NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2006. Preliminary estimates of the national per capita MA growth percentage and other payment methodology changes for CY 2006 are also discussed. For 2006, CMS will announce the MA capitation rates on the first Monday in April, 2005, in accordance with the new timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

In accordance with Section 1860D-15(c)(1)(D) of the Act, we are notifying you of the proposed health status risk adjustment methodology for Part D. We are also notifying you of the proposed payment methodologies for the direct, low-income, and reinsurance subsidies, in addition to risk sharing.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage for the minimum percentage increase applied to the MA capitation rates. All counties will receive the minimum update percentage for 2006. The CMS has decided not to rebase the county fee-for-service rates for 2006.

Attachment II sets forth in detail the changes in payment methodology for 2006 for MA organizations.

Attachment III provides an overview of payment for Medicare Advantage – Prescription Drug (MA-PD) plans and Prescription Drug Plans (PDP).

Attachment comments or questions may be addressed to:

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Mark Newsom (for Attachment III)
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Comments also may be submitted electronically to the following address: AdvanceNotice2006@cms.hhs.gov. In order to receive consideration prior to the April 4, 2005 announcement of MA and PDP capitation rates, comments must be received by 5:00 PM EST on March 4, 2005.

/ s /
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/ s /
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Attachments

Attachment I

Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year (CY) 2006

The MMA provides that the minimum percentage increase is the higher of two percent or the national per capita MA growth percentage, with no adjustment to this percentage for over- or under-estimates for years before 2004. The CMS has decided not to rebase the county fee-for-service (FFS) rates for 2006.

The current estimate of the change in the national per capita MA growth percentage for aged enrollees in CY 2006 is 4.0 percent. This estimate reflects an underlying trend change for CY 2006 in per capita costs of 4.5 percent and an adjustment for the fact that the current estimates of CY 2005 and CY 2004 aged MA growth percentages are .2 percent and .3 percent, respectively, lower than the estimates actually used in calculating the CY 2005 capitation rate book that was published May 10, 2004 (as required by Section 1853(c)(6)(C) of the Act).

The following table summarizes the estimates for the change in the national per capita MA growth percentage, which will be used for the minimum percentage increase.

Table I-1. National Per Capita Growth Percentage

	Aged	Disabled	ESRD	Aged+Disabled
2006 Trend Change	4.5%	4.7%	3.9%	4.5%
Revision to CY 2005 Estimate	-0.2%	-0.5%	-0.5%	-0.3%
Revision to CY 2004 Estimate	-0.3%	-0.3%	1.0%	-0.2%
Total Change	4.0%	3.9%	4.4%	4.0%

Note: The above percentages are multiplicative not additive.

These estimates are preliminary and could change before the final rates are announced on April 4, 2005. Further details on the derivation of the national per capita MA growth percentage will also be presented in the April 4 announcement.

Attachment II

Changes in the Payment Methodology for Original Medicare Benefits for CY 2006

The MMA revised the pricing and payment methodologies for MA organizations beginning in 2006. We provide an overview of the new bidding methodology in Section A, followed by a discussion in Section B of changes in payment that follow from the bidding methodology introduced by the MMA. In Section C, we discuss how payments for End-Stage Renal Disease (ESRD) enrollees and enrollees who have elected hospice will be made in 2006, the payment methodology for MSA plans, and several other payment policies. Section D addresses a payment provision unique to regional organizations – risk sharing (applicable to payments in 2006 and 2007; regional organization entry and retention bonus payments can be applicable in 2007 and thereafter but are not discussed in this notice). In Section E, we discuss the submission of bids by demonstration plans. In Section F, we discuss changes in risk adjustment for 2006, including the recalibration of the CMS-HCC models for aged/disabled and ESRD enrollees. Finally, Section G discusses developments in the budget neutral risk adjustment policy.

The terminology used in this Advance Notice differs from that in statute and regulation. Section 1854(b)(3)(C) of the Act refers to the "risk-adjusted benchmark" and "risk-adjusted bid" when describing the determination of savings. For the savings calculation, adjustment for risk is done at the plan level, based on the plan projected average risk score. However, based on how bids are actually constructed, the use of the terms "risk adjusted bid" and "unadjusted bid" has caused confusion.

The starting point for the bid is the plan's own estimate of its revenue requirements based on its projected enrollment. These revenue requirements are then reduced to reflect Medicare cost-sharing in order to produce the plan bid for A/B services (as explained below). Because this amount reflects the characteristics of the plan's projected enrollment, it is by definition "risk adjusted." However, referring to this amount as the "risk adjusted" bid has been construed to imply that this A/B bid amount results from applying risk adjustment factors to a standardized amount, when in fact the reverse is true. (This confusion is due to the fact that historically CMS has used the term "risk adjustment" to describe a payment adjustment using factors from CMS risk adjustment models.) That is, the standardized A/B bid amount is derived from normalizing what the statute refers to as the "risk adjusted" bid. So in this document we will be referring to the "risk adjusted" bid as simply the "plan A/B bid." The statutory term "unadjusted bid" will be referred to in this notice as the "standardized A/B bid." For consistency purposes we are making parallel changes to the terminology for benchmarks. In summary:

- The statutory term "risk adjusted bid" will be referred to in this notice as the "plan A/B bid" (which excludes Medicare cost sharing).

- The "risk adjusted benchmark" will be referred to in this notice as the "plan A/B benchmark" (the amount compared to the "plan A/B bid" to determine whether there are savings).

- The "unadjusted bid" will be referred to in this notice as the "standardized A/B bid."

- The "unadjusted benchmark" will be referred to in this notice as the "standardized A/B benchmark." (For plans with plan A/B bids above the plan A/B benchmark, the basic premium members will pay is the difference between the standardized A/B bid and the standardized A/B benchmark. That is, the premium is determined for a 1.0 beneficiary.)

Section A. Overview of Bidding Methodology for Non-drug Benefits

One purpose of bidding by MA organizations is to base payment for Medicare Part A and B benefits on an organization's monthly expected revenue needs for covering those benefits, rather than solely on an administratively set amount. The bidding process also determines how much (if anything) a Medicare enrollee would have to pay for Part A and B benefits, and how much an enrollee would receive in rebates or benefits in addition to A and B benefits. On the first Monday of June in each year beginning in 2005, MA organizations will submit a bid for the upcoming year based on their determinations of their monthly expected revenue needs, i.e. their medical and administrative costs, including profit. The Instructions for the Bid Pricing Tool (draft available at www.cms.hhs.gov/healthplans/) and the 2006 Call Letter (available this spring at www.cms.hhs.gov/healthplans/letters/), will describe the bidding method and policies in detail. We provide an overview of bidding below, as background to the discussion of payment methodology.

1. Bids. An MA organization's combined bid for its service area, for both local and regional organizations (or service area segment, in the case of a local organization), will have three parts:

- An amount for the provision of Medicare Parts A and B medical benefits – (This is the standardized A/B bid. It is exclusive of an amount actuarially equivalent to Medicare cost sharing.);

- An amount for basic coverage of Medicare prescription drug benefits (if any); and

- An amount for the provision of supplemental medical and prescription drug benefits (if any).

Note that for bidding purposes only, supplemental benefits will be divided into those related to prescription drug coverage and all other supplemental benefits. This treatment for bidding purposes does not affect how the benefits are offered to enrollees or the premium charged. That is, supplemental benefits include both medical and prescription drug benefits (if offered) and are offered for a single supplemental benefits premium.

2. Actuarially equivalent cost sharing. The plan A/B bid must reflect cost sharing as required under original Medicare, or an actuarially equivalent amount. As discussed in the preamble for Subpart F of the Final Rule implementing the Medicare Advantage program (Final Rule), which was published in the *Federal Register*, January 28, 2005 (70 FR 4588), plan-specific actuarially equivalent cost sharing will be determined based on cost sharing proportions in original Medicare that are applied to projected plan allowed costs for Medicare benefits. The actuarially equivalent amount will be determined using five service-specific proportions (proportions for inpatient facility, SNF facility, home health services, outpatient facility, and all other Part B services) that may vary by geographic area, and/or service type.

The proportions will be developed using 100 percent of Medicare FFS claim data for non-ESRD beneficiaries, as captured in our CY 2002 and/or CY 2003 National Claims History data files and projected to calendar year 2006. The development of the factors will take into consideration the validity and credibility of the data at the service-specific and county-specific level. For example, the Part B-other factor may reflect local (either county-level or metropolitan statistical area-level) variations in cost sharing proportions, or the same factor may be used in all counties (that is, a nationwide factor). Similarly, the local factor may be used for all non-home health Part B services, or separate factors may be provided for outpatient hospital and other Part B services. The CMS will publish the proportions each year for each county or other geographic area.

A single enrollment-weighted proportion across all counties in the organization's service area (or service area segment) for each of these five service categories will be used. Each service category proportion is multiplied by the appropriate allowed costs for that category, and then these amounts are summed to generate the cost sharing amount that is considered to be actuarially equivalent to average FFS cost sharing. The total actuarially equivalent cost sharing amount is then subtracted from the allowable costs to determine the plan A/B bid.

The factors to be used in the 2006 bids will be published by CMS on April 4, 2005.

3. Benchmarks. For both local and regional MA plans, the plan A/B benchmark, when compared against a plan A/B bid, determines whether a plan will have savings and offer rebates or additional benefits, or whether the MA organization will have to charge a basic premium for the plan's coverage of Part A and B benefits.

For local plans, the plan A/B benchmark is determined according to formulas established in the MMA. For a single-county plan (or segment), the plan A/B benchmark is the capitation rate for that county, adjusted to reflect the plan's projected risk profile to allow

comparison to the plan A/B bid. For local plans serving more than one county, the plan A/B benchmark is the enrollment-weighted average of all the county capitation rates in the plan's service area (or segment), adjusted by the projected risk profile of the plan. (In determining the enrollment-weighted average, the weights are based on the plan's projected enrollment in each county of its service area.)

Local plan A/B benchmarks are plan-specific, because the MA organization selects which counties to include in a plan's service area, and each plan's benchmark is weighted by the plan's projected enrollment. Regional plan A/B benchmarks are based on a different statutory formula that results in a single (standardized) benchmark amount for each region applicable to all regional plans in that region. The CMS will determine a standardized A/B benchmark annually for each of the 26 MA regions, and an MA regional plan will adjust the standardized benchmark to reflect the plan's projected risk profile.

The standardized benchmark for each MA region is a blend of two components: a statutory component consisting of the weighted average of the county capitation rates across the region; and a competitive component consisting of the weighted average of all of the standardized A/B bids for regional plans in the region. The weighting for the statutory component is based on MA eligible individuals in the region. "MA eligibles" refers to all Medicare beneficiaries in the FFS and MA programs. The MA eligibles will not include Part B-only enrollees. For 2006 only, ESRD beneficiaries are not included in the count of MA eligibles for the purpose of calculating the statutory component of the regional benchmark, because ESRD enrollee costs are not included in the bid for 2006. The weighting for the competitive component (which includes each regional plan's bid) is based on the projected enrollment of the regional plans competing in the region. The blend of the two components will reflect the market share of traditional Medicare (for the statutory component) and the market share of all MA organizations (for the competitive component) in the Medicare population nationally.

The statutory components of the 26 regional standardized A/B benchmarks will be published each year as part of the Announcement of CY 2006 Medicare Advantage Payment Rates. For the annual June bid submission, an MA organization will estimate the regional plan benchmark by weighting together the appropriate statutory component published by CMS with the regional plan's standardized A/B bid as a proxy for the competitive component of the benchmark. In early August each year, CMS will publish the final MA regional standardized A/B benchmarks which will reflect the average bid component and the statutory component. Regional plans will adjust the standardized regional benchmark by their plan projected risk profile to arrive at the regional plan A/B benchmark, which is used for the savings calculation. (Note on the weighting used for the competitive component of regional benchmarks: If an MA region has approved bids for regional plans only open to a specific subgroup of Medicare beneficiaries (e.g., special needs plans for institutionalized beneficiaries), the Office of the Actuary (OACT) will consider assigning one weight to standard plans and a different weight to plans enrolling a specific subgroup of beneficiaries.)

4. Computation of benchmarks based on transition payment blends. The schedule for the transition from demographic to fully risk adjusted payments requires that, for 2006, 75 percent of payments for A/B benefits will be based on the CMS-HCC risk adjustment model, and 25 percent of payments will be based on the demographic-only model. This means that, under the bidding methodology, the savings calculation must be done using a blended benchmark. This type of blending should be distinguished from the statutory requirement for calculation of regional MA benchmarks, which combines competitive and statutory components, as described above under item (3). For 2006, the Bid Pricing Tool will calculate a blended benchmark that combines aged and disabled demographic benchmarks with risk benchmarks. As a result, the savings and rebate amounts (if any) will be determined by subtracting a blended plan A/B bid from a blended A/B benchmark. The beneficiary premium amount (if any) will also be determined by using a blended benchmark (in this case the standardized A/B benchmark). However, the demographic and risk adjusted payment amounts are determined separately, as discussed in the next section.

5. Treatment of ESRD enrollee costs. For 2006, ESRD enrollees will not be included in the plan A/B bid. MA organizations will have the option to adjust a plan's supplemental benefit premium by an ESRD factor, based on an organization's estimate of higher supplemental benefit costs for ESRD enrollees in the plan.

6. Computation of savings, rebate, and premium. In order to calculate plan savings or beneficiary premiums, CMS will compare the plan A/B bid with the plan A/B benchmark. The plan A/B bid for Medicare-covered costs is the sum of the medical expenses for A/B services (reduced by Medicare cost sharing), non-medical expenses, and the gain/loss margin. For 2006, the plan transitional-blend A/B bid will be compared to the transitional-blend A/B benchmark described above in item 4 to determine whether an organization will have savings (for organizations with bids below benchmarks) and, therefore, offer rebates or additional benefits (equal to 75 percent of the savings), or whether an organization will have to charge a beneficiary basic premium (for organizations with bids above benchmarks). The basic premium is equal to the difference between the standardized A/B bid and standardized A/B benchmark. For local organizations 25% of savings is retained by the government in the Medicare Trust Funds. For regional organizations one-half of the 25% savings is retained in the Medicare Trust Funds and the other half is placed in the stabilization fund.

Note that after 2005, if an organization chooses to use savings to offer a full or partial reduction of the Part B premium, such reductions will be funded on the same basis as other uses of rebate dollars (e.g., provision of additional benefits); that is through the use of rebate dollars which equal 75% of plan savings. For example, if an organization chooses to apply $10 of a plan's rebate to buy-down the Part B premium, enrollees' Part B premiums will be reduced by $10. The BIPA Section 606 provision on Part B premium reductions, enacted at Section 1854(f)(1)(E) of the Act, applies only to years before 2006.

The MMA permitted CMS to choose among various alternatives, including using a statewide average risk factor for all plans, in order to determine savings at the plan level. As indicated in the Final Rule, we will be using the plan-specific risk adjustment approach – that is, an organization will determine a plan A/B bid based on projected costs for the expected enrollee mix in the plan. In this sense, risk is defined at the plan-level. For the purpose of plan payments, however, risk adjustment is applied at the level of the individual beneficiary, based on the CMS-HCC risk adjustment model.

Section B. Changes in Payment for Non-Drug Benefits

This section discusses several elements of the new payment formula:

- Basic payment rules, based on the bid-benchmark relationship;
- The geographic Intra-Service Area Rate (ISAR) adjustment (discussed in item 2 below);
- Risk adjustment (discussed in item 3 below and Section F);
- The rebate (discussed in Section A); and
- The government premium adjustment (discussed in item 4 below).

1. Statutory formulas for non-drug benefits. The MMA describes three formulas for payments to MA organizations beginning in 2006.

(a) If the plan A/B bid is less than the plan A/B benchmark, monthly payment from CMS for an individual is:

> [(Standardized A/B bid, adjusted by the plan's ISAR factor for the enrollee's county of residence) adjusted by the enrollee risk factor] + rebate minus amount for Part B premium reduction (if any).

(b) If the plan A/B bid is equal to the plan A/B benchmark, monthly payment from CMS for an individual is:

> (Standardized A/B benchmark, adjusted by plan's ISAR factor for the enrollee's county of residence) adjusted by the enrollee risk factor.
>
> There is no rebate and no basic beneficiary premium.

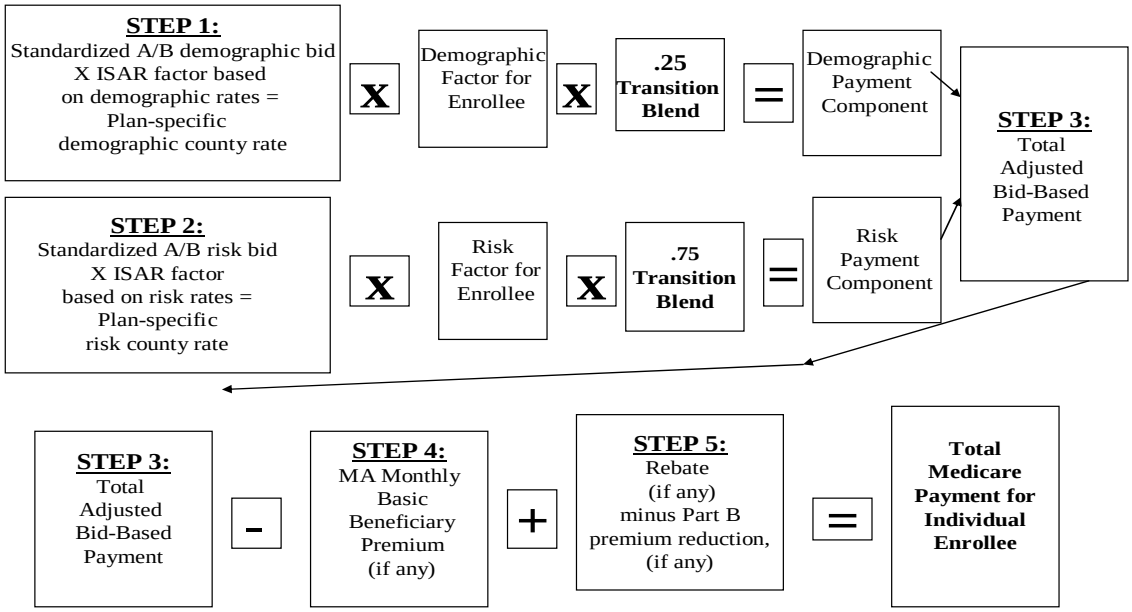
(c) If the plan A/B bid is greater than the plan A/B benchmark, monthly payment from CMS for an individual is:

[(Standardized A/B benchmark, adjusted by plan's ISAR factor for the enrollee's county of residence) adjusted by the enrollee risk factor] + government premium adjustment.

There is no rebate and the enrollee pays a basic premium. The combined payment from CMS and the enrollee will on average equal the organization's bid (based on enrollment assumed in the bid submission).

See Figure II-1 below for a diagram depicting the payment formula for 2006, which includes the impact of the 25%/75% transition blend on payment calculations. It is important to keep in mind that Figure II-1 describes the three statutory formulas listed above as a single formula, representing how payment calculations will be determined in the MMCS payment system. See Table II-1 for descriptions of 2006 payment formulas for non-ESRD enrollees and ESRD enrollees, and the MSA plan formula for 2006 and subsequent years.

Figure II-1. 2006 Payment for Non-ESRD Enrollees in Coordinated Care Plans or PFFS Plans (Payment System Formula Combining 3 Statutory Formulas)



2. Geographic Intra-Service Area Rate (ISAR) Adjustment: MA Rate as Basis of Adjustment. Under Section 1853(a)(1)(F) of the Social Security Act, payments to organizations must be adjusted "to take into account variations in MA local payment rates under this part among the different MA local areas" that are included in the service area, or segment, of the MA plan. As explained in the MA Final Rule, we are implementing this provision by providing for an adjustment of organization payments based on the variation among MA capitation rates in the counties of a MA plan's service area. According to the statutory formulas, this adjustment applies to the standardized A/B bid, in the case where the plan A/B bid is below the plan A/B benchmark, or to the standardized A/B benchmark, in the case where the plan A/B bid is at or above the plan A/B benchmark.

Plans with bids below benchmark. For both local and regional plans with plan A/B bids below the plan A/B benchmark, each plan-specific county rate equals the standardized A/B bid adjusted by the relationship between that county's MA capitation rate and the weighted average of all MA capitation rates for counties in the plan's service area, with each county MA rate weighted by the plan's projected enrollment in that county.

Plans with bids at or above benchmark. For local and regional plans with bids at or over the benchmark, the ISAR adjustment also results in a county-level payment rate for each county in the plan's service area. For a local plan serving a single county, the payment rate would be the county benchmark (i.e., the county MA capitation rate published by CMS, because no geographic adjustment is necessary). For multi-county local plans and for regional plans, each plan-specific county rate equals the standardized A/B benchmark adjusted by the relationship between that county's MA capitation rate and the weighted average of all MA capitation rates for counties in the plan's service area, with each county MA rate weighted by the plan's projected enrollment in that county.

Both bid-based and benchmark-based payments are further adjusted for the demographic and risk characteristics of the individual enrollee.

ISAR adjustment factors. The relationship (or ratio) of a county rate to the weighted average rate for the service area is expressed as an ISAR factor, such as .98 for county X, 1.12 for county Y, and .9 for county Z. The weighted average of all the county ISAR factors for a plan's service area must equal 1.0.

As discussed above in item (1), the MMA lays out three statutory formulas for plans with: (1) bids below benchmark; (2) bids equal to benchmark; and (3) bids above benchmark. See the diagram in Figure II-1, which rolls the three statutory formulas into a single formula, representing how the CMS payment system will actually process MA payments. The diagram is a bid-based depiction of payment.

For plans with bids above the benchmark, the statutory and payment system formulas are distinct but mathematically equivalent. This is because for bid-above-benchmark plans, the bid consists of two distinct payment streams: from CMS to the plan (monthly capitated payment based on the benchmark) and from the beneficiary to the plan (monthly basic premium payment).

Statutory formula for bid-over-benchmark plans:

> Standardized A/B benchmark, adjusted for enrollee risk plus a government premium adjustment amount.

Figure II-1 diagram (payment system) formula:

> Standardized A/B bid, adjusted for enrollee risk minus the standardized beneficiary premium

There are three basic steps to determine the ISAR-adjusted county rates for a plan, where the ISAR factors are based on the MA rates. (See below for a discussion of the alternative ISAR adjustment option for regional plans.) Because in 2006, payment will be based on a demographic rate book (25 %) and a risk rate book (75%), the steps outlined below would have to be done for each rate book to determine the risk adjusted and demographic components of payment. (The acronym SA, used below, is the plan service area.)

Step (a): Calculate the SA-level combined aged and disabled enrollment-weighted demographic rate using the published local MA rates. Calculate SA-level enrollment-weighted risk rate. The weights are the plan's projected enrollment in each county.

Step (b): Calculate county-level aged ISAR factor, county-level disabled ISAR factor, and county-level risk ISAR factor.

Step (c): From the perspective of the payment system formula (Figure II-1), calculate county-level aged ISAR-adjusted payment rate by multiplying the standardized A/B bid by the plan ISAR factor for the enrollee's county of residence. The same calculation of ISAR-adjusted county rates is done using disabled and risk ISAR factors.

Thus, for each county in the plan's service area, there will be a plan-specific county rate derived from the bid and the ISAR factor. For enrollees who are out of the service area, the base payment will be the 1.0 bid (with individual-level risk adjustment for demographic and health status factors).

Note that the rebate amount is not geographically or otherwise adjusted. It is a fixed amount determined through comparison of the plan A/B bid to the plan A/B benchmark based on the plan's projected enrollment.

Alternative ISAR Option for Regional Plans: Plan-Determined Adjustment Factors. A plan bid represents a statement of the average per member revenue that it needs to provide the Medicare A/B benefit. Particularly for regional plans covering a wide geographic area, underlying the single bid there could be significant variation in costs

across the geographic area that the organization is required to serve. If a plan's actual enrollment matches its enrollment projections—in terms of the proportion of beneficiaries coming from different counties—the ISAR adjustment has no effect on the average payment a plan will receive for its enrolled population (the total revenue received by the plan will match its bid). The purpose of the ISAR adjustment is to permit an adjustment to payments to compensate for any variation between the expected enrollment mix (by county) that formed the basis of a plan's bid, and the actual enrollment mix by county. By using the MA capitation rates as a basis for this adjustment, the presumption is that the variation in MA local rates among counties constitutes an accurate measure of the variation in plan revenue needs across different counties. That is, if, for example, one county has an MA rate that is twice that of another county, it is assumed that plan revenue needs for the former county are twice the plan's revenue needs for the latter county. The ISAR adjustment would pay an amount higher than the bid (which represents a multi-county average) in the former county, and a lower amount in the latter county.

In order to encourage the submission of regional MA plan bids, CMS will make available to MA organizations offering regional plans an alternative methodology for calculating the geographic ISAR adjustment. In the event that an MA organization believes that the variation in MA rates among the counties in the region covered by its regional plan is not an accurate reflection of the variation in its projected revenue needs in the region, the organization can request to have payments geographically adjusted at the county level using an organization-determined statement of the relative revenue needs for the provision of Medicare-covered services in the service area. We would review the organization-provided ISAR factors for reasonableness and actuarial soundness, as well as reviewing the enrollment projections (which are reviewed for all organizations, both those using the plan-specific ISAR factors and those using the MA rate-based factors for the geographic ISAR adjustment).

The MA organizations will be required to provide support for their plan-specific ISAR factors (such as the projected utilization and cost by service category for each county), with the understanding that we could ask for additional detail (for example, fee schedules) during bid negotiation or during an audit. The CMS reserves the right to ask for additional documentation of these plan-determined factors in order to assess their actuarial soundness. Approval of plan-determined factors will be contingent on the comprehensiveness, actuarial soundness, and reasonableness of the MA organization's cost, utilization and enrollment assumptions, and associated documentation. (We would note that this ISAR factor, like the MA rate-based ISAR factor, will result in a different average payment to the plan *only if* the actual enrollment mix differs from the projected mix that formed the basis of the plan bid.)

3. Risk adjustment of A/B payments. The county rates for the counties included in a local MA plan's service area will be adjusted for beneficiary health status using each individual enrollee's risk score to ensure that the MA organizations are paid appropriately based on the health status of their enrollees. For 2006, the CMS-HCC model will be applied at 75 percent risk adjusted payment, while the remaining 25 percent will be

calculated using a demographic payment. For more information on demographic and risk adjusted payments, please see the Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice Payment rates at http://www.cms.hhs.gov/healthplans/rates/. Also see Figure II-1 for a diagram showing how the individual enrollee's demographic and risk scores are applied in the payment formula. For more information on risk adjustment, please see Section F.

4. Government premium adjustment. Organizations with plan A/B bids above the plan A/B benchmark must charge a uniform basic beneficiary premium. Because beneficiary premiums are not adjusted for individual health status, organizations with bids above the benchmark will be subject to an additional adjustment to their payments pursuant to Section 1854(a)(6)(B). This adjustment, which we are calling the government premium adjustment, will adjust an organization's payment upward or downward to ensure that the organization's revenue needs are met, with regard to that portion of their payment coming from the basic premium, regardless of whether the plan enrolls more or less healthy beneficiaries. Organizations with bids at or below the benchmark do not charge a basic premium, and therefore are not subject to this adjustment.

Conceptually, this adjustment is the difference between the risk adjusted beneficiary basic premium and the beneficiary basic premium actually paid by enrollees, which is based on a 1.0 beneficiary. This incremental payment is ISAR-adjusted to reflect differences between projected and actual enrollment. Note that the government premium adjustment is called the "adjustment relating to risk adjustment" in Section 1853(a)(1)(G) of the Act.

Section C. ESRD and hospice enrollees, MSA plan payments, and other policies.

1. A/B payments for ESRD enrollees. In 2006, we will pay for ESRD enrollees using the same methodology as in 2005 because ESRD enrollee costs are not included in the plan A/B bid. For enrollees on dialysis and in transplant status, we pay the State capitation rate, adjusted by the enrollee risk score. For functioning graft enrollees, we pay the county rate, adjusted by the enrollee risk score. To the extent that the plan provides for a reduction in the Part B premium, the amount of the reduction would be netted from the adjusted rate.

2. Payments for enrollees electing hospice. Prior to the MMA, no payment was made to an MA organization on behalf of a Medicare enrollee who had elected hospice care except for the portion of the payment applicable to additional benefits. Effective 2006, the MA organization will be paid the portion of the payment attributable to the beneficiary rebate for the MA organization (minus the Part B premium reduction amount, if any) plus the amount of the subsidies related to basic prescription drug coverage for organizations that offer prescription drug coverage.

When a beneficiary enrolled in an MA organization elects hospice, that beneficiary is still an enrollee in the plan, and is still liable for any plan premiums and cost sharing for

benefits not covered under the hospice benefit. It is possible that an enrollee who has elected hospice will need prescription drugs for conditions not related to hospice care, which will be the organization's responsibility (to the extent that they are covered under Part D or under the plan). We believe that it is appropriate for Medicare Advantage Prescription Drug (MA-PD) organizations to manage the prescription drug coverage of enrollees who have elected hospice, and therefore CMS will pay MA-PD organizations the Part D premium for all enrollees.

For Program of All-inclusive Care for the Elderly (PACE) organizations, PACE enrollees must elect either their PACE organization or the hospice benefit as their provider of Medicare services. An enrollee who elects to enroll in hospice is thereby disenrolled from the PACE benefit. However, PACE organizations provide a service similar to hospice known as "end-of-life-care."

3. Payment Method for MSA plans. A Medicare MSA plan combines a high-deductible insurance policy with a MSA for health care expenses. The maximum annual MSA plan deductible is set by law. The Medicare program pays premiums for the high deductible insurance policies and makes a contribution to the beneficiaries' MSAs. The beneficiaries use the money in their MSAs to pay for their health care before the high deductible is reached. Once the deductible is met, the MA organization offering the MSA plan is responsible for payment of 100 percent of the expenses related to covered services. In both cases, whether it is the enrollee or the MSA that assumes responsibility for payment, providers and other entities are required to accept the amount that the Medicare FFS would have paid as payment in full.

The MMA did not amend Section 1853(e)(1), which governs the calculation of the CMS deposit into an enrollee's MSA. However, we have interpreted the existing language referencing capitation rates "applied under this section for the area" as incorporating the new MMA bidding and payment methodology that now applies to MA plans under section 1853. An MSA organization offering an MSA plan will submit the "MSA premium" for benefits under original Medicare, called the MSA plan A/B bid in this Advance Notice. The MSA plan may include optional supplemental benefits, and the MA organization would submit a bid amount for these supplemental benefits. The MSA premium (MSA plan A/B bid) reflects the expected risk profile of plan enrollees, so in this sense is risk adjusted at the plan level. (The requirement at Section 1854(a)(6)(A) that MA organizations submit a standardized A/B bid does not apply to MSA plans.)

The MA organization offering an MSA plan also will submit an expected plan average risk score. The plan A/B benchmark is then calculated using the same formula as for other local MA organizations: the plan-level risk score is multiplied by the standardized A/B benchmark. For 2006, the transition blend would also apply to MSA plan benchmarks. A blended standardized A/B benchmark reflecting the 25% demographic rates/75% risk rates transition blend will be calculated in same manner as the blended standardized A/B benchmark is calculated in the bid pricing tool for CCP and PFFS plans (see Section A, item 4).

MSA enrollee deposit and payment to plan. The deposit into each MSA enrollee's account is calculated at the service area or service area segment level as the plan A/B benchmark minus the plan A/B bid. The deposit is uniform for each enrollee in the service area or service area segment. The payment to an MSA plan for an MSA plan enrollee is determined according to the following formula: the standardized A/B benchmark, adjusted by the enrollee's risk factor, minus the MSA deposit. Thus, while the MSA deposit is uniform, the monthly payments that CMS will make to the MSA plans will vary based on the risk characteristics of the enrollee. The ISAR adjustment does not apply to MSA plans. The transition payment blend discussed below in Section F- Changes to the Risk Adjustment Method for MA Organizations also applies to MSAs.

4. Payment Method for Religious Fraternal Benefit Society (RFB) Plans. The RFB plans will be paid as provided for in the MMA. An RFB society may offer any type of MA plan (CCP, PFFS, or MSA plan), and the appropriate payment rules for that type of plan will apply.

Under Section 1859(e)(4), CMS is required to adjust MA payment rates to RFB plans to appropriate levels, taking into account "the actuarial characteristics and experience" of RFB enrollees. This provision pre-dates implementation of risk adjustment by CMS. In 2006, we will be using the third generation risk adjustment model and we intend to adjust payments to RFBs to account for the actuarial characteristics of their enrollees using this model (known as the CMS-HCC risk adjustment model). We believe that our risk adjustment model will appropriately adjust payments to RFB societies for the characteristics of their RFB plan enrollees. The CMS-HCC model was outlined in the Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates (http://www.cms.hhs.gov/healthplans/rates/2004/45day.pdf) and updates to the model are discussed in Section F of this notice.

Table II-1 below summarizes payment formulas for coordinated care plans, private fee-for-service plans, and medical savings account plans.

Table II-1. Payment Formulas for MA Plans

Payments for Non-ESRD Enrollees of Coordinated Care Plans and Private Fee-for-Service Plans

Step 1: Determine demographic payment component.
[("1.0" demographic bid multiplied by the plan's ISAR factor for enrollee county of residence based on demographic MA rates) multiplied by the enrollee demographic factor] multiplied by the transition blend of .25

Step 2. Determine risk payment component.
[("1.0" risk bid multiplied by the plan ISAR factor for enrollee county of residence based on risk MA rates) multiplied by the enrollee risk factor] multiplied by the transition blend of .75

Step 3. Sum demographic and risk payment components to get total adjusted plan A/B bid-based payment.

Step 4. Subtract monthly basic beneficiary A/B premium (if any).

Step 5. Add rebate, net of Part B premium reduction amount (if any)

Note: The rebate amount results from the savings calculation and thus reflects plan average projected risk. It is a uniform amount for all enrollees and is not adjusted for individual risk. The rebate is not ISAR-adjusted.

Payments for ESRD Enrollees of Coordinated Care Plans and Private Fee-for-Service Plans

Dialysis and Transplant Status: (State capitation rate multiplied by the enrollee risk score from ESRD CMS-HCC model) less Part B premium reduction amount (if any)

Functioning Graft Status: (county capitation rate multiplied by the enrollee risk score from ESRD CMS-HCC model) less Part B premium reduction amount (if any)

Payment for All Enrollees of Medical Savings Account Plans

Step 1 Determine lump sum annual deposit (CMS payment to enrollee MSA).
[(Blended standardized A/B benchmark multiplied by the plan projected average risk score) less MSA plan A/B bid for plan's projected enrollee mix] multiplied by 12 (to annualize)

Step 2. Determine CMS monthly payment
(a) Calculate demographic payment amount: [1.0 A/B demographic benchmark * enrollee demographic factor * .25]

(b) Calculate risk payment amount: [1.0 A/B risk benchmark * enrollee risk factor * .75]

(c) Sum demographic and risk payment amounts, and subtract monthly deposit.

Note: the geographic ISAR adjustment does not apply to MSA plan payments.

5. Changes to Payment Adjustment for the Effect of National Coverage Determinations. Section 1853(c)(7) of the Act requires us to "adjust" MA payments when a national coverage determination (NCD) or legislative change in benefits will result in a significant increase in costs to MA organizations sponsoring MA organizations. We historically interpreted what constituted "significant" costs at 42 CFR Section 422.109, where the costs of a coverage change are considered "significant" if either the average cost of providing the service exceeds a specified threshold, or the total cost for providing the service exceeds an aggregate cost threshold.

In CMS-4041-F, published August 22, 2003, we amended Section 422.109 to refine the definition of "significant" cost to include a new test. By adding a new paragraph at the end of Section 422.109(a)(2), we provided that, for purposes of determining whether to make an additional payment adjustment under Section 422.256, the tests for reaching the "significant" cost threshold were to include the aggregate costs of all NCDs and legislative changes in benefits made in the prior calendar year.

Under that new test, the "average cost" of every NCD and legislative change in benefits for the contract year would have been added together. If the sum of these average amounts exceeded the threshold under Section 422.109(a)(l), then an adjustment to payment would have been made in the following contract year under Section 422.256 to reflect this "significant" cost. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceeded the level set forth in Section 422.109(a)(2), an adjustment to payment would also have been made under Section 422.256 on that basis.

Among the reasons for the above change was that even when the "significant" cost threshold had been met under the existing definition, the methodology then employed for making a payment adjustment under Section 1853(c)(7) of the Act did not result in an adjustment in the capitation rate in those counties with the "minimum" update rate (the "2 percent minimum update" counties paid under Section 1853(c)(l)(C) of the Act.) In accordance with Section 1853(c) of the Act, the CMS' OACT used the annual growth rate to update only the floor and blended rates, so the "minimum" 2 percent update rate, which was 102 percent of the prior year's rate, did not reflect the costs of new benefits effective in the middle of the previous payment year. Therefore, we decided that payments in counties in which payment was based on the "minimum" 2 percent update rate were not appropriately adjusted to reflect new coverage costs as required by Section 1853(c)(7) of the Act.

This rationale for 2003 changes to Section 422.109 no longer applies, however, in light of changes to the MA payment methodology made in the MMA. Because the new "minimum" percentage increase is now the higher of 2% or the Medicare growth percentage, the costs of mid-year NCDs will be reflected in payment rates. We therefore have revised Section 422.109 to delete the revisions made in the August 22, 2003 final rule. NCDs for 2005 and 2006 accordingly will be subject to the pre-August 22, 2003 "significant cost" test.

Section D: Regional Plan Bonus Payments and Risk Sharing Payments

1. Regional Plan Stabilization Fund. The MMA provides that expenditures from the Stabilization fund will not be available until January 1, 2007. Therefore, we will not be making payments to organizations from the stabilization funds in 2006, or discussing the process for doing so in this notice.

2. Risk Sharing and Risk Corridors for Regional MA Plans. Section 1858(c) of the Social Security Act provides for risk sharing to be in effect for regional MA plans 2006 and 2007, if plan costs are above or below specific risk corridors. The risk corridors are symmetrical in that, beyond the initial corridor, the government pays organizations if plan costs are above the target and recoups its share of the savings when plan costs are below the target. Following are the steps involved in calculating risk corridor payments for MA regional plans.

Calculate the target ratio. The following are the key elements used to determine the risk sharing target ratio for a regional MA plan. Please note that the values are expressed on a per-member, per-month (PMPM) basis:

- Projected allowed medical expense is equal to the projected medical expense in the plan A/B bid for benefits covered under original Medicare, plus the medical component of rebatable integrated benefits. Rebatable integrated benefits are non-drug supplemental benefits that are funded through beneficiary rebates and are used for (i) additional medical benefits not covered under the original Medicare program option; and (ii) benefits that require expenditures by the plan (e.g., cost sharing reductions for A/B benefits).

- Projected allowed revenue is equal to the projected allowed medical expense plus projected non-medical expense and gain/loss margin included in (i) basic plan bid, and (ii) rebatable integrated benefits.

The risk sharing target ratio is calculated as the projected allowed medical expense divided by the projected allowed revenue.

The risk sharing target amount is: actual allowed revenue multiplied by the risk sharing target ratio.

- The actual covered revenue equals the net government capitation payments (including capitation payments, rebates allocated to buy-down supplemental A/B benefits, and government premium adjustment) plus basic enrollee premium revenue.

- The basic enrollee premium revenue represents premiums billed and does not include an offset for uncollected premiums.

As an attachment to the MA bid submission, an MA organization offering a regional plan must include description of the methodology that will be used to develop actual revenue and medical expense to be included in risk sharing reconciliation. Specifically, the organization must provide a description of adjustments that will be made to the plan's medical costs reported in the general ledger to account for (i) any differences in the level of cost sharing reflected in the risk sharing target and that required of plan enrollees; and (ii) the methodology to be used to capture expenditures for non-covered services that are implicitly included in the risk sharing target.

Calculate associated risk corridor limits. The first threshold upper limit is 103 percent of the target amount and the second threshold upper limit is 108 percent of the target amount. Similarly, the first threshold lower limit is 97 percent of the target amount and the second threshold lower limit is 92 percent of the target amount.

Calculate allowed risk corridor costs. The MA organizations will report to CMS the actual allowed revenue and medical expense for the regional plan that were incurred during the contract year and processed within 12 months after the end of the contract year. For example, any medical expenses incurred during 2006 and paid by December 31, 2007 will be reported as an actual incurred claim. Allowed medical expense will reflect reimbursements received, or expected to be received, by the plan under coordination of benefits, subrogation, reinsurance, Part B Rx rebates, or other sources. Further, excluded from medical expenses will be expenditures for case management and disease management services that are not considered to be an enrollee "encounter."

The calculation of the actual plan revenue and medical expense will be verified by an independent auditor, paid for by the plan.

Determine where actual allowed medical expenses are relative to thresholds; calculate payment adjustment. If actual allowed medical expenses fall within 3 percent of the target amount (above or below it), there is no risk sharing of additional cost or "savings." If actual allowed medical expenses are more than 3 percent outside the risk sharing target (above or below it), costs or savings will be shared in accordance with the following provisions:

- Actual allowed medical expense greater than 103 percent of target amount and less than or equal to 108 percent of target amount: CMS pays the MA organization 50 percent of the difference between actual allowed medical expense and 103 percent of target amount.

- Actual allowed medical expense greater than 108 percent of target amount: CMS pays the MA organization 2.5 percent of target amount plus 80 percent of the difference between actual allowed medical expense and 108 percent of target amount.

- Actual allowed medical expenses less than 97 percent of the target amount and greater than or equal to 92 percent of the target amount: CMS applies a negative

adjustment to the plan payment of 50 percent of the difference between 97 percent of target amount and actual allowed medical expense.

- Actual allowed medical expenses less than 92 percent of target amount: CMS applies a negative adjustment to the plan payment of 2.5 percent of target amount plus 80 percent of difference between 92 percent of target amount and actual allowed medical expense.

Section E. Submission of Bids by Demonstration Plans

In 2006, the Social/HMO (S/HMO) demonstration plans will submit bids for original Medicare A/B benefits, mandatory supplemental, prescription drug, and other benefits. The Wisconsin Partnership (WPP), Minnesota Senior Health Options and Minnesota Disability Health Options (MSHO/MnDHO) and Massachusetts Senior Care Options (SCO) demonstrations will submit bids only for Medicare-covered benefits. Medicaid covered benefits, including payment of Medicare cost-sharing, are not to be included in their bids.

Section F. Changes to the Risk Adjustment Method for MA Organizations

1. Update of the CMS-HCC risk adjustment model. The year 2006 will occasion the first major update and recalibration of the CMS-HCC model. (HCC refers to Hierarchical Condition Categories.) The model for Medicare Part C payment is being updated to reflect newer treatment and coding patterns in FFS, to use the additional codes being collected for the Part D model and to accommodate additional codes that complete an HCC or a hierarchy of disease groups. Many ICD-9-CM codes that were not recognized for payment in the first CMS-HCC model are needed for the new Medicare Part D drug risk adjustment model being implemented in 2006. As these codes will be submitted for Part D, they will also be used to enhance the model used to risk adjust the Part A and B benefits. A tentative list of additional codes to be submitted was published in May 2004. Most of the additional codes were included because they appeared to be significant in the drug model; other codes were added because they completed an almost complete HCC, or completed a hierarchy of disease groups.

The updated model will include additional disease categories to the CMS-HCC model. The same evaluation criteria that have been used in the past to determine a group's inclusion in the model will be used again, e.g., magnitude of costs predicted, relative lack of ambiguity of the ICD-9 codes, position in a hierarchy of diseases, etc. All segments of the risk adjustment system will be updated (the community, long-term institutional and ESRD segments). For this notice we are providing the new disease groupings and draft coefficients for the community model and the disease hierarchies (see Tables II-4 and II-5 at the end of Attachment II). Disease groupings will be the same across the community, long-term institutional and ESRD segments. The final coefficients for each of the segments will be provided in the Announcement of CY 2006 MA Payment Rates.

There will be some modification of the mappings of codes. For example, among the codes for neuropathy and retinopathy, the specific codes for diabetic neuropathy and diabetic retinopathy will be mapped directly or solely to the appropriate diabetes groups indicating diabetes with neurological or ophthalmologic manifestations. The other neurological and ophthalmologic codes will remain mapped to the neuropathy and retinopathy groups.

Calibration of the long-term institutionalized (LTI) segment of the model will be done with a larger sample than was used for the initial model. All persons in LTI status in the prediction year who otherwise meet the criteria for inclusion in risk adjustment modeling will be used for calibration. The effect of this work will be to refine the coefficients and better differentiate the costliness of the beneficiaries. Changes in predicted costs relative to the community population on average are not expected to result because of the larger sample.

As part of the model update, data from the years 2002 – 2003 will be used in the calibration. As the data are more current than the 1999 – 2000 data used for the initial model, the new model coefficients will reflect newer treatment and coding patterns in FFS Medicare. In association with the calibration on newer coding patterns, the FFS normalization factor, used to correct for population and coding changes between the data-year used in model calibration and data-year(s) used in implementation of the model for payment, will change. The FFS normalization factor is expected to be smaller than the 5% used in 2004 and 2005 because there will be fewer years between calibration and implementation and because the increase has been getting smaller.

We are proposing a change in how the risk adjustment methodology treats "working aged" enrollees, for whom Medicare is the secondary payer. This change would be reflected in the new model. Medicare secondary payer (MSP) status would no longer be an independent payment adjuster. Therefore all beneficiaries, regardless of MSP status will be merged in the model calibration. This will hold for all model segments including ESRD.

Due to the changes in the risk adjustment model as described above, county payment rates will be restandardized to reflect new average county risk score in the FFS sector. The Office of the Actuary intends to restandardize prior local county rates and then recalculate rates for 2004 using the payment formulas set in the MMA. OACT will then project forward to get the 2006 rates using the formula changes specified in the MMA and the latest growth trends for the intervening years.

2. Transition Payment Blends. Risk adjusted payment is being phased in for MA plan payments, including Special Needs Plans (SNPs), from 2004-2007. In 2006 the CMS-HCC model for MA plans will be applied at 75 percent risk adjusted payment, with the remaining 25 percent being a demographic payment. For the S/HMO, MSHO/MnDHO, WPP and SCO demonstrations, the CMS-HCC model with a supplemental frailty adjuster will be applied in 2006 at 50 percent risk adjusted payment, with the remaining 50

percent being based on the 2003 payment methodology for these demonstrations, respectively. For PACE organizations, the CMS-HCC model with a supplemental frailty adjuster will be applied in 2006 at 50 percent risk adjusted payment, with the remaining 50 percent being based on the 2003 PACE payment methodology.

3. Changes to Frailty Factors for PACE and Certain Demonstrations. Since January 2004, CMS has applied a Medicare payment approach known as frailty adjustment to the PACE and certain demonstrations. The frailty adjuster was developed as a further refinement to risk adjustment to ensure that capitated payments to organizations that serve frail community-based populations were accurate.

The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that were unexplained by risk adjustment. The frailty factors were originally estimated using the Medicare Current Beneficiary Survey (MCBS) cost and use files for 1994 through 1997. Individuals were grouped according to their difficulty with Activities of Daily Living (ADLs). Their Medicare payments were predicted by the CMS-HCC model, and the difference between actual expenditures and predicted payments (i.e., "residual expenditures") was determined. The frailty factors were derived based on the residual expenditures for each ADL group (0 ADLs, 1-2 ADLs, 3-4 ADLs, and 5-6 ADLs).

As explained previously in this Notice, CMS is modifying the CMS-HCC risk adjustment model for 2006 payment. The modifications are significant enough so that the predicted payments for frail community-based populations under the revised CMS-HCC model may (on average) differ from the predicted payments under the original model. Since the frailty adjuster is applied in conjunction with risk adjustment, the frailty factors must be consistent with the revised risk adjustment model. Thus, CMS intends to recalculate the frailty factors.

We will re-estimate the frailty factors using the MCBS files for 1994 through 1997. The new frailty factors will be published in the Announcement of the 2006 Medicare Advantage Payment Rates.

4. Medicare as a Secondary Payer for Risk Adjustment in 2006. The CMS standard system for the identification of Medicare as a Secondary Payer (MSP) has been the Common Working File (CWF). Information on MSP was obtained from three primary sources, the initial Medicare enrollment process, an Internal Revenue Service Data/SSA/CMS data match and voluntary MSP data match agreements. At the present time, MSP information is complied and maintained by a Coordination of Benefits Contractor (COBC), supported by input from Fiscal Intermediaries (FIs) and carriers. The COBC submits information to the CWF.

Historically, MA organizations have questioned CMS as to the reliability of determination of Medicare as a Secondary Payer (MSP) status. In response to complaints by the MA industry about the accuracy of this MSP data, CMS changed its determination of Working Aged for MA organizations from an individual level determination based on

the CWF flag to an organization level determination based on an annual survey conducted by the MA organizations of enrollees in their organization. Working Aged status, which is a subset of MSP, refers to those Medicare enrollees over age 65 with employer group health coverage (either through their own or spousal employment). Currently each MA organization surveys all its aged members annually and reports to CMS those with coverage primary to Medicare. This survey does not include disabled members (under age 65) or enrollees with ESRD. The status of aged enrollees who do not respond to the survey (non-responders) is still determined by the CWF flag. The CMS then calculates the proportion of each MA organization's enrollment that is Working Aged and makes an organization level payment adjustment to the organization's monthly capitated payment. To date, there has been no determination as to the reliability of this survey.

A number to changes have occurred that caused CMS to review how MSP is treated under risk adjustment, particularly the inclusion of ESRD under risk adjusted payment. The ESRD model was calibrated assuming that the payment system would identify MSP at the individual level using our standard systems. However, the current survey for identification of MSP in MA organizations does not include ESRD enrollees. The use of the CWF was judged to be in conflict with our current survey approach for identification of MA enrollees for whom Medicare is a secondary payer. Given that the ESRD payment rates are very high, that the Medicare ESRD population is primarily under age 65, and that a substantial proportion of ESRD enrollees have health insurance coverage that is primary to Medicare, this is a major issue in implementing correct payments for ESRD enrollees. Having considered the data reliability issues surrounding MSP, the impact of MSP determination on ESRD payments, and the burden of MSP survey, audits and reconciliations, CMS has recalibrated the Part C risk adjustment models (CMS-HCC and ESRD) for 2006 to include the costs associated with beneficiaries for whom Medicare is a Secondary Payer (MSP). This means that on average risk scores would be appropriately adjusted for MSP and that no further adjustment would be necessary.

5. Reporting of Medicaid Status for Demographic Payment and Part C Risk Adjusted Payment. In implementing Part C payment under the demographic payment and risk adjustment methods, CMS will use a definition of Medicaid status that promotes consistency across Part C and Part D. To implement Part D, CMS will be collecting comprehensive information on Medicare/Medicaid dual enrollment. We will use this information on Medicare/Medicaid dual enrollment to define Medicaid status under Part C for demographic and risk adjustment payments.

We propose assigning Medicaid status for demographic payment and risk adjustment under Part C to low-income-subsidy (LIS) individuals who are "deemed" under Part D. In practice, the new MMA Medicare/Medicaid Dual Eligible monthly submission file, provided to CMS from the States, will be the source of the "deemed" LIS indicator for Part D. This file, which all States are required to submit under the provisions of the MMA, provides monthly identification of each actively enrolled Medicare/Medicare dual eligible beneficiary. This includes those eligible for comprehensive Medicare and Medicaid benefits (whether eligible through the state plan or a section 1115

demonstration), as well as those for whom the State pays Medicare cost sharing (Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, and Qualifying Individuals).

The categories of dual eligibles identified on the file are listed in TableII-2. The categories of dual eligibles "deemed" eligible for the low income subsidy (LIS) under the Part D benefit include categories 1-4, 6, and 8 in Table II-2 below. These categories will be defined as Medicaid for Part C risk adjustment. The MMA Medicaid file includes a person month record for each Medicare/Medicaid dual eligible in the state Medicaid program in the reporting month, and records to report information on changes in the circumstances for individuals in a prior month.

Submission of state Medicare/Medicaid enrollment test files commences in March 2005 and production files are due to CMS each month beginning in June 2005. These files will be the source of reporting of Medicaid status for implementation of the low income subsidy provisions of Part D program. For prospective 2006 risk adjusted payments, we will use the current methodology. However, beginning in January of 2006, these files will be used as the sole source of Medicaid status for all Part C demographic payment and risk adjustment purposes, including reconciliations and payment adjustments. After January 2006, plan reported Medicaid will no longer be accepted as a source of the Medicaid indicator for payment under the demographic model or for Part C risk adjustment.

Table II-2. Categories of Dual Eligibles Identified on the Monthly Submission File

MEDICARE/MEDICAID DUAL STATUS CODE	01 = Eligible is entitled to Medicare- QMB only 02 = Eligible is entitled to Medicare- QMB AND Medicaid coverage including RX **(Medicaid drug coverage criterion only applies through December 2005)** 03 = Eligible is entitled to Medicare- SLMB only 04 = Eligible is entitled to Medicare- SLMB AND Medicaid coverage including RX (Medicaid drug coverage criterion only applies through December 2005) 05 = Eligible is entitled to Medicare- QDWI 06 = Eligible is entitled to Medicare- Qualifying individuals 08 = Eligible is entitled to Medicare- Other Full Dual Eligibles (Non QMB, SLMB,QWDI or QI)with Medicaid coverage including RX **(Medicaid drug coverage criterion only applies through December 2005)** 09 = Eligible is entitled to Medicare – Other Dual Eligibles but without Medicaid coverage, includes Pharmacy Plus and 1115 drug-only demonstration. If unknown = 99.

6. Elimination of Diagnostic Radiology Data from the Physician Specialty Type. The CMS has allowed the submission of diagnostic radiology data as a physician specialty type under the CMS-HCC payment methodology. In early 2004, CMS conducted a CMS-HCC validation pilot study to understand the extent to which payment inaccuracies could be identified when reviewing medical records from physician office settings. One key finding of the pilot study was that medical record documentation from ambulatory diagnostic radiology settings did not often provide sufficient information to confirm an ICD-9-CM code during data validation. That is, the diagnostic radiology medical record could not be used as a stand alone document (without additional follow-up information from the referring physician) to support a diagnosis. As a result of this finding, we are proposing to eliminate the radiology specialty as an acceptable risk adjustment physician provider type for payment year 2006 (dates of service: January 1 through December 31, 2005). This decision applies only to diagnostic radiology and does not impact other radiology codes (e.g. interventional radiology codes).

Section G. Budget Neutral Risk Adjustment in Payments for Local and Regional MA Organizations

There are three changes in budget neutrality for 2006, and the details on each change are discussed below:

- a change in the budget neutrality calculation to account for different payment methodologies for local MA plans versus regional MA plans;
- a phase out of budget neutrality; and
- changes in the technical adjustments we make to the budget neutrality calculation.

1. Change to account for different payment methodologies for local MA plans versus regional MA plans. Beginning in 2003, CMS has implemented risk adjusted payments in a budget neutral manner. Since that time, the budget neutrality amount has been calculated as the difference between payments to organizations at 100 percent of the demographic rate and payments at 100 percent of the risk adjusted rate. This amount was then incorporated into the rescaling factor, which redistributed payment reductions due to risk adjusted payments. This calculation used county rates, either demographic or risk, as the basis for the calculation.

Because of the difference in payment methods for local MA plans versus regional MA plans beginning in 2006, CMS will need to modify the budget neutrality calculation. Budget neutrality for 2006 will be calculated as the difference between aggregate MA payments at the local MA benchmark rate that would have been made using the demographic method for 100 percent of payments versus the aggregate payments that would be made using 100 percent of risk adjusted payments. Budget neutrality will be applied to both local and regional MA plans. For regional plans, this means that the budget neutrality factor will be applied to the statutory component of the benchmark.

2. Phase Out of Budget Neutrality. Consistent with the President's FY2006 Budget, CMS is proposing to implement a phase out of risk adjustment budget neutrality, with a transition through 2010. In order for competition to work in the long run, bidding and payment must take into account risk selection. Moreover, beginning in 2006 organizations will be paid separately for the Part D drug benefit, so organizations will be receiving direct payments for benefits (i.e., drugs) that they were previously providing as supplemental benefits

The phase out schedule is shown in Table II-3. Under the budget neutrality methodology this means that in 2006, 100% of the difference between payment under the demographic method and payment under risk adjustment will be added back to the risk payment rates via a rescaling factor. However, due to the payment blend for 2006 this will result in 75% of the budget neutrality amount being added back to the blended benchmark. In 2007, we will reduce the amount added back into the risk adjusted rates to 60% of the difference between payment under the demographic method and payment under risk adjustment and continue to reduce the percentage in accordance with the Table II-3 below until it reaches 0% in 2011.

Table II-3. Phase-Out Schedule for Budget Neutral Risk Adjustment Payments

Year	Budget Neutrality Percentage
2006	100% [1/]
2007	60%
2008	45%
2009	30%
2010	15%
2011	0%

[1/] 100% of the difference between payment under the demographic method and the payment under the risk adjusted method will be added to the risk adjusted payment rates. However, due to the payment blend for 2006 of 25% demographic and 75% risk adjustment, the net effect is a 75% budget neutrality adjustment.

The MA organizations will see payments that reflect this budget neutral approach in the beneficiary-level amounts that are shown on the Monthly Membership Reports (MMR.), beginning in January 2006. The reports for January 2006 will be available for downloading in late December 2005.

3. Technical Adjustments Applied to the Budget Neutrality Calculation. In 2005, CMS adjusted the budget neutrality calculation to consider the effects of lagged data, changes in organization enrollment during the year, and late data risk adjustment submission. Slight modifications in the methods used to make those three adjustments will be implemented for 2006 because of experience in implementing the CMS-HCC model, as well as differences in the amount of data available for making these estimates.

For 2005, we estimated budget neutrality based on non-lagged risk adjustment data (non-lagged risk adjustment data are defined as diagnoses collected for the calendar year immediately preceding the payment year). Using non-lagged risk scores for the estimation of budget neutrality was helpful because final payment for the payment year is

based on non-lagged risk adjustment factors and this procedure eliminated the need to estimate the effect of using lagged data for budget neutrality calculations. We intend to adopt the same approach for 2006. We will base the estimation of 2006 budget neutrality on a July 2004 cohort which represents the average organization enrollment for 2004. The risk scores used to calculate payment will be based on complete calendar year 2003 risk adjustment data updated through December 2004. This procedure should ensure that both the demographic information and the risk scores used in the calculation of budget neutrality are as accurate as possible.

In previous years, budget neutrality was estimated on a cohort of organization enrollees for a given month – e.g. for 2005 budget neutrality we used the January 2004 cohort. Because of changes in organization enrollment throughout the year, the average organization risk score for an organization's cohort typically occurs in the middle of the year (i.e., in July rather than in January). To account for this in 2005 we used a prediction model to estimate the effect of the change in average organization risk score through the mid point of the year. We then adjusted January risk scores on which 2005 budget neutrality was based by a factor which accounted for the decrease in average organization risk score. For 2006, we propose instead using the July 2004 cohort to estimate budget neutrality. Because July risk scores represent average organization risk scores for the calendar year, we propose not making any other adjustment for changes in organization enrollment in estimating budget neutrality for 2006.

Organizations continue to submit data for up to 17 months after the end of a data collection period for a payment year. This additional data submission typically increases risk scores, which, in turn, increases risk payments and decreases the budget neutrality estimate. In 2005, to account for these late data, we estimated a late data adjustment factor. For 2006, we propose not making any adjustment to take into account late data submissions. As stated above, we will use data for calendar year 2003 submitted through December 2004 in our budget neutrality calculations. This 12 month run-out of data past the end of the data collection year should ensure that our budget neutrality estimate accounts for most of the effects of late data submission.

In addition, because the average risk score of enrollees in regional PPOs is expected to be different from the average risk of beneficiaries who enroll in local MA organizations, we will make adjustments to the average risk of enrollees in our calculation. We expect to adjust the budget neutrality factor for the expected enrollment and risk scores of regional MA organizations as reflected in the FY2006 President's baseline budget.

Table II-4. Draft Community Annual Coefficients for the 2006 CMS-HCC Model with Constraints And Demographic/Disease Interactions, used in Calculation of Monthly MA Payments[1]

Note: For this notice we are providing the new disease groupings and draft coefficients for the community model and the disease hierarchies. Disease groupings will be the same across the community, long-term institutional and ESRD segments. The final coefficients for each of the segments will be provided in the Announcement of CY 2006 MA Payment Rates.

Variable	Disease Group	Community Estimate[2]	Constraint[7]
Female			
0-34 Years		600	
35-44 Years		600	
45-54 Years		900	
55-59 Years		1,400	
60-64 Years		1,800	
65-69 Years		1,400	
70-74 Years		1,800	
75-79 Years		2,300	
80-84 Years		2,700	
85-89 Years		3,200	
90-94 Years		4,200	
95 Years or Over		4,200	
Male			
0-34 Years		300	
35-44 Years		600	
45-54 Years		700	
55-59 Years		1,200	
60-64 Years		1,700	
65-69 Years		1,500	
70-74 Years		2,000	
75-79 Years		2,600	
80-84 Years		3,200	
85-89 Years		3,900	
90-94 Years		4,500	
95 Years or Over		5,400	
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Disabled		1,300	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
Medicaid_Female_Aged		1,100	
Medicaid_Male_Disabled		800	
Medicaid_Male_Aged		1,400	
Originally Disabled_Female		1,400	
Originally Disabled_Male		1,100	
Disease Coefficients			
HCC1	HIV/AIDS	5,400	
HCC2	Septicemia/Shock	4,500	
HCC3	Central Nervous System Infection	1,200	
HCC5	Opportunistic Infections	2,400	
HCC7	Metastatic Cancer and Acute Leukemia	9,100	
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	9,100	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	4,200	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	1,200	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation[3]	3,100	
HCC16	Diabetes with Neurologic or Other Specified Manifestation[3]	2,100	
HCC17	Diabetes with Acute Complications[3]	1,200	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation[3]	1,200	
HCC19	Diabetes without Complication[3]	500	
HCC20	Type I Diabetes Mellitus	1,500	
HCC21	Protein-Calorie Malnutrition	3,900	
HCC22	Other Significant Endocrine and Metabolic Disorders	1,000	
HCC25	End-Stage Liver Disease	5,100	
HCC26	Cirrhosis of Liver	2,800	
HCC27	Chronic Hepatitis	1,400	
HCC31	Intestinal Obstruction/Perforation	2,200	
HCC32	Pancreatic Disease	1,800	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
HCC33	Inflammatory Bowel Disease	1,500	
HCC34	Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders	1,100	
HCC37	Bone/Joint/Muscle Infections/Necrosis	3,300	
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	1,800	
HCC44	Severe Hematological Disorders	6,000	
HCC45	Disorders of Immunity	4,400	
HCC46	Coagulation Defects and Other Specified Hematological Disorders	1,000	
HCC48	Delirium and Encephalopathy	2,000	
HCC49	Dementia/Cerebral Degeneration	1,600	
HCC51	Drug/Alcohol Psychosis	700	
HCC52	Drug/Alcohol Dependence	700	
HCC54	Schizophrenia	3,200	
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	2,000	
HCC56	Reactive and Unspecified Psychosis	1,200	
HCC57	Personality Disorders	1,200	
HCC58	Depression	1,200	
HCC59	Anxiety Disorders	500	
HCC67	Quadriplegia, Other Extensive Paralysis	6,200	
HCC68	Paraplegia	5,600	
HCC69	Spinal Cord Disorders/Injuries	2,700	C1
HCC70	Cerebral Palsy and Muscular Dystrophy	700	
HCC71	Polyneuropathy	1,700	
HCC72	Multiple Sclerosis	2,600	
HCC73	Parkinson's and Huntington's Diseases	2,800	
HCC74	Seizure Disorders and Convulsions	1,200	
HCC75	Coma, Brain Compression/Anoxic Damage	2,200	C2
HCC77	Respirator Dependence/Tracheostomy Status	12,200	
HCC78	Respiratory Arrest	7,900	
HCC79	Cardio-Respiratory Failure and Shock	3,300	
HCC80	Congestive Heart Failure	2,000	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
HCC81	Acute Myocardial Infarction	1,800	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	1,800	
HCC83	Angina Pectoris/Old Myocardial Infarction	1,300	
HCC84	Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease	1,000	
HCC85	Heart Infection/Inflammation, Except Rheumatic	1,100	
HCC86	Valvular and Rheumatic Heart Disease	900	
HCC87	Major Congenital Cardiac/Circulatory Defect[4]	0	
HCC89	Hypertensive Heart and Renal Disease or Encephalopathy	500	
HCC90	Hypertensive Heart Disease	400	C3
HCC91	Hypertension	400	C3
HCC92	Specified Heart Arrhythmias	1,300	
HCC95	Cerebral Hemorrhage	1,600	
HCC96	Ischemic or Unspecified Stroke	1,300	
HCC97	Precerebral Arterial Occlusion and Transient Cerebral Ischemia	400	C3
HCC98	Cerebral Atherosclerosis and Aneurysm	400	C3
HCC99	Cerebrovascular Disease, Unspecified	400	C3
HCC100	Hemiplegia/Hemiparesis	2,400	
HCC101	Monoplegia, Other Paralytic Syndromes	1,900	
HCC103	Cerebrovascular Disease Late Effects, Unspecified	1,100	
HCC104	Vascular Disease with Complications	3,500	
HCC105	Vascular Disease	1,600	
HCC107	Cystic Fibrosis	1,900	
HCC108	Chronic Obstructive Pulmonary Disease	1,900	
HCC109	Fibrosis of Lung and Other Chronic Lung Disorders	900	
HCC110	Asthma	500	
HCC111	Aspiration and Specified Bacterial Pneumonias	4,300	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	1,800	
HCC113	Viral and Unspecified Pneumonia, Pleurisy	1,600	
HCC114	Pleural Effusion/Pneumothorax	1,500	
HCC119	Proliferative Diabetic Retinopathy (D E L E T E D)[5]	--	
HCC120	Vascular Retinopathies and Hemorrhages	600	
HCC122	Glaucoma	100	
HCC125	Significant Ear, Nose, and Throat Disorders	800	
HCC130	Dialysis Status	9,300	
HCC131	Renal Failure	1,600	
HCC132	Nephritis	700	
HCC133	Urinary Obstruction and Retention	1,300	
HCC146	Uncompleted Pregnancy With Complications	600	
HCC147	Uncompleted Pregnancy With No or Minor Complications	600	
HCC148	Decubitus Ulcer of Skin	7,100	
HCC149	Chronic Ulcer of Skin, Except Decubitus	2,800	
HCC150	Extensive Third-Degree Burns	2,500	
HCC154	Severe Head Injury	2,200	C2
HCC155	Major Head Injury	900	
HCC157	Vertebral Fractures without Spinal Cord Injury	2,700	C1
HCC158	Hip Fracture/Dislocation	2,400	
HCC161	Traumatic Amputation	4,100	
HCC164	Major Complications of Medical Care and Trauma	1,700	
HCC174	Major Organ Transplant Status	5,600	
HCC176	Artificial Openings for Feeding or Elimination	4,100	
HCC177	Amputation Status, Lower Limb/Amputation Complications	3,900	
Disabled/Disease Interactions			
D_HCC5	Disabled_Opportunistic Infections	5,400	
D_HCC44	Disabled_Severe Hematological Disorders	4,400	

Variable	Disease Group	Community Estimate[2]	Constraint[7]
D_HCC51	Disabled_Drug/Alcohol Psychosis	5,400	
D_HCC52	Disabled_Drug/Alcohol Dependence	2,900	
D_HCC107	Disabled_Cystic Fibrosis	5,800	
Disease Interactions			
INT1	DM_CHF[6]	1,100	
INT2	DM_CVD	600	
INT3	CHF_COPD	1,500	
INT4	COPD_CVD_CAD	700	
INT5	RF_CHF[6]	1,600	
INT6	RF_CHF_DM[6]	4,200	

NOTES:

[1] The dollar amounts in this table will be converted to relative risk scores. That is, these dollar amounts will be divided by the national average predicted expenditures to get relative risk scores.

[2] All estimates are rounded to the nearest hundred dollars.

[3] Includes Type I or Type II Diabetes Mellitus.

[4] Included in preliminary model, but estimated coefficient had t-statistic less than 1.0, and therefore was excluded from final model.

[5] Included in 2004 and 2005 CMS-HCC models, but deleted from 2006 CMS-HCC model.

[6] Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.

DM = diabetes mellitus (HCCs 15-19).
CHF = congestive heart failure (HCC 80).
COPD = chronic obstructive pulmonary disease (HCC 108).
CVD = cerebrovascular disease (HCCs 95-101, and 103).
CAD = coronary artery disease (HCCs 81-84).
RF = renal failure (HCC 131).

[7] Shading between adjacent boxes in the constraint column means coefficients of HCCs are constrained to be equal. C1, C2, and C3 denote non-contiguous constraints.

SOURCE: RTI International analysis of 2002/2003 Medicare 5% sample.

Table II-5. Draft List Of Disease Groups (HCCs) with Hierarchies

DRAFT DISEASE HIERARCHIES		
If the Disease Group is Listed in This Column…		...Then Drop the Associated Disease Group(s) Listed in this Column
Disease Group (HCC)	Disease Group Label	
5	Opportunistic Infections	112,113
7	Metastatic Cancer and Acute Leukemia	8,9,10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9,10
9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	10
15	Diabetes with Renal or Peripheral Circulatory Manifestation	16,17,18,19
16	Diabetes with Neurologic or Other Specified Manifestation	17,18,19
17	Diabetes with Acute Complications	18,19
18	Diabetes with Ophthalmologic or Unspecified Manifestation	19
25	End-Stage Liver Disease	26,27,34
26	Cirrhosis of Liver	27
31	Intestinal Obstruction/Perforation	34
33	Inflammatory Bowel Disease	34
44	Severe Hematological Disorders	46
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55,56,57,58,59
55	Major Depressive, Bipolar, and Paranoid Disorders	56,57,58,59
56	Reactive and Unspecified Psychosis	57,58,59
57	Personality Disorders	58,59
58	Depression	59
67	Quadriplegia, Other Extensive Paralysis	68,69,100,101,103,157
68	Paraplegia	69,100,101,103,157
69	Spinal Cord Disorders/Injuries	157
75	Coma, Brain Compression/Anoxic Damage	48
77	Respirator Dependence/Tracheostomy Status	78,79
78	Respiratory Arrest	79
80	Congestive Heart Failure	90,91
81	Acute Myocardial Infarction	82,83,84
82	Unstable Angina and Other Acute Ischemic Heart Disease	83,84
83	Angina Pectoris/Old Myocardial Infarction	84

85	Heart Infection/Inflammation, Except Rheumatic	86
89	Hypertensive Heart and Renal Disease or Encephalopathy	90,91
90	Hypertensive Heart Disease	91
95	Cerebral Hemorrhage	96,97,98,99
96	Ischemic or Unspecified Stroke	97,98,99
97	Precerebral Arterial Occlusion and Transient Cerebral Ischemia	98,99
98	Cerebral Atherosclerosis and Aneurysm	99
100	Hemiplegia/Hemiparesis	101,103
101	Monoplegia, Other Paralytic Syndromes	103
104	Vascular Disease with Complications	105,149
107	Cystic Fibrosis	108,109,110
108	Chronic Obstructive Pulmonary Disease	109,110
109	Fibrosis of Lung and Other Chronic Lung Disorders	110
111	Aspiration and Specified Bacterial Pneumonias	112,113
112	Pneumococcal Pneumonia, Empyema, Lung Abscess	113
130	Dialysis Status	131,132
131	Renal Failure	132
146	Uncompleted Pregnancy With Complications	147
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	48,75,155
161	Traumatic Amputation	177

How payments are Made with a Disease Hierarchy

EXAMPLE: If a beneficiary triggers Disease Groups 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then DG 149 will be dropped. In other words, payment will always be associated with the DG in the first column, if a DG in the second column also occurs during the same collection period. Therefore, the MA organization's payment will be based on DG 148 rather than DG 149.

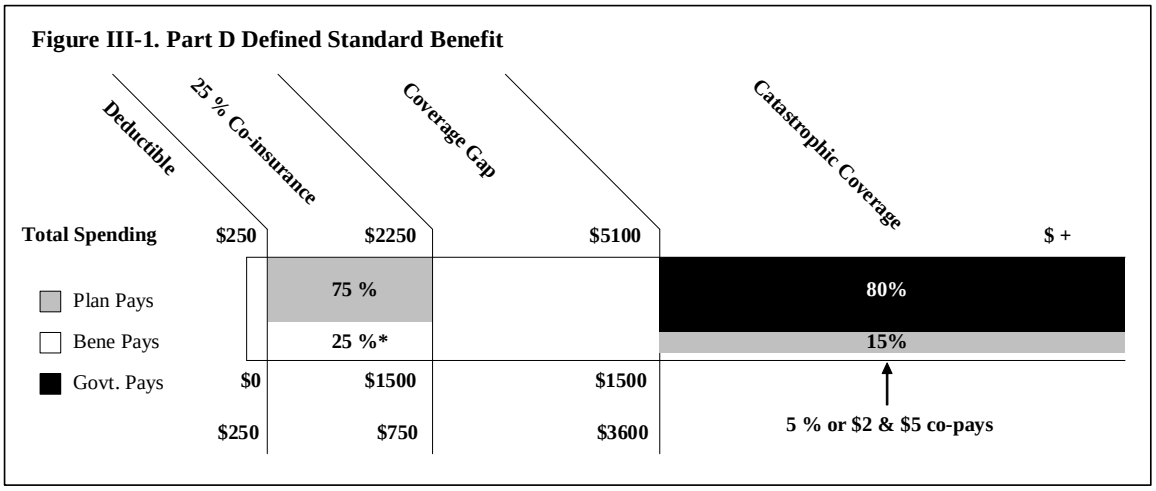
Attachment III

Overview of Payment for Medicare Advantage Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs)

Overview of Part D Payments

The Medicare Part D benefit established by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 (P.L. 108-173) and codified in 42 CFR Parts 400, 403, 411, 417, and 423, provides partially government subsidized drug coverage administered by private sector Part D plans. Part D plans predominantly fall into two categories: stand-alone prescription drug plans (PDPs) and Medicare Advantage health plans that also have a prescription drug benefit (MA-PDs). Part D plans may also be offered by other entities such as PACE organizations, section 1876 cost plans, and employers. The PDPs may have three levels of risk: full risk, limited risk and fallback (no risk). Limited risk plans are subject to the same payment rules as full risk plans except that the federal government has additional risk sharing. Fallback plan rules will be established separately from this Advance Notice.

Figure III-1. Part D Defined Standard Benefit



In 2006, the Part D defined standard benefit (illustrated above) begins with a $250 deductible the beneficiary (or another party on the beneficiary's behalf) is responsible for paying. Between $250 and the initial coverage limit of $2,250, the Part D plan is responsible for 75 percent of costs and the beneficiary pays a 25 percent coinsurance. Beneficiaries are responsible for all costs between the initial coverage limit and the $3,600 out-of-pocket threshold. Catastrophic coverage begins at the attachment point or threshold of $3,600 in beneficiary out-of-pocket spending. Costs in catastrophic coverage are split three ways, with the government providing reinsurance equal to 80 percent, the Part D plan covering 15 percent, and the beneficiary paying a 5 percent co-insurance, or co-payments of $2 for generic drugs and $5 for non-generic drugs. Note that the dollar figures given are for 2006 only and will be indexed to changes in per capita Part D spending in later years.

Government payments to Part D plans are made through the following four mechanisms: 1) the direct subsidy, 2) reinsurance subsidies, 3) low-income subsidies, and 4) risk sharing arrangements.

- The direct subsidy equals the standardized bid amount, adjusted for the risk characteristics of the enrollee, minus the monthly beneficiary premium for basic benefits. Part D plan sponsors will use the bid pricing tool to compute an estimate of its average monthly revenue requirements to provide defined standard drug coverage for a Part D eligible individual with a national average risk profile (standardized bid amount).

- Reinsurance subsidies are equal to 80 percent of the allowable reinsurance costs attributable to prescription drug costs after the Part D enrollee has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold.

- Low-income subsidies are government payments on behalf of certain beneficiaries based on their income and asset levels that cover part or all of the premium subsidy amount and plan cost sharing.

- Risk sharing arrangements involve symmetrical risk corridors in which the government either pays more of plan costs or recovers payments when a plan has allowable risk corridor costs above or below a target amount by certain percentages. The target amount equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for all risk-adjusted standardized bid amounts less the administrative expenses (including return on investment) assumed in the standardized bids.

More detailed descriptions of the four payment mechanisms are included in the following sections on prospective payments, reconciliations and risk sharing.

Prospective Payments

For 2006, the direct, reinsurance and low-income subsidies will all be prospectively paid based on the approved plan bid for basic benefits and estimates of expected reinsurance and low-income cost sharing provided along with the bid. These payments will be reconciled to actual enrollment, risk factors, and incurred allowable reinsurance costs and low income cost sharing after the close of the coverage year. Risk sharing will also be paid after the close of the coverage year following completion of all reconciliations, and is discussed in detail in a subsequent section. We note that the American Academy of Actuaries and consultants to CMS are reviewing the risk corridor and reinsurance methodologies discussed in this notice.

Direct subsidy

The CMS will provide a direct subsidy in the form of monthly payments equal to the product of the plan's approved Part D standardized bid and the beneficiary's health status risk adjustment factor, minus the monthly beneficiary premium for basic coverage.

- The standardized bid amount is the portion of the approved bid that is attributable to basic prescription drug coverage. The risk adjustment methodology is described in more detail below.

- The monthly beneficiary premium for basic coverage is the base beneficiary premium adjusted for the difference between the plan's standardized bid amount and the national average monthly bid amount. In determining the monthly beneficiary premium, the national average bid amount may be adjusted by CMS for geographic variations in prescription drug pricing if it is determined that such price variations exist and an appropriate adjustment methodology is developed. CMS is not going to geographically adjust the national average monthly bid amount for 2006.

- The national average monthly bid amount is the average of most approved Part D standardized bid amounts weighted by enrollment in these Part D plans (As provided in the final rule, some part D plan bids –such as the bids submitted by cost plans, PACE organizations, Special Needs Plans (SNP), and Private-Fee-For-Service (PFFS) plans – are excluded from the calculation).

- The base beneficiary premium is equal to the product of the national average monthly bid amount and the beneficiary premium percentage, which is a fraction with a numerator of 25.5 percent, and a denominator of 100 percent minus the percentage of total plan revenue attributable to reinsurance payments as estimated by CMS. The percentage of total revenue attributable to reinsurance will be calculated as estimated total reinsurance payments divided by the sum of these estimated total reinsurance payments plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

At least one commenter to our NPRM indicated that they foresaw the calculation of the monthly beneficiary premium for basic coverage resulting in a negative premium. This would happen if the base beneficiary premium adjusted for the difference between the plan's bid and the national average monthly bid amount is less than zero. For example, if the base beneficiary premium were $35 and the national average monthly bid amount were $115 and a plan bid $75, the statutory formula would result in a negative $5 premium. In this example, the direct subsidy payment (before risk adjustment) would provide an amount $5 greater than the plan's revenue needs. The final Part D rule allows this to happen but requires that these additional dollars be applied to a supplemental Part D benefit with no additional premium, or a reduction of the approved supplemental Part D premium, if applicable.

Reinsurance subsidy

When a beneficiary exceeds the out-of-pocket threshold (in 2006, $3,600 in "true" out-of-pocket costs, or "TrOOP"), the catastrophic coverage phase of the benefit begins in which CMS reimburses 80 percent of allowable drug costs above the out-of-pocket

threshold. Allowable reinsurance costs are the subset of gross covered prescription drug costs that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. "Actually paid" means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration which includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers from any source, including manufacturers, pharmacies, enrollees, or any other person, that would serve to decrease the costs incurred by the Part D sponsor for the drug. Hereafter we refer to all such direct or indirect remuneration as DIR.

The allowable reinsurance costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the defined standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation. During 2006, CMS will make prospective monthly reinsurance payments to plans based on estimated allowable reinsurance costs submitted with a Part D plan's bid.

The CMS is developing a contract for a facilitator that will provide real time TrOOP and coordination of benefits information. The system will be ready for plan use by January 1, 2006. As indicated in the final rule, CMS expects to charge user fees of no more than $1 per beneficiary per year.

Low-income subsidy (LIS)
Part D also provides for Medicare payments to plan sponsors to subsidize some or all of the costs that would otherwise be incurred by beneficiaries for certain qualifying low-income beneficiaries, including costs associated with premiums, deductibles, coinsurances, and late enrollment penalties. Part D divides these income-related subsidies into two categories: premium assistance and cost-sharing assistance (see Table III-1 and Figure III-2 for details). For premium assistance the percentages given are in relation to the premium subsidy amount calculated for the Part D plan.

The premium subsidy amount is based on the lesser of:

- the portion of monthly beneficiary premium attributable to basic coverage (for enrollees in PDPs) or the MA monthly prescription drug benefits premium (for enrollees in MA-PDs) or

- the greater of the low-income benchmark premium amount for a region or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the region.

The low-income benchmark premium amount for a PDP region is:

- in regions where all PDPs are offered by the same PDP sponsor, the weighted average, for the PDPs in the region, of the portion of the monthly beneficiary premium attributable to basic coverage;

- in regions where there are PDPs offered by more than one PDP sponsor, a weighted average, for all PDPs and MA-PDs in the region) of the portion of the monthly beneficiary premium attributable to basic coverage (for PDPs) and the MA monthly prescription drug beneficiary premium (for MA-PDs).

For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. In 2006, new MA-PD plans will be assigned zero weight as they will have no prior enrollment (this also applies to employer sponsored plans and SNPs). PACE, private fee-for-service plan and 1876 cost plan bids are not included in this calculation for any year.

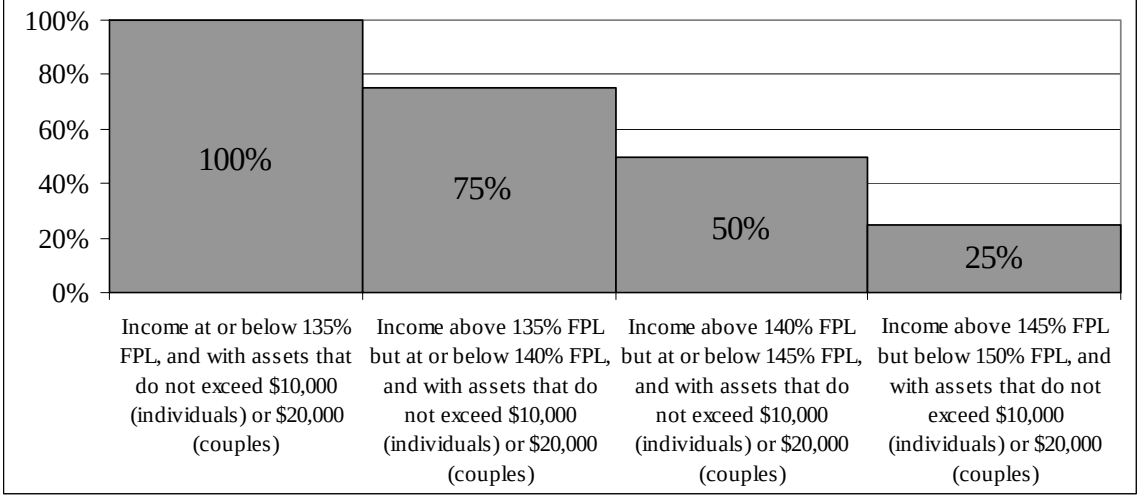
Table III-1. Premium and cost-sharing subsidy amounts for 2006

FPL & Assets	Percentage of Premium Subsidy Amount	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full-benefit dual eligible – institutionalized individual	100%*	$0	$0	$0
Full-benefit dual eligible– Income at or below 100% FPL (non-institutionalized individual)	100%*	$0	The lesser of: (1) an amount that does not exceed $1-generic/preferred multiple source and $3-other drugs, or (2) the amount charged to other full subsidy eligible individuals who are not full-benefit dual eligible individuals or whose incomes exceed 100% of the FPL.	$0
Full-benefit dual eligible –Income above 100% FPL (non-institutionalized individual)	100%*	$0	An amount that does not exceed $2- generic/preferred multiple source and $5-other drugs.	$0
Non-full benefit dual eligible beneficiary with income below 135% FPL and with assets that do not exceed $6,000 (individuals) or $9,000 (couples)	100%*	$0	An amount that does not exceed $2-generic/preferred multiple source and $5-other drugs.	$0

Non-full benefit dual eligible beneficiary with income at or below 135% FPL and with assets that exceed $6,000 but do not exceed $10,000 (individuals) or with assets that exceed $9,000 but do not exceed $20,000 (couples)	100%*	$50	15% coinsurance	An amount that does not exceed $2-generic/preferred multiple source drug or $5-other drugs
Non-full benefit dual eligible beneficiary with income at or above 135% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	Sliding scale premium subsidy (100%-0%)	$50	15% coinsurance	An amount that does not exceed $2-generic/preferred multiple source drug or $5-other drugs.

*The percentage shown in the table is the greater of the low income benchmark premium amount or the lowest PDP premium for basic coverage in the region.
Note that Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs) and Qualifying Individuals (QIs) are deemed full subsidy eligible.

Figure III-2. Sliding scale premiums for low-income eligible beneficiaries



Risk Adjustment Model

According to the MMA, payments to PDPs and MA-PDs are to be risk adjusted since they are based on a standardized bid amount which assumes an enrollee who has a risk factor of 1.0. As indicated above, Part D plan sponsors will use the bid pricing tool to compute this standardized bid amount. The starting point for this computation is the projected monthly revenue requirements to provide defined standard drug coverage for an enrollee with the plan's projected average risk factor. The underlying principles of the risk adjustment method used may be found in the research paper *Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment (Final Report); December 2000* found on the CMS Web site: http://www.cms.hhs.gov/researchers/projects/default.asp.

The model uses the presence of particular demographic characteristics and diagnoses to predict the following year's expected costs for an individual. The ICD-9-CM diagnoses are clustered within groups homogeneous both clinically and in costs. Each included characteristic and condition present contributes to the total prediction for an individual through a formula that sums the incremental costs. The groupings used to predict drug spending are variants of the groups used to predict Part A and B spending, and the data sources for diagnoses are the same as those used in Part C. Disease groups and draft coefficients for the Part D risk adjustment can be found on the CMS Web site at http://www.cms.hhs.gov/pdps/.

In development of the model, drug spending in dollars is used as the dependent variable of a regression model that estimates the marginal or incremental spending related to each of the explanatory variables (demographics and conditions) in the model. The model is ultimately expressed not in dollars, but as relative factors. The incremental dollars associated with each variable in the model are divided by the mean predicted dollars to produce a "relative costliness" or risk factor. Summing the risk factors for an individual yields a total risk adjustment factor that, when multiplied by a base rate, yields an individualized capitation rate, the direct subsidy described above.

Development of a risk adjustment model for drug spending is dependent on having appropriate data from which to create appropriate diagnosis groups and cost estimates. As there were no Part D data available, CMS used drug expenditure data for federal retirees with Medicare in the Federal Employee Health Benefit plan run by Blue Cross Blue Shield (BCBS). The pharmacy benefit of the BCBS plan is an uncapped benefit with a coinsurance amount for retail purchases and two tiers of copayment for mail order purchases. Only those retirees at least 65 years old were used from these data. For disabled beneficiaries, under 65, data from Medicare-Medicaid dual-eligibles were used. Other data sets were considered but none were superior to these. For both these data sets the development of the model could be done using the diagnoses from standard Medicare files and drug spending from each program's drug benefit. These files are the source of data for the model used for the first years of the Part D benefit. The BCBS spending year 2002 was used for calibration. For Medicaid, the latest available data linked to Medicare were for 2000.

Modifications to the data were necessary to remove certain drug claims from the data because the MMA specifically does not cover certain drugs. Only prescription drugs were included and Part B covered drugs were removed. Removal of the Part B drugs was straight-forward in the Medicaid data as each claim had both an NDC and amount paid. The BCBS situation was more complex. We had only total spending for each person with no paid amount on the claims. Using the Medicaid data we estimated the percentage reduction in spending associated with removal of part B drugs for people with conditions associated with high use, such as cancers and transplants. We then reduced spending for similar people in the BCBS files in the same proportion.

Other non-covered drugs, benzodiazepines and barbiturates, were intentionally left in the file because their costs proxy for the costs of substitutes. This was deemed preferable to removing the claims and costs altogether.

The model was first developed using the BCBS data. They reflect a benefit that is uniform nationally and has both retail and mail order pharmacies. The first task was to create a clinically credible model for spending. In forming the disease groupings, the large HCC clusters used for the CMS-HCC model, and the smaller constituent diagnosis groups, the DXGs were examined and tested for inclusion. Clinical and cost homogeneity, as well as cost magnitude associated with each group was examined. Pharmacist and physician consultations alternated with statistical tests in determining the diagnosis groupings. There was some reformulation and splitting of the disease groups in the move from predicting physician and hospital spending to predicting drug spending. An example is the simplification of the diabetes hierarchy. The Part A/B risk adjuster uses a hierarchy with 5 levels of diabetes; for Part D, only a distinction between uncomplicated and complicated diabetes is warranted to predict costs. When disease groups are in a hierarchy, only one, the highest one for which a code appears in the enrollee record, contributes to the risk factor. Conditions not in the same hierarchy contribute independently to the factor.

In forming the diagnosis grouper the dependent variable of the model was total spending, plan plus cost sharing. This allowed the clinicians to make reasonable judgments about the reasonableness of the cost coefficients. Though the model ultimately must predict the liability of drug plans, the structure of the cost sharing, which varies throughout the benefit range, makes it difficult to evaluate the size of plan liability coefficients. It is easier to evaluate a model that predicts the total cost of drugs needed for a condition than plan liability.

The initial model developed to predict spending omitted two groups that received special treatment at the end of the process – those who would receive the low income subsidy (LIS) and the long-term institutionalized (LTI). It was, however, necessary to bring in the Medicaid population to incorporate the disabled under 65 into the model. There were a number of problems in integrating the data sets: 1) The Medicaid group is low income and received drugs at out-of-pocket costs similar to costs under Part D LIS, not the cost sharing of BCBS; 2) They would probably spend at a different rate from those under the BCBS benefit even for the same diseases; 3) The cost data were from a different year and from many Medicaid programs. The following process was followed to convert the Medicaid data to spending patterns similar to that which would have occurred, on average, under a BCBS benefit.

The model, estimated with BCBS data for the aged, was applied to the dual eligible aged population to predict their spending as it would be under a BCBS benefit. This modeling incorporated the different demographic and risk profile of the duals in the predictions. The actual spending in the Medicaid data was then compared to the predicted spending. The ratio of the predicted to the actual spending was then used as a factor to convert the spending in the Medicaid files to levels compatible with BCBS. The conversion factor

was analyzed across the age/sex groups and, except for the sparse age 95+ groups, was quite stable.

With the data sets merged it became possible to estimate a full model across all ages and include age-specific add-ons for some diseases. One step has been omitted to this point because its relevance becomes clear only when estimating a model for plan liability. The spending data were multiplied by inflation factors that the CMS actuaries have used to project spending levels in 2006. This step is needed because the cost sharing ranges (described above) are defined in absolute dollar terms for 2006; thus, spending must be projected to levels appropriate to 2006 rather than the years of the development data. The decision to estimate a plan liability model based on the standard benefit was arrived at in consultation with industry actuaries and after studying the difficulties, both technical and operational, in modeling an unknown spectrum of possible benefit variations. Despite the discontinuous pattern of plan liability as spending varies, a model based on plan liability produces reasonable results.

The Plan Liability Model uses the grouper developed for the total spending model. The coefficients are estimated, however, on data altered to reflect plan liability. Before applying the cost sharing to create plan liability, the spending data went through another adjustment. It is generally observed that spending patterns are affected by income and prices. When insurance is present, as is the case here for drug purchases, the price to the consumer is the cost sharing. The model developed thus far has incorporated the cost sharing patterns of the BCBS benefit. The cost sharing in Part D is somewhat higher for the non-LIS population. Using estimates of the "induced demand effect" from the CMS actuaries, the spending for all people in the data was reduced to compensate for the higher cost sharing. This deduction was not made for the institutionalized, who were still excluded from the development data.

At this stage plan liability was computed for each person. As appropriate to each person's total spending, the first $250 were subtracted, 75 percent of the excess up to $2250 in spending was computed, $0 added till $5100, and 15 percent added for spending in the reinsurance range above $5100 in spending. There was no deduction from spending in the reinsurance range.

The data so structured were used to estimate plan liability coefficients for each characteristic important in the spending model. These coefficients reflected amounts that would be the plan's liability, on average, under the standard benefit. The coefficients expressed in dollars are smaller than the coefficients for the spending model as would be expected, some more changed than others. When the coefficients are expressed as relative factors, the differences will be smaller. This is because the conversion to relative factors entails dividing each coefficient by the national mean for spending or liability, as appropriate. Dividing a large spending coefficient by a large spending mean will produce a result similar to dividing the smaller liability coefficient by the smaller liability mean. The proportionality is not uniform, however. Diseases characterizing people who tend to have a large proportion of spending in the 100 percent cost sharing range, have their

factors reduced by a greater proportion than others. Much of drug spending has a zero impact on plan liability.

Both the Spending Model and the Plan Liability Model have good predictive power. The R^2 exceeds 0.20. This is higher than the explanatory power for the models predicting the more variable Part A/B costs. It is comparable to other models for drugs that we have seen reported. Analyses have been made of the predictive ratios (plan liability in the data/ predicted plan liability) for people in deciles of predicted liability. Because a substantial portion of a person's risk factor is associated with age and sex, even when diseases are accounted for, the model tends to overpay for beneficiaries who are predicted to be in the lowest deciles of costs. (There are always $0 spenders in any year, but the model will not predict $0 for the payment year.) Unlike the case for Part A/B, the model also overpredicts payment for the people in the high deciles of predicted costs. This is because the coefficients can not fully reflect the flattening of plan liability for high spenders. In the middle deciles of predicted costs there is a small degree of underprediction.

Low Income Subsidy and Institutionalization

By scaling the Medicaid spending to conform to the BCBS level of spending, the low-income effect has been removed. The CMS Office of the Actuary has estimated the effects of low cost-sharing on spending by the low-income population. The estimated percentage increase will be applied to the risk factors or the payment amounts after the base risk factors are computed.

Table III-2. Definition of the low income multipliers for Part D benefit

	Group 1	Group 1	Group 2	Group 2
Income test	Medicaid Dual <100% FPL	<135% FPL	<135% FPL	135-150% FPL
Asset test	<2× SSI	<3× SSI	>3× SSI & <$10,000 single $20,000 couple	<$10,000 single $20,000 couple
Deductible	$0	$0	$50	$50
Copay for generic drugs up to catastrophic threshold	$1	$2	—	—
Copay for brand-name drugs up to catastrophic threshold	$3	$5	—	—
Coinsurance up to catastrophic threshold	—	—	15%	15%
Coinsurance above catastrophic threshold	0%	0%	0%	0%
Copay for generic drugs above catastrophic threshold	$0	$0	$2	$2
Copay for brand-name drugs above catastrophic threshold	$0	$0	$5	$5
Premium subsidy	100%	100%	100%	Sliding scale

The low income multiplier is estimated to be 1.08 for Group 1 low income individuals (as defined above) and 1.05 for Group 2 individuals (as defined above). This multiplier is defined on a concurrent basis. (For example, if an individual were not defined as low income for January 2006 but was determined to be a Group 1 beneficiary for February 2006, the plan would receive the low income multiplier for February (and beyond) but not for January.)

An enhancement was also computed for the predicted spending by persons institutionalized in nursing facilities for more than 90 days. Spending for this group is expected to be higher because prices for the specific packages of drugs they receive are somewhat higher than the same drugs in the community. (An analysis of drug data done by IMS Health showed the price differences in the claims were small, particularly for brand name drugs that dominate the spending.) There are also effects related to compliance in acquiring and taking drugs in the institutional environment. On the other side, often patients take fewer drugs because more careful monitoring of interactions is occurring.

An analysis was done for the spending by the institutionalized by first using the base model to predict for this population and then comparing the actual spending and liability to the predicted. For the case of spending, there was a significant positive effect for the aged and the disabled who are in institutions. The effect for the disabled is greater than for the aged. It was also observed that average spending for both groups was in the 100% coinsurance range. The disabled mean was quite close to the catastrophic limit. The implications of additional demand being, to a large extent, in the range in which plans do not have incremental liability means that the effect on plan liability is much smaller than the effect on spending. The final payment adjustments for the institutionalized are smaller for the aged than for the disabled and smaller perhaps than some people expect because the final measure is plan liability rather than spending.

The long term care multiplier is 1.08 for aged individuals residing in a long term care institution and is 1.21 for Medicare disabled individuals residing in a long term institution. This multiplier, like the low income multiplier, is concurrent. We will use the Minimum Data Set (MDS) for identifying long term, institutional residents. If an individual is both a low-income subsidy eligible beneficiary and is in long-term care, then only the long-term care multiplier applies to that beneficiary.

Reconciliations and Risk Sharing

Introduction

At the conclusion of the payment year, CMS will undertake a sequence of reconciliations and risk sharing calculations for risk adjustment, low income cost sharing subsidies, reinsurance, and risk corridors. These reconciliations and risk sharing calculations are described below.

Risk Adjustment
Risk adjustment always uses one year of diagnostic data in combination with specific demographic factors to predict a future year's costs. In addition to other data requirements, plans offering Medicare Parts A and B, for instance MA and PACE organizations, demonstrations, and 1876 cost plans, are required to submit diagnosis data to support risk adjustment calculation. The diagnosis data on fee-for-service enrollees is collected by means of fee-for-service claims. This process allows the association of medical diagnoses with all Part D enrollees. We provide further detail on diagnostic data submission requirements below.

For initial payment in January 2006, risk adjustment factors will be based on diagnoses for dates of service from July 1, 2004 – June 30, 2005. The initial data collection deadline for these diagnoses is September 2, 2005. In mid-2006, we will update these factors utilizing dates of service January 1, 2005 – December 31, 2005. The mid-year data collection deadline is March 3, 2006. We expect that the mid-year factor updates will take place around July 2006, allowing all payments from that month forward to incorporate the updated factor. Retroactive adjustments for prior month's payments (January – June) will occur after the factor update has occurred.

Final reconciliation of risk adjustment for the prescription drug direct subsidy must occur prior to calculating the target amount for risk corridors. The direct subsidy component of the target amount will reflect the final reconciled direct subsidy payments actually made based on the final risk adjustment factors. Therefore, the reconciliation deadline for 2006 risk adjustment data (dates of service January 1, 2005 – December 31, 2005) will be January 31, 2007, earlier than previous risk adjustment reconciliation deadlines.

Low Income Cost-Sharing Subsidy
For qualifying low-income beneficiaries, cost-sharing amounts that would otherwise constitute beneficiary liabilities at the point of service (LICS amounts) will be paid by plan sponsors up front using LICS interim payments that CMS will advance to plans (see prospective payment above). As these costs are actually incurred during the coverage year, plans will identify incurred LICS amounts on claims. After the coverage year, CMS will reconcile interim payments with incurred amounts from claims and will make any necessary payment adjustment in 2007 (payment additions or recouping).

Reinsurance
After the end of the coverage year, CMS will reconcile reinsurance subsidies as follows:

- Identify incurred reinsurance costs above the out-of-pocket threshold at the individual beneficiary level (from claims)

- Sum incurred reinsurance costs at the plan level

- Apportion DIRs to incurred reinsurance costs by applying the ratio of covered Part D DIR to total allowed costs. (We refer to the apportioned DIR as "reinsurance DIR." "Covered Part D DIR" is defined in the DIR section under Implementation below).

- Subtract reinsurance DIR from incurred reinsurance costs, then multiply the difference by 80 percent to determine government liability.

In formula:
Reinsurance DIR = (covered Part D DIR/total allowed costs)*incurred reinsurance costs then
Adjusted reinsurance = (incurred reinsurance costs - reinsurance DIR)*0.80

Example
A plan had $1,000,000 in incurred reinsurance costs and total allowed costs of $6,100,000. Covered Part D DIR = $610,000.

Reinsurance DIR = ($610,000/$6.1m)*$1m =$100,000
Adjusted reinsurance = ($1m-$100,000)*0.80 = $720,000

The resulting adjusted reinsurance amount ($720,000 in the example) will be reconciled with prospective reinsurance payment amounts made to plans during the coverage year (see prospective payment above). Appropriate payment adjustment (payment additions or recouping) will then be made in 2007.

Risk corridor payments
Risk corridors are designed to limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through health status risk adjustment. The federal government and the plan share the profits or losses resulting from expenses for the standard benefit within defined symmetrical risk corridors around a target amount. Risk corridors work by determining the difference between (a) the target amount (what a plan was actually paid through the direct subsidy plus enrollee premium related to the standardized bid amount) and (b) a plan's actual allowable costs not including administrative expenses. A plans actual allowable costs are limited to those costs actually incurred or paid by the plan and must subtract out any DIR. Also if a plan provides supplemental coverage CMS takes into account how the presence of such coverage increases utilization beyond what it would be if the coverage were defined standard coverage. Finally, CMS will subtract out all federal reinsurance payments and low-income subsidy payments related to cost-sharing.

Calculating risk corridor payments can be considered as a 4-step process:

- Calculate the plan's target amount

- Calculate associated risk corridor thresholds

- Calculate adjusted allowable risk corridor costs

- Determine where costs fall with respect to the risk corridor thresholds, then calculate payment adjustment

Calculate the target amount

The target amount is the plan's total direct subsidy payments plus total beneficiary premiums (not including any negative premium amounts) related to the standardized bid amount due from enrollees or paid on their behalf plus MA rebates applied to buying down the basic premium minus administrative costsor (1.00 – administration cost percentage) * (total direct subsidy payments + total beneficiary premiums related to the standardized bid amount), where:

- the direct subsidy = (standardized bid * beneficiary risk adjustment factor) – beneficiary premium related to the standardized bid amount

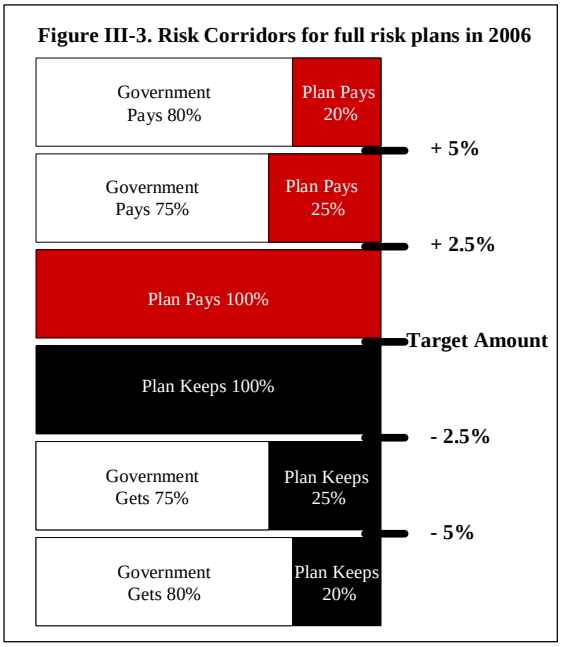
- the total direct subsidy is the sum of all monthly direct subsidy amounts paid for the entire coverage year; and

- the total beneficiary premiums (not including any negative premium amounts) related to the standardized bid amount is the sum of all monthly beneficiary premiums plus MA rebates related to the standardized bid amount, paid for the entire coverage year. Beneficiary premiums include premiums from enrollees or paid on their behalf, including low-income premium subsidies.

Example:

Direct Subsidy	$767,250
Beneficiary Premiums	$255,750
Administrative Costs	< $23,000 >
Target	$1,000,000

Calculate associated risk corridor threshold limits



As illustrated above, the first threshold upper limit is 102.5 percent of the target amount and the second threshold upper limit is 105 percent of the target amount; similarly, the first threshold lower limit is 97.5 percent of the target amount and the second threshold lower limit is 95 percent of the target amount. These percentages are for 2006.

Example (target amount = $1,000,000):
The first threshold upper limit is $1,025,000 or $1,000,000 + (.025*$1,000,000)
The second threshold upper limit is $1,050,000 or $1,000,000 + (0.050*$1,000,000)
The first threshold lower limit is $975,000 or $1,000,000 – (.025* $1,000,000)
The second threshold lower limit is $950,000 or $1,000,000 – (0.050*$1,000,000)

Calculate adjusted allowable risk corridor costs
The CMS will calculate adjusted allowable risk corridor costs from claims. These include covered prescription drug costs actually incurred and paid by the plan within the limits of the standard benefit that are not covered by reinsurance payments or low-income cost-sharing subsidies net of DIR.

Specifically, CMS will identify covered Part D drug costs from claims, then subtract the following amounts:

- From claims: patient liability amounts (e.g. deductibles and cost-sharing),LICS (equal to the plan's cost sharing not to exceed the maximum amount defined in the rule), amounts paid by non-TrOOP-eligible additional payers, and amounts identified by plans as costs related to supplemental benefits

- Induced utilization (for enhanced alternative plans only; the amount will be identified in their bids)

- Reinsurance subsidies

- Part D covered DIR dollars not allocated to reinsurance costs

The resulting difference is the adjusted allowable risk corridor costs that will be considered for payment adjustment. The statute indicates that allowable risk corridor costs must be reduced by reinsurance payments and by low-income cost-sharing subsidies, because plans are reimbursed separately for these costs. As discussed in the preamble to the final rule, since low-income premium subsidy payments are not plan costs, they are not subtracted from allowable costs for the purposes of risk corridor cost calculation.

Determine where costs fall with respect to the thresholds and calculate payment adjustment

If adjusted allowable risk corridor costs fall within 2.5 percent of the target amount (above or below it), there is no risk sharing of additional costs or "savings" compared to estimated (prepaid) amounts. But if adjusted allowable risk corridor costs are more than 2.5 percent outside the plan's target (above or below it), costs or savings will be shared in accordance with the following provisions:

- Adjusted allowable risk corridor costs > 102.5 percent ≤ 105 percent of target amount Government pays plan 75 percent of difference between adjusted allowable risk corridor costs and the 1st upper threshold limit; plan pays remainder.

Example (adjusted allowable risk corridor costs = $1,035,000):
Payment adjustment = 0.75*($1,035,000-$1,025,000) = $7,500 (government pays plan)

- Adjusted allowable risk corridor costs >105 percent of target amount Government pays plan the sum of 75 percent of difference between 2nd and 1st upper threshold limits and 80 percent of the difference between the adjusted allowable risk corridor costs and the 2nd upper threshold limit; plan pays remainder.

Example (adjusted allowable risk corridor costs = $1,063,000):
Payment adjustment = [0.75*($1,050,000-$1,025,000) + 0.80*($1,063,000-$1,050,000)] = $29,150 (government pays plan)

- Adjusted allowable risk corridor costs < 97.5 percent ≥ 95 percent of target amount Plan pays government back 75 percent of difference between 1st lower threshold limit and the adjusted allowable risk corridor costs but keeps 25 percent.

Example (adjusted allowable risk corridor costs = $973,000):
Payment adjustment = 0.75*($975,000-$973,000) = $1,500 (plan pays back to government)

- Adjusted allowable risk corridor costs < 95 percent of target amount Plan pays government back the sum of 75 percent of difference between 1st and 2nd lower threshold limits and 80 percent of the difference between the 2nd lower threshold limit and the adjusted allowable risk corridor; plan keeps remainder.

Example (adjusted allowable risk corridor costs = $945,000):
Payment adjustment = [0.75*($975,000-$950,000) + 0.80*($950,000-$945,000)] = $22,750 (plan pays back to government)

Note that in 2006, the 75 percent risk sharing for adjusted allowable risk corridor costs between the first and second upper threshold limits will change to 90 percent (or the higher percentage if negotiated as a limited risk plan) if the following two conditions have been met:

1. At least 60 percent of Part D plans that have adjusted allowable risk corridor costs for the Part D plan for the year that are above 102.5 percent of their target amount; and

2. Such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA-PD plan.

Note that condition 1 would exclude Fallback plans, PFFS plans, employer-sponsored plans that elect the 28% subsidy, and any plan that opts for limited risk under Section 1860D-11(f)."

Limited Risk Plans

PDPs assuming limited risk may be approved in geographic areas where access requirements for a PDP region have not otherwise been met. The statute requires that regions contain at least two qualifying plans offered by different entities, one of which must be a PDP; also, these plans must offer basic coverage or basic and supplemental benefits without any accompanying supplemental premium. In regions where access requirements are not met, the minimum number of limited risk plans needed to satisfy the requirements may be approved. Note that only PDPs may act as limited risk plans and that they must at least provide basic coverage. MA-PD plan sponsors may not assume reduced risk.

In making risk corridor payments to limited risk PDPs, we will apply the reduced risk provisions approved in their bids. In accordance with the statute, reduction in risk may be accomplished by 1) symmetrical increases in the federal risk percentages assumed within either risk corridor or 2) symmetrical narrowing of the risk corridors by reducing

the threshold risk percentages. As required under Section 423.272(c)(2) CMS may not approve any bid with a de minimis level of risk. In the preamble to the final rule we stated that our definition of de minimis in this context was a level of risk that was 10% or less of the statutory level of risk. In other words, the risk after modification cannot be less than 10% of the risk before the risk corridors were moved or federal risk percentages were increased. For example, a reduction of the first corridor from 25% to 2.5% and a reduction of the second corridor from 20% to 2%. This would also apply to the size of the corridors, e.g., one-tenth of 2.5% or one-tenth of 5%.

Part D - Implementation Issues

Prescription Drug Claims

To enable CMS to make timely and accurate plan payments, plans must submit 100 percent of claims data to CMS but only a limited number of data elements per claim. We used four criteria in determining claims submission requirements: 1) ability to make timely, accurate payment using the four legislated mechanisms (direct subsidy, low-income subsidy, reinsurance, and risk corridors); 2) minimal administrative burden on CMS, plans, and other entities including MA-PDs, PDPs, fallback plans, pharmacy benefit managers, pharmacies, and others; 3) legislative authority; and 4) validity and reliability of the data requested, such that the information will be useful.

Since multiple "claims" transactions typically take place between pharmacies, PBMs, and plans prior to final adjudication of a prescription drug claim, plans must only submit a summary record called the prescription drug event (PDE) record to CMS. This record must include covered drug costs above and below the out-of-pocket threshold and distinguish supplemental (enhanced alternative) costs from the costs of drugs provided under the standard benefit. The CMS will use these data to calculate reinsurance and risk corridor payments and to develop a second-generation Part D risk adjuster based on actual Part D experience.

Plans must also identify payers on PDE data, including LICS amounts paid by the plan at the point of service; beneficiary liability (cost-sharing) amounts; beneficiary cost-sharing for supplemental (enhanced alternative) benefits; and payments by additional third party payers other than a given Part D plan. Payments by TrOOP-eligible third parties on behalf of beneficiaries shall be included under beneficiary liability, and payments by non-TrOOP-eligible entities shall be reported separately. The CMS will use these payment data from PDE records to reconcile LICS and to validate TrOOP and entry into the catastrophic coverage phase.

In order to receive payment, plans must submit PDE records for year 2006 dates of service, including any adjustments, by the end of the third month of 2007. Specifically, prescription drug claims including adjustments for all dates of service within CY 2006 must be submitted to CMS by March 31, 2007 in order to be processed for payment reconciliation.

Reporting of Direct and Indirect Remuneration (DIR)

The final rule at 42 CFR Section 423.308 specifies that covered drug costs must be actually incurred and paid by the Part D sponsor and must be net of all direct or indirect

remuneration from any source that would serve to decrease the costs incurred by the Part D sponsor for the drug. In this notice, DIR refers to all such remuneration as described at 42 CFR Section 423.308. The DIR will be excluded from allowable reinsurance and risk corridor costs as described in the payment sections above.

Some DIR may already be reflected in the amount paid (sum of ingredient cost, dispensing fee, plus applicable sales tax) at the point of sale. However, all DIR that is not taken into account at the point of sale and thus is not accounted for on PDE records must be reported to CMS separately for exclusion from allowable costs.

Plans must report DIR not taken into account at the point of sale to CMS within six months of the end of the year. DIR dollars must be reported in full with no reduction for administrative cost or any other fees. Plans will submit DIR amounts in three categories: 1) DIR dollars for non-covered Part D drugs (statutorily-defined Part D drugs not covered by the plan); 2) DIR dollars for covered Part D drugs (statutorily-defined Part D drugs that are covered by the plan); and 3) total Part D DIR (the sum of 1 and 2). The differentiation between covered and non-covered Part D drug DIR dollars enables calculation of reinsurance and risk corridor payments based only on covered Part D drug costs.

Data Requirements
Diagnostic Data Submission for Part D Risk Adjustment
The rules for data submission for risk adjustment are the same as the rules for Part C, as described in Chapter 7 of the Medicare Managed Care Manual (http://www.cms.hhs.gov/manuals/116_mmc/mc86toc.asp).

Diagnostic data submission by 1876 cost plans and HCPPs for risk adjustment
In accordance with the SSA Section 1876(i)(3)(D), in September 2004 CMS required Section 1876 cost HMOs/CMPs to begin submitting all (medical and drug-related) diagnostic data to CMS to enable risk adjustment for their enrollees that may join Part D. We encouraged but did not require HCPPs to submit these data. We also provided for reimbursement to cost plans for data submission as an administrative expense.

Our goal in using these data is to make accurate risk adjusted Part D payments for enrollees that receive Part D coverage through Section 1876 plans that elect to offer Part D benefits, and for HCPP and Section 1876 plan enrollees that elect Part D coverage in a stand-alone PDPs. Diagnoses for dates of service 7/1/04 – 6/30/05 will be used to determine risk adjusted rates for Part D plan payments beginning 1/1/06.

We note that CMS may not have sufficient diagnostic data for making Part D risk adjusted payments where the beneficiaries have been enrolled in plans that are not required to submit diagnostic data (e.g., HCPPs). For this small group of enrollees, we are considering applying the new enrollee model for 2006 only. The CMS will identify alternative ways of risk adjusting these types of enrollees for 2007 and beyond.

Failure to provide adequate information for payment and reconciliation
In accordance with the MMA and as described in 42 CFR Section 423.322, organizations offering Part D plans must submit adequate data to enable CMS to make payment. Therefore, inadequate data submission may result in payment recovery through a lump-sum recovery; by adjusting or ceasing monthly payments throughout the remainder of a coverage year; or by adjusting monthly payments in a subsequent year. Note that payment recovery provisions apply even in the event of a change in ownership.

For example, if LICS payments exceed the costs eligible for subsidy under Section 423.782, CMS may recover payments through a lump-sum recovery or by adjusting monthly payments for the remainder of the coverage year.

Part D plans are specifically required to provide CMS with sufficient data for conducting reconciliation as discussed in Section 423.343. For risk-sharing arrangements, if the organization does not provide all rebate and PDE information data as prescribed below, we will assume or impute that the entity's adjusted allowable risks corridor costs are 50 percent of the target amount. CMS will recoup 80 percent of the difference between the 2nd threshold lower limit and the imputed adjusted allowable risk corridor costs, plus 75 percent of the difference between the 1st and 2nd threshold lower limits.

The 50 percent threshold constitutes a lower limit on government and plan liability. Also, we believe it is a reasonable limit because it would be unlikely for a plan to have costs that are less than 50 percent of their target amount.

For LIS, if the organization does not provide adequate documentation of LICS amounts on PDE records within the claims submission deadlines described below, CMS may recoup all interim LICS payments.

Throughout the coverage year, CMS will monitor plan data submission levels to detect outliers that are submitting low amounts of PDE data and may be experiencing technical or other difficulty. We will work with plans in an attempt to correct submission problems before the end of the year so they can meet reconciliation submission deadlines. However, the MMA places ultimate responsibility on the plan to submit adequate data for payment.

Part D enrollees who change plans during the coverage year
The CMS is examine different approaches to determining low income, reinsurance, and risk sharing payment amounts for individuals who change Part D plans during the payment year.

Appeals
As described in the final rule, Part D sponsors may appeal final payment decisions if the stated payment methodology has not been applied correctly. Under no circumstances may this process be used to submit new payment information after the established deadline.

Special Provisions for PACE Payment

The PACE plans are required by law to offer drugs to enrollees with no co-payments. This provision must be reconciled with the global provisions in MMA that require beneficiary out-of-pocket expenditures. Specifically, Sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act preclude PACE organizations from charging PACE enrollees any form of cost sharing and Section 460.186(d) of the PACE regulation precludes PACE organizations from charging a premium to any Medicaid eligible PACE enrollees. A discussion of our proposed payment methodology that accounts for the dual-eligible as well as the Medicare-only PACE enrollees is provided below, followed by our proposed premium methodology applicable to each of these categories of PACE beneficiaries.

We note that PACE organizations will need to have two separate benefit plans and two separate Part D bids. The dual eligible population will be enrolled in a standard benefit plan, and the Medicare-only population will be enrolled in an enhanced alternative plan.

CMS payment methodology applicable to dual eligible PACE enrollees

Dual eligible PACE enrollees will be deemed low-income eligible under Part D. Low-income beneficiaries are given additional cost-sharing subsidies for their Part D covered drugs. In a typical Part D plan, low-income individuals have a nominal co-payment responsibility for their Part D drugs, and the plan will provide the remainder of the usual co-payment through a low-income cost-sharing subsidy. Plans are reimbursed dollar for dollar for the cost-sharing subsidy.

However, PACE enrollees will have no co-payment responsibility under the PACE provisions. In recognition of this PACE prohibition on beneficiary co-payments, CMS proposes to cover the usual nominal co-payments for low-income beneficiaries under an additional capitated payment as provided in Section 1894(d)(2) of the Act. This section indicates that CMS may adjust Medicare payments to PACE organizations to take into account "…such other factors as the Secretary determines to be appropriate." For cost allocation purposes, CMS proposes to consider 2% of all costs below the out-of-pocket threshold to be appropriately categorized as the nominal beneficiary liability for full benefit dual eligible enrollees and therefore subject to this additional capitated payment. CMS will prospectively estimate this amount based on the cost assumptions submitted with the bid and will make an additional monthly payment to each standard benefit PACE plan for dual eligible enrollees.

To support the payment calculations, PACE plans must report the detailed drug costs for their beneficiaries. However, PACE will not need to report the payment breakdowns of those costs, because PACE will be paying 100% of the cost. CMS will use the standard benefit to array each beneficiary's costs into the standard benefit categories, i.e., deductible, initial cost sharing, coverage gap, and catastrophic coverage (reinsurance). Below we outline how CMS' intends to array the costs for dual eligible costs. The first $250 will be considered to be deductible, with 98% being LICS and 2% being attributed to additional capitated payment. The next $2,000 will be assumed to be a 75%-25% split between plan liability and beneficiary liability, divided as 23% LICS and 2% additional capitated payment. Because a supplemental cost sharing is not attributable to beneficiary

out-of-pocket spending, the normal coverage gap from $2,250 - $5,100 is extended slightly (We estimate this adjusted out-of-pocket threshold to be approximately $5204). In the coverage gap, again the LICS is 98% of all spending and the additional capitated payment accounts for 2% of the spending. All spending above the adjusted out-of-pocket threshold will be considered to be reinsurance, with the reinsurance subsidy representing 80% of the costs, plan liability 15%, and LICS 5%. There is no additional capitated payment required in this portion of the benefit, since dual eligible beneficiaries have no co-payment responsibilities under catastrophic coverage.

Premium methodology applicable to dual eligible PACE enrollees
In addition to the prohibitions on cost-sharing, PACE organizations are also precluded from imposing premiums upon any Medicaid eligible enrollee. We recognize the potential situation under which a PACE organization's bid may exceed the national average premium subsidy amount. The MMA indicates that this difference is to be borne by the beneficiary as a premium payment. Given the PACE prohibition of charging any Medicaid eligible enrollee a premium, we are considering an additional capitated payment adjustment that may be made to PACE organizations on behalf of dual eligible PACE enrollees in plans with bids above the low-income benchmark. This authority is also based on Section 1894(d)(2) of the Act. As a result, dual eligible PACE participants will not be responsible for Part D premium payments, and any premiums that would otherwise be incurred due to the bid will be accounted for as additional capitated payment amounts.

CMS payment methodology applicable to Medicare-only PACE enrollees
To support the payment calculations for Medicare-only enrollees, PACE also must report the detailed drug costs for these beneficiaries. As with the dual eligible population, PACE will not need to report the payment breakdowns of those costs, and we will map the reported costs to the benefit. The major difference is that no costs will be attributed to LICS. All cost sharing above the standard benefit will be attributed to supplemental cost sharing, which will be covered by the beneficiary premium as described below. Since there are no co-payments and no LICS, these beneficiaries will never incur any TrOOP costs and will never reach the catastrophic coverage. The calculations for these individuals will only involve allowable risk corridor costs. For any covered drug costs, the first $250 will be attributed to supplemental cost sharing and not allowable as risk corridor costs. For the next $2,000 up to the initial coverage limit, the costs will be split 75%-25% between allowable risk corridor costs and supplemental cost sharing. No costs above the initial coverage limit will be considered allowable for risk corridors; all costs above the initial coverage limit will be attributed to supplemental cost sharing.

Premium methodology applicable to Medicare-only PACE enrollees
For the Medicare-only PACE enrollees, we are proposing that PACE organizations develop a standardized bid for the basic benefit. These Medicare-only PACE enrollees will be responsible for paying the full base beneficiary premium amount Because the Medicare-only beneficiaries will never reach the catastrophic coverage, the standardized bid will only account for costs incurred up to the initial coverage limit.

A supplemental premium must also be calculated for Medicare-only PACE enrollees and supplied with the bid. This premium will apply to all Medicare-only enrollees, regardless of income level. The supplemental premium must account for all of the following costs:

1. $250 deductible,

2. 25% cost-sharing between $250 and $2250,

3. Full beneficiary responsibility for all costs above $2250.

Plans will be required to predict the cost of these amounts for all Medicare-only enrollees in aggregate in order to establish a single bid.

Special Provision for the Calculation and Payment of Reinsurance Amounts for Private Fee-For-Service Plans

As provided under Section 1860D-21(d)(4) of the MMA and Section 423.329(c)(3) of the final rule, CMS will adopt an alternative methodology for the payment of estimated reinsurance to private-fee-for-service (PFFS) plans. We propose to make interim estimated reinsurance payments to PFFS plans on a prospective monthly basis. We will base these interim estimated prospective payments on the average reinsurance amount for MA-PD plans as submitted in their Part D bids. In making this estimate, we propose to adjust the interim estimated average reinsurance payments for the projected risk of PFFS plan enrollment as compared to the MA-PD program.

We propose that final payment of estimated reinsurance to PFFS plans will be based on the average reinsurance payment actually made for payment year 2006 across the MA-PD program. We will adjust this average MA-PD reinsurance payment to take into account average reinsurance payments for populations of similar risk to the specific PFFS plan under consideration. This means the final estimated PFFS plan reinsurance amounts will be determined after final annual reinsurance payments (based on adjusted allowable reinsurance costs) to MA-PD plans are determined and MA-PD risk scores for payment year 2006 are reconciled.

Reinsurance Demonstration

We intend to use CMS's authority provided in section 402 of the Social Security Amendments of 1967 (42 U.S.C. Section1395b-1) and modified by Section 1860D-42(b) of the Act, to conduct a budget neutral Part D payment demonstration. This reinsurance demonstration proposal will require the provision of a supplemental benefit partially or completely filling in the coverage gap, with payment based on either one of the following two reinsurance options:

- Option One: Eligible Part D plans could offer an enhanced alternative drug benefit package and receive a capitated drug reinsurance payment, in addition to the normal direct subsidy, low income subsidy, and risk sharing payments. This reinsurance payment would be capitated instead of specific reinsurance payments of 80 percent of drug costs after the beneficiary incurred $3,600 in

TrOOP drug costs. The capitated reinsurance payment will be negotiated during the bidding process.

- Option Two: For eligible MA-PD plans that use MA premium rebates to cover the additional cost of enhanced alternative drug coverage, this option would permit enrollees to count supplemental benefit payments toward meeting the TrOOP spending requirement for Part D catastrophic coverage. For this option, all the supplemental benefit must be funded by MA Part A/Part B rebate dollars. To clarify, plans may not charge a supplemental premium for the supplemental benefit under this option. This is because it is not possible to distinguish A/B rebate dollars that would count toward TrOOP under this option from beneficiary premium dollars that would not count toward TrOOP.

All PDP sponsors may participate in option one. Medicare Advantage organizations offering Prescription Drug Plans (MA-PD plans) are eligible to participate in either options one or two with the exception of Program of All Inclusive Care for the Elderly (PACE) plans, cost-plans, and employer-sponsored plans.

Additional information about the demonstration will be provided both in a Federal Register notice and on the CMS Web site.