DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR DRUG AND HEALTH PLAN CHOICE

TO: Medicare Advantage Organizations
Medicare Advantage-Prescription Drug Organizations
Cost-Based Contractors
Prescription Drug Plan Sponsors
Employer/Union-Sponsored Group Health Plans
Programs of All-Inclusive Care for the Elderly Organizations

FROM: Jonathan Blum, Acting Director, Center for Drug and Health Plan Choice

RE: Issuance of the 2010 Call Letter

DATE: March 30, 2009

I am pleased to provide you with the 2010 Call Letter for Medicare Advantage (MA) organizations (MAOs); section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including employer/union-only group waiver plans (EGWPs). The Call Letter contains information these organizations will find useful as they prepare their bids for the upcoming contract year.

We received approximately 190 comments from plan sponsors and plan sponsor associations; advocacy organizations and consumer groups; pharmaceutical manufacturers and their associations; members of Congress; States and State associations; pharmacists and pharmacy associations; providers and provider associations; and other individuals on the draft Call Letter we issued for public comment on February 23, 2009. We carefully considered all comments we received and have made revisions and clarifications in response to these comments in this final 2010 Call Letter.

In some areas, we received a number of constructive comments which we will consider addressing for future contract years. For example, we requested comments regarding whether, and if so, how we should calculate and disseminate information about plans' medical loss ratios. Given this issue's complexity, we will continue evaluating methodologies for possible future implementation. We will also continue to study the issue of our reassignment processes for low-income subsidy (LIS) eligible individuals for potential future improvements that are consistent with our statutory authority. We will also continue to work with plans that are losing members to identify appropriate ways to reach out to these members to explain how they can remain in their current plan and what their premium liability will be if they choose to do so.

As we indicated in the draft document, the 2010 Call Letter focuses on new guidance necessary for preparing for contract year 2010. Sponsoring organizations continue to remain responsible for familiarizing themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Managed Care and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, HPMS data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

2010 Call Letter

How to Use this Document

The 2010 Call Letter contains information on the Part C, cost-based, and Part D programs combined into one document. Also, we indicate when sections apply to PACE and employer and union-sponsored group health plans. Section A provides MA, MA-PD, and cost plan guidance; Section B provides information for Part D sponsors; Section C contains marketing-related information that applies to all plan types; and Section D contains attachments to the material contained in Sections A-C.

If you have questions concerning this Call Letter, please contact Vanessa Duran at Vanessa.Duran@cms.hhs.gov or Rosetta Hicks at Rosetta.Hicks@cms.hhs.gov.

Section A – 2010 MA, MA-PD, and COST PLAN SECTIONS

Note on 2010 MA, MA-PD, and Cost Plan portion of the Call Letter

With few exceptions, Medicare Advantage organizations (MAOs) offering a prescription drug benefit (MA-PDs) and cost plans offering a Part D benefit (Cost-PDs) must follow all Part D requirements in addition to following MA or cost plan guidance as applicable. All MA-PDs and Cost-PDs should follow the Part D guidance as specified in Section B of this Call Letter and especially the Prescription Drug Benefit Manual and Part 423 of Title 42 of the Code of Federal Regulations (CFR). Such requirements include the formulary and pharmacy access requirements specified in Chapters 5 and 6 of the Prescription Drug Benefit Manual and the Part D portion of this Call Letter. Our discussion in Section A focuses primarily on the MA and cost plan operational guidance that we want to bring to your attention as you prepare for the 2010 contract year. Section C contains marketing-related information that applies to MAOs, cost plans, and PDPs. We will, however, highlight information related to the Part D benefit that is specific to MA-PDs and Cost-PDs. Unless otherwise indicated, all regulatory references in this section are to Title 42, Part 422 of the CFR.

2010 MA, MA-PD, and Cost Plan Calendar

In order to assist you in meeting all deadlines for renewal, enrollment, bidding, and other provisions as you prepare to offer health care benefits in 2010, we are including a calendar of key dates and timelines. Please note that, except as otherwise specified in statute or regulation, the dates given here are subject to change. Organizations should also note that these dates are not exhaustive, and they must consult the appropriate sections of the Part C, cost plan, and Part D regulations and guidance for important information associated with these timelines. The Part D section of this Call Letter includes a table of key dates for Part D sponsors including MA and Cost organizations offering a prescription drug benefit under Part D. Organizations should continue to monitor the general applications timeline posted on the CMS website at http://www.cms.hhs.gov/MedicareAdvantageApps/.

NOTE: Employer/Union-Only Group Waiver Plans (EGWPs) are subject to the same timeline and requirements set forth below, except for dates or requirements that do not apply or are modified due to existing employer group waivers.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
March 27, 2009	2010 Call Letter released.
March 30, 2009	Release of Health Plan Management System (HPMS) formulary submissions module.
April 1, 2009	Conference call with industry to discuss the 2010 Call Letter.
April 2, 2009	Medicare Advantage and Part D National Conference
April 6, 2009	Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies.
April 10, 2009	2010 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
April 20, 2009	2010 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT).
May 1, 2009	***Voluntary Non-Renewal***: CMS strongly encourages MA and MA-PDs to notify CMS of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members, by May 1, 2009. Additionally, CMS strongly encourages MA and MA-PDs to submit partial county service area reduction requests affected by non-renewal of a contract by May 1, 2009. Requests must include documents for justification that meet the county integrity rule as outlined in Chapter 4 of the Medicare Managed Care Manual.
May 15, 2009	CMS begins accepting CY 2010 bids via HPMS.
Mid-May 2009	CMS sends contract eligibility determinations to applicants based on review of the 2010 applications for new contracts or service area expansions.
Tentative Date May 29, 2009	Industry training on Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) and other marketing models.
Late Spring/Early Summer, June 2009	Update of the MA/PDP Enrollment, Eligibility, and Disenrollment Guidelines.
June 1, 2009	Deadline for submission of CY 2010 bids for all MA, MA-PD, cost, "800 series" EGWP and Direct Contract EGWP applicants and renewing organizations; deadline for cost plans wishing to appear in the 2010 Medicare Options Compare to submit PBPs (11:59 p.m. PDT). ***Voluntary Non-Renewal***: Deadline for MA and MA-PDs to submit a contract non-renewal, service area reduction notice to CMS for CY 2010. Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PDs Plan Benefit Package (i.e., Plan 01, Plan 02) for CY 2010. Medicare cost-based contractors and cost-based sponsors encouraged to submit a non-renewal or service area reduction notice to CMS.
June 5, 2009	CMS begins accepting CY 2010 marketing material for review.
June 8, 2009	CMS begins accepting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY 2010 Actuarial Certifications in HPMS.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
June 30, 2009	Final date for MA, MA-PD and cost-based organizations to submit CY 2009 marketing materials for CMS' review and approval. NOTE: This date does not apply to CY 2009 file and use materials since these may be filed with the regional office five calendar days prior to their use.
August, 2009	***Non-Renewal***: CMS to release a Special Election Period (SEP) letter to MA and MA-PDs plans remaining in the service areas of plans that have non-renewed. Additionally, CMS to post the model final non-renewal notification letter, and State-specific final notification letter. Release of the 2010 Part D National Average Monthly Bid Amount, the Medicare Part D Base Beneficiary Premium, the Part D Regional Low-Income Premium Subsidy Amounts, and the Medicare Advantage Regional PPO Benchmarks. Rebate reallocation begins. Five business day rebate reallocation period begins after release of RPPO benchmarks.
Early August, 2009	Cost-based plans are encouraged to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Options Compare" and the *Medicare & You* handbook.
August 1, 2009	Deadline for CMS to inform currently contracted organizations of CMS' decision not to authorize a renewal of a contract for 2010.
August 3, 2009	MA-PD plans are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review.
August 14, 2009	MA-PD plans are expected to submit Low Income Subsidy (LIS) riders to the regional office for review. Cost plans offering Part D are expected to submit Low Income Subsidy (LIS) riders for review. Dual eligible SNPs that are fully integrated with the State are expected to submit the Annual Notice of Change and Summary of Benefits to the regional office for review.
Late August, 2009	***Non-Renewal***: Final date for CMS to approve MA and MA-PD's final beneficiary notification letter of non-renewal.
Late August/Early September 2009	CMS completes review and approval of 2010 bid data. Submission of attestations, contracts, and final actuarial certifications.
September, 2009	MA, MA-PD organizations and, if applicable, Medicare cost-based plans preview the 2010 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
September 18, 2009	Broker/agent compensation structures must be submitted to CMS.
October 1, 2009	MA, MA-PD organizations and Medicare cost-based plans may begin CY 2010 marketing activities. Once an organization begins marketing CY 2010 plans, the organization must cease marketing CY 2009 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2009 materials upon request, conduct one-on-one sales appointments and process enrollment applications. MA, MA-PD organizations, and Medicare cost-based plans are required to include information in CY 2009 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2010. Deadline for Cost, MA, and MA-PD organizations to request a plan correction to the plan benefit package (PBP). Last date for contracting MAOs to provide CMS with evidence of contracting with the State in order to operate a Medicaid subset dual eligible SNP for CY 2010. Dual eligible SNPs that are fully integrated with the State that plan to use a non-standardized, non-combined EOC are expected to submit for regional office review.
October 2, 2009	***Non-Renewal***: Medicare cost-based contractors and cost-based sponsors to submit a non-renewal or service area reduction notice to CMS.
October 9, 2009	Tentative date for 2010 plan benefit data to be displayed on Medicare Options Compare and for 2010 plan drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).
Mid-October, 2009	***Non-Renewal***: CMS to issue an acknowledgement letter to all Medicare cost-based plans that are non-renewing or reducing their service area.
October 15-20, 2009	CMS mails the 2010 *Medicare & You* handbook to Medicare beneficiaries.
October 31, 2009	CY 2010 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to all MA, MA-PD members, and members of cost-based plans offering Part D. MA and MA-PD organizations must mail the combined ANOC/EOC before this

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
	date to ensure receipt by members by October 31. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC. Exception: Dual eligible SNPs that are fully integrated with the State are not required to use the standardized, combined ANOC/EOC. Dual eligible SNPs that are fully integrated with the State must mail an Annual Notice of Change and Summary of Benefits before this date to ensure receipt by members by October 31. All MA-PDs and cost-based plans offering Part D must mail their LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by October 31.
November 2, 2009	***Non-Renewal***: The final beneficiary non-renewal notification letter must be a personalized letter and received by MA, MA-PD, and cost-based plan enrollees by November 2, 2009.
November 15, 2009	2010 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.4.4). Marketing guidelines require that MA, MA-PD, and cost-based organizations mail a CY 2010 EOC to each new member no later than when they notify the new member of acceptance of enrollment. Organizations offering Part D must mail their Low Income Subsidy Rider (LIS) and abridged or comprehensive formularies with the EOC for new members. New members with an effective date of 1/1/2010 or later do not need to (but may) receive the ANOC portion of the standardized/combined ANOC/EOC.
Tentative Date – November 17, 2009	Notices of Intent for CY 2011 due for MA, MA-PD, cost, "800 series" EGWPs and Direct Contract EGWPs.
Tentative Date – November 25, 2009	CMS issues pending HPMS contract numbers for CY 2011 to MA, MA-PD, cost, and EGWP contracts.
November – December, 2009	***Non-Renewal***: CMS to issue "close out" information and instructions to MA, MA-PDs, and cost plans that are non-renewing or reducing service areas.
December 1, 2009	Medicare cost-based plans not offering Part D must send the combined ANOC/EOC for receipt by members by December 1, 2009.
December 1, 2009	***Non-Renewal***: Cost-based plans must publish a CMS-approved public notice of non-renewal in one or more newspapers of general circulation covering each community or county in their contract areas.

2010 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2009	
December 31, 2009	2010 Annual Coordinated Election Period ends. Dual eligible SNPs that are fully integrated with the State must mail an Evidence of Coverage, LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by December 31.
2010	
January 1, 2010	Plan Benefit Period Begins.
January 1 – March 31, 2010	MA Open Enrollment Period (OEP).
Early January, 2010	Automated CY 2011 applications released.
Early January, 2010	Industry training on CY 2011 applications.
Late February, 2010	Applications due for CY 2011.

I. Contracting Process

Multiple and Low Enrollment Plan Offerings by MAOs

Many MA organizations offer a large number of plan benefit packages per contract. In some cases, these plan offerings have very low enrollment and virtually indistinguishable benefit differences. MA organizations should undertake to eliminate plan offerings for 2010 that have little or no enrollment, and duplicative plan offerings that are not easily distinguished by beneficiaries and could cause beneficiary confusion. In order to facilitate this change, CMS will authorize the transition of existing beneficiaries in eliminated plans to another plan offered by the MAO under appropriate circumstances. An example of such a circumstance includes when a sponsoring organization has another MA plan with similar benefits, formularies, premiums, and network rules. If the organization does not offer such a plan, beneficiaries enrolled in a plan that the MA organization terminates will be disenrolled to Original Medicare absent an active election of a different plan. We note that these individuals will have a special election period (SEP) to change plans, consistent with our existing non-renewal policy.

Organizations offering more than one plan in a given service area should ensure plan differences are transparent, readily discernable to beneficiaries and meant to provide the highest value at the lowest cost. Examples of meaningful differences in plan benefit design include, but are not limited to, plans with and without the Part D benefit, and plans with and without specific supplemental benefit options, and different plan types.

Based on previous experiences in the Medicare Advantage program, we believe that multiple plan offerings by MAOs may not result in beneficiaries choosing a plan which best suits their health care needs, but can, instead, confuse beneficiaries. Additionally, we are concerned that the current multitude of MA plan offerings may conceal aspects of a plan, such as high cost sharing for certain services, which are not advantageous to beneficiaries. In order for beneficiaries to have a choice of plans that represent genuine differences we would expect MAOs to offer no more than three MA plans by plan type in a market area, and ensure that each plan offered is readily distinguishable from the others based on plan type, benefits offered, access, or other features that permit beneficiaries to choose a health care plan most suitable to their needs.

Similarly, low enrollment can be an indication of financial instability, and is detrimental to the spreading of risk, both of which can adversely affect the ability of health plans to provide high quality health care at an affordable price while continually protecting beneficiaries. There are currently large numbers of plan offerings with fewer than 10 enrollees. As a result, we will review all MA plans with low enrollments for more than three years. CMS recognizes that there may be factors, such as beneficiary population served and geographic location, which may make lower enrollments reasonable, and will take such information into account when evaluating specific plans.

CMS encourages MAOs that have questions about the appropriateness of plan offerings to contact CMS early in the process in advance of the bid filing deadline so that MAO plan offerings will have a greater likelihood of success in the application and bidding processes. The ultimate goal is that plan offerings will represent genuine choice and high value health care options to beneficiaries.

In response to public comments, CMS is considering rule making to limit plans to no more than a specified number of benefit designs in a given service area and to require consolidation of plans with low enrollment.

Dual Eligibles and Cost Sharing

MIPPA outlined several new provisions for dual eligibles enrolled in Special Needs Plans (SNPs). One provision put a limitation on out-of-pocket costs for full-benefit dual eligibles and qualified Medicare beneficiaries (QMBs) enrolled in SNPs. A dual SNP may not impose or permit providers to collect cost sharing that exceeds the amount of cost sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan.

The 4138 IFC2 regulation extends this cost sharing limitation to all MA plans that have dual eligible enrollees and to all dual eligible categories for which a State provides coverage and chooses to protect beneficiaries from the cost sharing for Medicare A and B services. Under the new regulatory requirements at 42 CFR §422.504(g)(l)(iii), all MA organizations are responsible for ensuring that they do not impose cost sharing amounts on their dual eligible members that exceed the amount of cost sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in an MA plan. In addition, all MA plans with dual eligible enrollees must inform providers and include in their provider contracts that dual eligible

enrollees will not be responsible for any plan cost sharing for Medicare A and B services when the state is responsible for paying those amounts.

Additionally, the contracts with providers should state that the provider will do this either by accepting the MA plan payment as payment-in-full or by billing the appropriate state source.

II. Benefit Design

Cost Sharing Guidance

CMS' goal is to establish a more transparent process so that beneficiaries will be able to better predict their out-of-pocket (OOP) costs in order to select a plan that best meets their individual health care needs and be protected from excessively high or unexpected cost sharing. Toward that end, for MA plans that impose co-insurance (i.e., a percentage rather than a flat copayment amount) for any Part A or B services, CMS will likely not consider the imposition of this co-insurance to discriminate against high cost enrollees who might need the service in question if (1) the plan has an overall OOP maximum of $3,400[1], and (2) the co-insurance for renal dialysis, Part B drugs, psychiatric hospitalization, home health, and skilled nursing facility (SNF) services does not exceed the co-insurance that applies under Original Medicare, and (3) the plan does not exclude (carve out) any Part A/B services from the OOP maximum.

For MA plans that do not impose co-insurance in any service category:

- Plans with a plan-level OOP maximum amount not greater than $3,400 will have flexibility in establishing cost sharing amounts for individual services without the plan being found to be discriminatory as long as copayments for renal dialysis, Part B drugs, psychiatric hospitalization, and SNF services do not exceed the Original Medicare coinsurance amounts.

- Plans with a plan-level OOP maximum amount greater than $3,400 will receive greater scrutiny of cost sharing amounts for individual services in determining whether the plan is discriminatory.

- Plans without a plan level OOP maximum will receive the greatest scrutiny with respect to whether cost sharing amounts for individual services result in the plan being discriminatory.

CMS is considering amending the regulations that would impose a requirement for an OOP maximum amount.

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[1] The Medicare Advantage out-of-pocket (OOP) threshold is based on a beneficiary-level distribution of A/B cost sharing for individuals enrolled in original Medicare. The CY 2010 OOP threshold of $3,400 represents the 85th percentile of projected beneficiary spending in 2010. Stated differently, 15 percent of original Medicare beneficiaries are expected to incur $3,400 or more in Parts A and B deductibles and coinsurance in 2010.

While reviewing all benefit packages, CMS will continue to review cost sharing for services usually associated with chronic and acute conditions, high utilization and high costs such as inpatient acute and psychiatric hospital, outpatient hospital, home health, renal dialysis, Part B drugs, skilled nursing facility (SNF) and durable medical equipment (DME) services. Also note that benefit design and cost sharing amounts approved for CY 2009 will not automatically be acceptable for CY 2010 since a separate and distinct review is conducted each contract year.

For additional cost sharing guidance, please see Section 20.13, "Guidance on Acceptable Cost sharing and Deductibles," of Chapter 4, "Benefits and Beneficiary Protections," of the Managed Care Manual located at: http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf.

Plan Corrections for 2010

Expectations are that with the experience gained over the last four years of bid submissions, requests for plan corrections for CY 2010 will be minimal. As required by 42 CFR 422.254, submission of the final actuarial certification and the bid attestation serve as documentation that the final bid submission has been verified and is complete and accurate at the time of submission. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. Please be advised that an MAO requesting a plan correction will receive a corrective action warning letter.

However, even though we expect MAOs to ensure that the original plan benefit package (PBP) submission is a true representation of the benefits package being offered, the plan corrections module will be available in HPMS for CY 2010 benefits for a limited period, from early September until October 1, 2009. Consistent with marketing and open enrollment coordination, MAOs will not be able to request plan corrections for CY 2010 benefits packages after the October 1, 2009 deadline. This will ensure that correct bid information will be available for review on Medicare Options Compare in time for the open enrollment start date of November 15, 2009. It is important to note that only changes to the PBP that are supported by the Bid Pricing Tool (BPT) are allowed during the plan correction period.

Preventive Services Incentives

An incentive is an item or service that a plan offers conditional to an enrollee taking some action (e.g., receiving a flu shot), or participating in some program (e.g., a smoking cessation program). The terms "rewards" and "incentives" are used interchangeably.

CMS is committed to promoting the appropriate use of Medicare preventive benefits. Medicare covers a broad range of services to: (1) prevent disease; (2) detect disease early when it is most treatable and curable; and (3) manage disease so that complications can be avoided. Unfortunately, Medicare beneficiaries even with frequent visits to physician offices are not receiving all recommended preventive services for various reasons. The offering of a limited incentives program will provide Medicare Advantage Organizations an opportunity to improve preventive care participation by Medicare Advantage enrollees.

Guidelines for Incentives

CMS recognizes the potential value of a skillfully developed Incentive program to facilitate participation in prevention activities. However, CMS would like to emphasize that the primary focus of any plan benefit package design should be the delivery of Medicare Parts A and B benefits at the lowest cost. CMS will recognize an incentive program as appropriate and permissible if it meets the following criteria:

Required Criteria for Incentives

The incentive:

1. Must be offered to promote the delivery of Medicare covered preventive benefits;

2. Must be earned by doing activities that are either Medicare Advantage benefits – such as flu shots – or educational (in person or online) and directly health related – such as nutrition, blood pressure, weight loss, etc.

3. May not be tied to a specific health outcome, such as lowering weight or blood pressure;

4. May not be an item that is itself a health benefit (e.g., a free checkup);

5. May not consist of lowering or waiving of co-pays;

6. May not be items that are otherwise available, to the general public, for free.

   Additionally, incentives must be offered to current plan members only, for the entire contract year, and uniformly to all plan enrollees;

7. May not be used in pre-enrollment advertising, marketing, or promotion of the plan, such as in the PBP, SB, ANOC or EOC (rewards and incentives may only be discussed in post-enrollment notifications). The incentive program must be described in the PBP Notes;

8. May not be structured to steer enrollees to particular providers, practitioners, or suppliers;

9. May be discussed in direct mailings to enrollees (as long as there is no violation of the Health Insurance Portability and Accountability Act (HIPAA) privacy laws);

10. Each item must be of nominal value with a retail value monetary cap not to exceed $10 per item or $50 in the aggregate on an annual basis per member per year, figures based on guidance from the Office of Inspector General; and

11. When an incentive program incurs a cost, then this cost must be priced in the bid and combined with the cost of other non-covered benefits in line q of the MA BPT. Supporting documentation is required with the initial June bid submission. This is for accounting purposes only. Combining the costs with “Other Non-Covered” does not change the nature of incentives – which cannot be “benefits” – see item #4. For more information, see the CY 2010 BPT instructions.

12. May not be cash, monetary rebates, or gift cards, which CMS considers analogous to cash;

13. Must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute (section 1128B(b) of the SSA) and civil monetary penalty prohibiting inducements to beneficiaries (section 1128A(a)(5) of the SSA);

14. Must be tracked and documented during the contract year;

15. Are subject to grievances by the enrollee: Consequently, the plan must explicitly advise enrollees of the right to grieve and the process for filing a grievance.

16. May not be tied directly or indirectly to the provision of any other covered item or service.

The Medicare Preventive services are as follows:

- "Welcome to Medicare" visit (includes a referral for an ultrasound screening for Abdominal Aortic Aneurysm for eligible beneficiaries)
- Adult Immunization--Influenza Immunization, Pneumococcal Vaccination, Hepatitis B Vaccination
- Colorectal Cancer Screening
- Screening Mammography
- Screening Pap Test and Pelvic Examination
- Prostate Cancer Screening
- Cardiovascular Disease Screening
- Diabetes Screening
- Glaucoma Screening
- Bone Mass Measurement
- Diabetes Self-Management, Supplies, and Services
- Medical Nutrition Therapy
- Smoking Cessation

More information on the Medicare Preventive Services can be found at:

http://www.cms.hhs.gov/PrevntionGenInfo/

http://www.medicare.gov/Health/Overview.asp

All incentive programs must also comply with section 1128A(a)(5) of the Social Security Act. This provision prohibits offering or transferring remuneration to a Medicare or Medicaid

beneficiary if the individual or organization making the offer knows or should know that the remuneration is likely to influence the beneficiary's choice of a particular provider, practitioner, or supplier. Incentives offered by a health plan to encourage a beneficiary to enroll in a plan generally do not implicate section 1128A(a)(5) (although such incentives may implicate the Federal anti-kickback statute or other fraud and abuse authorities); however, incentives that encourage a beneficiary to use a particular provider, practitioner, or supplier after enrollment potentially implicate the statute. There are exceptions for certain incentives to promote the delivery of preventive care services, provided that the incentives meet all of the conditions set out in the regulations. See 42 CFR 1003.101. The Office of Inspector General is responsible for enforcing section 1128A(a)(5). Further information about the application of section 1128A(a)(5) can be found on the Office of Inspector General's webpage at hppp://oig.hhs.gov.

Part C Supplemental Over-The-Counter (OTC) Benefit

The basic guidance on offering a supplemental, Part C over-the-counter (OTC) benefit was presented in the 2009 call letter. We update guidance in three areas:

- CMS will no longer use lists of OTC categories of items from outside sources. The CMS list of OTC categories of items is presented in Appendix I and will be incorporated in the next update of Chapter 4, "Benefits and Beneficiary Protections," of the Medicare Managed Care manual.

- OTC items belonging to categories on this list are classified as eligible, dual-purpose or non-eligible. A non-eligible item may not be offered by the plan either individually or as part of a packaged benefit. Any individual or combination of eligible items may be offered by the plan as a supplemental Part C benefit, either as an individual benefit or as part of a packaged benefit, and the enrollee may purchase these items without any further action. Any individual or combination of dual-purpose items may be offered by the plan as a supplemental Part C benefit, either as an individual benefit or as part of a packaged benefit; however, the plan must state in its marketing materials that an enrollee may only purchase these dual-purpose items if the enrollee a) first discusses the purchase of the items with their personal provider, and b) their personal provider orally recommends the item for a specific diagnosable condition. The plan is responsible for notifying its enrollees on the precise set of OTC categories of items that it furnishes.

- An OTC supplemental Part C benefit, whether of an individual or packaged set of items, whether paid for by direct reimbursement or through a debit card, must provide the enrollee with access to the benefit. CMS has interpreted access as meaning a) access at a wide variety of chains and stores and b) identical payment methods at a wide variety of chains and stores.

More specifically, an MAO may not provide a supplemental, Part C, packaged OTC benefit by offering a debit card that is usable in only one pharmacy chain and allow catalog or direct reimbursement payment at other chains. By restricting the more convenient debit card to one chain, the MAO may be inadvertently steering enrollees to that pharmacy chain, and all forms of such steerage are prohibited.

As a result of many inquiries, we have expanded our guidance on catalogs. The following rules apply:

- Catalog form: A catalog can take the form of a hard paper catalog, a simple collection of sheets, or a web catalog;

- Catalog information: At a minimum the catalog, in any form, must contain 1) a list of categories of OTC items, 2) the classification of these categories as eligible, dual purpose or non-eligible, 3) prices, 4) clearly written footnotes indicating which categories of items are potentially, in certain circumstances, purchasable under Part B or Part D with an explicit statement that enrollees, when in these circumstances, should purchase the given items, not as an OTC item, but the same way they purchase Part B or Part D items, and 5) an 800 number or a mailing address with instructions on how to obtain the items. Each plan must list the CMS non-eligible categories in its catalog. A plan may not offer any category of OTC item unless it is listed on its catalog;

- Postal costs: A plan must cover the postal costs of shipping. For example, if a plan offers up to $25 a month in OTC items including typical incurred shipping and handling costs of $5 a month, then the plan cannot cap OTC purchases at $20 a month; rather the plan must absorb the $5 shipping and handling cost;

- Minimum purchase amount: Because plans must absorb postal costs CMS allows plans to place a minimum purchase amount. For example a plan offering up to $25 a month in OTC items may require a minimum purchase of $15. Each enrollee can then make up to one purchase per month with aggregate cost between $15 and $25; and

- Web catalogs: Although plans may provide a catalog through a website, the plans must notify each enrollee of their right to obtain a hard copy of the catalog upon request.

Obtaining Benefits during a Federal Disaster or Other Public Health Emergency

CMS appreciates MA plans' responsiveness to the federal disasters that occurred in 2008 such as the Midwest floods and Hurricanes Gustav and Ike. We are taking this opportunity to provide additional guidance to MA plans on actions they may take in connection with future emergencies or disasters.

In any declared emergency or disaster (for example, if the governor of the state in which the MA plan is located declares an emergency, or if FEMA (http://www.fema.gov/) issues a major disaster declaration in the MA plan's service area, or if the President declares an national emergency or the Secretary of Health and Human Services declares a public health emergency) MA Plans that are concerned about disruption of provision of needed benefits, may, without waiting for explicit CMS guidance, voluntarily implement all, or portions, of the guidance presented below.

The voluntary actions that plans may choose in order to facilitate provision of benefits are as follows:

- Each MAO may, at its discretion, allow Part A/B and supplemental plan-benefits to be furnished at specified non-contracted facilities (note, that Part A/B benefits must, per 42 CFR 422.204(b)(3), be furnished at certified facilities);

- Each MAO may, at its discretion, waive in full, or in part, requirements for authorization or pre-notification; and

- Each MAO may, at its discretion, temporarily reduce plan approved cost sharing amounts. Furthermore, although MAOs are required to notify enrollees 30 days in advance of plan changes, this 30-day notification requirement can be waived by CMS during a declared emergency provided all the changes (such as reduction of cost sharing and waiving authorization) benefit the enrollee.

We expect MA plans to resume normal operations once the emergency or disaster is over. Typically the source that declared the disaster will clarify when the disaster ends. However, in the case of disasters declared by FEMA, if the disaster period has not closed 30 days from the initial declaration, and if CMS has not indicated an end date to the disaster, plans should resume normal operations 30 days from the initial declaration.

CMS still reserves the right to assess each disaster or emergency on a case-by-case basis and issue further guidance supplementing or modifying the above guidance.

In response to certain disasters or emergencies, the Secretary of Health and Human Services may exercise his waiver authority under Section 1135 of the Social Security Act. Under the Section 1135 waiver authority (when invoked), CMS may *require* MA plans to allow enrollees affected by the emergency or disaster to receive care from non-network providers at in-network cost sharing.

During emergencies or disasters in which the Secretary has invoked his authority under Section 1135, information about the waivers is posted on the Department of Health and Human Services (DHHS) website (http://www.dhhs.gov/). The CMS web site (http://www.cms.hhs.gov) also will provide detailed guidance for MA plans in the event of a disaster or emergency in which the Secretary's 1135 waiver authority is being exercised. During these disasters and emergencies, MA plans should check these web sites frequently.

Phase-Out of Discriminatory Copayment Rates for Medicare Outpatient Psychiatric Services

Section 102 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) phases-out the discriminatory higher Part B cost sharing for outpatient psychiatric services beginning in CY2010. Under the original Medicare program, the beneficiary coinsurance for outpatient psychiatric services is effectively 50% because only 62.5% of such expenses are considered "incurred expenses" when determining the amount of payment and deductible – see 42 CFR 410.155. Beginning in CY2010 68.5% of such outpatient psychiatric services will be considered "incurred expenses," effectively reducing the original Medicare beneficiary coinsurance for such services to 45.2%. By 2014, outpatient psychiatric services will have the same effective beneficiary coinsurance as almost all other Part B services, which is 20%.

Bids Under Puerto Rico's Medicare Platino Program

In the draft Call Letter, CMS requested that Medicare Advantage Organizations that wish to offer a Platino plan in Puerto Rico in 2010 include a description of the benefits they would be offering under their comprehensive Platino plan in the bids submitted to CMS by the bid deadline of June 1, 2009. CMS has received numerous comments suggesting that committing to final Platino benefits by this date might expose Medicare Advantage Organizations to undue financial risks. This is because Platino plan benefit requirements may not be finalized by June 1. On the basis of these comments, CMS is now clarifying that it is now up to the discretion of the Medicare Advantage Organizations seeking to offer Platino plans in the Commonwealth to determine which mandatory supplemental benefits to include in the bid. In determining which mandatory supplemental benefits to include in the bid, plans should keep in mind that benefits included for 2010 cannot be modified after the bid submission deadline of June 1, 2009, regardless of negotiations with the Commonwealth after that date. Any additional benefits required by the Commonwealth of Puerto Rico to be offered in order to participate in the Platino program would be a separate negotiation and must be paid for by the Commonwealth of Puerto Rico through a supplemental premium that would not be evaluated or approved by CMS.

Bundling of Part D Home Infusion Drugs Under a Part C Supplemental Benefit

We are making various clarifications to our policy allowing MA-PD and cost plans offering Part D to cover Part D home infusion drugs under a bundle of services as part of a Part C supplemental benefit. These clarifications address issues that came up in our benefits review for contract year 2008. In addition, we are establishing new requirements with respect to cost sharing for Part D home infusion drugs covered as a bundled service under a Part C supplemental benefit.

Since the bundling option was made available in 2007, the number of MA-PD and cost plans choosing the option has increased. In contract year 2009, 267 PBPs within 45 contracts chose to bundle their Part D home infusion drugs under a Part C mandatory supplemental benefit. To ensure appropriate formulary coverage, we have required sponsors to provide, through the formulary submission module in HPMS, a file that clearly identifies the Part D home infusion drugs that will be offered as part of a mandatory supplemental benefit under Part C. We have also directed sponsors to consistently apply the option for the contract year (i.e., to always cover the home infusion drugs under the Part C supplemental benefit or under the Part D benefit), and to appropriately apportion costs between the Parts C and D components of their bids.

For 2010 contract year, we further clarify that:

- An MA-PD or cost plan that elects to bundle its Part D home infusion drugs under a Part C mandatory supplemental benefit must always cover those Part D home infusion drugs under the Part C supplemental benefit. Given uniform benefits requirements, plans electing to bundle must ensure that the bundle of services, which includes drugs, is available to all plan enrollees (including those residing in long-term care facilities) as a mandatory supplemental benefit under Part C.

- CMS will review sponsors' home infusion drug files as part of our formulary review process to ensure that only home infusion drugs are included as part of the Part C supplemental benefit. (Note: For a list of common home infusion drugs, refer to Appendix A of Chapter 6 of the Prescription Drug Benefit Manual.)

- The bundle of home infusion services offered under a mandatory Part C supplemental benefit must include both the home infusion drugs that would otherwise be covered under their Part D benefit and the services and supplies associated with their infusion.

In order to address the possibility that the bundling of home infusion drugs results in Part D formularies without at least two drugs in each category or class, we had previously waived the requirement at 42 CFR 423.120(b)(2)(i) that Part D sponsors' formularies include at least two Part D drugs in each category and class of covered Part D drugs – except where a particular category or class includes only one Part D drug – for applicable formulary categories or classes when Part D home infusion drugs are provided under a bundle of service as part of a mandatory supplemental benefit under Part C. That waiver remains in effect for 2010.

However, in addition, effective contract year 2010, CMS waives the definition of a Part D drug at 42 CFR 423.100 with respect to Part D drugs covered as part of a bundled benefit under a Part C supplemental benefit. We believe this waiver of the definition of a Part D drug will improve benefit coordination of home infusion therapy between Parts C and D, particularly since the services and supplies necessary for home infusion are never covered under Part D but would be provided as part of a bundle of service under a Part C mandatory supplemental benefit. This waiver is conditioned on the application of zero cost sharing for the bundle of home infusion services provided under a Part C supplemental benefit. Sponsors will not qualify for the waiver and, in turn, will not qualify to cover Part D home infusion drugs as part of a bundle of services under a Part C supplemental benefit without indicating on their PBPs that the applicable cost sharing for this bundle of services is $0. We are requiring this condition because if any cost sharing were assessed, it would be difficult to determine whether an enrollee would be better off with coverage of home infusion drugs under a Part C supplemental benefit or under Part D. Since this uncertainty would threaten the coordination rationale on which this waiver would be granted, we believe this approach provides enrollees in need of home infusion with improved continuity of care and avoidance of more costly institutional care by facilitating continuous access to home infusion drugs.

III. Bidding

General Bidding Guidance

The pricing in the Bid Pricing Tool (BPT) reflects the benefits submitted in the plan benefit package (PBP). To protect the integrity of the bid, once the bid is approved, the pricing cannot be altered. Similarly, after bids are approved, benefits cannot be added if they were not explicitly priced in the BPT and specifically included in the supporting documentation, nor can benefits be taken away. This includes attempts to include or exclude referral and/or prior authorization requirements. After the initial bid is submitted, there is little flexibility in correcting errors in the pricing, and any BPT corrections are subject to pre-approval by CMS. As in CY 2009, once BPTs and PBPs are approved, there will be a short window for requesting

plan corrections in CY 2010, thus quality control must be an integral part of the PBP and BPT submission process. Please ensure that the documentation in both the PBP and BPT is clear and accurate.

All benefits must be directly health-related (i.e., health care items and services whose primary purpose is to prevent, cure or diminish, actual or future, illness or injury) for which the MA plan incurs a bid-priced cost that is not solely administrative. Items and services that do not meet this definition are not benefits. Value-added items and services (VAIS) should not be included within the bid (PBP or BPT).

Bidding Instruction Updates

All updates for bidding will appear in the Bid Pricing Tool instructions.

Late Bid Submissions

The deadline for CMS to receive bids is no later than 11:59 p.m. PDT on Monday, June 1, 2009. CMS will not accept any bids received after that time. If the MAO experiences a technical difficulty when submitting to HPMS, they should contact the HPMS Help Desk at1-800-220-2028 or hpms@cms.hhs.gov before the deadline.

Rebate Re-allocation

Following CMS' publication in August 2009 of the 2010 Part D national average monthly bid amount, the Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the MA regional benchmarks, MAOs are allowed to reallocate Part C rebate dollars in the MA BPT for certain MA plan bids. Detailed guidance will be provided in the CY 2010 instructions for the MA BPT, scheduled to be released in early April.

Please note that the rebate re-allocation process is not an opportunity to redesign the basic A/B benefits package (benefits or premium). Unauthorized benefit changes may not be made during the rebate reallocation period. Specifically, changes to previously negotiated cost sharing amounts are not permitted and the rebate re-allocation period is not an opportunity to revise OOP maximum amounts. Further, no changes are permitted to be made to the allowed costs, administrative costs, or gain/loss margin in the Part D basic and Part D supplemental benefits.

In situations when MA-PD plans are allowed to re-allocate Part C rebate dollars in order to return to the Target Part D basic premium (due to "insufficient allocation" resulting in a Part D basic premium larger than the target premium or due to a reduction in the total amount of rebate for a regional plan), MAOs should make re-allocations that reflect the following priorities. Specifically, there may not be any reduction of rebate allocated to priority (3) unless reductions have first been made to priority (1), then priority (2) noted below.

1. Reduce or remove non-Medicare covered benefits;

2. Increase cost sharing for widely-used services such as primary care visits; and

3. As a last resort**,** increase cost sharing for more limited-use services such as inpatient,

skilled nursing facility (SNF), and home health care.

MAOs that do not adhere to this guidance may be asked to resubmit.

IV. Quality and Performance Measures

Part C Quality Reporting

Sections 422.152 and 422.516 of volume 42 of the Code of Federal Regulations (CFR) specify that Medicare Advantage plans must submit performance measures as specified by the Secretary and CMS. These performance measures include Healthcare Effectiveness Data and Information Set (HEDIS®), Health Outcome Survey (HOS), and Consumer Assessment Health Providers Survey (CAHPS®). Each year through HPMS CMS will release information about which HEDIS® measures are required to be reported by Medicare coordinated care plan types (HMO, PPO, §1876 Cost, and SNPs) for the contract year. As discussed below, beginning in 2010, PFFS and MSA plans will also be required to report certain HEDIS® measures. CMS will release information about which plans are required to participate in HOS and CAHPS®.

Requirement for PFFS and MSA Plans to have a Quality Improvement Program

Effective January 1, 2010, MIPPA repealed the statutory exemption for Private Fee-for-service (PFFS) plans and Medical Savings Account (MSA) plans from the requirement that MA plans have ongoing quality improvement programs. Beginning plan year 2010, PFFS and MSA plans are required by CMS regulations at 42 CFR §422.152(a)(1), (2) and (3) to implement quality improvement projects on an annual basis, implement chronic care improvement programs, and encourage their providers to participate in CMS and HHS quality improvement initiatives. Note that PFFS and MSA plans are required to meet 42 CFR §422.152(a)(3) only for their direct-contracting providers. CMS is requiring all plans to participate in this assessment activity to meet its strategic goal of achieving confident, informed consumers through transparent public reporting on health plan performance. In order to implement the quality improvement requirements, organizations should follow Chapter 5 of the Medicare Managed Care Manual and seek assistance from State Quality Improvement Organizations as well as CMS.

Quality Data Collection and Reporting for PFFS and MSA Plans

MIPPA requires that beginning plan year 2010 PFFS and MSA plans must also provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality. This provision is implemented in the federal regulations at 42 CFR §422.152(h). Beginning in plan year 2011, the requirements for PFFS and MSA plans cannot exceed the data collection and reporting requirements established for MA local plans that are PPO plans under 42 CFR §422.152(e). Federal regulations at 42 CFR §422.152(e) limits data collection to providers who are under direct contract with the plan.

For plan year 2010, the requirements for PFFS and MSA plans are not restricted to the requirements established for MA local plans that are PPO plans and must comply with the data collection and reporting requirements using administrative claims data only. Therefore, we are

requiring that PFFS and MSA plans collect and report to CMS all of the administrative Healthcare Effectiveness Data and Information Set (HEDIS®) measures based on claims data that are related to health outcomes and quality. PFFS and MSA plans will be required to gather data on the appropriate HEDIS® measures during plan year 2010 (measurement year) and report the audited data to CMS in June 2011 (reporting year). Only those PFFS or MSA contracts with contract-level enrollment of 1,000 enrollees or more as of July 1 of the measurement year are required to report the HEDIS data to CMS. Also, MAOs that have terminated contracts effective January 1st of the reporting year will not be required to submit a HEDIS report. Therefore, MAOs that terminate their PFFS or MSA contracts effective January 1, 2011 will not be required to submit a HEDIS report for 2010 for those contracts.

PFFS and MSA plans are required to report the HEDIS® data based on administrative claims data only from direct-contract, deemed (applicable to PFFS plans only), and non-contract providers; however, we will not use the data from deemed and non-contract providers for evaluation or enforcement purposes since data from these providers is required to be collected only for one year. Once the specifications for CY 2010 HEDIS® are finalized, we will provide guidance to PFFS and MSA plans to inform them of the specific HEDIS® measures they will be required to collect in 2010 and report to CMS in 2011.

For plan year 2011 and subsequent plan years, similar to MA local plans that are PPO plans, PFFS and MSA plans will be required to collect, analyze, and report health outcomes and quality data to the extent that data are furnished by providers who have a contract with the PFFS or MSA plan. We will provide guidance on the implementation of the health outcomes and quality data collection and reporting requirements for PFFS and MSA plans for plan year 2011 in future guidance.

CAHPS® Survey Administration

Starting with the 2011 annual Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey administration, all MA and Part D contracts with at least 600 enrollees as of July 1, 2010 will need to begin to pay for the CAHPS® data collection costs. The following types of organizations are included:

- All Coordinated Care contracts, including local and regional preferred provider organizations (PPOs) and contracts with exclusively SNP plan benefit packages.
- Cost contracts under section 1876;
- Private-Fee-For-Service and MSA contracts; and
- Prescription Drug Plans.

The Programs of All Inclusive Care for the Elderly (PACE), HCPP – 1833 cost plans, and employer/union only (PDP and PFFS) contracts are excluded from the CAHPS administration.

The Medicare CAHPS survey administration will mirror the survey administration for the Medicare Health Outcome Survey (HOS) and Hospital CAHPS. In late 2010, all MA and Part D

contracts in effect on or before January 1, 2010 will need to select an approved vendor to administer the 2011 survey. This survey will be conducted in early 2011. The approximate cost per fielded survey is $8; however, all MA and Part D contracts will need to negotiate the price with one of the approved survey vendors. For most contracts, the sample size is approximately 600 enrollees. Contracts that cover large geographic areas may have larger sample sizes. If a contract does not have information about their sample sizes from previous years, they can email CMS at CAHPS_MA_PartD@cms.hhs.gov to obtain those sample sizes.

In addition to approving the survey vendors to conduct the survey on behalf of all MA and Part D contracts, CMS will continue to draw the sample of enrollees for each contract, oversee each of the approved vendors, analyze the CAHPS® data for the plan ratings and produce individual-level contract reports for contracts to use for quality improvement. Vendors will be trained by CMS to collect and submit the data within specified timeframes. Further information will be provided at a later date about how to access the approved vendor list.

HOS Survey Administration

The current year HEDIS reporting category that reports Medicare Health Outcomes Survey (HOS) results applies to the following organization types with a minimum of 500 members with six months of continuous enrollment that had a Medicare contract in effect on or before January 1, of the previous year: (1) all coordinated care contractors, including local preferred provider organizations (PPOs) and regional PPOs; (2) 1876 Cost Plans with open enrollment; and (3) MA contracts with exclusively special needs plan benefit packages, regardless of institutionalized, chronically ill, or dual-eligible enrollment. In 2010, the reporting of HOS results will also apply to PFFS and MSA contracts meeting eligibility requirements.

All Programs of All Inclusive Care for the Elderly (PACE) with contracts in effect on or before January of the previous year are required by CMS to administer the HOS-Modified (HOS-M) survey for current year HEDIS reporting. A minimum enrollment threshold does not apply to the HOS-M. Note that, starting in 2010, the Minnesota Senior Health Options, Minnesota Disability Health Options, Wisconsin Partnership Programs, and Massachusetts MassHealth Senior Care Options MA contracts are required to report HOS and will no longer participate in HOS-M.

V. Compliance and Monitoring

Response to Complaint Tracking Module (CTM) Complaints

To ensure that Medicare Part C enrollees receive the highest quality of service in a timely manner, CMS will apply case resolution time standards with respect to CMS recorded complaints within the Health Plan Management System (HPMS) Complaints Tracking Module (CTM) in 2010.

Effective January 1, 2010, MA organizations will be expected to resolve at least 95% of Part C CTM complaints designated as “immediate need” within two calendar days, “urgent need” within seven calendar days and 95% of CTM complaints without an issue level within 30 days. The table below defines and summarizes these resolution time requirements.

Designation	Part C Definition	Resolution Time
Immediate Need	Defined as a complaint when a beneficiary has no access to care and an immediate need for care exists.	At least 95% of cases resolved within 2 calendar days of receipt.
Urgent Need	Defined as a situation when a beneficiary has no access to care, but no immediate need for service exists.	At least 95% of cases resolved within 7 calendar days of receipt.
Unclassified	Any other CTM complaints.	At least 95% of cases resolved within 30 calendar days of receipt.

CMS continues to reserve the right to reclassify any complaint that does not fit the above definitions as "immediate need" or "urgent" at our discretion.

Should an MA organization not meet the aforementioned 95% thresholds with respect to Part C complaints, CMS will consider these organizations out of compliance with one or more Part C requirements, including, but not limited to, requirements related to enrollment; coverage determinations, appeals, and claims processing.

Audit Approach

CMS' audit strategy in 2010 will reflect a move away from routine audits to more targeted, data-driven and risk-based audits. We will produce a performance profile of MAOs and Part D sponsors based upon reported data and comparative data across all MAOs and Part D sponsors and will target organizations that demonstrate poor performance. We will also focus on high-risk areas that have the greatest potential for beneficiary harm (e.g., enrollment operations, appeals & grievances). In addition to this risk-based approach, there will be some degree of random selection. The goal of the audits will be earliest possible detection and correction of issues and improvement in quality and performance of Part D sponsors and MAOs.

As part of CMS' program oversight, we also intend to assess the effectiveness of MAO and Part D sponsors' compliance programs, including the requirement for effective internal monitoring and auditing.

Part C and Part D Data Validation

CMS has the authority to establish information collection requirements for MAOs and Part D sponsors under 42 CFR §422.516 (a) and §423.514 (a), respectively. Using this authority, CMS issued Part C and D reporting requirements[2] in order to respond to inquiries that we have received and, more importantly, to improve program operations.

CMS has received many inquiries from Congress, oversight agencies, and the public about costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and PDPs. However, to date, CMS has not been able to address many of these inquiries due to either an absence of data with respect to MAOs or, despite collecting over three years' worth of data, data of questionable validity submitted by Part D sponsors.

To be useful for monitoring and/or performance measurement, Part C and Part D data reported by MAOs, cost plans, and Part D sponsors must be reliable, valid, complete, and comparable among sponsoring organizations. To meet these goals, and to better enable CMS to respond to inquiries and manage our programs, sponsoring organizations should undertake a data validation audit on reported Part C and Part D data effective for CY2010. This data validation audit represents a separate activity from current audit functions, such as finance, bid pricing tool (BPT), or programmatic audits, since it will focus only on reporting data consistent with the technical specifications CMS has published with respect to the Part C and D reporting measures.

CMS will work with a contractor to develop data validation specifications to ensure that the goals of reliability, validity, completeness, and comparability are met at the conclusion of the audit. The data validation specifications will focus on how organizations and sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify calculations, computer code and algorithms. In addition, they will be used to inform how the MAOs, cost plans, and Part D sponsors collect, store, and report data. An inability to capture all the data that should populate a numerator or the denominator may result in an invalid measure. This is especially a consideration when health care organizations are reporting new measures and their IT reporting systems are not sufficiently developed to capture all the numerator or denominator data. The data validation audit process may be especially helpful to such organizations.

MAOs, cost plans, and Part D sponsors are responsible for acquiring the data validation audit resources through a contractor or through other means. As explained in the Part C and D Reporting Requirements Technical Specifications, auditing will be required at either the contract or PBP level as appropriate for each Part C and Part D measure. While organizations and sponsors should not use their own staff to conduct the data validation audit, they may use their own staff to assist the auditors in obtaining necessary information and documents. CMS believes

[2] See OMB #0938-1054 and OMB #0938-0992, respectively.

that use of external entities that are appropriately trained on the published technical specifications will ensure the independence of the data validation audits.

CMS expects to develop the methodology for data validation audits (i.e., the data validation specifications) for contract year 2010 in late 2009. Given the limited timeframe to produce the specifications, we do not believe that it will be possible to require a complete data validation audit of each data element reported for 2010. Thus, we expect to issue the data validation specifications in phases.

During the first phase, which will be performed in 2010, CMS will provide data validation audit specifications for the following measures:

Part C Measures	**Part D Measures**
Benefit Utilization, Grievances, Organization Determinations/Reconsiderations, Agent Compensation Structure	Grievances, Exceptions & Appeals, Drug Benefit Analyses

A sample of Part C and D sponsors will be asked to participate in a pilot study implementing the data validation specifications for the above listed measures in 2009. After the pilot study is completed, we expect to make information on the data validation specifications available to sponsoring organizations for a two-week comment period. During this comment period, sponsors and stakeholders will have an opportunity to provide input to CMS on the approach and procedures.

At the completion of the audits, MAOs, cost plans, and Part D sponsors should attest to meeting all the CMS-established technical specifications of the audit process. Additionally, MAOs, cost plans, and Part D sponsors will report to CMS the results of their audit and any measures for which they received a "not pass." We intend to treat a "not pass" on an audit as a failure to submit required data, which in turn may be considered non-compliance. In addition, MAOs, cost plans, and Part D sponsors that are found to be deficient may be requested to develop corrective action plans. Finally, we may adjust performance measurements to reflect the organizations' non-compliance with CMS audit specifications.

Further information on the data validation audit requirements, timing, and data submission requirements will be provided at a later date.

VI. Enrollment

Mandatory Use of the Online Enrollment Center (OEC)

CMS developed the OEC to facilitate enrollment into MAOs, MAOs offering Part D (MA-PDs), and Prescription Drug Plans (PDPs). The OEC is accessible through Medicare Options Compare (MOC) and Medicare Prescription Drug Plan Finder (MPDPF) on www.medicare.gov. In previous years, MAOs (with some exceptions) and Part D sponsors were encouraged, but not required, to participate in the OEC As of 2010, all MAOs (with the exceptions noted below) and Part D sponsors, must accept enrollment elections made via the OEC. The exceptions are as follows:

1) SNPs and Religious Fraternal Benefit (RFB) plans now have the option, but are not required, to participate in the OEC. Note that because SNPs must obtain additional eligibility information that is not captured by the OEC, enrollment requests received via the OEC cannot be considered complete until they obtain the required information, in accordance with Chapter 2, Section 20.11 of the Medicare Managed Care Manual.

2) Medical Savings Account plans (MSAs) still may not participate in the OEC because the beneficiary must provide additional financial and banking information in order to complete the enrollment request.

3) 800-Series Employer plans are prohibited from participating in the OEC because they are only available to certain employer groups, and availability through the OEC could cause beneficiary confusion.

4) Medicare Cost plans are not permitted to participate in the OEC because of enrollment format requirements specified at 42 CFR §417.430.

All MAOs and Part D sponsors participating in the OEC will have an "enroll" button associated with their offered individual market plans in MOC or MPDPF, as applicable. With the exception of MA-SNPs as described above, enrollments received through this method will constitute completed enrollment requests. At least once every business day, MAOs and Part D sponsors must log into the Administrative Console of the OEC and download pending enrollments. MAOs and Part D sponsors failing to download enrollments every business day are subject to compliance actions including, but not limited to, a request for a corrective action plan.

VII. Payment

PQRI Bonuses, E-Prescribing Incentives, and the Hospital Quality Initiative

Payments to physicians who have contracted with MAOs generally are governed by the terms of the contract, and it is up to the MAO whether to take eligibility for a Physician Quality Reporting Initiative (PQRI) bonus or e-prescribing incentive payment into account in establishing the amount the physician is paid. Payment of PQRI and e-prescribing amounts is optional with respect to contracting providers. It is optional in the sense that the MAO and contracting

providers are free to negotiate whether or not such bonus or incentive payments will be made part of the contract.

In the case of a PFFS plan, however, if the MAO offering the plan is meeting access requirements by paying what Medicare would pay, the MAO is required to include bonus and incentive amounts if the physician would receive them in connection with treating a Medicare beneficiary not enrolled in an MA plan.

Physicians who have not contracted with an MAO, but who provide covered professional services to an enrollee in an MA plan offered by the organization, are also potentially eligible for both the PQRI bonus payment and the e-prescribing incentive payment from the organization. When a physician is determined by original Medicare to have satisfied the requirements and qualified for an incentive under the PQRI, he or she should expect to receive a bonus check from any MAOs which he or she has billed as a non-contracted provider, or for which he or she has provided covered professional services under a PFFS plan that meets access standards by paying the Medicare payment rate. The amount of the PQRI payment is calculated just as it is calculated for traditional Medicare, that is to say a percentage (up to 1.5% for 2007 and 2008, and 2% for 2009 and 2010) of Medicare allowed charges for covered professional services submitted to the plan during the reporting period. When a physician is determined by Medicare to be a successful e-prescriber and qualifies for the 2% incentive under the 2009 E-prescribing Incentive Program, MAOs are required to pay non-contracted physicians 2% of the Medicare allowed charges for any applicable, covered professional services rendered in 2009 to a member of their plan. Such payments are due whether or not the non-contracting or "deemed" physician has participation status under the original Medicare program. This policy also applies to non-physician practitioners who would qualify for payments from traditional Medicare.

See the June 27, 2008, HPMS Notice entitled "Physician Quality Reporting Initiative (PQRI) 2007 Data File for additional information. CMS will provide a file in the summer of 2009 of 2008 PQRI bonuses that will be due. A file of 2009 PQRI and e-prescribing bonuses and incentives due will be provided in the summer of 2010. Bonus and incentive payments for claims incurred in a given year are payable the following year in a lump sum. Additional technical guidance will be provided at the time data files are released.

The Hospital Quality Initiative uses a variety of tools to stimulate and support improvements in the quality of care delivered by hospitals to Medicare beneficiaries. One initiative was introduced in section 501(b) of the MMA. In FYs 2005 and 2006 a hospital that did not submit performance data to original Medicare for ten quality measures received a 0.4% payment reduction in its annual payment update. Section 5001 of the DRA increased the payment reduction to 2% beginning in FY 2007. When reimbursing non-contracting and deemed providers, MAOs that rely on PC Group/Pricer to compute payment amounts need do nothing, since the statutory payment reduction has already been added to the file. Of the approximately 6,000 hospitals that received Medicare reimbursements each year, fewer than 100 did not participate in voluntary reporting under the Hospital Quality Initiative.

Risk Adjustment

Please see Appendix II – Risk Adjustment Implementation – for a timeline and additional information on risk adjustment for contract year 2010.

All Other Payment-Related Changes

All payment-related changes will appear in the *Announcement of CY 2010 MA Capitation Rates and Payment Policies & CY 2010 Part D Payment Notification*, which will be released in HPMS and posted on the CMS website on April 6, 2009.

VIII. Grievances, Organization Determinations, and Appeals

Including the Evidence of Coverage and Formulary in Case Files

For the 2009 plan year, CMS issued guidance strongly recommending that all Medicare health plans and Part D sponsors include complete copies of the relevant Evidence of Coverage (EOC) and formulary (Part D sponsors) with any case files sent to an independent review entity (IRE) for review. This recommendation is being extended for the 2010 plan year. The previous practice was to include relevant excerpts of these plan documents in case files. However, the Office of Medicare Hearings & Appeals (OMHA) ALJs have indicated that these documents are needed in their entirety in order to properly adjudicate appeals. Additionally, the Medicare Hearings & Appeals Council (MAC) recently declined to review certain Part D cases referred for motion review because the ALJ did not have access to a complete copy of the relevant Part D plan formulary and/or EOC at the time of the ALJ hearing. Therefore, it is in the plan's best interest to ensure that each case file sent to an IRE includes a CD with complete versions of the EOC and formulary relevant to an enrollee's specific case. Failure to include this information could result in an unfavorable appeals decision or CMS declining to refer an ALJ decision to the MAC for review.

If a plan chooses to implement this recommendation, the complete EOC and formulary (if applicable) that is relevant to the enrollee's appeal must be put on a CD and included with the case file that is sent to the IRE. Plans may not mail or fax hard copies of the complete EOC and/or formulary to the IRE. We will provide specific instructions about the process for submitting the CDs to the IRE in an upcoming HPMS memorandum and manual instructions.

IX. Special Needs Plans

Model of Care Reporting for New Applicants and Existing SNPs

MIPPA provides that all SNPs must have in place an evidenced-based model of care with appropriate networks of providers and specialists. The MAO offering the SNP must conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs for each enrolled individual. In consultation with the individual as feasible, the MAO must develop a plan that identifies goals and objectives for that individual under the SNP, including measurable outcomes as well as specific services and benefits to be provided. The MAO must use an interdisciplinary team in the management of care.

The MIPPA care management requirements apply to all MAOs offering any type of SNP for the 2010 contract year. MAOs and applicants seeking to offer a new SNP, and MAOs expanding an existing 2009 SNP service area or modifying their enrollment population for 2010 will submit care management information for the specific SNP being offered through the CMS HPMS in the SNP proposal application. The MAOs and MA applicants will complete the full SNP proposal application, including the section addressing care management. The deadline for submitting the SNP proposal application to CMS is the same due date as MA applications.

The care management section of the SNP proposal application is divided into 10 subsections. These subsections are: 1) targeted special needs individuals, 2) goals, 3) staff structure and roles, 4) interdisciplinary care team, 5) provider network, 6) model of care training, 7) health risk assessment, 8) individualized care plan, 9) communication, and 10) performance and health outcomes measurement. Each subsection has a number of questions which are answered by either a "yes" or "no" response. Responses should be specific for the SNP being offered by the MAO and MA applicant. Keep in mind that the questions in the care management section are designed to provide CMS with an understanding and knowledge of the care management composition and functionality for the specific SNP being offered by the MAOs and MA applicant.

MAOs making no change to their operational 2009 SNP, which will be offered in 2010, will submit their SNP care management information through HPMS, too. The same care management information required for new MA SNP applicants is required for existing SNPs. CMS is finalizing the process to accept model of care information for SNPs that are not submitting new applications, but it will be a HPMS-based application identical, or very similar to, the one used by new applicants.

Institutional Equivalent SNP - Level of Care Assessment Tool

Beginning January 1, 2010, MIPPA required that MAOs offering institutional equivalent SNPs (I-SNPs) use the Level of Care (LOC) assessment tool currently utilized by the State in which they operate to determine whether beneficiaries who reside in the community, but need a skilled nursing facility level of care, are eligible to join the I-SNP. CMS has surveyed the appropriate agencies in 50 States, the District of Columbia, and the Commonwealth of Puerto Rico to determine what is presently in use, and we will monitor I-SNPs to ensure that they are using the State-appropriate tool. For I-SNPs operating in multiple states, this will mean using a different LOC assessment tool in each State. Further, we note that many States are presently revising their LOC assessment tools, and MAOs offering SNPs must stay current on the LOC tool being used by their State. We strongly encourage MAOs offering SNPs to maintain an ongoing liaison with the relevant State agencies on this topic.

MIPPA further requires that a qualified independent party conduct the screening of community-based prospective enrollees. This independent party cannot be an employee of the MAO or its parent organization, but should be an independent contractor or grantee. The independent party should not receive any kind of bonus or differential payment for qualifying members for the SNP. Presently, there is a wide range of parties with professional credentials contracted to use the LOC tool and to complete the assessment inquiry for States. Agents most typically are either registered nurses (RNs) or social workers who focus on elderly disabled populations. MAOs

offering I-SNPs should search for individuals with these credentials to conduct the assessments. Alternatively, they can choose to contract with the entity that presently performs the LOC assessment for the State. Finally, if the organization offering the I-SNP can demonstrate that individuals with other credentials are presently employed by the State in which they are operating to conduct the LOC assessment, CMS will consider it an acceptable practice. However, the burden of proof is on the MAO to demonstrate they are adopting the State practice.

SNP Quality Improvement and Chronic Care Improvement Programs

In addition to the collection, analysis, and reporting of HEDIS and Structure and Process measures, MIPPA specifically requires that SNPs evaluate their care management system within their internal performance improvement program. As a Medicare Advantage product, SNPs are already required to conduct quality improvement projects (QIP) and a chronic condition improvement program (CCIP) as performance improvement initiatives. CMS recommends that SNPs incorporate the evaluation of their care management model into their CCIP and/or QIP to meet both requirements in a consolidated activity and conserve resources.

Care management has been defined through MIPPA and subsequent CMS regulation (4138 IFC and 4131 F) as an evidence-based model of care having the following components for each eligible beneficiary:

- Target an exclusive dual-eligible, SNP-specific chronic condition, or institutional special needs population.
- Conduct an initial and annual comprehensive health risk assessment.
- Establish an interdisciplinary care team to manage care.
- Develop and implement an individualized care plan having objectives, measurable outcomes, and specific services and benefits.
- Establish a provider network having medical specialists appropriate to the target special needs population.
- Assure that providers apply nationally recognized practice protocols and guidelines that are documented.
- Establish integrated systems of communication to promote coordination of care.
- Coordinate care across healthcare settings and providers; (i.e.,) transitions of care.
- Train employed and contracted staff on the organization's model of care.
- Deliver services to vulnerable individuals within the target population; (i.e.,) the frail/disabled, those having multiple chronic conditions, and those near the end-of-life.

- Deliver add-on services and benefits that meet the specialized needs of the unique targeted special needs individuals.

- Establish lines of accountability within the SNP to assure full implementation of the care management system

- Evaluate the effectiveness of the model of care for each plan benefit package.

MAOs offering SNPs may select one or more of these components to examine through a QIP or CCIP. The following examples illustrate this recommendation. While organizations offering program SNPs continue to have considerable latitude in selecting QIP and CCIP focus areas, CMS offers, based on our wide view of SNPs and the Medicare Advantage program, examples below of potentially beneficial QIP or CCIP projects.

Examples of QIPs for dual eligible SNPs:

- Evaluate whether the provision of add-on transportation services for low-income beneficiaries resulted in higher utilization rates of primary care and preventive health services (addresses the delivery of add-on services that meet beneficiary's specialized needs).

- Evaluate whether the medication reconciliation conducted by SNP personnel (a nurse, a case manager, an interdisciplinary care team member, or other SNP personnel) after beneficiaries were discharged from inpatient facilities resulted in a reduction of medication errors or adverse outcomes (addresses the coordination of care across healthcare settings).

Examples of QIPs for institutional or institutional equivalent SNPs:

- Evaluate whether the timely performance of the annual health risk assessment for institutional equivalent beneficiaries; (i.e., those not residing in nursing facilities) resulted in the identification of measurable functional decline and early intervention before an adverse outcome was experienced (addresses the annual performance of a health risk assessment).

- Evaluate whether the skilled nursing facility sent timely reports on beneficiary health status to the interdisciplinary care team resulting in a continuous update of the individualized care plan (addresses the integrated system of communication to promote coordination of care).

- Evaluate whether increased member visits by SNP-employed skilled personnel in participating nursing facilities resulted in the earlier identification and treatment of pressure sores and viral infections (address whether itinerant skilled personnel model is resulting in decline of treatable health problems).

Examples of QIPs for chronic condition SNPs:

- Evaluate whether the palliative care, pastoral care, and use of advance directives for beneficiaries near the end-of-life resulted in members or their caregivers reporting an improvement in quality of life (addresses whether end-of-life care planning approach is providing measurable aid and comfort).

- Evaluate whether beneficiaries having frequent direct contact with their interdisciplinary care team experienced fewer disease exacerbations requiring emergency room visits or hospital admissions (addresses whether interdisciplinary care team model is resulting in measurable decline in hospitalizations).

Examples of CCIPs:

- Cardiovascular disease – Develop and implement a physical exercise program (e.g., the 10,000 steps/day, chair-based exercising for the frail, aerobic exercise program), and evaluate whether regular participation in the physical exercise program reduced a targeted risk factor for heart attack.

- Chronic lung disease – Develop and implement a smoking cessation program, and evaluate whether participants' reduction in baseline cigarette consumption 1) reduced the number of visits to an Emergency Department for exacerbation of COPD or 2) reduced the frequency of contracting acute respiratory infections (pneumonia, acute bronchitis, etc.).

- Major depressive disorder – Develop and implement a depression screening program across the SNP provider network, and evaluate the rate of depression screening among providers in the network or the percentage of participants newly diagnosed with depression who receive timely treatment.

- Diabetes – Develop and implement a diabetic foot care clinic, and evaluate whether participants who regularly attended the clinic had a reduced incidence of new foot ulcers.

CMS reminds all MAOs, particularly those offering SNPs, that the requirement to conduct a meaningful QIP or CCIP is of great importance. These programs are an avenue by which MAOs not only improve the health outcomes of their members, but also raise their HEDIS scores and other quality indicators, which are reported publicly and increasingly factor into CMS's overall assessment strategy. QIP and CCIP monitoring has the potential to become an area of increased focus in CMS's oversight and audit activities.

In calendar year 2009, CMS will contract with an entity having quality improvement expertise to assist SNPs with development and implementation of their CCIP and QIP requirements. Contract initiatives will include asking SNPs about their current CCIP and QIP activities, identifying and publishing best practices, providing SNPs technical assistance to conduct their performance improvement activities, and producing a report on SNP performance improvement activity to inform CMS, the industry, and the healthcare community about trends and best practices. CMS will issue future guidance and contact information for SNPs to access this contracted technical assistance.

Chronic Condition SNPs Targeting More than One Condition

MIPPA directed CMS to convene a panel of clinical advisors to determine the specific chronic conditions that met the MIPAA statutory definition of a severe or disabling chronic condition in regard to SNPs. The convened panel identified 15 severe or disabling chronic conditions based on clinical criteria required by statute to ensure that only people who have these conditions are eligible to enroll in a chronic care condition SNP (C-SNP). These changes do not immediately impact Medicare beneficiaries, but become effective Jan. 1, 2010. The panel results are posted at http://www.cms.hhs.gov/specialneedsplans.

CMS believes that a C-SNP needs to have specific attributes beyond that of a standard Medicare Advantage (MA) coordinated care plan (CCP), in order to receive the special designation and marketing and enrollment accommodations. C-SNPs are expected to have specially designed PBPs that go beyond the provision of basic Medicare Part A/B services and care coordination that is required of all CCPs. These specially designed PBPs should include, but not be limited to:

1. Supplemental health benefits specific to the designated chronic condition;

2. Supplemental health services specific to the designated chronic condition;

3. Specialized provider networks (physicians, home health, hospitals, etc.) specific to the designated chronic conditions; and

4. Appropriate enrollee cost sharing structured around the designated chronic conditions and co-morbidities for all Medicare-covered and supplemental benefits.

Further, CMS believes that a C-SNP cannot be structured around multiple common co-morbid conditions that are not clinically linked in their treatment because this arrangement, by its very nature, leads to a general market product rather than a product tailored for a particular population.

CMS does recognize, however, that certain chronic conditions are commonly co-morbid and clinically linked. We also know that some MAOs presently operating a C-SNP serving multiple chronic conditions, in the interest of maintaining continuity for beneficiaries and their own operations, wish to maintain these multi-condition C-SNPs. Therefore, CMS is allowing multiple-condition C-SNPs under two scenarios – either a CMS-designated grouping of commonly co-morbid and clinically linked conditions, or a plan-customized multiple-conditions option.

Commonly Co-morbid and Clinically-Linked: Multiple condition C-SNPs will be permitted in cases where the conditions are commonly co-morbid and clinically linked.

- The conditions in question are, based upon CMS's data analysis, determined to be commonly co-morbid

- The conditions in question are, based upon recognized national guidelines such as those listed in the Guidelines Clearinghouse maintained by the Agency for Health Quality Research, clinically linked in their treatment.

Based on an analysis of commonly co-existing chronic conditions in the current Medicare population, CMS will allow the following multi-condition groupings of chronic conditions for Contract Year 2010:

Group 1	Diabetes mellitus and chronic heart failure
Group 2	Chronic heart failure and cardiovascular disorders
Group 3	Diabetes mellitus and cardiovascular disorders
Group 4	Diabetes mellitus, chronic heart failure, and cardiovascular disorders
Group 5	Stroke and cardiovascular disorders

For these groupings, CMS will accept applications (and bids) for multi-condition C-SNPs. For MAOs that are approved to offer a C-SNP targeting one of the above-listed groups, beneficiaries need only have one of the qualifying conditions (subject to verification of the condition) for enrollment. All beneficiaries in the service area with any one of the qualifying conditions (subject to verification) are entitled to enroll.

Of course, the application for the multi-condition SNP will still be assessed to determine adequacy in terms of creating a specialized product for the chronic conditions it serves. This includes the review of the model of care and provider network (examined via the application) and benefits package (examined via the bid).

Beneficiaries with All Qualifying Conditions: CMS will permit MAOs to develop their own multi-condition SNP combinations for enrollees with all of the qualifying chronic conditions in the combination. MAOs that pursue this customized option must verify that enrollees have all of the qualifying conditions in the combination. MAOs interested in pursuing this option for multi-condition C- SNPs are limited to groupings of the same fifteen conditions selected by the panel of clinical advisors that other C-SNPs must select. As with SNPs pursuing the Commonly Co-Morbid and Clinically-Linked Option, CMS will carefully assess the prospective multi-condition SNP proposal to determine the adequacy of its care management system for each condition in the combination.

In summary, MAOs may submit a proposal with their MA application by February 26, 2009 to offer one or more C-SNPs for Contract Year 2010 that meets one of the three required options:

1. A care management system (model of care), provider network, and plan benefit package that targets a single chronic condition from the list of 15 CMS-approved chronic conditions

2. A care management system (model of care), provider network, and plan benefit package that targets a group of commonly co-morbid and clinically linked chronic conditions

from the list of 5 CMS-approved multi-condition groupings outlined above in which the eligible beneficiary has **at least one** condition

3. A care management system (model of care), provider network, and plan benefit package that targets a plan-designed grouping of multiple chronic conditions from the list of 15 CMS-approved chronic conditions in which the eligible beneficiary has **all** conditions

Verifying Chronic Conditions for Enrollees in Chronic Condition Special Needs Plans

CMS understands that there is continued concern that some MA organizations offering C-SNPs may be enrolling beneficiaries who do not have the chronic condition(s) for which the C-SNP is structured. CMS reminds MA organizations offering C-SNPs of the requirement to verify that members have the chronic condition(s) appropriate for their product and that organizations should make sure their policies and operations are fully compliant with CMS's guidance on this subject. Further, CMS is informing MA organizations offering C-SNPs that CMS expects to conduct focused audits in the upcoming year to determine that they are verifying that enrollees have the condition(s) for which their product is designed.

SNP Enrollment Requirements for 2010

In view of the many changes in the statute and regulations that apply to SNPs for the 2010 contract year, CMS is providing general, preliminary guidance to MA organizations offering SNPs regarding the transition of existing membership during the 2009 to 2010 plan renewal process. Our goals are threefold: 1) consistent with the clear statutory intent of the recent MIPPA legislation, ensure that individuals in special needs plans are members of the groups that those plans are designed to serve; 2) carry out a seamless transition for all SNP members as we implement the new SNP requirements, and 3) ensure that all affected individuals are informed of their options in a clear and timely manner. CMS will issue detailed guidance later this spring that will outline the specific rules for plan transitions for SNP enrollees from 2009 to 2010.

General Guidance for Transitioning C-SNP Enrollees

As a general rule, MA organizations that currently offer a C-SNP that meets the criteria for renewal in 2010, or that will be modified to meet such criteria, must transition current enrollees of that C-SNP into the 2010 C-SNP under the following circumstances:

1. **A 2009 C-SNP is renewed as one of the allowable 2010 SNP plans.**

   Example: A C-SNP that serves beneficiaries with diabetes (at any stage) in 2009 will renew in 2010 as a C-SNP that targets the new category for beneficiaries with diabetes.

   In this situation, all enrollees in that C-SNP would remain enrolled for 2010, unless they elect another plan.

2. **A 2009 C-SNP targets multiple chronic conditions but for 2010 disaggregates into separate plans (PBPs), each targeting a single condition or multi-condition grouping.**

   Example: In 2009, a C-SNP serves individuals with diabetes, coronary artery disease, and COPD. In 2010, the organization non-renews this plan and offers three separate new plans.

   - One for cardiovascular disorders (covering four conditions: coronary artery disease, cardiac arrhythmias, peripheral vascular disease, or chronic venous thromboembolic disorder);
   - One for diabetes; and
   - One for chronic lung disorders (covering five conditions: asthma, emphysema, chronic bronchitis, pulmonary fibrosis, and pulmonary hypertension).

   In this example, individuals in the 2009 plan that fit one of the categories served by the 2010 plans will be transitioned via passive enrollment to the new plan that matches their condition, unless they elect to enroll in a different plan. Individuals in the non-renewed plan who do not fit into any of the new categories would not be eligible to enroll in one of the three new C-SNP plans.

3. **A 2009 C-SNP covers a condition that is subsumed into a larger category or into one of the five commonly co-morbid and clinically linked groups in 2010.**

   Example: In 2009, the SNP targets coronary artery disease which, in 2010, is part of the larger category of cardiovascular disorders.

   Assuming that the organization offers a plan that targets all cardiovascular disorders within that category, it would retain in the 2010 plan all beneficiaries with any of those conditions who were enrolled in the 2009 C-SNP, unless they elected to enroll in another plan.

We realize that these examples do not address all possible scenarios, such as situations where a 2009 SNP will not be renewed in 2010 and the organization does not offer a new C-SNP, or where an individual enrolled in a 2009 SNP that is continued in 2010 does not have the condition served by the plan in which he or she is enrolled. As noted above, the intent of the SNP program is that a plan serves exclusively those individuals who meet the established criteria for the SNP. We do not believe it is in the best interests of beneficiaries to be enrolled in a SNP that is not designed to serve their needs. Thus, in these situations, we will consider proposals for passively enrolling such individuals into a different plan in 2010. We would approve such proposals only if the organization can establish to CMS' satisfaction that the targeted plan is appropriate for that enrollee, that is, that the targeted plan has similar benefits, formularies, premiums, and network rules. Note that in all the cases described here, whether it involves the transition of an individual from one SNP to another, from a SNP to another MA plan, or from a SNP to original Medicare, affected beneficiaries would have a special election period (SEP) to choose a different plan.

Existing Dual Eligible SNP Members

In general, individuals who lose their Medicaid eligibility would retain the Medicaid benefits they received under the plan for the period of deemed continued eligibility described in section 50.2.5 of Chapter 2 of the Medicare Managed Care Manual. After this period, if they are no longer eligible for a SEP as dual eligibles, they would have an SEP to elect another MA plan or PDP. (See Section 30.4.4, #10).

General Reminder about Special Enrollments Periods for C-SNPs

In addition to the SEP opportunities discussed above, we would like to remind all MA organizations of the special enrollment opportunities for individuals with severe or disabling chronic conditions, as outlined in Section 30.4.4 of Chapter 2 of the Medicare Managed Care Manual:

- Individuals with severe or disabling chronic conditions have an SEP to enroll in a SNP designed to serve individuals with those conditions. This SEP ends once an individual enrolls in the C-SNP. Once the SEP ends, the individual may make enrollment changes only during applicable MA enrollment periods. This SEP also permits an individual who has a severe/disabling chronic condition that is not a focus of their current C-SNP to enroll in a C-SNP that focuses on this other condition. Eligibility for this SEP ends at the time the individual enrolls in the new SNP (See Section 30.4.4., #13).

- Individuals who are no longer eligible for the C-SNP because they no longer meet the specific special needs status also have an SEP to make a change (See Section 30.4.4, #10).

Definition of Subset

As a result of the MIPPA statute, effective January 1, 2010, any new dual eligible SNP, or existing SNP seeking to expand, must have a contract with the State Medicaid agency. According to CMS' current definition, dual eligible SNPs with contracts are termed as a "Medicaid subset." Therefore, in 2010, there will be only one definition for a Medicaid subset: a) serves dual eligible beneficiaries, b) has an executed State Medicaid Agency contract, and c) enrolls the Medicaid population identified in the executed State Medicaid Agency contract as the target population. We recognize the confusion caused by the wording of the attestation statements in the section entitled "State Medicaid Agency(ies) contract enrolled population", and have already identified that section as one that will be revised for 2011. For the 2010 SNP proposal, dual eligible SNP applicants should attest to the one (or more) enrolled population(s) that best describes the targeted population in their State Medicaid Agency contract. If that population is unknown at the time of proposal submission, dual eligible SNPs should indicate so in the State Medicaid Agency Contract Upload Document which permits a narrative description of the status of contract negotiations with the State.

New Dual Eligible SNPs Required to Contract with State Medicaid Agencies

Section 164 of MIPPA added a number of requirements specifically focusing on dual eligible SNPs with the goal of increasing coordination between the MAOs offering dual eligible SNPs and States. One such provision requires all organizations offering new dual eligible SNPs (i.e., those that provide for individuals eligible for both Medicare and Medicaid) or seeking to expand the service area of an existing dual eligible SNP have a contract with its respective State Medicaid agency in the 2010 contract year. CMS believes that dual eligible SNPs are best able to serve Medicare-Medicaid beneficiaries when they are well coordinated with State Medicaid programs. There is an exception to the State Medicaid agency contract requirement for dual eligible SNPs that were approved by CMS prior to 2009 and that do not currently have a State Medicaid agency contract. MA organizations may continue to operate these SNPs without a State contract in 2009 and 2010 (including accepting new enrollments) provided all other statutory requirements are met. This exception is specific to the aforementioned State contract requirement and does not relieve the organization of other MIPPA-created requirements, such as the care management, model of care and quality improvement program requirements that go into effect on January 1, 2010. Again, organizations cannot expand the service area of these SNPs if they do not have a State Medicaid agency contract.

The finalized State Medicaid contract is due to CMS by October 1, 2009 for the 2010 contract year. The plan must have a contract with the State Medicaid agency to provide benefits or arrange for benefits to be provided, for which such individual is entitled to receive as medical assistance under Title XIX. The contract between the MA dual eligible SNP and the State Medicaid agency must document each entity's roles and responsibilities with regard to dual eligible individuals. The required elements of the contract are discussed in 42 CFR 422.107.

Resources for State Medicaid Agencies

MIPPA also requires the Secretary of Health and Human Services to provide appropriate resources to assist the States in this contracting requirement. To accomplish this, CMS is seeking a contract creating a resource contact to work with States on Dual SNP contracts and related issues in 2009. Some of the responsibilities of the resource contact will include:

- Research issues raised by States;
- Address State inquiries regarding State and Federal policy coordination;
- Solicit and catalog relevant State materials; and
- Create communication forums for States to exchange ideas.

Concurrently, the resource contact will develop model and/or best practice documents to facilitate State-SNP relationships which foster Medicare-Medicaid benefit integration and meaningful coordination. This resource will provide technical assistance to the States as well as exist as a resource that is complementary to the interests of MAOs offering dual eligible SNPs.

X. Private Fee-For-Service Plans

Variation in Payment Rates to Providers

The MIPPA added a clarification to the statutory definition of a PFFS plan. Although payment rates cannot vary based on utilization of services by a provider (with the exception of certain preventive services), MIPPA clarified that a PFFS plan is permitted to vary the payment rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization. These changes were effective as of September 18, 2008. For a discussion of these changes, please see page 8 of our guidance document at

http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf.

PFFS Provider Payment Independent Review Entity

CMS has received complaints from individual providers and provider associations stating that PFFS MAOs are not correctly paying deemed providers in accordance with the MAO's terms and conditions of payment. We remind PFFS MAOs of their responsibility to pay deemed providers at the payment rates consistent with their terms and conditions of payment. PFFS MAOs that are meeting access requirements by paying deemed providers at least at the Original Medicare rates are required to pay these providers at the appropriate amounts applicable under Original Medicare. To pay less than an amount specified in the PFFS MAO's terms and conditions of payment, particularly on a pattern basis, is a significant compliance issue.

As we indicated in a previous program memorandum, we have contracted with an experienced organization to serve as the independent review entity (IRE) for provider payment disputes between deemed and non-contracting providers and PFFS MAOs. We expect MAOs to fully cooperate with the PFFS reimbursement adjudication IRE.

Changes in Access Requirements for PFFS Plans

Effective January 1, 2010, MIPPA requires PFFS plans that are meeting Medicare access requirements under 42 CFR 422.114(a)(2) based on signed contracts with respect to a particular category of provider establish contracts or agreements with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. Section 1852(d)(1) of the Act describes the requirements that MAOs offering a MA plan must meet when selecting providers to furnish benefits covered under the plan when the MAO offers a "network" plan. Providers who have direct contracts with PFFS plans must meet the provider credentialing requirements described in 42 CFR §422.216(i). A discussion of this MIPPA requirement can be found on page 11 of our guidance document at: http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf.

Requirement for Certain Non-Employer PFFS Plans to Use Contract Providers in 2011 and Subsequent Years

Effective January 1, 2011, MIPPA created a new requirement for certain non-employer MA PFFS plans to establish contracts with providers. Specifically, for plan year 2011 and subsequent plan years, MIPPA requires that non-employer/union sponsored PFFS plans that are operating in a "network area" must meet the access requirements described in section 1852(d)(4)(B) of the Act through contracts with providers. PFFS plans located in a "network area" may no longer meet access requirements by paying not less than the Original Medicare payment rate and having providers deemed to be contracted as provided under 42 CFR §422.216(f).

"Network area" is defined by MIPPA, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as having at least two network-based plans (such as an HMO plan, a PSO plan, a local PPO plan, a network regional PPO plan, a network-based MSA plan, or a section 1876 cost plan) with enrollment as of the first day of the year in which the announcement is made. Special needs plans and employer/union sponsored group health plans are not considered network-based plans. For plan year 2011, the list of "network areas" will appear in the *Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.* which will be posted on the CMS website on April 6, 2009. We will use enrollment data for January 1, 2009 to identify the location of "network areas".

For purposes of determining the network area of a PFFS plan, we will determine whether any network-based plans with enrollment exist in each of the counties located within the PFFS plan's service area. Beginning in plan year 2011, in counties CMS has identified as network areas as per the statute , a PFFS plan operating in these counties must establish a network of contracted providers to furnish services in these counties in accordance with the section 1852(d)(4)(B) of the Act in order to meet access requirements. In such counties, a PFFS plan would no longer be able to meet access requirements through providers deemed to have a contract with the plan at the point of service in these counties. In counties where there are no network-based plan options, or only one network-based plan, the statute allows PFFS plans to meet access requirements in accordance with section 1852(d)(4) of the Act and 42 CFR §422.114(a)(2).

A discussion of this MIPPA requirement can be found on page 9 of our guidance document at: http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf

CMS will issue guidance for MAOs making plans for contract year 2011 with respect to PFFS network requirements and beneficiary transitions in advance of the submission of Notices of Intent to apply for CY 2011.

A discussion of the requirement for all employer/union sponsored PFFS plans to use contracts with providers in 2011 and subsequent years can be found in Section A, subsection XIII, of this call letter.

PFFS Prior Notification

NOTE: Guidance explaining the prohibition on PFFS plans requiring prior authorization or referral requirements was included in the 2009 Call Letter, and in an HPMS memorandum dated May 29, 2008. This guidance explains the difference between the terms prior authorization and prior notification. In addition, this guidance explains the conditions under which PFFS plans may use prior notification, as well as actions CMS may take when plans improperly use prior notification as a form of prior authorization.

MA coordinated care plans may require prior authorization or referral as a condition for their plan members receiving certain covered services from providers. Prior authorization means that a coordinated care plan requires that an enrollee or provider obtain advance permission from the plan before a health care service will be paid for by the plan. It is important to note that PFFS plans are prohibited from imposing prior authorization requirements as a condition of their members obtaining health care services (MCM Chapter 4, Section 150.1). PFFS plans must pay providers according to their terms and conditions of payment for all medically necessary plan covered services enrollees receive from providers who are eligible to furnish Medicare services. PFFS plans must also furnish upon request of the member or a provider an advance determination of coverage if the provider or member wishes to confirm in advance of receiving or furnishing a service that it is a medically necessary plan covered service (see §422.216(e)).

Prior notification refers to a situation in which a PFFS plan offers a reduction in the standard plan cost sharing when:

- The provider from whom a plan enrollee is receiving plan-covered services voluntarily notifies the PFFS plan prior to furnishing those services; or

- The enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

Prior notification does not involve a medical necessity determination by the PFFS plan. It is simply notification by the member or a provider that a particular plan-covered service is being furnished.

Those PFFS plans requesting voluntary prior notification in their terms and conditions of payment for selected plan-covered services in return for reduced cost-sharing must:

- Clearly advise the enrollee that they may also obtain this service at the cost sharing level that applies in the absence of voluntary prior notification. (MCM Chapter 4, Section 50.1) and

- Have a CMS-approved bid that includes the differential cost sharing; and

- If an enrollee does not voluntarily prior notify a PFFS plan when obtaining a service, then the PFFS plan must still cover this service as long as it represents a medically-necessary service covered by the plan. However, in this case, the enrollee pays the cost sharing amount that applies in the absence of prior

notification. Plans may not otherwise impose fines or monetary penalties for non-participation in voluntary prior notification protocols.

We are issuing this guidance because CMS is concerned that the use of prior notification by PFFS plans is confusing to beneficiaries, misleading in terms of disclosing to plan members what cost sharing they must pay, and in some instances used inappropriately as a form of prior authorization. Specifically, CMS expects PFFS plans to market their plans in a way that prominently shows enrollees or prospective enrollees the standard plan cost sharing absent any prior notification cost sharing reductions that may be available. CMS will pay special attention to both the standard and the prior notification cost sharing amounts to ensure that they do not have the effect of discouraging the enrollment of beneficiaries requiring certain health care services. Any plan that does not clearly list its prior notification policies or uses such policies to require prior authorization will be considered not in compliance with the MA program regulations and subject to sanctions or civil money penalties.

In order to protect beneficiaries, CMS is considering rule making prohibiting prior notification.

XI. Medical Savings Account (MSA) Plans

A Medicare Medical Savings Account (MSA) plan is a type of Medicare Advantage plan that combines a high-deductible health plan with a medical savings account. Enrollees of Medicare MSA plans can use their savings account to help pay for health care that is not covered by the high-deductible health plan because the deductible has not been met. While generally, only Medicare-covered expenses will count towards the plan deductible, all MSA account dollars spent on "qualified medical expenses" are not taxed. Medicare MSA plans cannot offer Part D coverage. Under demonstration projects, some MSA rules have been waived to test MSA plans that are more similar to other consumer-directed health plans, like health savings accounts (HSAs) available in the private sector. Under these waivers, demonstration MSA plans may allow coverage of preventative services under the deductible, and cost sharing after the deductible has been met, up to a separate out-of-pocket limit.

Enrollees of MSA plans cannot receive Medicare Part D prescription drug coverage from their plan; however, MSA plan enrollees can join a stand-alone Medicare prescription drug plan (PDP). MSA savings account withdrawals can be used for Part D drug plan co-pays that will count towards TrOOP. If an enrollee does not have a PDP, MSA account dollars can be used for prescription or certain over-the-counter drugs that are qualified medical expenses and not be taxed.

We expect organizations offering this type of plan to fully explain its features to ensure that people with Medicare clearly understand the costs before and after the deductible is met, and how costs that count towards the deductible are tracked.

Further information:

- For more information on Medicare MSA plans, see CMS publication "Your Guide to Medicare Medical Savings Account Plans"

http://www.medicare.gov/Publications/Pubs/pdf/11206.pdf and the Medicare MSA website http://www.cms.hhs.gov/MSA.

- For information on Medicare MSA plans open for enrollment in 2009, see the Medicare Options Compare tool at http://www.medicare.gov/MPPF/Include/DataSection/Questions/Welcome.asp.

- CMS is in the process of developing a Medicare MSA manual, an audit guide for MSAs, marketing guidelines for MSAs, and a checklist to facilitate the development and review of draft MSA marketing materials.

MSA Transparency

Effective 2009, § 422.103(e) requires MSA plans to provide enrollees with available cost and quality information in their service area comparable to that provided to their commercial enrollees, and submit to CMS for approval a proposed approach to providing such information. Below are examples of what a plan could be expected to address:

- How the organization will provide cost and quality information to enrollees, including screenshots for any web-based tools used to meet this requirement.

- If they will use a web-based product to meet this requirement, how they will provide this information to enrollees that do not have access to the Internet.

- How their organization will obtain information regarding cost and quality in the requested service area and whether this information will be personalized to the member.

MIPPA Quality Improvement Program

We discuss the new MIPPA quality improvement program requirement for MSA and PFFS plans in Section A, Subsection IV, of this call letter.

XII. Section 1876 Cost Plans

Cost Plan Competition Provisions

Prior to MIPPA, for cases in which two or more local or regional coordinated care plans meeting minimum enrollment requirements were present in the service area or portion of a service area of a cost plan, CMS could not renew a contract during 2009 for the affected service area or portions of the cost plan's service area. MIPPA made several clarifications concerning these so-called cost plan competition provisions.

MIPPA revised current requirements by applying the competition provisions beginning in 2010. This means that plans will receive non-renewal notices in 2010 and will first be unable to offer a plan in the affected area(s) beginning 2011. As the statute requires that we use data over the

course of the entire year in making the determination, we will use 2009 enrollment data in determining whether a non-renewal for 2010 is required in 2011.

The MIPPA also clarified how the minimum enrollment requirements will be applied. For a discussion of these changes, please see page three of our guidance document at http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/MIPPA_Imp_memo091208Final.pdf or the September 18, final regulation codifying the MIPPA cost plan changes (73 FR 54226-54254).

Cost Plan Service Area Expansions

As has been the case since 1997, CMS cannot approve new cost plans for 2010. Also, we will continue our policy to deny applications for service area expansions (SAE) into areas where two or more local or regional plans meeting minimum enrollment requirements exist. Continuing cost plans not affected by the competition provisions and which meet all other requirements, can, however, apply to expand their service areas.

Consistent with our policy regarding cost plans offering a Part D benefit, we will no longer permit applications for mid-year service SAEs for cost plans that offer health care benefits only. Beginning January 1, 2010, no cost plan can apply for an SAE other than at the beginning of a program year.

Cost Contract Drug Benefits

A cost contract has the option of offering a Part D prescription drug benefit as an optional supplemental benefit. Each enrollee then has the option of purchasing this Part D drug benefit. If the enrollee declines to purchase the benefit, or if the plan does not offer the benefit, the enrollee has the right to enroll in a PDP. Cost contracts also have the right to offer a non-qualified drug benefit as an optional supplemental benefit if they do not offer a Part D prescription drug benefit.

The statute does not allow Medicare cost contracts to offer separate plans. Rather each cost contract may offer (none, one or many) optional supplemental benefit packages. As a matter of technological convenience, the PBP software calls each of these optional supplemental benefit packages a cost plan.

The following rules apply when a Medicare cost contract wishes to offer more than one optional supplemental benefit package: A Medicare cost contract:

- Cannot simultaneously offer both a qualified and non-qualified drug benefit in the same or distinct optional supplemental benefit packages; and

- Cannot offer an enhanced Part D drug benefit in one of its optional supplemental benefit packages unless the Medicare cost contract also offers a basic Part D drug benefit in the same or another optional supplemental benefit package.

XIII. Employer and Union-Sponsored Group Health Plans

Requirement for All Employer/Union Sponsored PFFS Plans to Use Contracts with Providers

Effective January 1, 2011, MIPPA revised the access requirements for employer/union sponsored PFFS plans. For plan year 2011 and subsequent plan years, MIPPA requires that all employer/union sponsored PFFS plans that have waivers under section 1857(i) of the Act must meet access requirements under 42 CFR §422.114(a) by establishing written contracts or agreements with a sufficient number and range of health care providers in their service area for all categories of services in accordance with the access and availability standards described in section 1852(d)(1) of the Act. A discussion of this MIPPA requirement can be found on page 12 of our guidance document at: http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf.

We will issue operational instructions for implementing this requirement in future guidance.

Section B – 2010 Prescription Drug Plan Sections

Introductory Note

Most of the information in Section B of the 2010 Call Letter applies to all types of Medicare Part D sponsors; (i.e., prescription drug plan (PDP) sponsors, Medicare Advantage organizations (MAOs), and Cost Plan sponsors). MAOs and Cost Plan sponsors offering Part D benefit plans must review both the Part C and Part D sections of the Call Letter to obtain complete information concerning their Medicare contract obligations for 2010.

CALENDAR – PREPARATION FOR 2010

NOTE: Employer/Union-Only Group Waiver Plans (EGWPs) are subject to the same timeline and requirements set forth below, except for dates or requirements that do not apply or are modified due to existing employer group waivers.

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
2009	
March 27, 2009	2010 Final Call Letter released.
March 30, 2009	Release of 2010 Health Plan Management System (HPMS) formulary submissions module.
April 1, 2009	Conference call to discuss 2010 Call Letter.
April 2, 2009	CMS Bid Conference
April 6, 2009	Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies.
April 10, 2009	2010 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.
April 20, 2009	Final day to submit 2010 formularies via HPMS (11:59 PM EDT).

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
May 1, 2009	Sponsors are strongly encouraged to notify CMS by May 1, 2009 of any type of service area reduction, or conversion to offering employer-only contracts, so that CMS can make the required changes in HPMS to facilitate a sponsor's ability to correctly upload its bid in June.
Tentative Date May 22, 2009	Final marketing model documents will be available for all organizations. (Models containing significant revisions will be released for public comment prior to this date).
Mid-May 2009	CMS sends PDP sponsor contract eligibility determinations to Applicants based on review of the 2010 applications for new contracts or service area expansions.
May 15, 2009	CMS begins accepting CY 2010 bids via HPMS.
Tentative Date May 29, 2009	Industry training on ANOC/EOC and other marketing materials.
Late Spring/Early Summer, June 2009	Update of the MA/PDP Enrollment, Eligibility, and Disenrollment Guidelines.
June 1, 2009	Final day for PDP sponsors to submit CY2010 bids via HPMS (11:59 PM PDT). Non-Renewal: Deadline for MAOs, PDP sponsors to submit a non-renewal or service area reduction notice to CMS for CY2010.
Tentative Date – Late June 2009	Federal Register posting of draft 2011 Part D Applications for 60-day comment period

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
June 5, 2009	CMS begins accepting CY2010 marketing material for review via HPMS Marketing Module.
June 8, 2009	CMS begins accepting 2010 supplemental formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY2010 Actuarial Certifications in HPMS.
June 30, 2009	Final date for PDP sponsors to submit CY2009 marketing materials for CMS' review and approval. NOTE: This date does not apply to CY2009 file & use materials since PDP sponsors may file these materials with the CMS regional office five calendar days prior to their use.
August 2009	CMS to release a Special Election Period (SEP) letter to PDP sponsors remaining in the service area of plans that have non-renewed. CMS to post annual non-renewal and service area reduction guidance that includes model final beneficiary letter. Release of the 2010 Part D National Average Monthly Bid Amount, the Medicare Part D Base Beneficiary Premium, the Part D Regional Low-Income Premium Subsidy Amounts, and the Medicare Advantage Regional PPO Benchmarks. Rebate re-allocation begins. Five business day rebate reallocation period begins after release of RPPO benchmarks.

2010 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
August 1, 2009	CMS issues contract non-renewal notices to those PDP sponsors CMS finds not qualified to offer Part D benefit plans in 2010.
August 3, 2009	PDP sponsors are expected to submit non-model Low Income Subsidy (LIS) riders to the CMS regional office for review.
August 14, 2009	PDP sponsors are expected to submit Low Income Subsidy (LIS) riders to the regional office for review.
Late August 2009	Final date for CMS to approve PDP's final beneficiary notification letter of non-renewal.
Late August/early September 2009	Submission of attestations, contracts, and final actuarial certifications. CMS completes review and approval of 2010 bid data.
September 2009	PDP sponsors preview the 2010 Medicare & You handbook plan data in HPMS prior to printing the CMS publication (not applicable to EGWPs).
September 18, 2009	Broker/agent compensation structures must be submitted to CMS.
Tentative Date – Late September 2009	Federal Register posting of draft 2011 Part D Applications for 30-day comment period
October 1, 2009	PDP sponsors may begin CY2010 marketing activities. Once an organization begins marketing CY 2010 plans, the organization must cease marketing CY 2009 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY

2010 Part D Calendar *(All dates, unless identified as statutory, are subject to change)*	
	2009 materials on request, conduct one on one sales appointments and process enrollment applications.
October 1, 2009	Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.
October 1, 2009	PDP sponsors are required to include information in CY2009 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2010.
October 9, 2009	Tentative date for 2010 prescription drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).
October 15-20, 2009	CMS mails *Medicare & You* handbooks to Medicare beneficiaries.
October 31, 2009	CY2010 standardized combined ANOC/EOC is due to all PDP members. PDP sponsors must mail the combined ANOC/EOCs before this date to ensure receipt by members by October 31. All PDP sponsors must mail their Low Income Subsidy (LIS) riders and abridged or comprehensive formularies before this date to ensure receipt by members by October 31.
November 2, 2009	Non-renewal: Final personalized beneficiary notification letter must be received by PDP enrollees.
November 15, 2009	Marketing guidelines require that PDP sponsors mail a CY 2010 EOC to each new member no later than when they notify the new member of acceptance of enrollment. PDP sponsors must mail their low income subsidy (LIS) riders and abridged or comprehensive

2010 Part D Calendar *(All dates, unless identified as statutory, are subject to change)*	
	formularies with the EOC for new members. New members with an effective date of 1/1/10 do not need to receive the ANOC portion of the standardized/combined ANOC/EOC.
November 15 – December 31	Annual Election Period: All PDP sponsors must hold open enrollment (EGWPs see Section 20.3.8 of the PDP Guidance: Eligibility, Enrollment and Disenrollment).
Tentative Date – November 17, 2009	Potential New PDP sponsors and existing sponsors seeking to expand currently contracted service areas must submit Notices of Intent to Apply for the 2011 contract year.
Tentative Date – November 25, 2009	CMS issues pending HPMS contract numbers to new Part D applicants for the 2011 contract year.
November – December, 2009	CMS to issue "close-out" information and instructions to PDP sponsors that are non-renewing or reducing service areas.
2010	
January 1, 2010	Plan benefit period begins.
Early January 2010	Final CY 2011 Part D applications are posted to the CMS website and HPMS. Applications released in HPMS for organizations seeking new Part D contracts or service area expansions.
Early January 2010	Industry training on CY 2011 applications.

2010 Part D Calendar *(All dates, unless identified as statutory, are subject to change)*	
Late February 2010	Applications due for CY 2011.

I. BIDDING/PAYMENT

Bidding Process

All updates and changes to the bidding process and bid pricing tool (BPT) will appear in the "Instructions for Completing the Medicare Prescription Drug Plan Bid Pricing Tool for Contract Year 2010."

Submission of a Valid Application, Bid, or Formulary Submission

Part D sponsors and organizations applying to qualify as sponsors are obligated by statute, regulation, and contract to meet several information submission deadlines in the course of applying to qualify to, or continuing to, operate a Medicare Part D contract. The most significant of these are deadlines related to applications for qualification as a sponsor, formulary submissions, and bid submissions. During the first four years of the Part D program (counting implementation activities during 2005), some organizations made submissions to CMS that have been either so lacking in required information or correct detail as to fail to constitute a valid, timely submission. In some instances, it even appeared to CMS that the organization might not have completed the preparation of its information and knowingly submitted incomplete or inaccurate information to avoid the significant consequences of failing to meet a Part D program deadline (i.e., failure to submit timely bid or formulary may result in non-renewal of a Medicare contract).

These submission deadlines are necessary to ensure that all applicants and Part D organizations are afforded the same period of time in which to prepare their files and that CMS substantially can meet its operational deadlines in preparation for the upcoming contract year. Organizations that make "placeholder" or substantially inaccurate submissions by stated deadlines may be attempting to defeat the purpose of deadlines. Therefore, during the application, formulary, and bid review processes for CY 2010 and beyond, CMS will consider the completeness and accuracy of the submission as factors in determining whether an organization has in fact met a submission deadline.

All three submission processes (application, formulary, and bid) afford sponsors opportunities to submit additional information after the initial deadline. However, CMS grants those additional submission opportunities only to allow organizations to provide clarifying information that builds on largely compliant initial submissions. Organizations must not rely on the period following the initial submission deadline as an opportunity to cure an incomplete or defective submission. When an organization's submissions appear to represent something other than a good faith effort to provide complete and accurate information, CMS may determine that the

organization has not met the submission deadline and may not accept any further submissions from the organization.

For each type of Part D-related information submission, CMS provides examples below of the application and formulary submission characteristics that would cause CMS to conclude that an organization had not, in fact, provided information that could be characterized as a valid, timely submission. CMS provides this list as an illustrative guide, and organizations should not read it as an exhaustive statement of the characteristics of an invalid application, formulary, or bid submission. CMS will evaluate the information provided in each submission in accordance with the principles described in this section.

Applications for Qualification as a Part D Sponsor

CMS wants to stress that organizations must submit complete applications. In order to submit a Part D application a series of attestations must be completed and a series of documents must be uploaded. CMS validates the documents that applying organizations provide and will reject any applications that are deemed invalid. Examples of invalid submission include applications that contain blank documents or blank spreadsheets. Such applications will not be considered to be completed applications under 42 CFR 423.502(b). In these instances, CMS would deny the application pursuant to 42 CFR 423.503(c).

Formulary Submissions

CMS wants to stress that organizations must upload complete formulary submissions. Submissions that do not indicate a good faith effort to provide an adequate formulary, as outlined in section 30.2 of Chapter 6 of the Medicare Part D Manual, will be considered a non-submission. In such an instance, CMS will non-renew or elect not to enter into a contract with the organization based on its failure to submit a timely bid, of which a formulary is a required element (42 CFR § 423.272(b)(2)(i)). This determination would not be subject to administrative appeal under 42 C.F.R. Part 423, Subpart N. (42 CFR § 423.506(d)). Submissions will not be considered if they are based solely on a previous year's Formulary Reference File (FRF), they include only one Part D drug in the majority of the formulary category and classes, or if they include a significantly lower number of Part D drugs as compared to all Part D sponsors' submissions.

Accuracy of Linkage Between HPMS Formulary and the Appropriate Contracts at Time of Formulary Upload

CMS reminds Part D sponsors that they must link all their associated contracts to an initial formulary submission on or before the formulary submission deadline. During the first four years of the Part D program, CMS spent significant time after the formulary submission deadline following up with sponsors to direct them to make the proper linkage. CMS is not obligated to double check on contracts that show no formulary link. Part D sponsors whose contracts are not linked to any timely formulary submission will be considered to have missed the formulary submission deadline and, therefore, may have their Medicare contract non-renewed.

Non-Renewals

CMS wants to emphasize that, pursuant to 42 CFR § 423.507(a)(3), existing Part D sponsors that voluntarily non-renew a Part D contract with CMS will be prohibited from offering a PDP in the specified service area for two years. CMS may, upon its determination that special circumstances exist, waive this prohibition.

Bids Under Puerto Rico's Medicare Platino Program

In the draft Call Letter, CMS requested that Part D sponsors that wish to offer a Platino plan in Puerto Rico in 2010 include the Platino benefits in the bids submitted to CMS by the bid deadline of June 1, 2009. CMS has received comments that persuaded us that this requirement might expose Part D plan sponsors to undue financial risks. This is because Platino plan benefit requirements may not be finalized by June 1. On the basis of these comments, CMS has now revised this requirement. Instead Part D sponsors seeking to offer a Platino plan in the Commonwealth should submit Part D bids that reflect only basic benefits, and should not include any Part D supplemental benefits, such as coverage of excluded drugs and cost sharing buy-downs that are (or will be) required by the Commonwealth for the Platino program in 2010.

The purpose of requiring all Platino plans to bid on a comparable benefit package is to be able to evaluate Platino plans bids on a "level playing field". Any supplemental benefits required by the Commonwealth of Puerto Rico will be a separate negotiation between the Commonwealth and the Part D sponsor and must be paid for by the Commonwealth of Puerto Rico through a supplemental premium that would not be evaluated or approved by CMS. We believe this policy places the Part D sponsors in a more comparable position to the stateside State Pharmacy Assistance Programs relative to the Commonwealth of Puerto Rico and CMS reconciliation. By having all Part D sponsors offering Platino plans in the Commonwealth submit only basic bids, their costs under the Part D benefit will be treated consistently with respect to Federal reinsurance subsidies and risk sharing.

II. FORMULARY

Access to Covered Part D Drugs

There will be no change in our six classes of clinical concern policy outlined in section 30.2.5 of Chapter 6 of the Prescription Drug Benefit Manual.

New PDE edits for NDCs not listed on the FDA's NDC Directory

CMS has been working on a project with the Food and Drug Administration (FDA) to increase transparency and clarity with respect to the regulatory status of prescription drug products in the marketplace. We are proposing to begin rejecting prescription drug event (PDE) submissions on January 1, 2010 with national drug codes (NDCs) for which the FDA is unable to provide regulatory status determinations through their regular processes. Specifically, CMS is exploring the feasibility of establishing PDE edits based on a comparison of NDCs that CMS uses to evaluate PDEs against NDCs listed on the FDA's NDC Directory. This comparison would help highlight NDCs for which it has not been affirmatively established that the product meets the

statutory definition of covered Part D drug [specified in Section 1860D-2(e)(1)(A) of the Social Security Act (the Act)].

Part D sponsors continue to be responsible for making coverage determinations regarding which drug products are Part D drugs based upon statutory and regulatory requirements. These determinations involve excluding non-prescription drug products (i.e. OTCs), excluding drug products in categories that are statutorily excluded from Part D (e.g., drugs used for the symptomatic relief of cough and colds), and excluding any remaining prescription drug products that do not otherwise satisfy the statutory definition of a Part D drug. Generally, these remaining prescription drug products can only satisfy the definition of a Part D drug if they are approved by the FDA for safety and effectiveness; however, some older unapproved prescription drug products on the market (and prescription drug products identical, related or similar to such older unapproved prescription drug products) potentially satisfy the definition.

Part D sponsors must rely on publicly available information, including information available from the FDA or CMS, to make these determinations. However, it has become increasingly clear that currently available information on the approval/marketing status of prescription drug products on the market is incomplete and that more guidance is needed to help ensure that Part D sponsors make consistent determinations across the Part D program. Specifically, it is unclear to the public that not all NDCs on the market (and listed on commercially available databases) have been appropriately reviewed and approved by the FDA or are eligible to be covered as older unapproved drugs, or that not all NDCs on the market (and included on commercially available databases) are properly listed with FDA as required by law.

As a result of collaborating with the FDA, CMS believes that it is best practice for Part D sponsors to consider the proper listing of a drug product with the FDA as a prerequisite for making a Part D drug coverage determination. Owners or operators of establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs must register their establishments and list all drug products for commercial distribution through the FDA drug registration and listing system. Requirements for drug establishment registration and listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (the Act) and section 351 of the Public Health Service Act (the PHS Act), and 21 CFR Part 207.[3] Prescription drug products that are properly listed will appear in the FDA's NDC Directory. Neither the assignment of an NDC number nor inclusion on the NDC Directory denotes FDA approval of the product.

Similarly, CMS has not determined that all prescription drug product NDCs listed on the FDA's NDC Directory satisfy the definition of a Part D drug, nor has CMS determined that all non-listed prescription drug product NDCs fail to satisfy the definition of a Part D drug. However, CMS relies on the FDA to make regulatory status determinations regarding drug products and the FDA can only make these determinations if a drug is properly listed. Therefore, a Part D sponsor's Part D drug coverage determination process should *begin* with confirming that the prescription drug product NDC is properly listed with FDA.

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[3] This guidance document does not apply to establishment registration and product listing information required solely under 21 CFR part 607, 21 CFR 807, and 21 CFR part 1271.

In support of our position that it is best practice for Part D sponsors to consider the listing of a prescription drug product NDC on the FDA's NDC Directory as a prerequisite for presuming a drug to meet the statutory definition of a covered Part D drug , CMS is proposing the following:

- CMS would request FDA assistance in performing the comparison and creating the resulting "Non-Matched NDC List." The Non-Matched NDC List would not be an all-inclusive list of NDCs that are unlisted with FDA; there may be other marketed drug products with NDCs that are not properly listed. Also, the fact that an NDC would be included on the Non-Matched NDC List would not be a finding that the drug product is improperly listed because, for example, the marketing and listing status of a prescription drug product may change over time

  Beginning January 1, 2010, CMS would establish PDE edits to reject NDCs on a prospective basis only for prescription drug product NDCs that are not listed on the FDA's NDC Directory because the FDA is unable to provide regulatory status determinations through their regular processes for these drug products. Specifically, CMS would establish edits based upon a comparison of NDCs that CMS uses to evaluate PDEs against NDCs listed on the FDA's NDC Directory.

- CMS would update its PDE edits to reflect the most current version of the Non-Matched NDC List. We anticipate that an initial comparison would be performed as early as possible in 2009 and an initial Non-Matched NDC List would be made available on the CMS website in the spring; however, we would utilize an updated version as the basis for establishing the January 1, 2010 PDE edits that would be made available as early as possible this fall so that Part D sponsors have sufficient time to make necessary systems changes and notify affected beneficiaries that would be negatively impacted. At this time, CMS does not expect the Non-Matched NDC list to be updated more than twice a year.

CMS cautions Part D sponsors about implementing changes to their CY2009 adjudication files based on the initial or updated Non-Matched NDC list. CMS is proposing a January 2010 implementation date for PDE edits to provide manufacturers, labelers, repackers, and distributors of unlisted products the opportunity to register and list with the FDA. Similarly, Part D sponsors should take steps to provide notice and inform their pharmacy benefit managers (PBMs) and network pharmacies about the NDCs that they determine not to be payable. This should discourage pharmacies from purchasing and stocking prescription drug products for Medicare Part D enrollees that potentially do not meet the statutory definition of a covered Part D drug. In addition, CMS will notify pharmacies on its pharmacy listserv when the Non-Matched NDC list is posted on the CMS website.

Part D sponsors, PBMs, pharmacies or other interested parties should contact the FDA's Drug Registration and Listing Team (nonlisted@fda.hhs.gov or 301-210-2897) if they believe that a prescription drug product NDC is improperly excluded from the FDA NDC Directory and therefore identified on the Non-Matched NDC list. Although CMS will accept NDC-level documentation in support of a determination that a prescription drug product is a Part D drug despite its inclusion on the Non-Matched NDC List, CMS will need to verify such documentation with the FDA before removing any related PDE edit. Therefore, submission of this information to CMS rather than to the FDA will only prolong the process. The most efficient method for getting CMS to remove such PDE edits is for the manufacturer, labeler, repacker, or

distributor to register and list the prescription drug product(s) NDC(s) with the FDA for listing on the FDA NDC Directory. Firms are encouraged to register and list electronically and may refer to the FDA draft guidance for industry on Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Listing, July 2008 at http://www.fda.gov/cder/guidance/OC2008145(2).pdf.

CMS will continue to work closely with the FDA to determine whether additional guidance is necessary to provide further clarification on the Part D status of prescription drug products on the market. In addition, the Medicaid Program and Medicare Part B are working with Part D and FDA on this initiative to determine whether the information provided can be used to assist in the administration of their respective programs. Future guidance may be issued by each program to their respective stakeholders.

CY 2010 Formulary Reference File

As CMS noted in last year's call letter, the Formulary Reference File (FRF) for CY 2010 HPMS formulary submissions will be based on the National Library of Medicine's (NLM) standardized nomenclature for drugs, RxNorm. We believe that incorporating RxNorm data as part of formulary submissions will eliminate issues associated with the use of National Drug Codes (NDCs) as unique drug identifiers, as well as differences in the representation of drugs in various commercial databases. In addition, this change supports RxNorm as a health information technology standard nomenclature.

As a result of the move to the RxNorm drug nomenclature, CMS has identified drug records that were contained on the CY 2009 FRF that will be absent from the CY 2010 file. These deletions are primarily due to the elimination of duplicate codes that represent the same drug product or the removal of inactive or obsolete codes, and thus, do not represent a reduction in the number of unique drug entities appearing on the file. CMS posted a draft version of the CY 2010 FRF in the HPMS formulary submission module to enable Part D plan sponsors to process the new file and provide feedback on its content. The final version is now available in HPMS and on the CMS website. The CMS website also includes materials explaining the use of the FRF and why CMS changes to the reference file will continue to occur annually in order to keep the file current.

Specialty Tier Threshold

We continue to analyze and evaluate the specialty tier for very high cost and unique drugs that are exempt from tiering exceptions. For contract year 2010, we will maintain the $600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed $600 per month may be placed in the specialty tier in accordance with section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual.

As part of our formulary review process, we will continue to carefully evaluate sponsors' formularies to ensure that they do not discourage enrollment by certain classes of beneficiaries. We encourage ongoing dialogue regarding our specialty tier policy and will evaluate whether further notice-and-comment rulemaking in this area is warranted.

Formulary Exceptions Tier

Part D sponsors have the flexibility to determine what level of cost-sharing will apply for all non-formulary drugs approved under the exceptions process. As provided in section 30.2.2 of Chapter 18 of the Prescription Drug Benefit Manual, CMS generally requires Part D sponsors to apply only one level of cost sharing from an existing formulary tier to all approved formulary exceptions. However, Part D sponsors may also elect to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost sharing is associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs.

Transition Notices in Long Term Care Settings

A successful transition process is contingent upon informing enrollees and their caretakers about their options for ensuring that enrollees' medical needs are safely accommodated within a Part D sponsor's formulary. This is particularly important in situations when a beneficiary resides in a long term care (LTC) facility where his/her medical needs may change quickly and require rapid modifications in drug therapy. With this in mind, for contract year 2010, we are permitting Part D sponsors the option of sending required transition fill notices to network long term care pharmacies. In addition to sending enrollees residing in LTC facilities a model transition notice via U.S. mail within 3 business days of the transition fill, Part D sponsors may elect to send the beneficiary transition notice to the LTC pharmacy serving the beneficiary's LTC facility. The LTC pharmacy must then ensure delivery of the notice to the beneficiary within 3 business days of the fill.

Part D sponsors electing this option must update their existing transition policy to specifically address that:

1. The sponsor maintains documentation of the LTC pharmacies' willingness to be delegated transition notice responsibilities; and

2. The sponsor maintains a fully functional electronic communication process with the LTC pharmacy once a transition fill has occurred (within three business days).

3. The LTC pharmacy will maintain a process that demonstrates notice has been provided to the beneficiary (or his/her representative) within the 3-day period.

This option must be in place prior to the start of the 2010 contract year; otherwise, the Part D sponsor must continue to provide notice directly to the beneficiary (or his/her designated representative) via U.S. mail.

Transition Across Contract Years

Section 30.4.5 of Chapter 6 of the Prescription Drug Benefit Manual describes our transition requirements with regard to formulary changes for current enrollees across contract years. Per that guidance, sponsors have two options for effectuating an appropriate and meaningful transition for enrollees whose drugs are no longer on the formulary in a subsequent contract year.

We clarify that these transition requirements apply both to drugs that are removed from a sponsor's formulary from one contract year to the next, as well as to formulary drugs that remain on formulary but to which a new prior utilization or step therapy restriction is added from one contract year to the next. Thus, for example, sponsors must effectuate a meaningful transition for a current enrollee whose Drug X is no longer on the formulary the following contract year, as well as for a current enrollee whose Drug Y, which previously had no prior authorization restriction on its use, has a prior authorization restriction added for the following contract year. This clarification ensures that the transition requirements for current enrollees across contract years are consistent with those for new enrollees.

Utilization Management Criteria

For contract year 2010, drugs identified on a Part D sponsor's formulary flat file with prior authorization (PA) or step therapy must have corresponding utilization management (UM) criteria reflected in HPMS. To ensure this occurs, Part D sponsors will again be required to submit a complete PA and step therapy UM file to CMS via HPMS, utilizing a standardized template. However, to achieve greater efficiency in the review of sponsors' 2010 submissions, any new 2010 or modified 2009 UM criteria will be required to be clearly marked in HPMS so CMS can focus its review on those changes identified. Further operational details associated with the upload of UM criteria will be released as part of the CY 2010 Formulary Submission Module and Reports Technical Manual in March 2009.

We note that, during the 2009 UM review, we identified a number of common errors associated with submission of Part D sponsors' UM criteria. To ensure a streamlined formulary submission in 2010, Part D sponsors must familiarize themselves with the following issues to remain compliant with our guidance:

1. P&T Committee Review

   Part D sponsors are reminded that the P&T committee must review the utilization management criteria submitted to CMS for clinical appropriateness. Those sponsors that submit criteria that are not consistent with widely used treatment guidelines or which contain significant quality control issues will have their submission returned and may be subject to a focused audit to ascertain if the P&T committee actually reviewed the criteria prior to CMS submission.

2. Lack of access to FDA labeled indications

   Generally, sponsors must cover formulary drugs for all FDA approved indications not otherwise excluded from Part D. In 2009, some Part D sponsors attempted to limit access to drugs by implementing prior authorization criteria that only covered certain labeled indications. Such UM criteria are generally not permitted. If we identify sponsors attempting to limit access of formulary drugs to only certain indications, those sponsors will have their criteria returned and will be asked to submit clinical justification supporting the necessity of such an approach. In the absence of any reasonable justification, the criteria will be rejected.

3. Use of "off-label" indications

   Part D sponsors will not be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication) unless the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices. Generally, CMS requires such authoritative guidelines to be endorsed or recognized by United States government entities or medical specialty organizations. We remind Part D sponsors of the definition of a medically-accepted indication outlined in Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 10.6.

4. Non-specific or vague criteria will not be accepted

   Part D sponsors must provide for a level of detail in their UM criteria that allows a prescriber to readily understand what criteria must be satisfied to permit access to the identified formulary drug. Non-specific or vague criteria will not be accepted. For example, Part D sponsors must not submit UM criteria requiring "laboratory values" without specifying the exact laboratory values considered as a component of the assessment. Furthermore, broad policies are not acceptable, such as "new drug PAs" or "alternate dosage form PAs" which cover a range of drugs, classes and/or categories. These policies are insufficiently specific for prescribers and beneficiaries to understand and will be returned to the sponsor for correction.

5. Overly burdensome criteria

   Part D sponsors must not submit overly burdensome UM criteria. For example, Part D sponsors should not generally maintain prior authorization criteria that require trial and failure of more than two formulary alternatives in advance of providing access to the prescribed drug. Any exceptions must be supported by clinical literature, such as situations where drugs are third or fourth line therapy.

6. Administrative Submission Errors

   Part D sponsors must follow the technical instructions regarding submission of UM criteria and ensure quality control of their work prior to submission. Part D sponsors with a high number of initial errors or those who fail to follow our guidance above will have their UM criteria returned without review. As a result, the Part D sponsor may fail to meet formulary submission timelines.

While we will focus our review on new and/or modified UM criteria relative to the prior year, CMS plans to continuously evaluate the Part D sponsors' UM criteria against a number of reported measures (e.g., exceptions and appeal statistics and beneficiary complaints) to ensure they reflect current medical practice and provide for appropriate access to Part D drugs. As has been our practice in previous contract years, on a case-by-case basis, we will reach out to specific sponsors and ask for revisions when necessary.

New Website Posting Requirement

In addition to posting PA criteria on plan websites in 2010, Part D sponsors must also post quantity limit restrictions and step therapy requirements. Accordingly, Part D sponsors will need to ensure that all UM applied to formulary drugs, including quantity limit amount, quantity limit days supply, prior authorization criteria and step therapy criteria, are available on their formulary websites for display by November 15, 2009. While Part D sponsors may make minor modifications on plan websites with regard to the HPMS prior authorization and step therapy criteria to address issues such as abbreviations and/or grammatical truncation, Part D sponsors will be expected to display all of the information contained within the HPMS files.

PACE Plan Formularies

PACE plans are not required to use a formulary to offer prescription drug coverage. However, we clarify that, if a PACE plan elects to use a formulary to offer its prescription drug coverage in 2010, the submitted formulary must meet all of our formulary requirements. We appreciate the frail nature of PACE enrollees; however, the uniqueness of this population will not automatically exempt the submitted PACE formulary from any of our formulary review checks. Similar to other Part D sponsors, clinical justifications for failure to meet our requirement are permissible where appropriate, but the justification cannot rest solely on the nature of the PACE enrollee population.

III. PART D BENEFITS

Beneficiary Understanding of Part D Benefits and Labeling of Part D Benefit Designs

Given the complexity of the Part D benefit, we continue to explore ways of conveying information about Part D plan benefit designs in ways that are meaningful and understandable to beneficiaries in order to promote informed decision-making. Opportunities for more clearly conveying information are present in terms of both pre- and post-enrollment communications, as discussed below.

Pre-Enrollment Provision of Benefits Information

In establishing the Part D program, CMS defined four benefit types in regulation – defined standard (DS) benefits, actuarially equivalent (AE) standard benefits, basic alternative (BA) benefits, and enhanced alternative (EA) coverage – in order to describe permissible benefit variations. These terms were intended to provide explicit guidance on permissible benefit design parameters for plan sponsors and actuaries. The first three benefit types are considered basic prescription drug coverage, and are actuarially equivalent to the defined standard benefit established in statute. These basic benefit designs vary only in terms of whether cost sharing tiers are applied versus one level of coinsurance, the deductible is lowered or eliminated, and the initial coverage limit is increased. However, there are a number of other benefit design features that are not captured by these actuarial distinctions (e.g., whether particular drugs are on the plan's formulary or a beneficiary's preferred pharmacy is included in a plan's network) that are critically important to beneficiary decision-making. In fact, our research has shown that the plan

features that are important to beneficiaries are whether a plan offers basic or basic plus supplemental benefits (particularly gap coverage), and what the premium, deductible, cost sharing, formulary, and pharmacy network offered by a particular plan are. The variations in those features among plans cannot be meaningfully captured in the foregoing four categories.

CMS provides some information about the various local MA plan and PDP options available to beneficiaries in the health plan charts included in the annual Medicare & You publication. However, because there are practical limitations to the display of detailed comparative information in a print format, CMS provides comparative plan information through other vehicles. We post landscape files to our web site (see http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/) that provide more detailed comparative information, such as information about benefit type (basic versus enhanced and also specific DS, AE, BA, or EA plan types), whether the plan has a $0 premium with full LIS subsidy, and a description of any gap coverage provided. However, this information is geared more toward beneficiary advocates and researchers than beneficiaries.

No static description of plan benefits design features can suffice to allow meaningful comparisons between plans. However, CMS designed and maintains the Medicare Prescription Drug Plan Finder (MPDPF) web tool to allow beneficiaries to customize their comparisons based on their particular needs and thus compare plan benefit packages in a meaningful way. For example, the MPDPF allows beneficiaries or their representatives to develop customized comparisons that are sensitive to a beneficiary's drug regimen, as well as tolerance for generic and therapeutic substitutes.

We continue to attempt to strike a balance between providing beneficiaries with more information and providing them with information that is useful in making an appropriate plan choice. For example, in 2008, CMS created an automated process to standardize the externally reported descriptions of Part D sponsors' levels of gap coverage. Previously, sponsors had self-identified their gap coverage descriptions, which resulted in descriptions that were not necessarily uniform or meaningful to beneficiaries. Our new process describes any gap coverage offered by plans using the labels identified in the table below. Each label – "all," "many," "some," "few" or "no" drugs – is associated with a certain percentage of formulary drugs covered in the gap. These gap coverage descriptions will be used to illustrate the degree of coverage for drugs labeled as generics and/or drugs labeled as brands on the HPMS formulary submissions. We used this new labeling process to describe gap coverage in the CY 2009 Medicare & You health plan charts listing coverage options in beneficiaries' areas of residence. Several commenters requested clarification regarding what the denominator should be when determining the percentage of covered drugs within the coverage gap. For CY 2010, plans will determine their unique denominator when determining gap coverage levels. We will consider the comments regarding the calculation of gap coverage levels for future plan years.

Gap Coverage Level Descriptions Applied to Gap Coverage for CY 2009

Level	**Percent of Formulary Drugs Covered in Gap**

All	100%
Many	≥65% to <100%
Some	≥10% to <65 %
Few	>0% to <10% (and must also be >15 products covered through the gap)
No Gap Coverage	0% (or ≤15 products covered through the gap).

Beginning in CY 2010, sponsors will be required to identify their gap coverage offerings for both generic and brand drugs in the plan benefit package (PBP) software using CMS-defined standardized thresholds. These thresholds represent the proportion of unique HPMS formulary drug entities (i.e., unique clinical drug component and dosage form) that are covered through the gap for drugs described on the formulary as generic and for drugs described as brand (as specified by the drug type label). Generic and brand gap coverage level determinations should be derived separately (e.g., *Many Generic drugs and Few Brand drugs*) and should not represent a combined coverage level for both brand and generic labeled formulary drug entities. Gap coverage descriptions for both brand and generic drugs will be communicated to beneficiaries through the Summary of Benefits (SB) and possibly other marketing and information dissemination materials.

Post-Enrollment Provision of Benefits Information

We believe it is equally important for beneficiaries to understand their plan's benefits, and particularly their own experience relative to those benefit design features, once they select and enroll in a plan. To this end, in 2008, CMS significantly revised the model explanation of benefits (EOB) plan sponsors use to convey information to enrollees about their year-to-date TrOOP and total drug spend balances. We had not updated the model since 2005, and our revisions – which were consumer tested in early stages of development – were focused on providing more tailored and better information for plan enrollees. We believe the new model, which was implemented in mid-2008, allows plan sponsors to provide a more nuanced understanding of each beneficiary's progression through a plan's particular benefit design, including for LIS eligible enrollees who, as a result of low-income cost sharing subsidies, experience a different benefit design than non-LIS eligibles enrolled in the same plan. Recently, CMS provided further guidance for sponsors further clarifying the use of the model for a variety of benefit designs, as well for enrollees with secondary coverage. In addition, we incorporated certain elements in response to requests from advocates for customization for LIS members. We continue to solicit comments regarding how plan benefit information can be best conveyed to beneficiaries after they enroll in a plan, particularly via the EOB.

Plan Corrections

CMS expects that with the experience gained over the last four years of bid submissions, sponsors' requests for plan corrections for CY 2010 will be minimal. As required by 42 C.F.R. § 423.265(c)(3) and 42 C.F.R. § 423.505(k)(4), sponsors' submission of their final actuarial certifications and bid attestations serve as documentation that the sponsor has verified the final bid submission and attests that it is complete and accurate at the time of submission. A request for a plan correction indicates the bid is inaccurate and/or incomplete and calls into question an organization's ability to submit correct bids and the validity of the sponsors' final actuarial certifications and bid attestations. Please be advised that CMS considers sponsors making plan correction requests to be out of compliance with the Part D program's bid submission and certification requirements.

The plan corrections module will be available in HPMS for CY 2010 benefits for a limited period, from early September until October 1, 2009. Consistent with marketing and open enrollment coordination, Part D sponsors will not be able to request plan corrections for CY 2010 benefits packages after the October 1, 2009 deadline. This will ensure that correct bid information will be available for review on the Medicare Prescription Drug Plan Finder in time for the open enrollment start date of November 15, 2009. It is important to note that only changes to the PBP that are supported by the BPT are allowed during the plan correction period.

Medication Therapy Management Program Requirements

Since the inception of the Part D program, CMS has stated that Medication Therapy Management (MTM) programs must evolve and become a cornerstone of the Medicare Prescription Drug Benefit. We required plans to report various details on their respective MTM programs and to proactively collect additional data on MTM. CMS intended to use these data to identify best practices that will improve MTM and achieve the statutory goal of improving therapeutic outcomes.

In 2008, we performed an extensive analysis and evaluation of MTM programs being offered by Part D sponsors to identify common practices. This review included analysis of Part D MTM program applications, plan-reported data, exploratory research on MTM, informal interviews with a number of Part D sponsors, and other relevant literature or data. Our review focused on enrollment methods, targeting mechanisms, eligibility criteria, interventions, and outcomes. In examining these areas and identifying best practices, we sought to maximize access to MTM and reduce eligibility restrictions. We want to promote greater consistency and raise the level of the MTM interventions offered to positively impact medication use. Based upon the results of our review, CMS is revising its existing MTM program requirements for 2010 by establishing more specific enrollment, targeting, intervention and outcomes-reporting requirements.

Beginning in 2010, Part D sponsors will be required to implement MTM programs that:

1. Enroll targeted beneficiaries using an opt-out method of enrollment only;

2. Target beneficiaries for enrollment at least quarterly during each year;

3. Target beneficiaries who:

    a. Have multiple chronic diseases; and

        - In defining multiple chronic diseases, sponsors cannot require more than 3 chronic diseases as the minimum number of multiple chronic diseases and sponsors must target at least four of the following seven core chronic conditions:

            1. Hypertension;
            2. Heart Failure;
            3. Diabetes;
            4. Dyslipidemia;
            5. Respiratory Disease (such as Asthma, Chronic Obstructive Pulmonary Disease (COPD), or Chronic Lung disorders);
            6. Bone Disease-Arthritis (such as Osteoporosis, Osteoarthritis, or Rheumatoid Arthritis);
            7. Mental Health (such as Depression, Schizophrenia, Bipolar Disorder, or Chronic and disabling disorders).

    b. Are taking multiple Part D drugs; and

        - In defining multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of multiple covered Part D drugs.

    c. Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

        - The existing cost threshold, $4000, will be lowered to $3000, and sponsors' targeting criteria should be adjusted accordingly.

4. Offer a minimum level of MTM services including interventions for both beneficiaries and prescribers, an annual comprehensive medication review for the beneficiary, which includes a review of medications, interactive, person-to-person consultation, and an individualized, written summary of interactive consultation, and quarterly targeted medication reviews; and

5. Measure and report details on the number of comprehensive medication reviews, number of targeted medication reviews, number of prescriber interventions, and the change in therapy directly resulting from the interventions.

All Part D sponsors must establish a MTM program per these requirements. The MTM requirement does not apply to MA Private Fee for Service (MA-PFFS) organizations. However, considering MA-PFFS organizations have an equal responsibility to provide a quality Part D

product, CMS encourages MA-PFFS organizations to establish an MTM program to improve quality for Medicare beneficiaries.

Opt-out Enrollment

Opt-out approaches have become the preferred method among sponsors and increase the number of beneficiaries offered MTM. Fewer than 15% of MTM programs in 2008 implemented an opt-in method of enrollment. In 2010, sponsors will be required to enroll targeted beneficiaries into MTM programs using only an opt-out method. A beneficiary that meets the targeting criteria would be auto-enrolled and considered to be enrolled unless he/she declines enrollment. The enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. This requirement will allow Medicare beneficiaries to have more access to MTM services and increase member compliance and enrollment into these programs. Part D sponsors are reminded that if an enrollee chooses to opt-out of the plan's MTM program, they must continue to apply their existing drug utilization management program to ensure the beneficiary receives high quality prescription drug coverage.

Targeting Frequency

Most MTM programs (over 95% in 2008) are already identifying targeted beneficiaries at least quarterly. Beginning 2010, sponsors will be required to target beneficiaries for enrollment at least quarterly during the year to allow more Medicare beneficiaries to have access to the MTM program earlier in the year. For example, daily, weekly, monthly, or quarterly targeting frequencies would meet this requirement.

CMS also expects Part D sponsors to promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same Plan. This targeting could be done to auto-enroll eligible beneficiaries in the plan's MTM program early in the next program year in order to provide MTM interventions with less interruption.

Targeting Criteria

Based on analysis of plan-reported data, a lower than anticipated number of plan enrollees have been eligible for MTM. In 2007, 13% of beneficiaries enrolled in Plans with an MTM program met the Plan's MTM program criteria (10% in 2006). Part D MTM programs must target beneficiaries who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary. CMS is further refining these targeting criteria to increase the number of beneficiaries eligible to receive MTM services and ensure that MTM programs manage the medication use for beneficiaries with the most prevalent health conditions affecting the Medicare population. The Part D sponsors may not include discriminatory exclusion criteria. If an enrollee meets all three of the required criteria as defined by the sponsor, the enrollee should be targeted for enrollment. CMS will monitor sponsors' movement to more restrictive criteria.

Multiple Chronic Diseases

Almost 85% of MTM programs in 2008 already targeted beneficiaries with a minimum of 2 or 3 chronic diseases. Beginning in 2010, sponsors cannot require more than 3 chronic diseases as the minimum number of multiple chronic diseases. Therefore, sponsors may set this minimum threshold at 2 or 3 and target beneficiaries with at least 2 chronic diseases or target beneficiaries with at least 3 chronic diseases.

Part D sponsors may continue to choose to target beneficiaries with any chronic diseases or limit enrollment in their MTM program to beneficiaries having specific chronic diseases. .However, at a minimum, sponsors must target at least 4 of the 7 core chronic diseases described previously in 3a. These are very prevalent conditions in the Medicare population based on the analysis of the RxHCC Risk Adjustment model, pose a risk to the Medicare Trust Fund, and are already the most common diseases targeted by Part D MTM programs.

Part D sponsors may target any chronic diseases in addition to the core diseases, but all Part D MTM programs must target at least 4 of these 7 diseases. Sponsors are encouraged to consider targeting additional diseases to meet the needs of their patient populations and improve therapeutic outcomes. In applying the criterion, the targeted beneficiary could have any combination of the chronic diseases targeted by the sponsor. As an example, if a sponsor targets beneficiaries with at least two chronic diseases and targets all seven of the core diseases plus five additional diseases, a beneficiary would meet these criteria by having at least two of these twelve diseases in any combination.

Multiple Part D Drugs

In 2008, over 85% of MTM programs already targeted beneficiaries with a minimum threshold of 8 or fewer Part D drugs. Beginning in 2010, in targeting beneficiaries who are taking multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of multiple Part D drugs. Therefore, sponsors may set this minimum threshold at any number equal to or between 2 and 8.

Dollar Cost Threshold

The existing cost threshold will be revised to $3000. Therefore, sponsors must target beneficiaries who meet the other two criteria and who are likely to incur annual costs for Part D drugs of at least $3000. This change will improve access to MTM.

MTM Services

For 2010, Part D sponsors must offer interventions to the enrolled beneficiary and his/her prescriber. The beneficiary and prescriber interventions may be provided independently or in combination to promote coordinated care. Approximately 90% of MTM programs in 2008 already target interventions to both beneficiaries and prescribers.

Part D sponsors must offer a minimum level of MTM services that include an interactive component of MTM as well as continued monitoring and follow-up. These services may be furnished by pharmacists or other qualified providers. Sponsors may incorporate passive or ‘lower touch’ interventions, such as educational newsletters, drug utilization review (DUR) edits,

refill reminders, and medication lists into their MTM programs, but these cannot be the sole offerings. Very few MTM programs currently provide only passive and "lower touch" interventions (less than 2% in 2008). Most MTM programs already offer an annual comprehensive medical review (CMR), and there is industry consensus that this is an essential element of MTM services to improve outcomes.

As stated above, the enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. At a minimum, Part D sponsors must offer MTM services that include the following:

1. Offer a CMR by a pharmacist or other qualified provider at least annually to all targeted beneficiaries enrolled in the MTM program by a pharmacist or other qualified provider. A CMR is a review of a beneficiary's medications, including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. While initial preparations to assess medication use and identify medication-related problems before the patient interaction may be conducted 'behind the scenes', they are only one piece of the overall comprehensive medication review. CMS recognizes the importance of offering an interactive, person-to-person consultation with the beneficiary for a complete assessment of the beneficiary's needs to improve medication use or outcomes.

This includes three components:

   a. Review of medications to assess medication use and identify medication-related problems. This may be conducted person-to-person or 'behind the scenes' by a qualified provider and/or using computerized, clinical algorithms.

   b. Offering to provide to each targeted beneficiary enrolled in the MTM program an interactive, person-to-person consultation performed by a qualified provider. This real-time interaction may be face-to-face or through other interactive methods such as the telephone. This interaction may include further assessment of the beneficiary's medication history and use (could enable sponsors to collect information from the beneficiary, such as OTC medications or supplements, that is outside of the claims data they have access to), health status, clinical information, adverse events, or other issues that could affect medication use or outcomes.

   c. Implementation of a systematic process to summarize the interactive consultation and provide an individualized written "take-away" to the beneficiary such as a personal medication record, reconciled medication list, action plan, recommendations for monitoring, education, or self-management, etc.

2. For ongoing monitoring, perform targeted medication reviews for all beneficiaries enrolled in the MTM program, no less often than quarterly, to assess medication use since the CMR, monitor whether any unresolved issues need attention, new drug therapy problems have

arisen, or if the beneficiary has experienced a transition in care. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary and if the intervention is warranted for the beneficiary and/or prescriber. These assessments could be person-to-person and/or system generated. The follow-up interventions should be interactive, if possible, but may be delivered via the mail or other means.

3. Offer interventions targeted to prescribers to resolve medication-related problems or other opportunities to optimize the targeted beneficiary's medication use. These interactions may be passive (e.g. faxed, mailed) or interactive when determined necessary.

For targeted beneficiaries enrolled in the MTM program that are in a LTC setting, sponsors are not required to offer the interactive CMR component, but still must perform quarterly medication reviews and offer interventions targeted to the beneficiaries' prescribers.

CMS expects that sponsors will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services. In addition, sponsors are expected to consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.

Outcomes Measurement

At the beneficiary level, Part D sponsors must measure and report to CMS through our reporting requirements the number of comprehensive medication reviews (CMRs), the number of targeted medication reviews, number of prescriber interventions, and the change(s) in therapy directly resulting from the MTM interventions. Sponsors are expected to analyze and evaluate their MTM programs and make changes to continuously improve their programs. An MTM Monitoring contract was recently awarded through 2010 to assist CMS in monitoring and evaluating Part D sponsors' MTM programs. These efforts, along with the efforts of the Pharmacy Quality Alliance (PQA) and other industry stakeholders may also assist CMS in identifying additional standardized measures that could be measured or reported by all Part D sponsors.

In the future, sponsors may be required to measure program process, output and/or outcomes in the following areas:

- Drug utilization (e.g., drug interactions, polypharmacy, and adverse drug events)
- Beneficiary health (e.g., clinical indicators and medical utilization)
- Financial impact (e.g., pharmacy cost and medical cost change)
- Customer satisfaction (e.g., usefulness of information provided)

Reference-Based Pricing

Since the program's implementation in 2006, we have allowed Part D sponsors to incorporate reference-based pricing, a commercial practice used to promote generic substitution, into their benefit designs. Under these programs, sponsors may require enrollees to pay a defined cost sharing amount plus supplemental cost sharing based on the differential in cost between the drug being dispensed and a lower-cost preferred alternative such as a generic equivalent. In contract year 2009, fewer than 10% of Part D contracts used reference-based pricing.

Although reference-based pricing is a legitimate utilization management tool, issues remain with respect to this practice in the Part D program. Moreover, given the complexity of reference-based pricing formulas, it is very difficult to accurately convey the extent of expected out-of-pocket spending for formulary drugs subject to reference-based pricing. For this reason, we have been unable to have the Medicare Prescription Drug Plan Finder (MPDPF) calculate correct pricing for drugs subject to reference-based pricing, which may distort projections of out-of-pocket expenditures for some beneficiaries (who do not select generic substitution) and significantly affect their ability to compare cost sharing obligations under different plans and choose the plan that best meets their needs.

Based on our experience and the increased complexity we have observed with these programs, we will eliminate the option of reference-based pricing in the Part D PBP for CY2010. Therefore, sponsors – including employer plans – may not utilize this cost-sharing design. The basis for this decision is our goal of improving transparency with regard to expected beneficiary cost sharing under Part D. We believe that Part D sponsors can (and should) employ alternative utilization management strategies (e.g., tiering and closed formularies) that are more transparent and equally effective in encouraging the use of preferred formulary products.

Bundling of Part D Home Infusion Drugs Under a Part C Supplemental Benefit

Please refer to Section A, Subsection II (Benefit Design), of this Call Letter for more information.

Cost Contract Drug Benefits

Please refer to Section A, Subsection XII (Section 1876 Cost Plans), of this Call Letter for more information.

IV. PHARMACY ACCESS

Pharmacy Access during a Federal Disaster or Other Public Health Emergency

CMS appreciates Part D sponsors' prompt and efficient response to the federal disasters that occurred in 2008 such as the Midwest floods and Hurricane Ike. While we believe enrollees residing in, or displaced from, these disaster areas received appropriate access to their Part D benefits, we want to reinforce that Part D sponsors should guarantee immediate refills of Part D

medications to any enrollee located in an "emergency area," as defined in Chapter 5 of the Prescription Drug Benefit Manual, section 50.12. Furthermore, we clarify that Part D sponsors may consider lifting edits in advance of an impending disaster. We also clarify that Part D sponsors may exercise some operational discretion as to how edits are lifted during a disaster as long as access to Part D drugs is provided at the point-of-sale. For instance, Part D sponsors could implement an edit that is readily resolvable at the point-of-sale through the use of a pharmacist override code. Consequently, if a displaced beneficiary presents at the pharmacy for a refill, and identifies him/herself as an affected enrollee, the pharmacist would be free to use the override code and provide the emergency refill without having to contact the sponsor (or PBM).

In our ongoing conversations with sponsors on this issue, we have become aware of sponsors' difficulties in determining the closure of a major disaster declared by the President or a U.S. Department of Health and Human Services (DHHS) declared public health emergency. We remind Part D sponsors that they must continuously monitor both the Federal Emergency Management Agency (FEMA) Web site (http://www.fema.gov/) and the DHHS Web site (http://www.dhhs.gov/) for updates, changes and/or closures of existing emergency declarations. In general, public health emergencies terminate when either the Secretary declares an emergency no longer exists, or upon the expiration of the 90-day period beginning from the initial declaration, whichever occurs first.

For major disasters declared by the President, Part D sponsors should pay particular attention to the closure of disaster incident periods listed in the Disaster Federal Register Notice section on FEMA's web site. In circumstances in which the incident period has not closed 30 days from the initial Presidential declaration, Part D sponsors may consider re-implementation of their edits. However, sponsors must remain prepared to work closely with enrollees who indicate they are still displaced or otherwise impacted by the disaster and need access to their Part D benefits. This extends to continuing to guarantee out-of-network (OON) pharmacy access to those enrollees who cannot reasonably access a network pharmacy (i.e., the locality is so badly impacted by the disaster that prescription drugs are only available through a severely limited distribution chain), as provided in Chapter 5 of the Prescription Drug Benefit Manual, section 60.1. CMS may contact individual plan sponsors to extend disaster edits or OON pharmacy access, as necessary, based on information from Federal, State, or local officials.

V. ENROLLMENT

Mandatory Use of the Online Enrollment Center (OEC)

Please refer to Section A, Subsection VI (Enrollment), of this Call Letter for more information.

VI. LOW-INCOME SUBSIDY POLICY

Reassignment of Low-Income Subsidy Eligible Individuals

CMS does not expect to make significant changes to its reassignment process for contract year 2010. Thus, we anticipate again reassigning certain low-income subsidy (LIS) eligible beneficiaries from PDPs with premiums that exceed the LIS benchmark in 2010 to PDPs with premiums at or below the benchmark, effective January 1, 2010. We will continue to provide

mailings to affected individuals. However, we are continuing to study this issue and welcome constructive suggestions consistent with the existing statute for improving the reassignment process. We will continue to work with plans that are losing members to identify appropriate ways to reach out to these members to explain how they can remain in their current plan and what their premium liability will be if they choose to do so.

Retroactive Auto-Enrollment of Full-Benefit Dual Eligible Individuals

Beginning on January 1, 2010, CMS intends to implement a demonstration in which it will assign new full-benefit dual eligible individuals with retroactive coverage to a single contractor for those retroactive periods. The contractor will pay for all claims for retroactive auto-enrollment periods plus immediate need point-of-service claims for unenrolled LIS eligibles. We will modify our auto/facilitated enrollment process, so that all individuals with retroactive effective dates are assigned to the demonstration contractor for those retroactive periods, but continue to be randomly auto/facilitated for prospective periods to standard LIS PDPs. We are currently conducting a competitive solicitation to select this contractor. This process will not affect individuals who are already enrolled in a Part D plan before they obtain dual eligibility. CMS will provide more detailed information about the demonstration after a contractor has been selected.

VII. GRIEVANCES/COVERAGE DETERMINATION, AND APPEALS

Please refer to Section A, Subsection VIII (Grievances, Organization Determinations, and Appeals), of this Call Letter for more information.

VIII. CLAIMS PROCESSING

New Medicare Secondary Payer (MSP) Edits

For 2010, Part D sponsors will receive new data elements related to Workers' Compensation Medicare Set-aside Arrangements (WCMSAs), but the requirements for Coordination of Benefits (COB) in all MSP situations will remain the same.

Existing requirements related to MSP are addressed in §50.13 of chapter 14 of the Medicare Prescription Drug Manual. In this section, we note that Part D sponsors should not immediately reject claims when they are secondary. Rather, for Workers' Compensation (WC), Black Lung (BL), and No-Fault or Liability coverage, the Part D sponsor must make conditional primary payment and then recover any mistaken payments where it should only have paid secondary -- unless the sponsor is already aware that the enrollee has WC/BL/No-Fault/Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury.

Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA Section 111) added mandatory reporting requirements with respect to Medicare beneficiaries who have coverage under group health plan (GHP) arrangements, as well as for Medicare beneficiaries who receive settlements, judgments, awards or other payment from non-GHP insurers including liability insurance (including self-insurance), no-fault insurance, or workers' compensation. The purpose of the data collection under the Section 111 MSP reporting is to permit Part D sponsors

and other Medicare payers to correctly pay for covered items and services furnished to Medicare beneficiaries by determining primary versus secondary payer responsibility. GHP and non-GHP insurers must submit data for both on-going claims processing and for MSP recovery actions, where applicable. These data will be reported to the CMS Coordination of Benefits Contractor (the COBC) that will manage the process. The implementation dates for the new reporting are January 1, 2009, for GHP arrangement information and July 1, 2009, for the non-GHP insurer information.

One method of protecting Medicare's interest in a Workers' Compensation (WC) situation is a WCMSA, which allocates a portion of the WC settlement for future medical treatment costs and future prescription drug expenses. "Future medical treatment costs and future prescription drugs" are those services and items provided after the final WC settlement. CMS reviews WCMSA proposals for Medicare beneficiaries with WC settlements greater than $25,000 and for individuals who are within 30 months of Medicare entitlement and possess a WC settlement greater than $250,000. WCMSA funds are administered by either the claimant or a professional administrator employed by the workers' compensation employer, carrier or the claimant. CMS keeps a record of the WCMSA amount determined by CMS to be adequate to protect Medicare's interests with regard to the claimant's future medical treatment and/or prescription drug expenses.

By the end of 2009, CMS will begin including costs related to prescription drugs in its settlements and reporting the WCMSAs under a distinct non-GHP MSP code on the COB file. The record will include the Administrator name and telephone number, WCMSA settlement date, and an indicator specifying whether prescriptions drug costs are included in the WCMSA amount.

In 2010, if the COB file record received from CMS indicates prescription drugs are included in the WCMSA, Part D sponsors must continue to make conditional primary payment under Part D and promptly contact the administrator to determine which claims should not be paid for under Part D. Once the Part D sponsor establishes that a certain drug is included in the set-aside, the sponsor should set appropriate point-of-sale edits, deny payment and reject the claim for billing to the primary payer.

At this time, CMS is not clear on the most efficient methodology for handling any retroactive payment recoveries on the part of the Part D plan. Multiple options exist concerning how recoveries should be calculated, who should handle recoveries and how recoveries might be distributed. Therefore, we propose at the next opportunity, to provide for public notice and comment rulemaking. Through rulemaking, we can present the options CMS has considered and solicit feedback on the best approach. In the meantime, sponsors must continue to comply with the COB requirements specified in Chapter 14 and handle recoveries on their own.

Claims for Drugs Prescribed by Excluded Providers

CMS wants to clarify the follow-up actions that Part D sponsors should take upon discovering that payment has been made for a drug prescribed by a provider (i.e., an individual or entity) who has been excluded from participation in the Medicare program. The existing requirement, as stated in 42 CFR 1001.1901, is that Medicare payment may not be made for items or services

prescribed by a physician or other authorized individual who is excluded. Therefore, Part D sponsors should regularly update their systems with the most current information on sanctioned providers. Lists of the excluded providers are available at: http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp and https://www.epls.gov/.

Also, sponsors must have processes in place to identify and prevent payment of Part D claims at point-of-sale (POS) when such claims have been prescribed by providers who have been excluded by either the Department of Health and Human Services Office of Inspector General or General Services Administration. To support the identification of excluded providers at POS, sponsors should request that network pharmacies obtain prescribers' national provider identifier (NPI) (when prescribers have one). We believe the majority of prescribers will have an NPI available. When sponsors identify these claims at POS, the claims should be denied.

If a Part D sponsor discovers that, due to timing issues associated with identifying excluded providers (such as those related to the timing of updates to the lists of excluded providers or to sponsor systems), any such claims have been submitted and paid:

- The Sponsor should follow the guidance in section 50.2.6.3.3 of Fraud, Waste and Abuse Chapter (9) of the Prescription Drug Manual. Therein, we state that the sponsor should investigate to determine whether other claims have been submitted for items prescribed by the excluded provider and report the claims to the Medicare Drug Integrity Contractor (MEDIC).

- The Sponsor should not reverse the claims, and no adjustment to the prescription drug event (PDE) data is required.

- However, the sponsor should immediately notify the beneficiary and their network pharmacies that further prescriptions from this prescriber, including refills on existing prescriptions written after the prescriber's exclusion, will not be filled because the prescriber has been excluded from participation in the Medicare program. CMS will develop a model letter for sponsors to use in these situations to notify the beneficiary, and will explore options for communicating with all Medicare beneficiaries concerning excluded providers. We will also work with the industry through the National Council for Prescription Drug Programs regarding electronic messaging that can be used to inform the pharmacies.

Coordination of Benefits (COB) Notification

As provided in the MMA, beneficiaries are legally obligated to report information about other prescription drug coverage or reimbursement for prescription drug costs that the beneficiaries have or expect to receive; any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from a Part D plan. Currently, Part D sponsors must survey their enrollees regarding any other prescription drug coverage they may have within 30 days of the date the sponsor processes a beneficiary's enrollment and annually thereafter. Section 50.2 of the chapter 14 of the Prescription Drug Manual, released on September, 26, 2008, provides guidance on the COB survey process and specifies the requirements for following up with non-responding beneficiaries.

Since the implementation of Part D, the number of other payers participating in voluntary data sharing agreements with CMS has grown, improving the volume and quality of the other payer information available to Part D sponsors on the COB file. In 2009, implementation of the new MSP reporting for group health plan and non-group health plan insurers, including liability (including self-insurance), no-fault insurance, and workers' compensation, will further expand the other payer information available for COB.

Given these developments, we are revising the Part D beneficiary COB survey requirements. Beginning in 2010, in lieu of a survey, Part D sponsors will be required to notify each beneficiary of his/her other payer information as reflected in the COB file from CMS and request the beneficiary to review the information and report back only updates (that is, corrections to existing information and new coverage information) to the sponsor. The new process will continue to be required within 30 days of the date the sponsor processes a beneficiary's enrollment and annually thereafter. Beneficiary notification will be required even in situations when there is no other coverage information in the file; thus enabling the beneficiary, when appropriate, to report other coverage. Absent a report of corrected or new information from the beneficiary, sponsors can assume the existing information or the absence of data, is correct and there will be no need for follow-up. CMS believes this new process, which provides for periodic review and correction of the CMS COB data, will further enhance the quality of the data available to Part D sponsors for COB.

Although this new process will be required in 2010, sponsors may elect to substitute the new approach sooner and are encouraged to do so. Sponsors electing to use the new approach in 2009 may substitute the new process for all beneficiaries or may use the new process for beneficiaries who failed to respond to the sponsor's current COB survey. In either situation, routine sponsor follow-up will not be required.

CMS is working on improvements to the process for sponsors to notify the COB Contractor via the Electronic Correspondence Referral System (ECRS) of updated COB information and for COB Contractor validation of the information submitted. We recognize that the new approach may require sponsors to implement systems changes and we intend to issue details on these improvements as early as possible.

Finally, these requirements are specific to Part D plans. As noted in Section A of the call letter, further guidance on the Part C MSP survey will be provided in the final 2010 Payment Announcement. Please see the Advance (Payment) Notice for Calendar Year 2010 dated February 20, 2009, where we explain our proposal to eliminate the requirement for the MSP survey that has been used to compute the Part C MSP payment factor. We will respond to comments and provide further guidance on that survey when we release the final 2010 Payment Announcement on April 6, 2009.

Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with COB activities. For contract year 2009, the Part D COB user fee was significantly

increased, and we undertook some major projects – automated TrOOP balance transfer, mandatory reporting of Medicare secondary payer information, and the de-linking of the enrollment and payment modules in MARx – to improve the quality reliability and timeliness of COB-related data. Upon review of the incremental ongoing costs of COB activities in 2010, the Part D COB user fee can be decreased to $1.89 per enrollee per year for contract year 2010. This COB user fee will be collected at a monthly rate of $0.21 for the first 9 months of the coverage year (for an annual rate of $0.16 per enrollee per month) for a total user fee of $1.89 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2010 bids.

IX. QUALITY AND PERFORMANCE MEASURES

New Part D Reporting Requirements for CY 2010

New Part D reporting requirements will be implemented for CY2010. CMS expects to propose the addition of the following reporting sections: network pharmacy support of electronic prescribing; prompt payment to pharmacies; fraud, waste and abuse compliance programs; enrollment, and employer/union-sponsored group health plan sponsors. CMS will also propose changes to current reporting sections. Examples of proposed changes include revising the MTM reporting section to collect specific data related to enrollment, targeting, intervention and outcomes, and streamlining some of the data elements listed in the grievance reporting section. We posted the first draft of the CY2010 reporting requirements in the Federal Register for public comment in January 2009.

Quality Assurance Requirements

As outlined in Section 20 of Chapter 7 of the Prescription Drug Benefit Manual, Part D sponsors must establish quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use. To further the quality of care provided to Part D enrollees, we are adding new expectations and further details to the following sections of Chapter 7:

1. Section 20.3: Concurrent Drug Utilization Review (cDUR)

   Part D Sponsors should maintain written cDUR policies and procedures that explain the level of the cDUR checks (pharmacy and/or plan level), system logic, established thresholds, and accompanying pharmacy messaging. These policies should detail how the aforementioned elements were established (i.e., thresholds that are based upon relevant clinical and drug information references), validated, and revised. Sponsors' cDUR polices should also address pharmacy requested overrides and detail how pharmacy override requests are evaluated and approved. Moreover, sponsors' policies should explain how trends in override requests (both approved and unapproved) are monitored and considered in ongoing formulary management.

   Part D Sponsors should be able to demonstrate how information obtained from their cDUR program is used in their overall quality assurance system and improves their enrollees' quality of care.

2. Section 20.4: Retrospective Drug Utilization Review (rDUR)

   Part D sponsors should maintain a written rDUR policy that establishes clear objectives and identifies the relevant claims data proposed for review, the evaluation period, criteria used in the evaluation, and proposed interventions. The policy should also include a periodic assessment that determines the success of the proposed objectives, interventions, findings and outcomes.

   Part D sponsors should be innovative in improving the quality of care provided to enrollees through application of rDUR. For example, Part D sponsors may want to apply rDUR upon FDA issuance of a new drug safety warning to ensure enrollees and/or physicians are aware of alternative therapies. Alternatively, Part D sponsors may consider application of rDUR for purposes of ensuring appropriate Part B versus Part D payment by working to obtain additional information after the point-of-sale adjudication.

3. Section 20.5: Medication Error Identification and Reduction (MEIR)

   The Part D sponsor's internal MEIR process should be fully documented and identify what types of medication errors will be collected internally. For example, Part D sponsors may receive calls or letters from enrollees containing a broad range of issues, including medication errors. Other operational functions may also receive and report medication errors, such as the sponsor's exceptions and appeal group, the clinical division involved in processing prior authorization forms, or the electronic prescribing group involved in the resolving issues with the implementation of new e-prescribing standards. As a result, appropriate sponsor staff should be trained to identify potential reportable medication errors and understand how to evaluate, resolve, document, and, if necessary, report to the appropriate authority (i.e., FDA, DEA).

   As a component of the sponsor's error reduction program, a periodic evaluation of the medication errors should be completed looking for trends and patterns that require the sponsor's attention and resolution. Additionally, when appropriate, reported medication errors should be shared and discussed with downstream contractors to ensure that corrective actions are implemented and future errors are prevented.

We believe these new expectations and clarifications will enhance Part D sponsors' existing quality systems and ensure Medicare beneficiaries receive the highest quality prescription drug coverage available in the marketplace.

Consumer Assessment Health Providers Survey (CAHPS) Administration

Please refer to Section A, Subsection IV (Quality and Performance Measures), of this Call Letter for more information.

X. COMPLIANCE/MONITORING

Prompt Payment of Retail Pharmacy Claims and Submission of LTC Pharmacy Claims

We remind Part D sponsors that MIPPA established new requirements with respect to Part D network pharmacy claims. Effective January 1, 2010, CMS' contract with Part D sponsors must include a provision requiring sponsors to issue, mail, or otherwise transmit payment for all clean claims submitted by network pharmacies – except for mail-order and long-term care pharmacies – within specified timeframes. Also effective on January 1, 2010, CMS' contract with Part D sponsors must include provisions such that LTC pharmacies have not less than 30 days, nor more than 90 days, to submit claims to the sponsor for reimbursement. Sponsors must also include these prompt payment and long-term care pharmacy claims submission requirements in their contracts with pharmacies or other providers, first tier, downstream, and related entities. For more detail about these requirements, please refer to our September 18, 2008 interim final rule with comment (CMS 4138-F) implementing a number of the new MIPPA requirements.

Response to Complaint Tracking Module (CTM) Complaints

To ensure that Medicare Part D enrollees receive the highest quality of service in a timely manner, CMS will expand case resolution time standards with respect to CMS recorded complaints within the Health Plan Management System (HPMS) Complaints Tracking Module (CTM) in 2010.

Currently, all Part D plan sponsors are required to resolve at least 95% of "immediate need" complaints entered into CTM within 2 calendar days. Effective January 1, 2010, Part D sponsors will be required to resolve at least 95% of CTM complaints designated as "urgent" within seven days, and 95% of CTM complaints without an issue level within 30 days. The table below defines and summarizes these resolution time requirements.

Designation	Part D Definition	Resolution Time
Immediate Need	Defined as a complaint that is related to the beneficiary's need for medication when the beneficiary has 2 or less days of medication left.	At least 95% of cases resolved within 2 calendar days of receipt.
Urgent Need	Defined as a complaint that is related to the beneficiary's need for medication when the beneficiary has 3 to 14 days of medication left.	At least 95% of cases resolved within 7 calendar days of receipt.

Unclassified	Any other CTM complaints.	At least 95% of cases resolved within 30 calendar days of receipt.

CMS continues to reserve the right to reclassify any complaint that does not fit the above definitions as "immediate need" or "urgent" at our discretion.

Should a Part D sponsor not meet the aforementioned 95% thresholds, CMS will consider these organizations out of compliance with one or more Part D requirements, including, but not limited to, requirements related to enrollment; coverage determinations, appeals, and formulary exceptions; and claims processing.

Audit Approach

Please refer to Section A, Subsection V (Compliance and Monitoring), of this Call Letter for more information

Part C and Part D Data Validation

Please refer to Section A, Subsection V (Compliance and Monitoring), of this Call Letter for more information.

Compliance with CMS' Requirements for Processing Out-of-Network Reimbursement Requests

Under 42 CFR 423.568(b), when a party makes a request for payment of an out-of-network reimbursement request, the Part D sponsor is required to notify the enrollee of its determination no later than 72 hours after receipt of the request. The intent of the existing 72-hour timeframe for processing reimbursement requests is to ensure that enrollees receive prompt responses to requests for payment. In practice, however, we have found that this deadline generally does not provide Part D sponsors a reasonable amount of time to process these payment requests particularly in situations involving out-of-network pharmacies. Sponsors have generally been unable to identify these requests among their incoming mail, transfer the requests to the appropriate department, manually enter and process the claims in the online adjudication systems, and then make reasoned and accurate determinations within the 72-hour timeframe for making a coverage determination. As a result, in many cases plan sponsors either are making negative coverage determinations in order to meet the 72-hour timeframe, or they are auto-forwarding the request to the Part D IRE based on their inability to make a timely determination. Although these steps achieve technical compliance with the existing requirement, we do not believe they serve the best interests of enrollees, who are in effect forced to resolve their requests in the appeals process, often in situations where a full review by the sponsor would result in favorable resolution at the coverage determination level. Even if the appeals process does result in a favorable decision, the enrollee may receive consecutive, conflicting notices on the case, which has a strong potential for creating confusion.

While we consider options for resolving this issue, we believe the best approach for addressing this problem is to exercise our enforcement discretion to decline to bring an enforcement action for non-compliance with the 72-hour deadline in 42 CFR 423.568 if the plan sponsor processes a reimbursement request and submits reimbursement (when appropriate) within 14 calendar days after receipt of the request (or auto-forward a request that cannot be processed timely). In other words, beginning January 1, 2009, sponsors that make a determination, and either send payment or the standard denial notice to the enrollee within 14 calendar days after receipt of the request will not have any enforcement actions taken against them for non-compliance with the 72-hour deadline in 42 CFR 568(b). However, if a plan sponsor notifies the enrollee of its favorable determination within 72 hours, the sponsor will still have 30 calendar days to mail the payment. We believe this short-term approach will strike a balance between affording plans sufficient time to make accurate coverage determinations and ensuring that enrollees are reimbursed for their out-of-network claims timely. While Part D sponsors will be afforded more time, if needed, to process enrollees' out-of-network reimbursement requests and enrollees may wait longer than 72 hours for decisions in such cases, enrollees will receive reimbursement in half the time than the current rules require when the decisions are favorable.

We emphasize that this enforcement approach is an interim measure only, and we intend to develop a permanent regulatory solution to this issue through notice-and-comment rulemaking as soon as possible.

Auto-Enrollment Readiness Audits

Based on our experience with auto-enrollments in the Part D program, we have identified several requirements that are critical to making sure that a plan's auto-enrolled dual eligible population receives effective drug coverage. To adequately protect Medicare beneficiaries, we are obligated to ensure that PDP sponsors receiving reassignees, auto-enrollees, and facilitated enrollees are fully prepared to accept these enrollments. To that end, we will conduct Auto-Enrollment Readiness Audits in late August and early September of 2009. Sponsors will be selected for audits based on a variety of factors, including whether they will qualify for auto-enrollments for the first time in 2010, whether they will be expanding the number of regions in which they will qualify to receive these enrollees in 2010, or whether the sponsor is operating under an existing corrective action plan (CAP) or is experiencing performance problems.

The critical functions that will be part of the Readiness Audit may include, but are not limited to: 4Rx data; LIS matching; call center performance; beneficiary notifications; transition policy; point-of-sale claims adjudication; systems testing; and best available evidence.

CMS may audit these functions through either an on-site audit or a self-audit request. Sponsors will be notified of their selection for an audit roughly 1 week prior to the audit team's arrival onsite. Sponsors selected for a self-audit will be notified at the same time as sponsors selected for an onsite audit and provided a deadline for their self-audit report (approximately 2 weeks). Based on the results of these audits, any organization that is not fully prepared to undertake this important role will be excluded from receiving reassignees and/or auto and facilitated enrollments. Also, CMS will require the sponsor to complete a CAP through which it must demonstrate that it meets the requirements associated with the autoenrollment process. CMS

will close the CAP only after the sponsor meets the requirements and has begun to accept autoenrollments.

XI. SPAP GUIDANCE

Prohibition of Mid-Year Enrollment by State Pharmaceutical Assistance Programs (SPAPs)

CMS has received a significant number of complaints from Part D sponsors about SPAPs performing mass mid-year plan enrollment changes. Sponsors have found that substantial disenrollment from one plan, followed by mass enrollment into another during the calendar year significantly impacts the financial operations of the Part D sponsor. Since the funding of the Part D benefit is uniform over the entire plan year, plans that lose beneficiaries mid-year are more likely to take losses, and plans that acquire beneficiaries mid-year from other Part D plans are more likely to experience gains. Specifically, plans that have beneficiaries early in the year are likely to incur expenses attributable to the initial coverage period, the portion of the benefit that includes 75% coverage. Plans that have beneficiaries later in the year are more likely to have beneficiaries during the coverage gap portion of the benefit, which requires 100% beneficiary cost sharing and no plan obligation.

In addition, aside from the financial disparities that may occur, we believe that re-enrollment into a new plan mid-year disrupts the continuity of care the beneficiary is accustomed to under his/her current Part D plan.

For these reasons, CMS will be monitoring this situation closely. We strongly discourage state pharmaceutical assistance programs (SPAPs), when authorized to enroll in Part D plans on behalf of beneficiaries, from performing substantial volumes of disenrollments and re-enrollments other than on a calendar year basis. If we learn that any SPAP is continuing to undertake substantial mid-year enrollment changes to Part D plans, we may determine that the SPAP has failed to meet the definition of state pharmaceutical assistance program set forth in Section 1860D-23(b) of the Act. Note that individual members of qualified SPAPs (or the State, acting as the authorized representative of members) will continue to have SEPs, as provided in the current CMS guidance, for case-by-case enrollment actions. (See Section 20.3.8, #9 of the PDP Guidance on Eligibility, Enrollment, and Disenrollment.)

XII. LICENSURE AND SOLVENCY

Licensure and Solvency Waivers

PDP Sponsors with expiring licensure waivers that have not obtained licenses before April 1, of the year in which the waiver expires, will be notified in April that CMS has determined that they are not qualified to be a PDP sponsor in the following contract year in any regions that include States for which a license is not held. These notices will also afford the sponsors the opportunity to complete a CAP prior to August 1st (the date by which CMS must issue non-renewal notices for the following contract year). (42 CFR 423.507(b)(2)(i), 423.642(d)). Sponsors that fail to complete a CAP (i.e., obtain risk-bearing licenses) will have their contracts non-renewed for any regions that include States for which a license is not held prior to August 1, of the current year.

Specific reporting requirements and deadlines related to the PDP sponsor's actions taken to obtain State licensure are specified in Appendix III.

In situations when the State cannot approve a license before the waiver expires because of State requirements that are beyond the PDP sponsor's ability to meet (e.g., a "seasoning" requirement or the need for a state to complete an audit report and the state has not scheduled an audit), CMS will allow the PDP sponsor to apply for a waiver extension. To qualify for such a waiver extension, the sponsor will need to submit documentation from the State explaining why the state has not been able to license the PDP sponsor. If the sponsor has contributed to the State's inability to approve the license application submitted to a State during the current licensure waiver period, then a CMS waiver extension will not be granted.

XIII. ELECTRONIC PRESCRIBING (E-PRESCRIBING)

CMS and HHS continue to encourage and support the utilization of electronic prescribing (e-prescribing) within the Part D program. We believe the migration to e-prescribing has the potential to result in programmatic cost-savings through reduction of administrative inefficiencies involved in handwritten prescriptions and may result in improved outcomes for beneficiaries through the reduction of adverse events that occur in the current prescribing environment.

In order to monitor the uptake of e-prescribing in the Part D program, CMS will require Part D sponsors to obtain the Prescription Origin Code via the NCPDP Telecommunication Standard 5.1 (see section 50.3 of Chapter 7 of the Prescription Drug Benefit Manual for more information on the standards for e-prescribing) option field 419 DJ beginning in 2010 and report this code on their prescription drug event (PDE) submissions. A corresponding Prescription Origin Code field already has been added to the PDE record file layout and PDE return file layout at field number 41. Field 41 is optional for 2009 but CMS strongly recommends that Part D sponsors work with their network pharmacies to voluntarily begin using the NCPDP Telecommunication Standard 5.1 option field 419 DJ in 2009.

In the draft Call Letter, CMS stated that we expected to require the Prescription Origin Code on all PDEs, not just PDEs for new prescriptions. Based upon industry comment, we now plan to require the Prescription Origin Code (using alphanumeric values 1 – 4) only on PDEs for new prescriptions submitted in Standard format (currently Standard format is NCPDP Telecommunication Standard 5.1). The Prescription Origin Code will remain optional for all PDEs for refills submitted in the Standard format and for all PDEs submitted in the Non-Standard Format. Further, the Part D sponsor has the option to report "blank" for PDEs for refills and Non-Standard format PDEs.

We believe this approach avoids any 2010 point-of-sale issues associated with refills, while not requiring any changes for future years. We will consider further industry input on this approach prior to releasing final operational guidance through HPMS early this summer.

XIV. EMPLOYER AND UNION-SPONSORED GROUP PLANS

Employer and Union Direct Contracts - Mutual Termination

CMS issues guidance each year for all sponsors seeking to non-renew their contract with CMS. It has come to our attention that some employers and unions that contract with CMS directly as PDP sponsors ("Direct Contractors") have failed to follow the non-renewal procedures, and instead have requested that CMS terminate their contracts by mutual consent after the non-renewal deadline established for the provision of sponsor-initiated contract non-renewal notices to CMS has passed. CMS has not waived the non-renewal deadline for such plans. Failure to comply with non-renewal procedures results in a failure to provide adequate notification to beneficiaries regarding their change in group coverage. CMS will not approve terminations by mutual consent as a substitute for the non-renewal process except under unusual circumstances as determined by CMS.

Section C - MARKETING/BENEFICIARY COMMUNICATIONS

This section applies to both MAOs and PDP Sponsors

Marketing Requirements Oversight

Marketing is the primary means for organizations to attract people with Medicare to their products – accuracy and timeliness in data file submissions and exchanges, compliance with systems requirements, and timely and reliable outreach are essential to helping inform people with Medicare about their choices. In addition, organizations are responsible for making sure that brokers or others authorized to represent an organization's plan or plans operate according to all guidance and requirements related to marketing, including those stated in our marketing guidance, the marketing chapters of the Managed Care and Part D manuals and the program requirements for Part C and, if offering a Medicare prescription drug benefit, Part D (Parts 422 and 423, respectively, of Title 42 of the Code of Federal Regulations).

CMS has taken many actions over the past few years to strengthen marketing requirements and oversight, particularly of agent and broker conduct. It appears that despite our efforts to ensure the protection of Medicare beneficiaries and preserve the integrity of the Medicare Managed Care program, some of our contractors and related third-party entities attempt to find ways to circumvent our rules and guidelines. CMS will not accept any continued attempts by some in the industry to avoid complying with our marketing requirements and guidance. CMS will take very strong action against any entity attempting to circumvent our rules.

Payment of Agents for Enrollments in 2009

CMS has received a number of questions about whether organizations offering MA plans or PDPs can withhold payments to agents until the report identifying new enrollments is released by CMS. The preamble of the compensation regulation (CMS-4138-IFC2) states that "for enrollments with effective dates in 2009, the MA or PDP plan initially pays the renewal compensation amount to the broker or agent enrolling an individual. Several times in 2009, we will run a report identifying those beneficiaries enrolled in an MA plan or PDP who were newly entitled or enrolled from original Medicare. Organizations can use the report to identify the agents or brokers who are entitled to an initial compensation amount" and adjust their payment accordingly. This policy does not require plans to wait to pay agents until the report is released. Rather, CMS thinks that it would be prudent to pay agents the renewal rate and then adjust the payment once the report is released. (Note that per our regulation, in 2009 plans may pay agents and brokers that enroll beneficiaries in their ICEP in a MA or PDP at the initial compensation rate without waiting for the enrollment report from CMS.)

Payment of Referral Fees to Agents

CMS has received and verified reports of Part C and D marketing activities that appear to be intentionally designed to attempt to circumvent the limits on agent compensation in our new agent/broker compensation regulations (CMS-4138-IFC2). Specifically, following the imposition of the limits on agent compensation in CMS-4138-IFC2, organizations offering Part C and D have begun for the first time, to offer exorbitant fees to agents for making a referral that

in some cases exceed regulatory limits that apply to compensation paid in connection with the sale of a Part C or Part D plan. We discovered that these fees are being paid in addition to compensation paid to the agent who ultimately enrolls the beneficiary in the plan. While historically referral fees have been of a nominal amount, such as $25-$100, in some cases we are finding that referral fees offered under these new referral fee programs exceed the total compensation that can be paid to agents under Medicare rules (the national fair market value cut-off amount released in the January 16, 2009, HPMS memo). Organizations must cease this practice immediately as it is not compliant with our regulation and guidance. The total compensation amount paid to agents for an enrollment including any referral fees paid in connection with that enrollment may not exceed the limits set forth in the agent compensation regulations and implementing guidance. The amount paid to the agent who enrolls the beneficiary thus may not, when combined with any referral fee paid in connection with the enrollment, exceed these limits.

Presumably, the referral fee programs that have been put in place subsequent to the imposition of the new limits on agent compensation are based on an erroneous belief that referrals are not governed by our new regulations and January 16th, 2009 guidance. However, new §§422.2274 and 423.2274 in CMS-4138-IFC2 specify that compensation "includes pecuniary and non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards and finder's fees." Referral fees are equivalent to finder's fees, and therefore are governed by CMS regulations. We clarify that these requirements apply to referral fees paid to independent agents only when the referral leads to an actual enrollment.

Multiple Organization Marketing Pieces Created by Agents

This year CMS is providing specific guidance with respect to agents/brokers that create customized advertising materials that include plan information for multiple organizations. The Medicare Marketing Guidelines require that all marketing materials be submitted to CMS via HPMS for approval or File & Use prior to use in the marketplace. In addition, CMS is reminding organizations that third party marketing materials, including materials created by agents/brokers must also be submitted to the MAO or PDP sponsor prior to use for review and approval. Under certain circumstances agents/brokers that create customized materials will not be required to submit to the MAO or PDP sponsor for CMS review. Essentially, materials that are generic in nature and do not discuss content specific to plan benefits, cost sharing or include the plan names will not require review and approval. Generic materials may reference the different product types (e.g., MA plan, MA-PD, Cost Plan, PDPs) offered by the agent.

Standardization of Plan Name Type

Section 103 of MIPPA requires both MAOs and PDP sponsors to include the plan type of the given plan in the plan name, using standard terminology as developed by the Secretary. This requirement is in effect for plan years beginning on or after January 1, 2010.

MAOs and PDP sponsors enter and maintain their plan names in HPMS. The plan name is used by internal CMS systems and in standardized marketing tools, including, but not limited to: the

Summary of Benefits (SB), Medicare Options Compare and Medicare Prescription Drug Plan Finder on www.medicare.gov, and the *Medicare & You* Handbook.

To ensure the consistent use of standardized plan-type terminology across all organizations, HPMS will auto-populate the plan type label at the end of each plan name beginning in Contract Year 2010. For instance, an HMO plan named "Golden Medicare Plan" would appear as follows: Golden Medicare Plan (HMO). The auto-generated plan type label will **not** count toward the 50 character maximum length reserved for the plan name field.

The following table outlines the standardized plan type terminology to be generated for each active HPMS plan type:

Standardized Plan Type Terminology	
Plan Type	**Plan Name with Standardized Plan Type Label**
HMO	Plan Name (HMO)
PPO	Plan Name (PPO)
HMOPOS	Plan Name (HMOPOS)
ESRD II	Plan Name (HMO-POS)
PSO	Plan Name (PSO)
MSA	Plan Name (MSA)
MSA Demo	Plan Name (MSA)
RFB PFFS	Plan Name (PFFS)
PFFS	Plan Name (PFFS)

Standardized Plan Type Terminology	
Plan Type	**Plan Name with Standardized Plan Type Label**
1876 Cost	Plan Name (Cost)
1833 Cost	Plan Name (Cost)
PACE	Plan Name (PACE)
PDP	Plan Name (PDP)
Regional PPO	Plan Name (Regional PPO)
Employer PDP	Plan Name (Employer PDP)
Employer PFFS	Plan Name (Employer PFFS)
RFB HMO	Plan Name (HMO)
RFB HMO-POS	Plan Name (HMO-POS)
RFB Local PPO	Plan Name (PPO)
RFB PSO	Plan Name (PSO)
CCRC	Plan Name (HMO-POS)

NOTE: HPMS cannot accommodate further differentiation among plan types this year; however, we will consider further refinement in future years. We note that in addition to standardizing the terminology in HPMS, organizations will need to display the plan name and plan type in the same format on all marketing materials, including advertising materials (i.e., banner ads, outdoor advertising, television, print ads, Internet ads and radio ads). Plans that have incorporated the standardized plan type in a position other than at the end of their plan name

must also place the plan type at the end on printed marketing materials. Plans should submit marketing materials with the plan name corrections on a flow basis recognizing that all materials intended to be used for the 2010 marketing season must contain the standardized plan type terminology. CMS will provide further clarity on this policy through training.

Part D Marketing Materials

CMS will be making minor modifications to the Part D marketing model materials and requirements for contract year 2010. We expect to release updated model materials, separate from the 2010 Call Letter, in the spring of 2009. Following are some of the process and model changes we anticipate for contract year 2010:

- **Changes to Printed Formularies**. Beneficiaries have a legitimate expectation that they will have access to the Part D drugs included on marketed formularies. While Part D sponsors can readily update their online formularies, the same is not true for printed formularies provided to plan enrollees. Given the potential perception of "bait and switch" related to mid-year non-maintenance formulary changes (defined in section 30.3.3.3 of Chapter 6 of the Prescription Drug Benefit Manual), beginning in contract year 2010, Part D sponsors will be expected to update all impacted abridged and comprehensive printed formularies with any CMS approved non-maintenance formulary changes. Part D sponsors may make any necessary changes via errata sheets mailed to beneficiaries; however, Part D sponsors retain the flexibility to utilize other processes for notifying beneficiaries of non-maintenance changes to their printed formularies. We clarify that this new requirement does not extend to mid-year maintenance changes defined in section 30.3.3.2 of Chapter 6 of the Prescription Drug Benefit Manual. Changes to previously printed formularies resulting from mid-year maintenance changes may be made at the time of the next printing.

- **OTC Drugs on Formularies**. Part D sponsors will be permitted to indicate any OTC drugs for which they pay as a Part D administrative expense in a new OTC section of their comprehensive or abridged formularies.

- **E-Prescribing Indicator on Pharmacy and Provider Directories.** For CY 2010, we are requesting that Part D sponsors indicate which of their network pharmacies support e-prescribing in their pharmacy directories. In addition, we request MAOs indicate which of their participating physicians or physician practices support e-prescribing.

- **Exceptions Cost Sharing in the Evidence of Coverage (EOC) and Summary of Benefits (SB).** Part D sponsors will be required to indicate in their EOC and SB which of their formulary cost sharing tiers is designated as their "exceptions tier" - in other words, the formulary tier cost share at which they will adjudicate all formulary exceptions. This is consistent with a change to the PBP software that we will be implementing for contract year 2010. Although CMS generally allows Part D sponsors to apply only one level of cost sharing from an existing formulary tier to all approved formulary exceptions, sponsors may also elect to apply a second less expensive level of cost sharing for all approved formulary exceptions for generic

drugs, so long as this second level is also associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs. When designating the exceptions tier in a PBP submission, sponsors can enter only one level of cost sharing for contract year 2010. Thus, a sponsor that has established a second (less expensive) level of cost sharing should indicate the more expensive cost-sharing level of the two tiers as its exceptions tier. The more expensive cost-sharing level of the two tiers will appear on their marketing material, as well as on the Medicare Prescription Drug Plan Finder, as a sponsor's exceptions tier.

- **Beneficiary Notice for Transfer of Prescriptions to Mail-Order**. Given previous beneficiary complaints that sponsors are transferring their prescriptions from network retail pharmacies to network mail-order pharmacies without their explicit consent, we will require sponsors to notify their affected enrollees prospectively of any such transferred prescriptions. We intend to provide a new model notice for this purpose.

New Model Explanation of Benefits (EOB)

We are aware that the transition to our new Part D EOB requirements in mid-2008 required a number of programming changes for sponsors and that there was a general need for additional guidance regarding CMS' expectations around the summary of year-to-date Medicare prescription drug costs in the EOB model, in particular. Although we provided additional guidance, including a number of examples using different benefit designs and beneficiary LIS status, via a February 9, 2009 HPMS memorandum, we received comments that additional guidance is needed relative to the examples provided. Commenters were also concerned about the timing of implementing the changes specified in the guidance. Please be aware that CMS expects to issue additional guidance this spring and will respond to concerns at that time regarding implementation timeframes for changes necessary so that EOB information is being conveyed consistently.

CMS Surveillance of Marketing Activities

In 2008, CMS issued final regulations designed to protect Medicare beneficiaries from deceptive or high-pressure marketing tactics by private insurance companies and their agents. In an effort to ensure compliance with these new marketing requirements and prohibitions, CMS initiated a comprehensive surveillance program that began during the 2008 Annual Election Period (AEP), and will continue through the end of the Medicare Advantage Open Enrollment Period (i.e. March 31, 2009). This surveillance strategy significantly expands on previously conducted surveillance activities. For example, CMS attended over 1,000 "secret shopping" marketing events, more than triple the number conducted in 2007. CMS also significantly expanded the scope of secret shopping to encompass at least one secret shopping event for each contracted Medicare Advantage (MA) and Prescription Drug Plan (PDP) parent organization in each of the 50 States. Further, CMS is focusing increased resources on high risk geographic areas and organizations by allocating additional surveillance resources to these MAOs and regions.

In addition to secret shopping, CMS also deployed a number of additional surveillance activities, including:

- **Use of a clipping service** to scan local media for advertisements to assess accuracy of marketing content and whether organizations are reporting all marketing events to CMS.

- **Secret shopping call centers** to test both the accuracy and understandability of CSR responses, as well as automated call center analyses such as hold times and disconnect rates.

- **Outbound calling** to selected recently enrolled beneficiaries to ensure that their enrollments were conducted properly.

- **Review of recorded enrollment calls** to determine if enrollments occurred appropriately or if there were instances of high-pressure marketing tactics employed, particularly for organizations identified as outliers in other surveillance activities.

- **Review of relevant data** for potential evidence of marketing violations, including data contained in CMS' complaints tracking module (marketing misrepresentation category).

- **Online readiness assessment** to assess organizations' readiness on implementation of the new marketing requirements and prohibitions. Organizations were asked to attest to their readiness, as well as provide feedback to CMS on implementation of best practices.

- **Regional Office surveillance** to obtain ground-level feedback on organizations' performance, gathering tips from local and state-government partners, and for conducting additional secret shopping.

CMS tracked the performance of all contracted organizations across the various surveillance activities. As a result of these efforts, CMS issued over 40 compliance letters at the end of the Annual Election Period to organizations that were found to be outliers in performance or that were found to be out of compliance with CMS' marketing requirements. Organizations that were specifically found to be outliers related to high rates of marketing misrepresentation complaints were required to report on their performance by investigating and reporting on their response to these complaints on a monthly basis. All other organizations were put on notice to improve performance or risk further compliance and/or enforcement actions. CMS continues to monitor performance of all organizations through the OEP and will take further actions, as warranted.

Due to continued concerns with the marketing activities of some MAOs and the brokers and agents who are marketing their products, CMS expects to continue to devote considerable efforts to similar surveillance activities in the future, and reminds MAOs that repeated violations that demonstrate a pattern of misconduct will be considered more substantial violations than those that merited initial noncompliance notices and warning letters this past AEP.

Section D – Appendices

APPENDIX I: CMS OVER-THE-COUNTER (OTC) LIST

In the body of the call letter we have presented the basic principles governing a supplemental, Part C, packaged OTC list. The table below presents a detailed list of categories of items. The following principles will facilitate correct usage of the list:

- Categories vs. items: The table below lists categories of items. MA plans should not steer enrollees to particular brands of items. For example, if an MA plan Part C OTC list includes headache medications, it must allow all brands of headache medications;

- Enrollee vs. Family: The plan must explicitly notify enrollees in its plan materials that OTC items may only be purchased for the plan enrollee. The plan must instruct enrollees that it is prohibited to purchase OTC items for family members and friends. The plan is responsible for ensuring that the Part C OTC benefit is properly used;

- Categories not on the list: Each MA plan must publish, on its plan website, or in catalogs or other marketing materials, the categories of items that a plan enrollee may purchase. The MA plan list need not be identical to the list below however the MA plan list may not include as eligible any items marked below as non-eligible. Should the plan wish to include categories of items not listed on the CMS list below – that is, the item is not listed in either the eligible, dual purpose, or non-eligible sections – it must first obtain permission from CMS;

- Three eligibility categories: The list has three types of items. The type is listed in the first column of the chart below:

    - Eligible items: These, if listed on the MA plan OTC list, may be purchased by the enrollee without further action. However, each MA plan, at its own discretion, may require written notes for purchase of OTC items;

    - Non-eligible items: The MA plan OTC list must specify all non-eligible items included in the CMS list. Enrollees must be instructed that non-eligible items, if purchased, will not be covered by the plan;

    - Dual Purpose items: These, if listed on the plan OTC list, may be purchased but the plan must, in its marketing materials, advise enrollees that prior to purchase (1) the enrollee must have appropriate conversations with the enrollee's personal provider, and (2) the enrollee's personal provider orally recommends the OTC item for a specific diagnosable condition. CMS does not require written recommendations. However, MAOs may require written recommendations for purchase of dual purpose or eligible items.

- Debit card linkages: If the plan provides a supplemental, Part C OTC benefit paid by a debit card then it should be aware of differences between its own MA plan Part C OTC list and the official list of items electronically linked to the debit card. The following three examples illustrate the situations that plans must formulate instructions for:

    - Dual Purpose: Many electronically linked cards do not allow purchase of dual purpose items. Consequently the plan must explicitly provide instructions to enrollees on how to purchase such dual purpose items, for example vitamins and minerals;

    - Acne / Sunscreen: Certain items – for example, acne treatment or sunscreen lotion– are classified as eligible on the CMS list, but are classified as dual-purpose or non-eligible on lists of items electronically linked to debit cards. In this case (should the plan for example, wish to cover acne treatment or sunscreen lotion) the plan must notify the enrollee that acne treatment or sunscreen lotion may only be purchased through a catalog or direct reimbursement; and

    - Baby Items: Many electronically linked cards allow purchase of baby items. The plan must explicitly notify enrollees of those categories of items which are prohibited, even if they are electronically linked to the plan debit card.

Eligibility Type	Category	Sub-categories	Exceptions
Dual Purpose	Minerals	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Vitamins	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Diagnostic Equipment	Equipment diagnosing: blood pressure, cholesterol, diabetes, colorectal screenings, HIV, etc.	Thermometers are eligible items not dual eligible; scales are non-eligible. Pregnancy diagnosis items are non-eligible.
Dual Purpose	Hormone replacement	Phytohormone, natural progesterone	

Eligibility Type	Category	Sub-categories	Exceptions
Dual Purpose	Weight loss items	Phenermine, FucoThin, Alli, Hoodia	Any OTC foods, such as protein shakes, even if heavily supplemented by nutrients, may not be offered as an OTC benefit
Eligible	Fiber supplements		Fiber supplements which are primarily food with fiber added are excluded.
Eligible	First Aid supplies	Includes: Bandages, dressings, non-sport tapes.	Flashlights are non-eligible.
Eligible	Incontinence supplies		
Eligible	Medicines, ointments and sprays with active medical ingredients that cure, diminish or remove symptoms	For examples see footnote #1.	Homeopathic and alternative medicines including botanicals, herbals, probiotics, dry skin lotions, and neutraceuticals are non-eligible. For further exceptions see footnote #2.
Eligible	Sunscreen lotion		
Eligible	Support items	Compression hosiery, rib belts, braces, orthopedic supports,	Arch and insoles are non-eligible.
Eligible	Teeth-related items / Dentures /	Toothbrushes, toothpaste, floss, denture adhesives, OTC items that treat gum	Mouthwashes, bad breath items, and teeth-whiteners

Eligibility Type	Category	Sub-categories	Exceptions
	Mouth care	problems, thrush, mouth sores	are non-eligible.
Non-eligible	Alternative medicines	Includes botanicals, herbals, probiotics and neutraceuticals	Vitamins and minerals are dual eligible
Non-eligible	Baby items		
Non-eligible	Contraceptives		
Non-eligible	Convenience (non medical) items	Scales, fans, magnifying glasses, ear plugs, foot insoles, gloves	
Non-eligible	Cosmetics	For examples see footnote #3.	Sun-tan lotions are eligible Medicated soaps, hand sanitizers, therapeutic shampoos, shampoos to fight dandruff are non-eligible.
Non-eligible	Food Supplements	Sugar / salt supplements, energy bars, liquid energizers, protein bars, power drinks, Ensure, glucema.	Vitamins and minerals are dual eligible. Probiotics are non-eligible. Fiber products are eligible unless they are primarily foods with fiber added.
Non-eligible	Replacement items, attachments, peripherals.	Includes: Hearing aid batteries, contact-lens containers, etc. when not factory packaged with	

Eligibility Type	Category	Sub-categories	Exceptions
		original item.	

NOTES:

1. Each item in the following alphabeticized list is either a medicine, ointment or spray, or a condition which is addressed by a medicine, ointment or spray, which has active medical ingredients: acne, allergy, analgesics (which reduce pain, inflammation), anti-acid, anti-arthritics, antibiotics, antiradicals, anti-diarrheas, anti-fungals, anti-gas, anti-histamines, anti-inflammatory, anti-insect, anti-itch, anti-parasitic, antiseptics, antipyretics (fever reducing), arthritis, asthma, blood clotting, bruises, burns, calluses, corns, colds, cold sores, cough, diabetes, flu, decongestants, dermatitis, eczema, digestive aids, ear drops, expectorants (mucus), eye drops, gastro-intestinal, hay fever, headaches, hemorrhoidal, incontinence, influenza, laxatives, (medicated) lactose intolerance products, lice, (medicated) lip products, menopausal, menstrual, sinus, motion sickness, nasal, osteoporosis, pain, psoriasis, pediculicide, rash, respitory, scars, sleep, smoking, snoring, sore throat, stomach problems, travel sickness, steroids, sunscreen, thrush, wart, worms, wounds.

2. The following are not eligible: Baby medicines are non-eligible. Dehydration drinks are non-eligible. Dry skin lotions (e.g. Eucerin, Aquaphor) are non-eligible. For Food supplements see below. Contraceptives are non-eligible. Dairy Care is non-eligible (it is non-medicated). Lactaid milk is a food (not a medicine) and non-eligible. Certain smoking cessation aides may be covered under Part B. Certain diabetic supplies may be covered under either Part B or Part D. Shampoos to fight dandruff are non-eligible. Hair-loss products are non-eligible.

3. Lip balm, deodorants, facial cleansers, feminine products, grooming devices, hair conditioners, hair removal, hair bleaches, moisturizers, perfumes, anti-perspirants, shampoos, shaving and men's grooming, and soaps.

APPENDIX II – Risk Adjustment Implementation

1. Risk Adjustment Data Submission Schedule

Table 1. Risk Adjustment Implementation Calendar (below) provides the updated submission schedule 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 adjustment model.

Table 1. Risk Adjustment Implementation Calendar

CY	Dates of Service	Initial Submission Deadline*	First Payment Date	Final Submission Deadline
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
2009	July 1, 2007 through June 30, 2008	September 5, 2008	January 1, 2009	N/A**
2009	January 1, 2008 through December 31, 2008	March 6, 2009	July 1, 2009	January 31, 2010
2010	July 1, 2008 through June 30, 2009	September 4, 2009	January 1, 2010	N/A**

2010	January 1, 2009 through December 31, 2009	March 5, 2010	July 1, 2010	January 31, 2011
2011	July 1, 2009 through June 30, 2010	September 3, 2010	January 1, 2011	N/A**
2011	January 1, 2010 through December 31, 2010	March 4, 2011	July 1, 2011	January 31, 2012

*March and September dates reflect the first Friday of the respective month.

**All risk adjustment data for a given payment year (CY) must be submitted by January 31st of the subsequent year.

Changes in payment methodology for 2010, including Part C and Part D payment and risk adjustment, are described in the February 20, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* and the April 6, 2009, *Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies* (which will be available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).

2. Part A Risk Adjustment Factor Options

Determinations of Risk Status

As stated in the April 3, 2006 Announcement of Calendar Year (CY) 2007 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/), plans subject to risk adjusted payments have the option of treating beneficiaries with 12 months of Part A data but less than 12 months of Part B enrollment in a data collection year.

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

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

*Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled to 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 sponsors of demonstration plans 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 as of 2006 payments, 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.

Option to Elect Full Risk Option for "Part A-only" Enrollees

Effective as of 2006 payments, 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:

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

This option is also available to §1876 Cost HMOs/CMPs offering Part D coverage for individuals who have been entitled to Part A for 12 or more months and who have been entitled to Part B for 11 or fewer months at the time of their enrollment in the Cost-PD plan. In such cases, the Part D payment will be risk–adjusted (new enrollee or full risk adjustment factor) based on the plan's election. In the absence of an election, the Part D payment will be risk-adjusted using the new enrollee factor.

Plans interested in electing this option for 2010 must contact: Henry Thomas, CMS, at henry.thomas@cms.hhs.gov by August 31, 2009.

3. Risk Adjustment Implementation

MA organizations must review the following:

- Changes in payment methodology for 2010 including Part C and Part D payment and risk adjustment, are described in the February 20, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* and the April 6, 2009, *Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies* (which will be available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).
- Two important risk adjustment memoranda dated November 27, 2007, which were published via HPMS on November 28, 2007:
    - CMS implementation of ICD-9 diagnosis codes for 2009
    - Medicaid status for Part C and D risk adjustment and Part D cost sharing; and

CMS implementation of ICD-10 diagnosis codes has been postponed until October 2013. CMS will provide plans with an opportunity for testing with ICD-10 diagnoses. More information will be forthcoming as CMS progresses with the development and implementation of changes to accept and process the new ICD-10 diagnosis codes.

For additional information on risk adjustment, see 42 CFR §422.310.

4. Impact of Hospital Acquired Conditions under the Inpatient Prospective Payment System on Diagnoses Reporting for Risk Adjustment

For purposes of risk adjustment, MA organizations are required to submit discharge diagnoses from hospital inpatient settings. To the extent that any ICD-9 codes attributable to the eight selected hospital acquired conditions (surgical site infections, blood incompatibility, air embolism, object left in surgery, catheter associated urinary tract infections, pressure ulcers, hospital acquired injuries, or vascular catheter associated infection) appear in the discharge diagnoses, these codes may be submitted for risk adjustment payment.

5. National Provider Identifier (NPI)

The January 23, 2004 final rule (69 FR 3434*), HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers*, established the standard for a unique identifier for health care providers and adopted the National Provider Identifier (NPI) number as that standard. The National Provider System (NPS) was established to assign unique NPI numbers to health care providers. The NPS was designed to be used by other Federal and state Agencies as well as by private health plans, if deemed appropriate, to enumerate health care providers that did not participate in Medicare. Consequently, the NPI can not be used to determine whether a provider is a Medicare certified provider.

On May 23, 2007, CMS implemented the use of the NPI, for claims submitted to Fee-For-Service (Original) Medicare and discontinued issuing the Medicare Provider Identifier Numbers (legacy or OSCAR numbers). In the past, Medicare plans could use the legacy number to verify that a provider was a Medicare provider and that the provider was an acceptable source for diagnosis data for the CMS risk adjustment process. Implementation of the NPI necessitates that Medicare plans that had been using the legacy Medicare provider numbers to verify the source of diagnoses submitted for risk adjustment purposes establish new methodologies for determining: 1) that providers are Medicare certified and 2) that diagnosis sources are acceptable. Implementation of the NPI does not change the requirement for Medicare plans to verify that the diagnosis data submitted to the CMS for risk adjustment are from Medicare certified providers and from acceptable data sources.

6. Testing Requirements

Submitter testing is required to ensure the proper flow of data from the submitter to the Risk Adjustment Processing System (RAPS). Testing also ensures the data submitted is valid and formatted correctly.

If you would like to send data in a test format, please contact the Customer Service and Support Center (CSSC) Help Line at (877) 534-2772. By calling the CSSC Help Line prior to transmission of your first production or test file, a CSSC representative will be able to give you information on how to properly submit a test and/or production file. Information regarding the CSSC and the Risk Adjustment Processing System (RAPS) is available on the CSSC web site at http://www.csscoperations.com/.

7. Acceptable Provider Types and Physician Data Sources

For purposes of risk adjustment, MA organizations must collect data from the following provider types:

- Hospital inpatient facilities
- Hospital outpatient facilities
- Physician

In addition, only those physician specialties and other clinical specialists identified in Table 3 – Acceptable Physician Data Sources of the Medicare Advantage, Medicare Advantage-Prescription Drug Plans CY 2007 Instructions (dated April 4, 2006) are acceptable for risk adjustment. To obtain a copy of this document, please visit the CMS web site at http://www.cms.hhs.gov/healthplansgeninfo/downloads/Rev%20MA-MAPD%20call%20letter%20final.pdf. Note that registered nurses, licensed practical nurses, and nursing assistants are not included in Table 3 – Acceptable Physician Data Sources as they are unacceptable physician data sources.

MA organizations are responsible for ensuring that the data they collect and submit to CMS for payment comes from acceptable provider types and 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 providers. Therefore, CMS requires MA organizations to filter and submit risk adjustment data in accordance with the appropriate provider types and acceptable physician data sources as approved by CMS.

8. Integrity of RAPS Submissions

Although a plan may designate another entity to submit claims on its behalf to CMS, the plan remains responsible for data submission, accuracy and content. If your MA organization needs assistance or is experiencing data submission issues, please contact our Customer Service and Support Center (CSSC) at 1-877-534-2772 or http://www.csscoperations.com/.

9. IT Technical Assistance Outreach

The purpose of the IT Technical Assistance Outreach program is to provide MA organizations with the IT support to perform the required Risk Adjustment data submissions skills and to understand the roles that data play in relationship to payment. This outreach will enable MA organizations to collect and submit the appropriate data in accordance with CMS requirements; thereby, this assistance's expected outcome seeks to provide a positive impact on "the correct payment." The outreach program contains two components: IT Participant User guides and IT User Group sessions.

IT Participant User Guides

CMS offers three user guides: Risk Adjustment, Enrollment and Payment, and Prescription Drug Event Data. These guides are structured in an interactive training format. They address the enrollment, payment, and data collection and submission provisions of Titles I and II of the MMA of 2003 as related to risk adjustment, drug risk adjuster, drug and low income subsidies, out-of-pocket costs, reinsurance and risk corridors. The guides are designed for employees of organizations responsible for the submission and maintenance of risk adjustment data, prescription drug event data and enrollment data. This designation also includes the staff of MA and MA-PD organizations' third party submitters, providers' training staff and demonstration programs. The expected objectives and outcomes are for the user to demonstrate a working knowledge of the fundamentals of payment provisions and methodologies for Parts C and D; enrollment, reenrollment and disenrollment; and the collection and submission of diagnostic health status data and prescription drug data events through applying information learned from real-life problem solving situations for Parts C and D. The IT guides may be found at www.csscoperations.com. CMS anticipates updating these materials annually sometime after April 2009.

IT User Groups

The Medicare Part C risk adjustment user groups are designed to provide a forum for identification, discussion and resolution of the operational and supporting components of the Part C payment provisions, data collection and submission and to provide feedback to CMS. The sessions are conducted monthly via teleconference, and extend from October, 2008 through September, 2009. The participants include MA organizations, PACE, other demonstrations and specialty programs, MA industry association representatives, CMS Contractors, and other CMS approved interested parties. Registration for the outreach sessions are located at http://www.TARSC

APPENDIX III – Part D Licensure Waivers-Reporting and Filing Deadlines

For PDP Sponsors With Licensure Waivers Expiring on December 31, 2009

Deadline	Action
2/27/2009	Deadline for submitting a waiver extension request from Part D sponsors with expiring state licensure waivers on 12/31/2009 that were unable to become licensed because of state requirements that are beyond the Part D sponsor's ability to meet. (Note that CMS issued notice of this deadline in early February 2009 to affected sponsors through an e-mail to their compliance officers).
4/1/2009	CMS will notify Part D sponsors that they are not qualified to offer Part D benefits during 2010 in the Part D sponsor regions where a licensure waiver will expire on 12/31/09. Part D sponsors will be afforded an opportunity to complete a CAP, either by obtaining licenses from all states for which a waiver will expire 12/31/2009 or reducing their service area.
4/1/2009	Part D sponsor will be requested to submit an exit plan* for each region which contains an unlicensed (waivered) state where the waiver will expire on 12/31/2009.
7/30/2009	Last day for Part D sponsors to obtain state licensure in states for which they have 2008 expiring waivers or to reduce their service areas, and not receive a notice of non-renewal from CMS.
7/31/2009	Non-renewals for contract year 2010 issued as appropriate
9/1/2009	Part D sponsor implements service area exit plans as appropriate.
12/31/09	Contract non-renewal or service area reduction becomes effective.

* Exit Plan – Must address the steps/schedule for ensuring the timely transfer of any data or files. Sponsor should indicate whether it wants to issue notices instead of CMS.

For Sponsors With Licensure Waivers Expiring on December 31, 2010

Deadline	Action
4/15/2009	Part D sponsor must submit confirmation from each state for which its licensure waiver will expire in 2010, that the state is in possession of a substantially complete application and expects to be able to approve or disapprove before 4/1/2010, or the state provides the earliest date on which it will accept an application if seasoning is an issue.
2/2010	Deadline for submitting a waiver extension request from Part D sponsors with expiring state licensure waivers on 12/31/2010 that were unable to become licensed because of state requirements that are beyond the Part D sponsor's ability to meet.
4/1/2010	CMS will notify Part D sponsors that they are not qualified to offer Part D benefits during 2011 in the Part D sponsor regions where a licensure waiver will expire on 12/31/10. Part D sponsors will be afforded an opportunity to complete a CAP, either by obtaining licenses from all states for which a waiver will expire 12/31/2010 or reducing their service area.
4/1/2010	Part D sponsor will be requested to submit an exit plan* for each region which contains an unlicensed (waivered) state where the waiver will expire on 12/31/2010
7/31/2010	Last day for Part D sponsors to obtain state licensure for states with 2010 expiring waivers or to reduce their service area, and not receive a notice of non-renewal.
8/1/2010	Non-renewals for contract year 2010 issued as appropriate
9/1/2010	Part D sponsor implements service area exit plans as appropriate.
12/31/10	Contract non-renewal or service area reduction becomes effective.

* Exit Plan – Must address the steps/schedule for preparing notifications to beneficiaries, the public and network providers, and for ensuring the timely transfer of any data or files.