prescription drug plans or PDP sponsors, on premiums applicable to Medicare enrollees of the prescription drug plans under Part F, or on any other payments made by us to PDP sponsors under subpart G of the regulations,--including the direct subsidy, reinsurance payments and risk corridor payments.

J. Coordination Under Part D Plans with Other Prescription Drug Coverage

1. Overview and Terminology

We propose in Subpart J of part 423 to implement sections 1860D-2(a)(4), 1860D-2(b)(4)(C), 1860D-2(b)(4)(D), 1860D-11(j), 1860D-21(c), 1860D-22(b), 1860D-23(a), 1860D--3(b), 1860D-23(c), 1860D-24(a), 1860D-24(b), and 1860D-24(c) of the Act that were added by section 101 of the MMA. We provide a brief summary of each of these provisions. Following this overview we provide a more detailed discussion of how we propose implementing each of these statutory provisions in this subpart.

We propose to implement section 1860D-21(c) of the Act at § 423.458 of the proposed rule and explain that the requirements of Part D generally apply under Part C for prescription drug coverage offered by MA-PD plans although certain waivers are available. We propose to implement section 1860D-22(b) of the Act at our proposed § 423.458(c)

that provides employer group waiver authority for prescription drug plans.

We outline options that we have identified related to the data-exchange that will be necessary between both State pharmaceutical assistance programs and other insurers and Part D plans in order to accurately apply incurred costs to appropriate Part D enrollee records. For purposes of this subpart, provisions in the statute that address coordination requirements generally apply in a similar manner to both State pharmaceutical assistance programs and other drug plans and to both prescription drug plans and MA-PD plans. The main difference between coordination requirements related to SPAPs and other drug plans is that we are prohibited from charging user fees to SPAPs. On the other hand, Part D plans may impose fees only related to the cost of coordination on both SPAPs and other drug plans.

We propose to implement section 1860D-11(j) of the Act at § 423.464(a) of the proposed rule and require sponsors of Part D plans to coordinate with State pharmaceutical assistance programs and other prescription drug plans. In this section we specify the other plans with which Part D plans must coordinate benefits in accordance with section 1860D-24(b) of the Act and define State Pharmaceutical

Assistance Programs, in accordance with section 1860D-23(b) of the Act.

a. Part D Plans

Wherever we mention or reference “Part D plans” we mean any or all of "MA-PD plans, prescription drug plans (PDPs) and fallback prescription drug plans”. Likewise, the term “Part D plan sponsor” refers to MA organizations offering MA-PD plans, PDP sponsors, and eligible fallback entities offering fallback plans. If a statement or reference applies exclusively to a specific type of plan, we use that exact term to limit the reference.

b. Employer-sponsored Group Prescription Drug Plan

Section 1860D-22(b) applies to “employment-based retiree health coverage” that is defined under section 1860D-22(c)(1) of the Act. This term means coverage for individuals (or their spouses and dependents) under a group health plan based on their status as retired participants. We use the term “employer-sponsored group prescription drug plan” to mean a prescription drug plan under a contract between a PDP sponsor and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage.

c. State Pharmaceutical Assistance Program

A State Pharmaceutical Assistance Program is a program operated by or under contract with a State for purposes of this part if it: (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 specified in this part; and (4) does not change or affect the primary payor status of a Part D plan. Since an SPAP cannot discriminate under the Part D plans with respect to either eligibility or the amount of assistance provided, in accordance with section 1860D-23(b)(2) of the Act and in our proposed rule at § 423.464(e)(1)(ii), to the extent that a program does discriminate it cannot, by definition, be considered an SPAP. A non-conforming State program that did discriminate in either of these ways (eligibility or amount of assistance provided) would not meet the definition of a State Pharmaceutical Assistance Program.

We are interpreting the non-discrimination language to mean that SPAPs, if they offer premium assistance or supplemental assistance on Part D cost sharing, must offer

equal assistance by all PDPs or MA-PD plans available in the State and may not steer beneficiaries to one plan or another through benefit design or otherwise. State programs cannot, for example, use the threat of withholding SPAP enrollees to negotiate coverage, premium or formulary changes with PDPs or MA-PD plans. Violations of the non-discrimination rule will jeopardize the program's special status with respect to true out-of-pocket costs. That is, a State program that discriminates does not qualify under the definition of an SPAP, and consequently, its contributions to cost sharing do not count toward the out-of-pocket limit.

Section 1860D-23(b) of the Act also provides that an SPAP is a State program that provides financial assistance for the purchase or provision of prescription drugs, and we interpret this to mean that it provides that assistance with State funds. Therefore, the definition of SPAP would exclude State Medicaid programs, section 1115 demonstration programs, and any program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding. (We would clarify that this does not exclude some Federal administrative funding or incidental Federal monies.)

For purposes of this part, we are proposing that a

Pharmacy Plus demonstration waiver under section 1115 of the Act shall not be considered a State pharmaceutical assistance program. Pharmacy Plus waivers are granted to allow states to treat these individuals as Medicaid eligible for the purposes of receiving drugs and primary care services. Expenditures for these limited services receive federal matching payments in the same manner as do services for full benefit Medicaid beneficiaries. We do not believe that these waivers, having expenditures that are federally matched in this manner, should be considered SPAPs as the effect of this would be to allow federally matched payments to be used to meet an out of pocket expense to gain further payments from the Federal Medicare program.

2. Application of Part D Rules to MA-PD Plans on and after January 1, 2006 (§ 423.458)

In accordance with section 1860D-21(c)(1) of the Act, and as provided under proposed § 423.458(a), the provisions of Part D apply under Part C to prescription drug coverage provided by an MA-PD plan in lieu of other Part C provisions that would apply to such coverage, unless otherwise provided. As permitted under section 1860D-21(c)(2) of the Act, we will waive Part D provisions to the extent that we determine they duplicate, or conflict with,

provisions under Part C, or as necessary in order to improve coordination of Part D benefits with the Part C program. For instance, under section 1860D-21(c)(3) of the Act, we will waive the pharmacy network access requirements as described at § 423.120(a)(3) of the proposed rule in the case of an MA-PD plan that provides access (other than through mail-order pharmacies) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization if we determine that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan. As discussed in other parts of this preamble, Part D rules generally apply to section 1876 cost HMOs/CMPs and PACE organizations in the same or in a similar manner as the rules apply to MA-PD local plans. The waiver provision under section 1860D-21(c)(2) of the Act applicable to MA-PD plans similarly extends to section 1876 cost HMOs/CMPs and PACE organizations. We provide for this waiver authority for cost HMOs/CMPs and PACE organizations by adding a paragraph (d) to section 423.458 of our proposed rule.

In reviewing requested waivers we will follow a process similar to the process we initially established under the M+C program related to the employer group waiver authority provided in section 1857(i) of the Act and

codified in regulation at § 422.106(c). Under § 422.106(c), MA organizations could submit written requests to our permission to waive requirements that hinder the design of or offering of MA plans to employers. We would make approved waivers available to all similarly situated MA organizations that meet the conditions of the waiver. Accordingly, we will use a similar approach to the one we established under § 422.106(c) in implementing our authority to waive those Part D provisions that can be shown to (1) duplicate or conflict with Part C requirements or (2) should be waived in order to improve coordination of the benefits provided under Parts C and D of Medicare. However, we will not, under our waiver authority, waive Part D rules that are specifically directed to MA-PDs or to the Part C program. We ask for your comments on both the process we propose for authorizing additional waivers under this section and for what additional waivers should, or should not, be permitted under this waiver authority.

3. Application to PACE Plans

Section 1860D-21(f) of the Act indicates that Part D provisions shall apply to PACE organizations in a manner that is similar to those of an MA-PD local plan and that a PACE organization may be deemed to be an MA-PD local plan. As discussed in detail in Subpart T, PACE organizations

would not be deemed as MA-PD plans but would be treated in a manner that is similar to MA-PD plans for purposes of payment. Proposed § 423.458(d) establishes regulatory authority for CMS to waive Part D provisions for PACE organizations and indicates that PACE organizations may request waivers from CMS. Because many of the Part D requirements duplicate, conflict with, or inhibit coordination of existing PACE requirements, we anticipate a significant number of waivers would necessary for PACE organizations. We are concerned about the potential burden this would place on PACE organizations and propose to include a provision that would allow for CMS to identify all Part D provisions requiring waivers and waive these provisions on behalf of PACE organizations. In other words, we are considering a special rule for PACE organizations that would automatically apply the waivers granted in the final rule (see discussion in Subpart T of this preamble) without a plan-specific application process.

We would like to receive comments on this proposed approach and on any other related suggestions for minimizing burden on PACE plans.

4. Application to Employer Groups

a. Employer Group Waivers

Section 1860D-22(b) of the Act extends the waiver authority that is provided for MA organizations related to Part C by section 1857(i) of the Act and implemented at § 422.106(c) to prescription drug plans related to Part D. This waiver authority is intended to provide prescription drug plans an opportunity, similar to the opportunity afforded MA organizations under Part C, to furnish Part D benefits to participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations in the most efficient and effective manner possible. Section 1860D-21(b) of the Act specifically authorizes prescription drug plans to establish separate premium amounts for Part D enrollees who are participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations. It also contemplates separate Part D plans for participants and beneficiaries of such employment-based retiree health coverage. In administering this waiver, we propose to follow the template first established at § 422.106(c) that we created under Part C to implement the waiver authority under section 1857(i) of the Act.

While we discuss coordination of Part D coverage with employment-based retiree health coverage at some length later in this part, we believe it is important to include a

brief discussion here on the Part D waivers that we specifically would not permit related to employer group retiree coverage under the authority provided in section 1860D-22(b) of the Act. Although the statute permits ". . . in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan . . ." we interpret "separate premium amounts" to mean the amount of premium the retiree or the enrollee pays. Under the MA program many employer groups subsidize the premiums that would otherwise be payable by their retirees through partial or full payment or subsidization of the MA plan premiums on their members' behalf. We believe that a similar practice related to PDP Part D plan premiums would be permissible and find support in section 1860D-22(a)(6)(B) of the Act. Alternatively, we do not believe that the statutorily defined Part D premium could be different for employees or retirees than it is for individuals enrolled in the same PDP plan. Thus, the combined Part D premium contributed by the employee or retiree and the employer group would need to be identical to the premium charged to an individual enrolled in the same PDP plan. These principles apply to waiver requests by MA-PD plans under section 1857(i) of the Act.

Generally, we also would not permit waivers that

directly increase Medicare spending. For example, a section 1860D-22(b) waiver would not be permitted that had the effect of changing the definition (in Subpart C of our proposed rules) for incurred costs (which are defined for purposes of calculating the true out-of-pocket threshold--TrOOP). An alternative example of a waiver we would not permit would be a waiver that would increase the premium subsidy. We also note that section 1860D-22(b) applies to "prescription drug plans," not non-Part D plans that "wrap around" or supplement the benefits provided under, the PDP. Consequently, section 1860D-22(b) of the Act would not apply to a request to waive rules under this Part that effect an employer-sponsored non-Part D plan that wraps around a Part D plan, including the TrOOP rules. The exclusion of costs paid by group health plans from TROOP is irrelevant when the group health plan is itself a part D plan (in other words, the exclusion applies when the group health plan pays costs not otherwise covered under the part D plan).

We invite comment on the process we propose for authorizing additional waivers that prescription drug plan sponsors can request under this section. We also ask for comment on the manner in which additional waivers should be permitted and what additional waivers, if any, we should

not allow.

b. Employer Options

The enactment of Title I of the MMA has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. For the benefit of the employers and unions, we discuss these options. We believe the availability of these various options will make it easier for sponsors to continue to assist their retirees in having access to high-quality prescription drug coverage.

Generally, employers and unions who offer drug benefits to their retirees (and their dependents) who are eligible for Medicare Part D may do so as follows:

1. Provide prescription drug coverage through employment-based retiree health coverage. If those coverage is at least actuarially equivalent to the standard prescription drug coverage under Part D, the sponsor is eligible for a special Federal subsidy for each individual enrolled in the sponsor's employment-based retiree health coverage who is eligible for Part D but elects not to enroll in Part D, directly reducing the cost of providing a high-quality drug benefit. It is important to note that employers can still make arrangements with Medicare Advantage organizations to offer a Medicare Advantage (MA) only plan without the Part

D benefit, but then still take the retiree drug subsidy and through a separate private contract with the MA organization arrange for an employer-sponsored retiree drug benefit that is not subject to the application of the true out-of-pocket provision and retains the employer's flexibility to design a benefit that is at least equivalent to the Part D benefit.

2. Provide prescription drug coverage that supplements, or "wraps-around," the coverage offered under the PDP or MA-PD plans in which the retirees (and their dependents) enroll. For example, this option would permit beneficiaries who receive retiree coverage from employers who provide some financial assistance, but not enough to qualify for the retiree drug subsidy, to supplement the new drug benefit subsidy from Medicare with their existing employer assistance and thereby receive more generous coverage than they have now.

3. Subsidize the monthly beneficiary premium for whatever PDP or MA-PD plan in which the employer or union's retirees (and their dependents) elect to enroll.

4. Provide a prescription drug plan (PDP) or Medicare Advantage-prescription drug plan (MA-PD plan) either under contract with a PDP sponsor or Medicare Advantage (MA) organization or by directly sponsoring a PDP or an MA-PD

plan. This plan may consist of enhanced alternative coverage (as defined under proposed § 423.104(g)), or drug coverage that is more generous than that offered under the standard prescription drug coverage under Part D (as defined under proposed § 423.104(e)). Medicare would subsidize the cost of this coverage through direct and reinsurance subsidies (as calculated under proposed § 423.329(a)(1) and (2)). At its option, the employer or union may elect to subsidize the monthly beneficiary premium (as calculated under proposed § 423.286). Many employers already have arrangements with Medicare Advantage plans and we expect that this will continue, as well as new arrangements being established.

The first option is the subject of subpart R of this preamble. The latter three options, all of which involve the employer or union's retirees (and their dependents) enrolling in Part D, are discussed in this subpart.

We note that if employers or unions elect to sponsor enhanced alternative coverage under Part D or to provide supplemental coverage that wraps around Part D, either election will have an impact on when its retirees (and their dependents) are eligible for the additional Medicare subsidies for catastrophic drug coverage. By delaying the provision of government-financed catastrophic coverage,

these plans would lower the cost of Part D to the Federal government by lowering our reinsurance payments while preventing beneficiaries from facing any gaps in coverage. As discussed in Subpart C, individuals enrolled in a PDP or MA-PD plan are eligible for Medicare subsidies on top of their employer subsidies for catastrophic drug coverage after they incur out-of-pocket drug costs in the amount specified under proposed § 423.104(e)(5)(iii). Under the reinsurance provisions discussed in Subpart G, Medicare would reimburse PDP sponsors and MA organizations offering MA-PD plans 80 percent of their gross costs for providing this catastrophic coverage (excluding administrative costs and net of discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count toward the annual out-of-pocket threshold, with the exception of amounts reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement. We refer to those drug expenditures that count toward the out-of-pocket threshold as "true out-of-pocket (TrOOP) expenditures."

Under these rules, employers and unions who provide retirees (and their dependents) enhanced alternative coverage or wrap-around coverage in effect push out the

total drug spending that triggers the Medicare subsidy for catastrophic coverage, since participants in the plan will have lower cost-sharing, and thus have lower out of-pocket costs. This approach limits the "crowd-out" of employer contributions by the new Medicare subsidy, resulting in more comprehensive coverage at a lower cost to the Federal government by lowering reinsurance payments.

When an employer or union elects to provide a PDP or MA-PD plan under contract with the PDP or MA-PD sponsor, the PDP sponsor, under proposed § 423.458(c), or the MA organization, under 42 CFR § 422.106(c), may submit written requests to us for permission to waive requirements under Part D that hinder the design of or offering of PDP or MA-PD plans to employers. We believe these waivers will help efficient administration and integration of their enhanced Part D coverage with other retiree health benefits offered by the sponsor. For example, the PDP sponsor or MA organization could request permission to restrict enrollment in its PDP or MA-PD plan to the sponsor's retirees (and their dependents) and offer a benefit that resembles or enhances the sponsor's existing coverage. We encourage employers and unions to carefully review each option and determine which one is most beneficial to it and its retirees (and their dependents). The variety of

options gives employers many ways to retain and enhance drug coverage for their retirees, and we seek comment on how we can use all of these subsidized options to maximize enhancements in retiree coverage.

c. Implications for Beneficiaries

For beneficiaries, the significance of the above discussion, as well as of the earlier discussion (in Subpart C) of incurred costs that count toward the true out-of-pocket threshold, is that these rules would lead to new options for drug coverage. All Medicare Part D coverage would at a minimum provide basic coverage, funded with a generous federal subsidy that did not exist before. In addition, there would be a number of ways in which some beneficiaries can get access to more comprehensive benefits, such as filling in any coinsurance requirements in coverage in whole or in part. Such access will be dependent on individual eligibility for other subsidies or coverage, and individual willingness to continue to pay for enhancements in their coverage, such as:

- If they are eligible for a more comprehensive retiree health benefits policy sponsored by their former employer, their retiree plan sponsor may qualify for a subsidy payment.

- If they have limited income, they may be eligible for Part D low-income subsidies of premium and cost sharing through a Part D plan.
- They may be eligible for financial assistance through a State Pharmaceutical Assistance Program that can pay for an enrollee's cost sharing and still have these payments count toward the out-of-pocket limit.
- They may qualify for charitable assistance from bona fide non-profit charities that can also pay for an enrollee's cost sharing and still have these payments count toward the out-of-pocket limit.
- They may have access to a PDP or MA-PD (through either individual enrollment or employer group enrollment) that offers an enhanced alternative prescription drug plan for an additional premium. In this case, either the plan sponsor and/or the beneficiary must bear some of the drug costs that would otherwise have been subsidized by Part D reinsurance subsidies. While they would consequently not receive the additional subsidy until they reached a higher level of drug expenditures, the substantial savings in drug costs as a result of the highly subsidized, standard drug benefit would permit such coverage to be financed while still saving money for the beneficiary and the plan sponsor.

5. Medicare Secondary Payer Procedures

Section 1860D-2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act and 42 CFR 422.108 to PDP sponsors. Section 1852(a)(4) of the Act provides that an MA organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made a secondary payer under section 1862(b)(2) of the Act. Accordingly, under § 423.462 of this proposed rule, PDP sponsors would be required to follow the same rules as MA organizations regarding:

- Their responsibilities under MSP procedures;
- Collection of payment from insurers, group health plans and large group health plans, the enrollee, or other entities for covered Part D drugs; and
- The interaction of MSP rules with State laws.

Because Medicare would not pay for covered Part D drugs to the extent that there is a third party that is to be the primary payer under the provisions of section 1862(b)(2) of the Act and 42 CFR 411, PDP sponsors must, for each prescription drug plan: (1) identify payers that are primary to Medicare under section 1862(b)(2) of the Act and 42 CFR 411, (2) determine the amounts payable by those

payers, and (3) coordinate their benefits to plan enrollees with the benefits of the primary payers.

The PDP sponsor may charge other individuals or entities for covered Part D drugs for which Medicare is not the primary payer. If an enrollee receives from a PDP sponsor covered Part D drugs that are also covered under State or Federal workers' compensation, no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PDP sponsor may charge the insurance carrier, the employer, any other entity that is liable for payment for the covered Part D drugs under section 1862(b) of the Act and 42 CFR 411, or the prescription drug plan enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered Part D drugs.

When Medicare, and thus a Part D plan, is secondary to other payers, beneficiary costs incurred for covered Part D drugs would not be considered "covered" costs under the Part D plan. Consequently, these costs would be excluded from a beneficiary's incurred costs, as described in section II.C.2.a of this preamble and would not count as incurred costs against the annual deductible or the out-of-pocket threshold.

When Medicare is a secondary payer to employer coverage in the case of certain working Medicare

beneficiaries, a PDP sponsor may charge a group health plan (GHP) or large group health plan (LGHP) for covered Part D drugs it furnishes to a Medicare enrollee who is also covered under the GHP/LGHP, and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP/LGHP.

Because Medicare Part D coverage is a Federal program operated under Federal rules, State laws do not--and should not--apply, with the exception of State laws regarding licensing or related to plan solvency or as otherwise provided by statute or regulation. Given the requirement in section 1860D-2(a)(4) of the Act that we extend MSP procedures applicable to MA organizations to PDP sponsors, PDP sponsors would also be permitted, under section 1852(a)(4) of the Act, to fully recover from liable third parties according to section 1862(b)(2) of the Act. In accordance with section 1860D-12(g) of the Act that extends the State preemption provisions under section 1856(b)(3) to Part D, under § 423.462 of our proposed rule that mirrors § 422.108(f), States would be prohibited from exercising authority over prescription drug plans in any area governed by Medicare Part D (including our regulations under chapter 423) other than State licensing laws and State laws relating to plan solvency. This is consistent with

specific preemption authority now provided by section 1856(b)(3) of the Act with respect to MA organizations.

6. Coordination Of Benefits With Other Providers Of Prescription Drug Coverage

Section 1860D-23(a) of the Act authorizes us to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and a State Pharmaceutical Assistance Program with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits. We are to establish procedures and requirements before July 1, 2005, to ensure effective coordination. In developing these procedures and requirements, we are to consult with State pharmaceutical assistance programs, prescription drug plan sponsors, MA organizations, States, pharmaceutical benefit managers, employers, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts. In addition, as specified at section 1860D-24(a) of the Act and implemented in this section of the regulations, we will apply the coordination requirements for State pharmaceutical assistance programs to other prescription drug plans including Medicaid (including a plan operating under a waiver under section 1115 of the Act), group health plans, the Federal employees health benefits plan, military

coverage (including TRICARE), and other coverage that we specify. Under section 1860D-23(c)(1) of the Act, coordination between State pharmaceutical assistance programs and Part D plans does not change or affect the primary payor status of a Part D plan with respect to a State pharmaceutical assistance program. Nor does it affect the primary or secondary payment position of the Part D plan related to the payments made by other plans providing prescription drug coverage. Under the requirements of section 1860D-11(j) of the Act, Part D plan sponsors will not be permitted to impose fees on SPAPs or other plans providing prescription drug coverage that are unrelated to the costs of that coordination.

The elements to be coordinated would include enrollment file sharing, claims processing, payment of premiums for both basic and supplemental drug benefits, third-party reimbursement of out-of-pocket costs, application of protection against high out-of-pocket expenditures (defined in section 1860D-2(b)(4) of the Act), and other administrative processes and requirements that we specify. Enrollment file sharing might include information such as beneficiary name, date of birth, health insurance claim number, sex, name and address of benefit administrator, insured's identification number, electronic

transaction routing information (RxBin, RxPCN, RxGRP), group number, patient relationship, and coverage effective dates. Claims processing information might include collecting information similar in nature to that currently contained in a Medicare provider Remittance Advice statement. Information must be sufficient to successfully link with enrollment files and in order to allow Part D plans to make a correct determination of true out-of-pocket (TrOOP) expenditures on the part of beneficiaries.

On rare occasions Part D plans would also be required to coordinate benefits with other Part D plans. In the event that a beneficiary disenrolled from one plan mid-year and enrolled in another, the two plans would be required to exchange information sufficient to allow the beneficiaries' claims to be processed as if there had been no break in enrollment. Specifically, the second plan would need to obtain the enrollee's claim data and adjust its claims processing system accumulators to reflect that a certain level of expenditures and out-of-pocket costs had been already been incurred in order that the correct sequence of claims processing could be maintained. This is not to say that the second plan could claim the first plan's costs as their own allowable costs, but that their systems would process future claims as if the earlier costs had been

incurred by the second plan. We solicit comments on any other issues that may be involved in coordination of benefits between Part D plans.

We may impose user fees for the transmittal of information necessary for benefit coordination related to third party reimbursement (other than by a SPAP) of Part D enrollees' costs for covered Part D drugs. Please see our later discussion on options we are considering related to coordination of benefits under the Part D program and also the critical nature of securing accurate and timely information for purposes of the TrOOP calculation. As we mention in that discussion, the statute permits us to impose user fees on the employer (or other third party) plan, but not on SPAPs under any method of operation, for the transmittal of benefit coordination information under Part D. Section 1860D-24(a)(3) of the Act specifically provides authority for imposing user fees under Part D similar to the authority under section 1842(h)(3)(B) of the Act for collection of user fees (otherwise known as "claim-based cross-over fees") under fee-for-service coordination with Medicare supplemental policies. However, we are also provided authority to retain a portion of these users fees to offset costs we incur for determining whether enrollee out-of-pocket costs are being reimbursed by third

parties and for alerting Part D plans when, in fact, they are being reimbursed.

As we also later discuss in this preamble, any user fees, if collected, would not be assessed until the benefit is implemented in 2006. Before that time, we will fund the development and implementation of coordination of benefit requirements. We will also fund the development and implementation of a system to assist in the coordination of benefits – if and when it is determined that our development of the system is the appropriate option. We request comment on the method we should employ in imposing user fees and especially concerning whether it would be advisable to impose user fees on a monthly or quarterly basis based on the volume of data exchanged, and whether we should require electronic payment of user fees.

In section 1860D-24(c)(1) of the Act, a Part D plan sponsor may continue to use cost management tools (including differential payments) when administering benefits. This could include cost management tools related to managing supplemental benefits financed by a State pharmaceutical assistance program or another plan providing prescription drug coverage offered through a Part D plan. However, we believe that the intent of the statute at section 1860D-24(c)(1) of the Act is clear in allowing

Part D plans to continue to use cost management tools (such as tiered or differential cost sharing) even if an SPAP or other drug plan provides wrap-around or supplemental coverage for individuals enrolled in the Part D plan. We solicit comment on how we can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans. We also request comment on the most effective way to administer this provision without creating undue administrative burden on either Part D plans or the SPAPs and other insurers that might choose to provide wrap-around coverage for eligible individuals.

a. Coordination with SPAPs

The statute envisions a closer coordination of benefits between SPAPs and Medicare drug plans. For example, as provided in § 1860D–23(c) and in § 423.464(e)(3), a Part D enrollment card may also be used to access benefits under an SPAP, and the SPAP's emblem may be used on the card. Additionally, payments for beneficiary cost sharing made by an SPAP may be counted toward the incurred costs that count in the calculation of the true out-of-pocket (TrOOP) threshold in providing protection against catastrophic costs as provided in § 1860D–2(b)(4)(C)((ii) and in § 423.464(e)(2) of this

proposed rule. SPAPs have filled a significant gap in prescription drug coverage for many Medicare beneficiaries in the absence of a Medicare drug benefit. Now that so many States are involved and so many beneficiaries have relationships with these programs, it will be important to ensure that coordination between Medicare Part D and SPAPs occurs as efficiently and effectively as possible. However, section 1860D-23(c)(5) of the Act provides that nothing in the statute should be construed to require that a State Pharmaceutical Assistance Program coordinate or provide financial assistance with respect to any Part D plan.

For purposes of this part, we are proposing that a Pharmacy Plus demonstration waiver program under section 1115 of the Act not be considered an SPAP. We grant Pharmacy Plus waivers that allow States to treat individuals participating in these waiver programs as Medicaid eligible only for the purpose of receiving prescription drug and primary care services. We do not believe that Pharmacy Plus waiver programs should be considered SPAPs. The statute makes a clear distinction between SPAPs, defined in section 1860D-23(b) of the Act, and the Medicaid program (which includes State plans operating under Title XIX of the Act as well as State plans

operating under a waiver under section 1115 of the Act) described in section 1860D-24(b)(1) of the Act. In so far as the Pharmacy Plus waiver programs operate under 1115 waivers, they are considered part of the Medicaid program and thus are not considered SPAPs. This distinction is important for purposes of the application of TrOOP. Section 1860D-2(b)(4)(C)(ii) of the Act is clear in allowing only a person, CMS, or an SPAP to make payments that will count toward TrOOP for an individual Part D enrollee. In so far as beneficiary cost sharing is reimbursed under Title XIX of the Act, including a waiver operating under section 1115 of the Act, or through any other mechanism including public assistance, it cannot be counted toward TrOOP. However, since the MMA allows states to use state-only SPAP funds to assist beneficiaries with out-of-pocket expenditures, States would be better off using their current contributions to wrap around the Federal Medicare Part D benefit than in continuing the their Pharmacy Plus programs.

Medicare Part D plans may coordinate with SPAPs in a number of ways including accepting premiums for basic Part D or enhanced alternative coverage; accepting a lump sum per capita payment from the State for enrollee coverage through Part D plans; and coordinating on a claim-specific

basis when Part D plan pays first and the SPAP is the secondary payor. All data exchanges between SPAPs and Part D plans are to be consistent with applicable privacy laws, in order to ensure the confidentiality of individually identifiable beneficiary information. In accordance with section 1860D-23(c)(2) of the Act, and in order to help coordination between State pharmacy assistance programs and Part D plans, a single card may be used to access benefits under both Part D and State pharmacy assistance programs. These cards may contain an emblem or symbol indicating that a connection between the two programs exists. We do not know how SPAPs will actually choose to coordinate with Medicare drug plans, and we welcome comment in this regard - particularly from States. We would like to better understand what SPAPs plan to do in 2006 relative to Part D interaction (such as in payment of premiums or claim-specific wrap-around), and how Medicare can assist State preferences in this regard. Our goal is to make the coordination of benefits process as functional for the beneficiary, pharmacy, and States as possible.

We assume that some SPAPS will pay Part D plans' premiums on behalf of enrollees. For SPAPs that choose to wrap-around coverage rather than paying premiums, we

propose to include SPAP information in a coordination of benefits system described below. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan.

We request comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also request comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should be required to provide feedback on how much of the remainder of the claim they have actually paid. Since SPAP payments count as true out-of-pocket spending toward catastrophic coverage, the Part D plans could simply assume that any amounts not paid by the Part D plan and sent to an SPAP for reimbursement would count toward calculating TrOOP. We are concerned that we may need information from SPAPs to determine more precisely the SPAP contribution or payment. But we are also mindful of systems implications for States and would appreciate comments in this regard, particularly from SPAPs.

b. Coordination with Other Prescription Drug Coverage

Other plans providing prescription drug coverage that Part D plans would need to coordinate with are any of the following (1) Medicaid programs (including a State plan

operated under a waiver under section 1115 of the Act); (2) Group health plans, as defined in § 411.101; (3) FEHBP; (4) Military Coverage (including TRICARE) under chapter 55 of title 10 of the United States Code; and (5) other prescription drug coverage as we specify. We discuss coordination issues in detail in sections (d) and (e), below.

There is a relatively limited applicability of coordination of benefits between Part D plans and State Medicaid programs under the statute. The drugs that must be excluded from Medicare coverage are, with limited exception, drugs that may also be excluded from Medicaid coverage under section 1927(d)(2) of the Act. We anticipate that there may be situations involving State Medicaid programs that choose to continue coverage of a drug that is excluded from Medicare Part D coverage. For example, States may wish to continue coverage for barbiturates, benzodiazepines, or prescription vitamins. In these situations, a Part D plan providing primary coverage would need to coordinate this coverage with a State on behalf of a dually eligible beneficiary. We request public comment on other situations that may involve benefit coordination between States and Part D plans (other than situations where the State is acting as an employer).

In general, we invite comment on the other administrative processes and requirements that we might identify in order to help coordination between Part D of Medicare and other prescription drug plans.

c. Coordination of Benefits

Sections 1860D-23(a)(1) and 1860D-24(a)(1) of the Act require that, by July, 1, 2005, we establish requirements for coordination of benefits between Part D plans and SPAPs and other insurers including Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage we may specify at a later date. As discussed previously, the elements that are to be coordinated must include: enrollment file sharing; claims processing and payment; application of the protection against high out-of-pocket expenditures (by tracking TrOOP and the annual out-of-pocket threshold); and, other processes we specify.

We envision a system of information sharing between Medicare, Part D plans, SPAPs, group health plans, insurers, and other third-party arrangements. Our goal is that the design and implementation of a Part D coordination of benefits system enable pharmacies to obtain information about secondary insurers as well as the correct billing order. Ideally, we would anticipate that a pharmacy would

query the system and be provided with information it can use to bill all the insurers involved in the correct order, as well as ascertaining and applying the correct TrOOP calculation in order to assess the correct beneficiary co-payment at the point of service. Since prescription drug benefits are administered at the point of sale, coordinating insurance coverage at the point of sale is a technical communications challenge. In the case of administering a drug benefit, the goal is that the beneficiary pays the correct coinsurance or co-payment at the point of sale and that the pharmacy is subsequently reimbursed the correct amount from the other source or sources. Unlike coordination of benefits under Medicare when data is exchanged in only a single direction (from Medicare to the employer or other insurer), coordination of benefits for beneficiaries enrolled in Part D plans must include a reliable feedback loop of paid claims data from the employer, union or other insurer back to the Part D plan for purposes of tracking TrOOP. Additionally, given the real-time claims environment for pharmacy benefits, the feedback would ideally be in real-time so that beneficiary liability (if any) can be known at the point of sale, the correct insurer pays the correct share of the total drug cost, and the TrOOP calculation can be updated as quickly

and accurately as possible. This suggests the need for an organized system to share, update, and push data back and forth between pharmacy benefit managers and pharmacies. This will be further discussed in the section on tracking true out-of-pocket (TrOOP) costs, below.

As mentioned above, under section 1860D-23(c)(1) of the Act, coordination between State pharmaceutical assistance programs and Part D plans does not change or affect the primary payor status of a Part D plan with respect to a State pharmaceutical assistance program. Nor does it affect the primary or secondary payment position of the Part D plan related to the payments made by other plans providing prescription drug coverage. Part B of Medicare has historically included limited coverage of certain outpatient prescription drugs. Part A of Medicare covers prescription drugs more extensively, but only when an individual is an inpatient in a Medicare-certified facility receiving Medicare-covered inpatient care. In additional circumstances, for instance when a person has elected Medicare hospice coverage, prescription drugs are also covered under original Medicare.

The new statutory definition of a covered Part D drug excludes drugs covered and paid for under Part A or Part B of Medicare for a given individual. Section

1860D-2(e)(2)(B) of the Act provides that a drug that would otherwise be a covered Part D drug will not be so considered if payment for the drug as so prescribed and dispensed or administered is available under Parts A or B for that individual. This language indicates that the Congress was aware that some drugs could qualify for payment under Part A or B in some circumstances, and Part D in other circumstances, depending on setting of dispensing or administration. This means, for example, that if a form of administration of a drug is covered under Part B in a region when injected incident to a physician office visit, that drug administered in that manner in that setting cannot meet the definition of a covered Part D drug. However, that same drug can be covered under Part D when picked up at a retail pharmacy to be self-administered by the patient. For another example, in certain instances a drug could be covered under Part B at certain times and under Part D at other times. Many patients, for instance, take their medicines at specific times throughout the day. If these patients receive a service in a hospital outpatient department and remain in the hospital for several hours of post surgery observation, he/she may receive one or more doses from the hospital pharmacy. This

medication would be considered part of their Part B service and covered under the hospital OPD payment.

We note that individuals can elect Part D of Medicare if they are entitled to Part A or enrolled in Part B. This means that individuals with only Part A or only Part B will still have access to Part D. Although most Medicare beneficiaries have both Parts A and B, there are nearly 2 million Medicare beneficiaries who have only Part A, while there are approximately 500,000 Medicare beneficiaries who have only Part B. We interpret the definition of covered Part D drug to exclude coverage under Part D for drugs otherwise covered and available under Parts A or B for individuals who choose not to enroll in either program. We interpret the words "payment is available" to mean that payment would be available to any individual who could sign up for A or B, regardless of whether they are actually enrolled. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. This includes individuals who are entitled to Part A based on age, disability, and ESRD. All individuals who are entitled to Part B only are age 65 and, in almost all instances, not eligible for premium-free Part A. However, they are eligible to buy into Part A for a premium. Thus, for all Part D individuals, Part A drugs

and Part B drugs are "available" if they choose to pay the appropriate premiums. Consequently, Part D would not be required to pay for drugs covered under Parts A and B on the basis of a Part D eligible individual's status with regard to Parts A and B. In addition, we believe that the phrase "for that individual" in § 1860D-2(e)(2)(B) of the Act is intended to capture the fact that under local medical review policies, a drug that might be covered under Part B for an individual in one area of the country may not be covered under Part B in another area of the country. Thus, what is covered "under Part B for that individual" may be different in different geographic regions. The result of these interpretations would be that any drug covered under A or B could not be covered under D, whether it was covered for that individual or not.

We would wish to ensure that Part D coverage coordination works seamlessly for beneficiaries with Parts A and B of Medicare, and that beneficiaries do not lose Medicare coverage otherwise available to them due to unforeseen difficulties encountered in the coordination process. This is a critical consideration for effective and efficient coordination between the original Medicare program and the new coverage provided under Part D.

Specific options concerning coordination of benefit procedures that we are considering are outlined below.

Pharmacy-dispensed drugs covered by Part B (for instance, DME drugs, immunosuppressive drugs, and oral anti-cancer drugs) are not reimbursed unless the pharmacy has a Medicare supplier number; thus, a beneficiary could lose Part B coverage by filling a prescription at the wrong pharmacy. (We recognized this problem in the interim final rule on the discount card program and stated that, for drugs potentially covered by Part B, "non-Medicare participating pharmacies should refer the beneficiary to a participating pharmacy." See 68 FR 69840, 69852). To reduce this risk, we are proposing to—

1. Encourage Part D plans to enroll pharmacies with Medicare supplier numbers in their networks;

2. Encourage Part D plans to inform beneficiaries whether their network pharmacies have a Medicare supplier number, and explain why this is important when filling prescriptions for drugs potentially covered by Part B, and

3. Develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collected from beneficiaries enrolled in Part B for Part B drugs unless they first notify the beneficiary

(through an advanced beneficiary notice (ABN)) that Medicare likely will deny the claim.

Statutory "refund requirements" apply to claims for "medical equipment and supplies" that Medicare denies because the supplier lacked a supplier number, unless—

1. The beneficiary signed an ABN notifying him or her that Medicare would deny payment, and agreed to be personally responsible for payment; or

2. The supplier did not know and could not reasonably have known that Medicare would deny payment.

For this purpose, coverage of medical equipment and supplies includes durable medical equipment (DME), certain drugs and other supplies necessary for use of an infusion pump, oral immunosuppressive drugs and anti-cancer drugs, and "such other items as the Secretary may determine." (See the Medicare Claims Processing Manual, Chapter 30, sections 150.1.3 and 150.1.5.) Suppliers are presumed to know that Medicare will not pay for medical equipment and supplies furnished by a supplier that lacks a supplier number. (See section § 150.5.4 of Chapter 30 of the Medicare Claims Processing Manual.) We are considering whether a drug denied Part B coverage for this reason should become a covered Part D drug, and the claim should thus be processed under Part D, and would like to receive

comments on the relative likelihood of this occurrence and on alternative means of addressing such circumstances.

We are also considering whether a drug denied Part B coverage for any other reason should become a covered Part D drug. For instance, we believe that a drug denied Part B coverage and payment for therapeutic inappropriateness, drug-disease contraindication, incorrect drug dosage, duration of drug treatment or for similar reasons related to medical necessity should not be considered a covered Part D drug. Rather, we believe that such a denial or non-coverage decision under Part B, while appealable under Part B, would not cause the drug to become a covered Part D drug. We welcome comment in this area.

For drugs potentially covered by Part B that are dispensed by a pharmacy that is a Medicare supplier, we are considering the development of automatic cross-over procedures. That is, we are considering requiring that: (1) the pharmacy submit the claim to the appropriate Part B carrier; and (2) the carrier, if it denies the claim, submit the claim automatically to the PDP (or its claims processing agent) through which the beneficiary has Part D coverage. This assumes that the beneficiary receives Part D through a PDP. For beneficiaries enrolled in MA-PD plans, coordination of benefits will generally occur

internally within the MA organization. (Similar cross-over procedures are used today in connection with dual-eligibles--individuals entitled to both Medicare and Medicaid and related to coordination between Medicare and Medicare supplemental insurers.)

We also believe that similar cross-over procedures for any physician-administered drugs that may be covered under Part B or Part D will need to be developed. This would involve: (1) the physician submitting the claim to the appropriate Medicare carrier; and (2) the carrier automatically submitting the claim to the Part D plan (or its claims processing agent) if it denies payment under Part B. We particularly welcome comment on the feasibility of these proposed Part D and Part B coordination of benefits proposals and welcome suggestions on other methods or procedures that might be more efficient or better suited to coordination of prescription drug benefits.

Another type of coordination of benefits occurs when Medicare pays secondary to another insurance (MSP). Medicare currently pays secondary when payment has been made or can reasonably be expected to be made by another party such as workers compensation, automobile insurance, a liability insurance policy, or another health insurance policy (for example, when a beneficiary's spouse has

primary insurance through their employment). Beneficiaries provide information, when available, regarding third party coverage as part of the initial enrollment questionnaire. Medicare also attempts to identify additional situations in which Medicare should pay secondary, and when we believe this is the case we follow up with employer plans for information. We do not anticipate significant changes to this mechanism, except that Medicare will now, in relatively limited circumstances, pay secondary for a Part D beneficiary who has other insurance. We do not know how many beneficiaries with employer-sponsored insurance that is the primary payor to Medicare will enroll in Part D. We do know that approximately two-thirds of individuals with primary employer-sponsored insurance do voluntarily pay for Part B coverage. We request public comment on the likelihood that beneficiaries with primary employer-sponsored insurance will elect Part D. We believe that the number of instances where automobile, workers' compensation or liability insurance will be paying primary on behalf of Part D enrollees will be relatively small. So, generally, we believe that most instances of coordination of benefits of under Part D will occur when Medicare is primary and another insurer is secondary.

d. Collection of Data on Third Party Coverage

Section 1860D-2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by a group health plan, insurance or otherwise, or another third-party arrangement. These procedures provide for—

- Determining whether costs for a Part D enrollee are being reimbursed through insurance or otherwise, a group health plan, or other third-party arrangement; and

Alerting Part D plans in which beneficiaries are enrolled about reimbursement of prescription drug costs they receive through insurance or otherwise, a group health plan, or other third party arrangement.

- Section 1860D-2(b)(4)(D)(ii) of the Act permits Part D plans to request information on third party insurance from beneficiaries. We would expect Part D plans to update Medicare records based on the information provided by beneficiaries to reflect changes in coverage, including the primary or secondary status of such coverage relative to Medicare. As discussed in the subpart B preamble, beneficiaries who materially misrepresent (as defined in standards and processes we propose to establish in § 423.108(b)(4)(iv) of the proposed rule) information on third parties may be disenrolled from any Part D plan for a

period specified by CMS and may also be subject to late enrollment penalties upon enrollment in another plan.

In the current Medicare fee-for-service claims processing environment, coordination of benefits when Medicare is the primary payor and another insurer is secondary (for example, employer-based retiree insurance, Medicaid, or Medigap) is performed as a convenience to the beneficiary and employer plan (coordination of benefits is required by statute for claims involving Medigap plans) and is voluntary on the part of the employer plans. The coordination of so-called "cross-over" claims is a one-way communication of claims information from Medicare to the secondary plan. This "cross-over" does not occur in real time. Instead, Medicare communicates with employer plans on a batch basis, and claims information may not reach the secondary insurer until weeks after the covered service is rendered. Coordination of benefits is, nonetheless, a valuable service to employers and Medicaid since these payors get an electronic claim that has already been subjected to claims edits and on which Medicare has already paid its portion. As a matter of fact, the service is so cost effective that employers willingly pay Medicare for the "cross-over" service. We have agreements with numerous employers purchasing "cross-over" data. In 2004 Medicare

expects approximately 550 million Part A and Part B claims to "cross-over" to a secondary insurers including Medigap, Medicaid, employers, other insurers, and third party administrators providing wrap-around coverage.

Section 1860D–2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining if costs for Part D enrollees are reimbursed by other payors, and for alerting Part D plans about such arrangements. This provision could be read to mean that we only have to determine the presence of alternative coverage and merely has to alert Part D plans of such. However, it could also be read to mean that we have to determine if specific claim costs have been reimbursed by alternative coverage. In contrast, section 1860D–24(a) of the Act directs us to establish requirements for Part D plans to coordinate benefits with other payors in the same manner as we are directed to coordinate Part D benefits with SPAPs. This provision could mean that the responsibility for coordination of benefits lies with the Part D plans. However, section 1860D-24(c)(2) of the Act provides that the requirements of section 1860D-24 shall not affect the application of procedures established under section 1860D-2(b)(4)(D) of the Act. This arguably preserves the flexibility CMS has under the later section to impose requirements on alternative coverage

arrangements. In addition, section 1871 of the Act generally authorizes us to prescribe such regulations as may be necessary to carry out administration of the insurance programs under title XVIII of the Act that now includes Part D.

We assume that employer and union plans may respond to the new Medicare prescription drug benefit in a number of ways. We expect that many of the employers and unions that currently provide supplemental drug coverage to their retirees will opt to pay premiums to Part D plan sponsors. In today's Medicare Advantage market, the most prevalent model is one that employers and unions pay premiums to MA organizations. We expect this model to continue to have wide appeal under Part D. In the case of the PDP market, while many employers and unions may choose to pay premiums to PDPs for Part D for their retirees, others may choose to coordinate benefits with PDPs. In general, employers and unions that continue to offer assistance to Medicare-eligible retirees will either (1) provide qualified coverage of prescription drugs in such a way that retiree-beneficiaries do not need to enroll in Part D of Medicare, in which case the employer may qualify for a Federal subsidy under section 1860D–22(a) of the Act; or (2) provide assistance that requires retiree-beneficiaries

to enroll in Part D (either by paying Part D basic or supplemental premiums); or (3) provide supplemental ("wrap-around") benefits through alternative secondary coverage. The last option has implications for coordination of benefits between Part D plans and employer/union-sponsored retiree drug coverage, and in particular, on the accurate processing of claims with respect to the out-of-pocket threshold.

e. Tracking True Out-of-Pocket (TrOOP) Costs

As we discuss in the preamble to subpart C of this rule, section 1860D-2(b)(4)(C) of the Act provides that beneficiary costs for covered Part D drugs are only considered incurred when those costs are incurred by a Part D enrollee for covered part D drugs covered under (or treated as covered under) a Part D plan that are not paid for under the Part D plan due to the application of any annual deductible or other cost-sharing rules for covered part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under proposed § 423.104(e)(5)(iii), including any price differential for which the Part D enrollee is responsible under proposed § 423.120(a)(6) and §423.124(b)(2). Further, section 1860D-2(b)(4)(C)(ii) of the Act provides that costs shall be treated as incurred by a Part D eligible individual only

when they are paid by another person (such as a family member, on behalf of the individual) and the individual (or other person) is not reimbursed by insurance or otherwise, a group health plan, or other third-party arrangements, with the exception of amounts reimbursed by a SPAP or under the low-income subsidy provided for under proposed § 423.782. We refer to beneficiary expenditures for covered Part D drugs meeting these requirements as "true out-of-pocket costs", or TrOOP. We are considering a number of options for facilitating the exchange of data needed to track TrOOP, and will discuss alternatives around both mandatory versus voluntary reporting of claim and out-of-pocket costs, and centralized versus distributed responsibility for tracking the information in the extended discussion, below.

The case in which the employer or union arranges wrap-around coverage through a third party administrator or insurer other than through a Part D plan in which the retiree-beneficiary is enrolled is the potentially complex and challenging to administer, especially given the true out-of-pocket costs (TrOOP) requirements. The degree of difficulty in making coordination of benefits work with respect to wrap-around coverage is related to the ability of plans to efficiently coordinate insurance coverage at

the point of sale. We cannot estimate the number of employer/labor plans that might choose to wrap-around prescription drug coverage other than through a Part D plan. We welcome comment that would help us estimate the scope and impact of such coverage, as well as the impact on the operational capabilities of plans (and their subcontractors).

Medicare Part D plans will need to be particularly involved with employer/union plans that wrap-around Part D coverage due to the implications such wrap-around coverage has for administering TrOOP maximums. Payments made on behalf of a beneficiary by a third party (such as by employer/labor-sponsored supplemental prescription drug coverage) are not considered incurred costs and, therefore, do not count in the TrOOP calculation. Thus, employer/labor-sponsored wrap-around coverage effectively pushes out the total spending "attachment point" or starting point at which protection from high out-of-pocket beneficiary expenditures begins.

As discussed in Subpart G of this preamble, although Part D plans will receive reinsurance payments from us for a portion of the costs they incur for prescription drug coverage provided to beneficiaries after the true out-of-pocket threshold has been met, Part D plans will also bear

"risk" for a portion of the costs they incur above the threshold. The critical nature of the TrOOP calculation makes coordination of benefits under the Part D program of vital interest to all parties. Both CMS and Part D plans must know how much an employer/union-based plan or other plan pays on a prescription drug claim following adjudication of that claim by the Part D plan. Likewise, beneficiaries have a vested interest in the TrOOP calculation due to the financial relief they receive after meeting the annual out-of-pocket threshold.

Responsibility for tracking TrOOP costs is somewhat unclear. On the one hand, the government is given authority to establish procedures for tracking TrOOP costs. For instance, as we discuss later in this preamble section and as we propose to codify in regulation at § 423.464(c), section 1860D-24(a)(3) of the Act authorizes us to impose user fees for disseminating information necessary for benefit coordination. On the other hand, responsibility for obtaining and applying the necessary information to prescription drug claims is assigned to the Part D plan sponsors. It is of great importance to establish clear responsibilities for TrOOP tracking and calculation processes in regulation in order to ensure that qualified beneficiaries receive appropriate coverage once they have

met the out-of-pocket cost limit.

There is sufficient ambiguity in the statutory language to support a proposal to mandate that group health plans, insurers, and otherwise, and other third-party arrangements provide claims data for Part D enrollees to us for purposes of administering TrOOP. Exercising such authority would not be in violation of HIPAA confidentiality requirements. However, exercising such authority would impose administrative burden on group health plans, insurers, and otherwise, and other third-party arrangements that provide coverage or reimbursement of health care expenses to Medicare Part D beneficiaries. Moreover, mandatory reporting of enrollment file and claims data will not be sufficient, in and of itself, to capture all forms of enrollee cost-sharing reimbursement.

For instance, if the third party reporting of claims payments and reimbursements are strictly voluntary, serious challenges to implementing a system for tracking TrOOP will continue to exist. A voluntary system would be incomplete and all payors that rely on voluntarily reported data would need to have back-up procedures for accounting for initially unreported data. A voluntary system would also leave CMS and Part D plans open to criticism that the data

is incomplete and that benefits paid out based on TrOOP calculations are inaccurate. However, group health plans, insurers and otherwise, and other third-party arrangements might prefer a voluntary system.

By way of comparison, the current (voluntary) Medicare Secondary Payor (MSP) program achieves $4.5 billion in savings. This means that there is some compliance with the provisions even though there is no mandatory insurer-reporting requirement. However, under the MSP provisions there are enforcement provisions. There are tax penalties for non-compliance with the MSP rules. In addition, there is a mandated reporting of some information through the IRS/SSA/CMS data match project that obtains tax and spousal information from the IRS and SSA. Our contractor then sends the employer a questionnaire concerning the identified Medicare beneficiary or spouse of a beneficiary to determine if there is coverage that is primary to Medicare. Failure to complete the questionnaire can result in the imposition of a Civil Monetary Penalty. However, even with these enforcement provisions, it is estimated that Medicare is still losing millions of dollars where employer plans should be primary. Payments made by plans primary to Medicare under the Medicare Secondary Payer provisions 1862(b) would not could against the TROOP.

In the cross-over area discussed previously in this section of the preamble, we are more successful, but there are still numerous payers who do not have cross-over agreements with us. So although there is substantial participation related to cross-over claims, there is also significant room for improvement. In the context of the current discussion, the issue is primarily that the sending of paid claims data to us for its use in the TrOOP calculation will be an added administrative cost on third-party payers, which (without explicit reporting requirements in the statute or an even an enforcement mechanism) may lead to lower compliance.

We are considering the following options for operationalizing the data exchange related to the Part D coordination of benefits system and TROOP accounting:

Option 1: The PDPs and MA-PD plans would be solely responsible for tracking TrOOP costs. This option places the entire responsibility for tracking TrOOP costs with the PDPs and MA-PD plans. As part of their overall benefit management responsibility they would be responsible for establishing the systems infrastructure and ensuring that all data points are reporting timely and accurate data about beneficiaries' Part D costs. Each PDP and MA-PD plan must establish arrangements with all payers for enrollment

file sharing and claims payment information exchanges. This coordination applies equally to plans that are primary or secondary payer to Medicare. Under this scenario, any payer who had a beneficiary on behalf of whom they expected to make either a primary or secondary payment to Medicare Part D would need to be able to (1) identify the Part D plan in which the beneficiary was enrolled, (2) establish the telecommunications links; (3) transmit enrollment information to the specific PDP or MA-PD plan in which their covered individual is enrolled, and (4) transmit claims payment data to the PDP or MA-PD each time a claim was paid which may need to be included in the TROOP calculation. Data collected by a PDP or MA-PD plan would be annotated to the Medicare Beneficiary Database and be available to pharmacies for the purposes of proper billing.

Option 2: We would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary. Under this scenario, we would procure a TrOOP facilitation contractor based on a strategy of voluntary compliance, similar to the existing MSP coordination of benefits model. We would procure a contractor to receive enrollment and claims payment information from all plans primary and secondary to Medicare. This would establish a single point of contact

between the Medicare program and employers, State Pharmacy Assistance Programs, as well as primary and secondary payers for enrollment and claims payment information.

Under this single point of contact option, a payer primary or secondary to a Part D plan would be required to send an enrollment file to the TROOP facilitation contractor (a contractor procured by us). The TROOP facilitation contractor would match the payer enrollment information to Medicare enrollment records and update the Medicare Beneficiary Database with the information. The other payer enrollment file information would also be used the TROOP facilitation contractor to match claims payment data which would also be submitted to the TROOP facilitation contractor. Once a claim was matched against the enrollment data, the TROOP facilitation contractor would aggregate the claim records files by Part D plan and transmit the information. The PDP or MA-PD plan would be responsible for using the data in applying the TROOP and applying other TROOP requirements such as the application of a formulary.

PDPs and MA-PD plans would also request information about other coverage during the enrollment process and could add change or delete information input into the system by the TROOP facilitation contractor. We can use

existing fee-for-service coordination of benefits processes to implement many of the processes needed to implement these provisions. Information concerning primary and secondary plans would be shared with and PDPs and MA-PD plans, as well as annotated in the Medicare common working file/Medicare Beneficiary Database to enhance pharmacy billing and beneficiary customer service.

Under either option, we would enter into voluntary data sharing agreements with employers/unions and other plans to participate in a shared system. The same mechanism would accept information provided directly by Part D plans, SPAPs, group health plans, FEHBP, military plans, and other insurance or payors as we may specify.

We are committed to ensuring that claims are processed appropriately under Part D. Therefore, to foster proper billing and coordination of benefits we are also considering the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query. Information collected under this section for the purpose of TROOP application would be available to be queried by pharmacies to facilitate proper billing. We are concerned that with the significant expansion of health care options available to beneficiaries that providing information to pharmacies about Medicare and

other coverage is essential to facilitate proper claims processing. We are requesting comments concerning the development of this system.

In either event, the system(s) would need to be operational by January 1, 2006. Note that user fees might be imposed on third-party payers (but not on SPAPs) for the transmittal of information under either model. Were responsibility to reside solely with Part D plans to develop and operate a coordination of benefits system or systems (without a defined role for us in such development and operation), the statute would still permit imposition and collection of user fees. Please see our preamble discussion on user fees earlier in this preamble related to proposed § 423.464(c).

We could propose (with or without mandatory reporting by insurers) placing requirements on Part D plans and enrollees that would facilitate private market arrangements to report the data. We are considering mandating that beneficiaries enrolling in Part D plans provide third-party payment information and consent for release of data held by third parties as part of their enrollment application and which could be validated through a HIPAA-compliant beneficiary "release" or authorization. For instance, if we were to clearly require that all Part D plans coordinate

benefits and that all Part D enrollees provide consent for release of third-party data on their Part D enrollment forms, the Part D plans would have the authority to implement inter-plan reporting mechanisms in order to coordinate benefits. However, back-up procedures would still be necessary to capture expense reimbursements made outside prescription drug claim processing systems as, for instance, by HRA administrators. Thus, although the statute is unclear as to which entity should have primary responsibility for tracking TrOOP costs (CMS or the Part D plans), to facilitate the accurate calculation of TrOOP we could do this either through reliance on data collection provisions in section 1860D-15(c)(1)(C) of the Act, or in reliance on our authority to collect information related to contracting in section 1860D-12(b)(3)(D) of the Act that incorporates into Part D section 1857(e) of the Act, allowing the contract to require the contracting organization to provide to us the information as we decide necessary and appropriate. However, section 911(c)(2) of the MMA strictly forbids matches of data between Medicare contractors and us to identify MSP situations. The fact that the MMA is silent with regard to matches or data exchanges for the purposes of Part D TrOOP cost administration could be taken in different ways. One way

to read the statute would be that the omission was intentional and the Congress specifically intended for the type of exception not to be applicable for TrOOP. However, an equally good case could be made that TrOOP administration procedures were to be defined by us and therefore the spirit of the provision contained in 911(c)(2) should be considered as it applies to TrOOP.

We ask for comment on these options and are seeking input on the best means to ensure an efficient and effective coordination of benefits related to the Part D Medicare program. We are also interested in discussion of other temporary or phased-in approaches that may be necessary or advisable given the short timeframe between publication of the final rule and program implementation. Under any of the scenarios presented it is clear that the ultimate responsibility for calculating TrOOP belongs to the Part D plan. The only issues are what role in facilitating TrOOP tracking CMS should have, if at all.

It is important to note that the sequencing of primary and secondary insurance claims will be a critical issue for tracking TrOOP costs. If, for example, a secondary plan does not provide feedback to the system in real time, it is possible that the TrOOP cost information the Part D plan has access to may not be entirely up to date at any given

time. Also, if a paper claim is submitted after the fact to the Part D plan or supplemental insurer (due to an appeal reversal, for instance), the TrOOP calculation would not be up to date in real time at the point of service. Another complicating factor in the sequencing of claims is cancelled prescriptions. Generally, a claim is adjudicated when a prescription is filled. If the prescription is not picked up, and is eventually cancelled, the claim needs to be cancelled. If, in the meantime, other claims have been adjudicated, the sequencing is thrown off by the cancelled prescription, potentially disrupting the calculation of the initial deductible and TrOOP, and making coordinating benefits and tracking TrOOP costs more difficult.

Ideally, we would prefer that the system actually coordinate the adjudication of claims and provide real-time claims processing across multiple insurers, but we do not believe that such a complex and unique system could be operational by January 1, 2006. And, as previously mentioned, we do not have statutory authority to enforce a mandatory reporting requirement that employers, group health plans, other insurance or third-party arrangements participate in such a system. We believe, however, that the type of voluntary system we envision would provide information sufficient to permit the coordination of

benefits that the statute requires and that beneficiaries and pharmacies desire. In any case, the goal would be to minimize the prevalence of paper claims submitted post point of service. In addition, we request public comment on methods for Part D plans to receive information from beneficiaries or others regarding payment made by entities that do not participate in this coordination of benefits system, since there is no requirement that third-party payers participate in this voluntary system.

We anticipate that the majority of employers, group health plans and other third-party payment arrangements would participate in a voluntary system since they would receive a clean claim from the pharmacy that has already been adjudicated by the Part D plan. In return for the clean claim, we would request that third-party payers provide information back to the coordination of benefits system regarding how much they paid on the claim for purposes of calculating the TrOOP under Part D. We anticipate that there will be times that the information in the system is not consistent with what the beneficiary informs the pharmacy is the most current state of insurance. We request comment and relevant information (if any exists from current market practices) on how these

situations should be resolved under Part D at the point of sale.

K. Proposed Application Procedures and Contracts With PDP Sponsors

[If you choose to comment on issues in this section, please include the caption "Subpart K—Proposed Application Procedures and Contracts with PDP Sponsors" at the beginning of your comments.]

1. Overview

Subpart K of proposed part 423, would implement provisions established by sections 1860D-12(b)(1), 1860D-12(b)(3)(A), 1860D-12(b)(3)(B), 1860D-12(b)(3)(C), 1860D-12(b)(3)(D) and 1860D-12(b)(3)(F) of the Act that relate to contract requirements for PDP sponsors. The proposed provisions in this rule would address conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements and termination procedures that would apply to Medicare-contracting PDP sponsors.

2. Background

Section 1860D-12(b)(1) of the Act provides that an entity seeking to participate in the Medicare program as a PDP sponsor must enter into a contract with us for that offering. The contract may cover more than one prescription drug plan in a region or across multiple

We are considering alternatives for the fallback plan payment process. Under one proposal, we would establish an account against which the claims costs and management fees would be debited. This means that the entity offering the fallback plan would debit the prescription drug claim costs and their negotiated administrative fees against this account in a manner to which we agree and would then be subject to certain cost reporting and settlement requirements, as, for instance, with regard to rebate allocation. An alternative approach would be to establish an estimated monthly payment per enrollee as a prospective payment for the fallback plan. Initially, that amount could change monthly to reflect differences between the costs of enrollees in a fallback plan versus payments to the plan under the prospective system. The objectives of this approach would be to provide the correct amount of money to the fallback plan to reflect their actual costs. We request comment on payment methodologies, particularly in regard to prospective or retrospective rebate allocation.

R. Payments to Sponsors of Retiree Prescription Drug Plans

1. Overview

Subpart R would implement section 1860D-22 of the Act, which provides for making subsidy payments to sponsors of qualified retiree prescription drug plans. Section 1201 of the MMA amends the Internal Revenue Code of 1986 to provide that these subsidy payments will be exempt from Federal tax. Further guidance on the Federal tax treatment of the subsidy will be under the auspices of the U.S. Department of the Treasury.

a. Options for Sponsors of Retiree Prescription Drug Programs

The enactment of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) on December 8, 2003 has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. We believe the availability of these various options will encourage employers and unions to continue to assist their retirees in having access to prescription drug coverage.

Generally, employers and unions who offer drug benefits to their retirees (and their spouses and dependents) who are also eligible for Medicare Part D could--

(1) Provide prescription drug coverage through employment-based retiree health coverage. If employment-

based retiree health coverage were at least actuarially equivalent to the standard prescription drug coverage under Medicare Part D, the sponsor would be eligible for a special Federal subsidy for each individual enrolled in the sponsor's plan who is also eligible for Medicare Part D, but who nevertheless elects not to enroll in Medicare Part D;

(2) Contract with a PDP sponsor or Medicare Advantage (MA) organization to enroll Medicare beneficiaries covered under the retiree plan into a prescription drug plan (PDP) or Medicare Advantage-prescription drug (MA-PD) plan. Alternatively, the sponsor itself could apply to be a PDP sponsor or MA organization and offer a PDP or MA-PD plan to its retirees. That plan could consist of "enhanced alternative coverage" (as defined under § 423.4 of our proposed rule), that is, drug coverage that is more generous than that offered under the standard prescription drug coverage under Medicare Part D (as defined under § 423.4 of our proposed rule). Medicare would subsidize the cost of such coverage through direct and reinsurance subsidies. At its option, the sponsor could elect to subsidize the monthly beneficiary premium (as calculated under § 423.286 of the Drug Benefit);

(3) Provide prescription drug coverage that supplements, or "wraps-around," the coverage offered under the PDP or MA-PD plans in which their retirees (and retirees' spouse and dependents) enroll.

The first option is the subject of this subpart of our proposed rule. The latter options, all of which involve employers' or unions' retirees (and their spouses and dependents) enrolling in Part D, are discussed in detail in the preamble to subpart J. We note that employers also have the option of subsidizing the monthly beneficiary premium for the PDP or MA-PD plan in which the employer or union's retirees (and their spouses and dependents) elect to enroll.

If employers or unions elect to sponsor either an enhanced alternative plan covered under Medicare Part D or supplemental coverage that "wraps around" Medicare Part D, either election will have an impact as to when their retirees (and retirees' dependents) will be eligible for catastrophic drug coverage, with important consequences for participants, sponsors, the plans, and the Medicare program. By delaying the provision of government-financed catastrophic coverage, these plans would lower the cost of Part D to the Federal government by lowering our reinsurance payments while preventing beneficiaries from

facing any gaps in coverage. As discussed in subpart C of this preamble, individuals enrolled in a PDP or MA-PD plan would be eligible for catastrophic drug coverage after they have incurred out-of-pocket drug costs in the amount specified under § 423.104(e)(iii)(A) of our proposed rule. Under the reinsurance provisions, Medicare would reimburse PDP sponsors and MA organizations offering MA-PD plans 80 percent of their gross costs for providing catastrophic coverage (excluding administrative costs and net of discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count toward the annual out-of-pocket threshold. Amounts reimbursed by insurance or otherwise, by a group health plan, or by another third-party payment arrangement would not count toward the threshold. We refer to those drug expenditures that count toward the out-of-pocket threshold as "true out-of-pocket expenditures" (TrOOP).

Under these rules, sponsors who provide retirees (and retirees' spouses and dependents) enhanced alternative coverage would, in effect, delay the total drug spending that would trigger catastrophic coverage, because plan participants would have lower cost sharing, and thus, have lower out-of-pocket costs. Similarly, employers or unions

who would sponsor supplemental coverage that would "wrap-around" Medicare Part D coverage would raise the total drug spending that would trigger government-financed catastrophic coverage, since drug costs paid for by those plans would reduce beneficiary costs and would not count toward the true out-of-pocket annual limit.

When an employer or union elects to contract with a PDP sponsor or MA-PD organization, the PDP sponsor, under § 423.458(c) of our proposed rule, or the MA organization, under § 422.106(c), may submit written requests to us for permission to waive requirements under Part D that hinder the design or offering of PDP or MA-PD plans to employers. We believe these waivers would facilitate efficient administration and integration of their enhanced Part D coverage with other retiree health benefits offered by the sponsor, as another subsidized option for employers to offer enhanced coverage instead of using Medicare's alternative retiree drug subsidy. For example, the PDP sponsor or MA organization could request permission to restrict enrollment in its PDP or MA-PD plan to the sponsor's retirees (and their spouses and dependents) and offer a benefit that resembles or enhances the sponsor's existing coverage. Similarly, should the plan sponsor wish to enroll its retirees (and their spouses and dependents)

in its own plan, with enrollment limited to those individuals, the sponsor could apply to be a PDP sponsor or MA organization offering a MA-PD plan and request such waivers as necessary.

We encourage plan sponsors to carefully review each option and determine which one is most beneficial to the sponsor and its retirees. We believe that the variety of options will encourage sponsors to retain drug coverage for their retirees (and their spouses and dependents), and we seek comment on how we can use all of these subsidized options to maximize enhancements in retiree coverage.

b. The Retiree Drug Subsidy Provision

During the past 15 years, the availability and generosity of employment-related retiree health coverage has been eroding due to rising health care costs, increasing numbers of retirees (who may be more costly to cover than younger active workers), and the impact of changes in accounting rules. For example, in 1988 approximately 66 percent of the nation's private sector firms with 200 or more workers that offered health benefits to active workers also offered retiree health benefits to any of their retirees, including both the pre-65 and the ages 65 and older populations, but by 2003 only 38 percent of these firms were offering retiree health coverage. Most

employers that offer retiree health benefits also provide retiree prescription drug coverage. A more detailed discussion of the trends in retiree coverage, as well as the limitations in the data available on these trends is provided in the impact analysis section of this proposed rule.

By providing heavily subsidized insurance coverage of prescription drug expenditures incurred by, or on behalf of, Medicare beneficiaries, the MMA would significantly reduce the cost of existing retiree beneficiary drug coverage. For retiree-beneficiaries who enroll in Part D, Medicare would become the primary insurer. MMA would then lower the sponsor's cost of drug coverage by having the sponsor's plan become a secondary payer of retiree drug coverage. However, plan sponsors may benefit from the greater flexibility and fewer prescriptive requirements of the alternative retiree drug subsidy.

The retiree drug subsidy is designed to accommodate plan sponsors seeking greater flexibility and less regulation. In addition, while the expenses associated with providing retiree drug coverage continue to be deductible expenses for Federal tax purposes, the payments associated with the retiree drug subsidy are not counted as taxable income for employers. As discussed in the

Regulatory Impact Analysis of this preamble, the after-tax nature of the retiree drug subsidy payments effectively increases the value of these payments for employers that are subject to the corporate income tax. For example, the tax-free $611 average retiree drug subsidy amount would be equivalent to about $940 of taxable income for employers with a marginal tax rate of 35 percent. As discussed further in the impact analysis, we believe that the tax treatment of the retiree drug subsidy payments will provide an additional incentive for employers to participate in the retiree drug subsidy program.

The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that

employers do not receive "windfalls" consisting of subsidy payments that are not passed on to beneficiaries.

We plan to conduct outreach to plan sponsors, retirees and retiree associations, and other interested parties on all aspects of the MMA. We encourage their input on the feasibility and advisability of the approaches we have identified, as well as any other issues presented by the new statute, or additional options beyond those we have identified. We look forward to employer, union, and other public comments on all aspects of this proposed regulation. We particularly seek comments on the sections noted in the preamble.

2. Definitions (§ 423.882)

The Act contains a number of definitions that are critical to understanding how the retiree drug subsidy functions. To make it easier to understand how these definitions work together to establish the subsidy amount, we first provide an overview of the structure of the subsidy program and then provide a description of the key concepts. As noted above, a significant portion of the Medicare population receives prescription drug coverage through employer and/or union sponsored retiree health benefits. The Act provides for Medicare payment to plan sponsors who choose to provide prescription drug coverage

that is at least as generous as the standard prescription drug benefit under Medicare Part D. The Congress intended for the subsidy to encourage as many sponsors as possible to retain this coverage for their retirees (and their spouses and dependents). The subsidy payment made to a sponsor of a qualified retiree prescription drug plan would be based on actual drug spending by individuals enrolled in the plan and not premium payments. The subsidy is 28 percent of certain costs that are incurred for certain prescription drugs for individuals covered under the qualified retiree prescription drug plan who are eligible for the Medicare Part D drug benefit but who are not enrolled in Medicare Part D. The statute defines a number of terms in order to distinguish between costs that are to be considered in determining the subsidy payment amount, and costs that may not be considered in determining the subsidy payment amount.

Only group health plans that provide health coverage to Part D eligible individuals based on their status as retiree participants (or spouses or dependents of retiree participants) may qualify as a retiree prescription drug plan. The term "group health plan" is defined later below. Additionally, to be considered a qualified retiree prescription drug plan, the sponsor's group health plan

must be at least actuarially equivalent to the standard drug coverage under Medicare Part D (in accordance with section 1860D-22(a)(2)(A) of the Act and as discussed below in section 3(b) of this subpart). As required under section 1860D-22(a)(2)(A) of the Act, the sponsor must submit an actuarial attestation that its plan is at least actuarially equivalent to the standard Medicare Part D prescription drug benefit for the plan to be a "qualified retiree prescription drug plan." In addition to meeting tests of actuarial equivalence, the plan must be a group health plan that provides prescription drug benefits to Medicare Part D eligible individuals, as defined in § 423.882, based on their status either as retirees or as spouses and dependents of those retirees.

The next step is to identify the "qualifying covered retirees" (that is, those Medicare beneficiaries eligible to enroll in Medicare Part D who are enrolled in the retiree plan, but who are not enrolled in the Medicare Part D benefit) and determine the "gross covered retiree plan-related prescription drug costs" (gross costs) under the plan for these individuals for the year. Gross costs refer to the costs directly associated with the dispensing of a prescription drug. (In the prescription drug industry, gross costs are frequently referred to as the "ingredient

costs" (the cost of the drug itself) and the "dispensing fee" (the pharmacy charge for dispensing the drug to a patient)). The statute, however, specifically excludes the retiree health plan's administrative costs from gross costs. Having established that gross costs are the base upon which the subsidy payment is to be determined, the statute then specifies that the payment may be made only for those costs that fall between the "cost threshold" and the "cost limit". For 2006, the cost threshold is $250 and the cost limit is $5,000. In other words, the first $250 in prescription drug costs for an individual during a year and any prescription drug costs for that year that exceed $5,000 is disregarded. The dollar values for the cost threshold and cost limit are adjusted annually.

The statute then specifies that the amount of gross costs that fall between the cost threshold and cost limit must be reduced by any discounts, chargebacks, rebates, and other price concessions. These net costs actually paid by the sponsor or by or on behalf of the retiree are referred to as the "allowable retiree costs." The intent of this provision is to ensure that Medicare subsidy payments take into account the pricing adjustments and discounts that actually occur in the market today. Some pricing adjustments, such as manufacturer rebates, typically occur

well after payment is made to the pharmacy. Since the ingredient costs and dispensing fees found in the claims data do not include the lower "prices" achieved as a result of manufacturer rebates and other price concessions, further adjustment is needed to account for these other pricing related factors when determining the costs under the plan that will be "allowable" for purposes of the Medicare subsidy payment amount.

To summarize, the statute provides that the retiree drug subsidy payment amount equals 28 percent of the allowable costs attributable to the portion of the gross costs that fall between the cost threshold and cost limit. The definitions below further articulate the meaning of the key terms involved in determining the subsidy payment amount. The definitions are organized to first describe the Medicare Part D eligible individuals, then terminology related to retiree plans, and finally, terminology related to the subsidy payment amount and the basis upon which the payment is determined.

Part D Eligible Individual

Section 423.4 of our proposed rule defines a Part D eligible individual as an individual who is entitled to or enrolled in benefits under Medicare Part A or who is enrolled under Medicare Part B.

Qualifying Covered Retiree

Section 1860D-22(a)(4) of the Act defines a qualifying covered retiree as a Part D eligible individual who is not enrolled in a Part D prescription drug plan (PDP) or Medicare Advantage-Prescription Drug (MA-PD) plan but who is covered under a qualified retiree prescription drug plan. We note that the qualifying covered retiree is not necessarily the retired employee who is the participant under the plan; it also includes coverage of a Part D eligible individual who is covered under the plan as a spouse or dependent of a participant. (Under ERISA, an employee or former employee who is covered under an employment-related plan is referred to as the "participant." Dependents of the participant are referred to as "beneficiaries," but to avoid confusion with "Medicare beneficiaries," we will refer to the beneficiaries under the health plan as "spouses and dependents.")

Employment-Based Retiree Health Coverage

Section 1860D-22 (c)(1) of the Act defines employment-based retiree health coverage. Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan or as the spouse or

dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage or pursuant to statutory or contractual obligation.

Group Health Plan

The term "group health plan" has the same meaning as defined in section 607(1) of ERISA, 29 U.S.C. 1167(1). Section 1860D-22(c)(3) of the Act specifies that the definition of a group health plan includes plans maintained for their employees by the Federal government (including the Federal Employee Health Benefits Program (FEHBP) and the TRICARE program); plans maintained by State or local government; and church plans exempt from Federal taxes under section 501 of the Internal Revenue Code of 1986 (despite the fact that those types of group health plans are not generally subject to ERISA requirements).

Qualified Retiree Prescription Drug Plan

A qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884(a) through § 423.884(d) for a Part D eligible individual who is a participant or the spouse or dependent of a participant under the coverage.

Sponsor

Sponsor means plan sponsor as defined in section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B). This term means an employer, an employee organization (generally a trade union) or a combination of employers and employee organizations. Section 1860D-22(c)(2) of the Act, however, modifies this definition in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, in which case the term "sponsor" means the employer.

Covered Part D Drug

Covered Part D drug has the meaning given in § 423.4 of our proposed rule and as discussed in subpart C of this preamble.

Retiree Drug Subsidy Amount

The retiree drug subsidy amount is defined as 28 percent of the allowable retiree costs for each qualifying covered retiree. Section 1860D-22(a)(3) of the Act describes the subsidy payment to be made to the sponsor of a qualified retiree prescription drug plan with respect to each qualifying covered retiree who is covered under the plan.

Gross Covered Retiree Plan-Related Prescription Drug Costs

Section 1860D-22(a)(3)(C)(ii) of the Act defines gross

covered retiree plan-related prescription drug costs to mean specified costs incurred for a qualifying covered retiree enrolled in a qualified retiree prescription drug plan "during a coverage year." (For ease of reference, we use the term "gross retiree costs" interchangeably with the defined term.) We explain below in the preamble discussion related to § 423.888, that we have tentatively determined that the subsidy should be based on calendar year data. For purposes of this definition, we simply use the term "year;" in the final regulation, we will clarify whether it is a plan year or a calendar year.

In accordance with section 1860D-22(a)(3)(C)(ii) of the Act, we define the term, gross covered retiree plan-related prescription drug costs, (gross retiree costs) to mean the costs incurred under a qualified retiree prescription drug plan for a qualifying covered retiree that are directly related to the dispensing of covered Part D drugs during the year (other than administrative costs), whether they are paid under the plan or by the retiree. Costs for covered Part D drugs incurred under the plan that are paid for by the retiree include all retiree cost sharing under the plan (for example, deductibles or copayments). Costs for non-covered Part D drugs are not

considered gross retiree costs, even if paid for under the plan.

As discussed above, dispensing fees are included in gross retiree costs, but administrative costs are excluded. Therefore, we expect to monitor dispensing fees carefully through our audit activities in order to ensure that other administrative costs are not improperly included in the dispensing fees.

Allowable Retiree Costs

In accordance with section 1860D-22(a)(3)(C)(i) of the Act, allowable retiree costs means gross covered retiree plan-related prescription drug costs between the cost threshold and cost limit that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions. For the purposes of determining the subsidy payment, allowable retiree costs include cost sharing paid "on behalf of" the qualifying covered retiree by any person or entity. This would include amounts paid by family members and charitable organizations to assist the retiree in his or her cost-sharing obligations. Amounts paid by other group health plans and insurers, such as under a spouse's plan that

provides secondary coverage towards the cost sharing, would also be considered allowable retiree costs.

We note that the rules for calculating allowable costs under the subsidy provisions of section 1860D-22 of the Act must not be confused with the rules that pertain to the amount of cost sharing that must be paid by beneficiaries who enroll in Medicare Part D. Under section 1860D-2 of the Act (§ 423.466(b) of our proposed rule), beneficiary cost sharing under the PDP or MA-PD plan only counts toward reaching the annual "out of pocket threshold" that triggers catastrophic coverage if it is paid by the beneficiary or by another person such as a family member. In general, beneficiary cost sharing for which the beneficiary is reimbursed through insurance, a group health plan, or other third-party payment arrangement will not count toward the annual out-of-pocket threshold. The employer/union subsidy provisions contain no similar limitation. Thus, beneficiary cost sharing is an allowable cost regardless of who pays the cost sharing.

Because allowable retiree costs exclude gross retiree costs below the cost threshold, a plan sponsor will be entitled to a subsidy payment for a qualifying covered retiree only if that individual's gross retiree costs, or

total drug spending under the plan for a year, exceed the cost threshold for that year.

As noted above, allowable retiree costs are drug costs that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), and therefore net of any drug discounts, chargebacks, rebates, and any other similar price concessions passed through to the plan or retiree. (For purposes of this discussion, we will refer to all of the immediately preceding terms as "rebates"; that is, discounts, chargebacks, rebates, and similar price concessions). We understand that much of the rebate accounting is not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that rebates are frequently reported along with administrative fees paid by the manufacturer. We are aware and concerned that, in some cases, plan sponsors may accept lower administrative costs or receive services at or below fair market value in lieu of some or all of the rebates. We are concerned that this practice may result in improper shifting of costs in order to inappropriately maximize subsidy amounts. We intend to monitor these arrangements closely to ensure that allowable retiree costs are not improperly inflated. We are also concerned that these

accounting and business practices would be incompatible with the requirement to disclose all price concessions for purposes of determining allowable retiree costs and we, therefore, are proposing to require that the true cost of rebates be segregated in all records. We require that all rebates passed through to the plan sponsor and retiree in any form be subtracted when calculating allowable retiree costs.

Due to the nature and timing of rebate accounting, we believe that this will require a form of step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees incurring allowable retire costs on a reasonable basis. Since Medicare beneficiaries would be expected to have higher per capita prescription drug utilization than other populations, we believe it would generally be appropriate to allocate rebates (and other similar price concessions) on the basis of percentage of dollars spent rather than of covered lives. The method of apportioning and applying rebates will be influenced by the payment methodology that is implemented for the retiree drug subsidy (see discussion in section 5 of this subpart). For example, in a one-time annual retroactive payment system, where payment of the subsidy is made after the close of the year, it should not

be too difficult to factor in the rebates credited to the sponsor (or plan) for the period in question since the subsidy payment may occur after the rebates have been credited. Conversely, under a monthly payment system, factoring in the rebates would require a process to reflect the rebates as they are realized, because they are not likely to be determined and known until after some subsidy payments occur.

We believe either approach would require a form of cost reporting in which rebates received at the aggregate plan level would be apportioned to plan enrollees. One approach would be to reduce the subsidy payments by a certain percentage calculated to equal the assumed size of the rebates expected to occur. After 2006, the amount of reduction could be based upon the rebates received in prior years. Once the actual rebates were credited for the year in which the subsidy payments were made, the payments could be reconciled. Alternatively, rebates could be accounted for and paid in the month in which they are received. We also briefly discuss how rebates could be applied to different payment methodologies in section 5(b) of this subpart.

In any case, plans must require and keep accurate records on all price concessions and ensure that these are

distinctly accounted for separately from administrative fees. We are considering how to best account for all of the price concessions and rebates. We welcome comments on the nature and scope of price concessions in this industry, and on the various forms these arrangements may take, as well as on the pass-through issue. We also welcome comments on how rebates and other forms of remuneration can be most accurately applied to the cost data to efficiently satisfy the requirement that all rebates must be netted out of allowable retiree costs, while minimizing the burden on sponsors. All cost reporting would be subject to inspection and audit (including periodic audits) by CMS and the OIG. As discussed later, to the extent either CMS or the OIG discover that a sponsor was overpaid for the retiree drug subsidy (that is, the records do not support the payments made, or there is insufficient documentation to determine whether the payments are correct), we may recoup the overpayments or take other appropriate action. The reopening and overpayment provisions are discussed in section 6 of this subpart R.

Dispensing Fees

For purposes of consistency, we plan to use the same definition that will be applied to PDP and MA-PD plans. See the discussion of dispensing fees in subpart C of the

preamble to our proposed rule, which discusses possible definitions.

3. Requirements to Apply for the Retiree Subsidy (§ 423.884)

a. General Requirements

This section outlines the general requirements related to applying for the subsidy payment described in this proposed rule. First, in order to be considered a qualified retiree prescription drug plan, a plan must meet the definition of employment-based retiree health coverage as defined in § 423.882 of our proposed rule, and must also comply with the requirements proposed in § 423.884 and discussed in this section of the preamble. Additionally, a plan sponsor that wishes to be paid the Medicare subsidy must apply annually for the subsidy. In paragraph b, below, we describe the actuarial attestation that must be submitted with the subsidy application; in paragraph c, we describe the application process, including the information that must be submitted to establish that the sponsor qualifies for a subsidy; and in paragraph d, we describe the disclosure notices that plan sponsors are required to provide to beneficiaries. Finally, the sponsor must meet the requirements of proposed § 423.888(d) with regard to

maintenance and access to records for purposes of audit, as discussed in section 5 of this subpart, below.

We intend to conduct outreach to plan sponsors, including State and local governments, who would be prospective applicants for these subsidy payments in order to encourage communication, better understand the needs of the employer community, and provide information on the retiree drug subsidy program, as well as to solicit suggestions on how we can best implement this program. We invite comments on the most effective methods of conducting outreach, as well as prospective venues for conducting that outreach.

b. Attestation of Actuarial Value Amount

1. Attestation Requirements

In § 423.884(a) of our proposed rule we would require that the sponsor submit an attestation to us that the actuarial value of the prescription drug coverage under its retiree plan or plans is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage. (A more complete discussion of actuarial equivalency follows, below.) In § 423.884(a)(1) of our proposed rule, we would require that the attestation be submitted annually after year 2006, but no later than 90 days prior to the earlier of the start of the calendar year

or plan year. (Our tentative decision is to use a calendar year.) For purposes of the initial application for the subsidy for 2006, the attestation must be submitted by September 30, 2005. Additionally, we would require that an updated attestation be submitted when mid-year changes to the drug coverage materially affect the drug coverage's actuarial value. (A material change means any change that potentially causes a plan to no longer meet the actuarial equivalence test.) These submissions would not be required when non-material changes are made to the coverage (for example, when there are changes in the period of open enrollment). We would require that the attestation be submitted 90 days prior to the effective date of any material changes. If the impending changes result in the plan either no longer being a qualified retiree prescription drug plan or no longer providing creditable coverage because its benefits are no longer actuarially equivalent to Medicare Part D coverage for purposes of either actuarial test, we would require that beneficiaries be notified of this change 90 days prior to the change taking effect and informed regarding opportunities to enroll in Medicare Part D. (See subsequent discussion regarding disclosure notices.)

We believe that requiring attestation on an annual

basis and 90 days prior to material changes in coverage, with a 90 day notice to beneficiaries when necessary, should provide sufficient assurance to beneficiaries and CMS that the plan meets requirements concerning actuarial equivalency and affords beneficiaries time to enroll in Medicare Part D without incurring a late enrollment penalty as provided for in § 423.56 of our proposed rule. We would also require that the attestation, which must be signed by an authorized representative of the plan sponsor (or a plan administrator designated by the sponsor), include a certification, signed under penalty of perjury, that indicates that the information contained in the attestation is true and accurate to the best of the attester's knowledge and which acknowledges that the information is being provided to obtain Federal funds. We welcome comments on whether these proposals provide sufficient protection for beneficiaries and whether these proposals would be operationally feasible without creating an undue burden for sponsors.

2. Establishing Actuarial Equivalency

Section 1860D-11(c) of the Act provides the Secretary with the authority to determine the standards and methods for determining actuarial equivalence. In developing standards for actuarial equivalence, our intent is to

consider how to maximize coverage for retirees while limiting costs for the government, and the retiree drug subsidy is one important option for achieving this objective. The MMA provisions creating Part D provide multiple options for plan sponsors, ranging from participating in the retiree drug subsidy to various mechanisms for enrolling retirees in Part D prescription drug plans while offering enhanced benefits. Our goal is not only to protect, but also to enhance coverage offered to retirees. As discussed elsewhere, prior to enactment of the MMA, employers have been systematically restricting drug coverage for future retirees. Taken together, these legal and behavioral factors introduce substantial uncertainty about how plan sponsors will assess their options and react to the new Part D benefit.

Congress has clearly and repeatedly articulated four key policy objectives for the Medicare retiree drug subsidy program. The first goal involves maximizing the number of retirees retaining employer-based drug coverage through the retiree drug subsidy program created by Section 1860D-22 of the Act. The second goal entails not creating windfalls, whereby retirees might receive a smaller subsidy from sponsors of their retiree drug plans than Medicare would pay on their behalf. The third goal is to minimize the

administrative burdens on beneficiaries, employers and unions. The final goal is to minimize costs to the government of providing retiree drug subsidies (and not exceed the budget estimates). While the first, third and fourth goals received extensive discussion during the creation of MMA, the second goal has emerged largely in response to the possibility that the MMA might have created an unintended windfall.

We believe the Secretary has authority to achieve these goals based on the requirements that plans qualifying for the retiree drug subsidy must offer at least actuarially equivalent benefits to those offered by standard Part D prescription drug plans (PDPs). Our proposed regulation reflects our attempt to accomplish the four objectives of maximizing the number of retirees benefiting from the retiree drug subsidy, avoiding windfalls, minimizing administrative burden and not exceeding budget estimates. In doing so, we are considering a range of potential options, each of which may have an impact on achieving the key objectives. We seek comments on how best to accomplish these goals, recognizing both that there may be tradeoffs, and that our implementation must be consistent with the statutory authority provided the Secretary.

The definition of actuarial equivalence in this context may have an impact on our policy objectives. One possible definition would stipulate that plans must meet the same test as for "creditable coverage." The test for creditable coverage requires that, on average, the total or "gross" value of the benefit package offered by the employer at least equal that of the standard Part D benefit offered by PDPs, without regard to the financing of this benefit package. As we discuss in subpart B of this preamble, the main concern in establishing creditable coverage is in determining the level of health benefit coverage the beneficiary has had, and not on how it was financed, since no payments are involved. However, when applying this gross value (of plan payout) test in the context of the retiree drug subsidy, we must be concerned with whether our subsidy payments to sponsors will exceed the costs that sponsors actually incur in sponsoring the coverage. This one test, or "single prong" approach, to defining actuarial equivalence could not by itself preclude the existence of windfall payments. This is because, without considering financing, an employer theoretically could impose the full cost of the benefit package on the employee through employee premiums, and still be eligible for a subsidy payment if the package the employee was buying

met the actuarial equivalence test. Or, the employer could contribute a smaller amount toward the financing of the package than it would receive in a subsidy payment. We seek comments on whether additional steps associated with this approach could ever preclude windfalls. In particular, some observers have argued that the forces in a competitive labor market, collectively bargained contracts, and constraints on changing state, local and other public sector retiree health plans obviate the likelihood of windfalls. We have serious reservations about the adequacy of such forces in precluding the existence of any windfalls without significant additional monitoring by Medicare or others to assure that benefit subsidy payments are passed on to augment benefits received by retirees. Such approaches may create excessive administrative burdens on retirees, employers, and unions, and thus alternative approaches to precluding windfalls are likely to be preferable.

Another possible policy option would be to use the "one prong" approach to determining actuarial equivalency, but to also limit the amount of the retiree drug subsidy so that it could not exceed the amount paid by plan sponsors on behalf their retirees. This would assure the elimination of windfalls. However, while this approach

would be simple both to describe and operationalize, we have questions about the adequacy of the legal basis underpinning such a policy.

A third approach, which could be implemented in a variety of ways, would establish a "two-prong" test of actuarial equivalence: a "gross" test would assure the total value of benefits, and a "net" test would reflect only the value of benefits not financed by beneficiaries. This third approach is structured specifically to preclude windfalls. The first prong of the actuarial equivalency would again be a test based strictly on plan design. This test would evaluate whether the expected amount of paid claims (or "plan payout") under the retiree prescription drug coverage is at least equal to the expected amount of paid claims under the standard Medicare Part D benefit. The second prong of the actuarial equivalency test would be a "net value" test in which the gross value of the plan design would be reduced to account for the level of benefits financed solely by the beneficiary. For instance, the net value of the coverage could be calculated by subtracting the retiree premium from the expected amount of paid claims under the retiree drug program. In order to qualify for the subsidy, a sponsor's plan would have to meet both prongs of the actuarial equivalence standard.

The "net" prong of the two-prong test of actuarial equivalence could have several variants. While each variant of the two-prong test would preclude windfalls, each would present a different balance among potentially competing objectives. At a minimum, we believe that the net value of the creditable coverage should as a policy matter at least equal the average per capita amount that Medicare would expect to pay as the retiree drug subsidy. (We estimate this value at $611 in 2006.) While there may be policy advantages to this approach, we have questions about the adequacy of the legal basis underpinning such a policy. We specifically invite comment on the question of whether the statutory language could reasonably be interpreted to support this approach. Alternatively, a higher threshold could be required. For instance, we could require that this value be more closely related to the net value of the standard Medicare Part D benefit (which is the expected amount of paid claims under Medicare Part D less the monthly beneficiary Medicare Part D premium under § 423.286 of our proposed rule). However, as the threshold was raised, it would be more difficult for retiree plans to qualify, that is, to (1) not provide windfalls and (2) offer coverage that is at least as generous in overall actuarial value as the Medicare subsidy.

Another alternative benchmark value for the net test could be the after-tax value of the expected average per capita retiree drug subsidy. (There is special tax treatment available for the retiree drug subsidy. Plan sponsors get to deduct all the associated expenses but the value of the subsidy payments is not recognized as income for tax purposes.) Unfortunately, determining the appropriate amounts to use for this benchmark would pose significant problems because of the heterogeneity of the plan sponsors. For example, we estimate that at least 60 percent of retirees that are age 65 and older receive retiree health benefits from entities that are exempt from taxation (including both public and nonprofit entities, based on data from the 2001 Medical Expenditure Panel Survey); for those plan sponsors subject to taxation, their rates of taxation vary markedly. In addition, as mentioned above, we have questions about the adequacy of the legal basis underpinning this approach.

As noted above, adopting a two-prong test with the higher value for the net test could arguably provide greater protection to beneficiaries, but might drive plan sponsors out of participating in the retiree drug subsidy and toward using the Part D-based options for supporting and enhancing drug coverage. Conversely, adopting a lower

value for the net test might qualify more plan sponsors to participate in the retiree drug subsidy, but it might also discourage some employers and unions from increasing their contributions to reach the higher threshold level, and thereby increasing generosity of coverage. Public comment would help limit uncertainty by clarifying the likely responses of plan sponsors to these different approaches. In addition, we solicit comments not only on the desirability of the different options, but also (as noted above) on the legal bases for possible options.

In any case, the actuarial equivalence test(s) established by CMS must be applied to each sponsor's retiree prescription drug plan in order to determine if it is a qualified retiree prescription drug plan for purposes of qualifying for a subsidy. In considering the point of reference for a "plan," we recognize that there is tremendous diversity and complexity in prescription drug coverage options among employers and unions for retirees. There may be either different employer/union contribution levels or benefit designs within a single plan for various segments of retirees (referred to as "tiered cost sharing"). A qualified retiree prescription drug plan is defined with reference to the definition of a "group health plan" which section 1860D-22(c)(3) of the Act specifies is

to be the definition of that term in section 607(1) of ERISA. That definition states that the term "means an employee welfare benefit plan providing medical care . . . to participants or beneficiaries directly through insurance, reimbursement, or otherwise. . . ." Section 3(1) of ERISA in turn defines an employee welfare benefit plan as "any plan, fund, or program [which is] established or maintained by an employer or by an employee organization, or by both, to the extent that the plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance, or otherwise, . . . medical, surgical, or hospital care or benefits…."

Section 1860D-22(a)(2)(A) of the Act clearly indicates that a plan must meet the actuarial equivalence test in order to qualify for a subsidy. We propose to apply the ERISA definition in a way that is appropriate in the context of section 1860D-22 of the Act, and recognizes the diversity in retiree drug coverage among employers and unions. Our proposal is modeled on the approach adopted by the Department of Treasury at 26 CFR § 54.4980(B)(2), in the context of a different definition of "group health plan." In the Questions and Answers that relate to that

section, Q-6 and A-6 take the position that all health benefits provided by a sponsor are presumed to be under a single plan unless it is clear from the plan instruments and instrumental operation that the plans are separate plan arrangements. We believe this proposed approach is familiar to plan sponsors, is appropriately flexible, and protects retiree-beneficiaries. We welcome comments on how best to apply the statutory definition of a "plan" within this context, especially to sponsors that offer a multiple choice of retiree plans with various levels of sponsor contributions.

We believe we have discretion as to whether to require that the sponsor demonstrate that the value of the retiree coverage under the group health plan is actuarially equivalent to standard prescription drug coverage under Part D for each individual based on: (1) the benefit package received by the individual, or (2) on average across all participants and beneficiaries receiving coverage under the sponsor's group health plan. We propose to require sponsors to apply the actuarial equivalence test to each group health plan as a whole, with the standard met if <u>on average</u> the actuarial value of retiree drug coverage under the plan is at least equal to the value of standard

prescription drug coverage under Part D. We believe that this approach would be less burdensome for sponsors.

As previously noted in subpart F of this preamble, we will provide additional information in the future on the processes for determining actuarial valuation, including that of retiree prescription drug coverage. We are currently considering the following guidelines--

- We anticipate that we would specify, as either recommended or required in further guidance, data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles. We would require that the actuarial attestation be provided to us and we would verify that the attestation was signed by a qualified actuary. In addition, we may select a random sample of attestations for which we would require additional information to provide a quality control review. Also, we expect that a detailed review of the actuarial attestation would be included in the auditing process.
- Section 1860D-11(c)(3)(B) of the Act specifies that PDP sponsors or MA organizations offering MA-PD plans may use qualified independent actuaries in developing bids. We believe it is appropriate to adopt this model with respect to this proposed rule, allowing retiree plan

sponsors to use outside actuaries in their processes. We would specify that a qualified actuary is an individual who is a member of the American Academy of Actuaries, because members of the Academy must meet not only educational and experience requirements, but also a code of professional conduct and standards of practice. These standards create a common ground for actuarial analysis. Furthermore, a member of the Academy is subject to its disciplinary action for violations of the code and standards. This same requirement is specified in the SCHIP legislation at section 2103(c)(4)(A) of the Act.

c. Sponsor Application for Subsidy Payment and Required Information

A plan sponsor who wishes to be paid the retiree drug subsidy must apply annually for the subsidy. We will provide the technical details (including important systems issues) to sponsors and other interested parties in the very near future in order to facilitate our developing appropriate guidance, which will, in turn, encourage sponsor participation and minimize the burden to sponsors to the maximum extent possible. We intend to actively seek comments from sponsors and to release guidance to sponsors in 2005. In order for plan sponsors to receive a subsidy payment for 2006, we would require that all plan sponsors

apply for the subsidy payment no later than September 30, 2005. For future years, as described above in the discussion of attestation, we would require that plan sponsors apply for the subsidy no later than September 30 of the previous year. Table R-1, containing the key dates involved in the sponsor application process, is included at the end of this section.

We request comment on this approach, including how such a deadline might interfere with a sponsor's open season, and whether or not sponsors will already know, as early as 90 days prior to the start of the year, which plan option a beneficiary has enrolled in. For sponsors that institute retiree prescription drug coverage after September 30, 2005, we would require that these sponsors apply at least 150 days prior to the start of the new plan for the first plan year.

We would require that sponsors (or an administrator of the plan designated by the sponsor) provide all of the following information as part of the application for special subsidy payment--

- Employer Tax ID Number (if applicable);
- Sponsor name;
- Sponsor address;
- Contact name, job title and email address;

- Actuarial attestation and supporting documentation for each qualified retiree prescription drug plan for which the sponsor will be seeking subsidy payments;
- Identifying information for each of the separate plans.

Additionally, the following information must also be submitted for each plan--

- Full names of each qualifying covered retiree (as defined previously) enrolled in the sponsor's prescription drug plan (including spouses and dependents if Medicare-eligible), and the following information--
  - Health Insurance Claim (HIC) number (when available);
  - Date of birth;
  - Sex;
  - Social Security number; and
  - Relationship to the retired employee.

(Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our proposed regulations.)

Since we will be dealing with individually identifiable health information, we provide elsewhere in

this preamble a separate discussion of privacy issues related to the submission of this information. We note that, in most cases, the plan sponsor would not have access to claims information or similarly protected health information regarding retirees. Therefore, throughout this preamble where we refer to information provided by the plan sponsor, we may in fact mean by the plan administrator, insurer, or group health plan on behalf of the plan sponsor. In addition, we are aware that sponsors may not have information on Medicare Part D eligible individuals who receive benefits under the employer-sponsored plan as spouses or dependents of a plan participant. We are also aware that many employers do not currently collect information about dependents, but plan administrators may maintain that information about dependents. Moreover, we are also aware that all plans do not consistently collect Medicare Health Insurance Claim (HIC) and Social Security numbers. Therefore, in order to be able to make and/or audit subsidy payments, we need a process to be able to identify the Medicare beneficiaries on whose behalf the subsidy payments would be made. We welcome comments on the proposed information list.

We encourage sponsors who plan to request a subsidy payment from Medicare to begin to evaluate the availability

of this information and to plan for the creation of a file with this type of information contained in it. Technical systems specifications for the file would be included in guidance to sponsors from CMS. We actively seek input from employers, plan sponsors, plan administrators, and other interested parties to facilitate our developing the most appropriate, efficient, and effective guidance.

We have worked with many employers and other insurers in the context of Medicare Secondary payer requirements, and we believe that this will help facilitate the identification process. We welcome the opportunity to work with employers and insurance companies in this regard. Additionally, we launched a "Voluntary Data Sharing" initiative in 2000 that allows CMS and employers to electronically exchange employee group health coverage information and Medicare entitlement information on a current basis. This process can, for example, identify whether a retiree or spouse is a Medicare beneficiary and the date of entitlement to Medicare. More information about the CMS Employer Voluntary Data Sharing initiative can be found at:

www.cms.hhs.gov/medicare/cob/employers/emp vdsa.asp.

Finally, an authorized representative of the requesting sponsor must sign the completed application.

The application will specify the terms and conditions of eligibility to receive a subsidy payment. The application would require the sponsor to comply with all Federal laws and regulations, as well as the terms and conditions of eligibility for a subsidy payment, including auditing of claims for subsidy payment and combating fraud and abuse, any further certification that CMS may require. The sponsor would be required to acknowledge that the information is being provided to obtain Federal funds. The signed application would constitute an agreement between the sponsor and CMS and would be referred to as the "sponsor agreement." The sponsor would be required to include in all subcontracts with third party administrators and other subcontractors performing functions in connection with the sponsor retiree drug benefit an acknowledgement that the subcontractor knows and understands that all information provided in connection with the contract will be used for purposes of obtaining Federal reimbursement.

Once the full application for subsidy payment is submitted, we would match the names and identification numbers of retirees submitted by the sponsor with the Medicare Data Base (MDB) to determine which individuals are both eligible for Medicare Part D (that is, individuals who are entitled to benefits under Medicare Part A or who are

enrolled under Medicare Part B) but who are not enrolled in Medicare Part D. We would then provide to the sponsor (or to a plan administrator designated by a sponsor) the names and other necessary identifying information, if any, of the sponsor's qualifying covered retirees.

We recognize that there would be a need to update information from sponsors on a routine basis in order to incorporate newly eligible retiree-beneficiaries and to prevent overpayments and underpayments as qualifying covered retirees make switches between Medicare Part D and the retiree drug plan. We are considering options for this enrollment update process. One possibility is to use a complete enumeration file submitted as part of the annual application process, with subsequent, periodic updating. We would appreciate public comments on this issue.

We are also considering and seek comment on whether to require a surety bond type of instrument or preferred creditor status – as part of the enrollment process - in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation.

Table R-1
Proposed Key Dates

Publication of Final Rule	Early 2005
Application for Subsidy Due Date for All Sponsors, regardless of whether they operate on a calendar or plan year	No later than September 30, 2005
Attestation of Actuarial Equivalence Due Date for all Sponsors	No later than September 30, 2005
Retiree drug subsidy Program Begins	January 1, 2006
Application for Subsidy Due Date for plans operating on a plan year basis	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years
Application for Subsidy and Attestation of Actuarial Value Due Date for plans operating on a calendar year basis	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years
Application for Sponsors that institute coverage after September 30, 2005	150 days prior to the start of the new plan
Notice to CMS of mid-year plan changes that materially affect actuarial valuation	90 days prior to the plan change
Notice to enrollees of plan changes that result in the plan no longer being a qualified retiree prescription drug plan	90 days prior to the plan change

d. Creditable Coverage and Notification

Section 1860D-22(a)(2)(c) of the Act specifies that in order for a sponsor's plan to meet the definition of a qualified retiree prescription drug plan, the sponsor must provide for disclosure of whether coverage is "creditable coverage" in accordance with the proposed requirements set forth under proposed § 423.56 of our proposed rule. The actuarial equivalence standard for creditable coverage is the same as one of the tests proposed for the actuarial equivalence standard for qualified retiree prescription drug plans in order to qualify for a retiree drug subsidy. The actuarial equivalence standard for creditable coverage is the "gross value" test (that is, whether the expected amount of paid claims (or "plan payout") under the retiree prescription drug coverage is at least equal to the expected amount of paid claims under the standard Medicare Part D benefit), which is the so-called first prong of the actuarial equivalence test for purposes of qualifying for the retiree drug subsidy.

As explained in subpart B of the preamble of our proposed rule, if a Medicare Part D eligible individual fails to enroll in Medicare Part D upon first becoming eligible for Medicare Part D, the individual would be subject to the late enrollment penalty if the individual

elects to enroll in Medicare Part D at a later date. However, the late enrollment penalty would be waived if the beneficiary had creditable prescription drug coverage during the time he or she was not enrolled in Part D.

Proposed § 423.56 of our proposed rule would require certain entities providing drug coverage, including group health plans, to disclose to Part D eligible individuals and CMS whether that coverage is considered "creditable coverage" as described in proposed § 423.56(a) of our proposed rule, or whether the value of the coverage to the individual is at least actuarially equivalent to standard prescription drug coverage under Medicare Part D. Consequently, plan sponsors under this proposed rule would be subject to the requirements in proposed § 423.56 of our proposed rule governing disclosure of creditable coverage.

As discussed in subpart B of our proposed rule and discussed below, we intend to describe the proposed process for providing this disclosure notice, including guidance on its content, placement, and timing of notice. The content of the disclosure notice and its timely receipt would be important components in the decision making process for beneficiaries, because the creditable status of the retiree's drug coverage would have a direct impact on the assessment of late enrollment penalties associated with

Medicare Part D premiums. Notifying the retiree of any subsequent changes in their creditable coverage status is equally important. Because retirees would have a limited time in which to make decisions about their Medicare Part D coverage without facing a penalty, it would be important that the notification of creditable status be provided in a timely and conspicuous manner. However, we are also concerned about the potential administrative burden imposed by this proposed requirement and therefore, we are soliciting comments on the format, placement, and timing of this notice.

We have considered several approaches to implementing this requirement. One possible approach would be to provide the sponsors with standard language that could be incorporated into the required disclosure materials the sponsors routinely disseminate to their enrollees in their retiree drug plans. (We could provide standard language to be inserted into these materials.) We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable.

Another possible approach would be to require each

sponsor to issue a separate notice to each Part D eligible enrollee in their retiree drug plan. This type of notice would be the most conspicuous and would subsequently increase the likelihood that beneficiaries are made aware of the creditable coverage status of their prescription drug coverage. Because retirees are subject to financial penalties for the failure to maintain creditable coverage when they enroll in Medicare Part D after the initial enrollment period, a separate notice may better inform beneficiaries and ensure that they take appropriate action to avoid the penalties. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 101-93, requires entities that offer health insurance coverage to inform their members, in writing, of the type and duration of "creditable coverage." Implementing regulations at 62 FR 16901 (April 8, 1997) provided a "Certification of Creditable Coverage" that must be produced and disseminated to individuals when their coverage ends. We considered requiring that information about the creditable status of prescription drug coverage be included in this certification. However, since the certification required under HIPAA is not provided until after the coverage has ended, it would arrive too late to assist beneficiaries in deciding whether to enroll in Part D. However, the HIPAA

certification may serve as a useful model, and we invite your comments about the administrative burden associated with producing and disseminating a similar notice of creditable status to beneficiaries.

The timing and frequency of these notices would also be a key consideration. The initial notice of creditable status would have to be coordinated with the first "Annual Coordinated Enrollment Period for Part D," which begins November 15, 2005, to ensure that retirees have this information when making their decisions regarding Part D coverage. Retirees would also need to know about any change in the creditable status of existing coverage before this change becomes effective so that they have sufficient time to decide whether to obtain Part D coverage. If a retiree's creditable drug coverage ends or is changed to the extent that it is no longer creditable, the retiree has a "Special Enrollment Period" during which he or she can enroll in Part D without financial penalty. Thus, we believe that this notice should be provided, at a minimum of these two important times, and also upon request by the beneficiary.

We view this process as an important one, and invite comments on how best to ensure that retirees receive timely and adequate notice of the creditable status of their

prescription drug coverage without imposing a significant administrative burden on sponsors that provide the coverage. We also note that section 1860D-22(a)(2)(C) of the Act requires sponsors to disclose the creditable status of this coverage to us, and we invite your comments on the possible methods of providing this disclosure.

4. Retiree drug subsidy amounts (§ 423.886)

As explained previously, § 423.886 governs the subsidy amount a sponsor of a qualifying retiree prescription drug plan receives for each qualifying covered retiree that is enrolled with the sponsor in a year. The sponsor is eligible to receive a subsidy payment for each qualifying covered retiree whose gross covered retiree plan-related prescription drug costs exceed the cost threshold. The amount of the subsidy would be 28 percent of the allowable retiree costs attributable to the gross retiree costs that are above the threshold and do not exceed the cost limit. For plan years ending in 2006, the cost threshold is $250 and the cost limit is $5000.

The cost threshold and cost limit for a plan year that ends after 2006 would be adjusted in the same manner that the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(e)(1)(ii) and § 423.104(e)(4)(iii)(B) of our

proposed rule, respectively. Accordingly, beginning in 2007, we will adjust the cost limit and cost threshold based on the annual percentage increase or decrease in average per capita expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12 month period ending in July of the previous year, with the cost threshold rounded to the nearest multiple of $5 and the cost limit rounded to the nearest multiple of $50.

CMS claims that are generated by an overpayment of the subsidy to a sponsor, including collection of interest, administrative costs, and late payment penalties would be governed by regulations at 45 CFR Part 30, subpart B.

5. Payment Methods, Including Provision of Necessary Information (§ 423.888)

a. Plan Year Versus Coverage (Calendar) Year

Under section 1860D-22(a)(3)(B) of the Act, the cost threshold and cost limits that determine the amount of the subsidy are calculated for "plan years that end in" 2006 and subsequent calendar years. However, section 1860D-22(a)(3)(A) of the Act refers to the subsidy amount for a qualifying covered retiree for a "coverage year," that is defined as calendar year. Thus, we believe that, in the context of section 1860D-22 of the Act, the reference to retirees enrolled in a qualified plan "during a coverage

year" can be read to mean that the retiree must be enrolled during either a calendar year or plan year that ends in the specified calendar year. As explained below, we would prefer a strict calendar year basis and believe our proposed requirements would permit sponsors with non-calendar plan years to comply with reasonable modifications. We are interested in receiving comments on whether we should maintain our initial policy based on the calendar year or whether we should consider a plan year as the basis for the subsidy.

While a calendar year approach is more straightforward from the perspective of Federal administration of the subsidy program, use of "plan year" may better conform to the accounting systems of the plans and the sponsors. However, we note that the Federal subsidy is related to drug spending, not plan coverage. If we do elect to use a "plan year" as the basis for payment, we would use the definition of a "plan year" in section 3(39) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(39), which includes, for a plan, the calendar, policy, or fiscal year on which the records of a plan are kept. If we do elect to use a "plan year," the statute makes clear that the cost threshold and the cost limit will apply based on the calendar year in which the "plan year"

ends. For example, in the case of a July 1, 2006 – June 30, 2007 "plan year," the cost threshold and the cost limit applicable in general in 2007 would also apply for this "plan year." Because the actuarial attestation would be due no later than April 1, 2006 (90 days in advance of the plan year), it is quite possible that the cost threshold and cost limits for 2007 would not yet have been calculated at that time.

Another issue that is unique to the use of a "plan year" as a basis for the subsidy payment that arises in the first year of the program is how to handle plan years that begin in 2005. For example, if a plan year ends on June 30, 2006, only six months of that plan year accrued after January 1, 2006. The following are at least three options for addressing this problem:

1) The first option is to start counting gross costs for prescriptions filled after January 1, 2006. That is, even though the plan year in this example began on July 1, 2005, gross costs of qualifying covered retirees would only take into account prescriptions filled beginning with January 1, 2006. These gross costs would have to exceed $250 before their associated allowable costs would be subsidy eligible. Since subsidy payments are not authorized prior to the

start of the Part D program, this option represents the strictest reading of the statute, in that gross costs and, therefore, allowable costs, are calculated without regard to the portion of the plan year that falls before January 1, 2006. It would, however, disadvantage plans that choose to use plan year instead of calendar year, since total subsidy payments for calendar 2006 would be lower than they would have been if calendar year had been used since the cost threshold must be met a second time in calendar 2006.

2) The second option is to determine a subsidy amount as if the sponsor were authorized to receive subsidy payments for the entire "plan year" and then to prorate this amount based on the number of "plan year" months that fall in 2006. First, gross costs would be determined for the entire "plan year". Allowable costs and the subsidy amount would be derived based on the proportion of the gross costs that exceed the cost threshold but are less than the cost limit. Finally, the subsidy amount for the plan year would be prorated by the number of months of the plan year that fall in 2006. In our example of a July 1- June 30 plan year, six months would fall in 2006 so the annual subsidy amount would be cut in half. This option, while still

consistent with the statute, would provide a larger payment than the first option.

3) The third option would determine subsidy amounts on monthly basis as if the sponsor were authorized to receive subsidy payments for the entire "plan year", but would then pay only the amounts for the "plan year" months that fall in 2006. The process for determining the subsidy is similar to that described in option two, but rather than calculating an annual subsidy amount, one would determine the subsidy payments applicable to costs incurred for each month of the plan year. The sponsor would then receive the subsidy payments for the months in the plan year that fell in 2006 (that is, January 1 through June 30, 2006). This option would require that the sponsor determine the month in which costs are incurred. Therefore, it adds some complexity to the calculation of the subsidy. However, since subsidy eligible expenditures are weighted more toward the latter part of the plan year, this option would produce a stream of subsidy dollars that would parallel the actual flow of the sponsor's plan expenditures.

We would like to receive your comments on these options or other possible approaches, as well as on the threshold

issue of whether we should rely only on calendar years, as explained below. We again note that relying on calendar years avoids the complications discussed above.

b. Payment Methodology

Section 1860D-22(a)(5) of the Act specifies that payments to plan sponsors are to be made "in a manner similar to" the payment rules in section 1860D-15(d) of the Act, which apply to payments made to PDP sponsors and MA organizations under Part D. We believe that section 1860D-15(d) of the Act gives us broad discretion to determine a payment method. We wish to develop a payment methodology that is beneficial to the sponsors, and is cost efficient. Some of the factors to consider in developing a system that will pay subsidies are whether it is technologically feasible and what it would cost. Another issue is that pharmaceutical rebates, which must be excluded from allowable retiree costs, are generally not factored into the payments at the point of sale but instead not until much later in the process. We also recognize that highly automated insurance carriers or pharmacy benefit managers (PBMs) are used by almost all the sponsors for collection of the claims data that will be key elements of the data required for the payment of the subsidy.

Our proposed policy is predicated on the assumption that plan sponsors utilize the services of sophisticated point-of-sale claims payment agents such as PBMs. We further understand that PBMs (or comparable administrative entities) routinely adjudicate prescription drug claims on a real-time basis and have very limited claims (sometimes referred to as incurred, but not received) or payment lags. As a result, actual monthly expenditures are routinely known shortly after the close of a month. We outline below our proposed approach to calculating and paying the alternative subsidy to qualified retiree prescription drug plans in 2006 (using an actuarial attestation based on a plan year, but with the alternative subsidy computed on a calendar year basis):

- For each month starting with January 2006, the plan sponsor would certify by the 15th of the following month (that is, February, 2006 for January, 2006) the total amount by which actual retiree-beneficiary gross drug spending exceeded the cost threshold yet remained below the cost limit. Medicare would pay 28 percent of the certified amount to the sponsor by the 30th of that month. Not later than 45 days after the end of the calendar year, the plan sponsor would submit a final reconciliation (but for outstanding rebates) to us for

payment by or, if applicable, to us. (We recognize that plan sponsors may not receive some rebates until after the close of the their plan year.)

- In the month in which they are received (or recognized), the appropriate share of any discounts, rebates, or other price concessions, along with any adjustments to the actual expenditures for prior months, are reflected. Any amounts owed the government would offset the subsidy payment for that month, to the extent that the amount owed to the government would exceed any applicable monthly payment, the plan sponsor would pay this amount to us.
- Plan sponsors (or more likely, plan administrators, insurers or group health plans on their behalf) would maintain detailed records of claims payment and other matters. The specifics of the data retention, data submission, audit and financial requirements would be determined in future instructions.

We note that, due to our need for monthly coverage and spending data, this system could work equally well for plans whether their plan year is coterminous with or is different than the calendar year. Because the special subsidy is based on allowable gross drug spending, without regard to the relationship of this spending to plan

coverage or reimbursement, we believe the amount of drug spending for each eligible retiree-beneficiary can be easily be extracted from the insurance coverage provided in a "plan year". We believe months, as opposed to a daily, weekly, or annual basis, constitute the appropriate unit for computing the special subsidy. We note that more detailed, disaggregated data would be needed for purposes of audits and annual reconciliations.

Actual monthly payments could be adjusted by the actual amounts received in that month for discounts, chargebacks and rebates appropriately attributed to allowable gross costs (as defined for purposes of claiming the special subsidy). Under this approach, payments would be based on actual drug spending and discount, chargeback or rebate payments. While arguably more data intensive, we believe this to be the most straightforward option, minimizing reliance on projections and actuarial representations. It also would facilitate expeditiously paying sponsors full subsidy amounts to which they would be entitled. Any underpayment or overpayment would generally be dealt with through an adjustment to subsequent periodic payments. This option would provide a payment stream, which comes closest to subsidizing actual plan expenditures as they occur.

The following items would be three possible alternative options to our proposed methodology discussed above and the broad outline of the process for receiving subsidy payments. Under all three alternative options, sponsors would have to meet the specified filing deadlines in order to receive subsidy payments:

1) The first alternative option would be to make a single payment after the close of the year. Under this option, by the start of the fourth month after the close of the plan or calendar year, sponsors whose attestation of actuarial equivalence had been approved for that year would submit to us the number of months of coverage for each qualifying covered retiree and their gross and allowable costs. (Partial years of coverage would result from individuals becoming qualifying covered retirees during the course of the year and also from decedents who die during the course of the year. In the case of new qualifying covered retirees, only their expenses from the month of their status change forward can be included in their gross and allowable costs, which would have to exceed the cost threshold in order for a payment to be made.) Gross and allowable costs would be derived directly from claims payments and retiree cost sharing for

prescriptions dispensed during the plan year offset by appropriate rebate cost reporting (as discussed in section 2 of this subpart with respect to allowable retiree costs). The portion of gross costs that exceeded the cost threshold but were less than the cost limit would be derived. Discounts, chargebacks, and rebates, which already would have been factored for the year, would be removed from these gross costs to calculate allowable costs and the subsidy amount. We would review this submission and make a payment for the year by the end of the following month. This alternative option would be the simplest to administer and would obviate the need for interaction between CMS and sponsors other than during the review process. From the perspective of sponsors, however, this option may be less desirable since payment would not be received until after the close of the year.

2) The second alternative option would be to make interim payments throughout the year with a settlement after the end of plan or calendar year. Under this alternative option, sponsors desiring to receive subsidy payments would develop an estimate of per capita subsidy payments based on the plan's claims history and the rebates or discounts received in the

prior period. Sponsors would submit the estimate, as well as the basis for the estimate, at the same time that they submit their attestation of actuarial equivalence (which we have proposed in section 3(b) of the preamble to be three months prior to the start of the plan year). If the sponsor files on a timely basis and we agree that the sponsor offers a qualified retiree prescription drug plan, we would review the estimate and the documentation and determine an interim monthly per capita amount. Plans would be paid a percentage (70 percent for 2006 and 2007, 90 percent for subsequent years) of this interim payment level on a periodic basis for each qualifying covered retiree based on the sponsor's enrollment information which would be matched against Medicare records to verify qualifying status. We would pay less than 100 percent of this amount to minimize the possibility of having to recoup large amounts of money at the time of settlement. We are proposing to pay 70 percent in 2006 and 2007 given the significant uncertainty that will exist in estimating subsidy payments. We request comments on whether estimating techniques as to qualifying covered retirees and as to levels of drug spending during the year are reliable enough to

justify a higher percentage. By the start of the fourth month after the close of the plan or calendar year, the sponsor would submit documentation on gross claim costs and rebates, as described in option 1, above. We would review the documentation and settle for the year by making an additional payment if more payment were due to the sponsor or by reducing subsequent interim payments to reflect any overpayment. This alternative option is more administratively complex than the first alternative option because it entails developing an interim payment amount and making those payments. It would, however, provide subsidy funding to sponsors during the plan or calendar year.

3) The third alternative option would be to make lagged payments based mainly on actual experience on a periodic basis throughout the year with a settlement after the end of the year limited to reconciling estimated versus actual discounts, chargebacks, and rebates. By the 15th of the month following the close of the payment period, sponsors whose attestation of actuarial equivalence had been approved would submit information to us on gross and allowable costs for the previous payment period for each qualifying covered

retiree whose gross costs, coverage (that is, calendar) year to date, exceeded the cost threshold, but were not in excess of the cost limit. The information submission would be based on actual claims experience. Actual monthly payments could then be adjusted on a percentage basis for estimated discounts, chargebacks, and rebates (the sponsor would submit a justification, which we would approve, for the percentage used). By the 15th of the following month, we would review the submission and make payment. By the start of the fourth month after the close of the plan or calendar year, the sponsor would submit documentation on actual discounts, chargebacks, and rebates received for the plan compared to those estimated. Any under payment or overpayment would be dealt with through an adjustment to subsequent periodic payments.

We would like your comments on the operational aspects of the proposed policy, as well as the broad alternative options, and on their desirability from the perspective of plan sponsors.

In addition to the question of payment methodology, there is the issue of the periodicity of the subsidy payments. While this is not an issue with regard to an

annual retroactive payment, the question of periodicity does arise with regard to the ongoing payment alternatives. We would like your comments on the use of bi-annual, quarterly or monthly payment periods under these approaches. We also considered a variable payment option in which the frequency of payment would vary in accordance with the size of the sponsor's plan. For example, a sponsor with 10,000 or more qualifying covered retirees would receive monthly payments while sponsors with less than 10,000 qualifying covered retirees would receive quarterly payments. We are concerned that this alternative may be inequitable in terms of cash flow and overly administratively complex to implement. Again we are asking for your comments, particularly with regard to the balance between timeliness versus administrative burden posed by monthly or quarterly payments versus annual payments. We are also asking for your comments on whether to use more than one of the payment alternatives described above based upon the size of the sponsor's plan. For example, in order to minimize administrative burden on small businesses, sponsors with less than 100 qualifying retirees could receive an annual retroactive payment. We solicit comments, in particular on the issue of whether less frequent payments might be preferable for small employers

because it would minimize their reporting burden.

Our understanding is that PBMs and other entities currently involved in the administration of claims are highly automated and capable of efficiently and effectively providing the necessary information at low (incremental) cost in a timely manner. We are particularly interested in your comments about the capabilities of the service providers and their views, as well as the views of the plan sponsors and others, on the most appropriate arrangement, as well as your comments on the feasibility of the proposed approach and proposed alternative options.

c. Data Collection

Regardless of what payment methodology is ultimately chosen for the subsidy, we would need certain data from the sponsors of the plans (or the plan administrators, insurers or group health plans designated by the sponsors) in order to accurately calculate the amount of the subsidy to which the sponsor is entitled. This data would include updating of the information that was provided during the application process such as the names of the qualifying covered retirees enrolled in the plan, including the spouses and the dependents, the Health Insurance Claim (HIC) numbers (when available), social security numbers, dates of birth, sex, and relationship to the retired employees. We would

also require an affirmation that the Medicare benefits of each qualifying covered retiree are not secondary to the sponsor's retiree health coverage (if the Medicare benefits are secondary to the sponsor group health plan, that would indicate that the participant is not in retiree status and, thus, is not a qualifying covered retiree except in certain situations in which the retiree qualifies for Medicare based on ERSD status), and dates of enrollment in the sponsor's retiree plan.

The plan sponsor (or the designated administrator, insurer, or group health plan) would be required to submit cost data for each qualifying covered retiree. The timing of the submission and the relevant time period of the cost data is contingent on the payment methodology that is adopted in the final rule for the subsidy. A separate issue, however, is the level of detail of the cost data. There are two options, and a combination of the two, to be considered:

1) First, we could require that the sponsor (or the plan administrator, insurer, or group health plan designated by the sponsor) submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This would be the cost incurred between the

cost threshold and cost limit with an appropriate adjustment for rebates. This aggregate cost would not be broken down to each qualifying covered retiree. The sponsor (or administrator, insurer, or group health plan) would have to maintain the claims data to support its submission for audit purposes. While this option would probably be easier for the sponsors and would be the most protective of the individual's privacy, it may be the most problematic in terms of assuring the accuracy of the subsidy payment.

2) A second option would be for the sponsor (or the plan administrator, insurer, or group health plan) to submit the aggregate allowable costs for each qualifying covered retiree for the time period in question. This would be more complex for the sponsor and would raise some privacy questions but would provide more assurance with regard to the accuracy of the subsidy payment.

3) A third option would be to combine various elements of the first two options. For example, the sponsor (or the administrator, insurer, or group health plan) would be required to submit information with the specificity outlined in the second option for each of the first two years of the subsidy's availability. In

the third and fourth years, however, the sponsor (or the administrator, insurer, or group health plan) would submit its claims data in accordance with the first option.

4) A fourth potential option that we considered and subsequently ruled out would have been for the sponsor (or the plan administrator, insurer, or group health plan) to submit the actual claims data for each qualifying covered retiree. This option, however, would have been the most complex in terms of administering the subsidy program and the most problematic in terms of privacy. In addition, the benefits of this option would not have outweighed the higher costs associated with submitting actual claims data for each qualifying covered retiree.

As discussed in the next section, we would require the creation and retention of detailed, individual records reflecting both claims and financial data. In assessing the merits of the two options, it is important to understand our plans for vigorous implementation of our audit authority. We believe that a vigorous audit program is consistent with permitting the reporting of more aggregated data. For example, plan sponsors could report the aggregate total of gross allowable drug costs for all

qualifying covered retiree-beneficiaries incurred in a month, adjusted to reflect discounts, chargebacks and rebates (we discuss the issue of adjustments based upon rebates and other price concessions in section 2 of this subpart in connection with the discussion of allowable retiree costs). In the end-of-year report, CMS could require more detailed information on eligibility, drug spending, and discounts, rebates and chargebacks. Finally, we might require the retention of detailed enrollee records for audit or other analytical purposes. We believe that by requiring different levels of detail for data and records, depending on the purpose for which they are to be used, provides sponsors and plan administrators, insurers, or group health plans with a minimum amount of burden and a maximum amount of flexibility and time in which to produce the required records. We welcome your comments on these options or your proposals for other options. Regardless of what option is chosen, we would require that the data include the period of time when the cost was incurred, the period of Medicare eligibility for each qualifying covered retiree, and the period of enrollment in the sponsor's retiree plan for each qualifying covered retiree. This is because, as mandated by section 1860D-22 of the Act, only costs incurred while the Medicare beneficiary is enrolled

in the sponsor's drug plan and not in Part D can be considered allowable retiree costs.

This proposed rule also specifies, as required by section 1860D-15(d) of the Act, that all information obtained pursuant to this subpart may be used by the officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subpart R of Part 423.

d. Audits

At § 423.888(d), we propose that the sponsor of the plan (or the plan administrator, insurer, or group health plan designated by the sponsor) would be required to maintain and provide access to sufficient records for our audits or audits of the OIG to assure the accuracy of the attestation regarding actuarial value and the accuracy of subsidy payments made under this subpart. This proposed rule specifies that the working documents and reports of the actuaries conducting the analyses that serve as the basis for the attestation, and all documentation of the costs incurred and utilization for the amount of the subsidy payment, including the underlying claims data, would be made available for audit inspection. All records would be maintained for at least 6 years after the end of

the plan year in which the costs were incurred. We believe that 6 years is a sufficient length of time to preserve our right to conduct follow-up audits and would not be too burdensome on the sponsors. Six years is also the length of time certain other Medicare records are required to be retained. In the event of an ongoing investigation, litigation or negotiation, we or the OIG may extend the 6-year retention period. We invite your comments on the appropriateness of this level of documentation, and any unique operational issues it may raise. We may conduct audits in a manner similar to the audits of financial records of PDP sponsors and MA organizations, as outlined in §423.504(d)(2) of our proposed rule.

6. Appeals (§ 423.890)

Although the statute does not contain provisions for administrative appeals of the retiree drug subsidy amount, and although we do not believe there is a constitutional property interest in the retiree drug subsidy (See American Manufacturers Mutual Insurance Co. v. Sullivan, 526 U.S. 40 (1999) (individual did not have a property right in the receipt of payment of a bill for medical services before an agency determined that the services were reasonable and necessary); Giese v. Barnhart, 55 Fed.Appx. 799, 2002 WL 31856 (9th Cir. 2002) (there is no "termination" of benefits

warranting due process when the individual never qualified for benefits in the first place), we believe that it is prudent policy to allow an opportunity for review of certain agency decisions issued in relation to this subpart. Examples of these decisions are as follows--

- A retiree prescription drug plan is determined not to be actuarially equivalent.
- An enrollee in a retiree prescription drug plan is determined not to be a qualifying covered retiree.
- A determination of the subsidy amount to be paid to a sponsor.

We propose using a three step process for review of subsidy determinations.

1) In the first step, the sponsor could request an informal written reconsideration by us of the subsidy determination. Initial subsidy determinations would be final and binding unless the sponsor requested reconsideration in a timely manner or we reopened the determination in accordance with the procedures discussed below. The request for reconsideration would have to be filed within 15 days of the date of the notice of the adverse determination. We believe a short time frame is necessary in order to ensure that subsidy amounts can be finalized in as expeditious a

manner as possible. We note that the 15-day time frame is used in MA contract termination appeals (see § 422.650) and we believe employers are similar to MA organizations in their level of sophistication. We expect that sponsors possess adequate resources to meet the time line and pursue the appeals in the proper manner. The written reconsideration would be entirely on the papers. Sponsors would be able to submit a position paper and any additional evidence they wished us to consider. We would make its informal reconsideration determination on these papers and inform the sponsor of its decision. We could inform the sponsor of its determination orally (over the telephone) or in writing (by electronic mail or by post); however, on a sponsor's request, we would put our decision in writing. We expect that when we make a reconsideration determination wholly favorable to the sponsor, a written decision will not be requested. Our reconsideration determination would be final and binding, unless the sponsor further appealed the determination or if we reopened the reconsideration determination in accordance with the reopening provisions discussed below.

2) The second step of the appeals process would be an informal hearing before our hearing officer (who was not a party to the initial decision). Requests for a hearing would need to be made within 15 days of the date the sponsor received our reconsideration decision. If there is a dispute as to the date of receipt, unless there was evidence to the contrary, we would assume that the sponsor received the decision at least 5 days from the date on the written reconsideration decision. Because we expect that we would deliver only favorable decisions orally, we do not expect receipt of an orally communicated decision would be an issue in determining whether a party has met the deadline for requesting a hearing of an adverse determination. The hearing officer's decision would be final and binding, unless further appealed to our Administrator. We have also proposed that the hearing officer appointed by the Administrator would be limited to a review of the record that was before us in making its initial or review determination and no new evidence could be presented at the hearing stage. The hearing officer's scope of authority would be limited to determining whether we applied our own policies in accordance with the facts that were before

us. Our hearing officer would have to render the decision in an expeditious manner as possible.

3) The third step of the appeals process would be a review by our Administrator. A sponsor could request an Administrator review or the Administrator, on his or her own motion, could take review, but in either case this review would have to be requested (or taken) within 15 days of the hearing officer's decision. Again, we would expect that sponsors received the hearing officer's decision within 5 days of the date on this decision.

We believe a three-step appeals process allowing an opportunity for informal written review, followed by an oral hearing would conserve both agency and sponsor resources and ensure that a more formal hearing process is not invoked unless necessary. However, we also have considered other options, including having at the second level of appeal a telephone hearing with a CMS hearing officer instead of an in-person hearing. Another option is for a hearing on the record with the Hearing Officer, but without the opportunity for oral testimony. Although we believe these rules are procedural rules not subject to notice and comment rulemaking, in the case of this new

benefit, we would welcome comments on the sufficiency of these rules and the other options discussed above.

In addition to the appeals process, we have included provisions for reopening and revising an initial or reconsidered determination. We believe the authority to reopen retiree drug subsidy determinations would be in keeping with our authority in section 1860D-22(a)(2)(B) of the Act to "perform audits and other oversight activities necessary to ensure... accuracy of payments," since this audit authority would not be meaningful if we could not reopen payment determinations we later determined to be erroneous. In addition, we believe that sections 1870 and 1871 of the Act provide us with the authority to reopen final determinations of the retiree drug subsidy to such employers. Therefore, in this proposed rule we would include reopening provisions based on those used in Medicare claims reopening, and found in Part 405 of the Code of Federal Regulations (subparts G and H). Including reopening provisions would allow us to ensure that any overpayments or underpayments discovered as a result of oversight or audit could be rectified. Under our proposed provisions, reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when the initial,

reconsidered, or revised determination was procured by fraud or similar fault. We could initiate a reopening on its own, or an employer could request reopening, but these requests would be at our discretion. The Supreme Court has determined that in the context of reopening cost reports, a fiscal intermediary's decision not to reopen a final determination is not subject to judicial review, (See Your Home Visiting Nurse Services, Inc. v. Shalala, 525 U.S. 449, 456 (1999)), and we believe the same reasoning would apply in the context of Part D.

Good cause would be interpreted in the same manner as in Part 405 and as further clarified in the Medicare Carriers Manual (MCM), section 12100. Thus, good cause would exist, if --(a) new and material evidence, not readily available at the time of the determination, is uncovered; (b) there is an error on the face of the evidence on which such determination or decision is based; or, (c) there is a clerical error in determination. In order to meet the standard under (a), the evidence could not have been available at the time the determination was made. A clerical error constitutes such errors as computational mistakes. An error on the face of the evidence exists if it is clear, based upon the evidence that was before us when we reached our initial

determination, that the initial determination is erroneous. For example, good cause would exist in cases where it is clear from the files that rebates or administrative costs were not appropriately accounted for, where computation errors had been made, where an employer included non-Part D drugs in their calculations, where individuals not enrolled in the plan were included in calculating payment, and in similar situations. Reopening could occur at any time if the underlying decision was obtained through fraud or similar fault – such as if an employer sponsor – or its subcontractor -- knew or should have known that it was claiming erroneous subsidies. We believe it would be necessary to include subcontractors in this standard, since we expect many sponsors will contract with benefit administrators to manage the benefit, and these administrators will be providing data to CMS. We have not included provisions for reopening hearing officer or Administrator decisions, but are considering allowing for the reopenings as well. We request comments on this issue.

7. Privacy

The HIPAA Privacy Rule at 45 CFR Part 160 and Subparts A and E of Part 164 ("Privacy Rule") applies to "covered entities," which include group health plans and health insurance issuers, as defined in 45 CFR 160.103. Third

party administrators would be business associates, as defined in 45 CFR 160.103, of group health plans. Sponsors would not become covered entities by sponsoring a plan and do not have access to claims information or similar Protected Health Information necessary to support the subsidy payment. Much of the data that we would need to support the subsidy payment outlined above would be protected health information held by group health plans, insurers, and "third party administrators" on behalf of self-funded group health plans.

Covered entities may only use or disclose protected health information as permitted or required by the Privacy Rule. A business associate contract generally must limit the business associate's uses or disclosures of protected health information to those the covered entity could make. Permitted uses and disclosures include those for treatment, payment, and health care operations as well as those for public priority purposes, such as those uses and disclosures required by law (45 CFR 164.512(a)).

Section 423.888(b) would require the plan (or the third party administrator on behalf of the plan, as applicable) or the insurer of the plan to disclose certain data to CMS that is related to the retiree drug subsidy when directed by the plan sponsor to do so. We believe we

have the authority to mandate the disclosure of this data to CMS pursuant to our oversight authority under section 1860D-22(a)(2)(B) of the Act, which provides that the Secretary shall have the access to such records as necessary to ensure the adequacy of subsidy payments made to sponsors. A sponsor applying for the subsidy can direct the plans that it sponsors (or the third party administrators or the insurers, as applicable) to disclose the protected health information to us, and disclosure will be permitted under the Privacy Rule because the disclosure is required by law, that is, by this regulation. In order to protect the privacy of the information, the protected health information would be provided directly to CMS and would not be shared with the sponsor. (CMS would disclose the information on the enrollees' Part D eligibility to the sponsors or the plan under § 423.884(b)(6).) We invite comment on the impact this will have on sponsors of retiree plans and on the group health plans, issuers, and third-party administrators of these plans.

8. Change of Ownership (§ 423.892)

Sponsors who apply for a subsidy payment would be required to comply with change of ownership requirements, similar to those set forth in proposed § 423.551 for the MA-PD and PDP plans. However, for purposes of the retiree

drug subsidy, we are proposing slightly different change of ownership provisions than those proposed in § 423.551 for PDPs. We request comments regarding how these provisions could be modified to accomplish these objectives. In particular, we seek comments regarding: the situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to a change of ownership, and whether sponsors should be subject to novation agreement and facility leasing provisions similar to those proposed in § 423.551.

In § 423.892, we would carry over the three situations that constitute change of ownership (CHOW) in § 423.551 of our proposed rule. We would state that a CHOW includes the following--

- The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law;
- A transfer of substantially all of the assets of the sponsor to another party; or
- The merger of the sponsor's corporation into another corporation, or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

The proposed exception to the three provisions discussed above would be that a transfer of corporate stock or the merger of another corporation into the sponsor's organization, with the sponsor organization surviving, would not usually constitute a CHOW.

We would require a sponsor that has a sponsor agreement in effect and who is considering or negotiating a CHOW, to notify us at least 60 days before the anticipated effective date of the change. In addition, we would also require that when there is a CHOW, and this results in a transfer of the liability for prescription drug costs, the existing subsidy agreement would automatically be assigned to the new owner. We would also require that the new owner to whom a sponsor agreement is assigned be subject to all applicable statutes and regulations and to the terms and conditions of the subsidy agreement.

We welcome comments on any aspect of the proposed section on change of ownership. We are particularly interested in comments on situations in which a sponsor transfers substantial assets, but substantially less than all of its assets, to another party. Please describe the different scenarios that might develop under such circumstances, especially the extent to which benefits covered by the sponsor agreement might reasonably be

expected to be provided by the old or new owner and the best approach for either transferring, issuing or reissuing sponsor agreements. We would also like to receive comments on scenarios that might develop if more than one entity retains or acquires liability for prescription drug costs as the result of the terms of a change in ownership.

9. Construction (§ 423.894)

Sections 423.890(a) through § 423.890(d) are based on section 1860D-22(a)(6) of the Act. It provides that nothing in section 1860D-22 of the Act must be interpreted as preventing--

- An individual who is eligible for Medicare Part D and who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in a MA-PD plan;
- The sponsor of employment-based retiree health coverage or an employer or other person from paying all or any part of any premium required for coverage under a prescription drug plan or MA-PD plan on behalf of an individual;
- Employment-based retiree health coverage from providing coverage that is supplemental to the benefits provided under a prescription drug plan or a MA-PD plan, including benefits to retirees who are not

covered under a qualified retiree prescription drug plan, but who are enrolled in a PDP or MA-PD plan;

- Employment-based retiree health coverage from providing coverage that is better than the standard prescription drug coverage (as defined in § 423.104(e)) to retirees who are covered under a qualified retiree prescription drug plan; and
- Sponsors from providing for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic Medicare Part D drug coverage, as long as the actuarial equivalence requirement (as defined in § 423.884(a)) is met.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

1. Eligibility Determinations (§ 423.904)

The MMA added a new section 1935 to the Act, "Special Provisions Relating to Medicare Prescription Drug Benefit," which specifies the requirements for States regarding low-income subsidies under the new part D benefit. In accordance with the statute, our proposed regulations at § 423.904(a) and (b) would require States to make initial eligibility determinations for premium and cost sharing subsidies based on applications filed with the States, to conduct periodic redeterminations consistent with the

(b) State premium taxes prohibited.

(1) Basic rule. No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA-PD plan or prescription drug plan enrollees under subpart G of this part; or with respect to any payment made to prescription drug plans or MA-PD plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) Construction. Nothing in this section shall be construed to exempt any PDP sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J--Coordination Under Part D With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans, establishes waivers for employer-

sponsored group prescription drug plans, and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions and Terminology.

For purposes of this subpart, the following definitions apply--

Part D plan or Medicare Part D plan is a prescription drug plan or an MA-PD plan.

Employer-sponsored group prescription drug plan means a prescription drug plan under a contract between a PDP sponsor or an MA organization offering an MA-PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage (as defined in §423.822). (Published elsewhere in this **Federal Register**.)

State Pharmaceutical Assistance Program (SPAP) means a State program (operated by or under contract with a State) that meets the requirements described under § 423.464(c).

§ 423.458 Application of Part D rules to MA-PD plans on and after January 1, 2006.

(a) Relationship to Part C. Except as otherwise provided in this Part, the requirements of this Part apply

to prescription drug coverage provided by Medicare Advantage prescription drug plans offered by Medicare Advantage organizations.

(b) MA Waiver. CMS waives any provision of this Part as applied to MA-PD plans to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organization or MA-PD plan under Part C of Medicare or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) Application of Waiver. Any waiver or modification granted by CMS under this section will apply to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) Request for waivers. Organizations offering or seeking to offer a Medicare Advantage-Prescription Drug plan may request from CMS in writing--

(i) A waiver of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to the MA-PD plan, or proposed MA-PD plan, under Part C of Medicare.

(ii) A waiver of a requirement under Medicare Part D, if such waiver would improve coordination of benefits provided under Part C of Medicare with the benefits under Part D.

(c) Employer Group Waiver. (1) General rule. Prescription drug plans may request, in writing, a waiver or modification of those requirements under Part D of Medicare that hinder the design of, the offering of, or the enrollment in, an employer-sponsored group prescription drug plan. This provision applies to prescription drug plans in the same manner that the provisions of section 1857(i) of the Act apply to an MA plan or MA-PD plan in relation to employer-sponsored group MA plans or MA-PD plans, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the employment-based retiree health coverage sponsored by the employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations.

(2) Use of waiver. Waivers or modifications approved by CMS under this section apply to any similarly situated prescription drug plan meeting the conditions of the waiver or modification.

(d) Other Waivers. CMS waives any provision of this Part as applied to a section 1876 cost HMO/CMP (as defined in § 417.401) or PACE organization (as defined in § 460.6)

that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the 1876 cost HMO/CMP under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act or as may be necessary in order to improve coordination of this Part with the benefits offered by 1876 cost HMOs/CMPs or PACE organizations.

(1) Application of Waiver. Any waiver or modification granted by CMS under this section will apply to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as an 1876 cost HMO/CMP or as a PACE organization that meets the conditions of the waiver.

(2) Request for waivers. Section 1876 cost HMOs/CMPs or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing—

(i) A waiver of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to 1876 cost HMOs/CMPs or PACE organizations.

(ii) A waiver of a requirement under Medicare Part D, if such waiver would improve coordination of benefits

provided by the section 1876 cost HMO/CMP or PACE organization with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to PDP sponsors in the same way as they apply to MA organizations under Part C of Title XVIII of the Act, except all references to MA organizations are considered references to PDP sponsors.

§ 423.464 Coordination Of Benefits With Other Providers Of Prescription Drug Coverage.

(a) General rule. A PDP sponsor and Medicare Advantage organization offering a MA-PD plan must permit State Pharmaceutical Assistance Programs described in paragraph (e) of this section and the plans described in paragraph (f) of this section to coordinate benefits with the prescription drug plan or MA-PD plan and must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and a State pharmaceutical assistance program and other plans providing prescription drug coverage for--

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(g)(1)(ii)(including payment to a

Medicare Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or other plan.

(b) Medicare as primary payer. The requirements of this subpart do not change or affect the primary or secondary payor status of a Medicare Part D plan and a SPAP or other plan. A Medicare Part D plan is always the primary payor relative to a State Pharmaceutical Assistance Program.

(c) User fees. CMS may impose user fees for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and a State Pharmaceutical Assistance Program and other plans providing prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B), except that CMS may retain a portion of user fees to defray costs in carrying out such procedures. CMS will not impose user fees under this subpart for a State pharmaceutical assistance program.

(d) Cost management tools. The requirements of this subpart do not prevent an organization sponsoring a Medicare Part D plan from using cost management tools

(including differential payments) under all methods of operation.

(e) Coordination with State Pharmaceutical Assistance Programs.

(1) Requirements to be a State Pharmaceutical Assistance Program (SPAP). A program operated by or under contract with a State will be considered to be a State Pharmaceutical Assistance Program for purposes of this part if it—

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) 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;

(iii) Meets the benefit coordination requirements specified in this part; and

(iv) Does not follow or adopt rules that change or affect the primary payor status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where the majority of the funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding.

(2) Special treatment under out-of-pocket rule. A PDP sponsor and Medicare Advantage organization offering a MA-PD plan shall collect information on and apply expenditures made by SPAPs for costs of covered Part D drugs meeting the definition of incurred costs (as described in § 423.100) for purposes of reaching the out-of-pocket threshold provided under § 423.104(e)(5)(iii).

(3) Use of a single card. A card that is issued under § 423.120(c) for use under a Medicare Part D plan may also be used in connection with coverage of benefits provided under a State pharmaceutical assistance program and, in such a case, may contain an emblem or symbol indicating such connection.

(4) Construction. Nothing in this subpart requires a State Pharmaceutical Assistance Program to coordinate with, or provide financial assistance to enrollees in, any Medicare Part D plan.

(f) Coordination with other plans. (1) Definition of other plans. Other plans that provide prescription drug coverage include any of the following:

(i) Medicaid programs. A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans. An employer group health plan as defined in § 411.101.

(iii) FEHBP. The Federal employees' health benefits plan under chapter 89 of title 5, United States Code.

(iv) Military coverage (including TRICARE). Coverage under chapter 55 of title 10, United States Code.

(v) Other health benefit plans or programs. Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Medicare Part D eligible individuals as CMS may specify.

(2) Treatment under out-of-pocket rule. A PDP sponsor and Medicare Advantage organization offering a MA-PD plan shall exclude expenditures made by other plans for costs of covered Part D drugs for purposes of reaching the out-of-pocket threshold provided under § 423.104(e)(5)(iii).

(3) Imposition of fees. A prescription drug plan sponsor or an organization offering an MA-PD plan may not impose fees on other plans that are unrelated to the cost of the coordination of benefits.

Subpart K--Application Procedures and Contracts With PDP Sponsors

Subpart R--Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) Basis. This subpart is based on section 1860D-22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) Scope. This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs in accordance with section 1860D-22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs between the cost threshold and cost limit, as defined under § 423.886(b), that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions.

Covered Part D drug has the same meaning as defined in § 423.100.

Retiree drug subsidy amount means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or gross retiree costs means, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for covered Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of covered Part D drugs.

Group health plan has the same meaning as defined in section 607(1) of ERISA, 29 U.S.C. 1167(1). This definition also includes the following plans:

(1) Federal and State governmental plan means a plan established or maintained for its employees by the Government of the United States, by the government of any

State or political subdivision of a State, or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) Collectively bargained plan means a plan established or maintained under or by one or more collective bargaining agreements.

(3) Church plan means a plan established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

Part D eligible individual is defined in § 423.4 of our proposed rule.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884(a) through (d) of this chapter for a Part D eligible individual who is a participant or beneficiary under the coverage.

Qualifying covered retiree means a Part D eligible individual who is a participant under the qualified retiree prescription drug plan or the spouse or dependent of a participant under the qualified prescription drug plan, who

is not enrolled in a Part D prescription drug plan or a Medicare Advantage-Prescription Drug (MA-PD) plan.

Standard Prescription Drug Coverage has the same meaning as defined in § 423.100.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

§ 423.884 Requirements for qualified retiree prescription drug plans. A qualified retiree prescription drug plan must meet the requirements of this section.

(a) Actuarial Attestation. The sponsor of the plan (or a plan administrator designated by the sponsor) provides to CMS an attestation that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the standard prescription drug coverage under Part D. The attestation must--

(1) Be provided annually, no later than 90 days prior to the start of the calendar year, except that for 2006, the attestation must be provided by September 30, 2005;

(2) Be provided no later than 90 days before the

implementation of a material change to the drug coverage of the plan that impacts the actuarial value of the coverage;

(3) Certify that the values have been calculated according to established CMS actuarial guidelines based on generally accepted actuarial principles;

(4) Be certified by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries.

(5) Be signed under the penalty of perjury;

(6) State that the information contained in the attestation is true and accurate to the best of the attester's knowledge;

(7) Contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(b) Sponsor application for the subsidy payment.

(1) Deadlines. The sponsor must submit an application for the subsidy, signed by an authorized representative of the sponsor, to CMS by no later than for:

(i) The year 2006, September 30, 2005.

(ii) All other years, 90 days prior to the start of the year.

(iii) Plans that begin coverage in the middle of a year, 90 days prior to the date the coverage begins.

(iv) New plans that institute coverage after September 30, 2005, 150 days prior to the start of the new plan.

(2) Required information. The following information must be submitted with the application:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation and supporting documentation for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) Full names of each qualifying covered retiree enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), and the following information:

(A) Health Insurance Claim (HIC) number (when available).

(B) Date of birth.

(C) Sex.

(D) Social Security number.

(E) Relationship to the retired employee.

(3) Terms and conditions. The application must specify acceptance of the terms and conditions of eligibility to receive a subsidy payment. The sponsor must --

(i) Agree to comply with all Federal laws and regulations, and the terms and conditions of eligibility for a subsidy payment, including those concerning auditing of claims for subsidy payments and combating fraud and abuse;

(ii) Acknowledge that the information is being provided to obtain Federal funds;

(iii) Require that all subcontractors, including administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds;

(iv) Sign any further certification that CMS may require.

(4) Signature by sponsor. An authorized representative of the requesting sponsor must sign the completed application. The signed application constitutes an agreement between CMS and the sponsor.

(5) Updates. The sponsor (or the plan administrator designated by the sponsor) must provide updates to CMS of the information required in paragraph (b)(2) of this section in the manner and frequency specified by CMS.

(6) Data match. Once the full application for the subsidy payment is submitted, CMS--

(i) Matches the names of the qualifying covered retirees and the identifying information of each retiree with the Medicare Data Base (MBD) to determine which retirees are qualifying covered retirees.

(ii) Provides to the sponsor (or to a plan administrator designated by a sponsor) the names, and other identifying information if necessary, of the sponsor's qualifying covered retirees.

(c) Disclosure of creditable coverage status. The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable coverage under § 423.4 in accordance with the notification requirements under § 423.56.

(d) Audits, CMS access to records. The sponsor must meet the requirements of § 423.888(d).

§ 423.886 Retiree drug subsidy amounts.

(a) Amount of subsidy payment. For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year in which the retiree's gross covered retiree plan-related prescription drug costs (as defined in § 423.882) exceeds the cost threshold defined in paragraph (b)(1) of this section, the sponsor receives a subsidy payment in the amount of 28

percent of the allowable retiree costs (as defined in § 423.882) attributable to the gross covered prescription drug costs between the cost threshold and the cost limit defined in paragraph (b)(2) of this section.

(b) Cost threshold and cost limit. The following cost threshold and cost limits apply--

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for calendar year 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for calendar year 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for years after 2006, is adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under §§ 423.104(e)(1)(ii) and (e)(4)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) Basis. The provisions of § 423.301 through § 423.343, including requirement to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886.

(b) Payment. Payment under § 423.886 is conditioned on provision of accurate and truthful information in a form and manner specified by CMS. When directed by the sponsor of a qualified retiree prescription drug plan applying for payment under this section, the qualified retiree prescription drug plan (or an administrator or insurer of the qualified retiree prescription drug plan, if applicable) must submit in the form and manner CMS specifies, the information required to CMS.

(c) Use of information provided. Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under paragraphs (a) and (d) of this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) Maintenance of records. (1) The sponsor of the qualified retiree prescription drug plan and the qualified retiree prescription drug plan (or an administrator or insurer of the qualified retiree prescription drug plan),

as applicable, must maintain, and furnish to CMS or the Office of Inspector General (OIG) upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement in the event of an ongoing investigation, litigation or negotiation.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

§ 423.890 Appeals.

(a) Informal written reconsideration. (1) Initial determinations. A sponsor is entitled to an informal written reconsideration of an adverse initial

determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) Effect of an initial determination regarding the retiree drug subsidy. An initial determination is final and binding unless reconsidered in accordance with this paragraph (a).

(3) Manner and timing for request. A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) Content of request. The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) Conduct of informal written reconsideration. In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) Decision of the informal written reconsideration. CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) Effect of CMS informal written reconsideration. A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) Right to informal hearing. A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) Manner and timing for request. A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) Content of request. The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) Informal hearing procedures. (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) Decision of the CMS Hearing Officer. The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) Effecting of hearing officer decision. The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) Review by the Administrator. (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) Reopening. (1) Ability to reopen. CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) Notice of reopening. (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) Effect of reopening. The revision of an initial or reconsidered determination is final and binding unless—

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) Good cause. For purposes of this section, CMS finds good cause if --

(i) New and material evidence that was not readily available at the time the initial determination was made is furnished;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

§ 423.892 Change in ownership.

(a) Change of ownership. Any of the following constitutes a change of ownership:

(1) Partnership. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) Asset sale. Transfer of substantially all of the assets of the sponsor to another party constitutes a change of ownership.

(3) Corporation. The merger of the sponsor's corporation into another corporation or the consolidation

of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) Change of ownership, exception. Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) Advance notice requirement. A sponsor that has a retiree drug subsidy agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) Assignment of agreement. When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs the existing sponsor agreement is automatically assigned to the new owner.

(e) Conditions that apply to assignment agreements. The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting--

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a prescription drug plan or in a MA-PD plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a prescription drug plan or MA-PD plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is--

(1) Supplemental to the benefits provided under a prescription drug plan or a MA-PD plan.

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(e)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to PDPs and MA-PD plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S--Special Rules for States—Eligibility Determinations for Subsidies and General Payment