DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

TO: Medicare Advantage, Medicare Advantage-Prescription Drug Organizations
Section 1876 Cost-Based Contractors
Demonstrations

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SUBJECT: Medicare Advantage, Medicare Advantage-Prescription Drug Plans CY 2007 Instructions

DATE: April 4, 2006

We are pleased to release the Contract Year 2007 instructions for Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD) Plans. The guidance in the 2007 MA, MA-PD Call Letter applies to all MA, MA-PD, Cost-Based Contractors, Cost-PD Plans, Capitated Demonstration Plans and Employer/Union-Only Group Waiver Plans (EGWPs) that expect to be operating in Contract Year 2007, including those that are currently applying to enter the program in 2007. A separate call letter has been issued for Stand-Alone Prescription Drug Plans.

The Call Letter contains new and clarified policy statements developed in response to lessons learned during the Part C and Part D program implementation. It also features re-statements of existing program requirements to emphasize their importance to CMS and to our beneficiaries. Finally, the letter provides practical information about the MA, MA-PD and Cost contract renewal and non-renewal processes for 2007.

This Call Letter is a key element of the guidance that CMS is providing to help organizations bid and contract for the upcoming contract year. Please note, however, that while we have captured the most significant operational and policy updates for 2007, contractors and applicants should also consult applicable laws, regulations and other guidance to gain the necessary familiarity with the applicable requirements. These resources and other information are available on our website at

http://www.cms.hhs.gov/home/medicare.asp. We will also issue guidance and information through the Health Plan Management System (HPMS). Please check these sites regularly for updated information. Please also note that we have included staff contacts in Section XVIII and current web-site addresses in Section XIX of the Call Letter for ready reference.

CMS will continue to conduct industry outreach through Conference Calls and other mechanisms. CMS will conduct a conference call to discuss the MA, MA-PD Call Letter on April 10, 2007, from 1:00 p.m. to 3:00 p.m. EDT. Additional information will be forthcoming.

Thank you for your continued service to Medicare beneficiaries. If you have specific questions about any of these instructions, please contact the analyst listed in Section XVIII or send an e-mail to Helaine.Fingold@cms.hhs.gov. She will distribute your inquiry to the appropriate contact person for a response.

We look forward to your continued participation in the Medicare managed care program.

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I. *Definitions and Acronyms*

Within the text of this document, we have used the following terms and acronyms with the meanings as described:

MA Organization — Refers to contracted organizations offering Medicare Advantage-only (MA-only) and/or Medicare Advantage-Prescription Drug (MA-PD) plans.

Cost-Based Contractors — Refers to entities offering Cost-Based plans pursuant to section 1876 of the Social Security Act.

Cost-PD — Refers to Cost-Based Contractors offering Part D Prescription Drug benefits.

EGWP — Refers to an employer/union-only group waiver plan (either employers and unions that directly contract with Medicare to provide benefits to their active employees/retirees or MA Organizations and Cost Sponsors that offer these types of plans to employer and union sponsors).

MA-PD Organizations or plans — Refers to MA Organizations that are also offering Part D Prescription Drug benefits.

MMA — Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Part D Sponsors — Refers to MA-PD Organizations and Stand-Alone Prescription Drug Plans (PDPs) that offer Part D Prescription Drug benefits.

Social Security Act — SSA or the Act.

All regulatory references are to Title 42, Part 422 of the Code of Federal Regulations, unless otherwise indicated.

II. *MA, MA-PD and Cost-Based Plan Renewals*

A. *2007 MA, MA-PD and Cost-Based Plan Renewal Calendar*

Please note that, except as otherwise specified in statute or regulation, the dates given here are subject to change. Organizations should continue to monitor the general applications timeline posted on the CMS website at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY2007timeline.pdf.

NOTE: Employer/Union-Only Group Waiver Plans (EGWPs) are subject to the same timeline set forth below, except for those dates that apply to marketing (see Chapter 13 of the Medicare Marketing Guidelines).

2007 MA, MA-PD and Cost-Based Plan Renewal Calendar	
2006	***All dates are subject to change***
April	April 3 — Issuance of Calendar Year (CY) 2007 MA Payment Rates. April 4 — Announcements of MA capitation rates, local area benchmarks, and adjustment factors for 2007. April 5-6, 11 — CMS Bid Conference. April 10 — Plan Creation module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS. April 10 — Call Letter Training for Industry. April 17 — Formulary Submissions Due from all MA-PDs, PDPs, Direct Contract EGWPs, and MA Organizations or Cost-PD Sponsors offering EGWPs.
May	May 1 — Deadline for CMS to inform currently contracted organizations that CMS has authorized renewal of their contract. May 6 — Last day to submit provider-specific plans for an effective date of January 1, 2007. May 19 — PBP/BPT Upload module available on HPMS. May 19 — CMS to begin accepting CY 2007 Bids via HPMS.
June	June 1 — CY 2007 Model Annual Notice of Change (ANOC) will be available to all organizations. June 5 — Deadline for submission of bids for all MA, MA-PD, Cost-PD, EGWP and Direct Contract EGWP applicants and renewing organizations. An MAO that intends to offer an MA coordinated care plan in an area must submit at least one Part D bid for that area by June 5th in order to offer any MA coordinated care plan in the area. June 6 — CMS begins accepting CY 2007 marketing material for review. June 30 — Final date for MA, MA-PD and Cost-Based Organizations to submit CY 2006 marketing materials for CMS' review and approval. NOTE: Organizations may continue to submit CY 2006 file & use materials as these may be filed with the Regional Offices 5 calendar days prior to use.
August	August 1 — 2007 Model Evidence of Coverage (EOC) and Model Low Income Subsidy (LIS) Rider will be available to HMO, PPO, RPPO, Cost-Based and Private Fee-for Service (PFFS) plans. August 5 — Cost-Based plans are encouraged to submit ANOCs and SBs by this date so that these materials can be reviewed and approved prior to the posting of "Medicare Personal Plan Finder" (MPPF) and included in the Medicare & You handbook.

2006	*All dates are subject to change*
September	September 1 — Final Date for Organizations to send non-model ANOCs to Regional Offices. September 8 – 11 — MA, MA-PD organizations and, if applicable, Medicare Cost-Based plans, preview the 2007 Medicare & You handbook plan data in HPMS prior to printing this CMS publication (not applicable to EGWPs). September 15 — MA, MA-PD and Cost-PD Organizations are expected to submit final 2007 ANOCs and SBs to the Regional Offices for review that are based on the organization's CMS approved benefit bid. NOTE: Organizations receiving bid approval prior to September 14 (as noted in HPMS), must submit the 2007 ANOC/SB with 72 working hours of approval. September 15 – 19 — First preview of Medicare Personal Plan Finder data for MA and Cost-Based organizations. September 25 – 26 — Final preview of Medicare Personal Plan Finder data for MA and Cost-Based organizations, prior to the 2007 data going on the web in October.
October	October 1 — MA, MA-PD Organizations and Medicare Cost-Based plans may begin marketing CY **2007** benefits to Medicare beneficiaries using CMS-approved and CMS File & Use accepted marketing materials. All organizations must cease marketing CY **2006** plans through public media when they begin marketing CY **2007** benefits. October 1 — MA Organizations and Medicare Cost-Based plans are required to include information in CY **2006** marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2007. October 10 — Final day for Medicare Cost-Based plans to send non-model ANOCs to CMS Regional Offices. Cost plans are encouraged to submit all ANOCs to CMS in advance of this date to ensure the ANOC can be reviewed, approved, printed, and received by members by December 1. NOTE: If the Medicare Cost-Based plan follows the model ANOC without modification, the final date to send the ANOCs to the CMS Regional Office is November 6. October 12 — Plan benefit data displayed on the Medicare Personal Plan Finder on the web. Tentative date for plan drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder (not applicable to EGWPs). October 12 — Final day for MA, MA-PD and Cost-Based Organizations to submit model ANOC to CMS Regional Office for review. October 15 – 30 — CMS mails the 2007 Medicare & You handbook which contains health plan and prescription drug plan benefit and cost information. October 31 — All MA Organizations must cease marketing CY 2006 plans through public media. October 31 — CY 2007 ANOCs (with SBs) are due to all MA, MA-PD members. MA, MA-PD Organizations must mail the ANOCs and SBs before this date to ensure receipt by members by October 31.
November	November 15 — 2007 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, *see* Chapter 2 of the Medicare Managed Care Manual, Section 30.4.4).

2006	***All dates are subject to change***
December	December 1 — CY 2007 ANOCs (with SBs) are due to all Cost-Based plan members. Medicare Cost-Based plans must mail the ANOCs and SBs before this date to ensure receipt by members by December 1. December 1 — Final date for MA Organizations and Medicare Cost-Based plans to send non-model EOCs and LIS Riders to CMS Regional Offices. Organizations are encouraged to submit all EOCs and LIS Riders to CMS in advance of this date to ensure the EOC and LIS Rider can be reviewed, approved, printed, and mailed to members by the January 31, 2007 deadline. NOTE: If the organization follows the model EOC or model LIS Rider without modification, the final date to send the EOCs to the CMS Regional Office is December 15, 2006. December 31 — 2007 Annual Coordinated Election Period ends.
2007	
January	January 1 — Plan Benefit Period Begins. January 31 — Final date for MA, MD-PD and Cost-Based Organizations to mail CY 2007 EOCs to members with an effective date of January 1, 2007.

B. *HPMS Crosswalk and MA Plan Renewal Guidelines and Operational Instructions for MA Organizations*

As with past years, MA Organizations will be required to complete the HPMS plan crosswalk when uploading their Contract Year 2007 bids. MA Organizations use the HPMS plan crosswalk to designate the relationships between plans offered in 2006 to those being submitted for 2007.

1. *Transition Rules for an MA-only to an MA-PD or an MA-PD to an MA-only*

An MA organization is free to change benefits, premiums, and cost-sharing under an MA plan or an MA-PD plan from year to year. A beneficiary enrolled in a plan maintains enrollment in that plan year to year, absent a change in election.

MA organizations that are consolidating the number of plans it offers are permitted to designate the plan that is the "continuing plan." MA plans may only consolidate plans which are the same plan type (e.g. HMO, PFFS, etc). Similarly, an MA plan and an MA-PD plan are different MA plan categories under the statute. Therefore, an MA-PD plan cannot be considered a “continuation” of an MA-only plan, and vice-versa. Additionally, multiple plan types cannot be consolidated into a single plan type (e.g. MA-only and MA-PD in 2006 into a single MA-PD in 2007).

If an MA Organization wishes to eliminate an MA-Only plan option, it may do so by terminating that plan for the following calendar year. Enrollees in that plan would then be free to actively enroll in an MA-PD plan offered by that organization, enroll in another MA-Only plan, or revert to original Medicare with no Part D benefits.

2. *HPMS Crosswalk*

The attached chart (see Attachment A) outlines the MA plan renewal guidelines and describes the relationships that can be established between CY 2006 and 2007 plans and how each one relates to the HPMS plan crosswalk, the enrollment system actions to be performed by either the MA Organization or CMS, whether and which type of enrollment application is required, and the requirements for beneficiary notifications. It is extremely important that MA Organizations review this chart for guidance when determining their plan structures for CY 2007. Technical instructions for completing the HPMS plan crosswalk for each type of relationship will be provided to MA Organizations in the *Bid Submission User's Manual for Contract Year 2007*.

C. *CMS Renewal Notice to Part D Sponsors*

As noted in our regulation, CMS will issue Part D Sponsor contract renewal notices on or before May 1, 2006, to those Sponsors we have determined, based on information available at that time, to continue to be qualified to hold a contract during 2007. Part D Sponsors are not required to apply for a contract renewal as CMS will make the determination based on an evaluation of each Sponsor's compliance with its contract.

As noted below, plan performance is an important element in CMS' final decision to re-contract with a Part D Sponsor for 2007. We will continue to do routine monitoring, conduct Sponsor audits and review the data resulting from the performance metrics that we have developed this year. Additional information indicating performance issues after May 1 may result in the initiation of further actions against a plan, including contract termination for 2007.

The renewal notices will indicate that the Sponsor is qualified to operate a Part D plan during 2007, but that CMS cannot renew the contract with any entity for 2007 unless the Sponsor receives CMS approval of the bids it submitted on June 5, 2006.

1. *CMS Evaluation Criteria*

CMS will review each Part D Sponsor's compliance with all Part D program requirements to determine whether contract renewal is warranted. CMS may consider non-renewing the contracts of Sponsors that substantially fail to comply with Part D program requirements.

While Part D Sponsors must comply with all Part D program requirements, CMS will pay particular attention to Sponsors' performance of those activities that significantly impact beneficiaries' satisfaction with their benefit plans. These areas include effective data systems, customer and provider service, exceptions and appeals processes, and pharmacy support. CMS has and will continue to develop comprehensive performance measures for each of these areas, and we will routinely collect and analyze data that measures each Sponsor's level of compliance.

a) Effective Data Systems

Determining a beneficiary's correct enrollment status, including copayment status, lies at the heart of ensuring his or her access to the Part D benefit. Because enrollment data are updated much more frequently than previously in the Medicare+Choice program, and timely and accurate data processing by plans is essential, CMS expects sponsors to develop and maintain information systems that accurately process updated enrollment information at least weekly, following recommended processing procedures to avoid significant delays or inaccuracies in processing enrollments. These requirements are particularly important for sponsors serving substantial numbers of beneficiaries, particularly those serving auto-enrolled dual eligible beneficiaries. In particular, Sponsors serving auto-enrolled dual eligible beneficiaries will continue to be expected to process enrollments and updated copayment information timely, and to verify enrollment and copayment status on a biweekly basis using enrollment files provided by CMS. Sponsors are also expected to establish business processes for quickly resolving urgent issues affecting particular beneficiaries, such as late changes in enrollment or copay status, in collaboration with CMS caseworkers. Sponsors are also expected to work with CMS to minimize data submissions that are rejected, and to provide timely and complete 4Rx information on their beneficiaries. We are refining measures related to the effectiveness of Part D Sponsors' information systems interactions with CMS to be used as part of our ongoing monitoring efforts.

b) Effective Customer Service

Contracts require that Part D Sponsors provide a high and consistent level of access and service for beneficiaries and their representatives, pharmacists, and other health care providers. These requirements include meeting all customer service centers. On March 31, 2006, CMS issued a memorandum to all Part D Plan Sponsors stating that we would begin making available weekly reports concerning Sponsor call center performance based on information collected by the Department of Health and Human Services (HHS). Excellent performance in responding to beneficiaries, pharmacists, and providers helps ensure a high level of beneficiary satisfaction. Therefore, CMS is conducting routine surveys to determine Sponsor compliance with Part D standards concerning call abandonment rates and percentage of calls answered within 30 seconds. Part D Sponsors should review this information to verify that they are maintaining or exceeding compliance with Part D call center requirements. Such monitoring will continue to occur periodically to assure that plans remain in compliance. We are also monitoring complaint rates related to customer service issues.

c) Follow Transition Guidance

CMS expects Part D Sponsors to follow both our transition guidance and their approved transition processes. All Part D Sponsors have committed to the provision of a temporary supply of non-formulary drugs of at least 30 days in the retail setting.

Part D Sponsors should provide enrollees receiving a transition supply with instructions explaining:

(1) That the transitional supply is temporary,
(2) That the beneficiary needs to work with the Sponsor and his or her physician to identify appropriate drug substitutions, and
(3) That the member has a right to request a formulary exception.
(4) The Sponsor's form should also provide the procedures for requesting such an exception.

In addition to reviewing Sponsor reports on its transition compliance, CMS is monitoring complaint rates related to transition coverage of drugs until the transition process is completed. Additional details on transition coverage requirements are provided in the 2007 formulary guidance and transition guidance.

d) Maintain and Strengthen Relationships with Providers through Effective and Efficient Exceptions and Appeals Process

CMS expects Part D Sponsors to provide prior authorization and exceptions forms and access to information to make transition procedures straightforward for providers and patients.

Part D Sponsors are expected to limit administrative burdens for physicians and other providers by implementing recommended best practices for consistent forms, including initial triggers for formulary exceptions and processes for providing needed clinical information for processing prior authorization requests for specialized drugs. Sponsors must also have a "one stop" area on their website that provides needed information on the procedures, the forms, and the contact information (see the March 31 memorandum issued by Gary Bailey, Deputy Director, Center for Beneficiary Choices) for their prior authorization and exceptions processes. CMS will be monitoring Sponsor wait times, compliance with timely responses for exceptions and appeals, and complaint rates to assure that Sponsors that continue to participate in the Part D program are meeting their requirements in this area.

e) Maintain and Strengthen Relationships with Pharmacists through Contractual Support and Avoiding Administrative Burdens

Part D Sponsors must comply with the contractual agreements they have made with their participating pharmacies, and CMS is monitoring pharmacists' complaints about plan compliance with these agreements and other pharmacy requirements of the Medicare program. Sponsors are also expected to follow recommended best practices for consistent code and secondary message responses when formulary, prior authorization, Part B coverage, or other rejection edits are activated.

2. *Part D Sponsor Notice of Renewal to CMS*

Part D Sponsors will provide notice to CMS of their decision to renew their contracts for 2007 simply by submitting a new set of bids on June 5, 2006. No other formal notice to CMS is required.

D. *Formulary*

1. *Formulary Submission*

Part D Sponsors that intend to offer Part D benefits in 2007 will be required to submit one or more formularies through HPMS by April 17, 2006 at 5:00pm EDT. CMS will approve only those submitted formularies that comply with the 2007 Final Formulary Guidance.

2. *Transition Process*

Organizations intending to offer Part D benefits in 2007 will be required to submit a description of their proposed processes for ensuring a smooth transition for plan enrollees who are stabilized on certain drug regimens that are not on the plan's formulary. In order for a submitted transition process to meet CMS's approval, it must be consistent with the 2007 Transition Process Guidance. A draft of the 2007 Transition Process Guidance will be posted on our website for comment.

E. *Pharmacy Access*

1. *Specialty Pharmacy Access*

CMS clarifies that Part D Plans may not restrict access for certain Part D drugs to "Specialty" pharmacies within their Part D network in such a manner that contravenes the convenient access protections of §1860D-4(b)(1)(C) of the MMA and §423.120 of the Title I regulations. Specifically, Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Therefore, Part D plans may not restrict access based solely on the placement of a Part D drug in a "specialty/high cost" tier because this tier placement alone is not indicative of any special requirements associated with such drug.

Part D plans may specify, on a drug by drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. We believe that only a limited number of drugs would qualify as needing special attention. Further, Part D plans may not require network pharmacies to qualify as a "Specialty" pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of

appropriately dispensing the particular Part D drug or drugs in question. The convenient access standards dictate that "Specialty" pharmacies be used to supplement network pharmacy access when necessary and not otherwise restrict it.

2. *I/T/U Addendum*

CMS has developed a new addendum for Part D Sponsor contracts with Indian Health Services, Indian Tribes and Tribal Organizations, and Urban Indian Organization (I/T/U) pharmacies (see Attachment D). All Part D Sponsors that contract with I/T/U pharmacies will be expected to have contracts with these providers incorporating the new addendum in place beginning January 1, 2007.

F. *Conflict of Interest*

An organizational conflict of interest provision was added to the 2007 MA, MA-PD and PDP applications. Entities will be required to provide financial and organizational conflict of interest reports to CMS, pursuant to instructions to be issued by CMS. CMS will make draft instructions available for public comment prior to final posting in late 2006.

G. *Minimum Enrollment Requirements*

MA Organizations should be aware of the minimum enrollment requirements in the Medicare regulations at 42 CFR 422.514. The regulations require urban based MA Organizations to have enrollment of at least 5000 and non-urban based MA Organizations of at least 1,500. The basis for the minimum enrollment rules is to ensure the financial viability of MA Organizations participating in the Medicare Advantage program.

H. *Instructions for Maintaining Dual Eligible Members in 2007*

For January 1, 2006, CMS instructed MA Organizations to assign those dual eligible members who would have been assigned to MA-only plans via renewal instructions to the organization's MA-PD plan with the lowest combined Part C and Part D premium.

Dual eligible members of a continuing MA-PD (or Cost-PD) plan in 2007 will continue as enrolled members, regardless of changes to the Part C and/or Part D premium, unless the member makes an enrollment election on his or her own. These members will be informed of plan changes in the annual notice of change (ANOC). The ANOC for these members will also include a list of all other plans offered by the organization in the service area with a premium at or below the low-income premium subsidy amount.

These instructions to maintain dual eligible members also pertain to Cost-Based plans who offer a Part D plan as an optional supplemental benefit and such individuals have

selected to enroll in the benefit offered by the Cost-Based plan. Individuals who are members of Cost-Based plans and enroll in a "standalone" Part D plan will be subject to those instructions provided in the 2007 PDP call letter for maintaining dual eligible members.

I. *Overlapping Cost and Risk Plans*

Medicare regulations prohibit MA Organizations from operating actively enrolling beneficiaries in Cost-Based plans in the same service area as their risk plans. The regulation, found at 42 CFR 422.503(b)(5), states that "as a condition necessary to contract . . . any organization seeking to contract as an MA organization must . . . [n]ot accept new enrollees under a section 1876 cost contract in any area in which it seeks to offer an MA plan." Prior to the issuance of the MMA implementing regulations, this provision was found at 42 CFR 422.501(b)(4). The preamble to the rule introducing this longstanding policy into regulation indicated CMS' intent was to "eliminate the potential for an organization to encourage higher cost enrollees to enroll under its cost contract while healthy individuals are enrolled in its risk-based M+C plan" 63 FR 35,014 (June 26, 1998). Additional guidance on this issue can be found in Chapter 17d, Section 30.1 of the Medicare Managed Care Manual.

Any Cost-Based Contractor that operates or seeks to operate an MA plan in the same service area, may continue to serve current enrollees under that Cost-Based Contract but must close that plan to new enrollments. Please contact your Regional Office Plan Manager if you have any questions.

J. *Cost-Based Contract Renewals and Service Area Reductions/Expansions*

Under certain circumstances, beginning on or after January 1, 2008, Cost-Based plans may only extend their service area or continue in their current service area where there are fewer than two coordinated care plan-model MA plans of the same type available to Medicare beneficiaries. The "competing" MA plans must also meet CMS' minimum enrollment requirements for the entire previous year in order to trigger mandatory cost plan non-renewal or service area reduction. Medicare law requires Cost-Based plan service area reduction where there are two or more MA plans of the same type meeting minimum enrollment requirements competing for Medicare members in a portion of the Cost-Based plan's service area.

We will permit existing Cost-Based plans to expand their service areas based on applications received by September 1, 2006, and for effective dates of January 1, 2007, if other requirements for expansion are met. After September 1, 2006, service area expansion applications received from Cost-Based plans will be initially evaluated and accepted only if there are less than two MA plans of the same type meeting minimum enrollment requirements in the area in which the Cost-Based plan proposes to expand. By early in the 2007 calendar year we will provide section 1876

Cost-Based plans data on "competing" MA plans in the service area in which they are offered. See 42 CFR 417.402 and 70 FR pp. 4592 – 4594 (January 28, 2005) for additional information.

A Cost-Based plan can offer a mid-year service area expansion consistent with 42 CFR 417.402. However, Cost-Based plans that offer Part D as Cost-PD plans are subject to the same restriction on mid-year service area expansions as are MA-PDs. In other words, where there is an already existing MA-PD plan or PDP plan in the area in which the Cost-PD plan proposes to expand, no mid-year service area expansion of the Cost-PD plan will be permitted into that area.

K. *Financial Reporting Requirements*

In compliance with reporting requirements that CMS established in July 2005, MAOs which were contractors during contract year 2005 must submit audited financial statements for the year ended December 31, 2005 to CMS by April 30, 2006 (2 copies of GAAP and if your state requires a statutory filing, 2 copies of SAP). Quarterly financial statements are no longer routinely required.

III. ***MA, MA-PD, Cost-PD Bidding***

A. *Reduction in Part B Premium Subsidy*

Section 1839 of the Act, as amended by Section 811 of the 2003 MMA and Section 5111 of the 2005 Deficit Reduction Act, provides for an income-based reduction in the government subsidy of the Medicare Part B premium. Under this provision, for those beneficiaries meeting specified income thresholds, a monthly adjustment amount will be added to the standard Part B premium. (Here, we use the term "standard" to mean the amount of the full-subsidy monthly Part B premium.) Generally, effective 2007, the standard Part B premium amount becomes the lowest Part B premium a beneficiary would pay, with higher-income beneficiaries paying greater Part B premiums. (The only beneficiaries who pay less than the standard Part B premium are those whose Part B premium increase is limited by the increase in their Social Security check (the "hold harmless" provision at Sec. 1839(f)).)

The addition of monthly adjustment amounts to the Part B premium obligation of higher-income beneficiaries will be phased-in, beginning in 2007. Given the MA requirement that benefits must be uniform within an MA plan, the effect of this provision on MA plans is that it will generally no longer be possible to offer a benefit package that describes the Part B premium as zero, i.e., marketing or member materials cannot describe the Part B premium as zero. However, MA Organizations will be permitted to explain to members that they will receive a Part B premium reduction of the amount of rebate dollars applied by the MA Organization to Part B premium reduction. Effective 2007, MA Organizations can apply rebate dollars to reduce the estimated standard Part B premium. Thus, the lowest Part B premium a plan can offer is the estimated standard amount net of rebates. OACT will continue

to provide the estimate of the standard Part B premium each year for bidding purposes.

B. *Plan Corrections*

Plan Corrections are intended to provide MA Organizations with the ability to correct data entry errors identified within the PBP, specifically, errors and/or omissions that are not consistent with the benefits that have been priced within the approved Bid Pricing Tool (BPT). Correction Requests must be supported by the approved BPT. Plan Corrections may not be used to "change" plan benefits after the bid has been approved or make changes to the BPT.

Many MA Organizations and PDPs requested plan corrections late in 2005, after attesting to their benefit packages. The vast majority of the Plan Correction requests resulted from MA Organizations'/PDPs' data entry errors, lack of internal coordination between the Plan Benefits Package (PBP) and Bid Pricing Tool (BPT), and lack of quality assurance activities to review submissions early in the process. The number of plan corrections must be reduced significantly. To assist MA Organizations/PDPs with this quality assurance, CMS has instituted a number of changes to improve the PBP and BPT interface. For example, CMS has implemented software edits between the BPT and PBP so that differences between the two tools will be flagged prior the plan's bid submission.

The most important step in reducing the need for plan corrections must be strengthened quality control by MA Organizations and PDPs. Quality control must be an integral part of each PBP and BPT submission. The tight timeframes during the bid season and in preparation for the enrollment period require significant upfront efforts. CMS expects MA Organization/PDP requests for plan corrections will be dramatically reduced for 2007. Benefit attestations must reflect accurate benefit packages that require no further corrections. Further, MA Organizations/PDPs must ensure that their marketing materials, such as the Summary of Benefits and Evidence of Coverage, reflect the accurate data that is submitted on the PBP/BPT.

We believe that beneficiaries have a reasonable expectation that when they receive marketing materials on an MA plan or PDP, that they will be able to access accurate information on the benefits under that plan through the Medicare Personal Plan Finder (MPPF) or Medicare Prescription Drug Plan Finder (MPDPF). We believe that marketing a plan that does not have such information available is inherently misleading. Accordingly, if we become aware that MPPF or MPDPF information is inaccurate because the PBP is inaccurate, or if an MA Organization/PDP requests suppression of its information on the MPPF or MPDPF because it was inaccurate due to the PBP being inaccurate, we will not approve marketing materials for that plan until the PBP contains accurate information on the plan. If an MA Organization/PDP requests suppression of its MPPF/MPDPF data during the MPPF/MPDPF preview period in September due to the PBP being incorrect, we will not be able to ensure that corrected information is included on the MPPF/MPDPF until November, 2006. As a

result, all or certain marketing materials submitted by that plan will not be approved under File & Use for use prior to November, 2006. Similarly, if an MA Organization/ PDP requests suppression of its MPPF/MPDPF data after the MPPF/MPDPF preview period in October due to the PBP being incorrect, we will not approve or accept under File & Use all or certain marketing materials of that plan prior to November 15, 2006. We believe these actions are the best way to support competition and reward organizations that submit accurate PBPs and ensure that inaccurate materials are not disseminated.

If inaccuracies are due to a fault or error on CMS' part, CMS will correct these deficiencies as quickly as possible and have the corrections reflected in the plan marketing material as expeditiously as possible.

CMS' timelines for review of marketing materials and other submissions by MA Organizations and PDPs will remain unchanged regardless of plan correction status.

C. *Medicare Personal Plan Finder Data*

On October 12, 2006, the CY 2007 health plan data will first appear on the "Medicare Personal Plan Finder" (MPPF). All plans covering Part D prescription drugs will also have CY 2007 prescription drug data displayed on the "Medicare Prescription Drug Plan Finder," tentatively starting on October 12, 2006. Out-of-pocket cost data, which was not included in the MPPF for CY 2006, will be displayed on the 2007 tool. In addition, the "Medicare Personal Plan Finder" will continue to include charts displaying several HEDIS and CAHPS measures, as well as disenrollment reasons data for the MA plans. Please note that employer/union-only group waiver plans (EGWPs) will not be included in the MPPF as these employer-only group plans are not open to general enrollment.

This year, the MPPF will be redesigned. The redesign will include some navigation changes as well as simplification of benefit descriptions. Also, MA-only plans will be able to offer online enrollment through the MPPF beginning with CY 2007. CMS will provide the industry with the opportunity to comment on MPPF benefit description changes in the spring of 2006.

Plans are expected to preview their plan data for MPPF twice in September. The first preview period will be September 18-20. The second preview period will be September 26-27. If there are any issues with the data, plans can notify CMS at compchart@cms.hhs.gov.

As noted in the "Plan Corrections" section of this Call Letter, quality control must be an integral part of the Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) submissions. Data entered into the PBP (and subsequently uploaded to HPMS) is the basis for the MPPF (and the MPDPF, as described in the section below). Therefore, early and strong quality control of the bid submission at the MA Organization/PDP level on all submissions is imperative. Previewing the MPPF (and the MPDPF) is another opportunity for the plan to confirm that the data it submitted is correct. As

noted above, CMS will link approval of MA Organization/PDP marketing and advertising with MA Organization's/PDP's submission of accurate PBPs. MA Organizations/PDPs must further ensure that attestations reflect the benefits they intend to offer in the manner they intend to offer them.

D. *Medicare Prescription Drug Plan Finder Data*

1. General Instructions

Tentatively starting October 12, 2006, the CY 2007 health plan drug data will appear on the "Medicare Prescription Drug Plan Finder." Please note that employer/union-only group waiver plans (EGWPs) will not be included in Medicare Prescription Drug Plan Finder as these employer-only group plans are not open to general enrollment.

MA-PD and PDP Sponsors will be able to preview their drug data in HPMS this fall. Specific dates for the preview will be provided at a later date.

2. Quality Checks

Quality checks for data submitted to CMS for display on the Medicare Prescription Drug Plan Finder tool will continue to be required for contract year 2007. Currently guidance has been released on HPMS that outlines the expected quality checks that MA-PD and PDP Sponsors should routinely perform on their data both prior to submitting it to CMS and after it has been posted on the Medicare Prescription Drug Plan Finder. Modifications and additions to the QA check list may be added for implementation in 2007. Failure to conduct these QA checks may result in suppression of the MA-PD and PDP Sponsor's pricing data from the website.

E. *ESRD Bidding Policy*

For 2007, ESRD enrollee costs will not be represented in either the MA benchmarks or the plan A/B bid. However, a new section IV of Worksheet 4 has been created where MA Organizations may enter an adjustment to A/B mandatory supplemental premiums to reflect the costs or savings for ESRD enrollees in the basic and supplemental benefits. Further guidance on this section will be included in the 2007 Instructions for the Bid Pricing Tool. CMS is evaluating methodological approaches for including ESRD enrollee costs in the plan bids for 2008.

F. *Bidding Instructions for Plans Serving Qualified Medicare Beneficiaries*

The MA bidding rules specify that the development of contract year total allowed medical expenses, which are reflected on a per-member per-month (PMPM) basis, include the sum of projected plan reimbursements and enrollee cost sharing. The plan reimbursements reflected in the bid must reflect the actual projected plan payments to providers for health care services.

The basis of each category of enrollee cost sharing is the product of per-service requirements, as reflected in the plan benefit package (PBP), and expected utilization. MA plans subtract from total allowed medical expenses the PMPM value of fee-for-service Medicare actuarially equivalent cost sharing.

Section 1902(a)(10)(E)(i) of the Act requires State Medicaid Agencies to pay cost sharing amounts on behalf of Qualified Medicare Beneficiaries (QMBs). (The term QMB is defined in section 1905(p)(1) of the Act.) Paragraphs (n)(1) and (2) of section 1902 of the Act provide authority, when certain conditions are met, for State Medicaid agencies to reduce or eliminate cost sharing amounts on behalf of such beneficiaries through the State Medicaid Plan. In such cases paragraph (n)(3) exempts QMB beneficiaries from paying Medicare Advantage plan Medicare cost sharing (see section 1905(p)(3)) and requires providers to accept the sum of Medicare Part C payments and any amount paid (or reduced/eliminated) by the State Medicaid Agency as payment in full for the item or service in question.

The MA Organization determines what level of cost sharing it wishes to have for any given MA plan. This is true for all plans, including those that primarily serve QMBs. The MA Organization may determine the desired level of plan cost sharing irrespective of whether a state Medicaid agency will pay the plan or its providers some, all or none of this cost sharing for QMBs.

These instructions clarify that the cost sharing component of the bids filed on behalf of QMBs must reflect plan cost sharing, as reflected in the PBP. That is, the cost sharing component of allowed medical expenses will include all cost sharing charged by the plan, even though some or all of that cost sharing may not be paid to the plan or its providers because of the application of SSA Section 1902(n). In other words, regardless of whether a state Medicaid agency pays on behalf of a QMB some, all, or no cost sharing — either directly to the provider, or through a contractual arrangement with the MA Organization — the full level of plan cost sharing must be reflected in the development of allowed costs (MA bid Worksheet 2) and enrollee cost sharing requirements (MA bid Worksheet 3A and 3B). Please note that this guidance is not intended to limit an MA Organization's flexibility to determine how much to pay its providers or how to determine projected payments to providers.

For example, an MA plan that charges cost sharing that is actuarially equivalent to full Medicare fee-for-service will include the PMPM equivalent of full Medicare fee-for-service cost sharing in their allowed costs. Per SSA Section 1902(n), CMS will consider Medicaid payments made on behalf of any QMBs enrolled in this MA plan as meeting the cost sharing obligation of these individuals.

This guidance does not change the requirement that plan cost sharing in the PBP must be the same for all enrollees. Therefore, if an MA Organization offers a plan that serves both QMBs and non-QMBs and includes cost sharing that is less than that charged in Medicare fee-for-service, the cost sharing component of the plan's allowed costs must reflect this plan-level cost sharing for both QMBs and non-QMBs.

Reimbursements of QMB cost sharing by Medicaid State Agencies may take the form of a payment to either MA Organizations or the providers. The reimbursements reflected in the allowed cost component of each bid must reflect the projected payments from the MA Organization to the providers, less any projected payments from Medicaid agencies to the MA organization for cost-sharing. Payments made directly from Medicaid State Agencies to providers should not be netted from allowed costs. To the extent that the provider does not collect from the State Medicaid agency (either directly or through the MA Organization) the full amount of cost sharing, CMS does not consider the plan to be waiving the Part C cost sharing amounts.

These instructions are consistent with last year's QMB bidding instructions and there is no change intended.

G. *MSA Plan Bids*

Plan A/B bid. An MA Organization will submit to CMS on or before the first Monday of June a bid submission for offering a Medicare MSA plan. Like other local MA plans, the Medicare MSA plan A/B bid (called the "monthly MSA premium" in statute) represents the organization's monthly revenue requirements for coverage of original Medicare benefits in a service area, except that the MSA plan bid is for a high deductible plan. The MSA plan A/B bid reflects the expected risk profile of plan enrollees.

Benchmark. Per Section 1853(j) of the Act, the local MA standardized A/B benchmark is based on capitation rates for a geographic area (county). The benchmark calculation for an MA MSA plan is the same as for other local MA plans: the weighted average of county capitation rates in the plan's service area, weighted by plan projected enrollment per county.

The MA Organization will provide in the bid pricing tool the expected plan average risk score that informed determination of the allowed costs for the bid. The plan A/B benchmark is then calculated using the same formula as for other local MA plans: the plan-level projected risk score multiplied by the standardized A/B benchmark. The plan A/B benchmark is used in the Medicare MSA deposit calculation (see below). The benchmark constitutes the upper limit of Medicare's monthly payment for an MA plan enrollee.

Deposit calculation. 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 all MA plans under section 1853. The deposit into each Medicare MSA enrollee's account is calculated at the MSA plan service area level, and it reflects the plan's projected plan average risk score:

Uniform lump sum deposit = (plan A/B benchmark minus the plan A/B bid), annualized

An MSA plan cannot charge a basic beneficiary premium (see Section 1854(b)(1)(B)), and cannot offer a mandatory supplemental benefit (see Section 1852(a)(3)(A)). An MSA plan may not offer Part D coverage, although MSA plan enrollees may enroll in a PDP. Any non-Medicare-covered benefits must be offered as optional supplemental benefit(s). The MA Organization would submit a separate bid amount for these optional supplemental benefits as part of the June bid submission.

See Section IV.C. for information on payments for MSA plans, and Section XIV for general information on MSA plans.

H. *Submission of Bids by Demonstration Plans*

Some demonstration plans will submit bids for Medicare-covered, mandatory supplemental, prescription drugs, and other benefits. These bids will be submitted in a manner that appropriately reflects the unique features of the demonstrations.

I. *Profit Margins*

CMS will review the reasonableness of various components of plan bids, including the profit component. CMS will use a statistical approach to assess whether a given plan's profit margin is fairly representative of the range of values expected by most plans. MA Organizations and Part D Plans that submit plan bids with profit margins outside of this range will be asked to further justify their values, and the results will be considered accordingly.

CMS would allow varied gain/loss margins for separate bids offered by an organization, under certain circumstances. The margin variability must be based on bid-specific factors such as risk margins, surplus requirements, taxes, and other key factors used in the development of the organization's aggregate gain/loss requirement. CMS will allow negative profit margins in certain circumstances, such as for new market entrants. However, we would not normally allow a plan to have negative profit margins over an extended period of time or without a business strategy that projects positive margins in future years.

For 2007, the gain/loss margin will be allocated proportionally between the plan's A/B bid and mandatory supplemental benefits on Worksheet 4 as will non-medical expenses. See the Instructions for the 2007 Bid Pricing Tool for details.

J. *Rebate Reallocation Rules, Including Premium Rounding*

See Attachment A for guidance on rebate reallocation. While much of Attachment A is based on guidance CMS released for CY 2006 bids, there is new guidance on premium rounding and additional examples have been incorporated.

K. *Review of Multi Plan Offerings by MA Organizations in a Service Area*

In 2007, CMS is advising all MA Organizations to review the choices of MA plans that it proposes to offer beneficiaries. In 2006, some multiple plan offerings by MA Organizations are proving confusing because some beneficiaries are unable to make meaningful distinctions between the various plans. For 2007, MA Organizations must ensure that the array of MA choices presented in each service area can be reasonably evaluated and compared by beneficiaries in terms of cost sharing, provider networks, and benefit design, including part D offerings. MA Organizations must eliminate those MA and MA-PD plans that are substantially duplicative in terms of cost sharing, provider networks, and benefit design, including Part D offerings. It is expected that the cooperation of MA Organizations in this matter will enable beneficiaries to meaningfully select the MA plan that is best for them.

L. *Rules for New Mid-Year Plans and SAEs for SNPs*

For purposes of the annual competitive bidding process, SNPs are like other Coordinated Care Plans and PFFS plans. The law imposes the same basic bidding and payment rules for SNPs as for other types of coordinated care plans. Both SNPs and non-SNP plans compete to enroll dual eligibles, institutionalized beneficiaries, and beneficiaries with chronic diseases. If SNPs were allowed to offer new mid-year plans or service area expansions (SAEs) in areas where there are plans already approved under the annual competitive bidding process, it would undermine the integrity of that bidding process. Any plan entering a market mid-year would have the advantage of knowing what the Part C and D benefit packages are in the market area, and would know the national Part D average bid, etc.

The rules for new mid-year plan entry and service area expansions (SAEs) are stated below, and these apply to all MA plans.

There are two basic criteria informing our policy on new mid-year plans and SAEs for all MA plans. Any mid-year new plan or SAE must satisfy both criteria. In a year when there is a national PDP being offered, no MA-PD plan, including SNPs, can come in mid-year because criterion 2 cannot be satisfied.

1. An MA Organization may offer a new mid-year plan or SAE only if that plan's bid is not included in a competitive benchmark calculation required by the MMA.
2. An MA Organization may offer a new mid-year plan or SAE only if there are no competitors in the geographic area(s) the new plan would serve.

There is an additional complexity to criterion 2:

- The determination of whether a new mid-year MA-PD plan or SAE of an MA-PD plan would undermine the integrity of annual competitive bidding

is whether there are other Part D competitors in the area. This means other MA-PD plans or Stand-Alone PDPs.

- The determination of whether a new mid-year MA-only plan or SAE of an MA-only plan would undermine the integrity of annual competitive bidding is whether there are other MA competitors (either MA-only or MA-PDs or both).

M. *Low Income Subsidy for Full Benefit Dual Eligibles Leaving Long Term Care Facilities*

CMS is exploring whether changes in the institutionalized status of a full-benefit dual eligible enrollee could generate a change in the Part D cost-sharing levels in our systems. This would allow plans to prospectively assess the appropriate cost-sharing to full-benefit dual eligibles who leave LTC facilities and reside in community settings for the remainder of the plan year. CMS is considering the feasibility of implementing this change in 2007 and will notify Part D Sponsors of any development on this issue in separate guidance.

N. *Cost-Based Plan Bidding*

Cost-Based Plans that will offer Part D as an optional supplemental benefit must submit complete Part D bids and information on A/B benefits (the MA PBP) on or before June 5, 2006. Cost-Based Plans that will not offer Part D are strongly encouraged to submit information on A/B benefits (the MA PBP) on or before August 5, since without a PBP submission cost-based plan information will not appear in Medicare Compare or in the Medicare and You Handbook. Cost-Based Plans that do not offer Part D are permitted to offer non-Part D prescription drug coverage to their members as an optional supplemental benefit.

O. Calculation of Low Income Premium Subsidy Amount

If an MA-PD plan's service area crosses two PDP regions, there are two different low-income premium subsidy amounts applicable to the plan premium. Generally, the rules would require the reallocation of two different amounts of Part C rebate dollars to reach the target premium, and allocating the rebate amount required for the PDP region with the lower subsidy would "waste" rebate dollars in the PDP region with the greater subsidy amount.

In this circumstance, CMS waives the provisions of Part D that result in a separate low-income premium subsidy amount for each PDP region for local MA-PD plans with service areas bridging more than one PDP region that targeted the low income subsidy premium amount. We believe this waiver is necessary in order to improve coordination of Part C and Part D benefits. This improved benefit coordination results from the ability of the plan to maximize the utility of MA rebates in providing additional MA benefits, which generally include non-Medicare covered services aimed at filling gaps in Medicare coverage, such as supplies, equipment and

professional services utilized in home infusion therapy. Such services improve the coordination of A, B and D benefits. Instead of two (or more) applicable subsidy amounts, CMS will compute a single low-income premium subsidy amount equal to a plan-enrollment-weighted average of the regional low-income premium subsidy amounts, with the enrollment weights taken from the same reference month used to compute the regional amounts.

IV. ***Payment***

A. *Reporting of Manufacturer Rebates in Part D*

We seek to clarify previous guidance on the pass through of rebates between a pharmacy benefit manager (PBM) and a Part D sponsor. This guidance clarification applies to contracted as well as captive (i.e., PBM is owned by the PDP Sponsor) relationships.

Under 42 C.F.R. 423.329(c), a Part D enrollee who incurs costs above the annual out-of-pocket threshold will pay minimal coinsurance or copayments. CMS subsidizes a portion of the increased cost to the Part D plan through reinsurance payments equal to 80 percent of "allowable reinsurance costs" attributable to the "gross covered prescription drugs costs" incurred above the out-of-pocket threshold. The definitions at 42 C.F.R. 423.308 specify that incurred costs are only allowable if they are "actually paid." The definition of gross covered costs excludes administrative costs. The definition of "actually paid" includes only actually incurred costs that are net of "any direct or indirect remuneration (including 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."

Part D Sponsors contract with PBMs for various services related to the administration of their Part D plans, including negotiating rebates from drug manufacturers on behalf of the Part D Sponsors. We must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D Sponsor, the direct payment the Sponsor pays the PBM for its services will be less, i.e., the Sponsor receives a price concession from the PBM. If the PBM passes through to the Part D Sponsor all manufacturer rebates, and charges the Sponsor directly for the full cost for the PBM's services, the charge would be an administrative cost that must be deducted from gross covered prescription drug costs. If, instead, the PBM retains a portion of the manufacturer rebates, and charges the Part D Sponsor less, or even nothing, for the services, this price concession must be deducted from the Sponsor's incurred costs to determine the costs "actually paid." We assume for purposes of calculating allowable reinsurance costs that the value of this price concession equals the portion of the manufacturer rebates retained by the PBM.

Because the calculation of gross covered prescription costs requires the Part D Sponsor to deduct from its costs both administrative costs and any price concessions

it receives, the Part D Sponsor should have the same gross covered prescription drug costs, and thus allowable reinsurance costs, regardless of what proportion of PBM services are paid for directly by the Sponsor (an administrative cost) and what proportion of services are compensated through manufacturer rebates retained by the PBM (a price concession).

Section 1860D-15(d)(2) of the SSA requires full disclosure to CMS of any information necessary for carrying out the payment provisions of Part D, including reinsurance payments. Accordingly, a Part D Sponsor is required to report 100% of the remuneration it receives, including any price concessions for PBM services. CMS expects that Part D Sponsors will take necessary steps to comply with this requirement, such as negotiating PBM contracts that ensure reporting of 100% of the manufacturer rebates paid for drugs provided under the Sponsor's Part D plan, including the portion of such rebates retained by the PBM as part of the price concession for the PBM's services. While specific contract provisions are at the discretion of the plan sponsor, best practices suggest the combined use of a 100% reporting requirement with an auditing clause in any contract with a PBM. Q&A ID#5002 06/21/2005 reflected that for the 2006 coverage year, contracts were already in effect that may not have included such provisions. However, for the 2007 coverage year, plans are expected to take whatever actions are necessary to comply with the statutory reporting requirements.

Note that this guidance in no way precludes CMS or OIG auditing of Sponsor and PBM records to determine that direct or indirect remuneration (DIR) has been appropriately allocated and reported.

B. *Disclosure of Rebates to Long-Term Care Pharmacies*

CMS has been examining the payment of access/performance rebates by pharmaceutical manufacturers to LTC pharmacies that participate in Part D plan LTC pharmacy networks. The term "access/performance rebates" refers to rebates manufacturers provide to pharmacies that are designed to prefer, protect, or maintain that manufacturer's product selection by the LTC pharmacy or to increase the volume of that manufacturer's products that are dispensed by the pharmacy under its formulary (referred to as "moving market share"). We have significant concerns about the continued payment of these rebates to LTC pharmacies that are providing covered Part D drugs and LTC pharmacy services as part of a Part D plan's network. We believe the MMA clearly contemplates that in the Part D context, formularies are to be managed by the Part D plans themselves.

In order to create a cost-effective Medicare prescription drug benefit, the MMA relies on the ability of Part D Sponsors to negotiate maximum price concessions from pharmaceutical manufacturers on behalf of Medicare beneficiaries, and to provide beneficiaries access to the negotiated prices. Negotiated prices must reflect price concessions for covered part D drugs, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remuneration. See Section 1860D-2(d)(1)(B). The

MMA requires Part D Sponsors to disclose to the Secretary the aggregate negotiated price concessions "made available to" the sponsor "by a manufacturer." See Section 1860D-2(d)(2).

Therefore, when a LTC pharmacy that is part of a Part D plan's network continues to receive access/performance rebates from a manufacturer with respect to drugs dispensed to Part D enrollees, we believe that the principles of MMA described above clearly contemplate that the rebates will inure to the benefit of the Medicare beneficiaries who purchase those drugs. This will not occur unless there is full disclosure to the Part D Sponsor that these rebates are being paid.

To the extent that a LTC pharmacy is being paid by a manufacturer to move market share in the context of a Part D plan without the knowledge or approval of a Plan, not only does this raise the same concerns about increased program and beneficiary costs, but if a manufacturer is paying price concessions to LTC pharmacies in exchange for formulary access or moving market share, the LTC pharmacy may be inducing demand for higher-tiered or non-formulary drugs and thus actually increasing the costs to the plan and the government.

We believe that the clear intent of Congress, as demonstrated in the framework of these MMA provisions, is that the benefits of discounts, rebates, and other price concessions on covered Part D drugs provided by Part D plans should accrue to beneficiaries. When discounts, rebates, or other price concessions that relate to Part D drugs purchased for enrolled beneficiaries are diverted to entities other than Part D plans, it increases costs to the Medicare Trust Fund and to Medicare beneficiaries. Given that Medicare will pay nearly 100 percent of the costs of the drug benefit for institutionalized individuals, we believe the only position that is consistent with the intent of the MMA with respect to LTC pharmacies that are part of a Part D plan's network, is that rebates or other price concessions paid based on covered Part D drugs purchased with these dollars should accrue to the government.

Given the critical role Part D plans will play in allowing access to the most competitively priced drugs and moving market share on drugs for which rebates were – prior to the MMA – negotiated directly between manufacturers and LTC pharmacies, it is unclear to what extent, if any, LTC pharmacies play an appropriate role as independent agents in moving market share on behalf of manufacturers. Furthermore, rebates or discounts paid to LTC pharmacies to provide access or move market share in the context of Part D could create significant fraud and abuse concerns, including potential Federal anti-kickback concerns under section 1128B(b) of the SSA [42 U.S.C. § 1320a-7b(b)].

Section 423.153(b) of the Final Rule requires Plan Sponsors to establish a reasonable and appropriate drug utilization management program that (1) Includes incentives to reduce cost when medically appropriate: (2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and (3)

Provides CMS with information concerning the procedures and performance of its drug utilization management program according to guidelines specified by CMS.

As part of this drug utilization management programs, CMS expects Plan Sponsors to maintain policies and systems to prevent over-utilization. Given the vulnerability of the LTC Plan enrollees and the strong potential for over-utilization of prescribed medications that exists in the LTC setting when a drug manufacturer is paying the pharmacy access/performance rebates for moving market share in the LTC setting, Plan sponsors must have policies and systems in place to protect beneficiaries and reduce costs when LTC pharmacies are subject to these types of incentives. For the purposes of managing and monitoring drug utilization, to the extent that Plan Sponsors allow such incentives to be utilized by contracting LTC pharmacies, Plan Sponsors shall include a provision in all LTC pharmacy contracts that requires pharmacies to fully disclose any and all discounts and rebate arrangements with or any other direct or indirect remuneration from, drug manufacturers or other parties when such remuneration is designed to or likely to directly or indirectly influence or impact utilization of Part D drugs. Such disclosure shall detail the source of the funds, the purpose and the specific dollar amounts paid to the pharmacy from the manufacturer for these purposes. In the event that pharmacies' information on rebates is not based on claims, pharmacies will develop a per-unit rebate calculation that the plans can use to equate to claims utilization data. Part D Sponsors may require pharmacies to indemnify them for the full amount of any such payments not disclosed to the Sponsor. Part D Sponsors should assure pharmacies that this information will remain confidential. CMS will specify in further guidelines the specific information CMS will require from Plan Sponsors concerning the procedures and performance of this aspect of the Sponsors' drug utilization management program.

C. *MSA Plan Payment*

CMS pays an MA organization for each Medicare Advantage MSA plan enrollee as follows:

> Standardized A/B benchmark * enrollee's risk factor [per Section 1853(a)(1)(B)(iii) of the Act] minus 1/12th of the annual lump sum deposit [per Sections 1853(a)(1)(A) and Sec. 1853(e)].

The Intra-Service Area Rates (ISAR) adjustment does not apply to MSA plans (per Sections 1853(a)(1)(B)(iii)) and 1853(a)(1)(F)(ii), as it does to other local MA plans. Thus, the bid is not converted to plan-specific county payment rates.

CMS' deposit into an enrollee's account is a uniform amount for each MSA plan enrollee (because the bid must be uniform for the service area and the benchmark is uniform to the service area). The uniform deposit reflects the plan's expected average risk score. CMS' monthly payment to the MA organization for each enrollee varies based on the risk factor of the respective enrollee.

D. *Medicare Secondary Payer Processing and the Coordination of Benefits Contract*

1. *Background*

Plans are currently required to survey their members to identify their Working Aged and MSP members. This data is sent to CMS in September of each year. CMS uses this information along with data obtained from the Common Working File (for nonrespondents) to compute contract-level factors. In 2005, the data received from the plans were sent to CMS via disk and this information was then uploaded into a "Working Aged Database." Working Aged Factors were sent to each plan in December in order to verify factors for the January 2006 payment calculation. For data collection in 2007 (for 2008 payment), CMS will move to a more electronic process utilizing the Part D Coordination of Benefits (COB) survey.

2. *Coordination of Benefits (COB) Survey Process*

The Part D COB survey is sent to each beneficiary 30 days after enrollment. The information that is received from these surveys is sent to the COB contractor GHI who forwards the raw data to a system which electronically validates the information. Once validated, this information is stored in the Medicare Beneficiary Database (MBD) and the Common Working File (CWF). Going forward, plans must survey all of their non-ESRD members, as identified in the March Monthly Membership Report (MMR). Results must be sent to GHI by September 1 of each year in order to be in place for computation of the next year's contract-level factors.

E. *Special Payment Rule for Federally Qualified Health Centers (FQHCs) Contracting with MA Organizations*

See section 1861(aa) of the Act for a definition of FQHC services. Also see the second section 1853(a)(4) and 1857(e)(3)

For FQHC services provided to enrollees of MA Organizations on or after January 1, 2006, CMS is required to pay a wrap-around payment to contracting FQHCs if all applicable requirements are met. One requirement is that an MA Organization pays the FQHC under a written contract the same amount that the MA Organization would pay other providers for similar services. If all requirements are met, CMS will pay an additional amount to make the FQHC "whole," up to the equivalent of the "all inclusive rate" the FQHC receives for covered FQHC services under original Medicare.

Any non-contracting FQHC providing services to the enrollees of MA plans is not entitled to an FQHC supplemental payment because the statute requires a written agreement between the plan and the FQHC in order for the special wrap-around payment to be invoked. However, if the FQHC becomes part of the network through an executed contract with the MA Organization sponsoring the plan, then the FQHC

would be potentially eligible for wrap-around payments from CMS for services provided to plan enrollees receiving services on dates on or after the date the written contract is executed.

MA Organizations are free to contract with FQHCs, but they are not required to do so for FQHC services. The Medicare law explicitly prevents CMS from mandating the entities with which MA Organizations contract to provide services. In order to ensure that requirements for enrollee access to needed services are met, MA Organizations are also able to request capacity limits on their enrollment if their network is not large enough to care for additional enrollees. We believe this change in the law may help facilitate contracts between MA plans and FQHCs.

F. *Essential Hospital Payments*

The category "Essential Hospital" was created by Congress under the MMA in connection with the Regional PPO program. Non-contracted hospitals may be designated essential by an RPPO if certain criteria are met. Essential hospitals must provide emergency services consistent with EMTALA to all individuals.

If an essential hospital provides inpatient services (emergency and non-emergency) to an RPPO enrollee, the hospital may be entitled to a bonus payment from CMS. This bonus payment is in addition to the out-of-network payment amount that the hospital will receive from the RPPO. The out-of-network payment amount from the RPPO plus the RPPO member's in network cost sharing is equal to the amount that the hospital would have been authorized to receive for inpatient services under Part A of Medicare.

Congress set aside $25 million in 2006 for essential hospital bonus payments (with an annual increase for inflation in subsequent years). Should that fund be exhausted prior to the end of the contract year, an essential hospital would remain designated as an essential hospital for the remainder of the contract year. Essential hospitals would still be paid as an out-of-network provider and in-network cost sharing would continue to apply for the RPPO enrollees. However, no additional essential hospital bonus payments would be made for the rest of that year.

To request the essential bonus payment for inpatient services provided to an RPPO enrollee, the essential hospital will submit a claim to the designating RPPO for payment. The RPPO will process the claim, make appropriate payment at the Medicare Fee-For-Service rate, then will forward the claims information to a CMS contractor, Noridian, to process and pay the additional bonus payment, if one is due. The hospital does not need to submit a separate claim for the bonus payment.

Bonus payments will be calculated as follows:

1) Total allowable costs will be calculated by applying the hospital's current inpatient operating and capital cost-to-charge ratios to the billed charges

2) Total allowable costs will be increased by one percent to calculate the total amount potentially due the hospital.

3) The total costs plus one percent less the amounts reported by the RPPO as paid to the hospital and less beneficiary liability for cost sharing equals the balance due to essential hospitals for the bonus payment.

No information beyond the initial claim submission will be required from the essential hospital for purposes of 422.112(c)(5). Noridian will utilize the hospital's cost-to-charge ratios from its last submitted or settled cost report, whichever is the most recent, to calculate the hospital's costs and determine whether it is entitled to a bonus payment for the inpatient services provided to the RPPO enrollee. If Noridian determines the essential hospital is due a bonus payment, the hospital will receive two payments – a base inpatient claim payment from the RPPO and the bonus payment from Noridian.

G. *"Bad Debt"*

MA Organizations are not required to pay plan cost sharing on their enrollees' behalf.

V. ***Benefit Design***

A. *What is a benefit*

CMS defines MA plan benefits at 42 CFR 422.2:

A benefit is a health care service that is intended to maintain or improve the health status of enrollees, for which the MA Organization incurs a cost or liability under an MA plan (that is not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

All MA plans are required to provide coverage of services under Part A and Part B of original Medicare (42 CFR 422.101) with certain exceptions (such as hospice services) as specified in the rules. In addition, MA plans may provide supplemental benefits for their enrollees. There has been some uncertainty as to what constitutes supplemental benefits. We revised the Medicare Managed Care Manual on September 30, 2005 to distinguish coverable supplemental benefits from those which are not. We provided several examples of each type.

In order for an item or service that is not covered by original Medicare to qualify as an MA supplemental benefit:

1. The item or service must be health care related:
2. The MA Organization must incur a direct medical cost for this item or service in an MA plan;

3. The MA Organization must submit this item or service in its annual bid; and
4. CMS must approve the bid with this item or service.

Before the items and services identified below as generally health related supplemental benefits can be classified as MA benefits, all four prongs of the above definition must be met. Consequently, when MA Organizations do not incur direct medical expenses for items and services for which they negotiate discounts, such discounted items and services are not MA benefits and cannot be submitted or approved as part of the annual MA plan bidding process. For example, if an MA Organization has negotiated a discount with a health club for which it incurs no direct medical cost, then it cannot submit discounted health club membership as a benefit on its MA plan bid. Such a discounted health club membership can, however, be offered as a value added item or service (VAIS). See Section 5 of the Marketing Guidelines and Section V.B below.

All benefits must be directly health-related. Benefits are health care services or items whose primary purpose is to prevent, cure or diminish actual or future illness or injury for which the MA plan incurs a cost that is not solely administrative. The following are examples:

Generally Health Related Supplemental Benefits:

Caregiver Resource services are services that provide information and assistance to relatives or friends of enrollees who are spending significant time as caregivers to these enrollees. These services may be considered a health benefit provided that the service is primarily targeted to situations where actual or future illness or injury is present and the service prevents, cures, or diminishes this actual or future illness or injury. Organizations must carefully define the situations in which these services will be provided.

Electronic monitoring of beneficiaries, besides the electronic monitoring covered by original Medicare, is considered a health benefit, and may be offered by plans as a supplemental benefit, provided that the sole purpose of the electronic monitoring device is communication on health related issues. (Consequently, purchase of cell phones for beneficiaries would not be considered a health benefit since their primary purpose is general communication.)

Dentures: A plan may offer dentures as a supplemental benefit.

Transportation: Medicare covers medically necessary transportation provided other means of transportation are contraindicated. As a supplemental benefit MA plans may provide transportation to covered services, when such transportation would not be covered by Medicare. This transportation is classified as a health benefit since its sole purpose is to provide access to covered services.

Safety items: Items such as shower safety bars may be offered as supplemental benefits since their exclusive purpose is to prevent immediate injury.

Travel for Transplants: Although all benefits must be accessible from the service area, not all contracting providers must actually be located in the service area. For certain services that are not frequently used by MA plan enrollees, such as transplant services, CMS will permit MA Organizations to contract with providers that may be remote or distant from the service area. However, CMS will require MA Organizations that use or contract with remote or distant transplant facilities, where more accessible providers are present that could have provided the service, to ensure that continuity of care by: (1) Providing reasonable transportation for the member and a companion to the remote facility; and (2) Providing reasonable accommodations for the member and a companion while present in the remote location for medical care.

Not Generally Health Related — Not Supplemental Benefits:

Homemaker services are not primarily medical in nature and therefore cannot be offered by an MA plan as a supplemental benefit. Homemaker services include such items as laundry, meal preparation, shopping, or other home care services furnished mainly to assist people in meeting personal, family, or domestic needs.

Beauty items: Hair care and salon benefits may not be offered as a supplemental benefit since they are not primarily health related. Similarly the provision of wigs for purely cosmetic purposes is not classified as a health benefit and consequently a plan may not offer them as a supplemental benefit. However MA plans may offer wigs to replace hair lost to cancer or leukemia treatment as a supplemental benefit.

Meals: To be classified as a health-care benefit under the MA program the nutritional service must be based on an underlying medical need, or reason, that requires either home delivery of meals, a special diet, or special diet foods. Social factors by themselves, such as limited income, or an inability to pick up meals cannot justify a classification of a nutritional service as an MA benefit. The provision of "meals" or "meal vouchers" to individuals, without an underlying health care need, cannot be classified as a health care benefit, because food is not primarily health-care related in nature.

B. *Value-Added Items and Services (VAIS)*

Value-Added Items and Services (VAIS) are items and services a plan offers to enrollees that do not meet the definition of benefits under the Medicare program and involve only administrative or minimal cost. VAIS may not be funded by Medicare program dollars. If VAIS services are discontinued at the end of a year, plans must notify enrollees in a timely manner. VAIS must be offered for the entire contract year. VAIS may be of value to some enrollees, and we do not wish to deprive MA enrollees of access to items and services commonly available to commercial enrollees. Therefore, MA Organizations may offer VAIS to Medicare enrollees, but

materials describing VAIS must clearly distinguish between VAIS and MA benefits, including clarifying that VAIS are not subject to the MA appeal procedures.

1. Health-Related VAIS

Health-related VAIS are intended to maintain or improve the health status of enrollees, where MA Organizations incur an administrative or minimal cost that is not included within their bid to CMS. Examples of health-related VAIS are discounts on eyeglasses and health clubs. Organizations are permitted to contact Medicare beneficiaries about VAIS health-related items and services provided by the organization without prior written authorization to the extent permitted under the HIPAA Privacy Rule.

2. Non Health-Related VAIS

Non health-related VAIS are not intended to improve or maintain the health status of enrollees, and the cost incurred by the Organizations is usually only administrative and is not included within the Organization's bid to CMS. Furthermore, to the extent required under the HIPAA Privacy Rule, Organizations must receive prior written authorization from Medicare beneficiaries before contacting them regarding non health-related VAIS items and Services.

Value-added items and services may also be offered by Medicare Cost-Based Plans. However, VAIS are non-covered services for which neither Cost-Based Plans nor MA Plans are reimbursed.

C. *Paying Premiums*

All plans must offer the option to enrollees of having their premiums deducted electronically from their Social Security payment; similarly, all plans must offer the option to enrollees of having their premiums deducted by an electronic-funds transfer mechanism, such as, for example, automatic charges of an account at a financial institution or a credit or debit card account. However, plans may not charge or provide a discount for these options. Furthermore, plans may not require electronic payment of premiums. All plans must allow premiums to be paid by monthly checks. Note: As in CY 2006, all beneficiaries enrolled in EGWPs in CY 2007 are ineligible for premium withhold from their Social Security payments.

D. *Mid-Year Benefit Enhancements*

CMS is reviewing its current policy on Mid-Year Benefit Enhancements as stated in the preamble to the rule implementing the Medicare Modernization Act amendments (see 70 FR 4587, 4639) (January 28, 2005)). Additional guidance will be forthcoming.

E. Cost Sharing Guidance

MA regulatory requirements specify that organizations may not design benefit packages that discourage enrollment or encourage disenrollment of severely ill or chronically ill beneficiaries. Consequently, CMS will not approve a bid if it determines that either the plan's cost sharing or deductible structure discriminates based on health status. CMS will closely scrutinize the cost-sharing and deductible structures of all plans.

Working with the CMS Office of the Actuary, we determined that an appropriate annual out-of-pocket (OOP) cap for original Medicare covered services, excluding monthly basic premium, is $3,100 for contract year 2007. This amount represents the 75th percentile of OOP costs for beneficiaries in original Medicare. This recommended maximum applies to Coordinated Care plans including regional MA plans.

CMS offers the following guidance for cost sharing for plans with Out of Pocket (OOP) maximums:

- If the plan's OOP max is not greater than $3,100: These plans will be granted latitude in establishing cost-sharing amounts for individual services;
- If the plan's OOP max is greater than $3,100: These plans will be granted less latitude in establishing cost-sharing amounts for individual services.

F. *Changes to the Plan Benefit Package (PBP) Software & Summary of Benefits (SB)*

CMS has implemented the following enhancements to the PBP/SB software in support of the Contract Year (CY) 2007 bid season:

- One of the PBP Section A notes field has been removed. Additionally, the PBP Section B general notes fields have been removed; the service category notes fields still remain.

- In the PBP Section B1 – Inpatient Hospital, cost share fields (coinsurance and copayment intervals) have been added for the 60 Medicare-covered lifetime reserve days.

- In PBP Section B6 – Home Health, the enhanced benefit data entry for "Homemaker Services" has been removed.

- In PBP Section B-14a – Health Education/Wellness, the pick-list for enhanced benefits has been adjusted to only include: Written health education materials (including newsletters), Nutritional Training (the provision of training to members that is focused on understanding the importance of nutrition/diet as it relates to a specific health need (ex., lowering cholesterol via diet),

Nutritional Benefit(the provision of food or other "nutritional" items/supplements to members primarily to meet the health specific needs of an individual (diabetic for ex.), Smoking Cessation, Alternative Medicine Program, Membership in Health Club (Fitness Classes), Nursing Hotline and Other.

- The Point of Service (POS) screens have been moved from PBP Section B19 to PBP Section C.

- In the PBP Section C, the out-of-network benefits data entry screens were revised to remove questions about maximum plan benefit coverage, maximum enrollee out-of-pocket cost, some deductibles, and pre-authorization/pre-notification.

- In the PBP Section C, data entry screens were added to collect information about reductions in cost sharing for members that voluntarily pre-notify or voluntarily obtain prior authorization for out-of-network services.

- In the PBP Section C, data entry screens were added to collect information about US and foreign based visitor/travel programs. The visitor/travel program questions were removed from PBP Section A.

- In the PBP Section D, the plan premium and Part B premium reduction data entry fields will be disabled for plans that submit a BPT as part of their Bid Submission. These data will be solely collected in the BPT. For plans that do not submit a BPT, this data will still be collected in the PBP.

- In the PBP Rx Section (Part D Prescription Drugs), data entry screens were added to collect information about gap coverage for plans electing to offer the Enhanced Alternative Part D benefit type. New SB sentences have been created to describe the benefits covered in the gap.

- In the PBP Rx Section (Part D Prescription Drugs), data entry screens were added to collect information about first dollar generic drug coverage for plans electing to offer the Enhanced Alternative Part D benefit type.

This list is not intended to represent the entire set of modifications made to the CY2007 PBP/SB software. CMS implemented these software changes in response to CMS policy and operational clarifications and the numerous comments and suggestions made by industry during the CY2006 lessons learned comment period.

G. *National Coverage Determination (NCD) and Legislative Change in Benefits*

As stated in section 1852(a)(5) of the SSA and 42 CFR 422.109(b), if CMS determines and announces that an NCD meets the significant cost criteria, an MA Organization is not required to assume risk for the costs of that service or benefit until

the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits.

CMS makes payments on a fee-for-service basis for services directly to the providers for a specified period of time until the payments to the MA plans are appropriately adjusted to take into account the cost of the new coverage. MA organizations must then furnish, arrange, or pay for these services and benefits and MA plan enrollees will be liable for the plan's cost sharing for these services.

Thus far this year, no services or benefits have been identified that have met the significant cost criteria necessitating that payments to the MA organizations be appropriately adjusted and effective January 1, 2007.

H. *Over-the-Counter Supplemental Benefit*

1. *Drugs and Related Health Benefits*

Neither Part C of the Social Security Act which governs the MA program nor implementing regulations at 42 CFR Part 422 specifically address coverage of OTC drugs and related health benefits (such as Band Aids). For calendar year (CY) 2007, CMS will be clarifying its interpretation of supplemental benefits to include coverage of OTC benefits under Part C.

2. *Diabetic Supplies*

Diabetic supplies associated with the injection of insulin, specifically syringes, needles, alcohol swabs and gauze are now covered under Part D. Therefore MA Organizations may not provide coverage of these items under Part A or Part B authority as "over-the-counters" (OTCs) or supplementary benefits within plan packages, but would cover them under Part D authority.

I. *Lifetime Reserve Days*

In previous years, the PBP identified the Medicare-covered inpatient hospital benefit as 90 days of coverage per benefit period. However, at 1812(a)(1) the Social Security Act describes the Medicare inpatient hospital benefit as 150 days of coverage per benefit period, to the extent the Medicare beneficiary uses his/her 60 lifetime reserve days to obtain coverage for days 91 - 150. In addition, 42 CFR 409.61(a)(2) makes clear that each beneficiary has 60 Lifetime Reserve Days for the Inpatient Hospital benefit.

To ensure that the Inpatient Hospital coverage available under Medicare is provided appropriately, Lifetime Reserve Day (LRD) variables have been added to the Inpatient Hospital service categories within the PBP. Since Medicare Advantage organizations must provide, at a minimum, the same coverage as original Medicare in all MA plans offered, the changes to the PBP are now consistent with original

Medicare. Data entry within these fields is not optional, MA organizations must offer Medicare covered benefits.

J. *Guidance on Appropriate Use of PBP Notes*

The PBP software provides mandatory and optional Notes fields to add text within each health care item or service category when the Plan's benefits cannot be clearly expressed in the regular data entry sections of the PBP. PBP notes should be used **only** when mandatory or when needed to clarify a benefit offered by the MA Organization. Further, notes may be used to provide clarity on supplemental benefits, when the standard data entry fields do not generate standardized Summary of Benefit sentences. Notes may not be used to limit coverage of Medicare covered benefits captured in the regular data entry sections. CMS will review all Notes fields in the PBP submissions to assure that MA Organizations do not limit or otherwise exclude aspects of the covered benefits captured in the regular data entry section. CMS will require coverage of benefits inappropriately limited in the notes section.

K. *Cash*

An MA Organization may not provide cash to an MA plan enrollee as an inducement for enrollment or for any other purpose. Except for cost-sharing, a plan may not require a beneficiary to pay a contracted provider and then get reimbursed.

Cash reimbursement to a member for health care services covered and paid by the member while out-of-country is allowed. Further, in situations where the MA Organization has not been able to contract with providers, such as for Transportation to Medicare-covered services, Vision, Dental and/or Hearing benefits the member may be directly reimbursed for covered services for which s/he paid. However, MA Organizations should be aware of their obligations at §422.100. Specifically, MA Organizations should; 1) have contractual arrangements in place with providers or, 2) reimburse non-contracted providers directly.

L. *MA Deductible Guidance*

1. *High Deductibles*

High deductible are a key feature of MA MSA plans. However, high deductibles in other plan types may indicate a discriminatory benefit design. CMS will scrutinize high deductibles in other plan types.

2. *RPPO Single Deductible*

If Regional PPO plans have any deductible related to A/B services, they can have only a single, unified deductible. Regional PPOs may not have service category-level

deductibles related to Medicare Part A/B services. Note that this single, plan-level deductible applies to both in-network and out-of-network A/B services. At their option, MA Organizations offering Regional PPOs are permitted to include supplemental benefits in their single, plan-level deductible.

Section 1858(b)(1) of the Act reads:

> An MA regional plan shall include the following: (1) Single Deductible.--Any deductible for benefits under the original Medicare fee-for-service program option shall be a single deductible (instead of a separate inpatient hospital deductible and a Part B deductible) and may be applied differentially for in-network services and may be waived for preventative or other items and services.

The regulation is found at 42 CFR §422.101(d)(1):

> (d) Special cost-sharing rules for MA regional plans. In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following: (1) Single deductible. MA regional plans, to the extent they apply a deductible, are permitted to have only a single deductible related to combined Medicare Part A and Part B services (to the extent they have a deductible). Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

M. *Medicare-Covered Flu and Pneumococcal Immunizations*

Section 422.100(g)(2) says that MA Organizations may not impose cost-sharing on their MA plan enrollees for influenza and pneumococcal vaccines. Both of these vaccines are covered under Part B, as is the hepatitis B vaccine – when risk of exposure has occurred.

CMS, as a public health agency, is strongly encouraging people with Medicare to receive preventative immunizations and strongly encouraging health care providers to provide them to Medicare beneficiaries. We require MA Organizations to also provide or arrange for coverage of influenza and pneumococcal and other Part B-covered vaccines in facilities in which their members reside.

MA Organizations are required to provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and B of Medicare that are available to fee-for-service beneficiaries residing in the plan's service area – see 42 CFR 422.101(a). It would be inconsistent with regulatory requirements if an MA Organization to impose cost sharing for flu or pneumonia vaccines if a plan enrollee is a resident of an institution (or homebound, in the case of an individual receiving covered home health care). Therefore, out-of-pocket liability cannot be associated with obtaining these immunizations for MA enrollees under these conditions. If we determine that the MA Organization is not arranging to provide (or pay) for covered

services, we will treat this as evidence that reasonable in-network accessibility to such services is not being provided. Under these circumstances, the plan will be responsible for paying such non-network providers for the shots they provide on behalf of the MA Organization.

VI. ***Enrollment***

A. *Overview of Election Periods*

The MA election periods are described in detail in Chapter 2 of the Medicare Managed Care Manual. It is important to highlight the timeframes for the annual coordinated election period (AEP) and the various open enrollment periods in 2007:

MA Election Period	**Effective Date**
Annual Coordinated Election Period (AEP): The AEP is from November 15, 2006 through December 31, 2006.	January 1, 2007.
Open Enrollment Period (OEP): In 2007 and in years the OEP is January 1, 2007 through March 31, 2007. Eligible individuals may make one election to the same type of plan with regard to Medicare prescription drug coverage. For example, an individual enrolled in original Medicare and a PDP may elect an MA-PD, but may not elect an MA-only (not an MA-PD) plan during the OEP. **IMPORTANT INFORMATION REGARDING DISENROLLMENTS DURING THE OEP:** If an individual wants to enroll in another MA plan, he/she simply submits an enrollment to the new MA plan; which results in disenrollment from the current MA plan. If an individual no longer wants to be enrolled in the MA-PD and wants to be in original Medicare, the individual cannot submit a disenrollment election to the MA-PD during the OEP. Instead, the individual MUST enroll directly with the PDP and this action will automatically disenroll the individual from the MA-PD plan. Only MA-only plans may accept disenrollment requests during the OEP.	OEP elections are effective on the 1st of the month following the month in which the election was made.
Open Enrollment Period for Newly Eligible Individuals (OEP NEW): In 2007, an individual who becomes MA eligible during 2007 may make **one** MA OEP-NEW election during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of entitlement, or on December 31, 2006, whichever occurs first, subject to the limitations described above for the OEP. An OEP-NEW election is separate from an OEP election.	OEP-NEW elections are effective on the 1st of the month following the month the election was made.

B. *New Special Election Periods (SEP)*

CMS has established the following two new SEPs, effective immediately:

1. Individuals who are enrolled into an MA-PD or PDP by an SPAP

State Pharmaceutical Assistance Programs (SPAP) may have authority under state law to make enrollment decisions on behalf of its members. Individuals enrolled in a plan by their SPAP have an SEP to make one change to enroll in a different PDP or MA-PD at any time through the end of the calendar year.

2. SEP for Individuals who Qualify for the Low Income Subsidy (LIS) Because They Have SSI or Applied for LIS at SSA

CMS is establishing an SEP for these individuals to choose a PDP or MA-PD plan on their own outside of existing enrollment periods. If no choice is made, the CMS/plan facilitated enrollment will take effect and the beneficiary can then use the SEP to change plans.

The SEP will begin on the date that the individual is notified of his/her LIS status, or the date that the facilitated enrollment is effective, whichever is earlier. The SEP continues until such time as the individual chooses a PDP or MA-PD on his/her own--the SEP would end when that enrollment is effective. Thus, for individuals who makes no choice before their facilitated enrollments occur, there is an ongoing SEP through November 15, 2006 under which they could make an alternative plan choice. Proof of eligibility for this SEP may include the subsidy award letter from SSA or the state, or notice from CMS informing beneficiary that s/he has been deemed eligible for the subsidy and enrolled in plan. The effective date for enrollments under this SEP will be prospective, effective the first day of the month following receipt of the enrollment request by the plan.

C. *Encouraging Early-in-Month Enrollments*

In early 2006, CMS issued guidance to PDP Sponsors suggesting that they encourage beneficiaries to enroll in a PDP early in the month. Enrollments early in the month give MA Organizations and PDP Sponsors time to update their systems, and mail important information like a membership card, acknowledgement letter, and welcome package to enrollees before their coverage becomes effective. In these cases, even if a beneficiary goes to the pharmacy on the first day of coverage, they can get their prescriptions quickly and accurately.

Enrollments later in the month make it far less likely that all of the information needed to file the claim correctly will be available at the pharmacy or other provider office or the MA Organization/PDP Sponsor. In those instances, the MA Organization/PDP Sponsor should provide the enrollee with some extra information to help manage expectations and help the beneficiary successfully fill prescriptions

and access needed covered services. This information includes instructions on appropriate documentation to bring to the provider or pharmacy (e.g., acknowledgement letter, plan welcome letter, enrollment confirmation number, a Medicare or Medicaid card, or other information about the plan in which the beneficiary has enrolled).

D. *Creditable Coverage & Late Enrollment Penalty*

With respect to each continuous period of 63 days or more following a beneficiary's initial enrollment period (IEP) for Part D, CMS may impose a late enrollment penalty (LEP) upon a beneficiary. The late enrollment penalty amount is based on the number of "uncovered" full calendar months after the end of the IEP. An uncovered month is a month in which the beneficiary had none of the following:

(1) Medicare prescription drug coverage (i.e., coverage through a Medicare plan that provides prescription drug coverage or coverage through a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare);
(2) Coverage through another type of plan actuarially determined to be creditable prescription drug coverage.

As of the date of this publication, the LEP will be assessed as 1% of the current year's national base beneficiary premium for each "uncovered" month during the plan year. [Note: Even if a beneficiary with an LEP enrolls during the Annual Election Period (November 15th – December 31st), his or her LEP will continue through December 31st of that year because his enrollment will not become effective until January 1st of the next year.]

Because CMS only has information about beneficiary enrollment in Medicare prescription drug plans, MAOs will be required to review creditable coverage documentation and report to CMS information upon which CMS will determine whether a late enrollment penalty applies, and if so, the penalty amount. Requiring MA-PDs to review creditable coverage documentation will allow each beneficiary an opportunity to present evidence that his prescription drug coverage was creditable. Without MA-PD involvement in creditable coverage review, it is more likely that the beneficiary would be penalized erroneously or penalized the wrong amount due to incomplete information. It is CMS' intent that in the future, an information system will be developed to (1) automate the capture of broader types of creditable coverage and (2) capture each beneficiary's historical record of creditable coverage such that MA-PDs will only need to request and assess creditable coverage documentation since the beneficiary's last enrollment in a Medicare prescription drug plan and under more limited circumstances than necessary today.

Specifically, beginning in July 2006, Part D Sponsors will be required to query the Batch Eligibility Query (BEQ) or the Medicare Beneficiary Database User Interface (MBDUI) to receive:

(1) the end date of the beneficiary's Part D IEP, and
(2) periods of enrollment in a Medicare plan that provides prescription drug coverage, and
(3) periods of enrollment in a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare.

Using BEQ or MBDUI data, Part D Sponsors must determine whether a beneficiary had any gaps of 63 days or more from the end of his or her Part D IEP to the proposed effective date in which the beneficiary did not have Medicare prescription drug coverage or other creditable prescription drug coverage. If at least one gap exists, the Sponsors must review the creditable coverage section of the enrollment form, including any evidence of creditable coverage the beneficiary provides. MA-PDs will be required to review creditable coverage evidence such as:

- a copy of a personalized disclosure notice from the covering entity, or
- a copy of a generic creditable coverage disclosure notice from the covering entity, with some sort of proof of beneficiary coverage, such as an identification card, a bill, or a summary plan notice, etc., or
- a model Personalized Disclosure Form that allows beneficiaries to provide Part D plans with written confirmation of creditable coverage at the time of enrollment or upon appeal.

Additional types of evidence may also be acceptable provided that the combined evidence contains proof that (1) the beneficiary's coverage was creditable and (2) that the beneficiary was enrolled in such coverage. CMS reserves the right to modify or add to the types of evidence of creditable coverage that Sponsors must review.

If the beneficiary provides insufficient information with the enrollment form, the Sponsor will be required to notify the beneficiary (model language will be available). The notice must explain the LEP, the type(s) of creditable coverage evidence needed to avoid a penalty, and the deadline, currently 60 days from the beneficiary's effective date, for providing such evidence to the MA-PD. Initially, the MA-PD will default to report to CMS that the beneficiary had no uncovered months. The purpose of the MA-PD reporting no uncovered months as a default is to provide the beneficiary an opportunity to submit evidence of creditable coverage without the risk of CMS charging a late enrollment penalty. If no creditable coverage evidence is provided within 60 days, the beneficiary will be noted and reported as such by the MA-PD as not having creditable coverage for any months not covered by a Medicare prescription drug plan or a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare. Upon receipt of acceptable creditable coverage evidence by the deadline, and in conjunction with data from the BEQ/MBDUI, the MA-PD will be required to assess the total number of uncovered months. MA-PDs will send the number of uncovered months to CMS via MARx. CMS will advise the MA-PD of any applicable monthly late enrollment penalty amount.

Upon notifying a beneficiary of any LEP determination, MA-PDs will advise the beneficiary of the right to ask for a review of CMS' LEP decision. CMS intends to have LEP-related appeals reviewed by an independent review entity, with final decisions issued by the Secretary or his or her designee. If the beneficiary disagrees with an LEP decision made by CMS, or believes that he/she was not adequately informed of the creditable coverage status pursuant to §423.56(g), the beneficiary may request reconsideration of that decision under a process established by CMS through operational guidance. MA-PDs must assist beneficiaries, for example, by making relevant documentation available to support the individual's case, such as notices or other materials related to the initial LEP decision. Additional specific guidance, model letters, and instructions will be provided in the Medicare Prescription Drug Benefit Manual.

Completion of the above set of activities will not delay enrollment of the beneficiary into the Part D Plan. MA-PDs will have a certain amount of time to complete this process post-enrollment. In some instances, therefore, beneficiaries may have to pay retroactive LEP amounts.

All MA-PDs will be required to collect LEPs through the beneficiary's payment of premium unless the premium is paid through Social Security withholding. An MA-PD will be required to collect LEPs even if its premium is $0. Depending on the beneficiary's income level and low income subsidy qualifying status, CMS may subsidize a portion of a beneficiary's LEP for a period of time. Since the LEP is considered part of the premium, MA-PDs must bill the LEP at the same time as the premium. MA-PDs will have the option, however, to bill Zero premium Plan enrollees for the late enrollment penalty on an other-than-monthly schedule with the beneficiary's consent. CMS believes that most beneficiaries with zero premium plans will choose to have any late enrollment penalties deducted from their Social Security checks; however, CMS will not allow sponsors to require such deductions.

As communicated in the preamble to the Final Rule, in the initial years of the program, CMS will keep the full amount of the late enrollment penalty. In later years CMS will specify, and the MA-PD may be able to keep, the portion of the penalty attributable to the MA-PD's increased actuarial costs.

Given that August 1, 2006 is the first effective date at least 63 days after May 15, 2006, August 1 is the earliest that CMS may impose an LEP for uncovered months (in this case, June and July).

Please refer to the Medicare Prescription Drug Benefit Manual for detailed guidance on the late enrollment penalty and MA-PD responsibilities in making creditable coverage determinations.

E. *Cost-Based Plan Enrollment Policy*

1) Enrollment periods: Cost-Based plans must be open for enrollment for a period of at least 30 consecutive days as described in the Medicare Managed Care Manual, Chapter 17, Subchapter D. Cost-Based plans may offer a Part D plan as an optional supplemental benefit. Individuals who want to enroll in this optional supplemental benefit must also enroll in the Cost-Based plan. Enrollment in this optional supplemental benefit must occur during a Part D plan enrollment period (refer to "PDP Enrollment and Disenrollment Guidance"). Individuals enrolled in a Cost-Based plan and its optional supplemental Part D plan who disenroll from the Cost-Based plan are automatically disenrolled from the optional supplemental Part D plan. Such individuals may enroll in another Part D plan only during established Part D enrollment periods.

2) Enrollment forms/mechanisms: The only option available to individuals to enroll in a cost plan is a written enrollment form. A cost plan that wants to integrate its enrollment processes for its cost plan and an optional supplemental Part D benefit that it offers may do so on a single paper enrollment form, provided that all elements for Part D enrollment outlined in section 30 in the PDP enrollment and disenrollment guidance are met.

The cost plan may also offer separate procedures for current members to select the Part D option at a separate point in time and through alternative mechanisms allowed for Part D plans (e.g. telephone or internet) with the exception of enrollment through 1-800-MEDICARE or the CMS Online Enrollment Center. Any subsequent enrollments in the Part D benefit can only be done during applicable enrollment periods, as outlined in section 20 of the PDP guidance mentioned previously.

VII. ***Quality***

A. *Quality Improvement Projects*

Beginning January 1st, 2006, MA plans will be responsible for selecting and initiating quality improvement projects on topics relevant to their population. Plans will no longer annually submit these projects via the QAPI module in the HPMS system, rather plans will report their projects using a Word template which they will submit directly to a QI project reviewer (to be determined later) once every three years in advance of their routine CMS compliance audit. The reporting template will be provided to plans in first quarter 2006. For more information about Quality Improvement project requirements, please consult Chapter 5 of the Medicare Managed Care Manual.

The new requirements are listed in Chapter 5 of the Managed Care Manual. This can be found at: www.cms.hhs.gov then click on Medicare, click on Health Plans general information, click on Quality in Managed Care.

B. *PPO and Cost-Based Contractor Quality Measurement*

Local and Regional PPOs are required to collect and submit HEDIS measures starting in 2008 for services covered in 2007 for all enrollees. The measures under Effectiveness of Care are: Breast Cancer Screening, Osteoporosis management in women with history of fracture, persistence of beta blocker treatment after a heart attack, cholesterol Management for patients with cardiovascular conditions (not all measures required), comprehensive diabetes care (not all measures required), use of Spirometry testing in the assessment and diagnosis of COPD, follow-up after hospitalization for mental illness, anti-depressant medication management, glaucoma screening in older adults, disease modifying anti-rheumatic drug therapy in Rheumatoid Arthritis, annual monitoring for patients on persistent medications, drugs to be avoided in the elderly. The measures under Access to/Availability of Care are: Access to preventive/ambulatory health services, initiation and engagement of alcohol and other drug dependence treatment, call answer timeliness, call abandonment. There is one measure under Health Plan Stability which is, years in business/total membership. The measures under the Use of Services are: frequency of Selected Procedures, Inpatient Utilization – General Hospital/Acute Care, Ambulatory Care, Inpatient Utilization – Non-Acute Care, Mental Health Utilization, Chemical Dependency Utilization, Identification of Alcohol and Other Drug Services, Outpatient Drug Utilization, antibiotic utilization. The measures under Health Plan Descriptive Information are: Board Certification, total enrollment by percentage, enrollment by product line, enrollment by State, race/ethnicity diversity of membership, language diversity of membership. Particular specifications of each measure can be obtained from the health plans HEDIS vendor.

CMS will not publicly report the PPO HEDIS data in 2007.

Cost-Based Contractors are required to collect and report HEDIS measures. These measures are similar to the HMOs. The difference from the Cost-Based contract requirements and the HMOs are in the Use of Service Measures. In the Use of Services measures, the cost plans have the following three measures to report: ambulatory care, outpatient drug utilization and antibiotic utilization.

C. *Special Needs Plans Quality Measurement*

Dual eligible and chronic condition Special Needs Plans (SNPs) are required to meet all of the MA requirements for collecting HEDIS, CAHPS and HOS. CMS is considering a set of measures for the chronic condition SNPs that are more meaningful to this targeted population.

Institutional SNPs will not be reporting HEDIS. CMS will extract the Minimum Data Set measures that are used for nursing homes by the Medicare program for evaluation purposes.

If the MA-PD has fewer than 1000 enrollees as of July 1 of the reporting year (2007 for 2008 reporting) then HEDIS is not required to be reported. There are no minimum enrollment requirements for CAHPS and HOS. If the health plan has fewer than 1000 enrollees, all of the enrollees would be surveyed for the HOS.

D. *Medicare Advantage Deeming*

Beginning January 1st, 2006 all accrediting organizations previously authorized to deem PPOs may deem Local PPOs only. Although additional areas of deeming pertaining to Part D subject matter were announced in the latter half of 2005, CMS has not incorporated these Part D areas into the current MA deeming program, and none of the current accrediting organizations' deeming authority extends to the Part D areas. For more information about the MA Deeming program, please consult Chapter 5 of the Medicare Managed Care Manual.

E. *Chronic Care Improvement Program (CCIP) Reporting*

Beginning January 1st, 2006, MA plans will be responsible for implementing and reporting on Chronic Care Improvement Programs. Plans will submit information about their CCIPs using a Word template in advance of their routine monitoring visits. The reporting template will be provided to plans in first quarter 2006. For more information about CCIP requirements, please consult Chapter 5 of the Medicare Managed Care Manual.

VIII. ***Marketing***

A. *Plan Submission and CMS Review of Marketing Materials*

Organizations may begin submitting Contract Year (CY) 2007 marketing materials (e.g., Summary of Benefits (SB) and Annual Notice of Change (ANOC)) on June 6, 2006, which is the day after the deadline for bid submission. Beginning June 6, 2006 all marketing materials must be submitted via the HPMS Marketing Module. The regional office will review the materials and approve or disapprove. Organizations that do not have a final CMS contract approval will receive a "conditional approval" on marketing materials. The organization may not use conditionally approved marketing materials for marketing purposes. Once the contract is approved, marketing materials will convert from a conditional approval to approved status. For marketing materials that are disapproved, the organization may revise and submit to the regional office. There can be no marketing of those materials until approval on the materials is granted.

After CMS approves the MA Organization's bid, any necessary changes to the conditionally approved or approved marketing materials must be resubmitted to CMS based on the CMS approved bid/PBP. If there were no changes to the bid, the organization does not need to resubmit these marketing materials. The organization must clearly highlight only changes that result from the approved bid/PBP. This will

ensure a timely review of the final materials. If an organization fails to submit materials timely or to clearly highlight changes in the submitted materials, then it is at risk of not being able to market by October 1, 2006.

In order for an organization to be able to market its plans, it is essential that it follow the review process found in the Marketing Guidelines.

B. *Co-Branding Requirements for CY 2007*

Co-branding is defined as a relationship between two or more separate legal entities, one of which is a sponsoring organization. The sponsoring organization displays the name(s) or brand(s), or both, of the co-branding entity or entities on its marketing materials to signify a business arrangement. Co-branding arrangements allow an organization and its co-branding partner(s) to promote enrollment into the Plan.

Based on feedback from beneficiaries and the health care industry, co-branding names and/or logos of contracted providers (pharmacies, physicians, etc.) placed on a plan's member identification card and other marketing materials may be confusing to enrollees. The provider co-branding names and/or logos may unintentionally convey a message that beneficiaries can only use the co-branded providers, rather than all participating providers listed in the plan's provider or pharmacy directory.

Organizations are reminded that beneficiaries must have access to a list of participating providers via each plan's provider or pharmacy directory, which, at a minimum, is required to be provided to enrollees at the time of enrollment and on the plan's Web site. Organizations should also reinforce that beneficiaries may use the MPPF, MPDPF, call 1-800-MEDICARE, contact the plan, and/or speak with providers to determine what providers participate with a specific plan.

Effective with the beginning of CY 2007 marketing (October 1, 2006), entities that contract with a provider or providers as co-branding partners will not be permitted to place co-branding names and/or logos on the member identification card. In addition, organizations will be required to include the following language located below all co-branding names and/or logos on applicable marketing materials:

Other <Pharmacies/Physicians/Providers> are available in Our Network

This statement will apply to any entity included in the organization's provider network (i.e., pharmacies, physicians, and providers). Organizations will be required to ensure that all existing marketing materials are compliant with these requirements for CY 2007. Organizations that co-brand with State Pharmaceutical Assistance Programs (SPAPs) and/or non-provider entities will be permitted to continue placing those co-branding names and/or logos on all marketing materials (including the member identification card).

C. *Customer and Provider Telephone Contact Standards*

CMS has updated for 2007 performance standards for certain customer service and provider contact telephone line operations.

Current and Prospective Enrollee Call Center:

During annual enrollment (i.e., November 15, 2006 to December 31, 2006) through 60 days past the beginning of CY 2007 (i.e., January 1, 2007 to March 1, 2007), sponsors will be required to operate a toll-free call center for both current and prospective enrollees that operates seven days a week at least from 8:00 A.M. to 8:00 P.M. according to the time zones for the regions in which they operate. During this time period, current and prospective enrollees must be able to speak with an individual.

However, from March 2, 2007, until the following annual enrollment period, sponsors are permitted to use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays, and holidays. For example, a PDP Sponsor may use an interactive voice response system or similar technology to provide the required information listed below, and allow a beneficiary to leave a message in a voice mail box. A customer service representative must then return the call in a timely manner, no later than within one business day.

The call center must provide information on at least the following: thorough information about benefits, including co-payments, deductibles, network pharmacies, respond to inquiries about claims processing, benefit coverage, claims submission, claims payment, and provide daily access to current TrOOP status.

The call center must have an explicit process for handling customer complaints.

The call center must provide service to non-English speaking and hearing impaired beneficiaries.

The call center must meet the following operating standards:

- 80 percent incoming calls must be answered w/in 30 seconds.
- Abandonment rate of all incoming calls not to exceed 5 percent.

Pharmacy Technical Help Call Center

Sponsors must operate a toll-free pharmacy technical help call center to respond to inquiries from pharmacies and providers regarding the applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission and claims payment. The call center must operate during the entire period during which the sponsor's network pharmacies in their plans' service areas are open. Note that sponsors whose pharmacy networks

include 24-hour pharmacies must operate their pharmacy technical help call centers 24 hours a day as well.

The call center must meet the following operating standards:

- 80 percent incoming calls must be answered w/in 30 seconds.
- Abandonment rate of all incoming calls not to exceed 5 percent.

Exceptions and Appeals Call Center

Sponsors must operate a toll-free call center to respond to physicians and other providers for information related to exceptions and prior authorizations as well as beneficiary appeals. The call center must operate during normal business hours and never less than 8:00 a.m. to 6:00 p.m., Monday through Friday according to the time zones for the regions in which they operate.

Voicemail may be used provided the message:

1) indicates that the mailbox is secure;
2) lists the information that must be provided so the case can be worked (e.g., provider identification, beneficiary identification, exception (or appeal, if appeals call) being requested, whether an expedited exception (or appeal, if appeals call) is being requested;
3a) for exceptions calls: articulates and follows a process for resolution within 24 hours of call for expedited coverage determination requests (including exceptions requests), 72 hours for standard coverage determinations,
3b) for appeals calls: articulates and follows a process for resolution within 72 hours for expedited appeals, and 7 calendar days for standard appeals; and
4) provides and follows a process for immediate access in situations where an enrollee's life or health is in serious jeopardy.

D. *Marketing Material Identification Systems*

Beginning in CY 2007, all organizations will be required to place on all marketing materials the CMS contract number as part of their unique material identification number. For non- File & Use materials, the identification number developed must include a place holder for the CMS material approval date (the date that appears on the CMS approval notice). The contract number and unique material identification number must be printed on the front page of the Summary of Benefits, and the Evidence of Coverage. In addition, the member identification card must include the contract number and Plan Benefit Package (PBP) number.

File & Use marketing materials must also include the CMS contract number and a unique material identification number. However, these materials will not require a placeholder for the CMS material date, since File & Use materials are not subject to a prospective marketing review.

CMS will provide specific guidance on this issue in a future update of the Medicare Marketing Guidelines.

E. *Use of Model Documents*

For certain pre- and post enrollment documents, CMS has developed model language that will entitle the organization to a 10-day marketing review period. Organizations that submit model marketing materials (e.g. EOC, ANOC) to CMS for review must use the model without modification except in bracketed areas. Model marketing materials that do not follow the model language will be reviewed within 45-days rather than the 10-day time frame. Even if the organization chooses not use the model language, it must include all required elements as outlined in the Medicare Marketing Guidelines.

The use of CMS model language is optional. However, organizations are strongly encouraged to use model documents in order to receive a 10-day review.

F. *Marketing of Contract Year (CY) 2006 Plans*

All organizations must cease using public media to market CY 2006 plans beginning October 31, 2006. If the organization begins marketing its CY 2007 plans between October 1 and October 31, 2006, it must cease using public media to market the CY 2006 plans on the day it begins marketing the CY 2007 plans. "Public media" includes billboards, radio, TV, print advertisements and direct mail.

Renewing plans must maintain their CY 2006 Web site content and may continue to present and send out CY 2006 plan information for individuals who specifically ask for it. Plans may continue to enroll individuals for effective dates before January 2007, based on an individual's election period and on other requirements of the law, regulations, and previously issued guidance. If a prospective enrollee inquires about the 2006 plan, the organization should provide the individual with both CY 2006 and CY 2007 plan information so that the individual is fully informed about changes that will take place on January 1, 2007.

In general, MA Organizations and Cost-Based plans must submit all remaining CY 2006 marketing materials to CMS by no later than June 30, 2006. This deadline will allow CMS to complete its CY 2006 reviews and begin focusing resources on the review of CY 2007 marketing materials. In unique and very limited circumstances an organization may need to have CY 2006 marketing materials reviewed after June 30, 2006. In those cases, the organization should contact its regional office to discuss its rationale as to why an exception should be granted.

Effective October 1, 2006 all MA Organizations and Medicare Cost-Based plans must include disclaimers in CY 2006 marketing materials whenever they advertise a CY 2006 benefit, formulary, pharmacy network, premium, or co-payment that may or will change effective January 1, 2007, or whenever it accepts an election for an

effective date in 2006 on or after November 1, 2006. MA-PDs must include disclaimers in CY 2006 marketing materials whenever they advertise a CY 2006 formulary and pharmacy network. The disclaimer is not required if the organization knows that its benefits will not change in 2006. The disclaimer must be in the form of an attachment or an addendum to all marketing materials, including advertisements and election forms, and must alert potential members that changes will occur effective January 1, 2007. Plans that will not change in 2007 are not required to use the disclaimer.

The following model disclaimer may be used by organizations with benefit changes in 2007. Additional regional office review and approval is not required if this disclaimer is used verbatim, but is required if it is modified.

> [Insert any or all of the following, whichever is appropriate:
> Benefits, formulary, pharmacy, network premiums and/or co-payments/co-insurance may change on January 1, 2007.]
> Please contact [insert organization name] for details.

G. *Marketing of CY 2007 Plans*

Beginning October 1, 2006 all organizations and Medicare Cost-Based plans may begin using approved or File and Use accepted CY 2007 marketing materials. Organizations must have an approved bid prior to marketing CY 2007 plans. At a minimum, the following materials (if applicable) must be reviewed and approved, and/or appropriately submitted and accepted under File & Use Certification, in accordance with the marketing guidelines by October 1, 2006: Web site content, Summary of Benefits, comprehensive formulary, pharmacy directory and an Annual Notice of Change (if applicable). All organizations must begin using approved CY 2007 marketing materials no later than October 31, 2006.

While marketing can begin on October 1, 2006, an MA organization may not accept any annual coordinated election period (AEP) requests prior to November 15, 2006. Pursuant to section 30 of Chapter 2 of the Medicare Managed Care Manual, individuals must make elections during a valid election period. Requests received outside of a valid election period must be denied. CMS encourages all plans to be explicit about this information in all plan marketing materials.

All marketing presentations and all mailings to Medicare beneficiaries concerning CY 2007 enrollment (annual election period) must include a Summary of Benefits (SB) describing CY 2007 benefit package information.

H. *CY 2007 Annual Notice of Change (ANOC)*

The ANOC highlights the specific changes in Medicare and plan benefits, plan premiums, and plan rules effective January 1, 2007. CMS will provide a model ANOC by June 1, 2006. The Summary of Benefits (SB) must be included with the

mailing of the ANOC. MA-PDs must include an abridged or comprehensive formulary with the mailing of their ANOC and SB.

All organizations, including those operating under demonstration authority, must ensure that members receive the ANOC with the SB and abridged or comprehensive formulary by October 31, 2006. Medicare Cost-Based plans must ensure that members receive the ANOC (with the SB) by December 1, 2006.

Please refer to the "2007 MA, MA-PD and Medicare Cost-Based Plan Renewal Calendar" for the time frames for submitting SBs and abridged or comprehensive formularies to the regional offices for review. The time frames were established to ensure that organizations submit ANOCs, SBs, and formulary documents in time to have them reviewed, approved, printed, and received by members by the October 31, 2006 (for MA Organizations) and December 1, 2006 (for Medicare Cost-Based plans) deadlines.

I. *CY 2007 Summary of Benefits (SB)*

All organizations and demonstrations must send a standardized SB to individual members with the ANOC.

All Medicare Cost-Based plans must send an SB to all members with the ANOC. They are not required to use the standardized SB. However, if a Medicare Cost-Based plan intends to have its plan in the Medicare Personal Plan Finder, it must complete the Plan Benefit Package (PBP) and create a standardized SB.

General instructions for the SB are included in the Medicare Marketing Guidelines.

Please refer to the "2007 MA, MA-PD and Cost-Based Plan Renewal Calendar" for the time frames related to submitting SBs into the regional offices for review. The time frames were established to ensure that organizations submit ANOCs and SBs in time to have them reviewed, approved, printed, and received by members by the October 31,2006 (for MA Organizations) and December 1, 2006 (for Cost-Based plans) deadlines.

Under unique circumstances, an organization may need to make a hard copy change to its standardized SB. The Medicare Marketing Guidelines summarizes the process for requesting such changes.

Any changes to organization and plan information (e.g., Customer service number, plan name, or other plan information) can be changed through HPMS by the organization/plan.

J. *CY 2007 Evidence of Coverage (EOC)*

All MA Organizations and Cost-Based plans must mail CY 2007 EOCs to all plan members no later than January 31, 2007. MA-PDs must include the Low Income Subsidy Rider (LIS) rider with the mailing of their EOCs. Organizations must mail CY 2007 EOCs to new members no later then when they notify the member of acceptance (confirmation) of enrollment. Time frame requirements for sending notices of acceptance of enrollment are contained in the enrollment and disenrollment guidelines.

The HMO, PPO, Cost and PFFS model EOCs will be available by August 1, 2006. Use of the model EOC without modification language is not mandatory; however, it will facilitate a 10-day review of the EOC.

Please refer to the "2007 MA, MA-PD and Cost-Based Plan Renewal Calendar" for timeframes related to submitting EOCs to the regional offices for review. The time frames were established to ensure that organizations submit EOCs in time to have them reviewed, approved, printed, and mailed to members by the January 31, 2007 deadline.

K. *Web Site Content*

MA-PDs and Cost-Based plans offering Part D are required to provide certain CY 2006 information on a Web site for members and prospective enrollees as defined in the Marketing Guidelines. Renewing contractors will be required to also provide CY 2007 Web site content for members and prospective enrollees by October 1, 2006. Information for both CY 2006 and CY 2007 must be accessible and organized in a way that is easily understood by the beneficiary. Web site content is considered marketing material and must be submitted to CMS prior to use in accordance with the Medicare Marketing Guidelines.

L. *Medicare Personal Plan Finder and Medicare Prescription Drug Plan Finder Data*

Starting October 12 the CY 2007 health plan data will appear on the "Medicare Personal Plan Finder" (MPPF). All plans covering Part D prescription drugs will also have CY 2007 prescription drug data displayed on the "Medicare Prescription Drug Plan Finder," tentatively starting October 12, 2006. Out-of-pocket cost data, which was not included in the MPPF for CY 2006, will again be displayed on the site. In addition, the "Medicare Personal Plan Finder" will continue to include charts displaying several HEDIS and CAHPS measures, as well as disenrollment reasons data for the MA plans.

This year, CMS will also be redesigning the MPPF. The redesign will include navigation changes as well as simplification of benefit descriptions. Also, MA-only plans will be able to offer online enrollment through the MPPF beginning with CY

2007. CMS will provide the industry with the opportunity to comment on benefit description changes in the spring of 2006.

Plans are expected to preview their plan data for MPPF in September 2006. The first preview period will be September 15 – 19. The second preview period will be September 25 – 26. If there are any issues with the data, plans can notify CMS at compchart@cms.hhs.gov.

M. *Medicare & You 2007*

The Medicare & You 2007 handbook will contain health plan benefit and Medicare prescription drug plan comparison information. This information may be similar to the health plan information provided in the Medicare & You 2006 handbook released last fall. One CAHPS measure will be included in Medicare & You 2007 handbook. Plans will be able to preview their handbook plan data September 8 through 11.

N. *Member ID Cards and Other Wallet Cards*

With the proliferation of MA PFFS and PPO plans and the possible introduction of MSA plans in 2007, many MA enrollees are self-referring to providers that do not have a contractual relationship with the MA plan in which they are enrolled. Therefore, from both a beneficiary protection and provider access standpoint, MA plan members and the non-contracting providers that treat them need to have ready access to plan payment and cost sharing information. Therefore, MA plans that provide coverage of routine care from non-network providers (including MSA, PFFS, and PPO plans) PPOs are strongly encouraged to provide members with wallet cards which list their non-network networking cost sharing responsibilities. The card should also say what the MA Organization will pay (in combined member cost sharing and MA Organization reimbursement) the amount that original Medicare would have paid. We also encourage such plans to also say that non-network providers cannot bill more than they would have billed (including permitted balance billing), had the beneficiary been an original Medicare enrollee. (See sections 1866(a)(1)(O) and 1852(k) of the Social Security Act.) The wallet card should also have a telephone number to call for plan payment and member cost sharing information, in case there are questions. Where an MA Organization has a website (see CFR 422.112(f)(12)), the URL, that includes the SB (Summary of Benefits) and EOC (Evidence of Coverage) should be noted..

Information on cost sharing for frequently used non-network services should be included on the wallet card including; emergency department copay; primary care and physician specialist copays; hospital copays; SNF copays; home health copays; DME copays and outpatient hospital department copays.

IX. ***Appeals/Grievances***

A. *Notification Procedures for Hospital Discharges – Intention to Publish Proposed Rule*

Currently, pursuant to 42 CFR 412.42(c)(3), a hospital must provide a Hospital-Issued Notice of Non-coverage (HINN) to any original Medicare beneficiary who expresses dissatisfaction with an impending hospital discharge. Similarly, 42 CFR 422.620 requires MA Organizations to provide enrollees with a Notice of Discharge and Medicare Appeal Rights (NODMAR) when an enrollee disagrees with a discharge decision or when the MA Organization (or hospital by delegation) is lowering (removing from inpatient) the enrollee's level of care.

CMS intends to propose new regulations that would set forth new requirements for hospital discharge notices under both original Medicare and the MA Program. Specifically, CMS intends to propose to require hospitals that are discharging patients from the inpatient hospital level of care to comply with a two-step discharge notice process that is quite similar to the processes described at 42 CFR 422.624-626 and 42 CFR 405.1200-1204, that currently apply to skilled nursing facilities (SNFs), comprehensive outpatient rehabilitation facilities (CORFs), and home health agencies (HHAs).

B. *Manual Guidance for Part D Plan Sponsors*

CMS has developed guidance in Chapter 18 of the Prescription Drug Benefit Manual regarding a Part D plan sponsor's responsibilities concerning Part D grievances, coverage determinations, and appeals. Additionally, the entity responsible for reviewing Part D reconsiderations (MAXIMUS) developed the Part D QIC Reconsideration Procedures Manual, which contains additional guidance concerning how Part D plan sponsors must coordinate with the Part D QIC to assist it in processing Part D reconsiderations and conducting related reconsideration activities. Part D plan sponsors must develop Part D grievance, coverage determination, and appeals procedures in accordance with the guidance contained in Chapter 18 of the Prescription Drug Benefit Manual and the Part D QIC Reconsideration Procedures Manual. MA plans, MA-PD plans and Cost-Based plans are also responsible for developing grievance, organization determination, and appeals procedures that involve Part C benefits in accordance with the guidance contained in Chapter 13 of the Managed Care Manual.

X. *Systems*

A. *HPMS*

1. Using HPMS to Submit Bids and Formularies

MA Organizations will use HPMS to electronically upload plan formularies and bids to CMS. Cost-Based plans will be required to use HPMS to electronically upload plan formularies and bids if they are offering the Medicare Part D benefit to their members. As with past years, Cost-Based plans may also voluntarily submit Plan Benefit Packages (PBP) if they wish to have their plan benefits displayed in the Medicare & You handbook and on Medicare Personal Plan Finder (MPPF).

MA Organizations and Cost-Based plans will upload their plan formularies to HPMS using a pre-defined file format and record layout. HPMS will begin accepting plan formulary uploads on March 27, 2006. Organizations may upload their formularies one or more times between March 27, 2006 and the formulary deadline of **5:00 p.m. EDT on April 17, 2006**. CMS will accept the last successful upload of each formulary received by this deadline as the official submission.

In order to prepare plan bids, organizations will use HPMS to define their plan structures and associated plan service areas and then download the PBP and Bid Pricing Tool (BPT) software. For each plan being offered, organizations will use the PBP software to describe the detailed structure of their benefit packages and the BPT software to define their bid pricing information. Each formulary submitted by April 17, 2006 must accurately crosswalk to a plan (or set of plans) defined during the bid process. The combination of the PBP and BPT for a plan comprises a bid.

For CCP and PFFS plans, once the PBP and BPT software has been completed for each plan being offered, organizations will upload their bids to HPMS. For MSA plans, organizations will use the HPMS functionality to upload the PBP, but for 2007 the BPT will be submitted to CMS outside of the HPMS upload functionality. CMS anticipates releasing the PBP and BPT bid upload functionality on **May 19, 2006**.

Organizations may upload their plan bids one or more times between May 19, 2006, and the CY 2007 bid deadline of **12:00 midnight PDT on June 5, 2006**. CMS will accept the last successful bid upload received for a plan by this deadline as the official bid submission for that plan.

CMS will provide detailed technical instructions upon release of the HPMS formulary and bid functionality as well as the PBP and BPT software.

2. *Instructions for Obtaining HPMS Access*

MA Organizations and Cost-Based plans have three alternatives for accessing HPMS:

- Internet access via a Secure Socket Layer Virtual Private Network (SSL VPN) using your corporate Internet Service Provider (ISP);
- T-1 lease line access via AT&T Global Network Services (AGNS); or
- Dial-up access via AGNS.

Internet users will access HPMS at https://gateway.cms.hhs.gov, whereas AGNS users will use http://32.91.239.68. All three methods require the use of a Microsoft Internet Explorer web browser and a CMS-issued user ID and password with access to HPMS.

If your organization requires assistance with establishing connectivity to HPMS, please contact Don Freeburger at either 410-786-4586 or Don.Freeburger@cms.hhs.gov. In order to obtain a CMS-issued user ID and password for HPMS access, please contact Neetu Jhagwani at either 410-786-2548 or Neetu.Jhagwani@cms.hhs.gov

B. *Required Use of the National Provider Identifier on Electronic Transactions*

The HIPAA Regulation, 45 CFR Part 162, subpart D, requires all health plans and providers to use the National Provider Identifier (NPI) as the only provider identifier on standard electronic transactions by May 23, 2007. Note that small health plans, as defined in 45 CFR Part 160.103 as plans with annual receipts of $5 million or less, have an additional year to be compliant. CMS may require some evidence of compliance.

XI. ***Compliance/Monitoring***

A. *Compliance Plan Requirements*

All MA Organizations are required to have a compliance plan in place as a condition of participation in the Medicare program. CMS, beginning in January 2007, will begin specifying key elements that must be included within the required components of the compliance plan described in 42 CFR § 422.503(b)(3)(vi). Compliance plans will be reviewed for these requirements as part of the regular monitoring/auditing of MA Organizations.

As of January 1, 2007, the requirements for compliance programs and plans are as follows:

(1) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards

CMS interprets this to require that MA Organizations have written standards of conduct for their Medicare business that clearly and unequivocally articulate the organization's commitment to comply with all applicable statutory, regulatory, and program requirements, and delineate the organization's expectations of employees involved with Medicare business to act in an ethical manner.

(2) Designation of Compliance Officer and Committee Accountable to Senior Management

In order for a Compliance Officer to be accountable to senior management CMS requires that the MA Organization designate a compliance officer who is employed at the organization holding CMS' Part C contract. This individual is accountable to senior management and has authority and independence within the organization as measured by the direct reporting access to the organization's senior management.

(3) Effective Lines of Communication between the Compliance Officer and Organization's Employees, Contractors, Agents, Directors, and Members of the Compliance Committee

CMS interprets effective lines of communication to require the MA Organization to demonstrate that it has in place mechanisms for the compliance officer to continually disseminate the compliance message in effective ways, (e.g., a newsletter, attendance at department staff meetings, visits to the various work units, intranet site, display posters, cafeteria table tents, or pop-up computer screen, etc.) to company leadership and employees.

(4) Effective Training and Education between the Compliance Officer and Organizations Employees, Contractors, Agents, and Directors

Effective training requires that all personnel, including contractors and agents, involved in Medicare programs receive general compliance training upon hire, or upon the initial adoption of a compliance program, and annually thereafter as a condition of employment. Documentation evidencing that this training has occurred shall be maintained by the organization or MA or PDP.

(5) Procedures for Effective Internal Monitoring and Auditing

CMS construes regulations requiring procedures for effective internal monitoring and auditing to require the organization have an internal audit plan identifying audits to be performed. [Note: CMS recognizes that this plan may change periodically.] Effective monitoring and auditing shall include the organization conducting a risk assessment regarding Medicare operations.

(6) Procedures for Ensuring Prompt Response to Detected Offenses and Development of Corrective Action Initiatives Relating to the Organization's Contract

The development of corrective action initiatives require that the organization has policies and procedures that ensure corrective action initiatives have been taken, implemented, and the detected offenses have been corrected.

(7) Enforcement of Standards through Well-Publicized Disciplinary Guidelines

CMS construes this regulation to require that written standards of conduct specify the disciplinary actions that can be imposed for non-compliance, including oral or written warnings or reprimands, suspensions, terminations, or financial penalties. The standards of conduct are approved by the organization's governing body or a committee of the governing body.

(8) Comprehensive Fraud and Abuse Plan to Detect, Correct, and Prevent Fraud, Waste and Abuse

MA Organizations that offer qualified prescription drug coverage (MA-PDs) are required to have a program to detect, correct, and prevent fraud, waste, and abuse as an element of their compliance plan. CMS plans to issue additional guidance in April 2006 to assist MA-PDs in the development of their fraud, waste, and abuse plans.

B. *Monitoring*

CMS is currently developing audit protocols for Special Needs Plans (SNP) and Regional PPOs (RPPOs). The Medicare Advantage (MA) Guide will contain additional elements for those MA Organizations that have SNPs. A new guide will be developed for RPPOs. CMS anticipates these guides will be ready for implementation in 2006.

The final version of the Part D Audit Guide will be released in the summer of 2006. CMS initially released a draft of the guide for industry review and comments in November of 2005. The final version of the guide will provide sponsors with the elements CMS will utilize while conducting regularly scheduled and focused audits.

C. *Medicare Advantage Deeming*

Beginning January 1st, 2006 all accrediting organizations previously authorized to deem PPOs may deem Local PPOs only. Although additional areas of deeming pertaining to Part D subject matter were announced in the latter half of 2005, CMS has not incorporated these Part D areas into the current MA deeming program, and none of the current accrediting organizations' deeming authority extends to the Part D

areas. For more information about the MA Deeming program, please consult Chapter 5 of the Medicare Managed Care Manual.

D. *Quality Improvement (QI) Projects*

Beginning January 1st, 2006, Medicare Advantage plans will be responsible for selecting and initiating quality improvement projects on topics relevant to their population. Plans will no longer annually submit these projects via the QAPI module in the HPMS system, rather plans will report their projects using a Word template which they will submit directly to a QI project reviewer (to be determined later) once every three years in advance of their routine CMS compliance audit. The reporting template will be provided to plans in first quarter 2006. For more information about Quality Improvement project requirements, please consult Chapter 5 of the Medicare Managed Care Manual.

E. *Chronic Care Improvement Program (CCIP) Reporting*

Beginning January 1st, 2006, MA plans will be responsible for implementing and reporting on Chronic Care Improvement Programs. Plans will submit information about their CCIPs using a Word template in advance of their routine monitoring visits. The reporting template will be provided to plans in first quarter 2006. For more information about CCIP requirements, please consult Chapter 5 of the Medicare Managed Care Manual.

XII. ***Special Needs Plans***

A. *Resources*

Resources available for the Special Needs Plans (SNP): The website at: www.cms.hhs.gov . Click on Medicare on the left. Click on Special Needs Plans under the Health Plan header on the left. This site will give you the latest guidance on up to date policy decisions. For information on the application process, refer to the instructions under the 2007 application review process in this call letter. For Marketing requirements, go to the same website. Click on Medicare on the left. Click on the Health Plan header on the left. Click on Managed Care Marketing.

B. *Deeming Continued Eligibility*

According to 42 CFR 422.52(d), a SNP enrollee who loses his or her special needs status, but who can reasonably be expected to regain that status within a 6-month period, will be deemed eligible for a period from 30 days through 6 months. The MA Organization sponsoring the SNP may choose any length of time within this range to deem a member eligible as long as it applies the criteria consistently among all members and fully informs members of its policy in writing in the Summary of Benefits and the Evidence of Coverage at the time of enrollment. During this deemed eligibility period the MA Organization must continue to provide all plan benefits.

This includes charging the deemed-eligible member the same premium and cost sharing as any other SNP-eligible member.

The MA Organization offering the SNP should take into consideration the length of time it will allow its members to be deemed-eligible when submitting its bid. This is because during the period of deemed-eligibility the MA Organization will be responsible for all services (at identical levels of cost sharing) that are covered for other enrollees that meet normal SNP eligibility requirements.

The health plan may change the length of its deemed eligibility period only once a year — at the time Annual Notices of Change are sent to members at contract renewal.

C. *Institutional SNPs*

For existing institutional SNPs, the MA Organization must set the enrollees' enrollment status at "I" for transmission to CMS each month. Additional tracking to confirm institutional status is not required. CMS will update its audit protocols accordingly.

XIII. ***Employer/Union-Only Group Waiver Plans (EGWPs)***

The following sections consist of various issues related to MA Organizations and Cost-PD Plan Sponsors who offer employer/union-only group waiver plans ("800 series" plans), and employers or unions that directly contract with Medicare to sponsor their own employer/union-only group waiver plans (Direct Contract EGWPs). These sections highlight important differences or clarifications on certain call letter topics.

A. *CY 2007 Timeline*

For CY 2006, all EGWPs (Direct Contract and 800 series plans) were subject to a different timeline than non-group plans for submission of applications, formularies, bids, etc. For the 2007 Contract Year, all EGWPs will be on the same timeline as non-group plans (applications, formulary submission, bidding, renewal and non-renewals, etc). The one exception to this rule will be for marketing materials and beneficiary communications. As outlined below, for CY 2007, CMS will continue to waive the requirement for prior review and approval of these materials (see Chapter 13 of the Medicare Marketing Guidelines). Therefore, none of these non-group marketing timelines will apply.

B. *Renewals*

All EGWPs (Direct Contract and 800 series plans) are subject to the same renewal process that applies to non-group plans.

C. *Bidding*

All EGWPs (Direct Contract and 800 series plans) are subject to the same bidding rules that were applied to these plans in CY 2006. These rules were set out in CY 2006 employer/union-only group waiver guidance.

For CY 2007, however, in addition to the option of submitting a bid based on Medicare fee-for-service benefit provisions and then enhancing the plan for different employers/unions, plans will have the option of bidding on a "composite" benefit package. Under this approach, each employer-only group bid must reflect the composite characteristics of the individuals expected to enroll in the plan for CY 2007. These assumptions include, but are not limited to, the following: risk scores, geographical distribution of enrollees, benefit package, non-medical expenses, and gain/loss margins.

For CY 2007, the same service area rules will apply to EGWPs that applied in CY 2006 (e. g., Service area for local CCP EGWP plans can be up to the state level). Service area restrictions have been automatically waived for all Direct Contract EGWPs. These plans have national service areas so they may cover retirees nationally. For PFFS EGWPs (800 series plans), the CY 2006 service area extension waiver granted to plans that are eligible (i.e., plans that are able to meet the "nexus" test) will be available for CY 2007. Please note that in order to allow coverage for retirees nationally in either Direct Contract or PFFS 800 series plans, CMS intends to automatically set all EGWPs service areas for CY 2007 to national service areas in HPMS in order to operationally allow these plans to cover retirees where ever they reside.

EGWP bids for PFFS plans may cover more than one MA region. In order to cover retirees where ever they reside, these plans must bid nationally as they did in CY 2006. With regard to providing sufficient Part D pharmacy access throughout the plan's service area, networks to cover these retirees must be in place prior to enrolling retirees.

For CY 2007, EGWP bids will continue to be excluded from the calculation of the Part D national average monthly bid amount and the low-income regional benchmark premium amounts. As in CY 2006, RPPO EGWPs will be included in the calculation of the CY 2007 MA Regional benchmark calculations.

D. *Payment*

All EGWPs (Direct Contract and 800 series plans) are subject to the same payment rules that were applied to these plans in CY 2006. These rules were set out in CY 2006 employer/union-only group waiver guidance.

With regard to Regional PPO EGWPs, the same payment rules for CY 2006 will apply to CY 2007. Thus, special bonus payments including, but not limited to Part C

risk sharing, regional stabilization fund payments, regional payment adjustments, and national bonus payments will not be available.

E. *Low-Income Subsidy*

The CY 2006 employer/union-only group waiver guidance for low-income subsidy beneficiaries will continue to apply for CY 2007. As in CY 2006, the base beneficiary premium (for CY 2006, $32.20) will be used as the plan premium (rather than the plan's premium as derived from their standardized bid) in the "lesser of" calculation for the low-income premium subsidy payment.

F. *Marketing/Beneficiary Communications*

The CY 2006 waivers for marketing and beneficiary communications will continue to apply in CY 2007. CMS has waived the prior review and approval requirements for marketing materials and enrollment forms for all EGWPs (Direct Contract and 800 series plans). *See* Chapter 13 of the Medicare Marketing Manual. Also, please note that the web site content requirements referenced in this call letter do not apply to 800 series plans. A waiver of these website requirements was granted in CY 2006 and will be continued for CY 2007. These plans are exempt from the requirement to post information on their website because these plans are not open to general enrollment.

G. *Formulary*

All EGWPs (Direct Contract and 800 series plans) are subject to the same formulary submission requirements that applied to these plans in CY 2006. As in CY 2006, after submission and approval of a base formulary, EGWPs may enhance the formulary (add new drugs or change cost sharing) without having to resubmit the formulary for review and approval by CMS. These formularies may not be modified to remove any drugs from the list, or to add any restrictions or limitations unless these modifications or removals are otherwise consistent with CMS requirements.

H. *Pharmacy Access*

The CY 2006 waiver of the TRICARE retail pharmacy access standards contained in 42 CFR 423.120(a) will continue to apply for all Part D EGWPs (Direct Contract and 800 series plans) in CY 2007. EGWPs must provide retail pharmacy access sufficient to meet the needs of its retiree population, including situations involving emergency access. CMS may review the adequacy of the plan's pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the plan's network is sufficient to meet the needs of its retiree population. No other waivers of pharmacy access requirements have been granted to these plans (i.e., home infusion, long-term care, I/T/U pharmacy access, and non-retail pharmacy access standards have not been waived).

I. *Non-Renewals*

All EGWPs (Direct Contract and 800 series plans) are subject to the same non-renewal process as for non-group plans.

J. *New Direct Contract EGWP Option for 2007*

For 2007, employers and unions will have the option to directly contract with CMS to offer MA Private Fee-for-Service (PFFS) plans. Applicants must have submitted the MA Solicitation for Application which is titled "Medicare Advantage Initial Application for Employer/Union Direct Contract Private Fee-For-Service (PFFS) Plans", located at http://www.cms.hhs.gov/EmpGrpWaivers/05_2007EGWPApps.asp#TopOfPage. There is also an additional application for Direct Contract MA Organizations who also want to provide Part D coverage with the MA coverage which is titled "Solicitation for Applications for New Employer/Union Direct Contract Medicare Advantage Prescription Drug Plan (MA-PD) Sponsors", located at http://www.cms.hhs.gov/EmpGrpWaivers/05_2007EGWPApps.asp#TopOfPage.

K. *Rebates*

The CY 2006 MA bidding rebate rules will continue to apply for CY 2007. However, EGWP MA bids will not be allowed to reflect an allocation of rebates to Part D basic premium or Part D supplemental premium.

XIV. ***Medicare Advantage Medical Savings Account (MSA) Plans***

Medicare Advantage Medical Savings Account (MSA) plans were made a permanent part of the MA program in 2003 with the passage of the Medicare Modernization Act. An MSA plan combines a high-deductible non-prescription drug MA Plan with a special tax favored savings account for medical expenses. The general rules for how an MA MSA works are below:

- A Medicare member must be entitled to Part A and enrolled in Part B of Medicare to enroll in a high-deductible MA MSA plan. Individuals eligible for Medicaid, or with ESRD, or those who have elected the Medicare hospice benefit are not eligible for enrollment. Additionally, individuals enrolled in a Federal Employees Health Benefits plan or eligible for health care benefits through the Department of Veterans Affairs of the Department of Defense as well as "working aged" individuals are not eligible for enrollment.

- A beneficiary can enroll in an MA MSA plan only during either the annual election period (generally November 15 – December 31) or during his or her initial coverage election period which begins 3 months immediately before the individual's entitlement to both Medicare Parts A and B. The initial coverage election period ends on the latter of the last day of the month preceding

entitlement to both Parts A and B or, after May 15, 2006, the last day of the individual's Part B initial enrollment period.

- Organizations offering MA MSA plans are responsible for obtaining MSA Account banking information from enrollees. Once the MSA Account is set up, CMS deposits into the MSA Account a lump-sum amount for the remaining months of the year and makes this deposit on the first day of the month of MSA plan election. The amount deposited into the MSA Account is the benchmark minus the bid, annualized.

- The amount of the deductible will vary by plan. (The maximum deductible for 2006 is $8,850.) The maximum deductible for 2007 will be released in April with the MA payment rates.

- After the deductible is reached, an MA Organization must provide coverage for original Medicare benefits. The plan payment must generally be 100 percent of the amounts that would have been paid under original Medicare including amounts that would have been paid by the enrollee as deductibles and coinsurance under Parts A and B of Medicare.

- Money left in an MSA at the end of the year rolls over to the following year. The following year's deposit is added to the amount left in the account, if any.

- Optional Supplemental benefits are allowed under an MA MSA plan. The types of supplemental benefits that are permitted to be offered are specified in 42 CFR §422.104(b). However, MA MSA plans cannot offer mandatory supplemental benefits. An MA MSA plan may charge additional premium for optional supplemental benefits. Optional supplemental benefits offered in an MA MSA plan may not reduce the deductible related to covered Medicare services.

- Enrollees of MA MSA plans are free to access services from any qualified Medicare provider. MA MSA plans can also contract with preferred providers but cannot require enrollees to use contracted providers for original Medicare services.

Additional guidance and Q&As on MA MSA plans can be found on CMS' webpage at http://www.cms.hhs.gov/MedicareAdvantageApps/02_Final%202007%20Applications.asp#TopOfPage.

XV. *Medicare Advantage Organization Non-Renewal Process for 2007*

A. *2007 MA, MA-PD and Cost-Based Plan Non-Renewal Calendar*

Please note that the dates given here are subject to change. Organizations should continue to monitor the general applications timeline posted on the CMS website at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY2007timeline.pdf.

CALENDAR – 2007 MA, MA-PD NON-RENEWAL PROCESS	
2006	***ALL DATES ARE SUBJECT TO CHANGE***
February	February 22 — Draft 2007 MA, MA-PD Call Letter, including draft non-renewal instructions, posted for public comment.
March	March 1 —Public comments on draft MA, MA-PD Call Letter must be received by 5:00 PM EST March 1 March 30 — Issuance of final 2007 Call Letter, including final non-renewal instructions.
May	May 1— Deadline for MA, MA-PDs to notify CMS of an intention to non-renew a county. May 1 — Deadline for MA, MA-PDs to submit partial county service area reduction requests. May 1 — Deadline for RPPOs to notify CMS of intention to withdraw from an MA Region.
June	June 5 — Deadline for MA, MA-PDs to submit a non-renewal or service area reduction notice to CMS. June 12 — CMS to issue acknowledgement letter to all for MA, MA-PDs that are non-renewing or reducing their service area.
July	July 15 — Optional: Deadline for MA, MA-PDs that opt to send an interim notification letter to its enrollees to submit the interim notification letter to CMS for approval. The interim notification letter must be mailed to enrollees no later than July 28.
August	August 2006 — CMS to post the model final notification letter, the state-specific final notification letter and a model public notice on the CMS website and send copies of the letters to MA, MA-PDs that are non-renewing or reducing their service area.

2006	ALL DATES ARE SUBJECT TO CHANGE
September	September 2006 — CMS to approve MA, MA-PD's final notification letter. September 2006 — CMS to release a Special Election Period (SEP) letter to MA, MA-PDs remaining in the non-renewed service areas. September 2006 — MA, MA-PDs can begin mailing the final notification letter. The final notification letter must be personalized and dated October 2, 2006. The letter must be in the beneficiaries' hands by October 2, 2006.
October	October 2 — MA, MA-PDs must publish a CMS-approved public notice in one or more newspapers of general circulation in each community or county in their contract areas. October 2 — Final beneficiary notification letter must be received by MA, MA-PD enrollees.
November — December	November-December 2006 — CMS to issue "close out" information and instructions to MA, MA-PDs that are non-renewing or reducing service area.

B. *Notices and Letters*

1. *Interim Notification Letter - For MA Organizations Giving Official Notification Prior to June 5, 2006*

An MA Organization that notifies CMS prior to June 5, 2006 of its intent to nonrenew all or a portion of its contract may at its option send a CMS-approved interim notification letter to affected beneficiaries if CMS finds that it is in the best interest of the program. Such documents would need to be submitted to the appropriate Regional Office for review and approval prior to release. When sent to beneficiaries, the organization must simultaneously send the RO a dated copy of the letter.

MA Organizations that wish to send an Interim Notification letter to its beneficiaries please contact Lettica Ramsey at Lettica.Ramsey@cms.hhs.gov no later than June 30, 2006 to get sample language for use in the Interim Notification letter.

2. *Final Notification Letter of Non-Renewal to Beneficiaries*

a) *Delivery Deadline*

All affected beneficiaries must receive their final notification letter no later than October 2, 2006. CMS strongly encourages MA Organizations to use first class postage to assure their meeting this delivery deadline. Regardless of when they are mailed, all letters must be dated October 2, 2006 to assure national consistency in the application of Medigap guaranteed issue rights to all beneficiaries.

b) Content and Format

As in years past, CMS will provide a Model Final Notification Letter. CMS will also prepare a CMS "State-Specific" Model Final Notification Letter that MA organizations must use if they serve beneficiaries in one of the 24 states that have certain special Medigap protections beyond Federal law requirements. These states are California, Colorado, Connecticut, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Vermont, Washington, and Wisconsin. CMS will notify non-renewing MA Organizations if additional states enact such special Medigap protections.

MA Organizations may **not** include information about their own Medicare supplemental policies in the body of the final notification letter. However, information on their Medicare supplemental policies may be mailed in the same envelope as the final notification letter.

The final notification letter may be up to 15 pages long and should be printed on 8 1/2" x 11" paper and mailed in a similarly sized envelope. Individual beneficiary names and addresses must be inserted in the letter to enable affected beneficiaries to prove their special rights to Medigap insurers and other Medicare health plans.

c) Information on Alternative Choices

Finally, in accordance with 42 CFR 422.506(a)(2)(ii), CMS will provide each non-renewing MA Organization with a list of those Medicare health plans (MA and Medicare Cost Plans), if any, that will be available to affected beneficiaries as alternative choices in 2007. MA Organizations must include this list of "remaining health plans" in final notification letters, including those health plans that have CMS-approved capacity limits. The letter must call special attention to the fact that Medicare Cost Plans may have a different open enrollment cycle from MA Organizations. The final notification letter should suggest that beneficiaries contact these remaining Medicare health plans to see whether these plans are accepting new members and to learn their open enrollment dates. Under separate cover, CMS will inform Medicare health plans that remain in non-renewing plans' service areas, of their responsibilities regarding non-renewal activity in the area and the Special Election Period (SEP).

d) Regional Office Review

Unlike the process for CMS review of interim notification letters, all final notification letters, including those based on the CMS Model Final Notification Letter, must be reviewed and approved by appropriate CMS Regional Offices (ROs) prior to release. MA Organizations may submit draft copies of their final notification letters to CMS ROs between August 28 and September 8, 2006. The final notification letter is not

subject to the 10-day rule for marketing material review, but the RO will give priority to the final notification letters. CMS strongly suggests that MA Organizations use the CMS Model Final Notification Letter with as few changes as possible to expedite the review process. If the model is used, CMS expects RO review and approval in 5 business days. All RO reviews of final notification letters based on the model should be completed before September 15, 2006. MA Organizations should consider this review period when they make plans to meet the October 2, 2006, deadline for delivery of final notification letters to beneficiaries.

3. Medigap Information

Non-renewing MA Organizations must inform all its Medicare beneficiaries, including the disabled and individuals with End Stage Renal Disease (ESRD), of the obligations of Medigap issuers. Full information on this topic is provided in the CMS Model Final Notification Letter, and the CMS "State Specific" Model Notification Letter with appropriate language. This model language will assure accurate communication of these provisions.

Special rules apply for affected beneficiaries in a managed care trial period. These individuals must actively and voluntarily disenroll from their non-renewing MA Organization in order to choose from a broader range of Medigap policies available on a guaranteed issue basis. MA Organizations must provide these beneficiaries with written documentation of their voluntary disenrollments, even if the voluntary request is made for a December 31, 2006, effective date. Beneficiaries may be required to submit this written documentation to a Medigap issuer as proof of their right to purchase certain Medigap policies on a guaranteed issue basis. CMS Model Beneficiary Letters Confirming Voluntary Disenrollment are found in the Medicare Managed Care Manual, Chapter 2, Exhibits 11 and 12 on CMS' website at http://www.cms.hhs.gov/manuals/downloads/mc86c02.pdf

4. Public Notice of Non-Renewal

Non-renewing MA Organizations must publish a public notice of non-renewal at least 90 days prior to the end of the contract year (i.e., October 2, 2006) in one or more newspapers of general circulation in each community or county in their contract areas. CMS will provide a Model Public Notice of Non-Renewal. MA Organizations that use the CMS Model Public Notice of Non-Renewal without revision are not required to submit the notice to their CMS ROs for review and approval prior to release. However, these MA Organizations must inform their ROs of the date the notice will be published and, within 5 days after publication, submit a photocopy or clipping of the notice(s) containing the name of the newspaper(s) and publication date.

MA Organizations that revise the CMS Model Public Notice of Non-Renewal must submit the notice to their RO for review and approval prior to its release for publication. CMS expects this process to take 5 business days. CMS encourages MA

Organizations to consider this review period when they make plans to meet the October 2, 2006 public notice deadline.

5. *Notice of Intent to Non-Renew for Purposes of Stabilization Fund Plan Retention Bonus*

Section 221 of the MMA added Section 1858(e) to the Act to create a new MA Regional Plan Stabilization Fund. The purpose of the fund is to provide financial incentives to MA Organizations to offer non-group MA Regional PPO plans in each MA region, and to retain MA regional PPO plans in regions with relatively low MA market penetration. To encourage plans to remain in regions with relatively low MA market penetration and few MA Regional PPO plans, CMS may make retention payments from the fund to MA Regional PPO plans. Therefore, we will require MA Regional PPO plans to notify CMS no later than May 1, if they will be withdrawing from the MA RPPO program in any of the regions they currently serve.

XVI. *Medicare Cost-Based Plan Non-Renewal Process for 2007*

A. *Calendar*

Please note that the dates given here are subject to change. Organizations should continue to monitor the general applications timeline posted on the CMS website at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY2007timeline.pdf

Calendar – 2007 Medicare Cost-Based Plan Non-Renewal Process	
2006	***ALL DATES ARE SUBJECT TO CHANGE***
February	Feb. 22 — Draft 2007 Call Letter, including draft non-renewal instructions, posted for public comment.
March	March 1 — Public comments must be received by 5:00 PM EST March 1 March 30 — Issuance of final 2007 Call Letter, including final non-renewal instructions for Cost-Based Contractors and Cost-Based Sponsors
August	August 2006 — CMS to post the model final notification letter, the state-specific final notification letter, and a model public notice on the CMS website and send copies of the letters to Medicare Cost-Based plans that are non-renewing or reducing their service area.
October	October 2 — Deadline for Medicare Cost-Based Contractors and Cost-Based Sponsors to submit a non-renewal or service area reduction notice to CMS. October 10 — CMS to issue and acknowledgement letter to all Medicare Cost-Based plans that are non-renewing or reducing their service area. October 13 — CMS to approve Medicare Cost-Based plans' final beneficiary letter and public notice. October 20 — Medicare Cost-Based plans can begin mailing the final notification letter to enrollees. The final notification letter must be personalized and dated November 2, 2006 and be in the beneficiaries hands by November 2, 2006.

2006	DATES ARE SUBJECT TO CHANGE
November	November 2 — Final beneficiary notification letter must be received by Cost-Based Plan Enrollees
November — December	November-December 2006 — CMS to issue "close out" information and instructions to Cost-Based plans that are non-renewing or reducing their service area.
December	December 2 — Cost-Based plans must publish a CMS-approved public notice in one or more newspapers of general circulation in each community or county in their contract areas.

B. *Notices and Letters*

1. *Interim Notification Letter - For Medicare Cost-Based Plans Giving Official Notification Prior to October 2, 2006*

CMS strongly encourages a Medicare Cost-Based plan to send a CMS-approved interim notification letter to affected beneficiaries if it is not renewing its contract. Medicare Cost-Based plans would need to submit their letter to their CMS Regional Offices (ROs) for review and approval prior to release. Concurrent with the mailing of such letter to the beneficiaries, the Medicare Cost-Based plan must send the RO a dated copy of the letter.

Medicare Cost-Based plans that wish to send an Interim Notification letter to their beneficiaries should contact Lettica Ramsey at Lettica.Ramsey@cms.hhs.gov by June 30, 2006 to get sample language for an Interim Notification letter.

2. *Final Notification Letter to Beneficiaries*

a) *Delivery Deadline*

All affected beneficiaries must receive their final notification letter by November 2, 2006. CMS strongly encourages Medicare cost plans to use first class postage to assure their meeting this delivery deadline. Regardless of when they are mailed, all letters must be dated November 2, 2006 to ensure national consistency in the application of Medigap guaranteed issue rights to all beneficiaries.

b) *Content and Format*

CMS will provide a Model Final Notification Letter. CMS will also prepare a CMS "State-Specific" Model Final Notification Letter that Medicare cost plans must use if they serve beneficiaries in the 24 states that have special Medigap protections beyond Federal law requirements. These states are California, Colorado, Connecticut, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Vermont, Washington, and Wisconsin.

CMS will inform all non-renewing Medicare Cost-Based plans if other states enact such protections.

Medicare Cost-Based plans may **not** include information about their own Medicare supplemental policies in the body of the final notification letter. However, information on their Medicare supplemental policies may be mailed in the same envelope as the final notification letter.

The final notification letter may be up to 15 pages long and should be printed on 8 1/2" x 11" paper and mailed in a similarly sized envelope. Individual beneficiary names and addresses must be inserted in the letter to enable affected beneficiaries to prove their special rights to Medigap insurers and other Medicare health plans.

c) Information on Alternative Options

Medicare Cost-Based plans must include a list of available Medicare health plans in the final notification letters, including plans with CMS-approved capacity limits. The final notification letter must call special attention to the fact that some Medicare health plans may have a different open enrollment cycle from Medicare Cost-Based plans. The final notification letter should suggest that beneficiaries contact these other Medicare health plans to see if they are accepting new members and their open enrollment dates. CMS will inform Medicare health plans that remain in non-renewing plans' service areas of their responsibilities and the Special Election Period (SEP).

d) Regional Office Review

All final notification letters, including those based on the CMS Model Final Notification Letter, must be reviewed and approved by appropriate CMS ROs prior to release. Medicare cost plans may submit draft copies of their final notification letters to CMS ROs between October 2, 2006 and October 16, 2006. CMS RO will give priority review to the final notification letter. CMS strongly suggests that Medicare Cost-Based plans use the CMS Model Final Notification Letter with as few changes as possible to expedite the review process. If the model is used, the RO review should take no more than 5 business days. CMS encourages Medicare cost plans to consider this review period when making plans to meet the November 2, 2006 deadline to deliver the final notification letters to beneficiaries.

3. Medigap Information

Non-renewing Medicare cost plans must inform all affected Medicare beneficiaries, including individuals who are eligible for Medicare due to a disability or End Stage Renal Disease (ESRD), of the obligations of Medigap issuers' obligations. Details on this topic are provided in the CMS Model Final Notification Letter and the CMS "State Specific" Model Notification Letter. This model language will ensure accurate communication of these technical provisions.

Medicare cost plans are required to provide or arrange for supplemental coverage of benefits related to a pre-existing condition with respect to any exclusion period for all Medicare beneficiaries age 65 or older. For beneficiaries under age 65 who are entitled to Medicare due to a disability or End Stage Renal Disease (ESRD), the cost plan must arrange for supplemental coverage if it is available in the marketplace. Please see §1876(c)(3)(F) and under CMS (HCFA) Medicare Cost Plan contract provision, Article IV, General Conditions, item R.

CMS regulations do not require provision of "Guaranteed Issue" (i.e., no medical screening, or coverage of pre-existing conditions) Medigap policy, if such a policy is not available in the marketplace. **If Medigap issuers in a particular state do not sell Medigap policies to beneficiaries who are eligible for Medicare due to a disability, the Medicare Cost-Based plan must provide supplemental coverage for pre-existing conditions.**

The Medicare Managed Care Manual Section 3004.5(A)(2) (entitled "Provide Services Directly"), states that the Cost-Based plan "may directly provide or arrange for the provision of services related to pre-existing conditions with no charge to the beneficiary." The terms of the Agreement signed by Medicare Cost-Based plans also refers to the requirement that, should the Cost-Based plan non-renew, it must provide or arrange for supplemental coverage for Medicare benefits related to a pre-existing conditions with respect to any exclusion period for "the lesser of six months or the duration of such period." See language at Article IV.R.

NAIC and HIPAA define "pre-existing conditions" as those "limited to a physical or mental condition for which medical advice, diagnosis, care or treatment was recommended or received within the 6 month period ending on the enrollment date in a plan or policy."

CMS's interpretation is that coverage for pre-existing conditions for the disabled is a requirement whether a disabled beneficiary: 1) applies for and obtains a Medigap policy with a pre-existing condition exclusion; or 2) applies for and is denied coverage under a Medigap policy. Individuals who are eligible for Medicare due to age have similar protections. The beneficiary will still need to be provided coverage for pre-existing conditions, even if the Cost-Based plan has to provide such coverage directly. CMS believes that an individual who is eligible for Medicare due to a disability must make an attempt to obtain a Medigap policy before the cost plan can be required to provide coverage directly. The Medicare Cost-Based plan will not be required to provide coverage for pre-existing conditions for those members (aged and disabled) who do not seek a Medigap policy.

Coverage for pre-existing conditions is limited to those costs **related to the pre-existing condition** that result in Medicare cost-sharing amounts, such as Part A and B deductibles and coinsurance and excess part B charges, up to the limiting charge.

The Medicare Cost-Based plan may require all disabled members go to its physicians for treatment, during the time the plan is providing coverage for the pre-existing condition. The Cost-Based plan must coordinate and track these beneficiaries during the enrollment period and during the time they are receiving services. CMS must be able to track compliance.

Special rules apply for affected beneficiaries in a managed care trial period. These individuals must actively and voluntarily disenroll from their non-renewing Medicare Cost-Based plans in order to choose from broader range of Medigap policies available on a guaranteed issue basis. Medicare Cost-Based plans must provide these beneficiaries with written documentation of their voluntary disenrollments, even if the voluntary request is for a December 31, 2006 effective date. Beneficiaries may be required to submit this written documentation to a Medigap issuer as proof of their right to buy certain Medigap policies on a guaranteed issue basis. CMS Model Beneficiary Letters Confirming Voluntary Disenrollment are found in the Medicare Managed Care Manual, Chapter 2, Exhibits 11 and 12 on CMS' website at http://www.cms.hhs.gov/manuals/downloads/mc86c02.pdf

4. Public Notice of Non-Renewal

Non-renewing Medicare Cost-Based plans must publish a public notice of non-renewal at least 30 days prior to the end of the contract year (i.e., December 2, 2006) in one or more newspapers of general circulation in each community or county in their contract areas. CMS will provide a Model Public Notice of Non-Renewal. Medicare Cost-Based plans that use the CMS Model Public Notice of Non-Renewal without revision are not required to submit the notice to their CMS ROs for review. However, these plans must inform their ROs of the date the notice will be released and, within 5 days after publication, submit a photocopy or clipping of the notice(s) containing the name of the newspaper(s) and publication date.

Medicare cost plans that revise the CMS Model Public Notice of Non-Renewal must submit the notice to their RO for review and approval prior to its release for publication. CMS expects this process to take 5 business days. Medicare Cost-Based plans should consider this review period when making plans to meet the December 2, 2006 deadline for release of these public notices.

C. *Systems Issues*

1. Non-renewed Contracts

Non-renewing Medicare Cost-Based plans should **not** submit disenrollments for any members who will remain in their organization through December 31, 2006. During the last month of the contract, CMS will conduct a mass disenrollment of all remaining plan members after all other normal transactions for all Medicare managed care organizations have been processed. This will allow enrollment of affected members into other Medicare health plans and will not interfere with any final month

disenrollments the Medicare Cost-Based plan submitted. This method will ensure that all affected members who do not enroll in another Medicare health plan or Medicare Cost-Based plan are placed in original Medicare in a timely manner.

Non-renewing Medicare Cost-Based plans should submit disenrollments for members who have requested disenrollment for the first day of the last month of the contract period. Members are entitled to be disenrolled effective the first day of the month after the month in which the Medicare Cost-Based plans receive the request. Should some members request disenrollment effective the first day of the last month of their contracts (i.e., December 1, 2006), Medicare Cost-Based plans must submit these disenrollments before or by the cutoff date in the last contract month. It is imperative that they do so because, during the mass disenrollment conducted by CMS, all remaining Medicare members enrolled at the close of business on the last day of the contract will be removed as of that date (i.e., December 31, 2006). Therefore, it is important that non-renewing Medicare Cost-Based plans submit any final month deletions in accordance with the scheduled cut-off date for the final month of their contract.

Medicare Cost-Based plans will receive a reply listing report for the members who are disenrolled through the CMS mass disenrollment.

D. *Service Area Reductions*

Medicare Cost-Based plans with service area reductions for 2006 must disenroll all members who reside in the non-renewed area or county**.** Medicare Cost-Based plans must submit disenrollment records for all affected members no later than their appropriate cut-off date (12/8/2006) in December, the last operating month of their current contracts.

CMS will provide Medicare Cost-Based plans with a reply listing of all submitted transactions. The organization must review this report as soon as it is received, approximately the third week of December 2006, and verify the disenrollments for all submitted members. Medicare Cost-Based plans will also receive a separate communication with specific systems instructions from CMS.

Medicare Cost-Based plans with any questions about the enrollment/disenrollment systems issues should contact Jacquline Buise at jacquline.buise@cms.hhs.gov or 410-786-7607.

E. *Other Information*

1. Partial County Service Area Reduction Requests

CMS has authority under its county integrity policy to approve limited exceptions to the principle of county integrity. The requirements for approving exceptions to the

county integrity policy and documentation requirements can be found in the Medicare Managed Care Manual: Chapter 4.

MA Organizations must submit partial county requests to CMS for approval in accordance with current policy. Specifically, CMS analyze demographic information to ensure a nondiscriminatory impact on excluded parts of a county or counties and excluded populations.

MA Organizations should send requests to the appropriate Regional Office Plan Manager with a copy to Lisa Little Axe in CMS' Central Office at lisa.littleaxe@cms.hhs.gov or 410-786-1106. The request must be received at CMS no later than May 1, 2006.

2. *"Close-Out" Information*

In the fall of 2006, CMS will send a "close-out" letter to non-renewing Medicare Cost-Based plans with complete details regarding their obligations after non-renewal. These instructions are to ensure that affected beneficiaries experience a smooth transition to another health coverage option and define those tasks that the Medicare Cost-Based plan must perform after the last day of its contract.

Non-renewing Medicare Cost-Based plans may be responsible for hospital costs incurred by affected Medicare beneficiaries after the last day of the contract.

If an affected Medicare Cost-Based plan member is hospitalized in a prospective payment system (PPS) hospital, the non-renewing Medicare Cost-Based plan is responsible for all appropriate costs and/or cost-sharing associated with Part A inpatient hospital services, until the beneficiary is discharged. Original Medicare or the next Medicare health plan that the beneficiary elects will assume payment for Part B services.

If a Medicare beneficiary is in a non-PPS hospital, inpatient bills should be "split" as follows. The non-renewing Medicare Cost-Based plan will pay appropriate costs and/or cost-sharing associated with the covered charges through the last day of the contract; original Medicare or the next Medicare health plan elected by the beneficiary will pay from the next day forward.

After the end of the contract period (i.e., December 31, 2006), Medicare Cost-Based plans' remaining obligations to CMS include:

a. Maintenance and provision to CMS of access to books, records, and other documents related to the operation of the Medicare Cost-Based plan contract for the six year period following non-renewal or 3 years following the issuance of the Notice of Program Reimbursement (NPR), whichever is later.

b. Update of plan contact information in HPMS, should the Medicare Cost-Based plan access HPMS. Should the Medicare Cost-Based plan not access HPMS, they will be required to keep the appropriate RO informed of contact information. This will allow CMS to continue to contact appropriate persons in non-renewing Medicare Cost-Based plans until all activity is complete.

c. Participation in the CMS process to complete final reconciliation of CMS accounts with the Medicare cost plans, including reimbursing CMS for any overpayments and seeking reimbursement from CMS for any previously identified underpayments.

d. Upholding its obligations under the Medicare appeals process to actions related to denials of services and payments made while its Medicare Cost-Based plan contract was extant.

Medicare Cost-Based plans with other questions about non-renewal of their Medicare Cost-Based plan contract should contact their RO Plan Managers.

XVII. ***List of Contacts***

Medicare Advantage (Part C) and Cost-Based Plan Contacts		
Subject Area	**Contact Name**	**Telephone Number**
Benefits	Frank Szeflinski	303-844-7119
	Russell Hendel	410-786-0329
Bid worksheet changes	Rich Coyle	410-786-6393
	Nancy Kitchen	410-786-7637
Contract – Cost-Based & Medicare Advantage	Helaine Fingold	410-786-5014
Cost-Based Plan Appeals and Grievance Issues	Tim Roe	410-786-2006
Cost-Based Plan Issues	Frank Szeflinski	303-844-7119
	Nancy Kitchen	410-786-7637
Cost-Sharing Guidance	Marty Abeln	410-786-1032
	Russel Hendel	410-786-0329
	Frank Szeflinski	303-844-7119
General HPMS Information	Tim Hoogerwerf	410-786-9962
	Kristin Finch	410-786-2873
Employer Sponsor Options	Jim Mayhew	410-786-9244
Employer/Union-Only Group Waiver Plans (EGWPs)	Jim Mayhew	410-786-9244
Enrollment and Eligibility	Lynn Orlosky	410-786-9064
HIPAA	Yolanda Robinson	410-786-7627
HPMS Help Desk		1-800-220-2028 or **hpms@cms.hhs.gov**
HPMS Connectivity	Don Freeburger	410-786-4586
HPMS User IDs and Passwords	Neetu Jhagwani	410-786-2548
HPMS Plan Crosswalk	Greg Buglio	410-786-6562
	Kim Miegel (enrollment system)	410-786-3311
Marketing Issues	Mike Fiore	410-786-0623
Medicare Personal Plan Finder Data	Michael McCann	410-786-2539
Medicare & You 2007	Amy Miner	410-786-5242
Mid-Year Benefit Enhancements	Yasmin Galvez	410-786-0434
	Frank Szeflinski	303-844-7119
Non-Renewal Process — 2007 Calendar & Guidelines	Lettica Ramsey	410-786-5262
PBP Changes	Pam Nicholson	410-786-0263
Part C Appeals and Grievance Issues	Tim Roe	410-786-2006
Renewal Process — 2007 Calendar & Guidelines	Helaine Fingold	410-786-5014

Medicare Prescription Drug Benefits (Part D) Contacts		
Subject Area	**Contact Name**	**Telephone Number**
Beneficiary Protections	Vanessa Duran	214-767-6435
Bidding — Prescription Drug Benefits	Mark Newsom	410-786-3198
Change of Ownership	Mark Smith	410-786-8015
Contract – Part D Appendix and Stand-Alone Prescription Drug Plan	Scott Nelson	410-786-1038
Coordination of Benefits, including Part B/Part D coverage interactions	Jean Stiller	410-786-0708
Coordination of Benefits, including Part D coverage interactions with: State pharmaceutical assistance programs (SPAPs), Medicaid, Retiree prescription drug plans	Christine Hinds	410-786-4578
Cost-Based Plans Offering Part D	Frank Szeflinski	303-844-7119
Creditable Coverage/Late Enrollment Penalty	Catherine Windfield-Jones	410-786-6674
	Tamara Jackson-Douglas	410-786-9417
Demonstrations – Part D Offerings	Rebecca Paul	410-786-0852
Enrollment and Eligibility	Lynn Orlosky	410-786-9064
Electronic Prescribing	Alissa Deboy	410-786-6041
Employer Sponsor Options	Jim Mayhew	410-786-9244
Employer/Union-Only Group Waiver Plans (EGWPs)	Jim Mayhew	410-786-9244
Formulary	Alissa Deboy	410-786-6041
Fraud and Abuse, Program Oversight	Deborah Larwood	410-786-9500
Grievances, Covg Determ, Appeals (PDPs)	John Scott	410-786-3636
Intermediate Sanctions	Mark Smith	410-786-8015
Low Income Subsidies	Christine Hinds	410-786-4578
Marketing	Mel Sanders	410-786-8355
Medication Therapy Management	Alissa Deboy	410-786-6041
Medigap	Julie Walton	410-786-4622
Pharmacy Benefit Cost & Utilization Mgmt	Alissa Deboy	410-786-6041
PACE organizations Offering Part D Benefits	Brenda Hudson	410-786-4085
Pharmacy Network Access Standards	Vanessa Duran	214-767-6435
Physician Self-Referral Prohibitions	Joanne Sinsheimer	410-786-4620
Plan Information Dissemination Reqs	Vanessa Duran	214-767-6435
Prescription drug benefits, including: benefit packages and Part D covered drugs	Vanessa Duran	214-767-6435
Privacy of Records	Deborah Larwood	410-786-9500
Quality Assurance	Deborah Larwood	410-786-9500
Termination Procedures	Mark Smith	410-786-8015
TROOP	Jean Stiller	410-786-0708

XVIII. ***WEB Reference List***

Employer/Union-Only Group Waiver Plan (EGWP) Guidance
http://www.cms.hhs.gov/EmpGrpWaivers/

Prescription Drug Coverage General Information
http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/

Medicare Health Plans http://www.cms.hhs.gov/HealthPlansGenInfo/

2006 Medicare Advantage Payment Rates
http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/AD/list.asp#TopOfPage

HIPAA
http://www.cms.hhs.gov/HealthPlansGenInfo/12_HealthInsurancePortabilityandAccountabilityActof1996(HIPAA).asp#TopOfPage

MA Applications http://www.cms.hhs.gov/MedicareAdvantageApps/

Attachment A — CY 2007 Guidance for Medicare Advantage and Medicare Advantage-Prescription Drug Plan Renewals

CY 2007 Guidance for MA and MA-PD Plan Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	Beneficiary Notification
1	New Plan Added	An MA organization creates a new plan benefit package.	A new 2007 plan with no link to a 2006 plan.	The MA organization must submit election transactions for 2007.	Beneficiaries are required to complete an enrollment request.	Beneficiaries are sent a regular ANOC.
2	Renewal Plan	An MA organization continues to offer a CY 2006 MA plan in CY 2007 and retains all of the same service area. The **same plan ID number must be retained** in order for all currently enrolled beneficiaries to remain in the same MA plan in CY 2007.	A 2007 plan that links to a 2006 plan and retains all of its plan service area from 2006.	**The renewal plan ID must remain the same** so that beneficiaries will remain in the same plan ID. The MA organization **does not** submit any transactions.	New enrollment transactions are not required for current members during the renewal process.	Beneficiaries are sent a regular ANOC.
3	Consolidated Renewal Plan	An MA organization ***combines*** two or more MA plans offered in CY 2006 into a single renewal plan so that all beneficiaries in the combined plans are offered the same benefits in CY 2007. The MA organization must designate which of the renewal plan IDs will be retained in CY 2007 after consolidation. **Note:** If an MA organization reduces a service area while performing this activity, the MA organization must follow the Renewal Plan with SAR rules for handling beneficiaries in the reduced service area.	Two or more 2006 plans that consolidate into one 2007 plan.	**The MA organizations designated renewal plan ID must remain the same** so that CMS can consolidate the beneficiary elections by moving them into the designated renewal plan ID. The MA organization **does not** submit any transactions.	New enrollment transactions are not required for current members during the renewal process.	Beneficiaries are sent a regular ANOC.
4	Renewal Plan with an SAE	An MA organization continues to offer a CY 2006 MA plan in CY 2007 and retains all of the same plan service area, but also adds one or more new service areas. The **same plan ID number must be retained** in order for all currently enrolled beneficiaries to remain in the same MA plan in CY 2007. **This option is available to local MA plans only.** **Note: During CY 2006 and CY 2007, an MA organization offering a local PPO plan may not offer the**	A 2007 plan that links to a 2006 plan and retains all of its plan service area from 2006, but also adds one or more new service areas.	**The renewal plan ID must remain the same** so that beneficiaries in the current service area will remain in the same plan ID. The MA organization **does not** submit any transactions for these members.	New enrollment transactions are not required for current members during the renewal process.	Current beneficiaries are sent a regular ANOC.

CY 2007 Guidance for MA and MA-PD Plan Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	Beneficiary Notification
		plan in a new service area not already present in the approved contract service area, that is in an area in which it was not present prior to December 31, 2005.				
5	Renewal Plan with a SAR	An MA organization ***reduces the service area*** of a CY 2006 MA plan and makes the reduced area part of a new or renewal MA plan service area in CY 2007. The MA organization must offer passive elections in CY 2007 to all of the current enrollees who reside in the reduced service area. **This option is available to local MA plans only.** ***Note:** When the reduced service area is not contained in another MA plan (i.e., contract-level SAR), the MA organization must submit transactions to disenroll the beneficiaries from the plan. Beneficiaries are sent a termination notice and receive guaranteed issue Medigap rights. To enroll in a different MA plan, these beneficiaries must complete an enrollment form. The model modified ANOC will be available on the CMS website: by **June 1, 2006**.	A 2007 plan that links to a 2006 plan and retains only a portion of its plan service area.	**The renewal plan ID must remain the same** so that beneficiaries in the renewal portion of the service area will remain in the same plan ID. The MA organization **does not** submit any transactions for these members. When the reduced service area is contained in another plan, the MA organization **must submit transactions** to passively enroll the beneficiaries into this other plan.	Beneficiaries in the renewal portion need do nothing. Beneficiaries impacted by the plan SAR will receive information on how their enrollment into the new plan offered by the organization will occur.	Beneficiaries continuing in the same plan that were not impacted by the SAR are sent a regular ANOC. Beneficiaries impacted by the plan SAR are sent a modified ANOC, which will explain their enrollment in the new plan (passive enrollment) and receive guaranteed issue Medigap rights.
6	Renewal Plan Split Based on Provider Groups	One CY 2006 MA plan splits into two or more CY 2007 MA plans in order to reflect the beneficiary's provider group choice. Both CY 2007 MA plans must have the same service area. The CY 2006 MA plan ID must be designated as the renewal plan in CY 2007. **Provider-specific plan splits require prior approval from CMS.** MA organizations wishing to offer provider-specific plans effective January 1, 2007 must submit their formal requests to their CMS Regional Office plan managers with a CC to their Central Office plan manager no later than **May 6, 2006**. CMS will review such requests on a case-by-case basis and make its determination based upon information that the MA organization submits as part of its proposal. For further information and format requirements, refer to the Health Plans section of the CMS website.	Two or more 2007 plans that are created from one 2006 plan with membership determined by provider choice.	No enrollment transactions will be required for beneficiaries whose appropriate plan based on provider group choice is the renewal plan ID. The MA organization **must submit transactions** to enroll beneficiaries associated with the other provider group(s).	Beneficiaries in the renewal plan need do nothing. Beneficiaries who will be associated with the other provider group(s) and associated plan will receive information on how their enrollment into the new plan offered by the organization will occur.	Beneficiaries continuing in the renewal plan receive the regular ANOC. Beneficiaries offered passive elections into the new plan are sent the regular ANOC with special instructions.

CY 2007 Guidance for MA and MA-PD Plan Renewals						
		Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	Beneficiary Notification
7	Terminated Plan	An MA organization terminates the offering a plan benefit package.	A 2006 plan that is no longer offered in 2007.	If the beneficiary elects to enroll in another plan with the same organization, the MA organization **must submit transactions** to enroll the beneficiary in another plan with the organization; CMS disenrolls beneficiaries to FFS who do not elect another plan with the same MA organization or a different MA organization.	Beneficiaries are required to complete an enrollment election if they choose to enroll in another plan.	Beneficiaries are sent a termination notice and receive guaranteed issue Medigap rights.

* Note: See the non-renewal instructions for a contract non-renewal or service area reduction.

Attachment B —Rebate Reallocation and Premium Rounding for 2007

This guidance is organized into five sections: Section I presents terminology. Section II discusses rules for rebate reallocation by plan type. Section III provides guidance for changes that can be made to funding of Part D and Part C benefits during the rebate reallocation period. Section IV covers several additional topics, and Section V discusses premium rounding rules.

I. Terminology

Rebate Reallocation Period. Following CMS' publication of the Part D national average monthly bid amount, the Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the MA regional benchmarks, MA organizations may reallocate Part C rebate dollars in the MA bid pricing tool for certain MA plan bids (BPT). Rebate reallocation is one aspect of the annual MA bid negotiation process that takes place in August. Rebate reallocation is required for some MA plans, is optional for others, and is not allowed for certain plans, as discussed in this guidance.

The rebate reallocation period is about five to seven business days. After changes to rebate allocation and/or premium rounding, the MA organization will re-submit the bid package via HPMS. CMS will announce the exact dates of the rebate reallocation period at the time we publish the Part D and MA regional plan amounts.

Target Part D basic premium. The target Part D basic premium is the Part D basic premium net of any Part C rebate dollars that were applied to reduce (buy down) the premium. For 2007, MA organizations will provide the target Part D basic premium in the initial June bid submission via the bid pricing tools. Once CMS publishes the national average Part D bid and other amounts, CMS calculates each plans' actual Part D basic and actual total plan premium. MA organizations that are required, or that can opt, to reallocate rebate dollars to return to the target Part D basic premium can do so only during the rebate reallocation period.

Standard Part B premium. The standard Part B premium is the full-subsidy monthly Part B premium amount. Beginning in CY 2007, beneficiaries meeting specified income thresholds will have a monthly adjustment amount added to the full-subsidy amount. Given the MA requirement of uniform premiums within a plan, effective 2007, the lowest Part B premium an MA plan can offer is the estimated standard amount net of rebates. This may not result in a zero Part B premium for all enrollees. OACT will continue to provide the estimate of the standard Part B premium each year for bidding purposes. See previous sections of the CY2007 Call Letter for further information regarding the standard Part B premium.

II. Rebate Reallocation Rules – When Can Rebate Be Reallocated?

II.A. MA-only Plans.

For local MA-only plan bids, the plan premium submitted in the initial June 2006 bid submission is considered the final 2007 premium, as these plans are not affected by calculations of the Part D national average bid or the MA regional plan benchmarks. Thus, the rebate reallocation period does not apply to local MA-only plans. That is, MA organizations will **not** have an opportunity during the rebate reallocation period to resubmit local MA-only plan bids to round their premiums. If an MA organization desires a "whole-dollar" premium, it should be submitted as such in the initial June submission. The 2007 Bid Instructions will include detailed instructions on premium rounding, e.g., minor adjustments to the total gain/loss amount.

II.B. Local and Regional MA-PD Plans with No Part C Rebate Dollars.

Local and regional MA-PD plans with no Part C rebate dollars would only participate in the Rebate Reallocation Period to round premiums in order to adjust the Part D basic premium resulting from application of the Part D national average bid. See Section III.B.4. for the case where the plan's target Part D basic premium is the Low Income Premium Subsidy (LIPS) amount.

Regional MA-PD plans with no Part C rebate dollars in the initial June bid submission that end up with rebate dollars after comparison of the final MA regional benchmark to the plan bid must participate in rebate reallocation to apply those rebate dollars to fund reduction(s) in supplemental benefit premiums, a Part B premium reduction, and/or a return to the target Part D basic premium.

II.C. Local and Regional MA-PD plans that Allocated Excess or Insufficient Part C Rebate to the Part D Basic Premium

Beginning in 2007, in the initial June bid submission, MA organizations must provide in the MA-PD plan BPT the target Part D basic premium. The MA organization has two options for specifying the target Part D basic premium: (1) The low-income premium subsidy benchmark for the region (i.e., whatever amount is equivalent to a zero premium for full subsidy low-income beneficiaries); or (2) a specific dollar amount net of Part C rebates (e.g., zero). The 2007 Bid Instructions will provide information on each option for specifying the target premium.

Once CMS has announced the national Part D Base Beneficiary Premium, the resulting Part D basic beneficiary premium may be higher or lower than the plan's target premium. If more rebate dollars were allocated to achieve the plan's target premium than are actually needed, this "excess" allocation results in premium lower than the target premium. This includes the possibility that the resulting premium is a negative number. Conversely, if none of the Part C rebate dollars were allocated to achieve the plan's target Part D basic premium or if not enough rebate dollars were allocated to achieve the plan's target premium, this "insufficient" allocation results in a premium is higher than intended.

Below are the rules for addressing excess and insufficient rebate allocation to the Part D basic premium.

II.C1. Rebate reallocation to adjust the Part D basic beneficiary premium (net of rebate) must return to the target premium provided in the initial June bid submission. We will not accept a partial return to the target premium except in the following situation: where the plan intends to return to the target premium and all of the rebate has been reallocated to reduce the Part D basic premium, but the resulting premium is still greater than the target premium.

II.C2. If the Part D basic beneficiary premium (net of rebate) is less than zero, rebate reallocation is <u>required.</u>

The amount of rebate allocated to buy down the Part D basic premium cannot exceed the amount of the pre-rebate premium. Therefore, if premium resulting from application of the National Average Monthly Bid Amount and the Base Beneficiary Premium is negative, the "excess" rebate allocated to buy-down the Part D basic premium must be reallocated to buy-down the Part C or Part D supplemental premiums or the estimated Part B standard premium, in order to return to the target premium.

Example II.C2: Required Rebate Reallocation, given "Excess" Allocation

June - initial bid submission	Estimate pre-rebate D basic premium	$36
	Identify **target premium** (post-rebate premium)	$0
	Determine rebate amount to apply to pre-rebate D basic premium to "buy down" to target	$36
August – Part D benchmarks published	Outcome of nat'l Part D average bid and base premium: August pre-rebate D basic premium August post-rebate premium, applying June rebate allocation	 $34 -$2 [$34-$36]
	Identify rebate allocation needed to move August pre-rebate premium to target premium [August pre-rebate – June target]	$34 [$34 – 0]
	Calculate "excess" rebate [June rebate – August rebate]	$2 [$36-$34]
Rebate Reallocation Required	MA organization must reallocate $2 of "excess" rebate to other benefits to return to target premium of $0	

In example C2 above, the required change is the shift from a $36 to a $34 rebate allocation to the Part D basic premium in order to return to the target premium of $0.

II.C3. Rebate reallocation to reduce the premium for Part C or D supplemental benefits is <u>optional</u> if the Part D basic beneficiary premium (net of rebate) is lower than the target premium but not less than zero.

The MA organization has two options: leave the final Part D basic premium (net of rebate) unchanged (i.e., at the level resulting from application of the National Average

Monthly Bid Amount and the Base Beneficiary Premium); or reallocate rebate to fund other portions of the plan benefit package in order to return to the target D basic premium. Rebate can be reallocated to reduce beneficiary premiums for the Part C and D supplemental benefits.

If the MA organization elects to allocate the "excess" rebate dollars to the other benefits, the final Part D basic premium must be the target premium. That is, we will not accept a partial return to the target premium (see rule C1). Thus, in example C3 below, if the MA organization does not want to maintain the August post-rebate premium of $15, only a return to $20 is acceptable, not $18.

Example II.C3: Optional Rebate Reallocation, given "Excess" Initial Allocation

June - initial bid submission	Estimate pre-rebate D basic premium	$35
	Identify **target premium** (post-rebate premium)	$20
	Determine rebate amount to apply to pre-rebate D basic premium to "buy down" to target premium	$15
August – Part D benchmarks published	Outcome of nat'l Part D average bid and base premium: August pre-rebate D basic premium August post-rebate premium, applying June rebate allocation	 $30 $15 [$30-$15]
	Identify rebate allocation needed to move August pre-rebate premium to target premium [August pre-rebate – June target]	$10 [$30-$20]
	Calculate "excess" rebate [June rebate – August rebate]	$5 [$15-$10]
Rebate Reallocation Options	(a) No rebate reallocation; leave at post-rebate D basic premium of $15.	
	(b) Reallocate $5 of "excess" rebate to other benefits to return to target premium of $20	

II.C4. Rebate reallocation from the Part C or D supplemental premiums to the Part D basic premium in order to meet the target premium is <u>optional</u> if the Part D basic beneficiary premium (net of rebate) is higher than the target premium.

The MA organization has two options: leave the final Part D basic premium (net of rebate) unchanged (i.e., at the level resulting from application of the National Average Monthly Bid Amount and the Base Beneficiary Premium); or reallocate rebate that had been applied to reduction of Part C and D supplemental premiums or the estimated Part B standard premium toward the Part D basic premium, in order to return to the target D basic premium.

If the MA organization does elect to reallocate additional rebate dollars from other benefits, the final Part D basic premium must be the target premium (see rule C1). Thus, in example C4 below, if the MA organization does not want to leave the August post-rebate premium of $25, only a return to $20 is acceptable, not $23.

Example II.C4: Optional Rebate Reallocation, given "Insufficient" Initial Allocation

June - initial bid submission	Estimate pre-rebate D basic premium	$35
	Identify **target premium** (post-rebate premium)	$20

	Determine rebate amount to apply to pre-rebate D basic premium to "buy down" to target premium.	$15
August – Part D benchmarks published	Outcome of nat'l Part D average bid and base premium: August pre-rebate D basic premium August post-rebate premium, applying June rebate allocation	 $40 $25 [$40-$15]
	Identify rebate allocation needed to move August pre-rebate premium to target premium [August pre-rebate – June target]	$20 [$40-$20]
	Calculate "insufficient" rebate [August rebate to achieve target premium – June rebate]	$5 [$20-$15]
Rebate Reallocation Options	(a) No rebate reallocation; leave at post-rebate D basic premium of $25.	
	(b) Reallocate $5 of rebate from other benefits to the Part D basic premium to increase total rebate to $20, thus buying the $40 premium down to the target premium of $20.	

II.C5. Regional MA plans also must adjust rebate allocation to account for any increase or decrease in total rebate dollars.

Once CMS has determined the MA regional benchmarks, there may be an increase or decrease in the total rebate dollars in a regional plan bid. The allocation of rebate dollars to fund the premium for Part C or Part D basic or supplemental benefits or the estimated Part B standard premium reduction must be revised to reflect the new total.

Example II.C5: Regional Plan Decrease in Total Rebate combined with "Excess" Initial Allocation to Part D Basic Premium

June - initial bid submission	Estimate total rebate dollars	$55
	Estimate pre-rebate D basic premium	$35
	Identify **target premium** (post-rebate premium)	$20
	Determine rebate amount to apply to pre-rebate D basic premium to "buy down" to target premium.	$15
August – Part D and MA regional benchmarks published	Outcome of nat'l Part D average bid and base premium: Final total rebate dollars August pre-rebate D basic premium August post-rebate premium, applying June rebate allocation	 $53 $30 $15 [$30-$15]
	Identify change in amount of total rebate	-$2
	Identify rebate allocation needed to move August pre-rebate premium to target premium [August pre-rebate – June target]	$10 [$30-$20]
	Calculate "excess" rebate [June rebate – August rebate]	$5 [$15-$10]
	Reconcile reduced total rebate with "insufficient" D basic allocation	$3 [$5-$2]
Rebate Reallocation Options	(a) Leave D basic premium at post-rebate premium of $15. Subtract $2 of rebate from other benefits to adjust for reduced total rebate	
	(b).Return to target premium of $20. Allocate $3 of rebate to other benefits.	

Section III. How Can Rebate Be Reallocated: Changes Allowed to Funding of Benefits during Rebate Reallocation Period

III.A. Changes Allowed to Funding of the Part D Basic and Supplemental Benefits

During the rebate reallocation period, rebate dollars not used to reach the target premium for basic Part D coverage may be used to buy down the Part D supplemental premium. However, no modifications are allowed to the benefit design or pricing of the Part D basic benefit or the supplemental benefit offered under the "enhanced alternative" design. Changing the Part D benefit design would affect projected reinsurance due to the change in induced demand for basic Part D benefits. This change in reinsurance has an impact on the pricing of basic Part D benefits and, in turn, affects both the National Average Monthly Bid Amount and the Base Beneficiary Premium. The National Average Monthly Bid Amount and the Base Beneficiary Premium should not be recalculated after being announced; thus, there can be no change in Part D benefit design.

Specifically, this prohibition includes the rule that no changes are allowed to the allowed costs, administrative costs, or gain/loss margin in the Part D basic and supplemental benefits.

III.B. Allowed to Funding of the Part C Supplemental Benefits

The Part C mandatory supplemental benefit includes additional items and services not covered by Medicare and reductions in cost sharing for Part A/B items and services from levels actuarially equivalent to average cost sharing under original Medicare. During the rebate reallocation period, for a plan with "excess" rebate, an MA organization could further buy down the initial Part C supplemental premium or could add new non-drug benefits (e.g., a vision benefit) to the Part C supplemental package and then buy down the new Part C supplemental premium to the initial level. Significant changes to the Part C benefits will result in additional benefit reviews. No changes in Part D benefits or pricing will be accepted.

CMS does not expect and will not allow MA organizations to substantially redesign Part C supplemental benefits during the rebate reallocation period. We expect only marginal adjustments during the rebate reallocation period, and we will evaluate reallocations for differences in materiality.

> Example: acceptable change in supplemental cost sharing. After application of the National Average Monthly Bid Amount and the Base Beneficiary Premium, an MA-PD plan's Part D basic premium shifts from $0 to -$3, which means it has credited $3 of rebate where it is not needed. Rebate reallocation is required. The MA organization may decide to reallocate this $3 to buy-down the cost of a benefit in the Part C mandatory supplemental package.
>
> However, we do not expect the MA organization to accomplish reallocation by moving $15 out of A/B cost sharing reductions and moving $18 into the

additional benefit. We would consider this to be a substantial redesign of the supplemental benefit.

III.B1. Administrative costs and gain/loss margins.
If the value of non-drug additional benefits is being increased as a result of reallocating rebate, there will be changes in the supplemental administrative costs and the gain/loss margin that reflect the new level of the benefit. Beginning in 2007, administrative costs and the gain/loss margin are allocated proportionately. Therefore, we generally expect only minor changes to administrative costs and margins.

III.B2. Elimination of a Part C supplemental benefit.
To return a MA-PD plan with insufficient rebate to the target Part D basic premium, the MA organization could eliminate a Part C supplemental benefit. To return a regional plan with a decrease in the total amount of rebate to the exact amount of total rebate, the MA organization could, for example, eliminate from the Part C supplemental benefit package the coverage of a non-Medicare covered item or service.

The value of the added or eliminated Part C supplemental benefit should match the amount of rebate that must be shifted to return to the Part D target premium. For a regional plan, the value of added benefits should match the net shift in total Part C rebate dollars due to an increase or decrease in those total rebate dollars after application of the regional benchmark and/or returning to the Part D target premium.

We reiterate that we do not expect substantive redesigning of the Part C supplemental package. For plans with excess rebate, we would not expect the MA organization to eliminate one additional benefit and add another additional benefit.

III.B3. First-time allocation of rebate dollars to the Part D basic premium during the rebate reallocation period.
Some MA-PD plans with Part C rebate dollars may have opted in the June bid submission to not allocate any of the rebate to buying down the Part D basic premium. For these plan bids, if the Part D basic premium after application of the National Average Monthly Bid Amount and the Base Beneficiary Premium ends up lower or higher than the target premium, CMS would allow a return to the plan's target premium. No partial return would be allowed.

In the first situation where the Part D basic premium ends up lower than the target premium, the MA organization may return to the target premium by adding an additional benefit to the Part C supplemental package, including the appropriate level of administrative cost and gain/loss margin. This additional benefit must have a value equal to the difference between the Part D basic target premium and the post-national average Part D basic premium.

For example, if no Part C rebate dollars were allocated to buy-down the Part D basic premium, resulting in a target premium of $25, but the plan's Part D basic premium

ended up being $23, the MA organization could add an additional benefit worth $2 pmpm to the Part C supplemental benefit to return to the target premium.

III.B4. MA-PD Plans with no Part C rebate and LIPS as Target Part D Basic Premium

If an MA-PD plan, including a Special Needs Plan, has no Part C rebate and specified that the Low Income premium subsidy amount is the target premium, but ends up with a Part D basic premium above the Low Income subsidy amount after the application of the National Average Monthly Bid Amount and the Base Beneficiary Premium, the plan cannot return to the target premium. The plan cannot have a final Part D premium that is zero for the full subsidy Low Income beneficiaries.

III.C. Changes Allowed to the standard Part B premium reduction.

The other use of rebate dollars allowed under §422.266 is reduction of the Part B premium. During the rebate reallocation period, rebate dollars may be shifted into or away from funding a reduction in the estimated standard Part B premium, under the reallocation rules described in other sections. Note that the maximum amount of rebate that can be allocated to reduce the Part B premium is equal to the amount of the estimated standard Part B premium. OACT will continue to provide the estimate of the standard Part B premium each year for bidding purposes. See previous sections of the CY2007 Call Letter for further information regarding the standard Part B premium.

Section IV — Miscellaneous Guidance

IV.A. Every plan bid must allocate the exact amount of the plan's total rebate.

The exact amount of the plan's total rebate must be allocated among the various options described above. MA organizations must account for all rebate dollars in a plan's bid. Moreover, the amount of rebate allocated to a supplemental benefit or the Part B standard premium reduction must not exceed the value of that benefit. For example, if the Part D supplemental premium is $50, an MA organization may not allocate more than $50 to buy down that premium. Rebate allocations to the standard Part B premium cannot exceed the estimated amount provided by CMS in the bid pricing tool.

IV.B. MA organizations must meet the §423.104(f) requirement on type of drug coverage offered by certain plans, and must reallocate rebate if necessary to meet this requirement.

In accordance with 42 CFR §423.104(f), MA organizations may not offer an MA coordinated care plan in an area unless either that plan (or another MA plan offered by the same MA organization in the same service area) includes required prescription drug coverage.

Required prescription drug coverage is defined by 42 CFR §423.100 as MA-PD plan coverage of Part D drugs that is either:

> -- Basic prescription drug coverage (i.e., defined standard coverage, actuarially equivalent standard coverage or basic alternative coverage); or
>
> -- Enhanced alternative coverage with no beneficiary premium for the Part D supplemental benefit. An MA-PD plan must apply rebate dollars to reduce to zero the beneficiary premium for the Part D supplemental benefit.

MA organizations are required to comply with this requirement. If necessary, MA organizations must reallocate rebate dollars from other benefits to achieve the required Part D supplemental benefit in the plan.

To restate: MA organizations offering coordinated care plans must offer in an area either (a) a basic-only Part D plan or (b) a basic plus supplemental Part D plan where the supplemental premium equals zero. Failure to meet this requirement will result in the inability to offer a Part D benefit. In addition, for MA organizations offering coordinated care plans, failure to offer a Part D benefit in an area will result in the organization being unable to offer a Part C benefit as well, pursuant to the rules of 42 C.F.R. §422.4(c).

IV.C. Local MA Plan Segments.

The above rules on rebate reallocation apply to bids for local plan segments, with the following clarifications.

The plan's health care benefit package must be the same across plan segments. However, the Part C package can be priced differently across segments, e.g., basic and supplemental premiums and cost-sharing may differ across segments.

Segmentation does not apply to the Part D benefit. The Part D prescription drug benefit must be uniform across a plan's service area; thus it may not vary across segments. The amount of rebate allocated to buy-down Part D premiums, the initial target D beneficiary premium, and the final D beneficiary premium must be identical across the entire service areas.

Section V. Rules for Rounding Premiums

1. The CY2007 bid pricing tools round the following premiums to one decimal (i.e., to the nearest dime) to comply with premium withhold system requirements: Part C (the sum of basic + mandatory supplemental), Part D basic and Part D supplemental. No pennies are allowed. See CY2007 Bid Instructions for more information.

Rebate dollars allocated to reduce the Part B standard and Part D premiums are rounded to one decimal.

Rebate dollars allocated to reduce the Part C mandatory supplemental premium are still rounded to two decimal places.

Note: Prescription Drug Plans (PDPs) express their intention to round the Part D premium in the initial June bid submission, because the rebate reallocation period does not apply to PDPs. In the Part D bid pricing tool, PDPs are permitted to round their premiums to either the nearest $0.10 or the nearest $0.50.

2. Local MA-only plans. For local MA-only plan bids, the plan premium submitted in the initial June bid submission is considered the final premium, as they are not affected by the Part D National Average calculation or the MA regional plan benchmark calculations. Local MA-only plans will **not** have an opportunity to resubmit bids to round their premiums. Therefore, if an organization desires a "whole-dollar" premium, it should be submitted as such in the initial June submission. See CY2007 Bid instructions for more information.

3. Regional plans and local MA-PD plans. Regional plans and local MA-PD plans may participate in the rebate reallocation process. During rebate reallocation, MA organizations may round the total plan premium to the nearest dollar (up or down) by increasing or reducing the gain/loss margin for Part A/B benefits, as long as there is an offsetting reduction of no more than $0.50. (The total plan premium is defined at 42 CFR §422.262(b) as the consolidated monthly premium consisting of some combination of the Part C basic and mandatory supplemental premiums and Part D basic and supplemental premiums).

If the plan has rebate dollars, the Part A/B gain/loss margin can be changed to result in an increase or decrease of $0.50 of rebate dollars. Note that in order to account for the 25 percent of savings retained by the Trust Funds for plans with bids below benchmarks, the margin can be changed up to a maximum change of $0.67 since this will result in a change of up to $0.50 in rebates ($0.67 x 75% = $.50).

If the plan A/B bid is equal to or greater than the A/B benchmark, the Part A/B gain/loss margin can be slightly changed to result in a premium increase or decrease of up to $0.50.

The rebate reallocation period is not an opportunity to significantly change the benefit package or the bid. For example, one-half of one percent (0.5%) of revenue is considered by CMS to be a significant amount of the average gain/loss margin, and thus a significant change in the bid.

Examples of rounding.

Example (a): An MA-PD plan has no premium for A/B basic or supplemental benefits, and an initial basic Part D premium (target premium) of $30. (This could happen if: (1) the bid equals the benchmark and no A/B supplemental benefits are offered; or (2) the bid is less than the benchmark, the plan has A/B mandatory supplemental benefits, and applies rebates to reduce the Part C supplemental premium to zero. If the post-national-average-drug-bid total plan premium is $30.42, the MA organization could round the plan premium to $30.00, and slightly reduce the gain/loss margin for Part A/B benefits to result in the $0.42 premium reduction. (The gain/loss margin for Part D benefits may not change.)

Example (b). An MA-PD plan has no premium for A/B benefits or supplemental benefits, and an initial basic Part D premium (target premium) of $30. (This could happen if the bid equals the benchmark and no A/B supplemental benefits are offered or if the plan applies rebates to reduce the Part C supplemental premium to zero). If the post-national average drug-bid results in a total plan premium of $32.42, the MA organization could opt to make a slight reduction in the gain/loss margin for A/B benefits that would result in a $0.42 premium reduction and a premium of $32.00.

The MA organization could not round the premium to anything lower than $32. For example, the organization could not round to a combined premium of $30 by reducing the gain/loss margin to result in a premium change of $2.42. To return to the target premium of $30, the MA organization would have to engage in rebate reallocation. See earlier sections of this appendix for guidance on rebate reallocation.

Example (c). An MA-PD plan has no rebates, and an initial total plan premium of $25. The post-national average drug-bid total plan premium is $26.52. The MA organization can round the premium to the nearest dollar (i.e., $27.00), up to a maximum change of $0.50 by increasing the gain/loss margin accordingly.

Example (d). The target Part D basic premium for an MA-PD plan with A/B supplemental benefits is the Regional Low Income Premium Subsidy amount. After the Part D national average monthly bid amount is calculated, the MA-PD plan ends up with a Part D basic premium of $32.00, which is 40 cents over the Regional Low Income Premium Subsidy Amount of $31.60. The MA-PD plan has the following 3 options.

Option 1. The MA-PD plan can maintain its Part D basic premium of $32.00. The plan's full subsidy eligible beneficiaries will pay a Part D basic premium of $0.40.

Option 2. The MA-PD plan can reallocate 40 cents of the rebates that were allocated to the Part C supplemental premium to its Part D basic premium, thus reducing the premium to the Regional Low Income Premium Subsidy Amount of $31.60. To account for the reduction in rebates applied to Part C mandatory supplemental premium, the MA-PD plan may either increase its Part C supplemental premium by 40 cents or reduce its gain/loss margin appropriately. Non-low income subsidy eligible enrollees would pay a Part D basic premium of $31.60.

Option 3. In order to be able to offer a rounded Part D basic premium to non-low-income-subsidy eligible enrollees, MA-PD plans are permitted in this situation to reallocate A/B supplemental rebates to reduce their Part D basic premium to the nearest whole dollar amount below the Regional Low Income Premium Subsidy Amount. Therefore, the MA-PD plan can reallocate $1.00 of its A/B supplemental rebates to its Part D basic premium, reducing the Part D basic premium to $31.00, the nearest whole dollar amount below the Regional Low Income Premium Subsidy Amount of $31.60. To account for the reduction in A/B supplemental rebates applied to Part C, the MA-PD plan must increase its Part C supplemental premium by $1.00. Please note that in this option, the MA-PD plan forgoes 60 cents in potential Low Income Premium Subsidy dollars per full subsidy eligible beneficiary.

Example (e). An MA-PD plan has 3 segments, with Part C premiums of $51, $76, $110. The post-national-average-drug-bid Part D basic premium is $37.90. To end up with whole- dollar total plan premiums, the MA organization could increase the MA gain/loss margin requirements to increase each Part C premiums by $0.10. When added to the $37.90 Part D premium, the total plan premium for each segment is a whole dollar amount - $89, $114, and $148.

Attachment C — Risk Adjustment Implementation

A. Risk Adjustment Data Submission Schedule

The following submission calendar is for all diagnosis data submitted for all risk adjustment models. This includes data for both the Part C CMS-HCC and ESRD models and the Part D Drug risk adjuster model.

Specific changes in implementation that differ include the updated risk adjustment data collection and submission dates as defined in *Table 1. Risk Adjustment Implementation Calendar* (below).

Table 1. Risk Adjustment Implementation Calendar

CY	Dates of Service	Initial	First Payment	Final Submission
2005	July 1, 2003 through June 30, 2004	September 3, 2004	January 1, 2005	N/A*
2005	January 1, 2004 through December 31, 2004	March 4, 2005	July 1, 2005	May 15, 2006
2006	July 1, 2004 through June 30, 2005	September 2, 2005	January 1, 2006	N/A*
2006	January 1, 2005 through December 31, 2005	March 3, 2006	July 1, 2006	January 31, 2007
2007	July 1, 2005 through June 30, 2006	September 1, 2006	January 1, 2007	N/A*
2007	January 1, 2006 through December 31, 2006	March 2, 2007	July 1, 2007	January 31, 2008
2008	July 1, 2006 through June 30, 2007	September 7, 2007	January 1, 2008	N/A*
2008	January 1, 2007 through December 31, 2007	March 7, 2008	July 1, 2008	January 31, 2009

* With the elimination of the payment lag, the final submission deadline (reconciliation) changes to May 15, 2006 for calendar year 2004 data and then becomes January 31st from 2007 forward.

Proposed changes in payment methodology for 2007, including Part C and Part D payment and risk adjustment, are described in the February 17, 2006, *Advance Notice of Methodological Changes for Calendar Year (CY) 2007 Medicare Advantage Payment Rates* and the April 3, 2006 *Announcement of Calendar Year (CY) 2007 Medicare Advantage Payment Rates* (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).

B. Risk Adjustment Factors

As stated in the April 4, 2005 *Announcement of Calendar Year (CY) 2006 Medicare Advantage Payment Rates* (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/), plans subject to risk adjusted payments have an option for how to treat beneficiaries with 12 months of Part A data but less than 12 months of Part B enrollment in a data collection year.

Table 2. Which Risk Adjustment Factors to Apply to Payment*

Time Period Beneficiary Has Been Enrolled in Part B Medicare**	Time Period Beneficiary Has Been Entitled to Benefits under Part A Medicare**	
	0 – 11 months	**≥ 12 months**
0 – 11 months	new enrollee factors	plan's option: New enrollee or full risk adjustment factors
≥ 12 months	full risk adjustment factors	full risk adjustment factors

*Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled benefits under Part A and enrolled in Part B.
**During data collection period (previous calendar year).

Table 2. Which Risk Adjustment Factors to Apply to Payment (above) illustrates that beneficiaries with 12 or more months of Medicare Part B enrollment during the data collection period (previous calendar year) are considered full risk enrollees. The new enrollee factors do not apply.

Beneficiaries with less than 12 months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period will be treated as new enrollees, as they are now.

Currently beneficiaries with 12 or more months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period (referred to as "Part A-only" enrollees) are considered new enrollees for the purpose of risk adjusted payments. Because of concerns expressed by some demonstrations that "Part A only" enrollees are always considered to be new enrollees, CMS has created an option for how the risk adjustment payments for this category of enrollees are determined. Effective for 2006 payments and beyond, organizations may elect to have CMS determine payments for all "Part A-only" enrollees using either new enrollee factors or full risk adjustment factors. The organization's decision will be applied to all "Part A-only" enrollees in the plan. Plans may not elect to move some eligible "Part A-only" enrollees into risk adjustment, while retaining others as new enrollees.

C. Election of Full Risk Option for "Part A-only" Enrollees

Effective for 2006 payments and beyond, organizations may elect to have CMS determine payments for all "Part A-only" enrollees using either new enrollee factors or full risk adjustment factors. If an organization elects to have CMS determine

payment factors (i.e., new enrollee factors or full risk adjustment factors) for all "Part-A only" enrollees, then—

1) The decision will be applied to all "Part-A" only enrollees in the plan; and
2) The option elected will remain turned "on" until CMS is otherwise notified prior to August 31st of any successive year.

CMS will apply this option during reconciliation for a payment year only (that is, it will not be applied prospectively). Plans interested in this option must contact: Henry Thomas, at henry.thomas@cms.hhs.gov by August 31, 2006 to elect this option.

D. Physician Data Sources

The collection of physician data relevant for risk adjustment is associated with the physician's specialty. That is, all ICD-9-CM diagnoses that are in the risk adjustment model and rendered as a result of a visit to a physician must be collected by the MA organization. This includes data collected from non-network as well as network physicians. Only those physician specialties and other clinical specialists identified in *Table XX. Acceptable Physician Data Sources* (below) are acceptable for risk adjustment. The Medicare provider number does not apply to the collection of physician data.

As discussed in the *Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage Payment Rates*: we have eliminated the diagnostic radiology specialty (code 30) from the list of Acceptable Physician Data Sources. (See *Table XX*.) This decision is effective as of January 1, 2006.

With the implementation of Medicare Part D, we have added the pain management specialty (code 72) to the list of Acceptable Physician Data Sources. (See *Table 3*.)

TABLE 3. ACCEPTABLE PHYSICIAN DATA SOURCES

CODE	SPECIALTY	CODE	SPECIALTY	CODE	SPECIALTY
01	General Practice	29	Pulmonary Disease	70*	Multispecialty Clinic or Group Practice
02	General Surgery	33*	Thoracic Surgery	72*	Pain Management
03	Allergy/Immunology	34	Urology	76*	Peripheral Vascular Disease
04	Otolaryngology	35	Chiropractic	77	Vascular Surgery
05	Anesthesiology	36	Nuclear Medicine	78	Cardiac Surgery
06	Cardiology	37	Pediatric Medicine	79	Addiction Medicine
07	Dermatology	38	Geriatric Medicine	80	Licensed Clinical Social Worker**
08	Family Practice	39	Nephrology	81	Critical Care (Intensivists)
10*	Gastroenterology	40	Hand Surgery	82	Hematology
11	Internal Medicine	41	Optometry (specifically means optometrist)	83	Hematology/Oncology
12	Osteopathic Manipulative Therapy	42	Certified Nurse Midwife	84	Preventive Medicine
13	Neurology	43	Certified Registered Nurse Anesthetist	85	Maxillofacial Surgery
14	Neurosurgery	44	Infectious Disease	86	Neuropsychiatry
16*	Obstetrics/ Gynecology	46*	Endocrinology	89*	Certified Clinical Nurse Specialist
18	Ophthalmology	48*	Podiatry	90	Medical Oncology
19	Oral Surgery (Dentists Only)	50*	Nurse Practitioner	91	Surgical Oncology
20	Orthopedic Surgery	62*	Psychologist	92	Radiation Oncology
22*	Pathology	64*	Audiologist	93	Emergency Medicine
24*	Plastic and Reconstructive Surgery	65	Physical Therapist	94	Interventional Radiology
25	Physical Medicine and Rehabilitation	66	Rheumatology	97*	Physician Assistant
26	Psychiatry	67	Occupational Therapist	98	Gynecologist/Oncologist
28*	Colorectal Surgery	68	Clinical Psychologist	99	Unknown Physician Specialty

*Indicates that a number has been skipped.

**Licensed Clinical Social Workers must comply with state licensure/certification requirements.

Note: Qualified physician data for risk adjustment requires a face-to-face visit with the exception of pathology services (professional component only).

Attachment D — I/T/U Addendum to Part D Plan Agreement

INDIAN HEALTH ADDENDUM TO
MEDICARE PART D PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____(herein "Part D Plan Sponsor") and _____ (herein "Provider") for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of Provider authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422 and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Part D Plan Sponsor's agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Part D Plan Sponsor's agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR 417.472, 42 CFR Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare Part D plans.

(b) The terms "Part D Plan" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472 and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements under subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422.

(c) The term "Provider" means the Indian Health Service (IHS) and all pharmacies and dispensaries operated by the IHS, or an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(k) The term "dispensary" means a clinic where medicine is dispensed by a prescribing provider.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

/_/ IHS operated Service Units, including hospitals, health centers and one or more pharmacies or dispensaries ("IHS Provider"). Where IHS service units operate more than one pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

/_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq*.

/_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Deductibles.

The cost of pharmaceuticals provided at a pharmacy or dispensary of Provider or paid for by the Provider through a referral to a retail pharmacy shall count toward the deductible applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of Provider.

a) The parties agree that the IHS provider is limited to serving eligible IHS beneficiaries pursuant to 42 CFR Part 136 and section 813(a) of the Indian Health Care Improvement Act (IHCIA), 25 USC §1680c-(a). The IHS Provider may provide services to non-eligible persons only under certain circumstances in section 813(b) and in emergencies under section 813(c) of the IHCIA.

(b) The parties agree that the persons eligible for services of the Provider who is an Indian tribe or a tribal organization or a Provider who is an urban Indian organization shall be governed by the following authorities:

(1) Title XVIII, Part D of the Social Security Act and 42 C.F.R. Part 423;
(2) Sec. 813(a) and Sec. 813(c) of the Indian Health Care Improvement Act, 25 USC §1680c (a) and (c);
(3) Part 136 of Title 42, Code of Federal Regulations; and
(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program.

(c) No clause, term or condition of the Part D Plan Sponsor's agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Part D Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

Federal laws and regulations affecting a Provider, include but are not limited to the following:

(a) An IHS provider:

(1) The Anti-Deficiency Act 31 U.S.C. § 1341;
(2) The Indian Self Determination and Education Assistance Act ; 25 USC § 450 *et seq.;*
(3) The Federal Tort Claims Act (FTCA), 28 U.S.C. § 2671-2680;
(4) The Federal Medical Care Recovery Act, 42 U.S.C. § 2651-2653;
(5) The Federal Privacy Act of 1974, 5 U.S.C. § 552a, 42 C.F.R. Part 2;
(6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;
(7) The Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. Parts 160 and 164.; and
(8) The Indian Health Care Improvement Act (IHCIA), 25 U.S.C. § 1601 *et seq*.

(b) A Provider who is an Indian tribe or a tribal organization:

(1) The Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.;*
(2) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(3) The Federal Tort Claims Act, 28 USC §2671-2680;
(4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
(5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(c) A Provider who is an urban Indian organization:

(1) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.;*
(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
(3) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

To the extent the Provider is a non-taxable entity, the Provider shall not be required by a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

(a) As an IHS provider, FTCA coverage obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of federal employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of federal employees acting within the scope of their employment. 28 U.S.C. § 2671-2680. Nothing in the Part D Plan Sponsor's Agreement shall be interpreted to authorize or obligate any IHS employee to operate outside the scope of his/her employment. The IHS Provider shall not be required to acquire insurance, provide indemnification, or guarantee that the Plan will be held harmless.

(b) A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain professional liability insurance to the extent such Provider is covered by the Federal Tort Claims

Act (FTCA) pursuant to Federal law (Pub.L. 101-512, Title III, §314, as amended by Pub.L. 103-138, Title III, §308 (codified at 25 USC §450 F note); and regulations at 25 CFR Part 900, Subpt. M. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224(g)-(n) of the Public Health Service Act, as amended by the Federally Supported Health Centers Assistance Act, Pub.L. 104-73, (codified at 42 USC §233(g)-(n)) and regulations at 42 CFR Part 6, such Provider shall not be required to obtain or maintain professional liability insurance. Further, nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify the Part D Plan Sponsor.

9. Employee license.

(a) States may not regulate the qualifications of Federal employees who are carrying out their authorized Federal activities within the scope of their employment. Consequently, the parties acknowledge that IHS employees are not subject to state licensure laws and IHS pharmacy departments are not licensed by individual states. The parties agree that during the term of the Part D Plan Sponsor's Agreement, IHS pharmacists are currently licensed in accordance with federal statutes and regulations, and the IHS facility is accredited in accordance with federal statutes and regulations. During the term of the Part D Plan Sponsor's Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

(b) Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of a Tribe, Tribal Organization or Urban Indian organization, , such employee is not subject to regulation of qualifications by the State in which such Provider is located. The parties agree that during the term of the Part D Plan Sponsor's Agreement, such Federal employees will be licensed in accordance with applicable Federal statutes and regulations. To the extent that any direct employee of such Provider is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan Sponsor's agreement and any addendum thereto.

11. Dispute Resolution.

a. For IHS Provider. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. The laws of the United States shall apply to any problem or dispute hereunder that cannot be resolved by and between the parties in good faith.

b. For Tribal and Urban Providers. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Part D Plan Sponsor's Agreement.

12. Governing Law.

The Part D Plan Sponsor's agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between such agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall subject an Indian tribe, tribal organization, or urban Indian organization to State law to any greater extent than State law is already applicable.

13. Pharmacy/Dispensary Participation.

The Part D Plan Sponsor's agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the attached Schedule -------- to this Indian Health Addendum. A pharmacy is required to use a National Council for Prescription Drug Programs (NCPDP) provider number for reimbursement. To the extent a dispensary does not have a NCPDP provider number, it is required to use an NCPDP Alternate Site Enumeration Program (ASEP) number for reimbursement.

14. Acquisition of Pharmaceuticals.

Nothing in the Part D Plan Sponsor's agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in such agreement and all addenda thereto require the Provider to acquire drugs from the Part D Plan Sponsor or from any other source.

15. Drug Utilization Review/Generic Equivalent Substitution.

Where the Provider lacks the capacity to comply with the information technology requirements for drug utilization review and/or generic equivalent substitution set forth in the Part D Plan Sponsor's agreement, the Provider and Part D Plan Sponsor agree that the Provider shall comply with the Part D Plan Sponsor's drug utilization review and/or generic equivalent substitution policies and procedures through an alternative method. Nothing in this paragraph shall be interpreted as waiving the applicability of the drug utilization review and/or generic equivalent substitution policies and procedures adopted by Part D sponsor in accordance with 42 C.F.R.§§ 423.153(b) and (c), as approved by CMS, to covered Part D drugs dispensed by the Provider to enrollees in the Part D Plan[s]. As specified at 42 C.F.R. §423.132(c)(3), the requirements related to notification of price differentials is waived for the Provider .

16. Claims.

The Provider may submit claims to the Part D Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim.

17. Payment Rate.

Claims from the provider shall be paid at rates that are reasonable and appropriate.

18. Information, Outreach, and Enrollment Materials.

(a) All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan Sponsor to Provider in paper and electronic format at no cost to the Provider.

(b) All marketing or informational material listing a provider as a pharmacy must refer to the special eligibility requirements necessary for service to be provided, consistent with the eligibility requirements as described in this Indian health addendum in paragraphs 5(a) for IHS providers and 5(b) for tribal and urban providers.

19. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Part D Plan Sponsor, Provider shall provide written notification of its hours of service.

20. Endorsement

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS provider or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under this agreement.

_____ _____
Signature of Authorized Representative

_____ _____
Printed Name of Authorized Representative

_____ _____
Title of Authorized Representative