

2008 Call Letter

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DATE: April 19, 2007

TO: Medicare Advantage Organizations
Medicare Advantage-Prescription Drug Organizations
Cost-Based Plans
Stand-Alone Prescription Drug Plans
Employer/Union-Sponsored Group Health Plans

FROM: Abby L. Block, Director, Center for Beneficiary Choices

RE: Introduction from CMS on 2008 Call Letter

Summary

I am pleased to provide you with the 2008 Call letter for Medicare Advantage (MA) organizations, Section 1876 cost-based contractors, prescription drug plan (PDP) sponsors, demonstrations, and employer and union-sponsored group plans, including employer/union-only group waiver plans (EGWPs). We have redesigned our call letter to direct your attention to CMS strategic goals for the Medicare Advantage (Part C) and prescription drug (Part D) programs, while also providing new information, and operational reminders to help you prepare for contract year 2008.

This Call Letter is dramatically different from previous versions in which we summarized many of the instructions issued over the past year. In contrast, the 2008 Call Letter discusses information we believe you will find especially useful as you prepare for the upcoming year. It references current CMS guidance and directs you to the documents or web sites where you can locate in-depth information on important topics. We hope this information helps you implement CMS policies and procedures and comply with critical program requirements. We also hope it will act as a catalyst in strengthening our partnership so that together we may design and provide a variety of high quality health care products to help people with Medicare meet their health care needs.

Because this Call Letter focuses on information designed to help you prepare for the 2008 contract year, it is essential that you review all program requirements, the Managed Care and Part D Manuals, Health Plan Management System (HPMS), and other CMS guidance for comprehensive information on both programs. As part of our efforts to help you meet all requirements, we are now updating the Managed Care and Part D Manuals quarterly and consolidating guidance so that these primary resources for the programs will contain detailed and current information.

I. Background

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) added outpatient prescription drugs to Medicare (offered by either stand-alone prescription drug plan sponsors or MA organizations) and significantly revised the Medicare + Choice (now Medicare Advantage) managed care program. The MMA changes make managed care more accessible,

efficient, and attractive to beneficiaries seeking options to meet their needs. The MA program has been reinvigorated, offering new kinds of plans and health care choices, such as regional preferred provider organization plans (RPPOs), private fee-for-service plans (PFFS), special needs plans (SNPs), and Medical Savings Account plans (MSAs).

The Medicare outpatient prescription drug benefit is a landmark addition to the Medicare program. More people have prescription drug coverage and are saving money on prescription drugs than ever before. Costs to the government for the program are lower than expected, as are premiums for prescription drug plans.

People with Medicare not only have more quality health care choices than in the past but also more information about those choices. We want to join you in continuing to add value to both programs and make them more accessible to the individuals they serve.

II. Our Goals for the Prescription Drug and Medicare Advantage Programs

We are excited by the successes of Part C and Part D, and this year's Call Letter focuses on making these programs even stronger and more attractive to people with Medicare. Some of our goals include improving the accessibility and usefulness of information about plan types and individual plans. We also are committed to ensuring that there are meaningful choices and value in health benefit packages. We discuss these and other goals in the sections that follow. As always, we will provide specific information on program changes, updated guidance, and other changes you will need to know as the new program year approaches.

A. High-Value Health Care

Based on our experiences with the new prescription drug benefit program and the revised MA program, we are thinking about ways to encourage organizations to offer RPPOs in areas that do not currently have them, to better integrate the MSA product with other choices available to people with Medicare, and to better focus SNPs on their unique potential for providing targeted care to the most vulnerable beneficiaries. In the case of RPPOs, for instance, we are pleased that in 2006 and 2007, the first two years this new plan type was available, most people could choose one of these plans. We want to encourage their growth even further so that all people with Medicare have the option of enrolling. In 2008, we also will strive for—

- an increase in the number of Part D plans offering at least some brand name as well as generic prescription drug coverage in the gap;
- a full range of MA and Part D plan options, and
- significant variations in benefits and meaningful choice among plan packages from organizations offering multiple products.

As our programs grow, we want to emphasize several areas that are crucial to providing high-quality health care. We discuss these below.

1. Ensuring Value. Benefit and premium stability from one year to the next and, in the case of Part D plans, formulary stability over the course of year, are an indication of dependability over

time. Significant premium increases or benefit reductions may signal that an organization is trying to discourage some people with Medicare from enrolling or staying in the plan. By tracking and analyzing significant year-to-year variations in plan premiums and benefit packages, we can alert organizations if we think there may be a problem. We also plan to provide information on various aspects of plan performance in report cards to help people with Medicare make informed decisions about the value of the choices available.

2. *Prevention and Quality Care.* Medicare continues to add preventive services to its list of covered benefits. In 1998, Medicare began covering colonoscopies for people at high risk for colorectal cancer. In 2001, Medicare expanded this coverage. In a December 20, 2006, article in the *Journal of the American Medical Association*, researchers identified Medicare's coverage of colorectal screenings as a primary reason that the ability to detect colon cancer at an earlier, more treatable stage has increased. In 2005, Medicare also began covering diabetes testing for those at risk for the disease and introduced a one-time "welcome to Medicare" physical exam. Recognizing the benefits of preventive services, many Part C organizations have expanded on the one-time physical exam and now offer an annual physical exam. Part C organizations have a unique opportunity to expand access to preventive services and we will expect that they continue to work to make additional preventive services available.

In recognition of the importance of preventive services, we strongly encouraged organizations that wanted to offer MSA demonstration plans in 2007 to cover such services before the deductible is met. This year, we also have expanded access under the original Medicare program to diabetes outpatient self-management training and medical nutrition therapy by covering these services at Federally Qualified Health Centers. In 2008, Part D coverage of vaccines will include coverage of the costs of administration, which should result in savings on and improved access to preventive vaccines for people with Medicare.

Preventive services save lives and money and we will continue to work with organizations to look for ways to expand access to these services.

3. *Organization Accountability.* We strive to provide organizations with the guidance and information they need to meet the requirements of our programs and, in most cases, organizations are meeting or exceeding our standards. Complying with the Part C and Part D program requirements is critical to meeting the needs of people with Medicare; consequently, we may take actions, including sanctions and civil money penalties, when organizations do not comply. Key aspects of accountability include:

- ***Meeting deadlines.*** If an organization thinks it will be unable to meet a deadline, it must notify us immediately. Often we can work with an organization to resolve issues and avoid delays. But we will take action against organizations that do not meet critical deadlines or exhibit a pattern of missed deadlines. In order to help you meet the requirements of the Part C and Part D programs, this Call Letter features a calendar of key dates and deadlines that organizations must meet.
- ***Meeting quality and performance standards.*** While we support a wide variety of coverage choices for people with Medicare, we want to ensure that those choices meet

quality and performance standards. Part C organizations are required to report HEDIS, HOS, and CAHPS data. We are increasingly using this information and other program information in connection with our oversight activities. To achieve our performance and quality goals, we intend to monitor minimum enrollment requirements and performance metrics, terminate contracts when licensure waivers expire, and streamline other processes. We will offer new contracts and renew existing contracts only of those organizations fully qualified to participate in the Part C and Part D programs and able to provide the high quality health care people with Medicare expect and deserve.

- ***Outreach and information about private-fee-for-service plans.*** In the coming year, we also will continue to strive to make certain that providers and people with Medicare have more useful information on Medicare PFFS plans. While Medicare PFFS plans are often making Medicare Advantage options available in markets not offering other MA products, providers and people with Medicare do not clearly understand this product. We have already taken several steps to ensure that providers and people with Medicare have more information more readily available, and we are working to refine our reporting requirements and marketing guidelines for PFFS plans. We expect that sponsoring organizations will describe the features of PFFS plans clearly and accurately and will make every effort to ensure that there is meaningful information available about how to obtain benefits, including prescription drug benefits when provided.

B. Confident, Informed Consumers

So people with Medicare can make confident, informed decisions about their health care and prescription drug needs, we have created tools to help them compare health plan and prescription drug plan benefits. With the launch in 2007 of our MSA demonstration, a consumer-driven, high-deductible managed care product; the recent addition of RPPOs; and the growth of Medicare prescription drug plans, PFFS and special needs plans, it becomes increasingly important that people with Medicare have the accurate and meaningful information necessary to help them make decisions about their expanding health care options.

We are improving ways of collecting performance data and are refining our performance measures for the development of comparative materials such as plan report cards, so that people with Medicare can better evaluate their health care options. As we expand our web-based and other resources, we expect organizations to provide comparative, in-depth plan information so people can choose the health care and prescription drug benefits that best meet their needs. Important CMS resources for consumer outreach include—

1. *The Health Plan Management System (HPMS)*. HPMS plays an important role in our efforts to provide people with Medicare with the information they need to make confident and informed decisions about their health care needs. Data submitted by organizations via HPMS is integral to the Medicare Prescription Drug Plan Finder and the Medicare Options Compare website tools, the plan-specific portion of *Medicare and You*, and standardized Summary of Benefits. We continually strive to enhance HPMS system and software functionality in support of our outreach efforts and to further streamline the bid and formulary submission processes. We

will provide organizations ample opportunity to preview plan data, and expect them to ensure that all plan data is accurate prior to its publication.

2. *Medicare & You.* We provide this handbook annually to all beneficiary households. It contains information about health plan and prescription drug plan options under the Medicare program and provides contact information so people with Medicare can contact plans to request information or make an enrollment decision. Because the plan data information in *Medicare & You* comes from HPMS and printing and distribution deadlines are fixed, organizations are responsible for ensuring that the information in HPMS is accurate and that changes and updates are made in accordance with CMS deadlines.

3. *Medicare Prescription Drug Plan Finder and Medicare Options Compare.* We have made many changes to these important resources on Medicare.gov. Several changes were based on comments from plans and from the public. We added more information, allowed people using the tools to save their changes, made use of the tools more intuitive, and simplified the web content. We evaluate these web tools frequently to make them even more informative and accessible.

C. Collaborative Partnerships

With the new plan type choices in the Medicare Advantage program and the numerous prescription drug plans offered in every state, it becomes even more important that people with Medicare have the information they need to make decisions about their health care options. Collaborative partnerships are essential to this process. Organizations must provide people with Medicare timely and relevant information. Similarly, they must work with CMS to offer people with Medicare significant choices among plan types and benefit packages. Key collaborative partnerships include—

1. *Partnerships between CMS, Plans, and Advocates such as State Health Insurance Programs.* We have been working to streamline the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) notification processes to achieve our goal that people with Medicare will receive timely and helpful information during the enrollment period. We have partnered with organizations to make these processes more efficient and will continue to work together to make sure that all marketing materials are accurate, informative, and timely.

As health care options and plan choices expand, our partnership with State Health Insurance Programs becomes increasingly important. We will continue to work closely with these programs to ensure that they have the tools they need to provide accurate, up-to-date information on the Part C and Part D programs and plans to individuals in their respective states.

2. *Partnerships with States to Coordinate Care of People Eligible for Medicare and Medicaid.* We are refining our guidance on SNPs to ensure they fulfill their promise to deliver specialized models of care, and to encourage partnerships with states in the case of SNPs serving people eligible for Medicare and Medicaid (dual-eligibles). Our goal is for organizations to fashion and deliver services in a manner best-suited to the specialized population in their SNP plans — whether, dual-eligible, institutional, or chronic care. In the case of SNPs serving dual eligibles,

we will continue to work closely with states to coordinate Medicare and Medicaid responsibilities, and we expect organizations to do the same as they develop models of care to seamlessly coordinate Medicare and Medicaid benefits.

3. *Partnerships with Physicians and other Providers.* Close partnerships with physicians and other providers of health care and prescription drug services are fundamental to our efforts to help communicate information about the Part C and Part D programs to people with Medicare. People with Medicare often rely on physicians, pharmacists and others to help them better understand their health care and prescription drug options and we will work closely with providers to ensure that beneficiaries have the information they need to make informed decisions and take an active role in their health care.

4. *Partnerships with Employers and Union Sponsors of Retiree Health and Drug Plans.* In our efforts to promote the retention of employer and union-sponsored group plan coverage, one of our main objectives is to partner with employers, unions, MAOs, PDP sponsors and others to provide more options for enhancing retiree health and prescription drug coverage through the employer/union-only group waiver plan (EGWP) program. Under the EGWP program, employers and unions may contract directly with us to offer coverage to group members or purchase a customized plan from a PDP sponsor or MA organization. Important elements of this partnership include—

- Using our waiver authority to provide employer and union sponsors, as well as the PDP sponsors and MAOs offering plans to employers and unions, with maximum flexibility and minimum administrative burden so that they can continue to offer high quality health care and prescription drug coverage;
- Ensuring beneficiary protections and plan compliance with all pertinent Part C and Part D program requirements.

III. Conclusion

As the 2008 program year approaches, we look forward to working with you to achieve our goals of ensuring high-value health care, confident and informed consumers, and truly collaborative partnerships. We are excited by the opportunities for the growth of the Part C and Part D programs in 2008 and beyond. We hope that you will find the information in the sections that follow useful as you prepare to offer a plan for the first time or continue to offer a plan under one of our programs.

How to Use this Document

As part of our redesign of the 2008 Call Letter we have combined into one document information on the Part C, cost-based, and Part D programs and significantly reduced the length of each section from last year by focusing on new or critical guidance we especially want to bring to your attention and by referencing our manuals and other instructions instead of replicating that information here. The goal of the redesign is for you to be able to quickly locate and move freely among topics most pertinent to your organization and the plan(s) it offers.

We have consolidated information for each program into distinct sections of the document, each with its own table of contents and internal organization. Section A provides MA, MA-PD, and cost plan guidance; Section B provides information for prescription drug plan sponsors; and Section C contains appendices for Sections A and B. The appendices contain important information such as calendars and crosswalks specific to the Part C and D programs. We are providing them as separate documents so that you may easily refer to and print them.

If you have questions concerning the MA, MA-PD, or cost sections of this Call Letter please contact Christopher McClintick at Christopher.McClintick@cms.hhs.gov. For questions on the prescription drug portions please contact Scott Nelson at Scott.Nelson2@cms.hhs.gov.

Section A—2008 MA, MA-PD, and Cost Plan Sections

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Note on 2008 MA, MA-PD, and Cost Plan portion of the Call Letter. With few exceptions, MA organizations 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 all 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 Part D 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 Chapter 6 of the Part D manual and the Part D portion of this Call Letter. In keeping with the redesign of the Call Letter and our efforts to make it more accessible and helpful to readers, our discussion in Section A is focused primarily on the MA and cost plan operational guidance we especially want to bring to your attention as you prepare for the 2008 contract year. 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 are to Title 42, Part 422 of the CFR.

MA, MA-PD, and Cost Plan 2008 Calendar

In order to help you during the renewal process and, more generally, as you prepare to offer health care benefits in 2008, we are including below a list 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 must consult the appropriate sections of our Part C, cost plan, and Part D regulations and guidance for important information associated with these timelines. Organizations should continue to monitor the general applications timeline posted on the CMS website at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY2008timeline.pdf>.

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

2008 MA, MA-PD and Cost-Based Plan Calendar		
(All dates, unless identified as statutory, are subject to change)		
2007		
April	April 2	Issuance of Calendar Year (CY) 2008 MA payment rates Announcements of MA aged/disabled county rates, ESRD State rates, and the statutory portion of regional plan (RPPO) benchmarks
	April 6	Plan Creation module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS
	Mid-April	CMS Bid Conference
	April 10	Call Letter Training for Industry. Additional dates to be determined
	April 16	Formulary Submissions Due from all MA-PDs, PDPs, direct contract EGWPs, and MA organizations or cost-PD sponsors offering EGWPs

2008 MA, MA-PD and Cost-Based Plan Calendar

(All dates, unless identified as statutory, are subject to change)

2007

May 1	<p>Deadline for CMS to inform currently contracted organizations that it has authorized renewal of a contract</p> <p>Non-Renewal: Deadline for MA, MA-PDs to notify CMS of an intention to non-renew a county or counties for individuals, but continue the county for employer group health plan members; deadline for MA, MA-PDs to submit partial county service area reduction requests</p>
May 18	CMS begins accepting CY 2008 bids via HPMS
Late May	CMS mails application approvals and denials
June 4	<p>Deadline for submission of bids for all MA, MA-PD, cost-, EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost plans wishing to appear in the 2008 Medicare Options Compare to submit PBPs</p> <p>Non-Renewal: Deadline for MA, MA-PDs to submit a non-renewal or service area reduction notice to CMS</p>
June 5	CMS begins accepting free first fill formulary files and limited coverage gap formulary files through HPMS
June 15	<p>Non-Renewal: CMS to issue acknowledgement letter to all for MA, MA-PDs that are non-renewing or reducing their service area</p> <p>2008 standardized combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), and model Low Income Subsidy (LIS) riders will be available for all organizations</p> <p>CMS begins accepting CY 2008 marketing material for review</p>
June 30	Final date for MA, MA-PD and cost-based organizations to submit CY 2007 marketing materials for CMS' review and approval. NOTE: This date does not apply to CY 2007 file and use materials since these may be filed with the regional office five calendar days prior to their use
July 15	Last date for an organization to receive a favorable decision on a contract determination and still offer a plan in 2008
July 16	Non-Renewal: CMS to post the model final beneficiary notification letter, the state-specific final beneficiary notification letter of non-renewal and a model public notice on the CMS website
August	Non-Renewal: CMS to release a Special Election Period (SEP) letter to MA, MA-PDs remaining in the non-renewed service areas

2008 MA, MA-PD and Cost-Based Plan Calendar

(All dates, unless identified as statutory, are subject to change)

2007

	August 1	<p>MA and MA-PD Organizations are expected to submit final CY2008 standardized combined EOC/ANOC and stand alone non-model ANOC to the regional office for review.</p> <p>MA-PD plans offering Part D are also expected to submit Low Income Subsidy (LIS) riders to the regional office for review</p> <p><i>Non-Renewal:</i> CMS to post the model final non-renewal notification letter, the state-specific final notification letter, and a model public notice on the CMS website</p>
	August 5	Cost-based plans are encouraged to submit SBs by this date so that materials can be reviewed and approved prior to the posting of “Medicare Options Compare” and included in the <i>Medicare & You</i> handbook
	Early August	Final regional plan (RPPO) benchmarks released.
	Late August	Submission of attestations and contracts.
	August 30	<i>Non-Renewal:</i> Final date for CMS to approve MA, MA-PD’s final beneficiary notification letter of non-renewal
	September 10-12	MA, MA-PD organizations and, if applicable, Medicare cost-based plans, preview the 2008 <i>Medicare & You</i> plan data in HPMS (not applicable to EGWPs)

2008 MA, MA-PD and Cost-Based Plan Calendar

(All dates, unless identified as statutory, are subject to change)

2007

October 1	<p>Cost plans and cost plans offering Part D must submit final 2008 standardized combined EOC/ANOC and non-model stand alone ANOC to the Regional Offices for review</p> <p>Cost plans are encouraged to submit all stand alone ANOCs to CMS in advance of this date to ensure the stand alone ANOC can be reviewed, approved, printed and received by members by December 1. NOTE: If the Medicare cost-based plan follows the stand alone model ANOC without modification, the final date to send the stand alone ANOCs to the CMS regional office is November 6</p> <p>Final day for MA and MA-PD organizations to send model stand alone ANOC to the regional offices for review</p> <p>Cost plans offering Part D are also expected to submit Low Income Subsidy (LIS) riders for review</p> <p>MA, MA-PD organizations and Medicare cost-based plans may begin marketing CY 2008 benefits to Medicare beneficiaries using CMS-approved and CMS File & Use accepted marketing materials</p> <p>MA organizations and Medicare cost-based plans are required to include information in CY 2007 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2008</p> <p>Last date for an applicant to provide CMS with evidence of contracting with state in order to operate a subsetted dual eligible SNP for 2008</p>
October 2	<p>Non-Renewal: MA, MA-PDs must publish a CMS-approved public notice on non-renewal in one or more newspapers of general circulation in each community or county in their contract areas</p> <p>Non-Renewal: Final beneficiary notification letter must be received by MA, MA-PD enrollees and must be a personalized letter</p> <p>Medicare cost-based contractors and cost-based sponsors to submit a non-renewal or service area reduction notice to CMS</p>
October 11	Tentative date for plan benefit data displayed on Medicare Options Compare and for plan drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs)
October 12	Non-Renewal: CMS to issue an acknowledgement letter to all Medicare cost-based plans that are non-renewing or reducing their service area
October 15-30	CMS mails the 2008 <i>Medicare & You</i> handbook

2008 MA, MA-PD and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)		
2007		
October 31	<p>All MA organizations must cease marketing CY 2007 plans through public media</p> <p>CY 2008 standardized combined EOC/ANOC or stand alone ANOC are due to all MA, MA-PD members. MA, and MA-PD organizations must mail the combined EOC/ANOCs or stand alone ANOC (with SBs) before this date to ensure receipt by members by October 31.</p> <p>All MA-PDs must mail their Low Income Subsidy (LIS) riders and abridged or comprehensive formularies before this date to ensure receipt by members by October 31.</p>	
November 2	Non-Renewal: Final beneficiary non-renewal notification letter--must be a personalized letter and received by cost-based plan enrollees by November 2, 2007	
November 15	2008 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, <i>see</i> Chapter 2 of the Medicare Managed Care Manual, Section 30.4.4).	
November-December	<p>Non-Renewal: CMS to issue “close out” information and instructions to MA, MA-PDs that are non-renewing or reducing service area</p> <p>Non-Renewal: CMS to issue “close out” information and instructions to cost-based plans that are non-renewing or reducing their service area</p>	
December 1	<p>CY 2008 combined EOC/ANOC or stand alone ANOC (with SBs) are due to all cost-based plan members. Medicare Cost-Based plans must mail combined EOC/ANOC or stand alone ANOC (with SBs) before this date to ensure receipt by members by December 1.</p> <p>Cost plans offering Part D must mail their Low Income Subsidy (LIS) riders and abridged or comprehensive formularies before this date to ensure receipt by members by December 1.</p>	
December 2	Non-Renewal: Cost-based plans must publish a CMS-approved public notice of non-renewal in one or more newspapers of general circulation in each community or county in their contract areas	
December 31	<p>2008 Annual Coordinated Election Period ends</p> <p>Deadline for plan corrections</p>	
2008		
January 1	Plan Benefit Period Begins	
January 31	<p>MA, MA-PD and cost-based organizations must mail CY 2008 stand alone EOCS to members with an effective date of January 1, 2008</p> <p>Organizations offering Part D must mail their low income subsidy (LIS) riders and abridged or comprehensive formularies with the EOCS</p>	

I. Benefit Design

A. General Guidance on Medicare Advantage Benefits for 2008

Crucial aspects of providing high-quality health care include making sure that people with Medicare will be able to select and retain a Medicare Advantage plan that has high quality benefits, does not discriminate against sicker beneficiaries, and represents value. In order to ensure that this is the case, we will closely review bids and benefit packages for the contract year to assure non-discrimination and value. Medicare Advantage organizations must consider all of these factors before applying to offer plans or if they continue to offer plans in 2008.

MAOs must balance benefit and cost stability with changes that share the burden across the widest range of beneficiaries possible, and we expect organizations to improve their offerings or, at a minimum, keep them stable from one year to the next, to provide all people with Medicare high value, predictable care.

1. Plan Benefit Package (PBP) for 2008

Medicare Advantage organizations have flexibility in developing and offering benefit packages that provide people with Medicare a range of high value health care choices that best suit their needs; organizations also have the responsibility to clearly indicate all benefits, the cost for these, and how services may be obtained, so that people with Medicare can be confident, informed consumers.

The PBP is the software tool that MAOs use to submit benefit packages to CMS during the annual bidding process; it is also the basis for key beneficiary tools such as the Medicare Options Compare website, the handbook, *Medicare and You*, and marketing materials that an organization uses to tell people with Medicare about its plans. It is critical, therefore, that MAOs complete the PBP fully, accurately, timely, and review submissions to prevent errors that result in plan suppressions, rejections of marketing materials, untimely beneficiary notices, and other costly problems.

We expect plan corrections to diminish substantially for the 2008 contract year, and are requiring the organization's overall assurance that benefit package information is clear and accurate, that it is thoroughly reviewed, and that the organization has in place a process to comply with all requirements and guidance concerning the PBP.

2. The Definition of Benefit

Section 10.10, "Health Benefit Definition and Requirements," of Chapter 4, "Benefits and Beneficiary Protections," of the Medicare Managed Care Manual, updates to CMS guidance on the definition of health benefit(s). For the full text visit, <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>

3. Cost Sharing Ranges

The MA program offers MAOs flexibility as long as they provide all Medicare-covered services—Parts A and B— and do not discriminate based on the enrollee’s health status.

Cost sharing for services should be clearly expressed within the Plan Benefit Package (PBP) software. When a plan offers a range of cost sharing (based on the location where services are received or provider type) but can not express the range within the standard variables in the PBP the highest cost share should always be entered. Plans should provide further clarification on the applicability of cost sharing amounts within the appropriate *Note(s)* field(s).

NOTE: For completing the plan benefit package (PBP) software in CY 2008, all dual eligible SNP plans have special data entry requirements. When the PBP asks for minimum/maximum variables, every dual eligible SNP (including both disproportionate and exclusive) must enter a “0” cost share amount as the minimum cost share, and enter the plan maximum amount as the maximum cost share. Additionally, when there is no minimum/maximum variable, SNPs should include only the highest cost share amount within the standard data variables. The summary of benefits (SB) will automatically generate a range from \$0—the maximum cost share amount when there is only one cost sharing variable. Exclusive \$0 cost share SNPs are also required to follow these requirements even though their SB sentences will generate \$0 cost shares. Please be sure to reference the Summary of Benefits Report in the PBP and the PBP-SB crosswalk located in both HPMS and the PBP when completing data entry. This will ensure the appropriate cost shares are entered in the PBP and the appropriate cost shares are showing on the SB based on what the beneficiary will actually pay.

B. Cost Sharing Guidance

Medicare Advantage organizations may not design benefit packages that discourage enrollment or encourage disenrollment of severely ill or chronically ill beneficiaries. Consequently, we will not approve a bid if the plan’s cost sharing or deductible structure discriminates based on health status. We will scrutinize the cost-sharing and deductible structures of all plans. For further guidance on cost-sharing please review section 20.13, “Guidance on Acceptable Cost-Sharing and Deductibles,” of Chapter 4, “Benefits and Beneficiary Protections,” of the Medicare Managed Care Manual which may be found at <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>.

Because we are concerned about beneficiary cost sharing that may be targeted based on the health status of the beneficiary, we will particularly scrutinize cost sharing for dialysis, mental health, chemotherapy drugs, home health, and inpatient hospital and skilled nursing facility stays to protect people with Medicare and ensure that they have access to high value health care choices. We will review each MA plan’s service-category cost sharing amount, and projected out-of-pocket expense liability to identify benefit packages that may have discriminatory benefit designs.

1. Out-of-Pocket Maximum

Every year, we establish an “out-of-pocket maximum (OOP)” amount for Medicare covered services that guides its review of plan cost-sharing. For calendar year 2008, CMS has determined that this figure is \$3250 for determining the flexibility plans have in establishing cost-sharing for individual services.

- If the plan’s OOP max is not greater than \$3250 it will be given greater flexibility in establishing cost-sharing amounts for individual services;
- If the plan does not have an OOP maximum (or it is narrowly applied to a subset of services) or it is greater than \$3250 it will be given less flexibility in establishing cost sharing amounts for individual services.

The maximum deductible for all MSA plans (both demonstration and non-demonstration) in 2008 is \$10,050. The minimum deductible for MSA demonstration plans is \$2,110. The minimum difference between the deposit amount and the deductible in an MSA demonstration plan is \$530. For MSA demonstration plans the separate limit on out-of-pocket enrollee costs cannot exceed \$10,050 in 2008.

See section XV for a description of out-of-pocket maximum and other maximum values that will apply to MSA plans in 2008.

2. Point of Service (POS) Deductible

MA POS plans may offer deductibles at the service category level or across all POS benefits (plan-level). Additional data entry options describing maximum plan coverage amounts and out-of-pocket caps for POS benefits will be available in the CY 2008 PBP. Detailed information on the PBP software may be found on CMS’ website at <http://www.cms.hhs.gov/BenePriceBid/Form/Plan/Package>.

3. RPPO Single Deductible Guidance

RPPOs must use a single combined deductible for all original Medicare services. We provide extensive clarification (with numerous examples) in Chapter 4 of the Medicare Managed Care Manual for the rules governing cost-sharing and the single deductible for RPPOs. For details, see section 30.2, “Cost Sharing Rules for MA Regional Plans,” and section 20.13, Guidance on Acceptable Cost-Sharing and Deductibles,” of Chapter 4, “Benefits and Beneficiary Protections,” at <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>.

C. Changes to Benefit Package during Rebate Allocation, Plan Corrections, and Mid-Year Benefit Enhancements (MYBEs)

1. Rebate Reallocation

Guidance on prioritization for adjusting benefits during rebate reallocation is found at II C of the Call Letter. Once the rebates have been reallocated, MAOs are required to re-submit via

HPMS the bid package, including the PBP. We will announce the exact dates of the rebate reallocation period when we publish the MA regional Part D plan amounts. For additional information, please see the 2008 BPT instructions available on our website at <http://www.cms.hhs.gov/BenePriceBid/Form/Plan/Package>.

2. Plan Corrections for 2008

Consistent with marketing and open enrollment coordination, we will not allow corrections to the PBP after December 31, 2007 for the 2008 benefit package. Note that once we approve a plan correction request, it cannot be rescinded without justification.

3. Mid-Year Benefit Enhancements (MYBE)

Our current MYBE policy will remain in effect for CY 2007. Guidance and instructions for 2007 MYBEs were posted on HPMS in a memo and attachments dated April 10, 2007. Additional guidance for 2008 will be forthcoming on HPMS. For 2007 MYBEs, we will generally follow the 2006 MYBE instructions. For the full text visit, section 20.10 of Chapter 4 of Managed Care manual at <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>

D. Value-Added Items and Services (VAIS)

Section 20.4 – “Value-Added Items and Services (VAIS)” of Chapter 4, “Benefits and Beneficiary Protections,” of the Medicare Managed Care Manual clarifies our definition of VAIS to emphasize that costs for VAIS must be administrative only. We clarify further that administrative costs can be used for clerical functions, communication, or distribution of database information. For the full text and other clarifications of VAIS see <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>.

E: Benefit Clarifications

1. Transportation

Section 20.23, “Transportation Benefits” of Chapter 4, “Benefits and Beneficiary Protections,” of the Medicare Managed Care Manual presents several situations involving transportation related to health benefits. This guidance clarifies when transportation may be classified as a health benefit. For the full text visit <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>.

2. Home Infusion Drugs

MA-PD plans may choose to provide Part D home infusion drugs as part of a bundled service as a supplemental benefit under Part C, provided the MA-PD plan consistently applies the option (i.e., in a given contract year, either always covers a particular home infusion drug as part of a bundled service as a supplemental benefit under Part C, or always covers a particular home infusion drug under Part D). For further guidance and requirements

associated with MA-PD plans and home infusion drugs see number 7 of section III of the Part D portion of this Call Letter.

3. Urgently Needed Services

Section 130.2, “Emergency and Urgently Needed Services”, of Chapter 4, “Benefits and Beneficiary Protections,” of the Medicare Managed Care Manual provides the definition of “urgently needed services.” Illustrative examples are carefully selected to show the applicability of urgently needed services. For the full text see the “Definitions” section of the chapter, at <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>.

The CY 2008 PBP software has been changed to support the statutory definition of urgently needed services. Services received at contracted urgent care facilities do not meet this definition. Users will now enter contracted ‘urgent care’ facility cost shares at B-7a (primary care) of the PBP. Cost sharing for statutorily defined urgently needed services should be entered at B-4b of the PBP. Detailed information on the PBP software may be found on our website at <http://www.cms.hhs.gov/BenePriceBid/Form/Plan/Package>.

4. Unbundling of Inpatient Physician Services

Cost sharing amounts entered into the PBP for Medicare-covered Part A services should include any pertinent cost sharing amounts for professional services (physicians). We will not allow MAOs to unbundle cost sharing for Part A services, therefore all cost sharing should be expressed within the standard data variables of the PBP.

5. Health Education and Wellness (Nutrition, Legal, and Financial)

Medicare generally does not cover health, education, and wellness programs. However, Medicare does cover medical nutritional services when it is based on an underlying medical need, or reason, consistent with the normal pattern of delivery of care for an illness, including diabetes education for people with diabetes, renal dialysis, and kidney disease. Similarly, Medicare does not cover legal or financial programs, therefore these programs should not appear in benefit packages, nor be bundled with approvable “benefits” under Medicare Advantage plans. For further details see section 20.24, “Meals,” of Chapter 4, “Benefits and Beneficiary Protections,” of the Managed Care Manual at <http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf>

6. U.S. Visitor/Travel Benefits under Private Fee for Service

People with Medicare enrolled in MA private-fee-for-service plans (PFFS) may obtain care anywhere in the U.S., and as a result U.S. visitor/travel benefits are not available for PFFS plan types. Residency requirements still apply regardless of where the individual is able to obtain services.

7. PPO Guidance

Where applicable, plans should identify the maximum plan benefit coverage amount for individual services (non-Medicare supplemental benefits). For all PPO plan-types, the coverage amount(s) must be the same in and out-of-network as PPO plan-types must provide the same benefits in and out-of-network (OON). Cost sharing for OON services may be higher than for in-network services and those amounts should be clearly identified within the PBP. CMS will review all PPO PBPs to ensure that all benefits are uniformly covered in and OON. PPO plan types that do not have OON cost sharing must enter a “0” within the appropriate service category data fields, a failure to enter an amount (leaving the field blank) will result in CMS establishing OON cost sharing equivalent to that offered in-network.

PPO plans may offer reduced cost sharing for members that voluntarily pre-authorize OON services. Within the cost share reduction section of the PBP (Section C) PPO plan-types should identify the *reduced* cost sharing amount that will be charged when enrollees voluntarily pre-authorize. These amounts must be less than cost sharing amounts identified in the OON benefits section.

8. Cash Reimbursement

Except for cost sharing, MAOs generally should not offer/cover benefits in a manner that requires a beneficiary to pay a provider, and then get reimbursement from the MAO. An exception to this rule allows MAOs to provide cash reimbursement to members who receive covered health services while out of the United States. If an organization finds it necessary in an unusual circumstance to provide benefits through non-contracted providers, the MAO should still reimburse the provider directly. (In plans that routinely cover out-of-network benefits (i.e., PPOs); MAOs should still reimburse non-contracted providers directly.) Note that the prior authorization and review rules at § 422.111(b)(7) of the MA program regulations require that--

“The MAO must instruct enrollees that, in cases where non-contracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MAO for processing and determination of enrollee liability, if any.”

In cases when an enrollee has paid a non-contracted provider out-of-pocket, the plan must reimburse the member, less cost sharing.

9. Medical Savings Account (MSA)

For 2008, CMS added to the PBP software the ability for an MSA demonstration plan to enter cost sharing for preventive services covered before the deductible, and for cost sharing after the deductible but before the out-of-pocket maximum is reached. Detailed information on the PBP software may be found on CMS’ website at <http://www.cms.hhs.gov/BenePriceBid/Form/Plan/Package>.

10. Notes Review

MAOs cannot use PBP notes to limit or diminish Medicare covered benefits. Notes fields should be used only when the PBP software requires information to be entered in them or when needed to further clarify a benefit when the standard data entry cannot be populated. We will review all notes fields in the PBP submissions to ensure that MAOs do not limit or otherwise exclude aspects of the covered benefits captured in the regular data entry section. Before approving a bid CMS will require MAOs to remove or modify any notes that improperly limit the scope of a Medicare-covered benefit. We will require a comprehensive benefit package providing all the required Part A and B Medicare benefits. MA plans should ensure all benefits included in the PBP meet the definition of a benefit.

11. Catalogs

An MAO may not provide catalogs containing merchandise to an MA plan enrollee as an inducement for enrollment. Items and services included in a catalog must meet the definition of a benefit, and should be provided to people with Medicare only to meet a health care need (prevent, diminish, or cure a present or future illness/injury). Supplying items and services without an underlying health care need is not appropriate and is not a benefit.

12. Segmented Plans

An MA Plan's benefit package must be the same across plan segments. However, the Part C premium and cost sharing may differ across segments. Segmentation does not apply to the Part D benefit. The Part D prescription drug benefit must be uniform across a plan's service area.

13. Plan-types (HMO and HMOPOS)

Every MAO should ensure that they download the appropriate PBP plan-type template that matches the intended benefit offering(s). HMO plans generally do not cover services OON. HMO plans opting to cover services OON may not charge enrollees higher cost sharing amounts than would be charged if the services were received in-network. HMO Point of Service (POS) plan types may elect to offer coverage of services out-of-network as mandatory or optional supplemental benefits with higher cost sharing amounts for services received OON. As such, HMOPOS plans should enter in their PBP any POS benefits they offer and the related cost sharing in the appropriate PBP screens.

14. Plan Benefit Package (PBP) Software and Summary of Benefits (SB) Changes for 2008

CMS has implemented the following enhancements to the PBP/SB software in support of the CY 2008 bid season:

- In the PBP Section A – the Online Provider Directory Web Address fields have been added to the information downloaded from HPMS. The network indication will also be downloaded from HPMS for PFFS, ESRD I, MSA, and MSA demonstration organizations.

- In the PBP Section B 1a/1b and B-2 – A question has been added under coinsurance and copayment allowing plans to indicate if it charges the Medicare-defined cost shares.
- In the PBP Section B 14j – This is a new category for CY 2008 that covers the Medicare Part B benefit for medical nutrition therapy services for people who have diabetes or renal disease.
- In the PBP Section B-15 – Cost sharing fields have been added for Medicare Part B covered chemotherapy drugs.
- In the PBP Section C – Local and regional PPOs must describe the cost sharing for all out-of-network (OON) benefits. The in-network cost sharing applies if no OON cost sharing is described.
- In the PBP Section D – the plan may separately select the Medicare-covered and non-Medicare covered benefits that apply for each plan-level deductible.
- In the PBP Section D – PFFS, standard MSA and demonstration MSA plans will have to answer questions on balanced billing.
- In the PBP Section D – The optional supplemental package screens have been redesigned, including the label and premium screens, service category screen and OON screens. A plan will now add or delete an optional supplement package on the option supplemental Management Screen.
- In the PBP Rx Section (Part D Prescription Drugs), data entry questions were added to collect information about over-the-counter medications (OTCs) covered under utilization management programs and restricting access to drugs to certain specialty pharmacies.
- In the PBP Rx Section (Part D prescription drugs), data entry questions were added to collect information about limited benefits offered by plans above the initial coverage limit (ICL).
- In the SB – A new SB category has been added ESRD (SB-28). All the SB sections following ESRD have been renumbered accordingly. The point-of-service (POS) sentences that were previously displayed under different categories will be combined into one POS category.
- In the SB – Special sentences will be generated for all populations of exclusive and disproportionate dual eligible special needs plans (SNPs).

This list is not intended to represent the entire set of modifications made to the CY2008 PBP/SB software. CMS implemented these software changes in response to CMS policy and operational clarifications and the numerous comments and suggestions made by industry during the CY 2007 lessons learned comment period. Detailed information on PBP software changes will be issued on HPMS and posted to the CMS website.

F. Actuarial Certification Process

During the first two years of the Part C bidding process, CMS and MAOs faced several challenges in developing an effective and efficient actuarial certification system. During the first year (2006), MAOs were required to submit actuarial certifications with each bid submission and re-submission, a burdensome process, much of which was not relevant to the final approved bids. During the second year (2007), MAOs were required to submit two certifications, one at the beginning of the bid review process and another accompanying the final bid upload in August. Each of these approaches raised several concerns, including the fact that actuaries did not have access to HPMS and therefore did not know exactly the content of the uploaded bids, could not verify that the benefits proposed matched the bid submitted, and that the certifications were free-form documents which required significant CMS resources to review.

We will revise the actuarial certification process for 2008 to address these concerns. We will grant certifying actuaries limited HPMS access, including the ability to review the submitted plan bid package. MA organizations will be required to designate for CMS their certifying actuaries during the bid creation period and will be permitted to designate multiple actuaries within each contract. Also, we will create an actuarial certification module within HPMS which will streamline the certification language into a standardized template that would still permit actuaries to input free-form text. The module will also feature links to the details of the submitted bid packages. Finally, MAOs will be required to make only two bid certification submissions. The first will be due shortly after the initial submission has been received and the data processed through HPMS (mid-June). The second will be made after the rebate reallocation process has occurred in mid-August, which will correspond to the final bid package and proposed benefits pending approval.

We believe that this process will cause some limited level of additional effort from both MAOs and actuaries. However, this effort will be offset by the advantage of a higher quality bid package and the likely significant reduction in the number of plan corrections. Actuaries will be more confident that their certifications are tied to the benefit package they relied upon in their analysis and that the BPT they intended to be submitted was uploaded to HPMS.

II. Bidding

Information submitted in connection with an organization's bid for the year is crucial to the marketing and outreach provisions of the MA program and our goal of helping people with Medicare make confident and informed decisions about their health care. As a result, information must be accurate and submitted timely. As we discuss in the Outreach and Marketing and Systems sections of this Call Letter, information in the plan benefit package is used in outreach publications such as *Medicare & You*, and the comparative tools Medicare Options Compare, and the Medicare Prescription Drug Plan Finder which are also primary sources of information to people with Medicare.

We are also concerned that the bidding process, in accordance with the MMA and our program requirements, remains a competitive one and that all organizations are able to

compete on a level playing field. In 2006, we limited the circumstances under which organizations can apply for mid-year benefit enhancements (MYBEs), as MYBEs can, if they are not limited, amount to a non-competitive revision of the bid. While we are continuing with our current MYBE policy for 2007, we are considering our options for 2008 and will inform organizations of any proposed changes. See Section I of this Call Letter for more info on MYBEs.

A. Bid-Pricing Tool (BPT) and Plan Benefit Package (PBP) Release

We will release via HPMS the 2008 BPT and PBP software to MAOs and interested parties on April 6, 2007. We will provide organizations and interested parties an opportunity to participate in informational seminars on the revised tools. See Section IV of this Call Letter for more information about the release of the BPT and PBP software.

B. New Date for Cost Plan PBP Submissions

We are notifying all cost-based plans wishing to appear in the 2008 Medicare Options Compare (MOC) that CY 2008 Bid (PBP) submissions are due on June 4, 2007. We have moved this date forward from previous years to be consistent with the submission deadline for all MA, MA-PD, and PDP plans. Cost-based plans will not be allowed to submit initial bids during rebate reallocation, nor any time after the June 4 deadline. Cost-based plans will be able to revise or correct premium amounts until October 2 (when budget and enrollment forecasts are due) by requesting resubmissions or via a plan correction request in HPMS.

C. Rebate Reallocation

If an MAO needs to generate additional rebate dollars during the rebate reallocation period to return to its target Part D basic premium, CMS recommends prioritizing adjustments to supplemental benefits as follows—

- (1) reduce or remove non-Medicare covered benefits,
- (2) increase cost sharing for widely-used services such as PCP visits, and
- (3) as a last resort, increase cost sharing for more limited-use services such as inpatient, SNF, and home health care.

As a last resort, an MAO can shift mandatory supplemental benefits to optional supplemental benefits to “free-up” rebate dollars. Please see the rebate reallocation guidance in the 2008 BPT instructions available on our website at <http://www.cms.hhs.gov/BenePriceBidFormPlanPackage/>.

We will not allow MAOs to substantially redesign Part C supplemental benefits during the rebate reallocation period and expect only marginal adjustments. We won't accept any changes in Part D benefits or pricing.

D. HPMS Crosswalk

Continuing MAOs must complete the HPMS plan crosswalk when uploading their CY 2008 bids. For more information on the crosswalk see Section IV of this Call Letter.

III. Outreach and Marketing

Because 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. The benefit information included in marketing and outreach materials must be based on information submitted in the bidding process and captured in HPMS through tools such as the Plan Benefit Package tool. It is essential that all information is accurate, and presented clearly and timely in the required format so that people with Medicare can make informed decisions about which plan types and plan benefit packages best meet their needs. In addition, MAOs 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 guidelines on the CMS website; the marketing chapters of the Managed Care and Part D Manuals; 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). Below, we highlight some of the aspects of outreach and marketing organizations should be aware of as they plan for the 2008 program year.

A. Marketing of CY 2008 Plans by Agents and Brokers

With the significant expansion of MA enrollment we remind organizations that they are responsible for the actions of sales agents/brokers whether they are employee or contracted. Organizations must ensure agents/brokers are properly trained in both Medicare requirements and the details of the products being offered. Medicare Advantage organizations must provide strong oversight and training for all marketing activities. This is especially critical for the marketing of private fee-for-service (PFFS) plans which are unfamiliar to many beneficiaries and providers. For example, organizations should be sure that brokers/agents explain to prospective enrollees that while they can see any provider who agrees to accept the plans terms and conditions, providers may decline to accept the PFFS terms and conditions. Employees of an organization or independent agents or brokers acting on behalf of an organization may not solicit Medicare beneficiaries door-to-door for health-related or non-health-related services or benefits. Employees, brokers and independent agents must first ask for a beneficiary's permission before providing assistance in the beneficiary's residence, prior to conducting any sales presentations or accepting an enrollment form in person. Additionally, beneficiaries must not be coerced into accepting an in-home appointment or enrolling into a plan in which they have indicated no interest.

B. Plan Submission and CMS Review of Marketing Materials

Medicare Advantage organizations may begin submitting CY 2008 marketing materials (e.g., Summary of Benefits (SB) and Annual Notice of Change (ANOC)) on June 15, 2007, in accordance with the marketing guidelines via the HPMS marketing module. The regional

offices will review the materials and approve or disapprove. Organizations that do not have a final CMS contract approval will receive a “conditional approval” on marketing materials. If the materials are conditionally approved, CMS is indicating to the organization that materials are approval based on the current plan bid submission which has not yet been approved. The organization may not use conditionally approved marketing materials in the market. If materials are disapproved, the organization must revise the materials and continue to work with the regional office until it receives a conditional approval on the materials.

After we approve the MAO’s bid, any necessary changes to the conditionally approved or approved marketing materials must be resubmitted to us based on the CMS approved bid/PBP. The organization must clearly highlight only changes that result from the approved bid/PBP. This step will ensure a timely review of the final materials.

In order for an MAO to be able to market its plans, it is essential that it follow the review process found in the Marketing Guidelines on the CMS website. If an organization fails to submit materials timely or to clearly highlight changes in the submitted materials, then it is at risk of not being able to market by October 1, 2007.

Note: If there are no changes to the bid or marketing materials from when the materials received the conditional approval, the MAO need not resubmit the marketing materials. Instead, all marketing materials with a status of “conditional approval” will be changed to an “approved status” upon approval of the bid and CMS contract.

C. Expedited Review Process Reminder

Medicare Advantage organizations are encouraged to submit qualified marketing materials under the expedited review process. The expedited review process permits organizations to submit template materials without cost sharing information for review and approval by the regional office. This process requires organizations to populate the appropriate cost sharing and benefit information once the bid is approved. These populated materials do not require resubmission to the Regional Office (RO) for additional approval prior to use, however organizations must submit each variation of the template to the RO through HPMS within 30 days of populating materials. Any changes or corrections that occur after the bid has been approved must be corrected in all marketing materials. The following materials qualify for an expedited review: Summary of Benefits (SB), Annual Notice of Change (ANOC), and Evidence of Coverage (EOC), provider or pharmacy directories.

D. Annual Beneficiary Notification Materials

For CY 2008 we encourage the redesign and streamlining of the annual renewal materials to provide better, timely information for beneficiaries; reduce the demand on staff resources (CMS and health plans); and create a more efficient process. Below are the steps we are taking to redesign the renewal materials and other actions we are taking to streamline the process and ensure that people with Medicare receive timely information so that they can make confident, informed decisions about their health care options.

- Integrate the ANOC and EOC into one document which beneficiaries can receive from MAOs by October 31.
- Standardize the formatting and certain sections in the ANOC/EOC. Medicare Advantage organizations and Part D sponsors will have the flexibility to enter plan-specific text in certain sections of the document, while other text will be standardized.
- Create one model ANOC/EOC with optional modules based on type of plan (e.g., cost, PDP, PFFS, etc.).
- Utilize the streamlined marketing review process so that organizations submit the ANOC/EOC template.
- Release the annual renewal material in late spring.
- Streamline the text/content of the ANOC/EOC to reduce duplication and unnecessary information. This will be a multi-year effort to reduce redundancy, improve the clarity of material, and organize materials to help people with Medicare understand their benefits, rights, and obligations.

The redesign process for annual renewal materials is optional. Organizations will have the following two options for the distribution of the ANOC and EOC:

Combined ANOC/EOC

Organizations that choose to utilize the combined standardized process will be required to mail annual notification materials (combined ANOC/EOC) by October 31, 2007. MA-PD organizations must send an abridged or comprehensive formulary in addition to the combined ANOC/EOC. In this option, the SB is only needed for pre-enrollment marketing. Organizations utilizing the combined (standardized) ANOC/EOC should utilize the streamlined marketing review process.

Stand Alone ANOC and EOC

Organizations that choose not to use the combined standardized ANOC/EOC option must mail ANOCs along with their SBs to existing members by October 31, 2007. ANOCs may be submitted as model or non-model. Additionally, MA-PD organizations must send an abridged or comprehensive formulary with the ANOC and SB. Under this option, EOCs and low income subsidy riders (LIS) must be mailed by January 31, 2008.

Organizations mailing the EOC separately will have the option of using the model EOC or creating a non-model EOC document. Non-model EOCs will be subject to a 45-day review period.

Organizations must mail CY 2008 EOCs to new members no later than when they notify the member of acceptance (confirmation) of enrollment.

We will be releasing additional guidance regarding these changes later in 2007.

E. Plan Comparisons

We received a significant negative response to the proposal in the draft Call Letter to allow plan comparison of Medicare Advantage and prescription drug plans in a specific service area. Based on these comments, we are persuaded that it is not practical or meaningful to develop a comparison that does not include formulary drug costs and availability specific to an individual beneficiary. .

F. Medicare Options Compare Data and Medicare Prescription Drug Plan Finder

1. General

On or about October 11, 2007, the CY 2008 health plan and health plan drug data will appear on the Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF) on Medicare.gov. The online tools are important components of our initiative to provide people with Medicare information to help make them confident and informed about their health care choices. The MOC will continue to include out-of-pocket cost data, charts displaying several HEDIS and CAHPS measures, and disenrollment reasons data for the MA plans. Please note that employer/union-only group waiver plans (EGWPs) will not be included in the MOC. Plans must preview their health plan data for MOC and drug plan data in HPMS this fall. We will issue instructions and specific dates for the previews at a later date. It is critical that plans review their information so that submitted data is not suppressed.

Online enrollment will continue to be available to MA organizations through the MOC and to MA-PD and PDP plans through MPDF. This year, the enrollment function will be available for 2007 plans through December 2007, and for 2008 plans beginning November 15, 2007. Online enrollments must be downloaded daily.

2. Quality Checks for the Medicare Prescription Drug Plan Finder

Quality checks for data submitted to CMS for display on the MPDPF will continue to be required for contract year 2008. Guidance has already been released via HPMS that outlines the expected quality checks that MA-PD and PDP Sponsors should routinely perform on their data both prior to submitting it to us and after it has been posted on the MPDPF. Modifications and additions to the quality assurance (QA) check list may be added for implementation in 2008. Failure to conduct these QA checks may result in suppression of the MA-PD and PDP Sponsor's pricing data from the website.

G. 2008 Medicare & You

The 2008 *Medicare & You* handbook will contain health plan benefit and Medicare prescription drug plan comparison information. This information may be similar to the health plan information provided in the 2007 *Medicare & You* handbook released last fall. One CAHPS measure will be included in the 2008 *Medicare & You* handbook. Plans will be able to preview their handbook plan data September 10 through 12.

IV. Systems, Data, and HPMS Crosswalk

An MAO's and cost plan's integration and coordination with CMS systems and compliance with system protocols is essential to providing accurate and timely data and other information and is at the core of successful outreach and marketing, bidding, and benefit design processes. As a result, we are featuring this section prominently to emphasize its importance to the outreach and marketing, and bidding sections. HPMS is the central repository of data submitted by organizations and data from this system allows us to track bid and formulary submissions and updates in addition to providing information for beneficiaries through the ANOCs; the handbook, *Medicare & You*; and comparative tools such as Medicare Options Compare and Medicare Prescription Drug Plan Finder. We are also considering capturing quality and performance measures now entered elsewhere through HPMS. We will issue more information on this subject sometime in 2008. Because this information is crucial to our programs it is imperative that organizations provide data timely and use the periods we allow for preview of data to ensure that all data submitted is up-to-date and meets all of our requirements. We are continually updating and looking for ways to improve our systems, and we expect MAOs and cost plans to do the same. This includes streamlining the bidding process while making it easier to generate and capture accurate and meaningful information in outreach documents based on bid and plan benefit package data so that people with Medicare will have the information they need to make confident and informed decisions about their health care options.

We discuss HPMS in this section; for more information on *Medicare & You* and comparative tools based on HPMS data see Section III, Outreach and Marketing. See also Section V, Quality and Performance Measures, of this call letter for information on quality and performance data.

A. HPMS

1. Using HPMS to Submit Bids and Formularies

MA organizations use HPMS to electronically upload plan formularies and bids to CMS. Cost-based plans are also required to use HPMS to electronically upload plan formularies and bids if they are offering the Medicare Part D benefit to their members. As with past years, cost-based plans may also voluntarily submit plan benefit packages (PBP) if they wish to have their plan benefits displayed in the *Medicare & You* handbook and on Medicare Options Compare (MOC).

MA organizations and cost-based plans offering the Part D benefit upload their plan formularies to HPMS using a pre-defined file format and record layout. HPMS will begin accepting plan formulary uploads on March 26, 2007. MAOs and cost-based plans offering the Part D benefit may upload their formularies one or more times between March 26, 2007 and the formulary deadline of 5:00 p.m. EDT on April 16, 2007. We will accept the last successful upload of each formulary received by this deadline as the official submission.

In order to prepare plan bids, MAOs and cost plans will use HPMS to define their plan structures and associated plan service areas and then download the PBP and bid pricing tool (BPT) software. For each plan being offered, organizations will use the PBP software to

describe the detailed structure of their benefit packages and the BPT software to define their bid pricing information. Each formulary submitted by April 16, 2007 must accurately crosswalk to a plan (or set of plans) defined during the bid process. The combination of the PBP and BPT for a plan comprises a bid.

Once the PBP and BPT software has been completed for each plan being offered, organizations will upload their bids to HPMS. We anticipate releasing the PBP and BPT bid upload functionality on May 18, 2007.

Medicare Advantage organizations and cost plans may upload their plan bids one or more times between May 18, 2007, and the CY 2008 bid deadline of 11:59 p.m. PDT on June 4, 2007. CMS will accept the last successful bid upload received for a plan by this deadline as the official bid submission for that plan.

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

2. *HPMS Crosswalk*

It is extremely important that MAOs and cost plans review the crosswalk (*Attachment B, Section C, Appendices*) for guidance when determining their plan structures for CY 2008. The crosswalk must be submitted by continuing organizations as they upload their bids. Because the crosswalk designates the relationships between plans offered in 2007 to those being submitted for 2008, indicating enrollment, notification, and other requirements associated with offering a plan, we believe this document will also help you prepare for 2008 and other MA and cost-based program requirements. We will provide technical instructions for completing the HPMS plan crosswalk for each type of relationship to MAOs and cost plans in the *Bid Submission User's Manual for Contract Year 2008* at <http://www.cms.hhs.gov/BenePriceBid/Form/Plan/Package>.

3. *Instructions for Obtaining HPMS Access*

MA organizations and cost-based plans have two alternatives for accessing HPMS:

- Internet access via a Secure Socket Layer Virtual Private Network (SSL VPN); or
- Medicare Data Communications Network (MDCN) access using either a T-1 lease line or dial-up account with AT&T.

Internet users via the SSL VPN will access HPMS at <https://gateway.cms.hhs.gov>, whereas MDCN users will use <http://32.90.191.19>. Both methods require the use of a Microsoft Internet Explorer web browser and a CMS-issued user ID and password with access to HPMS.

If your organization requires assistance with establishing connectivity to HPMS or with obtaining a CMS issued user ID and password for HPMS, please contact the HPMS access team at HPMS_Access@cms.hhs.gov.

B. Required Use of the National Provider Identifier (NPI) on Electronic Transactions

The HIPAA Regulation, 45 CFR Part 162, subpart D, requires all health plans and providers to use the NPI as the only provider identifier on standard electronic transactions by May 23, 2007. Note that small health plans, as defined in 45 CFR Part 160.103 as plans with annual receipts of \$5 million or less, have an additional year to be compliant. If, however, a complaint is filed against an entity for not meeting the deadline, we will evaluate the entity's good faith efforts to comply with the standards and would not impose penalties on covered entities that use contingency measures to ensure payment continues. Contingency plans may not continue beyond May 23, 2008. Further information concerning this issue is available on the CMS web site at <http://www.cms.hhs.gov>. The site also contains contingency plan guidance for the industry in a document titled "Guidance on Compliance with the HIPAA National Provider Identifier Rule."

V. Quality and Performance Measures

A. Value-Driven Health Care

The President issued an Executive Order that is intended to ensure that health care programs administered or sponsored by the federal government build on collaborative efforts to promote four cornerstones for health care improvement:

Interoperable Health Information Technology: Interoperable health information technology has the potential to create greater efficiency in health care delivery. Significant progress has been made to develop standards that enable health information systems to communicate and exchange data quickly and securely to protect patient privacy. Additional standards must be developed and all health care systems and products should meet these standards as they are acquired or upgraded.

Measure and Publish Quality Information: To make confident decisions about their health care providers and treatment options, consumers need quality of care information. Similarly, this information is important to providers who are interested in improving the quality of care they deliver. Quality measurement should be based on measures that are developed through consensus-based processes involving all stakeholders, such as the processes used by the AQA (multi-stakeholder group focused on physician quality measurement) and the Hospital Quality Alliance.

Measure and Publish Price Information: To make confident decisions about their health care providers and treatment options, consumers also need price information. Efforts are underway to develop uniform approaches to measuring and reporting price information for the benefit of consumers. In addition, strategies are being developed to measure the overall cost of services for common episodes of care and the treatment of common chronic diseases.

Promote Quality and Efficiency of Care: All parties - providers, patients, insurance plans, and payers - should participate in arrangements that reward both those who offer and those who purchase high-quality, competitively-priced health care. Such arrangements may include implementation of pay-for-performance methods of reimbursement for providers or the offering of consumer-directed health plan products, such as account-based plans for enrollees in employer-sponsored health benefit plans.

Medicare Advantage organizations are on the forefront of measuring and publishing quality information and promoting quality and efficiency of care. CMS commends these plans for the work they are doing in these areas. We strongly encourage MAOs to move toward the remaining cornerstones of Interoperable Health Information Technology and Measure and Publish Price Information.

B. Performance Metrics and Part C Report Cards

As part of our effort to provide people with Medicare high-quality health care we are committed to making available information that will help them make confident and informed choices about their health care options. Information we will provide will enable beneficiaries and their caregivers to compare the various Part C options available to them and include managed care quality, cost, and other performance information.

More specifically, we intend to make additional quality of care and performance information about its managed care contractors available to the public in Medicare Options Compare starting November 2007 in order to facilitate consumer decision making for contract year 2008 open enrollment. The information to be used in the consumer display will include HEDIS® and CAHPS® measures currently used in other CMS information products as well as other CMS performance metrics. We are also developing means to measure the capacity of an organization to address appeals as the program regulations require.

We are also working to design performance metrics for special needs plans (SNPs), a recent addition to managed care that serves people with Medicare who are institutionalized, eligible for both Medicare and Medicaid, or have chronic or severely disabling diseases. A combination of HEDIS-SNP measures will allow us to assess, monitor, and evaluate the health outcomes (clinical, functional, and patient experiences) of enrollees in SNPs and ensure that these plans offer high value health care for the specific populations they serve. For more information on SNP quality measures see Section XIII of this Call Letter.

C. MA, PPO and Cost-Based Contractor Quality Measurements: “Health of Seniors” (HOS) Requirements

Cost-based contractors with open enrollment and all MAOs, including local preferred provider organizations (PPOs) and regional PPOs, that had a Medicare contract in effect on or before January 1 of the previous year must comply with the Health of Seniors (HOS) requirement for current year HEDIS reporting. Also, there is a correction to previous guidance on minimum enrollment requirements: contract enrollment must be 500 or more

members at the time of sampling, regardless of how many members have 6 months of continuous enrollment.

For more information on quality measurements and quality provisions, in general, see Chapter 5 of the Medicare Managed Care Manual located on the CMS website at <http://www.cms.hhs.gov/manuals/downloads/mc86c05.pdf>.

VI. Compliance and Monitoring

In order to participate in the managed care program, all organizations applying for a contract or wishing to renew a contract must conclusively demonstrate that they meet all requirements of the Part C program or the Medicare cost program, as applicable, and, if offering a Medicare prescription drug benefit, the pertinent Part D program requirements. Although most organizations meet or exceed our expectations, we will impose sanctions and civil money penalties (CMPs) when a violation especially threatens the ability of a plan to provide services to beneficiaries or there is a pattern of continued violations or non-compliance with the guidance and regulations of the managed care program.

As we discuss below, we are considering revisions to our current procedures concerning contract determinations, intermediate sanctions, and CMPs. Organization accountability is a crucial component of our goal to provide high-value health care and we are focusing on ways to streamline and make more efficient these processes while giving us more flexibility to ensure that organizations are following all program requirements. As we perform our oversight activities, a particular focus will be on ensuring accurate information about Medicare health care plans by brokers and other representatives of plans. We will look especially at Medicare PFFS plans, to make sure that information about these plans accurately represents the access, network, and payment features of this plan type—features about which providers and people with Medicare often are unsure.

A. General

All MAOs must have written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State statutory, regulatory, and program requirements.

B. Compliance Procedures

Based on past experiences, we are considering revising our current procedures concerning contract determinations, intermediate sanctions, and CMPs. We anticipate that revisions will be final in late 2007. We will outline implementation dates for specific provisions at that time.

C. Long Term Risk Assessment Strategy

Due to unprecedented levels of contractor participation in CMS' Medicare Advantage and Part D programs, CMS is working to strengthen its Medicare oversight program. To that

end, we are currently developing a risk assessment tool to assist us in identifying Medicare contractors who are at high risk of program non-compliance. We will focus on conducting audits on those high risk contracts. We envision that this revised oversight program will include a mostly centralized data-driven program, fueled by data provided by contractors and beneficiaries. While receipt and analysis of data is central to this oversight strategy, regularly scheduled and focused/targeted program compliance and program integrity audits will be necessary to ensure program compliance and document the Agency's program oversight responsibilities. We anticipate the risk assessment tool to be ready for implementation and use in January 2008.

D. Audit Timeframes

Beginning CY 2008, we will be able to reopen an audit within 10 days of the exit conference. Reopening an audit will be based on information obtained during the audit but not actually audited prior to the exit conference. This will result in a more comprehensive audit to ensure continued compliance with program requirements.

Additionally, for the remainder of CY 2007 and in CY 2008, while we hope to provide plans up to 12 weeks prior notice for comprehensive audits, we are not always able to do so, and reserve the right to audit with less notice. If CMS is concerned about significant compliance issues an audit may occur with only two weeks notice, if appropriate.

E. PACE Audit Strategy

We are currently developing a new audit strategy and accompanying audit tools for the PACE program. The revised tool will streamline the audit process by limiting the audit areas based on risk instead of reviewing every record and every element. We anticipate that the strategy and tools will be ready for implementation in 2008. The final version of the guide will provide sponsors with the elements we will use while conducting regularly scheduled and focused audits.

F. Part C Reporting Requirements

In order to provide additional information concerning Part C program administration, we are developing a set of reporting requirements for Part C contractors. Part C contractors will be required to collect and self-report information beginning in 2008, most likely using a web-based data entry system. We are requesting this self-reported information under regulatory authority of 42 CFR 422.516 (a). Areas of interest to us include: staff turnover, provider network stability, grievances, sales and marketing violations, organizational determinations and denials of coverage, security breaches, enrollment and disenrollment, and financial viability.

G. Private-Fee-For-Service Oversight

Because of our concern that people with Medicare are often confused by the features of these plans and that MAOs and their sales agents may not always represent these plans accurately,

we are considering issuing updated oversight guidance in the future. We discuss this in more detail in Section XIV.

VII. Security Requirements

A. Securing Electronic Protected Health Data through Encryption and other Means

With the heightened state of awareness nationwide concerning privacy breaches and security violations, and in an effort to ensure security of Medicare and Medicaid data, we are taking actions toward minimizing plans' security risk. Plans are covered entities bound by the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II). The HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information (EPHI) addresses some of the ways a covered entity may protect EPHI when it is accessed or used outside of the organization's physical purview. The guidance states covered entities should be extremely cautious about allowing the offsite use of, or access to EPHI. There may be situations that warrant such offsite use or access, e.g., when it is clearly determined necessary through the entity's business case(s), and then only where great rigor has been taken to ensure that policies, procedures, and workforce training have been effectively deployed, and access is provided consistent with the applicable requirements of the HIPAA Privacy Rule.

There have been a number of security incidents related to the use of laptops, other portable and/or mobile devices and external hardware that store, contain or are used to access EPHI under the responsibility of a HIPAA covered entity. All covered entities are required to be in compliance with the HIPAA Security Rule, which includes, among its requirements, reviewing and modifying, where necessary, security policies and procedures on a regular basis. This is particularly relevant for organizations that allow remote access to EPHI through portable devices or on external systems or hardware not owned or managed by the covered entity. The kinds of devices and tools about which there is growing concern because of their vulnerability, include the following examples: laptops; home-based personal computers; PDAs and Smart Phones; hotel, library, or other public workstations and Wireless Access Points (WAPs); USB Flash Drives and Memory Cards; floppy disks; CDs; DVDs; backup media; Email; Smart cards; Remote Access Devices (including security hardware).

Due to the overwhelming need to manage data protection and endpoint security solutions, we now require plans to encrypt all hard drives or other storage media within the device as well as all removable media. In addition, plans must develop and implement a policy addressing the handling of portable media that is accessed or used outside of the organization's physical purview. The Centers for Medicare and Medicaid Services HIPAA Security Guidance dated December 28, 2006 is an important resource for possible risks and risk management strategies accessing, storing, and transmitting EPHI and recommended for plan use. The document is available at <http://www.cms.hhs.gov/SecurityStandard/Downloads/SecurityGuidanceforRemoteUseFinal122806.pdf>.

B. Privacy and Security Requirements and MAO Activities Performed Outside the United States

In addition to following all other HIPAA requirements, MAOs must ensure that all privacy and security requirements for the program are followed by contractors performing work for an MAO outside of the United States. Beginning in 2008, neither the MAO nor its subcontractors may perform any activities under the Part C contract at a location outside of the United States without the prior written approval of CMS. When making a decision to authorize the performance of work outside the United States, we will consider the following factors, including but not limited to—

- The MAO or subcontractor's compliance with, and enforceability of, Part C program system security requirements;
- The MAO or subcontractor's compliance with, and enforceability of, Part C program information and data confidentiality and privacy requirements;
- The Applicant's/subcontractor's compliance with, and the enforceability of, other relevant Part C program requirements;
- The MAO or subcontractor's compliance with, and enforceability of, Part C program corporate compliance plan requirements;
- The MAO or subcontractor's compliance with, and enforceability of all laws and regulations applicable to work outside of the United States; and
- The performance of the work outside of the United States is in the best interests of the United States.

VIII. Calendar of Key Timelines: 2008 MA, MA-PD and Cost-Based Plan Key Dates

In order to assist you in meeting all deadlines, including for renewal, enrollment, bidding, and other provisions we discuss in this Call Letter, we are including at the front of this section 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 our 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 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/>.

See also our discussion of the HPMS crosswalk in Section IV for enrollment, notification, and other requirements associated with offering a plan.

IX. Renewal and Non-Renewal Processes, Contracting Issues, and Change of Ownership

A. Renewals

1. Contracts are Automatically Renewed

This section serves as notice with regard to clarifying CMS intent for MA and cost-based contract renewals. Under §1857(c) of the Social Security Act, “[e]ach contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be automatically renewable from term to term without notice by either party of intention at the end of the term.” It has always been our intent that these contracts be “evergreen” and automatically renewed without a notice of intent to non-renew by the contractor or termination by CMS. Additional contract provisions or changes for subsequent years will be incorporated via an addendum to the original contract, as necessary. Beginning in 2008, for the contract year 2009, cost-based contracts can only be renewed as specified below.

2. CMS Renewal Notice to MA Organizations

Although it is our intention to ultimately not issue such notices, as contracts are automatically renewed, we will continue to issue to MA organizations contract renewal notices on or before May 1, 2007, to those entities we have determined, based on information available at that time, to continue to be qualified to hold a contract during 2008. We expect to issue further guidance on non-renewal notices later in 2007. Organizations are not required to apply for a contract renewal as we will make the determination based on an evaluation of each organization’s compliance with its contract. The renewal notices will indicate that the organization is qualified to operate a plan, but that we cannot renew the contract for 2008 unless the sponsor receives approval of the bids it submits on or before June 4, 2007. We will review each organization’s compliance with all Part C program requirements to determine whether or not to renew a contract. We will consider non-renewing the contracts of organizations that substantially fail to comply with the Part C program requirements.

3. Cost-Based Contract Renewals and Service Area Reductions or Expansions

As of September 1, 2006, cost-based plans may only extend their service area to include areas in which there are fewer than two MA local or two MA regional coordinated care plans that meet specified enrollment thresholds. Beginning January 1, 2009, cost-based plans may only continue in any portion of their service area where there are fewer than two MA local or two MA regional coordinated care plans that have met specified enrollment thresholds for the entire previous year. For purposes of plan renewal, the MA plans must meet minimum enrollment requirements for the entire previous year in order to trigger mandatory cost plan non-renewal or service area reduction. For purposes of service area expansion, the MA plans must only meet minimum enrollment requirements as of the date of the proposed expansion – CMS-4069-F, January 28, 2005 (FR 70 4593).

We will provide section 1876 cost-based plans data on MA plans in the service area. Data from 2007 will be used to determine if cost plans will receive non-renewal notices in 2008 based on the MA plan “competition” provisions; 2009 will be the first year a cost plan may be non-renewed or its service area reduced. See “42 CFR §417.402 and 70 FR pp. 4592 – 4594 (January 28, 2005) for additional information.

Cost-based plans can offer a mid-year service area expansion consistent with 42 CFR §417.402 and as noted above. Cost-based plans that offer Part D as Cost-PD plans are also subject to the same restriction on mid-year service area expansions as are MA-PD plans. Cost-PD plans cannot expand into an area served by an MA-PD or PDP plan.

B. Non-Renewals

We require managed care organizations and cost-based plans to provide written notice to us on the non-renewal or service area reduction of its CMS contract. Managed care organizations must comply with the beneficiary and public notice requirements as stated in §422.506 of title 42 of the Code of Federal Regulations and should consult our non-renewal guidance at <http://www.cms.hhs.gov/nonrenewal/>. Cost-based organizations must comply with beneficiary and public notice requirements as stated in §417.492 of Title 42 of the Code of Federal Regulations and should consult our non-renewal guidance at <http://www.cms.hhs.gov/nonrenewal/>.

Please see *Attachment A of Section C, Appendices, Calendar of Key Timelines*, for non-renewal dates. Organizations should continue to monitor the general applications timeline posted on the CMS website at <http://www.cms.hhs.gov/MedicareAdvantageApps/>.

C. Contracting Issues

1. Overlapping Cost and Risk Plans

Medicare regulations prohibit MA organizations from enrolling beneficiaries in cost-based plans in the same service area as their MA plans. Any cost-based contractor that operates or seeks to operate an MA plan in the same service area, may continue to serve current enrollees under that cost-based contract but must close that plan to new enrollments. See 42 CFR 422.503(b)(5) and Chapter 17d, Section 30.1 of the Medicare Managed Care Manual for more information.

2. End of Local Preferred Provider Organization Moratorium

The two year moratorium on offering local PPO plans ends in 2007, allowing MAOs to offer local PPOs in new services areas starting in CY 2008 (see §422.451 of Title 42 of the Code of Federal Regulations).

D. Change of Ownership (Novation Agreements)

In any type of change of ownership transaction, the legal entity wishing to contract with CMS should contact the Medicare Advantage Group's Division of Qualification and Plan Management listed in (C) as early in the process as possible to determine if it must submit a modified application to be deemed an eligible MAO prior to the transaction/novation. See section 10.1 of Chapter 12 of the Managed Care Manual for more information on specific requirements associated with a change of ownership.

If the change of ownership transaction involves an MA-PD plan, the organization must also separately notify CMS' Medicare Drug Benefit Group in addition to the central office plan manager. See section 20.1 of Chapter 12 of the Managed Care Manual for more information on notification requirements prior to an anticipated change of ownership.

We are clarifying that with a change of ownership the previous owner/transferor is responsible for guaranteeing *for the remainder of the contract year and, if the bid and PBP have already been submitted by the original owner, for the upcoming year* that the new owner will carry out the terms of the contract. (Alternatively, the new owner must guarantee its performance of all contract responsibilities.) For further information on specific provision of an acceptable novation agreement, see Section 30.2 of Chapter 12 of the Managed Care Manual on the CMS website at <http://www.cms.hhs.gov/manuals/downloads/mc86c12.pdf>.

Please note the new address below when sending required notifications associated with the novation. For a description of the required notifications see sections 20.1, 20.3, and 30.1 of Chapter 12 of the Managed Care Manual available on the CMS website cited in the preceding paragraph.

Division of Qualifications and Plan Management
Medicare Advantage Group
Center for Beneficiary Choices
Centers for Medicare & Medicaid Services
Mail Stop C4-22-04
7500 Security Boulevard
Baltimore, MD 21244-1850

X. Enrollment

All MA organizations must follow the eligibility, enrollment and disenrollment requirements issued by CMS for accepting and processing beneficiary requests. We expect to issue the next update to the MA enrollment/disenrollment guidance, which will be for enrollment transactions effective January 1, 2008, in late spring 2007. We also want to draw your attention to several enrollment-related issues of particular importance to beneficiaries. See the following CMS website for our current MA enrollment/disenrollment guidance and future updates:

http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/Chapter_2_+exhibits_Sept_8_2006_update_.pdf.

A. New Medicare Advantage Enrollment Period for MA-Only Plans

In 2007 through 2008 there will be a limited open enrollment period for MA-only plans for all beneficiaries enrolled in Original Medicare during any period when individuals would not otherwise have an enrollment opportunity to elect an MA plan. It does not apply for enrollment into Medicare MSA, MA-PD, or stand alone Part D plans. See the February 7, 2007 HPMS memo "New MA Enrollment Period for MA-Only Plans" available on the HPMS website for in-depth guidance.

B. Submission of Enrollment and Disenrollment Transactions

It is critical that organizations submit transactions to CMS in a timely and efficient manner to ensure appropriate beneficiary enrollment. To this end, organizations must submit enrollment and disenrollment transactions to us within 7 calendar days of receipt of a complete request, beginning with those transactions effective in 2008.

C. Coordination with Employer and Union-Sponsored Groups

MA organizations must ensure that employer or union groups with whom they contract understand and abide by the Medicare rules and requirements, unless those requirements have been specifically waived or modified by CMS employer group waiver policies. Organizations should review current agreements with these entities to ensure that they reflect our enrollment and disenrollment guidance, particularly the group enrollment and disenrollment process for employer or union sponsored plans, if applicable.

D. Enrollment of Full Benefit Dual Eligibles and Others Eligible for Low-Income Subsidy (Delegation of Auto and Facilitated Enrollment Process)

MA organizations and cost-based contractors are responsible for identifying full benefit dual eligible (FBDE) individuals identified as receiving the retiree drug subsidy (RDS) and who are enrolled in plans that do not offer a drug benefit and enrolling these members into an MA-PD plan or, if offered, a cost plan with a Part D optional supplemental benefit.

Starting January 1, 2008, we will no longer require MA and cost plans to move FBDE individuals identified as having the retiree drug subsidy from MA-only or cost-only plans into an MA-PD or the cost plan's Part D optional supplemental benefit. Further, plans will be required to instruct individuals that they will need to enroll in an MA-PD or the cost plan's Part D optional supplemental benefit on their own. As part of this process, MA organizations and cost-based contractors must contact their FBDE individuals with RDS and confirm they want to be enrolled into an MA-PD plan or cost plan's Part D benefit prior to submitting the transaction to CMS. We will update the MA and cost plan enrollment guidance to reflect this process.

The current enrollment guidance for MA plans is found at—

http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/Chapter_2_exhibits_Sept_8_2006_update.pdf.

The current enrollment and disenrollment guidance for cost plans is found at—

<http://www.cms.hhs.gov/manuals/downloads/mc86c17d.pdf>.

E. Transition from HMO Point-of-Service to Preferred Provider Organization Plan

Due to the preferred provider organization (PPO) moratorium, some organizations offer HMO-point-of-service (POS) plans that were designed with a POS benefit that covered all

Part A and B services out-of-network (OON). Under our current continuation rules, if an MA organization wants to transition HMO-POS plans to a PPO they must disenroll all members. However, to facilitate plan consolidation for contract year 2008, we will allow MAOs to continue enrollees in a 2007 MA HMO-POS (which covers all Part A and B services OON) in a 2008 PPO plan through the annual notice of change process.

XI. Payment

A. Advance and Final Payment Notices

We released to the public the Advance Notice of Methodological Changes for Calendar Year 2008 for Medicare Advantage Capitation Rates (Advance Notice) on February 16, 2007. After considering and responding to comments, we will publicly release the final Announcement of Calendar Year 2008 Medicare Advantage Capitation Rates and Medicare Advantage Policies (Announcement) on April 2, 2007. At public release these notices will be available at:
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/AD/list.asp#TopOfPage>.

B. Medicare Secondary Payer Issues

1. Responsibilities of MA Organizations and Cost-Based Contractors – Medicare Secondary Payer Procedures

MA Organizations and Cost-Based Contractors have specific responsibilities related to coordination of benefits or Medicare Secondary Payer (MSP) procedures – see 42 CFR §422.108 and §417.528. In addition, by identifying MSP situations and enforcing MSP rules, program dollars are conserved and competitive advantages are gained.

Organizations and Contractors have basic responsibilities related to MSP, including:

- Identifying individuals to whom the MSP requirements apply;
- Identifying and accounting for proper primary payments where, by law, Medicare is the secondary payer;
- Ensuring that your organization does not discriminate against employees and employees' spouses age 65 or over, people who suffer from permanent kidney failure, or disabled Medicare beneficiaries for whom Medicare is secondary payer; and
- Ensuring that your organization does not allow employers to enroll individuals in a Medicare plan offered by your organization in a manner contrary to MSP rules.

Federal law requires employers to offer their employees age 65 or over the same coverage offered to employees under age 65. If the employer offers health care coverage to spouses, the same coverage must be offered regardless of age. This equal-benefit rule applies to coverage offered to both full-time and part-time employees.

Medicare beneficiaries are free to reject employer plan coverage, in which case Medicare is their primary coverage. However, when Medicare is the primary payer, employers are

prohibited from offering employees or their spouses a supplemental plan that pays for services covered by Medicare. This includes a prohibition on the enrollment of such an employee or spouse in an employer-sponsored MA or Cost-Based plan.

In other words, an employer cannot sponsor or contribute to an individual's enrollment in an MA or Cost-Based plan unless that employer also maintains primary health insurance for that individual through the GHP. Note that even if the employer does not contribute to the monthly premium, but merely collects it and forwards it to the appropriate individual's insurance company (a so-called "employee pay-all" arrangement), the GHP policy is still considered primary payer to Medicare and MSP rules apply.

See section 80 of Chapter 4, of the Medicare Managed Care Manual:

<http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf> for a full discussion of MSP.

2. Submission of Medicare Secondary Payer (MSP) Data for Computation of the MSP Reduction Factor

Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD), Social Health Maintenance Organizations (SHMOs) and PACE plans must submit MSP data.

Plans will continue to survey their aged and disabled members as contained on the March 2007 monthly membership report (MMR). By September 17, 2007 plans must submit data for members that report that Medicare is secondary and also for members that fail to respond to the survey. Mail data to:

CMS
c/o Angela Wright
C1-05-07
7500 Security Blvd.
Baltimore, MD 21244

This year plans will submit only one file containing both populations. There will be a flag added to the required format to identify whether the member is MSP or a Nonrespondent. All data items are required. If erroneous or missing data is submitted, CMS will consider your entire membership to be Nonrespondent and will check status for all members in the Medicare Beneficiary Database (MBD).

FILE FORMAT

1. Member's Health Insurance Claim Number (HICN).
2. Member's Full Last Name
3. Member's Full First Name
4. Member's Date of Birth – **MUST BE IN CCYYMMDD FORMAT**
5. MSP Status Flag – **MUST CONTAIN W IF MSP OR N IF NONRESPONDENT**

There can only be 1 record per member (per HICN).

As in the past, the file is to be an EXCEL Worksheet; multiple worksheets can be used if necessary to accommodate large volume. If preferred, it can be sent as a comma delimited (.csv) file. The file is to be sent on a CD-ROM.

The file **CANNOT** be ZIPped (compressed) or sent as an .EXE (extractible) file. In addition, the file **MUST BE** password protected. The file must be sent via Fed-X and the password must be e-mailed to Angela Wright – Angela.Wright@cms.hhs.gov.

Again, failure to comply with these requirements will result in CMS considering your entire membership as Nonrespondent and their MSP status will be checked on the MBD.

MSA plans (including MSA demonstration plans) are also required to survey their aged and disabled members as contained on the March 2007 monthly membership report (MMR). For MSA plan members that identify themselves as having coverage that would make Medicare the secondary payer, MA organizations are required to investigate and determine if the last bullet of §20.10 of Chapter 2 of the MMCM applies. If it does apply, then retroactive disenrollment procedures should be initiated under §60.5 of Chapter 2 of the MMCM, as appropriate. Finally, MSA plans are to report MSP and Nonrespondent members per the above instructions.

MSA plans that are secondary to Medicare will be paid in accordance with the general MSP rules applicable to all MA plans. For both demonstration and non-demonstration MSA plans, CMS will apply the .215 WA/MSP factor to gross MSA plan payment at the H# level. The gross MSA plan payment includes both the risk-adjusted plan capitation payment and the beneficiary deposit. This is consistent with our method of applying the WA/MSP factor to all other MA plans. To the extent that an MAO offering MSA plans enrolls a significant proportion of individuals with primary health insurance coverage (WA/MSP individuals), plan payment (both plan capitation and beneficiary deposit) will be proportionally reduced.

C. RPPO Plan Stabilization Fund Delay

The Tax Relief and Health Care Act of 2006 postponed the availability of Stabilization Fund payments until January 1, 2012.

D. Risk Adjustment

It is essential for all providers to review *Attachment C—Risk Adjustment Implementation—of Section C, Appendices*. In *Attachment C*, we furnish new requirements for risk adjustment data submission and data validation. We also provide information on Part A risk adjustment factor options and risk adjustment training. For additional information on risk adjustment, see 42 CFR §422.310.

XII. Grievances, Initial Determinations, and Appeals

A. Medicare Managed Care Manual Guidance for Medicare Health Plans

MA plans and cost plans (Medicare health plans) are responsible for developing grievance, organization determination, and appeals procedures in accordance with the guidance contained in [Chapter 13 of the Managed Care Manual](#).

B. Notification Procedures for Hospital Discharges – Final Rule

We published a final rule on November 27, 2006 setting forth requirements for how hospitals must notify beneficiaries who are hospital inpatients about their hospital discharge rights. Notice is required for original Medicare beneficiaries and for beneficiaries enrolled in MA plans and other Medicare health plans subject to MA regulations. Similar to the process of governing SNFs, CORFs, and HHAs, whenever an enrollee appeals a discharge decision, plans will be responsible for providing the enrollee with a notice that details the reasons for the discharge. See: 71 Fed. Reg. 68,708 (to be codified at 42 CFR Parts 405, 412, 422, 489).

XIII. Special Needs Plans

The Medicare Modernization Act (MMA), Section 231, allows MA organizations to target enrollment to individuals with special needs. “Special needs individuals” were defined by Congress as an MA eligible individual who: (1) is institutionalized; (2) entitled to Medicaid (dual eligible); or (3) has a severe or disabling chronic condition as recognized by the Secretary. Like Medicare Regional PPO plans and Medicare MSA plans, special needs plans (SNPs) contribute to there being a variety of health plan types and high-value health care for people with Medicare. Because of the population that SNPs serve—people who are more frail than the general population and need specialized care—this plan-type offers a unique opportunity to tailor care based on the special needs of people with chronic care needs, who are institutionalized, or are eligible for both Medicare and Medicaid. CMS is being asked to evaluate the value of the SNP program since the MMA includes a sunset provision for January 1, 2009. It is incumbent on these Medicare Advantage contractors to design and articulate models of care specific to the needs of this population and to demonstrate how these plans are special relative to other MA options or to Original Medicare.

We also want to assure uniform benefits for all beneficiaries enrolled in the plan who meet the special eligibility requirement. In the case of dual eligibles, we are working closely with states, toward better integration and Medicare and Medicaid services administration. This collaboration has great promise to deliver higher-quality health care to this population. We strongly encourage SNPs to work closely with the States in which they operate to coordinate Medicare and Medicaid services to offer as integrated a product as possible. In order to realize these possibilities, we expect organizations to develop models of care designed to provide specialized services targeted to the SNP special populations. In general, as our guidance below suggests, we greatly value the flexibility SNPs offer to bring specialized care to people with Medicare and will work diligently in 2008 and beyond to further develop and refine the capabilities of this unique plan type to serve people with Medicare that have special needs.

A. Model of Care

The term “specialized MA plans” in the statute clearly contemplates that the SNP product provides for “specialized” benefits that are targeted to meet the needs of the SNP population. The following clarifies CMS’ expectations concerning the existence of an appropriate model of care for all special needs plans (SNP), including institutional, dual eligible and chronic SNPs. These policy elements for the SNP program are articulated in the SNP solicitation which is contained in the coordinated care plan application for 2008. The application can be accessed at the following website:

http://www.cms.hhs.gov/MedicareAdvantageApps/02_Final%202008%20Applications.asp#TopOfPage

However, it is critical that existing SNPs also comply with this new guidance. To that end, MAOs offering SNPs should be prepared to demonstrate how they meet these requirements. The audit guide is being updated to accommodate these items.

1. Description of Model of Care

The model of care needs to focus on the unique needs of the targeted population as defined by the SNP (e.g., full benefit dual eligibles, beneficiaries living in the community but requiring an institutional level of care, beneficiaries with congestive heart failure, etc.). In addition, for each targeted population, the SNP is expected to address its approach to frail/disabled beneficiaries, beneficiaries with multiple chronic illnesses, and beneficiaries who are at the end of life, as these subsets are likely to be more prevalent among the special needs populations. As the MA-SNP program is intended to provide specialized services and these beneficiaries are among the most complex to treat, all SNP programs are expected to include goals and objectives as well as specialized care for these categories of beneficiaries within the overall model of care for individuals who are dually eligible, institutionalized, or have a severe or disabling chronic condition.

The model of care is, in essence, the system of care which reflects (1) pertinent clinical expertise and the staff structures; (2) the types of benefits; and; (3) processes of care (organized under protocols) that will be used to meet the goals and objectives of the SNP. The model of care should be specific enough to imply what process and outcome measures could be used by the SNP to determine if the structures and processes of care are having an intended effect on the target population.

Examples of pertinent clinical expertise and staff structures include clinicians with a certificate to treat individuals with mental illness for a SNP that is targeting beneficiaries with mental illness, or availability and use of nurse practitioners and case managers. Another example is an explanation of how a nursing home staff interacts with the SNP staff to implement assessment and care management under the SNP.

Examples of types of benefits and processes of care include protocols that drive frequency and character of assessment, case and care management, disease management and poly-

pharmacy management. Protocols are specific enough to define the beneficiary circumstances or conditions for which a set of actions should be taken.

B. Dual Eligible SNPs

1. Categories of Dual Eligible SNPs

Dual Eligible SNPs are divided into the following four categories:

1. All dual eligibles (those with comprehensive Medicaid benefits as well as those with more limited cost sharing such as QMBs, SLMBs, and QIs);
2. Full dual eligibles (those with comprehensive Medicaid benefits);
3. Zero Cost Sharing (QMB-only or QMB with comprehensive Medicaid benefits); and
4. Other dual eligible subsets based on coordination with a state Medicaid program.

All dual eligibles. This SNP enrolls beneficiaries who are MA eligible and entitled to medical assistance under a State/Territorial plan under Title XIX. An all dual SNP must enroll all categories of dual eligible individuals.

Full dual eligibles. This SNP limits enrollment to all dual eligible beneficiaries with comprehensive Medicaid benefits. This group would include any QMB, SLMB, or QI who also is entitled to comprehensive Medicaid benefits. A full benefit dual eligible individual is a Medicare beneficiary who is determined eligible by the State for medical assistance for full benefits under Title XIX of the Social Security Act for the month under any eligibility category covered under the State plan, or comprehensive benefits under a demonstration under section 1115 of the Act, or medical assistance under 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individuals was eligible for medical assistance in any part of the month.

Zero cost sharing dual (QMB-only and QMBs with comprehensive Medicaid benefits): This SNP limits to QMBs only and QMBs with comprehensive Medicaid benefits, the two categories of dual eligible beneficiaries who are not financially responsible for payment of Medicare cost sharing.

Other dual eligible subsets based on coordination with State Medicaid programs. Effective with contract year 2008, MAOs that offer Dual Eligible SNPs may exclude specific groups of dual eligibles based on the MAO's coordination efforts with State Medicaid agencies. Requests for dual eligible subsets are reviewed and approved by CMS on a case-by-case basis. For contract year 2008 and beyond, the request must be included as part of response to the 2008 solicitation for a special needs plan proposal. Any MAO seeking to offer a SNP based on a Medicaid subset is required to submit documentation that the MAO has contracted with the State to serve this Medicaid population.

To the extent a State Medicaid agency excludes specific groups of dual eligibles from their Medicaid contracts or agreements, those same groups may also be excluded from enrollment

in the SNP. For example, if an MAO offering a Dual Eligible SNP has a Medicaid managed care contract with a State Medicaid agency for all dual eligibles except for those who are medically needy with a spend down, the MAO may also exclude those dual eligibles from enrollment in the SNP.

Those dual eligible groups which are included in the SNP request are those in which the MAO offering a SNP coordinates its Medicare related efforts in an integrated way with the State's Medicaid coverage and administration. For example, a targeted group could be aged dual eligibles for which the SNP and State provide coordinated care.

A complete breakdown of dual eligible categories is located at the following website:

http://www.cms.hhs.gov/DualEligible/02_DualEligibleCategories.asp#TopOfPage

C. Institutional SNPs

1. Ensuring Delivery of Institutional SNP Model of Care

An institutionalized individual is defined by regulation at 42 CFR 422.2 as an individual who continuously resides or is expected to continuously reside for 90 days or longer in a long term care (LTC) facility which is a skilled nursing facility (SNF), nursing facility (NF), intermediate care facility for the mentally retarded (ICF/MR); or inpatient psychiatric facility.

The preamble to the final rules on the implementation of the Medicare Advantage program specified that CMS would also consider an institutional SNP to serve individuals living in the community but requiring an institutional level of care. (Many beneficiaries who would qualify for institutional status in the community reside in some type of assisted living facility (ALF) or continuing care community.)

Institutional SNPs can be restricted to enrollment of those individuals residing in long term care facilities or to individuals living in the community requiring an institutional level of care. An institutional SNP may elect to serve one or both of these populations.

2. Requirement to Limit Enrollment to LTC Facilities under Contract

MAOs offering an institutional SNP to serve Medicare residents of LTC facilities must have a contractual arrangement with (or own and operate) the LTC facility to deliver its SNP model of care for the entire term of the CMS contract. The contracted/owned approach provides assurances that beneficiaries will be assessed and will receive services as required under the SNP model of care. The institutional setting is complex and requires coordination between the SNP and facility providers and administrative staff, which can not be attained without a strong, well articulated MAO/facility relationship. Without a contractual or ownership arrangement, the MAO can not ensure the complex interface will function appropriately and care will be delivered in accordance with the model of care. Furthermore,

this approach to limiting enrollment to contracted LTC facilities assures the delivery of uniform benefits.

MAO marketing materials and outreach efforts must make clear that enrollment is limited to the CMS approved targeted population and to those beneficiaries who live in, or are willing to move to, contracted LTC facilities. If the MAO's institutional SNP enrollee changes residence, in order for the beneficiary to remain enrolled, the MAO must have appropriate documentation that it is prepared to implement the SNP model of care at the beneficiary's new residence. Appropriate documentation includes that the MAO has a contract with the LTC facility to provide the SNP model of care, and written documentation of the necessary arrangements in the community setting to ensure beneficiaries will be assessed and receive services as required under the SNP model of care.

3. Contract with Long Term Care Facilities

An MAO is required to provide CMS with a list of its long term care (LTC) facilities contracted to serve the institutional population under this SNP model of care.

In addition to the terms listed in the Medicare Advantage Managed Care Manual, Chapter 11, Section 100.4, located at <http://cms.hhs.gov/Manual/IOM/list.asp> the MAO's contract with an LTC facility must adequately address the following information, either in the contract with the long term care provider or in provider materials including, but not limited to, written policies and procedures and provider manuals. If the information is addressed in the provider materials, then each element listed below must be referenced in the contract in a meaningful way referring the facility to the particular part of provider materials where the details concerning the element can be found.

Facilities in a chain organization that are contracted to deliver the SNP Model of Care

- If the MAO's contract is with a chain organization, the chain organization and the applicant agree to a list of those facilities that are included to deliver the SNP Model of Care.

Facilities providing access to SNP clinical Staff

- The facility agrees to provide appropriate access to the applicant's SNP clinical staff including physicians, nurses, nurse practitioners and care coordinators, to the SNP beneficiaries residing in the MAO's contracted facilities in accordance with the SNP protocols for operation.

Providing protocols for the SNP Model of Care

- The MAO must agree to provide protocols to the facility for serving the beneficiaries enrolled in the SNP in accordance with the SNP Model of Care. These protocols must be referenced in the contract.

Delineation of services provided by the SNP staff and the LTC facilities under the SNP Model of Care

- A delineation of the specific services provided by the MAO's SNP staff and the facility staff to the SNP enrollees in accordance with the protocols and payment for the services provided by the facility.

Training plan for LTC facility staff to understand SNP Model of Care

- A training plan to ensure that the LTC facility staff understand their responsibilities in accordance with the SNP Model of Care, protocols and contract. If the training plan is a separate document it should be referenced in the contract.

Procedures for facility to maintain a list of credentialed SNP clinical staff

- Procedures that ensure cooperation between the SNP and facility in maintaining a list of credentialed SNP clinical staff in accordance with the facilities' responsibilities under Medicare conditions of participation.

Contract Year for SNP

- Contract must include the full CMS contract cycle which begins on January 1 and ends on December 31. The MAO may also contract with additional LTC facilities throughout the CMS contract cycle.

Grounds for early termination and transition plan for beneficiaries enrolled in the SNP

- Termination clause must clearly state any grounds for early termination of the contract. The contract must include a clear plan for transitioning the beneficiary should the MAO's contract with the long term care facility terminate.

4. Assisted Living Facility

An institutional SNP serving individuals living in the community but requiring an institutional level of care may restrict enrollment to those individuals that reside in, or agree to reside in, a contracted assisted living facility (ALF) or continuing care community as this is necessary to ensure uniform delivery of specialized care.

If a community-based institutional SNP is limited to specific assisted living facilities, a potential enrollee must either reside or agree to reside in the MAO's contracted ALF in order to enroll in the SNP.

Proposals for this type of institutional SNP are reviewed on a case-by-case basis for approval in the annual Medicare Advantage application cycle the SNP must demonstrate the need for the limitation, including how community resources will be organized and provided.

D. SNP Enrollment

1. Deeming Continued Eligibility

As provided in 42 CFR 422.52(d), the MA Organization sponsoring the SNP must continue to provide care for at least 30 days for a member who no longer has special needs status if an individual can reasonably be expected to again meet that criteria within a 6-month period.

During this time period, the individual is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months. Further, section 50.2.5 of the Medicare Advantage enrollment and disenrollment guidance located at <http://cms.hhs.gov/Manual/IOM/list.asp> clarifies that the MA SNP may choose any length of time from 30 days through 6 months for deeming continued eligibility as long as the plan can provide appropriate care, applies the criteria consistently among all members and fully informs members of its policy.

It is important to clarify that during this deemed eligibility period the MAO must continue to provide all plan benefits, and also charge the deemed-eligible member the same premium and cost sharing as any other eligible enrollee of the plan, and continue coverage of the supplemental Medicare benefits under this SNP (e.g., vision, dental, etc.) during the projected temporary loss of eligibility for the SNP, such as loss of Medicaid status.

E. Audit Protocols for SNPs

1. SNP Section of MA Audit Guide

Recently, the Medicare Advantage Audit Guide was updated to contain a section specifically designed to review critical aspects of a special need plan. Beginning in 2007, the new guide will monitor enrollment, disenrollment and marketing of the SNP. The review will determine if the MAO adequately describes the eligibility requirements in the marketing materials and provides appropriate information to the public that the SNP offered by the MAO is open for enrollment to all individuals who meet SNP criteria.

The guide also includes review elements on SNP eligibility criteria, the policies and procedures utilized to determine eligibility for the SNP and verification of eligibility by the MAO. The review will include how the MAO handles involuntary disenrollment when a change in special needs status requires disenrollment from the SNP.

The guide for 2008 SNP audits will be updated to cover the guidance provided in the 2007 application and in this call letter. For example, existing Medicare Advantage organizations (MAO) that offer SNPs may not have previously documented information on the SNP model of care since it was not specifically addressed in earlier versions of the SNP proposal. For SNPs that are currently operating, the MAO must document the model of care it uses to serve the special needs population through the SNP. We will review the SNP model of care through the MA audit review process, including but not limited to, the MAO policies and procedures related to the SNP model of care. Another example is review of LTC facility contracts for institutional SNPs.

F. SNP Quality Measures

To ensure that these plans are delivering quality care, SNPs are currently subject to the same quality improvement program requirements as all other MA organizations. This includes the reporting of performance measures, the inclusion of a chronic care improvement program, and participation in self-directed quality improvement projects.

We recognize the importance of developing a set of scientifically sound, feasible, measures for the vulnerable populations SNPs serve. It is our intention to develop Medicare SNP measures that will allow us to assess, monitor, and evaluate the health outcomes (clinical, functional, and patient experiences) of enrollees in special needs plans.

G. Relation of SNP Product to State Medicaid Services in the Event of Certain Dual Eligible Subsetting

In circumstances when an MAO has been approved to offer a dual eligible SNP and the dual eligibility applies to a subset that requires State contracting, then in future years when the plan is being re-contracted with the State, there must be a signed contract effective for the next year with the State Medicaid agency to continue offering the subsetting plan. Specifically, the contract must be signed by October 1 of the year preceding the effective date of January 1 for the new contract year.

XIV. Private-Fee-For-Service Plans

Private-fee-for-service (PFFS) plans are a growing health care option for people with Medicare. These plans can play an important role in our efforts to ensure a variety of health care options for people with Medicare. Because these plans are primarily non-network plans and have other features that are different than HMOs and other managed care products, some beneficiaries are joining these plans thinking they are Medicare fee-for-service or a supplemental plan. Providers sometimes will not provide service because they do not understand how payment works. It is essential, therefore, that organizations make efforts to clear up these misunderstandings by working closely with us, and by accurately informing providers and people with Medicare about the distinctive features of Medicare PFFS plans and the options they provide along with other managed care products.

In order to ensure that the marketing and outreach of these plans is accurate and complies with all program requirements, we are in the process of developing additional PFFS marketing documents and other outreach materials.

A. PFFS Oversight

We are concerned that people with Medicare may sometimes be confused about the differences between original fee-for-service Medicare and MA PFFS plans, and about access, payment, and other features of MA PFFS plans. As a result, we are considering several plan oversight features to improve the operation and accountability of MA PFFS plans to ensure that these plans are correctly represented by organizations and their sales agents, so that people with Medicare can be confident and informed when choosing such a plan from among their various health care options. Some of the oversight features we are considering include--

- ***Marketing.*** Requiring PFFS plans to include specific CMS disclaimer language in all marketing and enrollment materials as well as sales presentations.

- **Training.** Requiring PFFS plans to provide documented training of marketing agents and brokers on Medicare Advantage policy as well as unique aspects of the PFFS product.
- **Secret shopper.** Utilizing a contractor to visit various sales and outreach activities to determine the accuracy of such presentations and their compliance with program regulations.
- **Outbound verification calls.** Requiring PFFS plans to call all new applicants signed to confirm that applicants do, in fact, wish to enroll and that they understand the features of the plan. In certain cases telephone contact may not be possible. If so, other verification means may be acceptable. We will provide further guidance on this subject in the near future.
- **Performance data.** Strongly encouraging PFFS plans to participate in HEDIS and Health of Seniors surveys (HOS). While PFFS plans are not required to provide HEDIS and HOS information, if plans do not do so, they will not be included in the report cards we will issue and, as a result, may be at a disadvantage when people with Medicare view this comparative information when choosing a plan. We will review enrollment, appeals, and other data for trends and, if necessary, require appropriate corrective action, and will require MAOs to provide CMS on an annual basis with information on especially those grievances related to marketing and access to care.
- **Transparency of payment.** Strengthen requirements on transparency of payment rates, timeliness and payment dispute processes.
- **Provider education.** Encouraging PFFS plans to develop good provider relations to ensure providers are willing to participate.

B. Provider Dispute Process

Private-fee-for-service plans are required to create a provider-dispute process to reconcile disagreements that sometimes arise between the PFFS plan and the deemed providers who do not contract with the PFFS plan but agree to their terms and conditions.

C. Informing Providers

In general, CMS encourages guidance and outreach to providers so that they may be aware of the PFFS program and its opportunities. Several minor updates have been made to section 150, “PFFS Plans” or Chapter 4, “Benefits and Beneficiary Protections,” of the Medicare Advantage manual which may be reviewed at <http://www.cms.hhs.gov/manuals/downloads/mc86c10.pdf>.

D. Pharmacy Access and PFFS plans

As provided in previous guidance, CMS will waive pharmacy access standards for private fee-for-service (PFFS) sponsors offering Part D coverage that: (1) provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies, and (2) do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy. Therefore, PFFS sponsors choosing to have either no contracted pharmacy network or a limited pharmacy network that does not meet our pharmacy access

requirements must ensure that their enrollees are able to access their benefits at all non-network pharmacies without paying any more cost-sharing than they would under their approved Part D benefit structure.

We clarify, for CY 2008, that when accessing their drugs at non-network pharmacies in non-emergent situations, enrollees of PFFS plans that have received waivers of the pharmacy access standards will pay only their required cost-sharing at the point of sale. Moreover, such claims should be adjudicated electronically whenever pharmacies support electronic billing. In other words, PFFS sponsors with pharmacy access waivers should not routinely rely on out-of-network pharmacy billing practices that require an enrollee to pay the usual and customary (U&C) price upfront and then submit a paper claim to the plan sponsor for reimbursement.

We note that Part D sponsors are required to accurately track enrollee TrOOP and gross covered drug spend amounts in order to correctly position the beneficiary in the benefit. Our coordination of benefits guidance reflected in Chapter 14 of the Medicare Prescription Drug Benefit Manual indicates that plans are required to process claims in real-time and track TrOOP in real-time. Consistent with this guidance, sponsors, including PFFS sponsors receiving waivers of the pharmacy access standards, must establish policies and procedures appropriately restricting the use of paper claims only to the situations in which online claims processing is not available at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative cost to the Part D plans and the Medicare program and opportunities for fraudulent duplicate claims reimbursement. Therefore, PFFS sponsors choosing to obtain a waiver rather than meet our pharmacy access requirements must arrange for automated, online billing at non-network pharmacies (similar to the way in which our point-of-sale contractor has allowed for online billing by non-contracted providers.)

XV. Medicare Advantage Medical Savings Account (MSA) Plans

We have updated our guidance for Medicare MSA original and demonstration plans, consumer-driven, high-deductible health plans with medical savings accounts. These plans represent a new and unique health care option for people with Medicare and play an important role in our goal of offering meaningful choices among plan types and benefits and ensuring high-value, high-quality health care in general. We expect that an organization offering this type of plan fully explain its unique features, and ensure that people with Medicare who choose such a plan clearly understand their treatment options, the costs associated with treatment both before and after the deductible is met, and how costs counting towards the deductible are tracked. Please see the “Medicare Advantage Applications” web page at <http://www.cms.hhs.gov/MedicareAdvantageApps/> for information on both Medicare MSA plan types including frequently asked questions, applications, Q&As, payment, enrollment, and forms.

XVI. Employer and Union-Sponsored Group Health Plans

Everyone benefits when employers and unions provide health care coverage to their members. In recognition of this, the MMA provided several incentives to encourage the growth of group health coverage, and CMS will strive to strengthen our partnership with employer groups in the coming years to ensure that such plans remain vibrant and a viable option for people eligible for Medicare. One such incentive is the flexibility employer and union group sponsors have to customize coverage. We are especially interested in partnering with employers and unions to enhance retiree health coverage and have established an employer and union-only group waiver program (EGWP) that permits employers and unions to contract directly with us to offer coverage to group members or purchase a customized plan from a prescription drug plan sponsor or MA organization. We will continue to strengthen our partnership and refine the features of the employer and union group health plans to permit flexibility while reducing administrative burden so that we may realize our goals of providing high value plans tailored to the needs of their members which meet all Part C and, if offering Medicare prescription drug benefits, Part D program requirements.

Employer and union group plan sponsors may choose to enroll their members in individual MA plans open to general enrollment (“mixed enrollment” plans). They may also elect to work with MAOs that offer or administer employer-only customized group plans, including those organizations offering Part D prescription drug benefits (i.e., MA-PDs). These kinds of customized employer group plans offered by MAOs are frequently referred to as “800 series” plans because of the way they are enumerated in HPMS which distinguishes them from individual plan benefit packages. Employers and unions also may choose to directly contract with CMS to offer these kinds of customized group benefits to their members (hereinafter referred to as “Direct Contract” plans). These “800 series” and Direct Contract employer group plans are referred to collectively as employer/union-only group waiver plans (“EGWPs”).

The following highlights important differences in the 2008 contract year for MAOs offering employer or union-sponsored group plans and/or clarifications on certain topics.

A. Elimination of “Nexus” Test Requirements for Certain MAOs

For CY 2006 and 2007, CMS employer group waiver policy requires MAOs to offer plans to individual Medicare beneficiaries as a condition of being able to offer employer/union-only group waiver plans (i.e., “800 series” plans) associated with the same contract. Also, during 2006 and 2007, if individual coverage is offered in the service area where the most substantial portion of an employer’s employees reside, non-network Private Fee-For-Service (PFFS) plans offered by MAOs may extend coverage in “800 series” plans to the employer’s retirees in other service areas. (This service area extension policy is commonly known as the “nexus test”).

Beginning with CY 2008, MAOs offering non-network PFFS plans are not required to offer these plans to individual beneficiaries as a condition of offering associated “800 series” plans. This change includes the elimination of the “nexus” test. In addition, beginning with the 2008 contract year, regular (i.e., standard) “800 series” Medical Savings Account (MSA)

plans will be treated the same as “800 series” demonstration MSA plans and will not be required to offer plans to individual beneficiaries.

The changes described above will apply to entities renewing “800 series” plan benefit packages in 2008, as well as to entities offering “800 series” plans for the first time in 2008. Notwithstanding these changes, entities offering these plans will continue to have to meet all CMS requirements that are not otherwise waived or modified, including the requirement to be licensed as a risk bearing entity eligible to offer health insurance or health benefits. For entities that choose to offer only “800 series” plans for a particular MA PFFS or MA MSA contract, this requirement will be met if the entity is licensed in at least one state.

Please remember that MAOs that wish to utilize this new waiver policy to offer only “800 series” plans and wish to enroll/cover retirees where ever they reside must set national service areas and submit corresponding national Part C (i.e., MA) bids. With regard to providing sufficient Part D pharmacy access throughout the plan’s service area, networks to cover these retirees must be in place prior to enrolling retirees.

B. Service Area Extension Waiver for Certain MA Local Coordinated Care Plans

For CY 2008 CMS will retain the current requirement that all MAOs (other than non-network PFFS, Regular and Demonstration MSA plans as outlined above) and Section 1876 Cost Plan Sponsors offer plans to individual beneficiaries as a condition of offering “800 series” plans. The design and operation of these plans differ appreciably from non-network MA PFFS plans and MA MSA plans. For example, MAOs must furnish Medicare Parts A and B health care services generally through local networks that they must establish and maintain and that are approved by CMS and therefore it is important to continue to provide incentives for these entities to offer these plans and promote greater choice and robust availability for Medicare beneficiaries.

However, to enable employers and unions to offer coordinated care plans to all their Medicare-eligible retirees wherever they reside, CMS will grant a waiver of service area requirements for the 2008 contract year to MAOs offering “800 series” local coordinated care plans (e.g., local PPOs and HMOs) under certain circumstances. A MAO offering a coordinated care plan in a given service area (i.e., state) can extend coverage to an employer or union sponsor’s beneficiaries residing outside of that service area when the MAO, either itself or through partnerships (i.e., arrangements) with other MAOs, is able to meet CMS provider network adequacy requirements and provide consistent benefits to those beneficiaries.

Please remember that local coordinated care MAOs that wish to utilize this new waiver policy to extend their EGWP service area beyond the particular state(s) in which they also offer individual plans must ensure that they set their service areas and submit Part C (i.e., MA) bids according to where they anticipate enrolling/covering retirees. With regard to providing sufficient MA and Part D network access throughout the local coordinated care plan’s extended service area, networks to cover these retirees must be in place prior to enrolling retirees.

C. Marketing and Beneficiary Communications

Customizing Medicare Dissemination Materials

In order to meet the requirements of 42 CFR 422.111(a)(2) and/or 42 CFR 423.128(a)(2), which require a MAO to disclose information about the plan in a clear and accurate form, MAOs should provide customized marketing/dissemination materials to “800 series” and Direct Contract plan enrollees to reflect the modified/supplemental benefits being provided to that particular employer or union group. More specifically, CMS has waived any rules that would otherwise prohibit these entities from offering customized dissemination materials to the extent those customized materials will more clearly and accurately describe the benefits available to employer group members when the supplemental coverage is taken into account. Please note that this waiver includes those instances where a MAO offers an employer or union group plan sponsor the ability to cover its retirees using an individual (“mixed enrollment”) plan and a supplemental non-Medicare plan designed to “wrap around” or enhance the individual Medicare plan.

With regard to premium amounts (including premium amounts for low-income premium subsidy eligible individuals) that are required to be accurately reflected on any customized beneficiary dissemination materials (e.g., Evidence of Coverage, Low-Income Premium Subsidy Rider), MAOs should ensure these materials reflect the actual premium amount the beneficiary pays when the supplemental coverage and any corresponding employer or union-sponsored group plan premium subsidization is taken into account. Alternatively, if accurate premium information concerning the amount the beneficiary actually pays is not available to the MAO, the MAO may substitute language such as the following in lieu of providing actual premium amounts: “For information concerning the actual premiums you will pay for this customized coverage (taking into account any supplemental coverage and/or subsidization of premiums provided by your employer, [insert employer name], please contact directly your group benefit plan administrator.”

All customized employer group materials are not required to be submitted for review and approval by CMS prior to use. However, they must be submitted to CMS as informational copies at the time of use in accordance with the procedures outlined in Chapter 13 of the Medicare Marketing Guidelines (none of these customized materials should be submitted through HPMS). CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. Please note that the waiver of the prior review and approval of these customized employer group materials and the requirement to provide informational copies to CMS at the time of use also will apply to MAOs that offer an individual Medicare plan and a supplemental non-Medicare plan designed to “wrap around” or enhance the individual Medicare plan.

Please note that MAOs should not use the standardized Summary of Benefits that is generated from HPMS for employer/union members because these materials will not be accurate for these plans (unless the standardized Summary Benefits reflects the actual benefit being offered to an individual employer/union group).

D. Renewals and Non-Renewals

All EGWPs (Direct Contract and “800 series” plans) are subject to the same renewal and non-renewal processes as for non-group plans. MAOs offering 2007 non-network PFFS or MSA plans that elect to non-renew individual plans in 2008 because of the elimination of the “nexus text” will receive further instructions concerning the non-renewal process, if more specific instructions are determined necessary.

E. Employer and Union-Sponsored Group MSA Plans

In 2008, an MAO can offer “800 series” regular or demonstration MA MSA plans without offering corresponding individual plans (*see* Section A. above). In 2007, only Demonstration “800 series” MSAs could offer “800 series” plans without offering corresponding individual plans.

Under Section 1851(e)(5) of the Social Security Act, an individual’s election to enroll in an MSA plan is restricted to: (1) the beneficiary’s initial open enrollment period; or (2) the annual, coordinated election period (November 15-December 31). *See also* 30.7 and 50.8 of Chapter 2 of the Medicare Managed Care Manual. To facilitate the offering of employer/union-sponsored group MSA plans, CMS has modified the enrollment rules for employer-sponsored group enrollments in regular and demonstration MSA plans to allow a special election period (SEP) for these plans. Specifically, Section 30.4.4.1 of the MA enrollment manual now applies to employer/union-sponsored group enrollments into “800 series” regular and demonstration MA MSA plans. This SEP also will apply to employer/union sponsored group plan enrollments in MA MSA plans open to general enrollment (“mixed enrollment” plans). Like the SEP for other MA plans, this will allow a SEP for individuals making MA elections into or out of employer-sponsored MA plans and for individuals to disenroll from an MA plan to take employer-sponsored coverage of any kind, and for individuals disenrolling from employer-sponsored coverage to elect an MA plan.

A Medicare beneficiary that is an active employee (i.e. working aged) enrolled in an employer-sponsored group plan that covers any part of an MSA deductible (aside from the permitted preventive care and supplemental coverage) should not be permitted to enroll in an MSA plan. However, there will be instances when an employer-sponsored group plan will not cover any part of the deductible of the MSA high deductible health plan (HDHP). For example, an employer or union sponsor could offer a HDHP with a deductible that is the same or higher than the MSA deductible. In that scenario, since the employer sponsored group HDHP does not offer coverage in the MSA deductible, the Medicare eligible active employees in the employer-sponsored group plan should be permitted to enroll in an MSA plan.

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Introductory Note: Most of the information in Section B of the 2008 Call Letter applies to all types of Medicare Part D sponsors (i.e., prescription drug plan (PDP) sponsors, Medicare Advantage (MA) organizations, and Cost Plan sponsors). The applicability of the information in each subsection is indicated in brackets next to the heading for that subsection. MA organizations 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 2008.

I. CALENDAR – PREPARATION FOR 2008

2008 Contract Year Renewal Dates [PDP sponsors only]

(Dates are Subject to Change)

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

2007	Item Description
March 26	CMS begins accepting formularies through HPMS.
April 6	CY 2008 Bid Software Package (bid pricing tool (BPT) and plan benefit package (PBP)), and technical instructions available for download from (HPMS).
April 16	Final day to submit formularies via HPMS (5:00 p.m. EDT).
Early April	Conference call to discuss 2008 Call Letter.
May 1	CMS issues renewal/non-renewal notices to prescription drug plan (PDP) sponsors.
May 18	CMS begins accepting CY 2008 Bids via HPMS.
June 4	Final day for PDP sponsors to submit CY 2008 Bids via HPMS (11:59 p.m. PDT).
June 5	CMS begins accepting Free First Fill formulary files and Limited Coverage Gap Coverage formulary files through HPMS.
June 15	2008 standardized combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), and model Low Income Subsidy (LIS) rider to the EOC will be available for PDP sponsors CMS begins accepting CY 2008 marketing material for review via HPMS Marketing Module.

June 30	Final date for PDP sponsors to submit CY 2007 marketing materials for CMS's review and approval. NOTE: This date does not apply to CY 2007 file & use materials since PDP sponsors may file these materials with the regional office five calendar days prior to their use.
August 1	PDP sponsors are expected to submit final CY 2008 standardized combined EOC /ANOCs or stand alone non-model ANOC and Low Income Subsidy (LIS) riders to the regional offices for review.
September 10 - 12	PDP sponsors preview the 2008 Medicare & You handbook plan data in HPMS prior to printing the CMS publication (not applicable to EGWPs).
October 1	<ul style="list-style-type: none"> • PDP sponsors may begin marketing CY 2008 benefits to Medicare beneficiaries using CMS-approved and CMS-File & Use accepted marketing materials. All PDP sponsors must cease marketing CY 2007 plans through public media when they begin marketing 2008 benefits. • IMPORTANT ENROLLMENT NOTE: While marketing of CY2008 benefits can begin on 10/1/07, PDP sponsors receiving unsolicited enrollment requests on or after 10/1/07, but before the start of the 11/15/07 – 12/31/07 Annual Coordinated Election Period, may process these requests following the procedures outlined in Section 30 of the PDP Eligibility, Enrollment and Disenrollment Guidance. • PDP sponsors are required to include information in CY 2007 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2008. • Final day for PDP sponsors to submit stand alone ANOC to CMS regional office for review
October 15 - 30	Medicare & You handbooks are mailed to Medicare beneficiaries.
October 31	<ul style="list-style-type: none"> • All PDP sponsors must cease marketing CY 2007 plans through public media. • CY 2008 standardized combination ANOC/EOC or stand alone ANOC and SB (with abridged or comprehensive formularies) and Low Income Subsidy (LIS) riders are due to all members. PDP sponsors must mail the required documents <u>before</u> this date to ensure

	receipt by members by October 31.
November 15 – December 31	Annual Election Period. All PDP sponsors must hold open enrollment. (for EGWPs, <i>see</i> Section 20.3.8 of the PDP Guidance: Eligibility, Enrollment and Disenrollment)
December 31	Deadline for submitting Part D PBP plan corrections (11:59 p.m. PST).
January 1, 2008	2008 plan benefit begins.
January 31, 2008	PDP sponsors must mail CY 2008 stand alone EOCs and LIS riders to members with an effective date of January 1, 2008.

II. BIDDING/PAYMENT

Bid Pricing Tool (BPT) and Plan Benefit Package (PBP) Release [All Part D sponsors]

CMS released via HPMS the 2008 BPT and Instructions to Part D sponsors and interested parties on April 6, 2007. CMS will also release 2008 PBP software and instructions at a later date. CMS will provide organizations and interested parties an opportunity to participate in informational seminars on the revised tools. Please refer to Section XI below (Systems) for more information about the release of the BPT and PBP software.

Advance and Final Payment Notices [All Part D sponsors]

We publicly released the Advance Notice of Methodological Changes for Calendar Year 2008 for Medicare Advantage Capitation Rates (Advance Notice) on February 16, 2007. After considering and responding to comments, we publicly released the final Announcement of Calendar Year 2008 Medicare Advantage Capitation Rates and Payment Policies (Announcement) on April 2, 2007. These notices are posted at:
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/AD/list.asp#TopOfPage>.

On April 2, 2007, CMS also released the Notification of Changes in Medicare Part D Payment for Calendar Year 2008 (Part D Payment Notification). In this notification, CMS describes key changes in payment methodologies applied under Part D for 2008 including the updated benefit parameters for the defined standard benefit and Retiree Drug Subsidy (RDS) as well as the calculations of the national average monthly bid amount and the regional low-income benchmark premium amounts. This notification is posted at
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/AD/list.asp#TopOfPage>

III. FORMULARY

As we enter into the third year of the Part D benefit, our policy and review processes surrounding Part D formularies continue to stabilize and mature. This is a process consistent with CMS' efforts to work with sponsors to ensure that beneficiaries have access to stable formularies that

promote high quality health care. Unlike previous years where we have issued separate formulary review guidance, we have consolidated and formalized our formulary guidance in Chapter 6 of the Medicare Prescription Drug Plan Manual, *Part D Drugs and Formulary Requirements*. We expect that prior to the release our final 2008 Call Letter, the final version of Chapter 6 will be posted on our website at the following location:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp.

Consequently, we highlight specific areas of our formulary guidance that will be updated for 2008 from the current version of Chapter 6. Part D sponsors must consider these updates prior to submission of their 2008 formulary.

1. Drug List Review [All Part D sponsors]

In order to ensure Part D formularies continue to be robust, we are augmenting our formulary sub-review process. While continuing our review of the six classes of clinical concern and commonly used drugs in the Medicare population, we are expanding our review of the Medicare/Medicaid eligible commonly used drugs to 200 drugs and incorporating the top 100 drugs used in the Medicare Drug Discount Card. We are also expanding the number of treatment guidelines used in our review to ensure best practice drugs are included in Part D formularies. In addition, we are using the presence of the U.S. Pharmacopeia (USP) Formulary Key Drug Types as an outlier test to ensure that these drug types are strongly represented on all Part D formularies.

2. Specialty Tiers [All Part D sponsors]

We will continue to scrutinize drugs placed in a specialty formulary tier for very high cost and unique items that are exempt from tiered cost-sharing exceptions. A new dollar threshold of \$600 dollars for a sponsor's specialty formulary tier will be in place for Contract Year 2008, meaning that only Part D drugs with sponsor negotiated prices that exceed \$600 per month may be placed in the specialty tier. We will be conducting a statistical analysis of drugs found on 2008 specialty tiers to determine if further adjustment of the specialty tier threshold is necessary in future contract years.

3. Six Classes of Clinical Concern [All Part D sponsors]

There will be no change in policy regarding the six classes of clinical concern as outlined in section 30.2.5 of Chapter 6. We note, however, that for Contract Year 2008, formularies must include all or substantially all drugs in these six categories that are available on April 16, 2007. New drugs or newly approved uses for drugs within the six classes that come onto the market after April 16, 2007 will be subject to an expedited Pharmacy and Therapeutics committee review.

4. Transition Processes [All Part D sponsors]

Part D sponsors intending to offer Part D benefits in 2008 will be required to submit an attestation that their transition processes meet the requirements delineated in Chapter 6 of the PDP Manual. We expect to make a transition process attestation available to sponsors by late April 2007 with a submission due date sometime in May 2007.

We have received complaints regarding that sponsor transition process information is very difficult to locate on sponsor websites. For this reason, we emphasize that in Contract Year 2008, sponsors must ensure that their transition process information is prominently posted on their websites. Sponsors may accomplish this by including a link from their formulary pages to a narrative describing their transition process. Alternatively, sponsors may include a specific page outlining their transition process on their plan websites.

We have also received questions regarding the transition process for beneficiaries who enroll in a Part D plan so late in the contract year that the full transition period established by the plan's sponsor extends into the following contract year. We clarify that sponsors must extend their transition policies across contract years should a beneficiary enroll into a Part D plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. For example, if a beneficiary enrolls effective December 1, 2007 in a plan whose 2007 transition policy affords a 90-day transition period for LTC enrollees and that beneficiary requires a transition supply in mid-December, the plan must offer a full 90-day transition period beginning December 1, 2007 (including a one-time, 30-day transition supply) and extending into the following contract year. In addition, sponsors must send beneficiaries with a November 1 or December 1 effective enrollment date an ANOC as soon as practicable after the effective enrollment date. This ANOC will serve as advance notice of any formulary or benefit changes in the following contract year.

5. Vaccine Formulary Coverage [All Part D sponsors]

We will be adding a new section to Chapter 6 applicable to Contract Year 2008 sponsors to address formulary requirements related to vaccines. Specifically, we will review all sponsors' formularies to ensure they contain all commercially available vaccines (unless excluded due to available reimbursement under Part B, e.g., influenza or pneumococcal vaccines). Sponsors will be allowed to use drug utilization management tools to:

- Assess the necessity of vaccines that are less commonly administered in the Medicare population, such as anthrax and yellow fever vaccines;
- Facilitate use of vaccines in line with Advisory Committee on Immunization Practices (ACIP) recommendations; and
- Evaluate potential reimbursement of those vaccines that could be covered under Part B when directly related to the treatment of an injury or direct exposure to a disease or condition (e.g., tetanus).

6. Vaccine Administration [All Part D sponsors]

We received a significant number of comments – many of them quite technical in nature – in response to our Draft 2008 Call Letter language related to the statutory shift of Part D vaccine

administration reimbursement from Part B to Part D in 2008. Given the extensive and quite thoughtful nature of these comments, we are taking additional time to finalize our operational guidance on administration fees for Part D vaccines. Detailed operational guidance will be finalized in May 2007 in order for sponsors to make the appropriate allowances for vaccine administration fees in their Contract Year 2008 bids. In the interim, sponsors should be prepared to implement various methods of Part D vaccine administration payment, both in-network and out-of-network, for Contract Year 2008.

7. Home Infusion Drugs *[All Part D sponsors]*

In previous guidance, we have clarified that plans must require the delivery of home infusion drugs within a reasonable time period based on assurances that the necessary professional and ancillary supplies required for home infusion therapy are in place before dispensing home infusion drugs. Such assurances must be incorporated into sponsors' contracts with network home infusion pharmacies. In addition, we expect to specify a reasonable time period for the delivery of home infusion drugs for Contract Year 2009. In the meantime, however, we recommend that sponsors provide covered home infusion drugs either by the next required dose or within 24 hours of discharge from an acute setting. In our ongoing discussions with home infusion providers we have learned that best practices involve the availability of infusion services upon discharge from a hospital either by the next required dose or within twenty-four hours of the discharge.

NOTE FOR MA-PD SPONSORS ONLY: MA-PD plans may choose to provide Part D home infusion drugs as part of a bundled service as a supplemental benefit under Part C, provided the MA-PD plan consistently applies the option (i.e., in a given contract year, either always covers a particular home infusion drug as part of a bundled service under Part C, or always covers a particular home infusion drug under Part D). Given uniform benefits requirements, MA organizations must also ensure that the bundled service is available to all enrollees of any MA-PD plan in which it chooses to provide Part D home infusion drugs as part of a supplemental benefit under Part C. Interested MA organizations must appropriately apportion costs between Part D and C components of their bid to account for these drugs, as well as provide, in the Medicare Part D Rx notes section of the PBP, a list that clearly identifies the home infused covered Part D drugs that will be offered as part of a supplemental benefit under Part C for Contract Year 2008.

IV. PART D BENEFITS

CMS expects that sponsors will develop a variety of benefit designs for meeting the needs of our beneficiaries consistent with our commitment to afford them access to high value health care. We will ensure that the range of benefit packages offered will allow optimal choice for the beneficiary and further assure that each benefit package is designed to be non-discriminatory. Clarity and transparency of the benefit package continues to be essential for educated beneficiary choice.

Number of Plans Per Region Per PDP Sponsor Contract *[PDP sponsors only]*

Similar to 2007, CMS will negotiate with PDP sponsors to ensure that each bid they submit represents a meaningful variation based on plan characteristics that will provide beneficiaries with substantially different options. Key plan characteristics we will look at include deductibles versus no deductibles, substantial formulary differences, coverage in the gap versus no coverage, premiums, and substantial 2007 enrollment versus limited interest. We expect that organizations will take steps to ensure that the array of PDP benefit packages submitted can be reasonably understood and compared by beneficiaries in terms of key plan characteristics.

In general, we expect that more than two bids from a sponsoring organization would not provide meaningful variation, unless one of the bids is an enhanced alternative plan that provides coverage in the coverage gap. But if a sponsor wishes to offer two plans with gap coverage and at least one of these plans offers coverage of all generics and all preferred brands through the entire gap, CMS will consider allowing four bids from that sponsoring organization.

In order to offer an enhanced alternative plan design, sponsors must offer a basic benefit design. However, the basic benefit design option does not have to be a defined standard plan. A basic benefit design includes any one of the following plan types: defined standard, actuarially equivalent, or basic alternative. As you know, the actuarially equivalent and basic alternative plan types allow for variations from the defined standard plan.

Impact of PDP Sponsor's Purchase of Another PDP Sponsor on Maximum Number of Bid Submissions

Where a PDP sponsor (or a parent organization to the sponsor) purchases another PDP sponsor, the result can be that a single parent organization is, at least temporarily, permitted to offer more than the expected two basic benefit plans (i.e., multiple subsidiaries of the same parent offering two or more plans each). The result may be a situation in which the multiple plan offerings do not present meaningful choices to beneficiaries because they are not designed by competing organizations. Rather they are designed by a single entity with no incentive to compete against its own products.

Therefore, CMS is adopting a policy under which parent organizations with new acquisitions will be afforded a period of up to 3 years to transition their benefit offerings back to the point where the parent offers no more than 2 basic benefit plans total throughout all of its subsidiary PDP sponsors, except under extraordinary circumstances. Parent organizations currently offering more than 2 basic benefit plans throughout all of their subsidiary sponsors must make the required transition on or before the start of the 2010 program year (i.e., parent organizations may operate more than 2 basic benefit plans during 2008, 2009, and 2010). Organizations that complete acquisitions of other sponsors after the date of this call letter will be afforded the following three years for which bids may be submitted to make this transition. For example, a PDP sponsor parent organization purchasing another PDP sponsor in November 2008 would need to complete its transition to the maximum number of basic benefit plan offerings by the

2013 program year (i.e., bids would next be due in June 2009 for the 2010 program year; transition would occur during 2010, 2011, and 2012).

Covered Part D Drugs with Limited Distribution [All Part D sponsors]

We have previously stipulated that Part D sponsors may not restrict access to a Part D drug by limiting distribution through a subset of network pharmacies. Exceptions to this stipulation are as follows: when necessary to meet Food and Drug Administration (FDA) limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination or patient education, when such extraordinary requirements cannot be met by a network pharmacy. If a sponsor finds it necessary to restrict access to any Part D drugs for either of these reasons, it must now indicate the affected Part D drugs in its formulary upload for 2008.

Benefits Through the Coverage Gap [All Part D sponsors]

Part D sponsors may include, as part of an enhanced alternative benefit design, coverage of a subset of drugs – including either an entire tier or particular covered Part D drugs – through out the entire coverage gap. Coverage of less than an entire tier only throughout the entire coverage gap or coverage of a specific monetary amount within the coverage gap will be considered Limited Gap Coverage. For example, offering coverage of a capped dollar amount of covered Part D drugs (i.e., coverage of \$250 of generics) above the initial coverage limit is not considered coverage gap coverage but, rather limited gap coverage.

Limited Coverage Gap Benefits [All Part D sponsors]

For CY 2008, if a sponsor indicates that it will provide coverage gap coverage for only certain covered Part D drugs (as opposed to an entire tier), the applicable covered Part D drugs must be uploaded in a separate formulary file through the HPMS Formulary Submission module beginning on June 5, 2007. Instructions for this upload will be available in the CY 2008 Bid User's Manual. All covered Part D drugs covered through the gap will be indicated individually on the MPDPF, the plan's website, and other appropriate plan marketing material.

Please note that benefit designs that include gap coverage for a subset of covered Part D drugs will be carefully reviewed to ensure that the benefit offered does not violate the non-discrimination provisions in statute and regulation. Sponsors are encouraged to be mindful of discrimination implications if their proposed benefit design limits coverage gap coverage to less than an entire cost-sharing tier.

Free First Fills [All Part D sponsors]

As indicated in previous guidance, a sponsor may establish a generic-use incentive program permitting zero (or reduced) co-pays on first generic fills if an enrollee agrees to use the generic rather than the brand-name version of a medication. For 2008, a sponsor that elects this benefit design must indicate that it will cover certain covered Part D drugs in this manner in its PBP and upload those covered Part D drugs in a separate Free First Fill formulary file through the HPMS

Formulary Submission module beginning on June 5, 2007. Instructions for this upload will be available in the CY 2008 Bid User's Manual. All Free First Fill drugs will be indicated individually on the MPDPF, the plan's website, and other appropriate plan marketing material.

Out-of-Network Benefits [All Part D sponsors]

Given previous guidance that sponsors must establish reasonable rules to appropriately limit out-of-network (OON) access to covered Part D drugs, we clarify that sponsors may not routinely allow more than a month's supply of medication to be dispensed at an OON pharmacy. In creating their out-of network benefit structure, sponsors may choose one of the following options:

- The plan's In-Network co-insurance;
- The plan's In-Network co-pay plus the differential between the OON billed charge and their In-Network allowable charge; or
- The plan's In-Network co-pay with a limited days supply (note that this limited days supply must be greater than or equal to 10 days).

Plans may override the 30 day limit on a case-by-case basis when warranted by extraordinary circumstances.

Over-the-Counter Medications [All Part D sponsors]

If a plan pays for over-the-counter (OTC) medications associated with a utilization management program, its over the counter medications may not be listed on a unique tier. Since these OTCs are covered under administration costs and there is no cost share for the beneficiary, there is no required tier designation for these medications. However, the specific OTCs that will be covered must be listed in the Medicare RX notes section of the PBP.

Cost Shares [All Part D sponsors]

To ensure a non-discriminatory benefit CMS expects that sponsors must assign preferred cost shares in alignment with preferred formulary tiers. To this point cost shares for a preferred tier must be lower than cost shares for a non-preferred tier. In addition, plans whose cost shares fall above the mean will be rigorously examined under the discrimination review.

Plan Corrections for 2008 [All Part D sponsors]

Consistent with marketing and open enrollment coordination, CMS will not allow PDP corrections to the PBP any later than December 31, 2007 for 2008 benefits

Actuarial Certification Process [All Part D sponsors]

During the first two years of the Part D bidding process, CMS and Part D sponsors faced several challenges in developing an effective and efficient actuarial certification system. During the first year (2006), sponsors were required to submit actuarial certifications with each bid submission

and re-submission, a burdensome process, much of which was not relevant to the final approved bids. During the second year (2007), sponsors were required to submit two certifications, one at the beginning of the bid review process and another accompanying the final bid upload in August. Each of these approaches raised several concerns, including the fact that actuaries did not have access to HPMS and therefore did not know exactly the content of the uploaded bids, could not verify that the benefits proposed matched the bid submitted, and that the certifications were free-form documents which required significant CMS resources to review.

CMS will revise the actuarial certification process for 2008 to address these concerns. We will grant certifying actuaries limited HPMS access, including the ability to review the submitted plan bid package. Sponsors will be required to designate for CMS their certifying actuaries during the bid creation period and will be permitted to designate multiple actuaries within each contract. Also, CMS will create an actuarial certification module within HPMS which will streamline the certification language into a standardized template that would still permit actuaries to input free-form text. The module will also feature links to the details of the submitted bid packages. Finally, sponsors will be required to make only two bid certification submissions. The first will be due shortly after the initial submission has been received and the data processed through HPMS (mid-June). The second will be made after the rebate reallocation process has occurred in mid-August, which will correspond to the final bid package and proposed benefits pending approval.

CMS believes that this process will cause some limited level of additional effort from both sponsors and actuaries. However, this effort will be offset by the advantage of a higher quality bid package and the likely significant reduction in the number of plan corrections. Actuaries will be more confident that their certifications are tied to the benefit package they relied upon in their analysis and that the BPT they intended to be submitted was uploaded to HPMS.

V. PHARMACY ACCESS

Continued Compliance with Pharmacy Access Requirements [All Part D sponsors]

Currently, our oversight activities regarding Part D sponsors' compliance with our requirements to maintain a pharmacy network sufficient for ensuring access to network pharmacies for beneficiaries residing in their service areas include: (1) audits; (2) investigation of individual complaints received from enrollees and providers; and (3) required notification of Part D account managers by Part D sponsors when there is a substantive change in their pharmacy networks. CMS continues to seek methods to improve monitoring of pharmacy access requirements, as pharmacy networks have thus far only been reviewed during the initial application process. Beginning in Contract Year 2008, Part D sponsors must re-run their pharmacy access analyses on a biannual basis and demonstrate that their retail, home infusion, and long-term care pharmacy networks continue to meet our pharmacy access standards.

Pharmacy Access under Private-Fee-for-Service (PFFS) Plans [MA-PFFS sponsors only]

As provided in previous guidance, CMS will waive pharmacy access standards for private fee-for-service (PFFS) sponsors offering Part D coverage that: (1) provide coverage for drugs

purchased from all pharmacies, regardless of whether they are network pharmacies, and (2) do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy. Therefore, PFFS sponsors choosing to have either no contracted pharmacy network or a limited pharmacy network that does not meet our pharmacy access requirements must ensure that their enrollees are able to access their benefits at all non-network pharmacies without paying any more cost-sharing than they would under their approved Part D benefit structure.

We clarify, for Contract Year 2008, that when accessing their drugs at non-network pharmacies in non-emergent situations, enrollees of PFFS plans that have received waivers of the pharmacy access standards will pay only their required cost-sharing at the point of sale. Moreover, such claims should be adjudicated electronically whenever pharmacies support electronic billing. In other words, PFFS sponsors with pharmacy access waivers should not routinely rely on billing practices that require an enrollee to pay the usual and customary (U&C) price upfront and then submit a paper claim to the plan sponsor for reimbursement.

We note that sponsors are required to accurately track enrollee TrOOP and gross covered drug spend amounts in order to correctly position the beneficiary in the benefit. CMS's coordination of benefits guidance reflected in the recently issued Chapter 14 of the Medicare Prescription Drug Benefit Manual indicates that plans are required to process claims in real-time and track TrOOP in real-time. Consistent with this guidance, sponsors, including PFFS sponsors receiving waivers of the pharmacy access standards, must establish policies and procedures appropriately restricting the use of paper claims only to the situations in which online claims processing is not available at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and opportunities for fraudulent duplicate claims reimbursement. Therefore, PFFS sponsors choosing to obtain a waiver rather than meeting our pharmacy access requirements must arrange for automated, online billing at non-network pharmacies (similar to the way in which our point-of-sale contractor has allowed for online billing by non-contracted pharmacies).

VI. MARKETING/BENEFICIARY COMMUNICATIONS

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. The benefit information included in marketing and outreach materials must be based on information submitted in the bidding process and captured in HPMS through tools such as the Plan Benefit Package tool. It is essential that all information is accurate, and presented clearly and timely in the required format so that people with Medicare can make informed decisions about which plan types and plan benefit packages best meet their needs. 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 guidelines on the CMS website, 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). Below, we draw your

attention to some of the aspects of marketing and outreach you should be aware of as you plan for the 2008 program year.

A. Marketing of CY 2008 Plans by Agents and Brokers [All Part D sponsors]

With the significant expansion of MA and PDP enrollment we remind organizations that they are responsible for the actions of sales agents/brokers whether they are employed or contracted. Organizations must ensure agents/brokers are properly trained in both Medicare requirements and the details of the products being offered. Part D sponsors must provide strong oversight and training for all marketing activities. Employees of an organization or independent agents or brokers acting on behalf of an organization may not solicit Medicare beneficiaries door-to-door for health-related or non-health-related services or benefits. Employees, brokers and independent agents must first ask for a beneficiary's permission before providing assistance in the beneficiary's residence, prior to conducting any sales presentations or accepting an enrollment form in person. Additionally, beneficiaries must not be coerced into accepting an in-home appointment or enrolling into a plan in which they have indicated no interest.

B. Plan Submission and CMS Review of Marketing Materials [All Part D sponsors]

Organizations may begin submitting Contract Year (CY) 2008 marketing materials (e.g., Summary of Benefits (SB) and Annual Notice of Change (ANOC)) on June 15, 2007, in accordance with the marketing guidelines via the HPMS Marketing Module. The CMS Regional Office (RO) will review the materials and approve or disapprove, as appropriate. Organizations that do not have a final CMS contract approval will receive a "conditional approval" on marketing materials. If the materials are conditionally approved, CMS is indicating to the organization that materials are approved based on the current plan bid submission which has not yet been approved. The organization may not use conditionally approved marketing materials in the market. If materials are disapproved, the organization must revise the materials and continue to work with the regional office until it receives a conditional approval on the materials.

After CMS approves the Part D sponsor's bid, any necessary changes to the conditionally approved or approved marketing materials must be resubmitted to CMS based on the CMS approved bid/PBP. If there were no changes to the bid, the organization does not need to resubmit these marketing materials. The organization must clearly highlight only changes that result from the approved bid/PBP. This step will ensure a timely review of the final materials.

In order for an organization to be able to market its plans, it is essential that it follow the review process found in the Marketing Guidelines. If an organization fails to submit materials timely or to clearly highlight changes in the submitted materials, then it is at risk of not being able to market by October 1, 2007.

Note: If there are no changes to the bid or marketing materials from when the materials received the conditional approval, the organization need not resubmit the marketing materials. Instead, all marketing materials with a status of "conditional approval" will be changed to an "approved status" upon approval of the bid and CMS contract.

C. Expedited Review Process Reminder [All Part D sponsors]

Part D sponsors are encouraged to submit qualified marketing materials under the expedited review process. The expedited review process permits organizations to submit template materials without cost sharing information for review and approval by the regional office. The following materials qualify for an expedited review: Summary of Benefits (SB), Annual Notice of Change (ANOC), and Evidence of Coverage (EOC). This process requires organizations to populate the appropriate cost sharing and benefit information once the bid is approved. These populated materials do not require resubmission to the RO for additional approval prior to use, however organizations must submit each variation of the template to the RO through HPMS within 30 days of populating materials. Any changes or corrections that occur after the bid has been approved must be corrected in all marketing materials.

D. Annual Beneficiary Notification Materials

For CY 2008 we encourage the redesign and streamlining of the annual renewal materials to provide better, timely information for beneficiaries, reduce the demand on staff resources (CMS and health plans) and create a more efficient process. Below are the steps we are taking to redesign the renewal materials and other actions we are taking to streamline the process and ensure that people with Medicare receive timely information so that they can make confident, informed decisions about their health care options.

- Integrate the ANOC and EOC into one document which beneficiaries can receive by October 31.
- Standardize the formatting and certain sections in the EOC/ANOC. Medicare Advantage Organizations and Part D sponsors will have the flexibility to enter plan-specific text in certain sections of the document while other text will be standardized.
- Create one model ANOC/EOC with optional modules based on type of plan (e.g., Cost, PDP, PFFS, etc.)
- Utilize the streamlined marketing review process so that organizations submit the ANOC/EOC template.
- Release the annual renewal material in late spring.
- Streamline the text/content of the ANOC/EOC to reduce duplication and unnecessary information. This will be a multi-year effort to reduce redundancy, improve the clarity of material, and organize materials to help people with Medicare understand their benefits, rights, and obligations.

The redesign process for annual renewal materials is optional. PDP sponsors will have two options for the distribution of the ANOC and EOC.

Combined ANOC/EOC

PDP sponsors that choose to utilize the combined standardized process will be required to mail annual notification materials (combined ANOC/EOC) by October 31, 2007. Abridged or comprehensive formularies must be mailed in addition to the combined ANOC/EOC. In this option, the SB is only needed for pre-enrollment marketing. Organizations utilizing the

combined (standardized) ANOC/EOC should utilize the streamlined marketing review process.

Stand Alone ANOC and EOC

PDP sponsors that choose not to use the combined standardized ANOC/EOC option must mail ANOCs along with their SBs to existing members by October 31, 2007. ANOCs may be submitted as model or non-model. Additionally, PDP sponsors must send an abridged or comprehensive formulary with the ANOC and SB. Under this option, EOCs and Low Income Subsidy Riders (LIS) must be mailed by January 31, 2008.

PDP sponsors mailing the EOC separately will have the option of using the model EOC or creating a non-model EOC document. Non-model EOCs will be subject to a 45-day review period.

PDP sponsors must mail CY 2008 EOCs to new members no later than when they notify the member of acceptance (confirmation) of enrollment.

We will be releasing additional guidance regarding these changes later in 2007.

E. Plan Comparisons [All Part D sponsors]

We have received a significant negative response to the proposal in the draft Call Letter to allow plan comparisons of Medicare Advantage and prescription drug plans in a specific service area. Based on these comments, we are persuaded that it is not practical or meaningful to develop a comparison that does not include formulary drug costs and availability specific to an individual beneficiary.

F. Medicare Prescription Drug Plan Finder Data [All Part D sponsors]

1. General

On or about October 11, 2007, the CY 2008 prescription drug plan data will appear on the Medicare Prescription Drug Plan Finder (MPDPF) on Medicare.gov. The online tools are important components of our initiative to provide people with Medicare information to help make them confident, and informed about their drug plan choices. It is critical that sponsors review their information so that data submitted is not suppressed.

Online enrollment will continue to be available to MA-PD and PDP plans through MPDPF. This year, the enrollment function will be available for 2007 plans through December 2007, and for 2008 plans beginning November 15, 2007. Online enrollments must be downloaded daily.

2. Quality Checks for the Medicare Prescription Drug Plan Finder

Quality checks for data submitted to CMS for display on the MPDPF will continue to be required for contract year 2008. Guidance has already been released on HPMS that outlines the expected

quality checks that MA-PD and PDP Sponsors should routinely perform on their data both prior to submitting it to CMS and after it has been posted on the MPDPF. Modifications and additions to the quality assurance (QA) check list may be added for implementation in 2008. Failure to conduct these QA checks may result in suppression of the MA-PD and PDP Sponsor's pricing data from the website.

G. 2008 Medicare & You [All Part D sponsors]

The *Medicare & You* 2008 handbook will contain Medicare prescription drug plan comparison information. This information may be similar to the drug plan information provided in the Medicare & You 2007 handbook released last fall. Plans will be able to preview their handbook plan data September 10 through 12, 2007.

VII. ENROLLMENT [*PDP sponsors only*]

All PDP sponsors must follow the eligibility, enrollment and disenrollment requirements issued by CMS for accepting and processing beneficiary requests. CMS expects to issue the next update to the PDP enrollment and disenrollment guidance in late spring 2007.

CMS would like to take the opportunity to remind PDP sponsors of the following:

- A. *Submission of enrollment & disenrollment transactions* -- It is critical that sponsors submit transactions to CMS in a timely and efficient manner to ensure appropriate beneficiary enrollment. To this end, sponsors must submit enrollment and disenrollment transactions to CMS within 7 calendar days of receipt of complete requests, beginning with those transactions effective in 2008.
- B. *Coordination with employer and union sponsored groups* – PDP sponsors must ensure employer and union groups with whom they contract understand and abide by the Medicare rules and requirements, unless those requirements have been specifically waived or modified by CMS employer group waiver policies. Please review your current agreements with these entities to ensure that they reflect CMS' PDP enrollment and disenrollment guidance, particularly the group enrollment and disenrollment process for employer or union sponsored plans, if applicable.

VIII. LOW-INCOME SUBSIDY POLICY

Reassignment of Low-Income Subsidy Eligible Individuals: [*PDP sponsors only*]

In the fall of 2007, Medicare will again re-assign certain low income subsidy beneficiaries with full premium subsidy into new Medicare Prescription Drug Plans effective January 1, 2008, as follows:

Population	Reassignment Rules
<i>LIS-eligible enrollees who remained in their auto/facilitated assigned PDP.</i>	<p>Current PDP has premium at or below the “de minimis” amount in 2008 → Beneficiary remains in current PDP</p> <p>Current PDP has premium above the “de minimis” amount, converting to enhanced benefit, or is terminating in 2008 → Reassigned within PDP region as follows:</p> <p>1) CMS reassigns beneficiaries to another plan in the same region offered by that same PDP sponsor that offers basic prescription drug coverage and has a premium at or below the low-income benchmark amount. (If there is more than one such plan offered by the same PDP sponsor, CMS will randomly assign beneficiaries among these plans.)</p> <p>2) If no such plan exists → CMS reassigns beneficiaries randomly among PDP sponsors with at least one plan in the same region that offers basic prescription drug coverage and has a premium at or below the low-income benchmark amount.</p>
<i>LIS-eligible enrollees who elected a plan other than the one to which they were auto-assigned.</i>	Beneficiaries remain in current, chosen plan regardless of change in premium amount; informed of other plan options in ANOC sent from his/her current plan.
<i>Enrollees who were LIS eligible in 2007, but are no longer eligible in 2008; will only be eligible for partial premium subsidy (25-75%) in 2008; or are LIS-eligible enrollees in MA Plans, Cost Plans, Employer-Sponsored Plans, Program of All Inclusive Care for the Elderly (PACE) organizations, or PDPs in U.S. territories.</i>	Beneficiaries remain in current plan regardless of change in premium amount; informed of other plan options in ANOC sent from his/her current plan.

* Basic benefit package -- includes defined standard, actuarially equivalent standard, or basic alternative; it does not include enhanced alternative benefit packages, even if the premium is below the low-income premium subsidy amount.

Policy for Individuals Claimed for Retiree Drug Subsidy (RDS) [PDP sponsors only]

In order to minimize the disruption of prescription drug and other benefits provided to full-benefit dual eligibles (FBDE) who have other coverage through a retiree drug subsidy (RDS) plan, CMS will modify the process of auto-enrolling these individuals into PDPs. CMS will still create an auto-enrollment transaction, but will utilize the process used for others with RDS (see section 10.4 of the PDP enrollment and disenrollment guidance). Only when the beneficiary confirms will the PDP re-submit the transaction with the RDS override.

Refining CMS' State Pharmaceutical Assistance Program (SPAP) Non-Discrimination Policy [All Part D sponsors]

In order to promote collaborative partnerships between Part D plans and SPAPs with respect to coordinating benefits, we are further clarifying our SPAP non-discrimination policy. Leading up to, and including this benefit year, CMS has issued guidance taking a fairly narrow view with respect to the SPAP non-discrimination provisions found in section 1860D-23 of the Social Security Act based on preventing SPAPs from steering their beneficiaries into a preferred plan or plans. We described acceptable approaches in our Qualified SPAP Guidelines and Coordination of Benefit (COB) Guidelines (now Chapter 14 of the Part D manual) that would not result in violation of the non-discrimination provisions of the Act. We generally have required SPAPs to provide wrap-around benefits to their beneficiaries regardless of the Part D plan the beneficiary chooses to enroll in¹, and we permitted SPAPs (when acting as authorized representatives) to enroll their beneficiaries in Part D plans using only beneficiary-specific criteria to limit the selection of Part D plans. Our policy goal has been aimed at ensuring qualified SPAP coverage does not either steer a beneficiary towards a preferred plan, thus unduly limiting the beneficiary's choice of Part D coverage, or otherwise adversely impact the competitive nature Congress intended for the Part D program, thus limiting the number of plans available for beneficiary choice.

During 2006, we saw SPAPs and Part D sponsors work collaboratively to facilitate the transition of SPAP beneficiaries to Part D plans. We observed requests for proposals (RFPs) that set forth reasonable coordination criteria in order for the Part D plan to qualify for beneficiary level evaluation and assignment. These criteria were deemed to be in accordance with CMS enrollment rules as they were sufficiently broad to allow all plans to meet them. For instance, participating plans agreed to add network pharmacies or formulary drugs, or provide administrative services such as exchange of claims data, enrollment information, and quarterly Medication Therapy Management (MTM) Program reports. In other instances, plans also agreed

¹ Note that SPAPs may limit wrap-around benefits to beneficiaries joining certain plans if they choose to administer their wrap-around benefits in the form of a "lump-sum" methodology, in accordance with the guidance provided in Chapter 14 of the Part D manual. If the SPAP chooses to administer its wrap-around benefits in the form of secondary coverage at the point-of-sale, it must do so for all beneficiaries regardless of their primary Part D coverage plan.

to offer a 90-day transition period for current prescriptions² and access to dedicated customer service lines.

Based on the experience of 2006, in which the market moved Part D plans to work with SPAPs in order to ease the transition of SPAP beneficiaries into the Part D benefit, we are clarifying our policy to explicitly permit states to adopt reasonable coordinating criteria that will allow the SPAPs and plans to provide quality coordination of care and benefits in the interest of our beneficiaries. This approach will allow SPAPs with authorized representative status to facilitate enrollment of their beneficiaries into plans that agree to the state specific coordination criteria, like offering similar formulary and pharmacy network structures and sharing historical claims data. CMS will require any such coordinating criteria to be of the sort that any Part D plan could meet if it so chose, consistent with all other Part D rules. We will not permit SPAPs to specify coordinating criteria of the sort that would be difficult for plans to meet. We believe such burdensome coordinating criteria would result in a narrow pool of preferred Part D plans into which the SPAP (when acting as its beneficiaries' authorized representative) would enroll its beneficiaries, in violation of the SPAP non-discrimination requirement. In other words, SPAPs may not implement burdensome coordinating criteria that in effect would result in the SPAP steering its beneficiaries into a preferred plan or plans.

In addition, consistent with the SPAP non-discrimination requirement, the SPAP must permit its beneficiaries wishing to enroll in a Part D plan that does not meet the SPAP's coordinating criteria to do so, and must provide these beneficiaries the same SPAP wrap-around benefits or assistance. In other words, this policy recognizes a distinction between (1) the SPAP's ability to establish reasonable coordinating criteria for purposes of acting as the beneficiary's authorized representative in enrollment decisions, and (2) the SPAPs obligation to provide wrap-around benefits to any of its beneficiaries regardless of the Part D plan elected. An SPAP that fails to provide such benefits to its beneficiaries electing to enroll in a Part D plan not meeting the coordinating criteria will not meet the requirements to be a qualified SPAP, as specified in § 42 CFR 423.464(e).

We will issue further instructions for SPAPs on submitting their coordinating criteria and enrollment methodologies for CMS review to ensure these conditions are met. The timeframe for this submittal must be no later than August in order for SPAPs to receive approval of these plans in time for issuance of RFPs as soon as Part D plans have been announced for the next coverage year. For coverage year 2008, all SPAPs wishing to implement coordinating criteria as a prerequisite for enrollment methodologies may submit their coordinating criteria as early as desired, but no later than August 1, 2007. For future coverage years, SPAPs must either inform CMS that their program will be operating without changes for the next coverage year, or would submit revised methodologies for CMS approval by August 1.

CMS will review each state's coordinating criteria in a timely manner and will determine if the state's criteria are (1) reasonably related to the SPAP's objective of ensuring quality coordination of care and benefits, (2) not unduly burdensome for plans, and (3) consistent with Part D

² Any change made to a Part D plan's benefit design to satisfy the SPAP's coordinating criteria must be applied uniformly to all plan enrollees, e.g. a change to the transition policy must be applied to all beneficiaries, not just SPAP beneficiaries.

requirements. In other words, CMS will review the state's criteria to ensure that Part D plans could meet the criteria if they chose to (e.g., by adding drugs or pharmacies to its network, or submitting claims and enrollment data to the SPAP) without violating any Part D requirements, such as the uniform benefit requirement. States would only need to submit their coordinating criteria once for CMS review, unless the criteria are changed. After CMS' review and approval, SPAPs must announce, via their standard public process, their RFPs from the plans in response to the state-defined coordination criteria. All Part D plans in the state's region must have sufficient notice and opportunity to submit proposals to the state.

IX. GRIEVANCES/COVERAGE DETERMINATIONS, AND APPEALS

Prescription Drug Benefit Manual Guidance for Part D Plan Sponsors [All Part D sponsors]

CMS has developed guidance in [Chapter 18 of the Prescription Drug Benefit Manual](#) regarding a Part D plan sponsor's responsibilities concerning Part D grievances, coverage determinations, and appeals. Additionally, the independent review entity (IRE) responsible for performing Part D reconsiderations (MAXIMUS) developed the [Part D Qualified Independent Contractor \(QIC\) Reconsideration Procedures Manual](#), which contains additional guidance concerning how Part D plan sponsors must coordinate with the Part D IRE to assist it in processing Part D reconsiderations and conducting related reconsideration activities. Part D plan sponsors must develop Part D grievance, coverage determination, and appeals procedures in accordance with the guidance contained in Chapter 18 of the Prescription Drug Benefit Manual and the Part D QIC Reconsideration Procedures Manual.

X. CLAIMS PROCESSING

Transition Period for Plan-to-Plan Reconciliation [All Part D sponsors]

In Phase I of the Plan-to-Plan Reconciliation Process, PDE data were accepted for any dates of service January 1 through April 30, 2006. Phase II extends the reconciliation process between Part D plans to claims incurred after April 30, 2006. With the resolution of most of the start-up issues from early 2006, we believe that, in most instances, plans will be notified of beneficiary disenrollments before the effective date of the beneficiary's enrollment in a new plan. However, because beneficiaries have the opportunity to change plans throughout the month and lags are associated with the enrollment process as well as information system updates, there will continue to be instances in which a plan continues to pay for covered prescription drug costs incurred after the effective date of a disenrollment.

Using the authority established under §423.464(a) of the Part D regulations, CMS is establishing the following transition period for Phase II to permit the coordination of benefits between the disenrolling plan and the new (enrolling) plan in a fair and equitable manner. Under our Phase II transition policy, the effective ending date of the minimum required transition period occurs on the later of:

- 30 days after the effective date of coverage, or

- 30 days after the new plan of record submits the enrollment to CMS and it is processed by CMS.

Plan-to-Plan Reconciliation will continue in 2008 to support the coordination of benefits between Part D plans when a beneficiary changes plan enrollment during the coverage year. To ensure all sponsors understand the importance of the Plan-to-Plan reconciliation process and our associated transition policy, we are reiterating the rules in this call letter.

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 2007, the Part D COB user fee was \$1.36 per enrollee per year. Upon review of the anticipated costs of COB activities in 2008, the Part D COB user fee will remain at \$1.36 per enrollee per year for contract year 2008. This COB user fee will be collected at a rate of \$0.15 per enrollee per month from January to August and \$0.16 per enrollee per month will be collected in September for a total user fee of \$1.36 per enrollee per year in contract year 2008. Part D sponsors should account for this COB user fee when developing their 2008 bids.

XI. SYSTEMS/HPMS

Using HPMS to Submit Bids and Formularies *[All Part D sponsors]*

Part D Sponsors will use HPMS to electronically upload plan formularies and bids to CMS. Part D Sponsors will upload their plan formularies to HPMS using a pre-defined file format and record layout. HPMS will begin accepting plan formulary uploads on March 26, 2007. Part D Sponsors may upload their formularies one or more times between March 26, 2007 and the formulary deadline of **5:00 p.m. EDT on April 16, 2007**. CMS will accept the last successful upload of each formulary received by this deadline as the official submission.

In order to prepare plan bids, Part D Sponsors will use HPMS to define their plan structures and associated plan service areas and then download the PBP and BPT software. For each plan being offered, Part D Sponsors will use the PBP software to describe the detailed structure of their benefit packages and the BPT software to define their bid pricing information. Each formulary submitted by April 16, 2007 must accurately crosswalk to a plan (or set of plans) defined during the bid process. The combination of the PBP and BPT for a plan comprises a bid.

Once the PBP and BPT software have been completed for each plan being offered, Part D Sponsors will upload their bids to HPMS. CMS anticipates releasing the PBP and BPT bid upload functionality on **May 18, 2007**. Part D Sponsors may upload their plan bids one or more times between May 18, 2007, and the CY 2008 bid deadline of **11:59 midnight PDT on June 4, 2007**. CMS will accept the last successful bid upload received for a plan by this deadline as the official bid submission for that plan.

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

Instructions for Obtaining HPMS Access [All Part D sponsors]

Part D Sponsors have two alternatives for accessing HPMS:

- Internet access via a Secure Socket Layer Virtual Private Network (SSL VPN); or
- Medicare Data Communications Network (MDCN) access using either a T-1 lease line or dial-up account with AT&T.

Internet users via the SSL VPN will access HPMS at <https://gateway.cms.hhs.gov>, whereas MDCN users will use <https://32.90.191.19>. Both methods require the use of a Microsoft Internet Explorer web browser and a CMS-issued user ID and password with access to HPMS.

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

Additional HPMS Contacts [All Part D sponsors]

General HPMS Information: Kristin Finch, 410-786-2873; Sara Walters 410-786-3330.

HPMS Help Desk: 1-800-220-2028 or hpms@cms.hhs.gov

HPMS Connectivity, User IDs and Passwords: Don Freeburger, 410-786-4586

HPMS Plan Crosswalk: Greg Buglio, 410-786-6562

Transferring TrOOP Balance When a Beneficiary Changes Part D Plans [All Part D sponsors]

Currently, the process used to facilitate the required coordination of benefits between plans, and the plan-to-plan transfer of true out-of-pocket (TrOOP) and gross covered drug costs for beneficiaries transferring between plans, is the TrOOP balance transfer or explanation of benefits (EOB) transfer process. In this process, when a plan receives a disenrollment transaction reply report (TRR) indicating that a member has disenrolled, the disenrolling plan must create a special transfer EOB. The transfer EOB must contain information concerning the beneficiary's TrOOP balance and gross covered drug costs and must be sent to the new plan of record within seven days of the date of the disenrollment TRR.

In 2008, CMS will be moving to an automated process for the transfer of TrOOP-related data when beneficiaries transfer between plans during the coverage year. Details on the automated process will follow the call letter. However, we anticipate that implementation of the automated process will require that Part D sponsors develop the systems capability to receive and respond

to real-time (or batch) transactions requesting TrOOP-related data for disenrolling Part D beneficiaries as well to receive these data for newly enrolling Part D beneficiaries transferring mid-year from another plan. As the process is envisioned, these transactions will involve new messaging that sponsors must receive and process. Part D sponsors will also need to develop the capacity to integrate data received via these electronic transactions into those systems that track and apply beneficiary-level TrOOP and gross covered drug costs. CMS is cognizant of the need to provide timely information on the new process and sufficient lead time for implementation. As the automated process is developed, CMS will be providing further details on the process and will be requesting that Part D sponsors participate in its testing and implementation.

XII. COMPLIANCE/MONITORING

2008 Reporting Requirements [All Part D sponsors]

To ensure that Part D sponsors continue to provide beneficiaries high value health care, we will continue to require sponsors to submit plan-reported data according to our reporting requirements document. Changes and enhancements will be reflected in the CY 2008 reporting requirements document. The document is projected to be released upon OMB's grant of final approval. The following changes are anticipated from the CY2007 Reporting Requirements:

- The LTC rebates may be requested to be submitted at the National Drug Code (NDC) level. *(This will allow sponsors to distinguish among the different dosage forms or routes of administration for the drugs receiving rebates.)*
- The drug benefit analysis data will be required to be submitted monthly. In addition, this information will need to be reported separately for both LIS and non-LIS enrollees. *(This will allow CMS to receive more timely information about where beneficiaries are in the benefit.)*
- The MTM section will be expanded to require Part D sponsors to submit for CMS review a file with beneficiary specific information for all individuals identified as meeting their criteria for the MTM program. In addition, pursuant to § 1860D-21(d)(3), MA private fee-for-service (PFFS) organizations as described in 42 CFR §422.4(a)(3) are not subject to the MTM program requirement. However, MA-PFFS organizations have an equal responsibility to provide a quality Part D product. Therefore, CMS encourages MA-PFFS organizations to establish an MTM program to improve quality for their Medicare beneficiaries. *(Beneficiary-specific information will allow CMS to validate that those individuals identified actually meet MTM requirements.)*
- There will be a new section on vaccine administration. Data elements that may be requested include, but are not limited to: The total number of vaccine administration charges adjudicated and the method of adjudication including those vaccines administered through standard out-of-network access, in-network pharmacies (where the pharmacy does and does not administer the vaccine), a paper enhanced process (where the provider used or navigated a process that facilitated standard out-of-network access), an internet based web tool, or other process. *(CMS will use this information to develop aggregate data on vaccine administration methods used by sponsors.)*
- There will be a new section on pharmacy access. We are looking for plans to run their access standard tests on their pharmacy networks at least twice a year and attest that the networks

meet access requirements. Plan sponsors will be required to submit data on the percent of beneficiaries who meet the Tricare standards for the urban, suburban, and rural settings. Sponsors may also be requested to report their organizations' contracted home-infusion and LTC pharmacy lists. In addition, information will be requested on the number of contracted pharmacies (separately for retail, LTC, and home infusion) at the beginning of a reporting period, the number of pharmacies that are newly contracted in the period, the number of pharmacies terminated in the period, and the number of pharmacies contracted at the end of the period. *(These data will provide CMS a mechanism for ensuring sponsors' continuing compliance with Part D pharmacy access requirements.)*

- There will be a new section on home infusion. We will be looking for the number of beneficiaries receiving home infusion drugs and services and the number of home infusion doses dispensed. *(These data will help CMS analyze whether sponsors are affording their enrollees appropriate and adequate home infusion pharmacy access)*
- There will be a new section on COB. We will be looking for the number of supplemental payer claims transactions post point-of-sale. *(These data will help CMS ensure that sponsors are using the TrOOP facilitator to conduct coordination of benefits at the point of sale, according to CMS guidance.)*

Part D sponsors will be expected to comply with any other requests by CMS for additional data necessary to support payment, program integrity, program management, and quality improvement activities under Part D.

Compliance Procedures [All Part D sponsors]

We are considering revisions to our current procedures concerning contract determinations, intermediate sanctions, and CMPs. We anticipate that the revisions will be final in late 2007. We will outline implementation dates for specific provisions at that time.

Long Term Risk Assessment Strategy [All Part D sponsors]

Due to the large number of entities participating in CMS' Medicare Advantage and Part D programs, the Agency must maximize its resources to operate an effective Medicare oversight program. To that effect, CMS is currently developing a risk assessment tool which will assist us in identifying Part D sponsors that are at high risk of program non-compliance. CMS will redirect its limited resources to conduct audits on those high risk contracts. We envision that this revised oversight program will include a mostly centralized data-driven program, fueled by data provided by contractors and beneficiaries. While receipt and analysis of data is central to this oversight strategy, regularly scheduled and focused/targeted program compliance and program integrity audits will be necessary to ensure program compliance and document the Agency's program oversight responsibilities. CMS anticipates the risk assessment tool to be ready for implementation and use in January 2008.

Report Card/ Quality and Performance Metrics [All Part D sponsors]

CMS will be developing a comprehensive Part D report card that incorporates new quality measures and enhancements to the current performance metrics on the MPDPF.

The new areas of the proposed measures may include, but are not limited to, the following: MTM services, prescription drug utilization, patient safety, disenrollment, and member satisfaction. The measures to be included as part of the report card will come from multiple data sources, most of which are already currently collected by CMS. Plans will continue to have the opportunity to preview their own data in HPMS prior to the public release of these data.

Audit Timeframes [All Part D sponsors]

Beginning in CY 2008, CMS will be able to reopen an audit within 10 days of the exit conference. Reopening an audit will be based on information obtained during the audit but not actually audited prior to the exit conference. This will result in a more comprehensive audit to ensure continued compliance in CMS programs.

In addition, for both the remaining contract year 2007 and in 2008, while CMS would hope to provide sponsors up to 8 weeks prior notice for comprehensive audits, CMS is not always able to do so and reserves the right to audit with less notice. We anticipate that many of the remaining focused audits scheduled for 2007 will routinely occur with only 2 weeks notice.

XIII. LICENSURE AND SOLVENCY

General [PDP sponsors only]

Sponsors continue to be required to promptly report to CMS if they are placed under some type of supervision, corrective action plan or special monitoring by the State licensing authority in any State.

Sponsors with any State licensure waivers are required to continue to actively pursue licensure in any State for which CMS has granted a waiver of the licensure requirements, and to notify CMS as soon as a State license is obtained.

Sponsors with CMS-approved licensure waivers that are not licensed in any state must continue to meet CMS' Federal Solvency Standards and must notify CMS when licensure has been obtained in at least one state.

Licensure Waiver Grounds [PDP sponsors only]

Beginning in the 2008 contract year, CMS can no longer grant "special waivers" of the risk bearing license requirement pursuant to section 1860D-12(c)(2)(B)(ii) and the regulations at 42 CFR §423.410(d). Sponsors currently operating under special waivers must obtain risk bearing licenses in all the States in which they offer a Part D benefit prior to the expiration of the three-year term of the special waiver. CMS may grant new licensure waivers to these organizations based on the criteria described below, but only upon a sponsor's application and qualification for such a waiver. CMS does not have the authority to extend the term of a "special waiver."

In order for CMS to grant a state licensure waiver pursuant to section 1860D-12(c)(2)(A) of the Act and 42 CFR §423.410(b), the waiver applicant must demonstrate that by the time the waiver application is submitted to CMS, either:

- 1) The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application (States must confirm "the receipt and completeness of the application" which is necessary to establish that the 90-day period has been met.); or
- 2) The State has denied the license application for one of the reasons specified in 42 CFR §423.410(b)(2) through (b)(4).

Expiring Licensure Waivers [PDP sponsors only]

Sponsors that have licensure waivers which expire on December 31, 2008, and that have not obtained licenses before the annual CMS renewal notice deadline stated in the Part D regulations will be notified at that time that their contracts will not be renewed for 2009 for any regions that include states for which a license is not held (42 CFR 423.507(b)(2)(i), 423.642(d)). CMS will also inform these sponsors that they should begin to prepare to issue notices to beneficiaries, the public and network providers by October 1, 2008.

CMS fully expects that all waived organizations (with rare exceptions) will be operating under State risk bearing licenses by January 1, 2009. By that time, States will have had sufficient time to adopt requirements for stand-alone prescription drug plan products and also sponsors will have had time to meet those requirements. CMS has worked closely with both sponsors and the States to address any licensure-related issues brought to our attention. For those applicants whose waivers expire on December 31, 2008, it is imperative that both the State and the applicant (sponsor) be actively engaged in determining the current status of any outstanding application requirements. CMS will be closely monitoring each sponsor's progress in obtaining licensure during the upcoming months.

Specific reporting requirements and deadlines related to the sponsor's actions taken to obtain state licensure are specified in Attachment B. Each sponsor must submit to CMS by May 15, 2007 confirmation from each State for which its licensure waiver will expire in 2008 indicating that the State is in possession of a substantially complete application and expects to be able to approve or disapprove the application before April 1, 2008. Alternatively, the State provides the earliest date on which it will accept an application if seasoning is an issue. Sponsors must also report this information to CMS by August 15, 2007, and by December 1, 2007.

In situations where the state cannot approve a license before the waiver expires because of state requirements that are beyond the sponsor's ability to meet (e.g., a "seasoning" requirement or the need for a state to conduct an audit report and the state has not scheduled an audit), CMS will allow the sponsor to apply for a new waiver, based on the grounds available to an applicant in March 2008. To qualify for such a waiver, the sponsor will need to submit a new license application to the state before December 1, 2007. If the sponsor has contributed to the state's

inability to approve the license application submitted to a state during the original licensure waiver period, then a new CMS waiver will not be granted.

XIV. SECURITY AND PRIVACY STANDARDS

Sponsor activities performed outside the United States [All Part D sponsors]

Assuring security is of critical concern to CMS, including sponsor's use of contractors operating outside the United States. As a result, CMS is adopting a policy under which Part D sponsors will be required to account for how they have ensured that personally identifiable information will be handled outside the United States in a manner consistent with the federal information security and privacy requirements.

CMS will require Part D sponsors, beginning in 2008, to obtain prior CMS written approval of any subcontracts the sponsor enters into for the performance of any activities under its Part D contract. In making a decision to authorize the performance of work outside of the United States, CMS will consider the following factors, including but not limited to:

- The Applicant's/subcontractor's compliance with, and the enforceability of, Part D program requirements concerning system security;
- The Applicant's/subcontractor's compliance with and the enforceability of, Part D program requirements concerning information and data confidentiality and privacy;
- The Applicant's/subcontractor's compliance with, and the enforceability of, other relevant Part D program requirements;
- The Applicant's/subcontractor's compliance with, and the enforceability of, Part D corporate compliance plan requirements;
- The Applicant's/subcontractor's compliance with, and enforceability of all laws and regulations applicable to work performed outside of the United States; and
- The performance the work outside of the United States is in the best interests of the United States.

CMS will issue further guidance on this requirement, including the process for submitting subcontracting information to CMS for review, later in 2007.

Securing Electronic Protected Health Data through Encryption and other Means [All Part D sponsors]

With the heightened state of awareness nationwide concerning privacy breaches and security violations, and in an effort to ensure security of Medicare and Medicaid data, we are taking actions toward minimizing plan's security risk. Plans are covered entities bound by the **Health Insurance Portability and Accountability Act** of 1996 (HIPAA, Title II). The HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information (EPHI) addresses some of the ways a covered entity may protect EPHI when it is accessed or used outside of the organization's physical purview. The guidance states covered entities should be extremely cautious about allowing the offsite use of, or access to EPHI. There may be

situations that warrant such offsite use or access, e.g., when it is clearly determined necessary through the entity's business case(s), and then only where great rigor has been taken to ensure that policies, procedures, and workforce training have been effectively deployed, and access is provided consistent with the applicable requirements of the HIPAA Privacy Rule.

There have been a number of security incidents related to the use of laptops, other portable and/or mobile devices and external hardware that store, contain or are used to access Electronic Protected Health Information (EPHI) under the responsibility of a HIPAA covered entity. All covered entities are required to be in compliance with the HIPAA Security Rule, which includes, among its requirements, reviewing and modifying, where necessary, security policies and procedures on a regular basis. This is particularly relevant for organizations that allow remote access to EPHI through portable devices or on external systems or hardware not owned or managed by the covered entity. The kinds of devices and tools about which there is growing concern because of their vulnerability, include the following examples: laptops; home-based personal computers; PDAs and Smart Phones; hotel, library, or other public workstations and Wireless Access Points (WAPs); USB Flash Drives and Memory Cards; floppy disks; CDs; DVDs; backup media; Email; Smart cards; Remote Access Devices (including security hardware).

Due to the overwhelming need to manage data protection and endpoint security solutions, we now require plans to encrypt all hard drives or other storage media within the device as well as all removable media. In addition, plans must develop and implement a policy addressing the handling of portable media that is accessed or used outside of the organization's physical purview. The Centers for Medicare and Medicaid Services HIPAA Security Guidance dated December 28, 2006 is a great resource for possible risks and risk management strategies accessing, storing, and transmitting EPHI and recommended for plan use.

XV. PDP RENEWAL/NON-RENEWAL PROCESS

There has been no change in these policies, but CMS wants to remind sponsors of some important points concerning the contract renewal and non-renewal process for CY 2008.

CMS Renewal Notice to PDP Sponsors [PDP sponsors only]

As required in our regulations, CMS will issue contract renewal notices on or before May 1, 2007 to those sponsors we have determined, based on information available at that time, to continue to be qualified to hold a contract during 2008. PDP sponsors are not required to apply for a contract renewal as CMS will make the determination based on an evaluation of each sponsor's compliance with its contract.

The renewal notices will indicate that the sponsor is qualified to operate a PDP during 2008, but that CMS cannot renew the contract with any entity for 2008 unless the sponsor receives CMS approval of the bids and benefits it submits by June 4, 2007.

PDP Sponsor Notice to CMS [PDP sponsors only]

PDP sponsors that elect to non-renew their contract for 2008 must notify CMS of their decision in writing by June 4, 2007. PDP sponsors that submit neither a 2008 bid nor a notice of non-renewal by June 4, 2007, will be considered by CMS to have non-renewed their PDP sponsor contracts. Please keep in mind that failure to meet either of these criteria (non-renewal notice or bid submission) will result in being considered a de facto non-renewal by the sponsor and thus will trigger the requirements at 42 CFR §§423.507(a)(2)(ii) and (iii), (a)(3) and (a)(4).

Non-Renewal of All Plans in a PDP Region [PDP sponsors only]

PDP sponsors that renew their PDP sponsor contract but elect not to offer any plans in a given PDP region must provide notice to CMS, enrollees residing in the affected region(s), and the general public in the region(s) on the same schedule and in the same manner as required of PDP sponsors that non-renew their contracts.

XVI. EMPLOYER AND UNION-SPONSORED GROUP PLANS

I. Employer/Union-Sponsored Group Plans [PDP sponsors only]

Employer and union group plan sponsors may choose to enroll their members in individual PDPs open to general enrollment (“mixed enrollment” plans). They may also elect to work with PDP sponsors that offer or administer employer-only customized group plans. These kinds of customized employer group plans offered by PDPs are frequently referred to as “800 series” plans because of the way they are enumerated in HPMS which distinguishes them from individual PBPs. Employers and unions also may choose to directly contract with CMS to offer these kinds of customized group benefits to their members (hereinafter referred to as “Direct Contract” plans). These “800 series” and Direct Contract employer group plans are referred to collectively as employer/union-only group waiver plans (“EGWPs”).

The following highlights important differences in the 2008 contract year for PDP sponsors offering employer or union-sponsored group plans and/or clarifications on certain topics.

Elimination of “Nexus” Test Requirements [PDP sponsors only]

For contract years 2006 and 2007, CMS employer group waiver policy requires PDP sponsors to offer plans to individual Medicare beneficiaries as a condition of being able to offer employer/union-only group waiver plans (i.e., “800 series” plans) associated with the same contract. Also, during 2006 and 2007, if individual coverage is offered in the service area where the most substantial portion of an employer’s employees reside, PDP sponsors may extend coverage in “800 series” plans to the employer’s retirees in other service areas. (This service area extension policy is commonly known as the “nexus test.”).

Beginning with the 2008 contract year, PDP sponsors are not required to offer plans to individual beneficiaries as a condition of offering “800 series” plans. This change includes the elimination of the “nexus” test.

The changes described above will apply to PDP sponsors renewing “800 series” PBPs in 2008, as well as to those PDP sponsors offering “800 series” plans for the first time in 2008. Notwithstanding these changes, entities offering these plans will continue to have to meet all CMS requirements that are not otherwise waived or modified, including the requirement to be licensed as a risk bearing entity eligible to offer health insurance or health benefits. For entities that choose to only offer “800 series” plans for a particular PDP contract, this requirement will be met if the entity is licensed in at least one state.

Please remember that PDPs that wish to utilize this new waiver policy to only offer “800 series” plans and wish to enroll/cover retirees wherever they reside must set national service areas. With regard to providing sufficient Part D pharmacy access throughout the plan’s service area, networks to cover these retirees must be in place prior to enrolling retirees.

Marketing/Beneficiary Communications [PDP sponsors only]

Customizing Medicare Dissemination Materials

In order to meet the requirements of 42 CFR 423.128(a)(2), which require a Part D sponsor to disclose information about the plan in a clear and accurate form, PDP sponsors should provide customized marketing/dissemination materials to “800 series” and Direct Contract plan enrollees to reflect the modified/supplemental benefits being provided to that particular employer or union group. More specifically, CMS has waived any rules that would otherwise prohibit these entities from offering customized dissemination materials to the extent those customized materials will more clearly and accurately describe the benefits available to employer group members when the supplemental coverage is taken into account. Please note that this waiver includes those instances where a PDP sponsor offers an employer or union group plan sponsor the ability to cover its retirees using an individual (“mixed enrollment”) plan and a supplemental non-Medicare plan designed to “wrap around” or enhance the individual Medicare plan.

With regard to premium amounts (including premium amounts for low-income premium subsidy eligible individuals) that are required to be accurately reflected on any customized beneficiary dissemination materials (e.g. Evidence of Coverage, Low-Income Premium Subsidy Rider), PDP sponsors should ensure these materials accurately reflect the actual premium amount the beneficiary pays when the supplemental coverage and any corresponding employer or union premium subsidization is taken into account. Alternatively, if accurate premium information concerning the amount the beneficiary actual pays is not available to the PDP sponsor, the PDP sponsor may substitute language such as he following in lieu of providing actual premium amounts: “For information concerning the actual premiums you will pay for this customized coverage (taking into account any supplemental coverage and/or subsidization of premiums provided by your employer, [insert employer name], please directly contact your group benefit plan administrator.”

All customized employer group materials are not required to be submitted for review and approval by CMS prior to use. However, they must be submitted to CMS as informational copies at the time of use in accordance with the procedures outlined in Chapter 13 of the Medicare Marketing Guidelines (none of these customized materials should be submitted

through HPMS). CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. Please note that the waiver of the prior review and approval of these customized employer group materials and the requirement to provide informational copies to CMS at the time of use also will apply to PDP sponsors that offer an individual Medicare plan and a supplemental non-Medicare plan designed to “wrap around” or enhance the individual Medicare plan.

Renewals/Non-Renewals [PDP sponsors only]

All EGWPs (Direct Contract and “800 series” plans) are subject to the same renewal and non-renewal process as for non-group plans. PDP sponsors offering 2007 plans that elect to non-renew individual plans in 2008 because of the elimination of the “nexus test” will receive further instructions concerning the non-renewal process, if more specific instructions are determined necessary.

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Attachment A — CY 2008 Guidance for Medicare Advantage and Medicare Advantage-Prescription Drug Plan Renewals

CY 2008 Guidance for MA and MA-PD Plan Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	Beneficiary Notification
1	New Plan Added	An MA organization creates a new plan benefit package.	A new 2008 plan with no link to a 2007 plan.	The MA organization must submit election transactions for 2008.	Beneficiaries are required to complete an enrollment request.	
2	Renewal Plan	An MA organization continues to offer a CY 2007 MA plan in CY 2008 and retains all of the same service area. The same plan ID number must be retained in order for all currently enrolled beneficiaries to remain in the same MA plan in CY 2008.	A 2008 plan that links to a 2007 plan and retains all of its plan service area from 2007.	The renewal plan ID must remain the same so that beneficiaries will remain in the same plan ID. The MA organization does not submit any transactions.	Current plan members do not need to take any action.	Beneficiaries are sent a regular ANOC.
3	Consolidated Renewal Plan	An MA organization combines two or more MA plans offered in CY 2007 into a single renewal plan so that all beneficiaries in the combined plans are offered the same benefits in CY 2008. The MA organization must designate which of the renewal plan IDs will be retained in CY 2008 after consolidation. Note: If an MA organization reduces a service area while performing this activity, the MA organization must follow the Renewal Plan with SAR rules for handling beneficiaries in the reduced service area.	Two or more 2007 plans that consolidate into one 2008 plan.	The MA organizations designated renewal plan ID must remain the same so that CMS can consolidate the beneficiary elections by moving them into the designated renewal plan ID. The MA organization does not submit any transactions.	New enrollment Current plan members do not need to take any action.	Beneficiaries are sent a regular ANOC.
4	Renewal Plan with an SAE	An MA organization continues to offer a CY 2007 MA plan in CY 2008 and retains all of the same plan service area, but also adds one or more new service areas. The same plan ID number must be retained in order for all currently enrolled beneficiaries to remain in the same MA plan in CY 2008. This option is available to local MA plans only.	A 2008 plan that links to a 2007 plan and retains all of its plan service area from 2007, but also adds one or more new service areas.	The renewal plan ID must remain the same so that beneficiaries in the current service area will remain in the same plan ID. The MA organization does not submit any transactions for these members.	Current plan members do not need to take any action.	Current beneficiaries are sent a regular ANOC.

CY 2008 Guidance for MA and MA-PD Plan Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	Beneficiary Notification
5	Renewal Plan with a SAR	<p>An MA organization <i>reduces the service area</i> of a CY 2007 MA plan and makes the reduced area part of a new or renewal MA plan service area in CY 2008. The MA organization must offer passive elections in CY 2008 to all of the current enrollees who reside in the reduced service area.</p> <p>This option is available to local MA plans only.</p> <p>*Note: When the reduced service area is not contained in another MA plan (i.e., contract-level SAR), the MA organization must submit transactions to disenroll the beneficiaries from the plan. Beneficiaries are sent a termination notice and receive guaranteed issue Medigap rights. To enroll in a different MA plan, these beneficiaries must complete an enrollment form. The model modified ANOC will be available on the CMS website: by June 1, 2007.</p>	A 2008 plan that links to a 2007 plan and retains only a portion of its plan service area.	<p>The renewal plan ID must remain the same so that beneficiaries in the renewal portion of the service area will remain in the same plan ID. The MA organization does not submit any transactions for these members.</p> <p>When the reduced service area is contained in another plan, the MA organization must submit transactions to passively enroll the beneficiaries into this other plan.</p>	Beneficiaries in the renewal portion need do nothing. Beneficiaries impacted by the plan SAR will receive information on how their enrollment into the new plan offered by the organization will occur.	Beneficiaries continuing in the same plan that were not impacted by the SAR are sent a regular ANOC. Beneficiaries impacted by the plan SAR are sent a modified ANOC, which will explain their enrollment in the new plan (passive enrollment) and receive guaranteed issue Medigap rights.
6	Renewal Plan Split Based on Provider Groups	<p>One CY 2007 MA plan splits into two or more CY 2008 MA plans in order to reflect the beneficiary's provider group choice. Both CY 2008 MA plans must have the same service area. The CY 2007 MA plan ID must be designated as the renewal plan in CY 2008. Provider-specific plan splits require prior approval from CMS.</p> <p>MA organizations wishing to offer provider-specific plans effective January 1, 2008 must submit their formal requests to their CMS Regional Office plan managers with a CC to their Central Office plan manager no later than May 7, 2007. CMS will review such requests on a case-by-case basis and make its determination based upon information that the MA organization submits as part of its proposal. For further information and format requirements, refer to the Health Plans section of the CMS website.</p>	Two or more 2008 plans that are created from one 2007 plan with membership determined by provider choice.	<p>No enrollment transactions will be required for beneficiaries whose appropriate plan based on provider group choice is the renewal plan ID.</p> <p>The MA organization must submit transactions to enroll beneficiaries associated with the other provider group(s).</p>	Beneficiaries in the renewal plan need do nothing. Beneficiaries who will be associated with the other provider group(s) and associated plan will receive information on how their enrollment into the new plan offered by the organization will occur.	Beneficiaries continuing in the renewal plan receive the regular ANOC. Beneficiaries offered passive elections into the new plan are sent the regular ANOC with special instructions.

CY 2008 Guidance for MA and MA-PD Plan Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	Beneficiary Notification
7	Terminated Plan	An MA organization terminates the offering a plan benefit package.	A 2007 plan that is no longer offered in 2008.	If the beneficiary elects to enroll in another plan with the same organization, the MA organization must submit transactions to enroll the beneficiary in another plan with the organization; CMS disenrolls beneficiaries to FFS who do not elect another plan with the same MA organization or a different MA organization.	Beneficiaries are required to complete an enrollment election if they choose to enroll in another plan.	Beneficiaries are sent a final non-renewal notification letter and receive guaranteed issue Medigap rights.

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

Attachment B — Risk Adjustment Implementation

1. Requirements for Submitting Risk Adjustment Data to CMS

a. File Size, Format and Filtering of Risk Adjustment Processing System (RAPS) Data

Front End Edit to Limit File Size

MA organizations have submitted files of varying sizes—some in excess of 2 million records—to our Front End Risk Adjustment System (FERAS) at the Customer Service and Support Center (CSSC). Large files require considerable data processing time and resources. In order to more efficiently process submissions to the FERAS and the CMS Data Processing Center, we are instituting the following maximum file size limits effective immediately:

Table 1. FERAS Submissions

Method of Submission	Front End Limit Per Submitter Per Day
Connect:Direct (formerly NDM)	1,000,000 CCC Records
File Transfer Protocol (FTP)	1,000,000* CCC Records
Gentran	1,000,000 CCC Records
Secure Website	1,000,000 CCC Records

*NOTE: In the past a file size of 146K was recommended. As some FTP sites can send files considerably larger than the 146K based on their systems, CMS limits the file size for FTP to 1M.

This limit applies regardless of the number of files submitted (i.e., a submitter could submit one file with 999,999 CCC records or multiple files as long as their total does not exceed 1M CCC records). In the event that a submitter has a file larger than the 1M CCC record limit that it would like to submit, the submitter must notify the CSSC one week in advance; this will enable us to schedule the file in the production run.

For additional information regarding FERAS submissions, please see *Table 4a – Connectivity Options* in the *2006 Risk Adjustment Data Basic Training For Medicare Advantage Organizations, Participant Guide* available on our contractor's web site at http://www.csscooperations.com/new/usergroup/july2006_regtrn/raps-participant-guide_081606.pdf.

Risk Adjustment Processing System (RAPS) Format

Effective October 1, 2007—the beginning of fiscal year (FY) 2008—we will accept only risk adjustment submissions that are in RAPS format. We will continue to accept data in RAPS format as batch data files (i.e., via Connect:Direct, FTP, and Gentran) and direct data entry (DDE) (i.e., via secure website) files. This data submission requirement will enable us to 1) more efficiently process the data at CSSC and within the CMS Data Processing Center and 2) ensure appropriate payment under the risk adjustment payment models. In addition, effective immediately we will not authorize an electronic data interchange (EDI) agreement for a plan that requests to submit risk adjustment data using a non-RAPS format.

Therefore, effective October 1, 2007, the following options for submitting risk adjustment data will be discontinued:

- American National Standards Institute (ANSI)
- National Standard Format (NSF)
- Universal Bill – 92 (UB-92).

Filtering for 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.

MA organizations are responsible for ensuring that the data they collect and submit to CMS for payment comes from acceptable 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 as approved by CMS. 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>.

b. Risk Adjustment Data Submission Schedule

Table 2. 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 adjuster model. Specific changes in implementation include the updated risk adjustment data collection and submission dates.

Table 2. Risk Adjustment Implementation Calendar

CY	Dates of Service	Initial Submission Deadline	First Payment Date	Final Submission Deadline
2007	July 1, 2005 through June 30, 2006	September 1, 2006	January 1, 2007	N/A*
2007	January 1, 2006 through December 31, 2006	March 2, 2007	July 1, 2007	January 31, 2008
2008	July 1, 2006 through June 30, 2007	September 7, 2007	January 1, 2008	N/A*
2008	January 1, 2007 through	March 7, 2008	July 1, 2008	January 31, 2009

CY	Dates of Service	Initial Submission Deadline	First Payment Date	Final Submission Deadline
	December 31, 2007			
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

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

** For 2006 forward, March and September dates reflect the first Friday of the respective month.

Changes in payment methodology for 2008, including Part C and Part D payment and risk adjustment, are described in the February 16, 2007, *Advance Notice of Methodological Changes for Calendar Year (CY) 2008 Medicare Advantage Payment Rates* and the April 2, 2007, *Announcement of Calendar Year (CY) 2008 Medicare Advantage Payment Rates* (available at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/>).

c. Updated Policies and Procedures

In order to clarify requirements for the submission of risk adjustment data by Medicare Advantage (MA) organizations, we have updated and distributed [via the Health Plan Management System (HPMS)] the following policies and procedures for—

- New MA organizations (effective on or after October 1, 2006)
 - Electronic data interchange (EDI) agreements—must complete and submit an EDI agreement to our Customer Service and Support Center (CSSC) within one month of your HPMS effective date;
 - Submission of risk adjustment test data—must submit test data within three months of your HPMS effective date; and
 - Submission of risk adjustment production files—must submit production files within four months of your HPMS effective date and continue to submit at least one time per quarter thereafter.
- Current MA organizations (effective date before October 1, 2006)
 - Electronic data interchange (EDI) agreements—must have completed and submitted an EDI agreement to our Customer Service and Support Center (CSSC) within four months of your HPMS effective date. (If your contract has a current EDI agreement, then this requirement has been met for that contract.);

- Submission of risk adjustment production files—must submit at least once every calendar quarter; and
- Reduction of duplicate risk adjustment submissions—must adhere to no more than five percent (5%) per file. We define a duplicate submission as a diagnosis cluster with the same attributes as that already stored in the RAPS database; duplicate submissions result in 502 errors.

In the event your MA organization acquires a new or different contract number, a new EDI agreement must be submitted to the CSSC within one month of your HPMS effective date. Since your MA organization has submitted data in the past on behalf of other contract number(s), the requirement to submit risk adjustment test data does not apply.

We will generate and distribute written CMS noncompliance letters to MA organizations that fail to fulfill these requirements; the letters will be distributed via HPMS. In addition, we will furnish copies of the letters to CMS plan managers and regional office and compliance division staff. An MA organization's failure to comply with the requirements for risk adjustment data submissions may result in suspension of its data submission privileges and, thus, impact risk adjusted payments.

To ensure appropriate payment under the risk adjustment payment models, your MA organization must submit complete and accurate risk adjustment production data at least each calendar quarter.

d. 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 www.csscooperations.com.

2. Part A Risk Adjustment Factor Options

a. Determinations of Risk Status

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

Table 3. Which Risk Adjustment Factors to Apply to Payment*

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

*Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled benefits under Part A and enrolled in Part B.

**During data collection period (previous calendar year).

Table 3. Which Risk Adjustment Factors to Apply to Payment (above) illustrates that beneficiaries with 12 or more months of Medicare Part B enrollment during the data collection period (previous calendar year) are considered full risk enrollees. The new enrollee factors do not apply.

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

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

b. 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—

1) The decision will be applied to all “Part-A” only enrollees in the plan; and

2) The option elected will remain turned "on" until CMS is otherwise notified prior to August 31st of any successive year.

Plans interested in electing this option must contact: Henry Thomas, CMS, at mhenry.thomas@cms.hhs.gov by August 31, 2007.

3. Risk Adjustment Training

The purpose of the training is to provide participants who are new to risk adjustment the support necessary to understand risk adjustment. This information will enable new participants to collect and submit risk adjustment data in accordance with CMS requirements. CMS offers Monthly Risk Adjustment Trainings at its Baltimore headquarters. We anticipate holding our regional trainings in June and August 2007.

Risk adjustment trainings will be announced via the Risk Adjustment User Group and listed on our risk adjustment training contractor’s web site. For additional information or to register for the Risk Adjustment Training and the Risk Adjustment User Group, please visit our risk adjustment training contractor’s web site at <http://www.medicaretraining.net>.

4. Risk Adjustment Data Validation

42 CFR §422.310(e) requires MA organizations and their providers and practitioners to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. CMS will increase emphasis on MA organization compliance with the medical record submission guidelines.

The Centers for Medicare & Medicaid Services (CMS) conducts medical record reviews to validate the accuracy and integrity of the risk adjustment data submitted by the Medicare Advantage (MA) for payments. CMS selects MA organizations to participate in the medical record review based on a number of criteria. For example, some organizations are randomly selected while others are targeted; thus, every MA organization has a chance of being selected for validation.

Risk adjustment data validation is the process of verifying that diagnosis codes submitted for payment by the MA organization are supported by medical record documentation for an enrollee. The primary goals of risk adjustment data validation are to:

- Identify
 - Confirmed risk adjustment discrepancies
 - MA organizations in need of technical assistance to improve risk adjustment data quality
- Measure
 - Accuracy of risk adjustment data
 - Impact of discrepancies on payment
- Improve/Inform
 - Quality of risk adjustment data
 - The CMS-Hierarchical Condition Category (CMS-HCC) model.

a. Missing Medical Records

If your MA organization is selected for inclusion in the data validation, your MA organization would be required to submit all necessary medical record documentation as requested within the allotted timeframe. Medical records not submitted to CMS within the required timeframe will be identified as “missing medical records.” A missing medical record is a risk adjustment discrepancy. Risk adjustment data characterized as “discrepant” are used to evaluate the accuracy of payments to your MA organization. The results of the risk adjustment data validation will be used to develop an estimated payment error rate for your MA organization.

b. Guiding Principle & Guidelines

Since implementation of the CMS-HCC model in 2004, we have included hospital inpatient, hospital outpatient, and physician medical records in our risk adjustment data validation. Additionally, we modified our Guiding Principle to account for acceptable provider types and physician data sources for medical record documentation. Our Guiding Principle now states:

The medical record documentation must show that the HCC diagnosis was assigned within the correct data collection period by an appropriate provider type (hospital inpatient, hospital outpatient, or physician) and an acceptable physician data source as defined in the CMS instructions for risk adjustment implementation. In addition, the diagnosis must be coded according to *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Guidelines for Coding and Reporting*.

MA organizations are allowed flexibility to select and submit supporting medical record documentation when responding to a medical record request. Since plans are not required to submit multiple occurrences of a unique diagnosis for a given enrollee, a medical

record from any risk adjustment data source would be acceptable. This means that the medical record submitted for validation could be based on an encounter other than the one for which the data were submitted.

According to the risk adjustment data validation guidelines:

- Enrollee risk adjustment records are selected for validation based on risk adjustment diagnoses submitted to the Risk Adjustment Processing System (RAPS).
- Since CMS does not collect provider identifiers for risk adjustment, MA organizations must be able to track and locate supporting medical record documentation for its providers.
- MA organizations must select the “one best medical record” to support each HCC identified for validation. This means the MA organizations decide whether to submit a hospital inpatient, hospital outpatient, or physician medical record when more than one type of record is available.
- The medical record documentation must support an assigned HCC.
- Once a MA organization selects its “one best medical record,” a date of service must be identified to facilitate the medical record review process. CMS coders who review medical records will not search beyond the date of service identified in the medical record by the MA organization for review.
- Payment adjustments are based on confirmed risk adjustment discrepancies.
- An appeals process is in place to address a MA organization’s disagreement with a payment adjustment based on a confirmed risk adjustment discrepancy.

c. Acceptable Risk Adjustment Data Sources

CMS has provided a list of ambulatory services that are “non-covered services” and, therefore, are unacceptable for risk adjustment. (To obtain a copy of *Table 3C – Hospital Outpatient*, please visit the *2006 Risk Adjustment Data Basic Training For Medicare Advantage Organizations, Participant Guide* available on our contractor’s web site at http://www.csscooperations.com/new/usergroup/july2006_regtrn/raps-participant-guide_081606.pdf.) However, we continue to receive inquiries about the use of two specific “non-covered services”—laboratory and diagnostic radiology—and their potential use in risk adjustment payment and data validation. Therefore, we would like to clarify the importance of associating risk adjustment data submission with valid clinical documentation for physician specialties.

MA organizations must not submit documentation from laboratory and diagnostic radiology services as a standalone medical record for data validation. This type of medical documentation is insufficient for coding purposes. The following ICD-9-CM guideline

updated November 2006 (available on the CDC web site at <http://www.cdc.gov/nchs/datawh/ftp/ftp9/icdguide06.pdf>) clarifies the appropriate use of documentation from “non-covered source” providers for determining clinical significance:

Abnormal findings (laboratory, X-ray, pathologic, and other diagnostic results) are not coded and reported unless the physician indicates their clinical significance. If the findings are outside the normal range and the physician has ordered other tests to evaluate the condition or prescribed treatment, it is appropriate to ask the physician whether the diagnosis should be added.

The previous version from October 2002 included the above statement along with further clarification and examples:

The coder should not arbitrarily add an additional diagnosis to the final diagnostic statement on the basis of an abnormal laboratory finding alone. To make a diagnosis on the basis of a single lab value or abnormal diagnostic finding is risky and carries the possibility of error.

It is important to remember that a value reported either lower or higher than the normal range does not necessarily indicate a disorder. Many factors influence the value of a lab sample. These include the method used to obtain the sample (for example, a constricting tourniquet left in place for over a minute prior to collecting the sample will cause an elevated hematocrit and potassium level), the collection device, the method used to transport the sample to the lab, the calibration of the machine that reads the values, and the condition of the patient. An example is a patient who because of dehydration may show an elevated hemoglobin due to increased viscosity of the blood.

As stated above, it is inappropriate for MA organizations to submit a risk adjustment diagnosis and medical documentation on the sole basis of a “non-covered service.” Thus, we will identify documentation from “non-covered services” as “invalid” and, therefore, deem such documentation as a risk adjustment discrepancy.

Note that we will accept documentation from “non-covered services” provided the documentation is reviewed by the physician and the outcome of the physician’s review (i.e., diagnosis) is appropriately documented by the physician in the medical record. However, we will not accept for data validation documentation whereby a MA organization submits a diagnosis based on a laboratory service within the data collection period and physician medical record documentation that is outside of the data collection period.

For additional information on data validation, please visit our contractor’s web site at <http://www.csscooperations.com/new/usergroup/2006rapstrn/2006-participant-guide.pdf>.

d. Signatures and Credentials

For purposes of risk adjustment data submission and validation, the MA organizations must ensure that the provider of service for face-to-face encounters is appropriately identified on medical records via their signature and physician specialty credentials. (Examples of acceptable physician signatures are: handwritten signature or initials; signature stamp that complies with state regulations; and electronic signature with authentication by the respective provider.) This means that the credentials for the provider of services must be somewhere on the medical record—either next to the provider’s signature or pre-printed with the provider’s name on the group practice’s stationery. If the provider of services is not listed on the stationery, then the credentials must be part of the signature for that provider. In these instances, the coders are able to determine that the beneficiary was evaluated by a physician or an acceptable physician data source. (For additional information on acceptable physician data sources, see the above section titled *Filtering for Acceptable Provider Types and Physician Data Sources*.)

We have identified medical records where it is unclear if the beneficiary is actually evaluated by a physician, physician extender, or other. In several cases, we have found encounters that are documented on physician’s stationery but appear to be signed by a non-physician provider. For example, a medical record appears on group stationery for a given date of service. The medical record is signed but the provider’s name and credentials are not furnished on the stationery. Thus, the coders are unable to determine whether the beneficiary was evaluated by a physician, medical student, nurse practitioner, registered nurse, or other provider. This type of medical record documentation is incomplete and unacceptable for risk adjustment and, therefore, will be counted as a risk adjustment discrepancy.

II. Prescription Drug Plan Attachments

Attachment A - Contract Year 2008 Guidance for PDP Sponsor Renewals/HPMS Plan Crosswalk [PDP sponsors only]

Contract Year 2008 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC
1	New Plan Added		A new 2008 plan with no link to a 2007 plan.	The PDP sponsor must submit election transactions.	Beneficiaries are required to complete an enrollment form. Beneficiaries who are already enrolled in another plan with the same PDP sponsor can complete the short enrollment form.	None.
2	Renewal Plan	If a PDP sponsor continues to offer a CY2007 prescription drug plan in CY2008, it must retain the same Plan ID number in order for all currently enrolled beneficiaries to remain in the same prescription drug plan in CY2008.	A 2008 plan that links to a 2007 plan.	The renewal plan ID must remain the same so that beneficiaries will remain in the same plan ID. The plan sponsor does not submit any transactions.	No enrollment election is required.	Beneficiaries are sent an ANOC.

Contract Year 2008 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC
3	Consolidated Renewal Plan	If a PDP sponsor combines two or more prescription drug plans offered in CY2007 into a single renewal plan so that all beneficiaries in the combined plans are offered the same benefits in CY2008, the PDP sponsor must designate which of the renewal Plan IDs will be retained in CY2008 after consolidation.	Two or more 2007 prescription drug plans that consolidate into one 2008 plan.	The PDP sponsor's designated renewal plan ID must remain the same so that CMS can consolidate the beneficiary's election by moving them into the designated renewal plan ID. The PDP sponsor does not submit any transactions.	No enrollment election is required.	Beneficiaries are sent an ANOC.
4	Renewal Plan with an SAE (applicable only to employer/union-only group waiver plans (EGWPs) because these PDPs are permitted to cover	If a PDP sponsor continues to offer a CY 2007 prescription drug plan in CY 2008 and expands its EGWP service area to include additional regions, it must retain the same Plan ID number in order for all currently enrolled beneficiaries to remain in the same prescription drug plan in CY 2008.	A 2008 prescription drug plan that links to a 2007 plan and retains all of its plan service area from 2007, but also adds one or more new regions.	The renewal plan ID must remain the same so that beneficiaries in the current service area will remain in the same plan ID. The PDP sponsor does not submit any transactions for these members. However, the PDP sponsor must submit election transactions for new enrollees.	Employers/unions who wish to enroll their retirees in a PDP EGWP have the option of group enrolling its beneficiaries (<i>see</i> PDP Eligibility, Enrollment and Disenrollment Guidance) or having its retirees complete an individual enrollment election.	Only existing beneficiaries are sent an ANOC.

Contract Year 2008 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC
	multiple regions within one "800 series" plan benefit package).					
		Model ANOCs will be available on the CMS Web site at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_Marketing.asp#TopOfPage .				
5	Terminated Plan		A 2007 plan that is no longer offered in 2008.	If the beneficiary elects to enroll in another plan with the same plan sponsor, the PDP sponsor must submit transactions to enroll the beneficiary in another plan with the PDP sponsor;	Beneficiaries are required to complete an enrollment election if they choose to enroll in another plan.	No ANOC sent. Beneficiaries are sent a notice that coverage under the plan will not continue and receive a written description of options for obtaining prescription drug coverage in the service area.

Contract Year 2008 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC

* Note: See the nonrenewal instructions for a contract nonrenewal or service area reduction.

Attachment B

PDP Sponsor Licensure Waivers-Reporting and Filing Deadlines
[PDP sponsors only]

Deadline	Action
5/15/2007	Sponsor must submit confirmation from each state for which its licensure waiver will expire in 2008, that the state is in possession of a substantially complete application and expects to be able to approve or disapprove before 4/1/2008, or the state provides the earliest date on which it will accept an application if seasoning is an issue.
8/15/2007	Sponsor must submit confirmation from each state for which its licensure waiver will expire in 2008, that the state is in possession of a substantially complete application and expects to be able to approve or disapprove before 4/1/2008, or the state provides the earliest date on which it will accept an application if seasoning is an issue.
10/1/2007	Sponsor must submit an exit plan* for each region which contains an unlicensed (waivered) state where the waiver will expire on 12/31/2008.
12/1/2007	Sponsor must submit an updated confirmation from each state for which its licensure waiver will expire in 2008, that the state is in possession of a substantially complete application and expects to be able to approve or disapprove before 4/1/2008, or the state provides the earliest date on which it will accept an application if seasoning is an issue.
3/12/2008	CMS will accept new licensure waiver applications from sponsors with expiring state licensure waivers who were unable to become licensed because of state requirements that are beyond the sponsor's ability to meet.
Mid-2008**	Last day for sponsors to obtain state licensure for states with 2008 expiring waivers and not receive a notice of non-renewal.
9/2/2008	CSM advises sponsors to implement exit plans as appropriate.
10/1/2008	Sponsor notifies its Medicare enrollees in writing. Sponsor notifies the public by publishing a notice in one or more newspapers of general circulation in each community or county in the service area from which it is withdrawing.

* 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.

** Deadline for obtaining state licensure is the date by which CMS is required under the Part D regulations to issue a contract renewal or non-renewal notice to sponsors for contract year 2009.