

MEMORANDUM

TO:	All Medicare Advantage, Medicare Advantage-Prescription Drug Organizations, Cost-Based Contractors, and Employer/Union Only Sponsored Groups
FROM:	Patricia Smith, Director, Medicare Advantage Group Cynthia Tudor, Acting Director, Medicare Drug Benefit Group
RE:	Public Comment Period for Draft 2007 MA, MA-PD and PDP Call Letters
DATE:	February 21, 2006

We are pleased to issue this notice announcing the release of the DRAFT 2007 Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD) and Stand Alone Prescription Drug Plan (PDP) Call Letters for public comment. We are sending these letters out via HPMS and will post them on our website at http://www.cms.hhs.gov/HealthPlansGenInfo/02_WhatsNew.asp#TopOfPage and http://www.cms.hhs.gov/PrescriptionDrugCovContra/01_Overview.asp#TopOfPage.

This year, we are issuing two separate Call Letters to facilitate plan access to information. One Call Letter contains information for MA, MA-PD, Cost-Based Plan Organizations and related employer/union-only sponsored group waiver plans. The other Call Letter contains information specifically for Stand-Alone PDPs and employer/union-only sponsored group waiver PDPs.

When submitting comments on either Call Letter, please indicate in the subject line either MA or PDP to reflect the letter on which you are commenting. Send comments to <u>MA_newyear_issues@cms.hhs.gov</u>. We will be accepting comments until 5:00 PM EST March 1, 2006.

Thank you in advance for your input into this process. If you have any questions on the draft MA, MA-PD Call Letter, please contact Helaine Fingold at <u>Helaine.fingold@cms.hhs.gov</u> or 410-786-5014. If you have questions on the draft PDP Call Letter, please contact Scott Nelson at <u>scott.nelson2@cms.hhs.gov</u> or 410-786-1038.

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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.

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

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.pd f.

2007 MA, MA-PD and Cost-Based Plan Renewal Calendar	
2006	All dates are subject to change
February	Feb. 17 — Issuance of the Advance Notice of Methodological Changes for Calendar Year (CY) 2007 Medicare Advantage (MA) Payment Rates. Feb. 22 — Draft 2007 MA, MA-PD Call Letter 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 20 — Deadline for submission of: ALL 2007 initial Applications MA, MA-PD (including Special Needs Plans and Demonstrations), PDP, Direct Contract Employer/Union-Only Group Waiver Plans (Direct Contract EGWPs), and MA Organizations or Cost Based Plan Sponsors offering EGWPs. ALL 2007 Service Area Expansion (SAE) applications. March 27 — Release of Health Plan Management System (HPMS) formulary submissions module. March 30 — Issuance of Final 2007 MA, MA-PD and PDP Call Letters.
April	 Early April — Call Letter Training for Industry. April 3 — Issuance of Calendar Year (CY) 2006 MA Payment Rates. April 4 — Announcements of MA capitation rates, local area benchmarks, and adjustment factors for 2007. April 4-5 — CMS Bid Conference. April 7 — Plan Creation module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS. April 17 — Formulary Submissions Due from all MA-PDs and PDPs.
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, PDP, EGWP and Direct Contract EGWP applicants and renewing organizations. June 6 — CMS begins accepting CY 2007 marketing material for review. June 6 — MA Organizations may submit 2007 Annual Notice of Change (ANOCs) and Summary of Benefits (SBs) to the Regional Offices for review.
July	July 15 — Final date for MA, MA-PD, Cost and PDP 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) 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 so that these materials can be reviewed and approved prior to the posting of "Medicare Personal Plan Finder" (MPPF).

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2006	All dates are subject to change
September	September 1 — Final Date for Organizations to send non-model ANOCs to
	Regional Offices.
	September 14 – 15 – 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.
	September 15 — MA, MA-PD, Cost-PD, and PDP Organizations are expected to submit final 2007 ANOCs and SBs to the Regional Offices for review. These
	documents must be based on the organization's CMS approved benefit bid. Note:
	Organization receiving bid approved prior to September 14 (as noted in HPMS),
	must submit the 2007 ANOC/SB with 72 working hours of approval. If bids are
	not approved, then SB cannot be approved.
October	October 1 — MA, MA-PD Organizations and Medicare Cost-Based plans may
000000	begin marketing CY 2007 benefits to Medicare beneficiaries using CMS-approved
	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 Pased plans to send non-model
	October 10 — Final day for Medicare Cost-Based plans to send <u>non-model</u> 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 the December 1 deadline. 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.
	October 15–30 — CMS mails the 2007 Medicare & You handbook which
	contains health plan and prescription drug plan benefit and cost information.
	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 <u>before</u> this date to ensure receipt by members by October 31.
	November 1 — Final date for MA Organizations and Medicare Cost-Based plans
November	to send <u>non-model</u> EOCs to CMS Regional Offices. Organizations are
	encouraged to submit all EOCs to CMS in advance of this date to ensure the EOC
	can be reviewed, approved, printed, and mailed to members by the
	December 31, 2006 deadline. Note: If the organization follows the model EOC
	without modification, the final date to send the EOCs to the CMS Regional Office
	is November 15, 2006.
	November 6 — Final date to send the ANOCs to the CMS Regional Office
	November 15 — 2007 Annual Coordinated Election Period begins. All
	organizations must hold open enrollment.
	November 15 — Final date for MA Organizations and Medicare Cost-Based plans
L	to submit model EOCs without modification to Regional Offices for review.

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 <u>before</u> this date to ensure receipt by members by December 1. December 31 — Final date for MA, MD-PD Organizations to mail CY 2007 EOCs to members with an effective date of 1/1/2007. December 31 — 2007 Annual Coordinated Election Period ends.
2007	
January	January 1 — Plan Benefit Period Begins.

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.

The following chart 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. 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.

- D. 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. Nevertheless, 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 2). 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.

E. Conflict of Interest

Contracts with CMS will be amended to add an organizational conflict of interest provision. This requirement 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.

F. 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.

G. 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 Part D (or lowest combined Part C and Part D) premium.

Dual eligible members of a continuing MA-PD plan in 2007 will continue those enrollments, 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.

H. 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.

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.

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 beneficiaries 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 no longer be possible to offer a benefit package that describes the Part B premium as zero, i.e., no marketing or member materials can describe the Part B premium as zero. 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 submissions. 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, 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). We believe that marketing a plan that does not have such information available is inherently misleading. Accordingly, if we become aware that MPPF information is inaccurate, or if an MA Organization/PDP requests suppression of its information on the MPPF because it was inaccurate, we will not approve marketing materials for that plan until the MPPF 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 until November 1, 2006. As a result, marketing materials

submitted by that plan will not be approved for use prior to November 1, 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 marketing 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 distributed.

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 Personal 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.

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 will be able to preview their plan data for MPPF in September. Due to the redesign, the exact dates for the preview are not yet scheduled. A separate memorandum outlining the preview dates will be provided later this summer.

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. Therefore, early and strong quality control of the bid submission at the MA Organization/PDP level on all submissions is imperative. Previewing the MPPF 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 data will appear on the "Medicare Personal Plan Finder" and "Medicare Prescription Drug Plan Finder" in the standardized summary of benefits format. In addition, "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.

MA-PD and PDP Sponsors will be able to preview their data in HPMS this fall. Specific dates for the preview will be provided at a later date. If there are any issues with the data, plans can notify CMS at <u>compchart@cms.hhs.gov</u>.

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 which will allow 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 the completion of 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-forservice 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). 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 cost sharing 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 Medicare Advantage 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.

G. MSA Plan Bids

<u>Plan A/B bid.</u> An MA Organization will submit to CMS 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.

<u>Benchmark.</u> Per Sec. 1853(j), the local MA standardized A/B benchmark is based on capitation rates for a geographic area (county). The benchmark calculation for MSA plans is the same as for other local MA plans: the weighted average of county capitation rates in the plans' 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 Organizations: 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

<u>Deposit calculation</u>. 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 service area level, and it reflects the plan's projected plan average risk score:

Annual 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 of the Act)), 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 bid amount for these 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

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 between the plans 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 <u>MA-PD plan</u> 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 <u>or</u> Stand-Alone PDPs.
- The determination of whether a new mid-year <u>MA-only plan</u> 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

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) 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.

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. 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 Medicare Modernization Act (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. 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." 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. The plan sponsor would then have to account for this benefit in the plan's bid, as provided in 42 CFR 423.265, and the price concessions would have to be netted out for the purposes of allowable reinsurance and risk corridor costs per 42 CFR 423.308.

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 Social Security Act [42 U.S.C. § 1320a-7b(b)].

For the purposes of bid submission, Part D Sponsors must report all direct and indirect remuneration to CMS. In order to report the full amount of compensation that a Sponsor is providing to pharmacies for participation in the Part D program, Sponsors shall have a provision in all pharmacy contracts that requires pharmacies to fully disclose any and all discounts and rebates or any other direct or indirect remuneration from drug manufacturers or other parties when such remuneration is designed 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. Part D Sponsors shall require pharmacies to indemnify them for the full amount of any such payments not disclosed to the Sponsor. 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 should assure pharmacies that this information will remain confidential.

C. MSA Plan Payment

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

Standardized A/B benchmark * enrollee's risk factor [per Sec. 1853(a)(1)(b)(iii)] minus $1/12^{th}$ of the annual lump sum deposit [per Sec. 1853(a)(1)(A) and Sec. 1853(e)].

The Intra-Service Area Rates (ISAR) adjustment does not apply to MSA plans (per Sec. 1853(a)(1)(B)(iii)), as it does to coordinated care and private-fee-for-service 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 payments to the MA organization for each enrollee vary based on the risk factor of the 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. 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 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 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 part of the annual MA plan bidding process. So, for instance, 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:

<u>Caregiver Resource services</u> 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 <u>primarily</u> 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.

<u>Electronic monitoring of beneficiaries</u>, 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.

<u>Transportation</u>: 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.

<u>Safety items</u>: Items such as shower safety bars may be offered as supplemental benefits since their exclusive goal is to prevent immediate injury.

<u>Travel for Transplants</u>: 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 <u>remote</u> or <u>distant</u> 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:

<u>Homemaker services</u> 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.

<u>Beauty items</u>: 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. Consequently, a wig in these limited situations can be considered a health care item or service.

<u>Meals</u>: 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 <u>primarily</u> 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; a plan may also offer the option of electronically paying for premiums from sources other than their Social Security payment, but may not charge or discount for this option. Furthermore, plans may not require electronic payment of premiums. All plans must allow premiums to be paid by monthly checks. Note: All Employer Group Waiver Plans (EGWPs) (MA and MA-PD plans offered by employers and unions to their employees and retirees) are ineligible for premium withhold.

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 <u>cost sharing</u> for plans with Out of Pocket (OOP) maximums:

- <u>If the plan's OOP max is not greater than \$3,100</u>: These plans will be granted latitude in establishing cost-sharing amounts for individual services;
- <u>If the plan's OOP max is greater than \$3,100:</u> These plans will be granted less latitude in establishing cost-sharing amounts for individual matters.
- 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, Nutritional Benefit, 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 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, specifically; lancets, syringes, needles and Insulin 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 <u>should</u>; 1) have contractual arrangements in place with providers or, 2) reimburse non-contracted providers directly.

L. Rules Applicable to Dual Eligible Enrollees in MA Plans

Section 1903(p)(3) of the Act requires State Medicaid Agencies to pay cost sharing amounts on behalf of Qualified Medicare Beneficiaries (QMBs). Paragraphs (n)(1) and (2) of section 1902 of the Act provide authority for State Medicaid agencies to eliminate cost sharing amounts on behalf of such beneficiaries through the State Medicaid Plan. Further, paragraph (n)(3) eliminates the requirement that QMBs pay cost sharing and requires the sum of Medicare Part C payments and any amount paid (or eliminated) by the State Medicaid Agency to be considered payment in full for the item or service in question. Thus, not collecting Part C cost sharing in such cases does not constitute a waiver of Part C cost sharing amounts.

Please note that CMS policy permitting different disenrollment policies for nonpayment of premium for dual eligibles – as discussed in PDP Guidance for Eligibility, Enrollment, and Disenrollment and in Chapter 2 of the Medicare Managed Care Manual – does not authorize plans to waive premiums for these enrollees. Plans must make the same reasonable efforts to collect premiums from all enrollees, including dual eligibles.

- M. 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.

N. 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
<u>Annual Coordinated Election Period (AEP)</u> : The AEP is from November 15, 2006 through December 31, 2006.	January 1, 2007.
<u>Open Enrollment Period (OEP)</u> : 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,	OEP elections are effective on the 1 st of the month following the month in which the election was made.
(OEP, cont.) 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.	
Open Enrollment Period for Newly Eligible Individuals (OEP <u>NEW</u>): 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 3 rd month of entitlement, or on December 31, 2006, whichever occurs first, subject to the limitations described above for the OEP.	OEP-NEW elections are effective on the 1 st of the month following the month the election was made.
An OEP-NEW election is separate from an OEP election.	

B. New Special Election Periods (SEP)

The following new SEPs will be established and included in future MA and PDP updates to guidance:

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 play 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

CMS is establishing an SEP for these individuals to choose a PDP or MA-PD plan on his/her own. If no choice is made, CMS will facilitate his/her enrollment into a PDP. If CMS facilitates the enrollment, the beneficiary can use the SEP to change plans.

The SEP will begin on the earlier of notification to the individual of LIS status or the effective date of facilitated enrollment, and will extend through December 31st of that year. Proof of eligibility for this SEP may include the subsidy award letter from SSA or the state, or a notice from CMS informing beneficiary that he/she has been deemed eligible for the subsidy and enrolled in a plan. LIS approval

letter, the CMS letter of facilitated enrollment, or the LIS deemed notice. The effective date for this SEP for MA-PD elections will be prospective, effective the first day of the month following receipt of the enrollment request by the plan.

C. Effective Dates for Auto-Enrollment for Full-Benefit Dual Eligible Individuals and for Facilitated Enrollments of Other LIS Individuals

Current guidance in Chapter 2 of the Medicare managed care guidance (section 40.1.6) directs MA Organizations to facilitate enrollments of full-benefit dual eligibles who elect an MA-only plan into an MA-PD with enrollment effective the first day of the 2nd month after these individuals are identified. In order to prevent any gap in prescription drug coverage for these individuals, CMS is <u>revising this guidance</u> and instructing MA plans to facilitate the enrollment for these individuals into MA-PD plans retroactive to the first day of the month in which the individual's enrollment into the MA-only plan was effective. The MA Organization must first notify the full-benefit dual eligible of facilitated enrollment. If the individual does not respond within 10 business days of the notice being sent, the MA Organization must submit an enrollment transaction to enroll the individual in the MA-PD retroactive to the effective date of enrollment in MA-only plan. Exhibit 27 of Chapter 2 will be revised to reflect this. The organization should follow existing procedures for submission of transactions with retroactive effective dates.

Please note the instruction for retroactive effective date applies only to those new enrollees who are full dual upon enrollment in the MA-only plan. However, for existing MA-only enrollees who later become a full-benefit dual eligible (i.e. become Medicaid eligble after a month or more of enrollment in the MA-only plan), the existing instructions in Chapter 2 for prospective effective dates will be maintained and apply.

These instructions also apply to Cost-Based plans that offer a Part D optional supplemental benefit, and to MA Private Fee-For-Service plans that offer a Part D benefit.

D. 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).

NOTE: As a potential means of improving the process of benefit delivery to new enrollees, we are considering the possibility of changing the effective date for enrollments received late in the month. We welcome plan comments or suggestions in this regard.

E. 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:

- 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.]

Part D Sponsors 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. 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.

However, 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. Unless and until the beneficiary provides acceptable evidence of creditable coverage to the MA-PD within 60 days of the beneficiary's effective date, the MA-PD will default to report to CMS that the beneficiary had no uncovered months. If no creditable coverage evidence is provided by the deadline, 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 that provides prescription drug coverage 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 BEO/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. If the beneficiary disagrees with an LEP decision made by CMS, 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 Managed Care 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.

In the initial years of the program, CMS will keep the full amount of the late enrollment penalty. In later years CMS may specify, and the MA-PD may be able to keep, the portion of the penalty that will be attributable to the MA-PDs' 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 Managed Care Manual for detailed guidance on the late enrollment penalty and MA-PD responsibilities in making creditable coverage determinations.

F. Cost-Based Plan 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.

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,

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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: <u>www.cms.hhs.gov</u> 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. Please note that all EGWPs are exempt from these requirements of prior review and approval.

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.

Plans 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. Plans 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.

CMS is proposing the following change in co-branding requirements. Effective with the beginning of CY 2007 marketing (October 1, 2006), entities that contract with a provider or providers as co-branding partners will be required to include the following language located below all co-branding names and/or logos on the member identification card and other marketing materials:

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

CMS invites comment on this issue, and on whether further restrictions may be warranted, including whether we should consider disapproving co-branding under section 1851(h)(2) of the Act.

C. Customer and Provider Telephone Contact Standards

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

Sponsors must operate a toll-free pharmacy technical help call center that operates 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.

Sponsors must also 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, 3) articulates and follows a process for resolution within one calendar day of call of expedited exceptions requests (3 calendar days for expedited 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 except the member identification card, the CMS contract number and a 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 elements of the model language and 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 and for employer/union group members. 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 July 15, 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 July 15, 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 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 copayments/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, and pharmacy directory. 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 11/15/06. Per 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.

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-Bsed 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. Organizations and demonstrations must also send an SB to employer/union group members with the ANOC; however, they are not required to use the standardized SB for these members.

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 December 31, 2006. 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 notice 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 December 31, 2006 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 Personal 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 Personal 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.

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

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

Plans will be able to preview their plan data for MPPF in September 2006. Due to the re-design, the exact dates for the preview are not yet scheduled. A separate memorandum outlining the preview dates will be provided later this summer.

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 14 and 15.

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 must provide members with wallet cards that say what their non-network cost sharing responsibilities will be. The card must say what the MA Organization will pay (in combined member cost sharing and MA organization reimbursement) the amount that FFS would have paid. The card must also say that non-network providers cannot bill more than they would have billed (including permitted balance billing), had the beneficiary been a FFS enrollee. The wallet card must also have a telephone number to call for plan payment and member cost sharing information and a URL where detailed payment and cost sharing information can be found on the Internet — if the MA Organization has a website.

Additional information on frequently used non-network services that should be included on the wallet card; emergency department copay; primary care and 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 MA-PDs

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

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 <u>https://gateway.cms.hhs.gov</u>, whereas AGNS users will use <u>http://32.91.239.68</u>. 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 <u>Don.Freeburger@cms.hhs.gov</u>. In order to obtain a CMS-issued user ID and password for HPMS access, please contact Neetu Jhagwani at either 410-786-2548 or <u>Neetu.Jhagwani@cms.hhs.gov</u>

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.

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: <u>www.cms.hhs.gov</u>. 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 Plans

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

The following sections consist of various issues related to MA Organizations or Cost-Based Plan Sponsors who offer Employer/Union-Only Group Waiver Plans (EGWPs), and Employers or Unions that contract with Medicare directly to sponsor their own Employer/Union-Only Group Waiver Plans (Direct Contract EGWPs). These categories represent policy and/or operational issues that will differ for 2007 as compared to 2006, as well as clarifications on certain issues for these types of plans.

B. 2007 EGWP Timeline (EGWPs and Direct Contract EGWPs)

For 2006, in areas such as application deadline, formulary submission, and bid submission, EGWPs operated under a separate timeline from the non-group market.

For 2007, all EGWPs will operate under the exact same timeline as the non-group market.

C. New EGWP Options for 2007 (Direct Contract EGWPs)

For 2007, employers and unions will have the option to directly contract with CMS to offer MA Private Fee-for-Service (PFFS) plans. Prospective Direct MA Organizations will complete their own Direct Contract EGWP version of 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 <u>http://www.cms.hhs.gov/EmpGrpWaivers/05_2007EGWPApps.asp#TopOfPage</u>. 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.

D. 2007 EGWP Renewal and Non-Renewal Process

Current EGWPs will not be required to apply for contract renewal. On or before May 1, 2006, CMS will issue a notice to each sponsor stating whether or not that sponsor is qualified to renew its contract for the following program year.

EGWPs that intend to non-renew their Medicare contracts must provide to CMS notice of their decision on or before June 5, 2006. EGWP procedures for notification to beneficiaries of non-renewal are the same as that in the non-group market.

E. 2007 EGWP Service Area Expansion and Reduction Process

If current MA Organizations want to expand their EGWP service area for 2007, they are to complete the 2007 Service Area Expansion Application for MA Organizations, PDP Sponsors and Cost Based Plan Sponsors located at http://www.cms.hhs.gov/EmpGrpWaivers/05_2007EGWPApps.asp#TopOfPage. MA Organizations will need to supply basic information on their organization, as well as a listing of all additional areas that are included in the expansion that were not included in the 2006 service area. Such expanded service areas must have convenient Part D pharmacy access sufficient to meet the needs of enrollees wherever they reside.

If current MA Organizations should want to reduce their service area, they should notify CMS before the June 5th deadline.

XIV. Medicare Medical Savings Account (MSA) Plans

Medicare Medical Savings Accounts (MSA) were made a permanent part of the MA program in 2003 with the passage of the Medicare Modernization Act. A Medicare MSA combines a high-deductible non-prescription drug MA Plan with a special tax favored savings account for medical expenses. The general rules for how a Medicare 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 Medicare MSA Plan. Enrollees eligible for Medicaid, or with ESRD, or those receiving hospice care are not eligible for enrollment. Additionally, individuals enrolled in a Federal Employees Health Benefits program or eligible for health care benefits through the Department of Veterans Affairs of the Department of Defense and "working aged "individuals are not eligible for enrollment.

- A beneficiary can enroll in a Medicare MSA 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 Part A and B. The initial coverage election period ends on the latter of the last day of the month preceding entitlement to both Part A and B or, after May 15, 2006 the last day of the individual's Part B initial enrollment period.
- Organizations offering Medicare MSA plans are responsible for obtaining MSA Account banking information from enrollees. Once the MSA account is set up, CMS deposits into the MSA a lump-sum amount for the first month the election is effective and all successive months of the year and makes this deposit in the month that the election and the enrollee has designated the account. 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.
- Optional Supplemental benefits are allowed under the Medicare MSA plan. The types of supplemental benefits that are permitted to be offered are specified in 42 CFR §§422.102(b), 422.104(b). However, Medicare MSA plans cannot offer mandatory supplemental benefits. A Medicare MSA plan may charge additional premium for optional supplemental benefits. Optional supplemental benefits offered in a Medicare MSA plan may not reduce the deductible related to covered Medicare services.
- Enrollees of Medicare MSAs are free to access services from any qualified Medicare provider. Medicare 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 Medicare MSAs 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 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.

2006	<i>IDAR – 2007 MA, MA-PD NON-RENEWAL PROCESS</i> <i>All dates are subject to change</i>
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 for individuals, but continue the county for Employer/Union Group members. May 1 — Deadline for MA, MA-PDs to submit partial county service area reduction requests.
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.
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

CMS may require an MA Organization to send a CMS-approved interim notification letter to affected beneficiaries if it finds that it is in the best interest of the program. MA Organizations that use the 2006 CMS Model Interim Notification Letter <u>without</u> any revisions do not need to submit their letter to their CMS Regional Offices (ROs) for review and approval prior to release. However, these MA Organizations must inform their RO of the dates the letter was mailed. They must simultaneously send the RO a dated copy of the letter.

MA Organizations that revise the CMS Model Interim Notification Letter must submit their letter to their RO for review and approval prior to release. Revised letters must not exceed two pages in length. It is anticipated that the RO review and approval process for interim notification letters will be expedited and take no more than 5 business days.

MA Organizations that wish to send an Interim Notification letter to its beneficiaries please contact Lettica Ramsey at Lettica.Ramsey@cms.hhs.gov to get a copy of the CMS Model Interim Notification letter no later than June 30, 2006.

- 2. Final Notification Letter to Beneficiaries
 - *a) Delivery Deadline*

All affected beneficiaries must <u>receive</u> 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 <u>October 2, 2006</u> 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 <u>not</u> 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 nonrenewing 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 CMSapproved 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, <u>all</u> 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 <u>without revision</u> 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. We strongly encourage MA Regional PPO plans to let us know by May 1, if they are thinking about withdrawing from the MA program.

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	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.
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.

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- 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 that use the 2006 CMS Model Interim Notification Letter <u>without any revisions</u> do not need to submit their letter to their CMS Regional Offices (ROs) for approval prior to release. However, a Medicare Cost-Based plan must inform its RO of the date the letter was mailed and send the RO a dated copy of the letter.

Medicare Cost-Based plans that revise the CMS Model Interim Notification Letter must submit their letters to their CMS ROs for approval prior to release. Revised letters must not exceed two pages in length. The RO review process for interim notification letters should be completed in 5 business days.

Medicare Cost-Based plans that wish to send an Interim Notification letter to their beneficiaries should contact Lettica Ramsey at <u>Lettica.Ramsey@cms.hhs.gov</u> to get a copy of the CMS Model Interim Notification letter by June 30, 2006.

- 2. Final Notification Letter to Beneficiaries
 - *a) Delivery Deadline*

All affected beneficiaries must <u>receive</u> 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 <u>not</u> 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 nonrenewing plans' service areas of their responsibilities and the Special Election Period (SEP).

d) Regional Office Review

<u>All</u> 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 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 preexisting 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 nonrenewal 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 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 plan submitted. This method will ensure that all affected members who do not enroll in another Medicare health plan or Medicare cost plan are placed in original Medicare in a timely manner.

Non-renewing Medicare cost 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 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 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 plans submit any final month deletions in accordance with the scheduled cut-off date for the final month of their contract.

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

D. Service Area Reductions

Medicare cost plans with service area reductions for 2006 must disenroll all members who reside in the non-renewed area or county. Medicare cost 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 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 plans will also receive a separate communication with specific systems instructions from CMS.

Medicare cost plans with any questions about the enrollment/disenrollment systems issues should contact Jacquline Buise at <u>jacquline.buise@cms.hhs.gov</u> 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 Littleaxe in CMS' Central Office. 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 & Medicare Advantage	Helaine Fingold	410-786-5014		
Cost Plan Appeals and Grievance Issues	Tim Roe	410-786-2006		
Cost 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		
Enrollment and Eligibility	Lynn Orlosky	410-786-9064		
HIPAA	Yolanda Robinson	410-786-7627		
HPMS Help Desk		1-800-220-2028 or		
•		new e-mail address		
		TBD		
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	410-786-3311		
	system)			
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 &	Lettica Ramsey	410-786-5262		
Guidelines				
PBP Changes	Pam Nicholson	410-786-0263		
Part C Appeals and Grievance Issues	Tim Roe	410-786-2006		
Renewal Process — 2007 Calendar &	Helaine Fingold	410-786-5014		
Guidelines	<u> </u>			

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-	Scott Nelson	410-786-1038	
Alone Prescription Drug Plan			
Coordination of Benefits, including	Jean Stiller	410-786-0708	
Part B/Part D coverage interactions			
Coordination of Benefits, including Part D	Christine Hinds	410-786-4578	
coverage interactions with: State			
pharmaceutical assistance programs			
(SPAPs), Medicaid, Retiree prescription			
drug plans			
Cost Plans Offering Part D	Frank Szeflinski	303-844-7119	
Creditable Coverage/Late Enrollment	Catherine Winfield-Jones	410-786-6674	
Penalty	Tamara Jackson-Douglas	410-786-9417	
	Tammi Hessen	410-786-1025	
Demonstrations – Part D Offerings	Rebecca Paul	410-786-0852	
Enrollment and Eligibility	Lynn Orlosky	410-786-9064	
Electronic Prescribing	Craig Miner, RPH.	410-786-1889	
Employer Sponsor Options	Jim Mayhew	410-786-9244	
Employer Group Waivers	Jim Mayhew	410-786-9244	
Formulary	Craig Miner, RPH.	410-786-1889	
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	Craig Miner, RPH.	410-786-1889	
Medigap	Julie Walton	410-786-4622	
Passive Enrollment — SNPs	Jane McClard	410-786-4460	
Pharmacy Benefit Cost & Utilization mgmt	Craig Miner, RPH.	410-786-1889	
PACE organizations Offering Part D	Brenda Hudson	410-786-4085	
Benefits			
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:	Vanessa Duran	214-767-6435	
benefit packages and Part D covered drugs			
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_HealthInsurancePortabilityandAccount abilityActof1996(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	
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CY	Y 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 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.	2006 plan and retains all of	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.	transactions not required	Beneficiaries are sent a regular ANOC.
3	Consolidated Renewal Plan	An MA organization <i>combines</i> 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.		The MA organizations designated renewal plan ID must remain the same so that CMS can consolidate the beneficiary's election by moving them in the designated renewal plan ID. The MA organization does not submit any transactions.	transactions not required for current members during the renewal	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 service area, but also add 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.	2006 plan and retains all of its plan service area from 2006, but also adds one or	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.	for current members	Current Beneficiaries are sent a regular ANOC.
		This option is available to local MA plans only.				

CY	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
5	SAR	An MA organization <i>reduces the service area</i> 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 (contract 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 at: URL TBD by April XX, 2006 .	2006 plan and retains only	portion of the service area will remain in the same plan ID. The MA organization does not submit any transactions for these members.	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	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 CMS website at: URL TBD	Two or more 2007 plans that are created from one 2006 plan with membership determined by provider choice.	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	Y 2007 Guidance for MA and MA-PD Plan Renewals					
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	Beneficiary Notification
8	Renewal Plan Split by Segmentation	difference between the resulting MA plan segments is premium and/or cost-sharing. A segment cannot be smaller	A 2006 plan (no segments) that maps into one 2007 plan with plan segments that share identical benefit packages with the exception of premium and/or cost-sharing. A segment ID is added to the PBP identifier for each plan segment defined.	The MA organization must submit transaction type 72 change transactions to move the members to the appropriate segments based on their county of residence.		Beneficiaries are sent a regular ANOC.
9	Consolidated Renewal Plan with Segments	segments are offered the same benefits in CY 2007. The	Multiple 2006 plans (no segments) that are mapped to one 2007 plan with segments that share identical benefit packages with the exception of premium and/or cost- sharing. A segment ID is added to the PBP identifier for each plan segment defined.	The MA organization must submit transaction type 72 change transactions to move the members to the appropriate segments based on their county of residence.		Beneficiaries are sent a regular ANOC.
10	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.	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

<u>Rebate Reallocation Period.</u> Following CMS' publication of the Part D national average monthly bid amount, the Part D base beneficiary premium, the Part D regional lowincome 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.

<u>Target Part D basic premium</u>. 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

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. DRAFT 2/21/2006 5:02 PM

Thus, the rebate reallocation period does not apply to local MA-only plans. That is, MA organizations will <u>not</u> 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.

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.

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 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.

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.

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.

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

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

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.

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 C3: C	Jptional Rebate Reallocation, given "Excess" Initial A	llocation	
June - initial bid	Estimate pre-rebate D basic premium	\$35	
submission	Identify target premium (post-rebate premium)	\$20	
	Determine rebate amount to apply to pre-rebate D basic premium	\$15	
	to "buy down" to target premium		
August – Part D	Outcome of nat'l Part D average bid and base premium:		
benchmarks	August pre-rebate D basic premium	\$30	
published	August post-rebate premium, applying June rebate allocation	\$15 [\$30-\$15]	
	Identify rebate allocation needed to move August pre-rebate	\$10 [\$30-\$20]	
	premium to target premium [August pre-rebate – June target]		
	Calculate "excess" rebate	\$5 [\$15-\$10]	
	[June rebate – August rebate]		
Rebate	(a) No rebate reallocation; leave at post-rebate D basic premium of \$15.		
Reallocation	(b) Reallocate \$5 of "excess" rebate to other benefits to return to target premium of		
Options	\$20		

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.

June - initial bid	Estimate pre-rebate D basic premium	\$35	
submission	Identify target premium (post-rebate premium)	\$20	
	Determine rebate amount to apply to pre-rebate D basic	\$15	
	premium to "buy down" to target premium.		
August – Part D	Outcome of nat'l Part D average bid and base premium:		
benchmarks published	August pre-rebate D basic premium	\$40	
	August post-rebate premium, applying June rebate	\$25 [\$40-\$15]	
	allocation		
	Identify rebate allocation needed to move August pre-	\$20 [\$40-\$20]	
	rebate premium to target premium		
	[August pre-rebate – June target]		
	Calculate "insufficient" rebate \$5 [\$20-\$15]		
	[August rebate to achieve target premium – June rebate]		
Rebate Reallocation	(a) No rebate reallocation; leave at post-rebate D basic premium of \$25.		
Options	(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.		

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

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.

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

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

Section III. Changes Allowed to Funding of Benefits during Rebate Reallocation Period

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.

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B. Allowed to Funding of the Part C Supplemental Benefits

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.

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.

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 eliminate a Part C supplemental benefit.

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.

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 than the target premium, CMS would allow a return to the plan's 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.

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.

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

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.

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).

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. <u>Local MA-only plans</u>. 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 <u>not</u> 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. <u>Regional plans and local MA-PD plans</u>. 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 \times 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

Examples of rounding.

<u>Example (a)</u>: 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 <u>\$30.42</u>, 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.)

<u>Example (b)</u>. 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 <u>\$32.42</u>, 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 <u>not</u> 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.

<u>Example (d).</u> 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-lowincome-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.

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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.

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. Kisk Aujustment 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

Table 1. Risk Adjustment Implementation Calendar

* 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.

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

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*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). <u>Plans interested in this option must contact: Henry</u> 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*.)

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

TABLE 3. ACCEPTABLE PHYSICIAN DATA SOURCES

*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 supersede 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.

(j) 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 CFR. 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 USC § 1341;
- (2) The Indian Self Determination and Education Assistance Act; 25 USC § 450 et seq.;
- (3) The Federal Tort Claims Act (FTCA), 28 USC § 2671-2680;
- (4) The Federal Medical Care Recovery Act, 42 USC § 2651-2653;
- (5) The Federal Privacy Act of 1974, 5 USC §552a, 42 CFR 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.

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.

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 Provider which is an Indian tribe, tribal organization or urban Indian organization.

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