive drugs given to Medicare beneficiaries whose transplants were not paid for by Medicare, which are excluded from coverage under Part B. Industry clients are encouraged to

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<sup>32</sup> *Id.*

<sup>33</sup> *Id.* § 423.100; 69 Fed. Reg. at 46646.

<sup>34</sup> 69 Fed. Reg. at 46647.

submit comments regarding potential gaps in the combined Part B and Part D coverage and are invited to comment upon particular drugs that would require specific guidance with respect to their Part D coverage.

## V. Negotiated Prices and Rebates

PDP sponsors and MA-PD organizations will negotiate with manufacturers for discounted prices on Part D drugs and pass on some amount of these discounts to beneficiaries. These negotiated prices, along with the plan premium, are the primary bases for competition between the drug plans. Unlike the drug discount card program regulations, the proposed Part D regulations do not limit the amount by which plan sponsors may increase the prices for covered drugs during the plan year.

**Medicaid Best Price.** The discounted prices offered by manufacturers for the Part D program will not be taken into consideration when determining a drug's "best price" for the Medicaid program. CMS envisions that a manufacturer may offer more substantial discounts to PDP and MA-PD plans, as well as to retiree health plans qualifying for the 28% direct subsidy, knowing that the manufacturer will not be required to provide equivalent prices to the Medicaid program. Because Medicare is becoming the primary payor for Medicaid-Medicare dual-eligible enrollees, however, the Medicaid program will pay for fewer prescription drugs. As a result, the impact of this exemption is uncertain.

Although the discounted prices will not be considered in best price calculations, PDP sponsors and MA-PD organizations must report to CMS all aggregate negotiated price concessions, including discounts, direct or indirect subsidies, and direct or indirect remunerations, from each pharmaceutical manufacturer that the sponsor passes through to the Medicare program. This information would be protected under the confidentiality provisions applicable to Medicaid pricing data,<sup>35</sup> although the HHS Office of the Inspector General may audit and evaluate the data.

**Impact of Rebates on Payments.** The MMA requires CMS to pay sponsors and employers for certain reinsurance, risk corridor, and qualified employer coverage subsidy purposes. In calculating these payments, CMS will consider only the sponsor's net drug costs, *i.e.*, the amount actually paid by the sponsor after deducting all discounts, chargebacks, and average percentage rebates received from manufacturers, pharmacies, and other sources.<sup>36</sup> When apportioning the rebates received at the aggregate level to plan enrollees incurring expenses, sponsors may use any reasonable basis.<sup>37</sup> For

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<sup>35</sup> Social Security Act § 1927(b)(3)(D).

<sup>36</sup> *Proposed* 42 C.F.R. § 423.882, -.886; 69 Fed. Reg. at 46827.

<sup>37</sup> 69 Fed. Reg. at 46687, 46740.

instance, sponsors may allocate rebates on the basis of percentage of dollars spent rather than covered lives.

Sponsors must account for all price concessions and segregate them from administrative fees.<sup>38</sup> CMS is proposing to require that all administrative fees received by PDP sponsors and MA-PDP organizations be based on the fair market value of the services provided.<sup>39</sup> Administrative fees that are above or below the fair market value will be considered to be additional price concessions for reinsurance and risk corridor purposes.

CMS acknowledges that some qualified employer plan sponsors might agree to accept lower administrative fees or perform services for lower than market value in lieu of rebates, in order to maximize subsidy payments.<sup>40</sup> CMS therefore will require that the “true cost” of rebates be described in all retiree plan records.

## **VI. Patient Assistance Programs Sponsored by Pharmaceutical Manufacturers**

In general, a payment for a prescription drug will be an “incurred cost” and count toward an enrollee’s out-of-pocket expenditure threshold only if the payment is made by or on behalf of the enrollee.<sup>41</sup> If the enrollee is reimbursed for the costs by insurance, a group health plan, or other third-party arrangement, the costs will not be considered “incurred” for the purposes of the TrOOP threshold. Payments for drugs that are not on the plan formulary and that are not treated as if they were on the formulary as a result of a coverage determination also will not be counted toward the TrOOP threshold.<sup>42</sup>

CMS is proposing to allow appropriate charitable assistance to count toward enrollees’ incurred costs.<sup>43</sup> All charitable assistance must comply with federal fraud and abuse laws. CMS is considering whether patient assistance programs (“PAPs”) sponsored by pharmaceutical manufacturers should be deemed appropriate charitable assistance that, unlike third-party insurance, would count toward enrollees’ incurred costs for purposes of the TrOOP threshold. Industry clients may want to comment on this proposed policy.

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<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 46687.

<sup>40</sup> *Id.* at 46739.

<sup>41</sup> *Proposed* 42 C.F.R. § 423.100.

<sup>42</sup> 69 Fed. Reg. at 46649.

<sup>43</sup> *Id.* at 46650.

## VII. Topics for Comment

Before the October 4, 2004 deadline, industry clients might consider commenting, at a minimum, on the following topics:

- *Review of Negotiated Prices:* The appropriateness of CMS's conducting intensive review of the prices negotiated between plans and pharmaceutical manufacturers as part of the bid negotiation process.
- *Fallback Plans:* Whether fallback plans should be required to provide only actuarially equivalent standard coverage, and the appropriateness of incentives tied to average discounts negotiated with manufacturers.
- *Part B / Part D Coordination:* Potential gaps in the combined Part B and Part D coverage, and particular drugs that would require specific guidance with respect to their Part D coverage.
- *Formularies:* Standards for determining whether a formulary discriminates against a class of eligible beneficiaries, and need for special requirements relating to vulnerable populations.
- *Pharmaceutical & Therapeutic Committees:* Composition and role of the P&T committee.
- *Patient Assistance Programs:* Whether patient assistance programs sponsored by pharmaceutical manufacturers should be deemed appropriate charitable assistance so that such assistance counts toward enrollees' incurred costs for purposes of the true out of pocket threshold.
- *Medicaid Drug Quality Standards:* Appropriateness of applying Medicaid prescription drug quality standards (regarding drug utilization review, patient counseling and patient information record-keeping) to the Part D benefit.
- *Medication Management Therapy Program:* Procedure and methodology for setting the appropriate dollar threshold for determining criteria for populations targeted for medication therapy management programs.

We are continuing to analyze the implications of this proposed rule and to identify other issues upon which industry clients may wish to comment.

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