Analysis of Final Rule Implementing Medicare Part D Prescription Drug Benefit

The Centers for Medicare and Medicaid Services ("CMS") has published its final rule\(^1\) to implement the Medicare prescription drug benefit authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA").

In a previous memorandum,\(^2\) we gave a high-level overview of the final rule. The purpose of this memorandum is to explore in more detail aspects of the final rule that are of particular interest to industry clients.

This memorandum focuses on plan structure, pharmaceutical pricing, formulary requirements and review, utilization management, grievance procedures, employer subsidies, and third-party assistance.

**Part D Plan Structure**

**A. Types of Part D Plans**

**Overview.** Medicare Part D prescription drug benefits will be offered by several types of plans. The primary types of plans will be private prescription drug plans ("PDPs") and Medicare Advantage organizations that will provide health care benefits under Medicare Part C as well as the Part D drug benefit ("MA-PDs").\(^3\) Program for All-Inclusive Care for the Elderly ("PACE") plans and health maintenance organizations ("HMOs") or competitive medical plans ("CMPs") operating in accordance with a cost-reimbursement contract with CMS may also offer Part D prescription drug plans.\(^4\)

Part D-eligible individuals enrolled in Medicare Advantage plans or PACE plans generally are required to enroll in the prescription drug plans offered through that organization and are ineligible to enroll in stand-alone PDPs.\(^5\) Part D-eligible individuals enrolled in a cost-based HMO or CMP, however, may elect to enroll in a PDP as long as they have not enrolled in a drug plan through their HMO or CMP.\(^6\)

\(^1\) 70 Fed. Reg. 4194 (Jan. 28, 2005).
\(^3\) 42 C.F.R. § 423.4.
\(^4\) Id.
\(^5\) Id. § 423.30(b)-(c).
\(^6\) Id. § 423.30(d).
Each Part D-eligible individual will have access to a choice of at least two plans in the area in which the individual resides (the “plan access requirement”). Different sponsors must offer the two qualifying plans, and at least one of the plans must be a PDP. As discussed in greater detail below, in any PDP region (or portion thereof) where the plan access requirement is not met, CMS will approve a non-risk-bearing fallback plan.

**Full Risk versus Limited Risk Plans.** CMS anticipates that most bids submitted by potential Part D sponsors will be bids for “full risk” plans, meaning that the plan is not requesting any modification of the statutory risk-sharing arrangements. The risk-sharing arrangements provided under the MMA limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through risk adjustment. Such arrangements are structured as symmetrical risk corridors that are agreements to share, between CMS and the plan sponsor, a portion of any unexpected losses or profits resulting from the plan’s provision of basic benefits.

A PDP sponsor may also choose to participate as a “limited risk” plan, meaning that it provides basic prescription drug coverage but enters into a modified risk-sharing arrangement with CMS. The modification may take the form of an increase in the federal percentage of risk assumed in the risk corridors or a decrease in the size of risk corridors. While there is no limit to the number of full risk plans that CMS may approve, CMS may approve a limited risk plan only if the plan access requirement cannot otherwise be met for a PDP region or a part of a region. CMS will give priority to those limited risk plans bearing the highest level of risk, and CMS generally will not approve a limited risk plan with a proposed risk-sharing agreement under which the plan would assume less than 10% of financial risk.

**Fallback Plans.** For any PDP region (or portion thereof) where the plan access requirement is not met, CMS will approve a non-risk-bearing fallback plan to meet the plan access requirement.

An eligible fallback entity is an entity that, for a particular contract period, meets all of the requirements to be a PDP sponsor except that it need not be a risk-bearing entity. In addition, in order to be a fallback entity, the entity may not submit a risk bid for offering a prescription drug plan for any PDP region (or serve as a subcontractor to an entity submitting such a bid) for the first year of the contract.

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7 *Id.* § 423.859(a).
8 *Id.*
9 70 Fed. Reg. at 4288.
10 *Id.* at 4314.
11 *Id.*
12 42 C.F.R. § 423.265(e).
13 *Id.*
14 *Id.* § 423.272(c)(1).
15 *Id.* § 423.272(c)(2)-(3).
16 *Id.* § 423.272(c)(2); 70 Fed. Reg. at 4295.
17 *Id.* § 423.859(b).
period. A fallback plan may provide either defined standard coverage or actuarially equivalent standard coverage, but not enhanced alternative coverage. CMS’s payments to fallback entities will consist of reimbursement for actual costs and management fees tied to performance measures established by CMS. The bidding process for administering fallback plans is separate from the bidding process for risk-based plans and will be provided in separate guidance.

A contract with a fallback entity will be in effect for three years. Submitting a bid to administer a fallback plan and/or administering a fallback plan will restrict a PDP sponsor’s ability to contract with CMS for a full risk or limited risk plan. First, if an entity submits a bid to administer a fallback plan for a particular PDP region, it may not submit a risk bid (or serve as a subcontractor to an entity submitting such a bid) that year in that or any other PDP region. Second, if an entity administers a fallback plan in a particular region, it may not offer a risk plan (or serve as a subcontractor) in that or any other region during the three years of its fallback contract. In the particular region in which it administered the fallback plan, the entity (or its subcontractor) also would be barred from offering a risk plan for an additional year after the fallback contract expires.

B. Coverage Structure

Types of Drug Coverage. CMS has defined two types of standard prescription drug coverage for purposes of Medicare Part D: “defined standard coverage” and “actuarially equivalent standard coverage.” “Defined standard coverage” is coverage that is subject to an annual deductible ($250 in 2006), 25% 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). A beneficiary who has reached this true out-of-pocket (“TrOOP”) threshold is responsible for cost-sharing equal to the greater of: (1) 5% coinsurance; or (2) $2 for a generic drug or a preferred multiple source drug and $5 for any other drug.

“Actuarially equivalent standard coverage” is standard prescription drug coverage that provides for cost-sharing that is either actuarially equivalent to an average expected coinsurance of no more than 25% of actual cost for initial coverage or, above the catastrophic coverage limit, actuarially equivalent

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18 Id. § 423.855.
19 Id.
20 70 Fed. Reg. at 4400.
21 42 C.F.R. § 423.863(a).
22 Id. § 423.871(b).
23 Id. § 423.504(b)(6)(i)(A).
24 Id. § 423.504(b)(6)(i)(B).
25 Id. § 423.504(b)(6)(i)(C).
26 Id. § 423.100.
27 Id. § 423.104(d).
28 Id. § 423.104(d)(5)(i).
to the expected cost-sharing that applies to catastrophic coverage under defined standard coverage plans.29

The MMA also allows plans to offer “alternative prescription drug coverage.” CMS has defined two forms of alternative coverage: “basic alternative coverage” and “enhanced alternative coverage.”30 “Basic alternative coverage” is coverage that is actuarially equivalent to defined standard coverage.31 In a basic alternative coverage design, a Part D sponsor could combine features such as a reduction in the deductible, changes in cost-sharing, and a modification of the initial coverage limit and still provide coverage with an actuarial value equal to that of the defined standard prescription drug coverage.32

“Enhanced alternative coverage” refers to alternative coverage that exceeds defined standard coverage by offering supplemental benefits.33 Supplemental benefits may include reductions in the annual deductible or cost-sharing, an increase in the initial coverage limit, or coverage of drugs excluded from the definition of Part D drugs.34 A PDP sponsor may not offer enhanced alternative coverage in a service area unless the sponsor also offers a plan in that area that provides basic prescription drug coverage.35

For the first three types of plans, CMS estimates that the average monthly Part D premium will be $37 in 2006, but the actual amount will vary by plan. Plans may charge an additional premium for enhanced alternative coverage.

1. Calculation of TrOOP. A payment for a prescription drug will constitute an “incurred cost” and count toward a beneficiary’s out-of-pocket expenditure threshold only if the payment is made by or on behalf of the beneficiary.36 If the beneficiary is reimbursed for the costs by insurance, a group health plan, or other third-party payment arrangement, the costs will not be “incurred” for the purposes of the TrOOP threshold.37 As discussed in greater detail below, assistance from a state pharmaceutical assistance program or from a patient assistance program sponsored by a pharmaceutical manufacturer generally will be considered an incurred cost that will count toward the beneficiary’s TrOOP threshold. Payments for drugs that are not included on the plan formulary (or not treated as if they were on the formulary as a result of a coverage determination, redetermination, appeal, or exception) also will not be counted toward the TrOOP threshold.38

29 Id. § 423.100.
30 Id.
31 Id.
33 42 C.F.R. § 423.100.
34 Id. § 423.104(f)(1)(ii).
35 Id. § 423.104(f)(2).
36 42 C.F.R. § 423.100.
37 Id.
38 70 Fed. Reg. at 4238.
2. **Low-Income Subsidies.** A beneficiary who is eligible for a full subsidy (i.e., lives in one of the 50 states or the District of Columbia, has income below 135% of the federal poverty level for the beneficiary’s family size and has limited assets) will receive a benefit package that is substantially more generous than the standard benefit package. In 2006, a beneficiary who is eligible for a full subsidy will have no deductible, no premium if he or she enrolls in a plan with a monthly premium at or below the low income premium subsidy amount, continuation of coverage beyond the initial coverage limit (i.e., no “donut hole”); co-payments of $2 for generics and preferred multiple source drugs and $5 for all other drugs, up to the out-of-pocket limit; and once the out-of-pocket limit is reached, no co-payment for all prescriptions. The government subsidy for cost-sharing counts toward the TrOOP limit.

If a beneficiary qualifies for the “other low income subsidy” (i.e., lives in one of the 50 states or the District of Columbia, has income between 135% and 150% of the federal poverty level for the beneficiary’s family size and has limited assets), he or she will receive the following benefit package in 2006: a sliding scale monthly premium, a $50 deductible; continuation of coverage beyond the initial coverage limit (i.e., no “donut hole”); co-insurance of 15% up to the out-of-pocket limit (the subsidy for cost-sharing counts toward the TrOOP); and once the out-of-pocket limit is reached, co-payments of $2 for generic drugs and preferred drugs that are multiple source drugs or $5 for any other drug.

3. **Enrollment of Dual-Eligible Individuals and Individuals Who Are Eligible for a Low-Income Subsidy.** In order to ensure that full-benefit dual eligibles (i.e., persons who are eligible for both Medicare and Medicaid) experience no gap in coverage, CMS will auto-enroll these individuals in PDPs no later than January 1, 2006. Full-benefit dual eligibles who become eligible for Medicare after January 1, 2006 will be enrolled as soon as their Medicare Part D eligibility is determined. Any full-benefit dual eligible, including one who has been

40. Id. § 423.782(a)(1).
41. Id. § 423.780(a)-(b).
42. Id. § 423.782(a)(2).
43. Id. § 423.782(a)(2)(i). A full benefit dual eligible individual with an income of under 100% of the federal poverty line and limited savings will have a reduced co-payment of $1 and $3. Id. § 423.782(a)(2)(iii). Institutionalized full benefit dual eligible individuals will have no co-payment. Id. § 423.782(a)(2)(ii).
44. Id. § 423.782(a)(3).
45. 70 Fed. Reg. at 4385.
46. 42 C.F.R. § 423.773(d).
47. Id. § 423.780(d).
48. Id. § 423.782(b); 70 Fed. Reg. at 4385.
49. 42 C.F.R. § 423.34(f)(1).
50. Id. § 423.34(f)(2).
automatically enrolled by CMS, retains the right to change Part D plans at any time or to decline participation in the Part D program.\textsuperscript{51}

CMS will soon be issuing operational guidance that will include details of its plans to facilitate the enrollment in a Part D plan of all individuals who are eligible for a low-income subsidy.\textsuperscript{52}

**Pharmacy Access.** A Part D plan must have a contracted pharmacy network consisting of retail pharmacies.\textsuperscript{53} At least 90\% of beneficiaries must live within 2 miles of a network retail pharmacy in urban areas and within 5 miles of a network retail pharmacy in suburban areas, and at least 70\% of beneficiaries must live within 15 miles of a network retail pharmacy in rural areas.\textsuperscript{54} Compliance with these pharmacy access requirements will be determined on a statewide basis, even if the PDP or MA-PD region is larger than a state.\textsuperscript{55} The network must provide adequate access to home infusion pharmacies.\textsuperscript{56} A plan's pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering delivery via mail-order and institutional pharmacies.\textsuperscript{57} The pharmacy access requirements are waived for MA-PD plans or cost plans that provide beneficiaries with access to drugs through in-house pharmacies.\textsuperscript{58}

Under the MMA’s “any willing pharmacy” requirement, a plan must contract with any pharmacy that meets the plan's standard terms and conditions. A plan may not require a pharmacy to accept insurance risk as a condition of participation.\textsuperscript{59} Even though 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), the plan may negotiate different terms with specific pharmacies. A plan may 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.\textsuperscript{60}

A plan must offer standard contracting terms and conditions to all long-term care pharmacies and all pharmacies operated by Indian tribes in its service area and must provide convenient access to such pharmacies.\textsuperscript{61}

A Part D plan also must ensure that beneficiaries have adequate access to covered drugs dispensed at out-of-network pharmacies when a beneficiary cannot reasonably be expected to obtain such drugs

\textsuperscript{51} Id. § 423.34(e), § 423.38(c)(4).
\textsuperscript{52} 70 Fed. Reg. at 4209.
\textsuperscript{53} 42 C.F.R. § 423.120(a)(1).
\textsuperscript{54} Id.
\textsuperscript{55} Id.
\textsuperscript{56} Id. § 423.120(a)(4).
\textsuperscript{57} Id. § 423.120(a)(3).
\textsuperscript{58} Id. § 423.120(a)(7).
\textsuperscript{59} Id. § 423.120(a)(8).
\textsuperscript{60} Id. § 423.120(a)(9).
\textsuperscript{61} Id. § 423.120(5)-(6).
at a network pharmacy and does not access covered drugs at an out-of-network pharmacy on a routine basis.\textsuperscript{62} The plan may require a beneficiary to assume financial responsibility for the difference between the out-of-network pharmacy's usual and customary price and the Part D sponsor's plan allowance.\textsuperscript{63} The plan must establish rules to limit out-of-network access to covered Part D drugs.\textsuperscript{64} For example, a plan may limit the amount of covered Part D drugs dispensed at out-of-network pharmacies or require a plan notification or authorization process for beneficiaries who fill their prescriptions at out-of-network pharmacies.\textsuperscript{65}

**Public Disclosure of Pharmaceutical Prices for Generic Alternatives.** A Part D plan must require pharmacies that dispense a covered Part D drug to inform the beneficiary of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy.\textsuperscript{66} Disclosure of this information is not necessary if the drug is the lowest-priced therapeutically equivalent and bioequivalent version of the drug available at that pharmacy.\textsuperscript{67} CMS has waived the disclosure requirement in certain situations, such as when covered drugs are dispensed by out-of-network pharmacies.\textsuperscript{68}

**Late Enrollment Penalty.** A Medicare beneficiary's enrollment in Part D prescription drug coverage is voluntary. To prevent adverse selection and preserve the actuarial soundness of the program, however, a beneficiary who does not enroll within 63 days after the end of his/her initial period of eligibility will pay a financial penalty in the form of higher monthly Part D premiums.\textsuperscript{69}

For 2006 and 2007, CMS has set the late enrollment penalty at one percent of the base beneficiary premium for each month in which the beneficiary was uncovered, but may revisit the issue when appropriate data becomes available.\textsuperscript{70} Beneficiaries will receive a waiver of the late enrollment penalty only if they can convince CMS that they had not been adequately informed that their prescription drug coverage was not creditable prescription drug coverage, as discussed in more detail below.\textsuperscript{71} CMS, however, has agreed to a review process for individuals who are penalized under this provision and will issue further guidance on this topic.\textsuperscript{72}

\begin{itemize}
  \item \textsuperscript{62} Id. § 423.124(a)(1).
  \item \textsuperscript{63} Id. § 423.124(b).
  \item \textsuperscript{64} Id. § 423.124(c).
  \item \textsuperscript{65} 70 Fed. Reg. at 4268.
  \item \textsuperscript{66} 42 C.F.R. § 423.132(a).
  \item \textsuperscript{67} Id.
  \item \textsuperscript{68} Id. § 423.132(c).
  \item \textsuperscript{69} 42 C.F.R. §§ 423.46 and 423.286(d)(3).
  \item \textsuperscript{70} Id. § 423.286(d)(3)(i)(B)(ii).
  \item \textsuperscript{71} 70 Fed. Reg. at 4217.
  \item \textsuperscript{72} Id.
\end{itemize}
Negotiated Prices, Formularies and Utilization Management

A. Definition of “Part D Drugs”

Under the final rule, the term “Part D drugs” refers to the full universe of drugs that meet the standards for coverage described below.\(^\text{73}\) A “covered Part D drug” is a drug within this universe that is either included in a Part D plan’s formulary or that a plan has determined to cover for the beneficiary as a result of a beneficiary appeal, despite the drug’s non-formulary status.\(^\text{74}\)

To meet the standards for coverage, a 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.\(^\text{75}\) A medically accepted indication is any use that is FDA approved or that is supported by citations in specified medical compendia.\(^\text{76}\) Part D drugs thus include prescription drugs, biologics, insulin (and medical supplies associated with the injection of insulin) and vaccines. The MMA and the final rule specifically exclude, however, products that may be excluded under Medicaid (except for smoking cessation products that otherwise meet the standards).\(^\text{77}\) Weight loss agents, fertility agents, and certain hair growth agents, for example, are excluded from coverage.\(^\text{78}\) In addition, if payment for a drug is available to a beneficiary under Medicare Part A or B, the drug is excluded from the beneficiary’s coverage under Part D.\(^\text{79}\)

The final rule confirms the policy that only prescription drugs may be Part D drugs.\(^\text{80}\) While the rule does not explicitly address whether a Part D plan could pay for certain over-the-counter medications and include such costs in the administrative expenses that are built into its premium structure -- a concept supported in previous oral comments by a CMS official -- the final rule appears to preclude this strategy.

B. Negotiated Prices and Pass-Through

A Part D plan must provide beneficiaries access to negotiated prices for covered Part D drugs.\(^\text{81}\) Negotiated prices for covered drugs must “take into account” price concessions that the plan obtains from drug manufacturers and pharmacies, including discounts, direct or indirect subsidies, rebates, and direct or indirect remuneration. Negotiated prices must also incorporate dispensing fees associated with transferring the covered Part D drug from the pharmacy to the beneficiary, including fees relating to mixing drugs, drug delivery, and overhead. The negotiated price applies even when the beneficiary is not otherwise eligible for benefits due to the deductible or the donut hole gap in coverage.

\(^\text{73}\) 42 C.F.R. § 423.100.
\(^\text{74}\) Id.
\(^\text{75}\) 70 Fed. Reg. at 4228.
\(^\text{76}\) Id. at 4228-29.
\(^\text{77}\) 42 C.F.R. § 423.100.
\(^\text{78}\) 70 Fed. Reg. at 4228.
\(^\text{79}\) 42 C.F.R. § 423.100.
\(^\text{80}\) Id.
\(^\text{81}\) 42 C.F.R. § 423.104(g)(1).
Price concessions by manufacturers for covered Part D drugs are statutorily excluded from “best price” determinations under the Medicaid drug rebate program. The exemption from “best price” will apply regardless of whether the covered Part D drug is provided under a Part D plan or under an employer- or union-sponsored plan that is eligible for the Medicare retiree drug subsidy.

A risk-bearing plan is required to pass through some, but not all, of the price concessions obtained from pharmaceutical manufacturers and pharmacies, and thus has considerable discretion in determining pass-through levels. CMS believes that market competition will ensure that plans pass through a high percentage of negotiated price concessions to beneficiaries and the Medicare program. In the preamble to the final rule, CMS explains that establishing a minimum pass-through threshold could undermine the beneficial effects of market competition, since plans “might cluster their negotiated prices around that threshold.” In contrast to risk-bearing plans, CMS requires that fallback plans pass through all price concessions.

C. Disclosure of Prices and Concessions to CMS

A Part D plan must disclose to CMS all data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, including the portion that is passed through to the Medicare program or to beneficiaries in the form of lower subsidy payments, lower monthly premiums, or lower covered drug prices at the point of sale. This disclosure of negotiated price concessions is protected under the confidentiality provisions of the Social Security Act applicable to Medicaid pricing data. Under these confidentiality provisions, however, CMS or the Office of the Inspector General for the Department of Health and Human Services may conduct periodic audits of the financial records of a plan pertaining to prescription drug coverage offered under a Part D plan. The goals of such audits include protecting the Medicare program against fraud and abuse and ensuring proper disclosure and accounting under the Part D program. CMS intends to provide further information on negotiated price concession reporting in a separate guidance.

CMS believes that the agency must know the final drug price levels implicit in plan bids in order to evaluate the bids submitted by potential plan sponsors. In evaluating bids, CMS is required to use the Federal Employees Health Benefits Program (“FEHBP”) standard that the plan bid “reasonably and equitably reflects the costs of benefits provided.” If a plan’s data differ drastically from that of its peers without any apparent justification, CMS will require the bidder to provide, in addition to aggregate pricing data, information about rebates and discounts it has received from manufacturers and other entities. CMS states that such a review will ensure that plan sponsors are negotiating “as vigorously as possible.”

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82 Id. § 423.104(g)(2).
83 70 Fed. Reg. at 4244.
84 Id.
85 42 C.F.R. § 423.104(g)(3)(i).
86 Id. § 423.104(g)(3)(ii), citing Social Security Act § 1927(b)(3)(D).
87 Id. § 423.104(g)(4).
89 Id.
CMS believes that it can request information about rebates and discounts without violating the non-interference provision of the MMA. That provision prohibits CMS from intervening in negotiations among pharmacies, manufacturers, and plan sponsors, or from requiring a particular formulary or pricing structure. CMS asserts that the statutory provision prohibits the agency from setting a regulated price for any particular drug or from requiring an average discount in the aggregate on any group of drugs, but allows the agency to require justification of aggregate price levels and to negotiate the levels of the overall bids.

CMS will require reporting of aggregate rebates at the product level on a quarterly basis. This is a change from the requirement in the proposed rule for the reporting of average percentage rebates, which CMS has concluded “would represent only a rough estimate on the part of a Part D plan.” This data will assist CMS in calculating the “allowable costs” paid by the plan sponsor, which are necessary to the calculation of the payments for reinsurance and risk corridor purposes. To determine the “allowable costs,” CMS will count only the costs actually incurred by the plan sponsor (excluding administrative costs but including dispensing fees), net of any direct or indirect remuneration, including discounts, chargebacks, rebates, or other price concessions.

In the preamble to the final rule, CMS clarifies that the agency “will expect reporting of all rebate dollars with no allowance for separate administration fees in order to prevent inaccuracies in reporting.” Furthermore, CMS explains that the agency has the responsibility “to ensure that price concessions are not masked as administrative fees,” and notes that to the extent that an administrative fee paid to a Part D plan is above the fair market value of the services rendered, or that an administrative fee paid by a Part D plan to a manufacturer or other entity is below the fair market value of the services rendered, the differential must be considered a price concession.

D. Plan Formulary Requirements and CMS Review

A Part D plan must include two or more chemically distinct drugs in all therapeutic categories and classes of its formulary, making different strengths and dosage forms available for each of those drugs, unless only one drug is appropriate for a particular category. However, if a plan demonstrates to CMS’s satisfaction that only two drugs are available in a particular category or class and that one of those drugs is clinically superior to the other, the plan may include only one Part D drug in that category or class. The two-drug requirement is intended to provide plans with leverage to negotiate with manufacturers while ensuring sufficient choices for plan beneficiaries.

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90 Id. at 4300-4301, citing Social Security Act § 1860D-11(i).
91 Id. at 4300.
92 Id. at 4308.
93 42 C.F.R. § 423.308; 70 Fed Reg. at 4308.
94 Id.
95 70 Fed. Reg. at 4308-4309.
97 42 C.F.R. § 423.120(b)(2)(ii).
A Part D plan cannot change therapeutic categories and classes in a formulary other than at the beginning of a Part D plan year, except as permitted to take into account new therapeutic uses and newly approved Part D drugs.\textsuperscript{98} A plan sponsor will periodically be required to evaluate and analyze treatment protocols and procedures related to its formulary to ensure that beneficiaries are receiving the best possible care for conditions related to their use of covered Part D drugs.

A Part D plan must provide 60 days' notice to CMS, state pharmacy assistance programs, entities providing other prescription drug coverage, authorized prescribers, pharmacists, and network pharmacies regarding any decision to remove a drug from the plan formulary or to make any change in the preferred or tiered cost-sharing status of a drug.\textsuperscript{99} A plan also must provide affected beneficiaries with direct written notice 60 days prior to the date the change is to become effective, or provide a 60-day supply with written notice at the time the affected beneficiary requests a refill of the drug.\textsuperscript{100} A plan may not remove a drug from its formulary or make any changes in the preferred or tiered status of a drug between the beginning of the annual coordinated election period and for 60 days after the beginning of the contract year associated with that election period.\textsuperscript{101} Drugs pulled from the market by FDA or the manufacturer may be removed from the formulary immediately. A pharmaceutical and therapeutics committee (discussed below) must review new Part D drugs, or drugs for which new clinical information is made available by FDA, within 90 days of the availability of the information.\textsuperscript{102}

The model formulary guidelines developed by USP will serve as a starting point for CMS to review the Part D benefit structure. CMS will require plans to include the types of drugs most commonly needed by Part D beneficiaries, as recognized in widely-accepted treatment guidelines.\textsuperscript{103} Regardless of whether a plan uses the model guidelines, CMS will review the plan's benefit design to ensure that it does not discourage enrollment by certain classes of Part D-eligible individuals. If the design of the categories and classes within a formulary is consistent with the model guidelines, the formulary categories and classes alone will not be found to discourage enrollment.\textsuperscript{104} However, such a plan may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary. The plan review will focus on plan features such as utilization management processes, pharmaceutical and therapeutics committee utilization and structure, and exceptions and appeals processes.\textsuperscript{105}

A plan will be expected to accommodate national guidelines and offer complete treatment options for a variety of medical conditions, including (but not limited to) asthma, diabetes, depression, lipid disorders, hypertension, and HIV.\textsuperscript{106} This is necessary in order to ensure that a Part D plan does not substantially discourage enrollment by certain Part D-eligible individuals by excluding certain classes of drugs from its formulary. To determine whether a plan provides an “adequate benefit,” CMS will

\textsuperscript{98} Id. § 423.120(b)(4).
\textsuperscript{99} Id. § 423.120(b)(5)(i).
\textsuperscript{100} Id. § 423.120(b)(5)(i)(A)-(B).
\textsuperscript{101} Id. § 423.120(b)(6).
\textsuperscript{102} 70 Fed. Reg. at 4258.
\textsuperscript{103} Id. at 4260.
\textsuperscript{104} Id. at 4259.
\textsuperscript{105} Id.
\textsuperscript{106} Id. at 4260.
consider not only the drugs included on the formulary, but also the plan benefit design features described above.

E. Off-Label Use

CMS recognizes that off-label use is critically important and may be the mainstay of medical practice for managing certain conditions, such as mental illnesses, chronic pain, chronic heart failure, arthritis, Parkinson’s, HIV/AIDS, and dementia. The USP model guidelines do not require plans to create classes of drugs for which there is no drug with a FDA-approved label indication, even if FDA-approved drugs with commonly accepted off-label uses would fall within the class.

CMS states in the preamble to the final rule that formularies do not preclude physicians from prescribing a drug for an off-label indication, provided the prescribed use is medically accepted. Further, the USP model guidelines would not preclude a plan from assigning an FDA-approved drug to a category or class based on an off-label use of that drug (provided that FDA has not declared the drug unsafe for that use). CMS received many comments expressing the concern that physicians would be required to document and justify off-label use, which could prevent patient access to medically necessary therapies. In response to these comments, CMS clarifies that prescribers are “strongly encouraged” to document and justify off-label use, but that this statement should not be interpreted as imposing new and onerous reporting requirements on prescribers. In fact, CMS notes that onerous documentation requirements for off-label uses could be cause for finding that a plan’s proposed benefit structure does not meet the Part D benefit requirements.

CMS states that it does not have the authority to require plans to cover off-label uses. However, CMS believes that its evaluation of plan design for non-discrimination will help ensure access to medically appropriate off-label uses.

F. P&T Committees

To the extent that a Part D plan uses a formulary to provide qualified prescription drug coverage, it will be required to use a pharmaceutical and therapeutic (“P&T”) committee to develop that formulary. The majority of members of the P&T committee must be practicing physicians or practicing pharmacists. At least one practicing physician member and one practicing pharmacist member must be experts in the care of elderly or disabled individuals.

\begin{itemize}
\item \textsuperscript{107} Id.
\item \textsuperscript{108} Id.
\item \textsuperscript{109} Id. at 4261.
\item \textsuperscript{110} Id.
\item \textsuperscript{111} Id.
\item \textsuperscript{112} Id.
\item \textsuperscript{113} 42 C.F.R. § 423.120(b)(1).
\item \textsuperscript{114} Id. § 423.120(b)(1)(i).
\item \textsuperscript{115} Id. § 423.120(b)(1)(iii).
\end{itemize}
At least one practicing physician and one practicing pharmacist on the P&T committee must be “independent and free of conflict.”\textsuperscript{116} The “independent and free of conflict” committee members can have no stake, financial or otherwise, in formulary determinations. A committee member is not free of conflict if the member has any direct or indirect interest in any entity, including the plan or a drug manufacturer, that would benefit from a formulary decision.\textsuperscript{117}

Each P&T committee member must sign a conflict-of-interest statement revealing economic or other relationships that could affect pharmaceutical decisions.\textsuperscript{118} Conflicts must be disclosed to other committee members. CMS states that a plan should implement disclosure and conflict-of-interest requirements consistent with standard practices of the pharmacy benefit management industry.

The primary function of the P&T committee is to provide expertise on clinical issues. Committee recommendations regarding the inclusion of drugs on the plan’s formulary will be binding on the Part D plan. A P&T committee is required to base clinical decisions on the strength of scientific evidence and standards of practice.\textsuperscript{119} This includes, but is not limited to, assessing peer-reviewed medical literature, pharmacoeconomic studies, and outcomes research data.\textsuperscript{120}

The committee must consider whether a particular Part D drug on the formulary or a formulary tier has any therapeutic advantages in terms of safety and effectiveness.\textsuperscript{121} Where applicable, the committee should consider therapeutic advantage in relation to the interaction of a drug therapy regimen and the use of other health care services.\textsuperscript{122} Generally, a Part D plan should consider total health care costs, rather than only drug costs, in making its decisions.\textsuperscript{123} CMS will issue further guidance on cost considerations and evidence-based decision-making.

CMS expects that the committee will have an advisory role in reviewing policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.\textsuperscript{124} The P&T committee must have a role in evaluating treatment protocols and procedures, including tiering, related to the Part D plan’s formulary at least annually.\textsuperscript{125} The committee must document in writing its decisions regarding formulary development and revision and utilization management activities.\textsuperscript{126} However, committee recommendations in this area are only advisory; the ultimate decision on plan design issues that incorporate clinical and non-clinical factors will reside with the Part D plan.

\begin{thebibliography}{99}
\bibitem{116} Id. § 423.120(b)(1)(ii).
\bibitem{117} Id. § 423.120(b)(1)(i)(A)-(B); 70 Fed. Reg. at 4256.
\bibitem{118} 70 Fed. Reg. at 4256.
\bibitem{119} 42 C.F.R. § 423.120(b)(1)(iv).
\bibitem{120} Id. § 423.120(b)(1)(iv).
\bibitem{121} Id. § 423.120(b)(1)(v).
\bibitem{122} 70 Fed. Reg. at 4257.
\bibitem{123} Id.
\bibitem{124} 42 C.F.R. § 423.120(b)(1)(vi).
\bibitem{125} Id. § 423.120(b)(1)(vii).
\bibitem{126} Id. § 423.120(b)(1)(viii).
\end{thebibliography}
G. Medication Therapy Management Programs

Each Part D plan must establish a medication therapy management program (“MTMP”) to optimize therapeutic outcomes for targeted beneficiaries.\(^\text{127}\) Targeted beneficiaries are defined as plan beneficiaries who have multiple chronic diseases, are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a level determined by CMS.\(^\text{128}\) Under the final rule, targeted beneficiaries will be identified according to policies adopted by each individual plan.\(^\text{129}\) Although CMS has concluded that it does not have the authority to delegate the cost threshold determination to the plans, it declines to set the amount in this rulemaking and will address the issue in a separate guidance.\(^\text{130}\) Factors that CMS will consider in setting the threshold include typical costs associated with the most common chronic diseases and co-morbidities for Medicare beneficiaries, the relationship between cost and the number of medications a beneficiary is taking, the impact specific cost thresholds have on the size of the target population, and the alignment of incentives for providing MTMP services within the standard part D benefit structure.

A MTMP may include education and counseling programs, medication regimen compliance measures, and patient status assessments. The programs must be developed in coordination with licensed and practicing pharmacists and physicians; must be designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries; and must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (“CCIP”) under the MMA.\(^\text{131}\) Beneficiaries will not be required to pay cost-sharing or other fees for MTMP services because CMS considers MTMPs to be administrative activities incident to appropriate drug therapy.

CMS received many comments on MTMP standards and requested a literature review by Booz Allen Hamilton. However, the agency has decided not to adopt further specifications for MTMPs beyond what had been included in the proposed rule. At this time, CMS believes it is best to maintain a flexible approach to MTMP requirements because widely accepted standards of practice in this area do not exist.\(^\text{132}\) The final rule includes a reporting requirement regarding MTMPs; CMS will specify the required information in a separate guidance.

H. Coordination Between Part D and Part B

The statutory definition of “covered Part D drug” excludes any drug for which, as dispensed and administered to a beneficiary, payment would be available under Part A or B of Medicare for that beneficiary, even though a deductible may apply. Under this definition, some drugs could qualify for

\(^{127}\) Id. § 423.153(d)(1).

\(^{128}\) Id. § 423.153(d)(2).

\(^{129}\) 70 Fed. Reg. at 4280.

\(^{130}\) Id. at 4282.

\(^{131}\) 42 C.F.R. § 423.153(d).

\(^{132}\) 70 Fed. Reg. at 4281.
payment under Part B in some circumstances and Part D in others.\textsuperscript{133} The MMA requires CMS to issue a report on the issues raised by drugs covered under Part B for the administration of Part D.\textsuperscript{134}

In the proposed rule, CMS solicited comments concerning any drugs that may require special guidance with regard to their coverage under Part D, and any gaps that may exist in the combined "Part D and B" coverage package. In the final rule, CMS concludes that a Part D plan can best wrap around existing Part B coverage by understanding the scope of the definition of a covered Part D drug, becoming familiar with the general categories of Part B covered drugs, and planning for potential Part B interactions that are likely to be encountered in specific settings with regard to some of these categories.\textsuperscript{135}

The implementation of the Part D benefit does not alter coverage or associated rules for drugs under Part B. CMS believes that in most settings, the question of whether coverage should be provided under Part B or Part D will not arise since most Part B drugs are provided in the context of a service or procedure. CMS notes that for a limited number of categories, however, pharmacists and infusion providers will have to determine whether to bill Part B or Part D, and a Part D plan will need to confirm whether Part D is being billed correctly.

CMS explains that in some cases, the Part B or Part D determination can be made on the basis of the drug. For example, there is a list of oral anti-cancer drugs meeting the statutory criteria for coverage under Part B. All other oral anti-cancer drugs will be covered under Part D, provided they otherwise meet the definition of a Part D drug.\textsuperscript{136}

In other cases, such as with drugs used in immunosuppressive therapy, the pharmacist or infusion provider will need information about the beneficiary in order to determine whether to bill Part B or Part D. The final rule requires Part B to be billed if the beneficiary's transplant was covered by Medicare, but payment would be made under Part D in all other instances.\textsuperscript{137} CMS will provide more information on the relation between Part B and Part D coverage in a separate guidance.\textsuperscript{138}

CMS believes that a plan could implement utilization management strategies to identify potential Part B drug coverage overlap for individuals and verify appropriate coverage. For example, if a beneficiary were filling a retail prescription for an antiemetic, the plan could require prior authorization to ensure that the drug would not be covered by Part B.\textsuperscript{139} Prior authorization also could be used to flag drugs dispensed via home infusion that are covered under the Part B durable medical equipment policy.\textsuperscript{140}

\textsuperscript{133} Id. at 4232.

\textsuperscript{134} The Report is mandated by section 1860D-42(c) of the Act.

\textsuperscript{135} 70 Fed. Reg. at 4233.

\textsuperscript{136} Id.

\textsuperscript{137} Id.

\textsuperscript{138} Id.

\textsuperscript{139} Id.

\textsuperscript{140} Id.
Grievances, Coverage Determinations, and Appeals

A. Grievance Procedures

A Part D plan must establish procedures to ensure that beneficiary grievances are heard and resolved in a timely manner.\textsuperscript{141} Grievance procedures are distinct from appeals procedures, which address coverage determinations, and from the quality improvement organization complaint process.\textsuperscript{142} The same grievance procedures that are applicable under the MA regulations are applicable under Part D.\textsuperscript{143}

A plan must notify a beneficiary who has filed a grievance of its decision as expeditiously as the case requires, but no later than 30 days after the date the grievance was filed.\textsuperscript{144} If certain prerequisites are met, the plan may extend the 30-day time frame by up to 14 days.\textsuperscript{145} If the grievance involves the plan’s refusal to grant a beneficiary’s request for an expedited coverage determination or redetermination and the beneficiary has not yet received the drug in dispute, the plan must respond to the grievance within 24 hours.\textsuperscript{146}

B. Coverage Determinations

A Part D plan must establish procedures for making coverage determinations and redeterminations.\textsuperscript{147} A plan makes a coverage determination when it makes a decision not to provide or pay for a Part D drug, fails to make a coverage determination in a timely manner, makes a decision concerning an exception request, or makes a decision regarding the amount of cost-sharing for a drug.\textsuperscript{148} The coverage determination and redetermination requirements for Part D plans are essentially the same as those for the MA program.\textsuperscript{149} The primary structural difference between the Part D requirements and the MA rules is that, in Part D, a beneficiary may request exceptions to a plan’s formulary and tiered cost-sharing structure.\textsuperscript{150} Adjudication timeframes also are shorter under Part D than under MA.\textsuperscript{151}

A plan will have 24 hours to make an expedited coverage determination (including exception request) and 72 hours to make an expedited redetermination.\textsuperscript{152} Expedited procedures apply in situations where the beneficiary’s life, health, or ability to regain maximum function could be seriously jeopardized.

\begin{footnotesize}
\begin{enumerate}
\item[141] 42 C.F.R. § 423.562(a)(1).
\item[142] Id. § 423.564(b)-(c).
\item[143] 70 Fed. Reg. at 4344.
\item[144] 42 C.F.R. § 423.564(e)(1).
\item[145] Id. § 423.564(e)(2).
\item[146] Id. § 423.564(f).
\item[147] Id. §§ 423.566(a), and 423.582.
\item[148] Id. § 423.566(b).
\item[149] 70 Fed. Reg. at 4344-4346.
\item[150] Id. 4346.
\item[151] Id. 4346-4347.
\item[152] 42 C.F.R. §§ 423.572, and 423.590(d).
\end{enumerate}
\end{footnotesize}
if the determination is made within the standard timeframe.¹⁵³ For standard requests, a plan will have up to 72 hours to make a coverage determination (including acting on an exception request) and no more than 7 days for a standard redetermination.¹⁵⁴

C. Exceptions

As noted above, decisions regarding requests for tiering and formulary exceptions are types of coverage determinations. A Part D plan must establish a process for granting exceptions to the formulary and to the tiers in the formulary and must obtain CMS approval of these procedures.¹⁵⁵ A plan must grant an exception if it determines that the drug is medically necessary to treat the beneficiary’s condition (i.e. the preferred drug would not be as effective for the patient as a non-preferred drug, would have adverse effects for the individual, or both) and, for a request for a formulary exception, if it determines that the drug would be covered but for the fact that it is an off-formulary drug.¹⁵⁶ A beneficiary can apply for an exception only if, at minimum, his or her physician determines that a preferred drug would not be as effective for the beneficiary as a non-preferred drug, would have adverse effects for the beneficiary, or both.¹⁵⁷ The plan may require the physician to certify this determination in writing.¹⁵⁸

The final rule includes provisions to protect beneficiaries in certain circumstances. Once a plan approves an exception, for instance, the beneficiary is entitled to refills of the drug as long as the physician prescribes it, the drug is safe and effective for the beneficiary’s condition, and the beneficiary’s enrollment period has not expired.¹⁵⁹ Furthermore, a plan may not assign drugs covered under an exception to a special formulary tier, co-payment, or other cost-sharing requirement.¹⁶⁰

Exceptions to Formulary. A Part D plan must allow plan beneficiaries, their authorized representatives, and physicians to request coverage of Part D drugs not on the formulary, continued coverage of drugs that the plan has removed from its formulary, and exceptions to step therapy requirements and dosing limitations.¹⁶¹ The plan must describe the criteria that it will use to evaluate the physician’s determination of medical necessity, 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.¹⁶²

Exceptions to Tiering. A plan must consider many of the same criteria that apply to exceptions to the formulary when considering exceptions to tier structure.¹⁶³ If a plan establishes a formulary tier for very

¹⁵³ Id. § 423.570(c)(3)(i)-(ii).
¹⁵⁴ Id. §§ 423.590(a)-(b), and 423.568(a)-(b).
¹⁵⁵ Id. § 423.578.
¹⁵⁶ Id. § 423.578(a)-(b).
¹⁵⁷ Id. § 423.578.
¹⁵⁸ Id.
¹⁵⁹ Id. § 423.578(c)(3)-(4).
¹⁶⁰ Id. § 423.578(c)(4).
¹⁶¹ Id. § 423.578.
¹⁶² Id. § 423.578(b).
¹⁶³ Id. § 423.578.
high cost and unique items, the plan may design its exception process so that drugs on this tier are not eligible for a tiering exception.\textsuperscript{164} When a request for a tiering exception is approved, the beneficiary is entitled to the amount of cost-sharing that applies for a preferred drug, but not for a generic drug if the plan maintains a separate tier dedicated to generic drugs.\textsuperscript{165}

\textbf{D. Appeals}

Only adverse coverage determinations are subject to the appeals process. A beneficiary can request redeterminations of unfavorable coverage determinations.\textsuperscript{166} The final rule imposes specific requirements regarding request handling, timeframes for responding to requests, and follow-up.\textsuperscript{167}

If the Part D plan’s redetermination affirms its original decision, the beneficiary then may request reconsideration by an independent review entity (“IRE”).\textsuperscript{168} The only time a plan must automatically forward a beneficiary’s request to the IRE is when the plan fails to meet the adjudicatory timeframe for the request in question.\textsuperscript{169}

When making its decision, the IRE will review the record de novo using the plan’s exceptions criteria, and will make an independent medical necessity determination.\textsuperscript{170} The IRE, however, has no authority to rule on the validity of a plan’s formulary or exceptions criteria.\textsuperscript{171} The IRE finding will be binding on all parties unless the beneficiary requests a hearing by an administrative law judge (“ALJ”).\textsuperscript{172}

A beneficiary may appeal an adverse ALJ decision to the Medicare Appeals Council (“MAC”), and may appeal an adverse MAC decision to federal court.\textsuperscript{173}

\textbf{Employer Provisions}

\textbf{A. Employer Cost-Saving Options}

Employers that provide prescription drug benefits to Medicare-eligible retirees will have opportunities to realize savings by coordinating employer-provided drug benefits with the Part D benefit. The final rule includes the following cost-saving options.

\begin{itemize}
  \item \textsuperscript{164} Id. § 423.578(a)(7).
  \item \textsuperscript{165} Id. § 423.578(a)(6).
  \item \textsuperscript{166} Id. § 423.580.
  \item \textsuperscript{167} Id. §§ 423.580-.590.
  \item \textsuperscript{168} Id. § 423.600(a).
  \item \textsuperscript{169} Id. §§ 423.568, 423.572, and 423.590.
  \item \textsuperscript{170} 70 Fed. Reg. at 4359. As stated above, plans’ exception procedures must include measures to grant an exception when the plan determines that an exception will be medically appropriate. Because a plan determination of medical necessity is subject to review by the IRE, the IRE must also review whether the drug is medically necessary. \textit{See id.}
  \item \textsuperscript{171} Id.
  \item \textsuperscript{172} 42 C.F.R. § 423.604.
  \item \textsuperscript{173} Id. §§ 423.620, and 423.630.
\end{itemize}
Provide Retiree Drug Coverage and Receive a Direct Subsidy. An employer who offers primary prescription drug coverage to Medicare-eligible retirees (and their Medicare-eligible spouses and dependents) who do not enroll in Part D can receive a tax-free subsidy directly from CMS for these individuals. The subsidy equals 28% of the plan's allowable drug expenses (including amounts paid by the retiree) between annual dollar limits ($250 and $5,000 in 2006).\textsuperscript{174}

Sponsor a PDP. An employer can sponsor a PDP if the employer meets the qualification standards either on its own or with a business partner.\textsuperscript{175} Like other PDPs and MA-PD plans, an employer-sponsored PDP will receive Part D premium subsidies from CMS, as well as reinsurance subsidies for retirees who reach the catastrophic coverage limit. Although PDPs ordinarily are required to accept all Part D-eligible individuals in a region, an employer can apply to CMS for a waiver that will permit the employer to limit enrollment in its PDP to the employer's own Medicare-eligible retirees (and their Medicare-eligible spouses and dependents).\textsuperscript{176} The preamble to the final rule indicates that CMS intends to adopt a streamlined approach for implementing employer group waivers that allows maximum flexibility for employers to retain retiree prescription drug coverage.\textsuperscript{177}

Provide Supplemental "Wrap-Around" Coverage. An employer can provide secondary prescription drug coverage that "wraps around" Part D coverage for its retirees who enroll in Part D.\textsuperscript{178} Secondary payments will not qualify for the 28% direct employer subsidy, and any benefits the employer's plan pays will not count toward the retiree's TrOOP threshold.\textsuperscript{179}

Contract with a PDP or MA-PD. An employer can contract with PDPs or MA-PD plans established by an independent organization to provide Part D drug benefits in regions with concentrated numbers of the employer's eligible retirees.

Pay Retirees' Part D Premiums. Instead of (or in addition to) contracting with a Part D plan or providing "wrap-around" secondary coverage, an employer may pay all or part of the Part D premium for the employer's Medicare-eligible retirees.

\subsection*{B. Key Administrative Requirements for Employers}

An employer who provides retiree drug coverage will be subject to new recordkeeping and reporting requirements beginning in 2006. Below is a discussion of the administrative requirements of most interest to industry clients associated with: (1) receiving the 28% direct subsidy; (2) providing secondary "wrap-around" coverage; and (3) providing notice of creditable coverage (which is required of all employers who provide retiree drug coverage).

\textsuperscript{174} \textit{Id.} § 423.886.

\textsuperscript{175} 42 C.F.R. § 423.454.

\textsuperscript{176} \textit{Id.} § 423.581(c).

\textsuperscript{177} 70 Fed. Reg. at 4323.

\textsuperscript{178} 42 C.F.R. § 423.464(f)(1).

\textsuperscript{179} \textit{Id.} § 423.464(f)(2).
Administrative Requirements for the 28% Direct Subsidy.

1. **Determining Actuarial Equivalence.** In order to qualify for the 28% direct employer subsidy, an employer's drug plan must be "actuarially equivalent" to the Part D standard benefit package. The final rule includes a two-part test to determine whether actuarial equivalence has been met:

   - **Gross Value Test:** The first prong of the test is satisfied if the expected gross value of the plan's benefit payout (without regard to the source of funding) is at least equal to the expected payout for the same beneficiaries under the Part D standard benefit package.\(^{180}\)

   - **Net Value Test:** The second prong of the test measures the value of the plan's benefit payment financed solely by the employer. The net value of the employer's retiree plan must be at least equal to the net value of the Part D standard drug benefit.\(^{181}\)

The final rule provides employers with some flexibility in applying the actuarial equivalence test. For example, the final rule allows an employer to choose whether to apply the net value prong of the actuarial equivalence test for each benefit option within a group health plan that satisfies the gross value test or to apply this prong for all benefit options within a group health plan that satisfy the gross value test.\(^{182}\) In addition, an employer who is offering retirees medical and drug benefits as an integrated package is afforded maximum flexibility in allocating the premium between the medical and drug benefits.\(^{183}\)

2. **Calculating Retiree Drug Subsidy Amounts.** To determine the amount of the subsidy payment for a plan year, the employer must first determine the amount of gross retiree costs between annual dollar limits ($250 and $5,000 for 2006), and then determine allowable retiree costs attributable to the gross retiree costs.\(^{184}\) Allowable costs are gross costs minus any manufacturer or pharmacy discounts, chargebacks, and similar price concessions received by the employer that are predicated on actual drug costs.\(^{185}\) In the preamble to the final rule, CMS indicates that price concessions attributable to matters such as customer service performance standards or identification card delivery do not have to be taken into account in determining allowable costs.\(^{186}\) Moreover, any point-of-sale discounts and other price concessions that are passed through to the beneficiary and plan at the point of sale for any drug expense do not have to be further subtracted from gross costs.\(^{187}\)

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\(^{180}\) Id. § 423.884(d)(1)(i).

\(^{181}\) Id. § 423.884(d)(5)(ii)(B).

\(^{182}\) Id. § 423.884(d)(5)(iv).

\(^{183}\) Id. § 423.884(d)(5)(ii)(B); 70 Fed. Reg. at 4410.

\(^{184}\) Id. § 423.886(a).

\(^{185}\) Id. § 423.882.

\(^{186}\) 70 Fed. Reg. at 4404.

\(^{187}\) Id.
In determining allowable costs, the final rule also permits an employer that sponsors a fully insured plan and that elects to receive subsidy payments on a periodic basis to allocate actuarially a portion of the premiums charged to the employer (excluding administrative costs but including the portion paid by retirees) to gross covered prescription drug costs incurred for qualifying covered retirees between the annual limits, provided that the employer submits a revised cost determination that reflects the actual allowable retiree costs attributable to gross retiree prescription drug costs within the annual limits within 15 months after the close of the plan year. 188 Upon receiving this revised cost determination, CMS will adjust the payments made for that plan year.

3. **Record Retention.** Employers are required to retain records relating to the actuarial attestation and calculation of subsidy payments for six years after the expiration of the plan year in which the costs were incurred. 189

**Coordinating Benefits to Provide Wrap-Around Coverage.** Prescription drug expenses reimbursed by an employer plan do not count toward a retiree’s TrOOP threshold. Accordingly, PDPs and MA-PD plans will need information on benefit payments made under employer-sponsored retiree health plans, including wrap plans, to track a covered beneficiary’s TrOOP expenses. Moreover, an employer that wishes to provide secondary coverage for retirees enrolled in Part D will face administrative complications in coordinating benefits with Part D plans at the point of sale. CMS understands these challenges and is considering procuring a TrOOP facilitation coordinator to establish a single point of contact between primary and secondary payers at the point of sale. 190 CMS also expects to expand its Medicare beneficiary database to help employers identify retirees who are eligible for Part D. 191 CMS anticipates that it will make its final decision regarding its strategy for facilitating coordination of benefits by July 1, 2005. 192

**Providing Notice of Creditable Coverage.** As discussed above, a Medicare-eligible individual who does not enroll in the Part D prescription drug program during his/her initial period of eligibility will be required to pay a late enrollment penalty. 193 This penalty will be waived for periods during which the individual has received comparable prescription drug coverage from another source, including an employer-sponsored retiree health plan. 194 Thus, all employers that provide prescription drug benefits to Medicare-eligible individuals, whether retirees or active employees, will be required to determine whether the prescription drug coverage under each group health plan they sponsor is actuarially equivalent to Part D coverage and to notify Medicare-eligible individuals and CMS of the results of this analysis. 195

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188 42 C.F.R. § 423.888(b)(5).
189 Id. § 423.888(d).
190 70 Fed. Reg. at 4401.
191 Id. at 4329-30.
192 Id.
193 42 C.F.R. § 423.46.
194 Id.
195 Id. § 423.56(a).
C. **HSAs, FSAs, and HRAs**

Employees often pay health expenses through flexible spending accounts (“FSAs”) financed by payroll deduction or through employer-financed health reimbursement accounts (“HRAs”). In addition, the MMA creates a new category of individual health savings accounts (“HSAs”) which can be funded by employers, employees, or both. Generally, if any drug expense is reimbursed by an employer-sponsored group health plan, the final rule excludes the reimbursement from a retiree’s TrOOP expense, with the result that the reimbursement does not count toward the catastrophic coverage threshold. The final rule, however, includes HSA and FSA reimbursements as TrOOP expenses. CMS regards these funds as “essentially analogous to a beneficiary’s bank account.”\(^{196}\) HRAs are not excluded from the definition of “group health plan” for TrOOP purposes, however, because CMS believes that HRAs are fundamentally different from HSAs and FSAs in that HRAs are solely funded by employers.\(^ {197}\)

For purposes of the 28% direct employer subsidy, it is unclear to what extent an employer will be able to demonstrate that these account-type arrangements are actuarially equivalent to Part D. The preamble to the final rule acknowledges this and states that CMS intends to offer further guidance regarding the types of account-based arrangements can be considered for the subsidy.\(^ {198}\)

**Third-Party Assistance Programs**

**A. ** **State Pharmaceutical Assistance Programs**

For the purposes of Part D, CMS has defined a state pharmaceutical assistance program (“SPAP”) as a program operated by, or under contract with, a state that (1) provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D-eligible individuals; (2) 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; (3) meets the benefit coordination requirements of the Part D rule; and (4) does not change or affect the primary payer status of a Part D plan.\(^ {199}\) In order to qualify as a SPAP, a program must be funded solely with non-federal money.\(^ {200}\) CMS has interpreted the non-discrimination requirement to mean that a SPAP must offer equal assistance to beneficiaries enrolled in all Part D plans available in the state and may not steer beneficiaries to one plan or another. SPAPs are prohibited from automatically enrolling beneficiaries into a preferred plan.\(^ {201}\)

A SPAP may help Part D beneficiaries by paying all or part of a beneficiary’s Part D premium and/or the cost-sharing amounts the beneficiary is obliged to pay.\(^ {202}\) A SPAP may also provide supplemental

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\(^ {196}\) 70 Fed. Reg. at 4241-4242.

\(^ {197}\) Id. at 4242.

\(^ {198}\) Id. at 4402.

\(^ {199}\) 42 C.F.R. § 423.464(e)(1).

\(^ {200}\) Id.

\(^ {201}\) 70 Fed. Reg. at 4320-4321.

\(^ {202}\) 42 C.F.R. § 423.464(a).
prescription drug benefits to beneficiaries enrolled in Part D. A Part D plan will always be the primary payer relative to a SPAP. If a state program qualifies as a SPAP, then any financial assistance that the SPAP provides to a Plan D beneficiary counts towards the beneficiary’s TrOOP threshold.

B. Patient Assistance Programs Sponsored by Pharmaceutical Manufacturers

Payments made on behalf of a beneficiary by a patient assistance program ("PAP") sponsored by a pharmaceutical manufacturer will count toward the beneficiary’s incurred costs for purposes of the TrOOP threshold unless the organization qualifies as a group health plan, insurance or otherwise, or similar third-party payment arrangement. All such charitable assistance, however, must comply with federal fraud and abuse laws, including the anti-kickback statute at Section 1128(b) of the Social Security Act and the civil monetary provisions prohibiting inducements to beneficiaries at Section 1128(a)(5) of the Act.

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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 health care reimbursement group:

Anna Kraus 202.662.5320 akraus@cov.com
Alan Spielman* 202.662.5852 aspielman@cov.com
Ruth Miller 202.662.5363 rmiller@cov.com
Ellen Flannery 202.662.5484 eflannery@cov.com
Richard Kingham +44.(0)20.7067.2018 rkingham@cov.com
Michael Labson 202.662.5220 mlabson@cov.com
Ethan Posner 202.662.5317 eposner@cov.com
Peter Safir 202.662.5162 psafir@cov.com

* Senior Advisor for Healthcare Reimbursement Policy (non-lawyer)

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203 Id.
204 Id. § 423.464(b).
205 Id. § 423.100.