DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

MEMORANDUM

TO: Medicare Advantage Organizations
Medicare Advantage-Prescription Drug Organizations
Cost-Based Contractors
Prescription Drug Plan Sponsors
Employer/Union-Sponsored Group Health Plans

FROM: Cynthia Tudor, Director, Medicare Drug Benefit Group
David Lewis, Director, Medicare Advantage Group

RE: Public Comment Period for Draft 2009 Call Letter

DATE: January 16, 2008

We are pleased to issue this notice announcing the release of the DRAFT 2009 Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD), Cost-Based Plan, and Prescription Drug Plan (PDP) sponsors Call Letter for public comment.

We are sending these letters out via HPMS and will post them on our website at http://www.cms.hhs.gov/HealthPlansGenInfo/ and http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf

When submitting comments, please send comments to 2009CallLetter@cms.hhs.gov ***and please utilize the attached EXCEL comment/response form.***

We will be accepting comments until 5:00 PM EST January 30, 2008.

If you have any questions on the Call Letter comment process, please contact:

- Sabrina Ahmed on issues relating to MA, MA-PD, and cost plans [Sections A, C and D] at Sabrina.Ahmed@cms.hhs.gov or 410-786-7499.
- Julie Gover on issues relating to prescription drug plan issues [Sections B, C and D] at Julie.Gover2@cms.hhs.gov or 410-786-0525.

Thank you in advance for your input into this process.

2009 Call Letter

DATE: January 16, 2008

TO: Medicare Advantage Organizations
Medicare Advantage-Prescription Drug Organizations
Cost-Based Contractors
Prescription Drug Plan Sponsors
Employer/Union-Sponsored Group Health Plans

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

RE: Introduction from CMS on 2009 Call Letter

I am pleased to provide you with the draft of the 2009 Call Letter for Medicare Advantage organizations (MAOs), 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 are providing you with new information and operational reminders for the Medicare Advantage and other private plan options (Part C) and prescription drug (Part D) programs to help you prepare for contract year 2009.

The draft of the 2009 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. Because this Call Letter focuses on new information designed to help you prepare for the 2009 contract year, it is essential that you also review all program requirements, the Managed Care and Prescription Drug Benefit Manuals, Health Plan Management System (HPMS), and other CMS guidance for comprehensive information on both programs.

We hope this information helps you implement CMS policies and procedures and comply with critical program requirements as you prepare to offer a plan for the first time or continue to offer a plan under one of our programs. 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.

How to Use this Document

The draft of the 2009 Call Letter contains information on the Part C, cost-based, and Part D programs combined into one document. Section A provides MA, MA-PD, and cost plan guidance; Section B provides information for prescription drug plan sponsors; Section C contains marketing-related information that applies to all plan types. Section D contains the attachments and includes important information such as calendars, crosswalks, and model marketing documents specific to the Part C, cost-based, and D programs.

If you have questions concerning the MA, MA-PD, or cost sections of this Call Letter, please contact Sabrina Ahmed at Sabrina.Ahmed@cms.hhs.gov . For questions on the prescription drug portions, please contact Julie Gover at Julie.Gover2@cms.hhs.gov .

Section A – 2009 MA, MA-PD, and COST PLAN SECTIONS

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NOTE ON 2009 MA, MA-PD, AND COST PLAN PORTION OF THE CALL LETTER

With few exceptions, Medicare Advantage organizations (MAOs) offering a prescription drug benefit (MA-PDs) and cost plans offering a Part D benefit (cost-PDs) must follow all Part D requirements in addition to following 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 Prescription Drug Benefit Manual and Part 423 of Title 42 of the Code of Federal Regulations (CFR). Such requirements include the formulary and pharmacy access requirements specified in Chapters 5 and 6 of the Prescription Drug Benefit Manual and the Part D portion of this Call Letter. Our discussion in Section A is focused primarily on the MA and cost plan operational guidance that we especially want to bring to your attention as you prepare for the 2009 contract year. Section C contains marketing-related information that applies to MAOs, cost plans, and PDPs. We will, however, highlight information related to the Part D benefit that is specific to MA-PDs and cost-PDs. Unless otherwise indicated, all regulatory references are to Title 42, Part 422 of the CFR.

2009 MA, MA-PD, and Cost Plan Calendar

In order to assist you in meeting all deadlines for renewal, enrollment, bidding, and other provisions, as you prepare to offer health care benefits in 2009, we are including a calendar of key dates and timelines. Please note that, except as otherwise specified in statute or regulation, the dates given here are subject to change. Organizations should also note that these dates are not exhaustive, and they must consult the appropriate sections of 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/.

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).*

2009 MA, MA-PD and Cost-Based Plan Calendar **(All dates, unless identified as statutory, are subject to change)**	
2008	
March 15, 2008	CMS releases 2009 Call Letter. Attachments include 2009 standardized combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), pharmacy directory, provider directory, transition notice, and abridged and comprehensive formulary marketing models.
Late February/Early March 2008	Conference call with industry to discuss the 2009 Call Letter.
March 25, 2008	Industry training on ANOC/EOC and other standardized marketing models.

March 31, 2008	Release of Health Plan Management System (HPMS) formulary submissions module.
April 7, 2008	Issuance of Calendar Year (CY) 2009 MA payment rates. Announcement of CY 2009 MA Capitation Rates and Payment Policies & CY 2009 Part D Payment Notification.
April 10, 2008	CMS Bid Conference.
April 11, 2008	Plan Creation module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.
April 21, 2008	2009 Formulary Submissions Due from all MA-PDs, PDPs, Direct Contract EGWPs, and MA-PDs, PDPs, and cost-PD sponsors offering "800 series" EGWPs (11:59 p.m. EDT). Transition policies and procedures due to CMS for new contracts.
May 1, 2008	***Non-Renewal***: Deadline for MA and MA-PDs to notify CMS of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members; deadline for MA, MA-PDs to submit partial county service area reduction requests.
May 15, 2008	Model Low Income Subsidy (LIS) riders will be available for all organizations.
May 16, 2008	CMS begins accepting CY 2009 bids via HPMS.
Late May 2008	CMS sends contract eligibility determinations to Applicants based on review of the 2009 applications.
June 2, 2008	Deadline for submission of CY 2009 bids for all MA, MA-PD, cost, "800 series" EGWP and Direct Contract EGWP applicants and renewing organizations; deadline for cost plans wishing to appear in the 2009 Medicare Options Compare to submit PBPs (11:59 p.m. PDT). ***Voluntary Non-Renewal***: Deadline for MA and MA-PDs to submit a non-renewal or service area reduction notice to CMS for CY 2009. Medicare cost-based contractors and cost-based sponsors encouraged to submit a non-renewal or service area reduction notice to CMS.
June 9, 2008	CMS begins accepting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY 2009 Actuarial Certifications in HPMS.
June 16, 2008	***Non-Renewal***: CMS to issue acknowledgement letter to all for MA, MA-PDs that are non-renewing or reducing their service area. CMS begins accepting CY 2009 marketing material for review.
June 30, 2008	Final date for MA, MA-PD and cost-based organizations to submit CY 2008 marketing materials for CMS' review and approval. NOTE: This date does

	not apply to CY 2008 file and use materials since these may be filed with the regional office five calendar days prior to their use.
July 15, 2008	Last date for an organization to receive a favorable decision on a contract determination and still offer a plan in 2009.
July 16, 2008	***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 2008	***Non-Renewal***: CMS to release a Special Election Period (SEP) letter to MA, MA-PDs remaining in the non-renewed service areas.
August 1, 2008	MA-PD plans offering Part D are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review. Deadline for CMS to inform currently contracted organizations of non-renewals in 2009. ***Non-Renewal***: 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.
August 5, 2008	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 *Medicare & You* handbook
Early August 2008	Final Regional Preferred Provider Organization plan (RPPO) benchmarks released. Rebate reallocation period begins.
August 15, 2008	MA and MA-PD Organizations are expected to submit final CY 2009 standardized combined ANOC/EOC to the regional office for review. MA-PD plans offering Part D are also expected to submit model Low Income Subsidy (LIS) riders to the regional office for review.
Late August 2008	Submission of attestations, contracts, and final actuarial certifications.
August 30, 2008	***Non-Renewal***: Final date for CMS to approve MA, MA-PD's final beneficiary notification letter of non-renewal.
September 8-10, 2008	MA, MA-PD organizations and, if applicable, Medicare cost-based plans, preview the 2009 *Medicare & You* plan data in HPMS (not applicable to EGWPs).
October 1, 2008	MA, MA-PD organizations and Medicare cost based plans may begin CY 2009 marketing activities MA organizations and Medicare cost-based plans are required to include information in CY 2008 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2009. Deadline MA and MA-PD organizations to request a plan correction to the PBP. Cost plans and cost plans offering Part D must submit final 2009 standardized combined ANOC/EOC to the Regional Offices for review to ensure it can

	be reviewed, approved, printed, and received by members by December 1. Cost plans offering Part D are expected to submit Low Income Subsidy (LIS) riders for review. Last date for contracting MAs to provide CMS with evidence of contracting with state in order to operate a Medicaid subset dual eligible SNP for the 2009 contract year.
October 2, 2008	***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. ***Non-Renewal***: Final beneficiary notification letter must be received by MA, MA-PD enrollees and must be a personalized letter. Medicare cost-based contractors and cost-based sponsors to submit a non-renewal or service area reduction notice to CMS.
October 9, 2008	Tentative date for 2009 plan benefit data to be displayed on Medicare Options Compare and for 2009 plan drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).
October 13, 2008	***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, 2008	CMS mails the 2009 *Medicare & You* handbook.
October 31, 2008	All MA organizations must cease marketing CY 2008 plans through public media. CY 2009 standardized combined ANOC/EOC are due to all MA, MA-PD members. MA, and MA-PD organizations must mail the combined ANOC/EOC before this date to ensure receipt by members by October 31. All MA-PDs must mail their Low Income Subsidy (LIS) riders and abridged or comprehensive formularies in the same package as the combined EOC/ANOC. Package must be mailed before this date to ensure receipt by members by October 31.
November 3, 2008	***Non-Renewal***: Final beneficiary non-renewal notification letter--must be a personalized letter and received by cost-based plan enrollees by November 3, 2008.
November 15, 2008	2009 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, *see* Chapter 2 of the Medicare Managed Care Manual, Section 30.4.4).
November-December 2008	***Non-Renewal***: CMS to issue "close out" information and instructions to MA, MA-PDs that are non-renewing or reducing service area.

	Non-Renewal: CMS to issue "close out" information and instructions to cost-based plans that are non-renewing or reducing their service area.
December 1, 2008	CY 2009 combined ANOC/EOC are due to all cost-based plan members. Medicare Cost-Based plans must mail combined EOC/ANOC before this date to ensure receipt by members by December 1. Cost plans offering Part D must mail their Low Income Subsidy (LIS) riders and abridged or comprehensive formularies in the same packaged as the combined ANOC/EOC before this date to ensure receipt by members by December 1.
December 2, 2008	***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.
Early December 2008	Submission of Notices of Intent for Contract Year 2010 due for MA, MA-PD, cost, "800 series" EGWPs and Direct Contract EGWPs.
Late December 2008	CMS issues pending HPMS contract numbers for Contract Year 2010 to MA, MA-PD, cost, and EGWP contracts.
December 31, 2008	2009 Annual Coordinated Election Period ends.
2009	
January 1, 2009	Plan Benefit Period Begins.
Mid January 2009	Automated Contract Year 2010 applications released for MA, MA-PD, "800 series" EGWPs and Direct Contract EGWPs.
Late January 2009	Industry training on applications for Contract Year 2010.
Early March 2009	Applications due for Contract Year 2010 for MA, MA-PD, cost, "800" series EGWPs and Direct Contract EGWPs.

I. Benefit Design

A. Cost Sharing Guidance

MAOs may not design benefit packages that discourage enrollment or encourage disenrollment of severely or chronically ill beneficiaries. We will not approve a bid if the plan's cost sharing or deductible structure discriminates based on health status. For further cost-sharing guidance, please see Section 20.13, "Guidance on Acceptable Cost-Sharing and Deductibles," of Chapter 4, "Benefits and Beneficiary Protections," of the Managed Care Manual located at http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf. We will continue to scrutinize cost sharing amounts for inpatient acute and psychiatric hospital, home health, and DME services. CMS will examine cost sharing with greater scrutiny if beneficiary liability is not limited by an out-of-pocket maximum that is equal to, or less than, the amount specified in item 1 below. **In addition, MA plans with cost sharing amounts greater than Original Medicare for renal dialysis, Part B drugs, or skilled nursing facility services may be considered discriminatory** Also note that benefit design and cost sharing amounts approved for CY 2008 will not

automatically be "acceptable" for CY 2009 as each contract year a separate and distinct review is conducted.

1. Out-of-Pocket Maximum

For calendar year 2009, CMS has determined that increased scrutiny will be applied to cost sharing in the case of plans that have an out-of-pocket (OOP) maximum amount for Medicare-covered services that exceeds $3,350.

- Plans with a plan level OOP maximum amount not greater than $3,350 will be given greater flexibility in establishing cost sharing amounts for individual services (i.e., other than the areas referenced above, CMS is less likely to scrutinize cost sharing for individual services to look for discriminatory cost sharing).
- Plans with a plan level OOP maximum amount that is greater than $3,350, or that apply the OOP cap on a sub-set of Medicare-covered services will have less flexibility in establishing cost sharing amounts for individual services, and will receive greater scrutiny by CMS.
- Plans without a plan level OOP maximum amount will have the least flexibility in establishing cost sharing amounts for individual services, and will be subject to the greatest scrutiny in looking for potential prohibited discrimination.

2. Copayments (tiered)

When the PBP software does not permit the user to enter a range of cost sharing, please ensure that the highest cost sharing is entered in the standard variables of the PBP. Lesser cost shares may be described within the Notes fields.

3. Cost Sharing for Dialysis Services

MA plans must offer the same cost sharing for in and out-of-area renal dialysis. Please keep in mind that we will be monitoring cost sharing for renal dialysis. Plans offering cost sharing greater than Original Medicare will face increased scrutiny during the desk review process, regardless of whether they have adhered to the OOP maximum guidance. For cost plans, the out-of-area data entry for renal dialysis cost sharing has been disabled for CY 2009. Cost plan Summary of Benefits (SB) language will now indicate that cost plan enrollees may obtain out-of-area dialysis through Original Medicare, in which case 20% cost sharing would apply.

B. Fiscal Soundness Reporting Requirements (FSRR)

All new and renewing MAOs in 2008 are obligated to provide the Fiscal Soundness Reporting Requirements (FSRR). The FSRR instructions and FAQs are located at: http://www.cms.hhs.gov/HealthPlansGenInfo/50_FSRR.asp#TopOfPage. Note that, in accordance with federal regulations at 42 CFR §422.516(a)(5) Reporting Requirements, the Division of Benefits (DB) reserves the right to request additional information beyond the listed requirements in order to ensure all MAOs are maintaining a fiscally sound organization. MAOs are requested to cease filing all paper-based financial statements with the Division of Benefits

(e.g., paper versions of the NAIC Quarterly and Annual Health Blanks) unless requested by one of the reviewers.

C. Plan Corrections for 2009

Consistent with marketing and open enrollment coordination, MAOs will not be able to request plan corrections for CY 2009 benefits packages any later than October 1, 2008. It is expected that MAOs that anticipate contracting for 2009 will make every effort to submit error-free PBPs when bids are submitted in June. However, the plan corrections module will be available in HPMS for CY 2009 benefits for a limited period, from early September until October 1, 2008. It is important to note that only corrections (to the PBP) that are supported by the BPT are allowed.

D. Benefit Clarifications

1. Coverage of Over the Counter (OTC) Items

Typically, some OTC items do not meet the CMS definition of a MA benefit, as presented in Section 10.10 of Chapter 4, "Benefits and Beneficiary Protections," of the Medicare Managed Care Manual, located at http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf. Additionally, under Part D, plans may not include OTCs as part of their drug benefit or supplemental coverage.

CMS is hereby informing plans that they may offer a packaged OTC Part C benefit comprised of the items on the FSAFEDs OTC list located at https://www.fsafeds.com/forms/OTC_QRG000.pdf. This allowance is specific to this package of OTC items and should not be transferred to other benefit situations. This packaged OTC benefit is subject to all requirements of benefits such as pricing in the bid, proper line itemization in the PBP, etc.

The current FSAFEDs list is located at https://www.fsafeds.com/forms/OTC_QRG000.pdf. The conditions below ensure that the package of FSAFEDs OTC items are being covered appropriately for MA plan enrollees. Each MA organization offering a plan with a Part C OTC benefit should clarify, in its enrollee notifications that only items found on the FSAFEDS OTC item list are covered by the plan, and that this coverage is subject to the following conditions:

- While the FSAFEDS list allows items to be purchased for enrollees and family members, the MA plan may only permit items to be purchased for the enrollee.

- The FSAFEDS list requires a written provider note for the OTC items listed in the “Eligible OTC Expenses section” of the document. While a written note is not required for coverage under an MA plan, there must be (a) a recommendation by the enrollee’s personal provider and (b) a specific diagnosable condition for which the item is being purchased.

- Although the FSAFEDS document states that this list is not exhaustive of covered OTC products, MA plans should not cover additional types or classes of products not belonging to categories on the list.

- While the FSAFEDS document indicates a specific method of reimbursement, MA plans have greater flexibility. See the three methods of reimbursement indicated below that are recognized as acceptable by CMS.

    1) Catalogs - A plan can allow enrollees to order approved items from a catalog without an exchange of money. The plan is responsible for the cost of mailing. In such a case, the plan may not include, without clear identification, Original Medicare items in their catalogs (See Section 10.10 of Chapter 4 of the Medicare Managed Care Manual for additional details).

    2) Debit Cards - Organizations may use debit cards for their OTC benefits. Debit cards are prepaid by the MAO and supplied to the enrollee. The debit cards allow the enrollee to purchase OTC items. CMS has imposed certain requirements on the use of debit cards with OTC benefits.

        - Since the MA regulations prohibit an MA organization from offering cash as a benefit, (see 42 CFR 422.80(e)(i)), the MAO must clearly state that: a) the debit card is not a credit card; b) It cannot be converted to cash or c) loaned to other people; and d) Any unused allocated money reverts back to the plan at the end of the appropriate period;
        - The debit card must be electronically linked to the CMS-approved list of allowable items;
        - The plan must clearly notify its members of the locations where the debit card can be used;
        - The MAO must clearly state the rules relating to debit card balances rolling over from month to month; and
        - Plans are responsible for ensuring that debit cards are only used for the purchase of approved OTC items.

    3) Direct Reimbursement - A plan can use a direct reimbursement method. The enrollee purchases items, sends in the receipts, and any further proofs of purchase. Subsequently, the enrollee gets reimbursed by the plan.

The responsibility for ensuring that the Part C OTC benefit is properly used lies with the MAO.

This allowance of the use of debit cards only applies to the Part C OTC benefit. Debit cards may not be used as a method of payment for any other Part C or Part D benefit.

An MA organization that is offering prescription drug coverage may also provide certain OTCs under Part D: As outlined in Chapter 7, section 60.1, of the Medicare Prescription Drug Benefit Manual, Part D sponsors may provide OTCs as part of a cost-effective drug utilization management program that is provided to the beneficiary without any direct cost-sharing at the point-of-sale. Costs under this option are included in the administrative portion of the Part D bid and, thus, ultimately reflected in premiums. Part D sponsors choosing to include OTC products within their utilization management programs should understand and be prepared to

appropriately educate enrollees on the difference between OTCs, provided as part of the organization's administrative costs, and covered Part D drugs.

2. Incentives and Rewards

An incentive or reward is an item or service that a plan offers conditional to an enrollee taking some action (e.g., receiving a flu shot), or participating in some program (e.g., an online weight loss tutorial). We use the terms incentives and rewards interchangeably. As per the guidance in Sections 20.1 and 20.13 of Chapter 4 of the Medicare Managed Care Manual, located at http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf, in designing a reward and incentive program, the overall benefit design should focus on the delivery of Medicare Parts A and B benefits at the lowest cost, prior to adding items like rewards and incentives. CMS allows incentives provided the criteria below are strictly adhered to.

Rewards and incentives:

- Must be offered to promote the delivery of preventive care;
- Must be earned by doing activities that are either Medicare Advantage benefits – such as flu shots – or educational (in person or online) and directly health related – such as nutrition, blood pressure, weight loss, etc.
- May not be tied to a specific health outcome, such as lowering weight or blood pressure;
- May not be an item that is itself a health benefit (e.g., a free checkup);
- May not consist of lowering or waiving of copays; and
- May not be items that are otherwise available, to the general public, for free.

Additionally, rewards and incentives must be offered to current plan members only, for the entire contract year, and uniformly to all plan enrollees who fulfill the criteria.

The offering of rewards and incentives must be consistent with other CMS requirements. More specifically, rewards and incentives:

- May not be used in pre-enrollment advertising, marketing, or promotion of the plan, such as in the PBP, PBP Notes, SB, ANOC or EOC (rewards and incentives may only be discussed in post-enrollment notifications);
- May not be structured to steer enrollees to particular providers, practitioners, or suppliers;
- May not be cash or monetary rebates;
- May be discussed in direct mailings to enrollees (as long as there is no violation of the Health Insurance Portability and Accounting Act (HIPAA) privacy laws);
- Must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries;
- Must be tracked and documented during the contract year;
- Are subject to grievances by the enrollee: Consequently, the plan must explicitly advise enrollees of the right to grieve and the process for filing a grievance. Grievance procedures can be found at 42 CFR §422.564 as well as in Chapter 13 of the Medicare Managed Care Manual located at http://www.cms.hhs.gov/manuals/downloads/mc86c13.pdf;
- Are subject to CMS review;

- While there is no monetary cap on rewards and incentives, they must be reasonably priced relative to the expected outcome; and
- If a reward or incentive incurs a cost, then this cost must be priced in the bid and included in line q of the MA BPT, "Other Non-Covered". Supporting documentation is required with the initial June bid submission. For more information, see the CY 2009 BPT instructions.

3. *Transportation*

There continue to be ongoing questions regarding coverage of ambulance and other transportation services. An MA plan may, or in certain cases, must, cover transportation services. For detailed guidance, see Section 20.23 of Chapter 4, "Benefits and Beneficiary Protections," of the Medicare Managed Care Manual for detailed guidance located at http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf.

4. Coverage of Benefits outside of the U.S.

MA plans may only offer coverage beyond emergent, urgent, and post-stabilization care outside of the U.S. as an optional supplemental benefit. MA plans, similar to Original Medicare, will not be permitted to cover benefits provided outside of the U.S as Part A or Part B benefits. However, MA plans are still permitted to provide worldwide coverage of emergent, urgent and post stabilization care as a mandatory supplemental benefit.

5. TeleHealth

As specified in federal regulations at 42 CFR §410.78, the Original Medicare Plan covers certain telehealth items in limited circumstances. Consequently, all MA plans must cover these telehealth items in applicable circumstances. An MAO may offer additional telehealth coverage provided all communications are done through a secure means (such as https:// protocols) and with the privacy of the enrollee fully respected, as specified in HIPAA.

Additionally, the provided services must meet the definition of health benefit as specified in Section 10.10 of Chapter 4 of the Medicare Managed Care manual located at http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf. Enrollees must be clearly informed about the benefit, including cost sharing, methods of obtaining the benefit, and any restrictions that apply. The benefit must be priced appropriately in the submitted bid. Enrollees may not be deprived of their right to obtain medically necessary Original Medicare benefits in the traditional manner.

6. New Original Medicare Plan Benefit

Please note that Medicare will pay for a one-time preventive ultrasound screening for Abdominal Aortic Aneurysms (AAA) for beneficiaries who are at risk (has a family history of AAA or is a man age 65 to 75 who has smoked at least 100 cigarettes in his lifetime). Eligible beneficiaries must receive a referral for the screening as a result of their "Welcome to Medicare" physical exam. There is no Part B deductible applied to this benefit, but coinsurance/copayment applies.

7. Cost Plans

Cost HMOs/CMPs may offer the following options in CY 2009. Options (1) and (2) are mutually exclusive. Thus, if a Cost HMO/CMP offers option (1) Qualified Prescription Drug Coverage in any of its plans, it may not also offer option (2) drug coverage that is not Qualified Prescription Drug Coverage in any other plan:

1) Qualified (Part D) Prescription Drug Coverage; or
2) Drug coverage that is not Qualified Prescription Drug Coverage (D-lite); and
3) No drug coverage other than that required under Parts A and B of Medicare.

Note that D-lite can only be offered by a Cost HMO/CMP if it does not offer Part D coverage. Finally, Cost HMOs/CMPs offering D-lite must provide disclosure to Part D eligible individuals and CMS in accordance with 42 CFR §423.56(c) – (f) as to whether that drug coverage is creditable prescription drug coverage.

8. Out-of-Network Data Entry (PBP Section C)

Plans offering out-of-network (OON) benefits must include cost sharing amounts for the OON benefits within Section C of the PBP. Plans failing the edit check for their OON benefits will not be written off to desk review and will be sent back to the plan for resubmission. Please ensure your benefits are accurate and entered correctly prior to submission on June 2, 2008 as failure to do so could delay the approval of your bid.

9. Inpatient Hospital/SNF and Professional Services

Cost sharing for inpatient services should be expressed in the PBP as a single amount for the enrollee. MAOs should not separately bill for a physician service(s) that was part of an inpatient hospitalization, skilled nursing visit, or for lab or radiology services received as part of an inpatient stay. The total cost sharing amount for these services must be identified within the standard variables of the PBP. Notes in the PBP reflecting separate physician cost sharing for these services will not be permitted.

10. Part B-Only Plans

MA and cost plans offering Part B-only plans must submit separate **B-Only bids**. MA and cost plans may **not** use A/B PBPs to submit a B-only plan. Furthermore, cost sharing for B-only plans should not be described in the context of an A/B benefit package. B-only bids do not assume any Part A coverage.

11. PFFS "Opted Out" Provider Network and Non-Network Plans

- Some private fee-for-service (PFFS) plans have attempted to include language in the PBP indicating, "There is no coverage for services obtained from providers who have opted out of the Medicare program." This language is incorrect, and may not be included. Federal regulations at 42 CFR §422.220 state that an MAO can/must pay for emergency/urgently

needed services provided by opt-out physicians where there is no signed agreement with the patient.

- Please ensure your organization has created the correct PFFS plan-type (direct contract (network) or deemed contract (non-network)) during "Plan Creation" in HPMS. PFFS plans that do **not** have partial networks of physicians or other providers who have signed contracts should not have references to out-of-network services included in the PBP (including Notes fields).

12. Segmented Plans

Segments are comprised of one or more MA payment areas. A separate and distinct bid must be submitted by an MAO for each segment. Segments must be mutually exclusive and may not overlap (i.e., a county may not be included in more than one segment in a plan's service area). Segments permit an MAO to offer the same plan (package of benefits) with different cost sharing and/or premiums for A/B and non-drug supplemental benefits in different areas. **No segments are allowed in Part D plans;** therefore no elements (formulary or cost sharing) of the Part D benefit design may vary throughout the service area of an MA-PD's segmented plans.

13. In-Network Urgent Care

The PBP will permit data entry for contracted/network urgent care. Cost sharing for contracted urgent care centers, walk-in clinics, and after-hours care centers will now be captured in the PBP Section B-7a and SB Section 8. The PBP software will continue to collect in Section B-4b cost sharing amounts for urgently needed care, which are typically provided out-of-area by non-network providers while the member is temporarily absent from the plan's service area.

14. Withholding Part C Benefits

MA plans may **not** withhold Medicare Part C services from enrollees that have unpaid/outstanding bills.

15. Notes Changes

Notes fields should only be used within the PBP when they are needed to specifically clarify information that cannot otherwise be entered into the standard variables of the PBP. Notes limiting Medicare covered benefits are not permitted in the PBP. Once bids are approved, additions to the Notes fields during the Plan Correction process **will not be accepted**. Benefits information requiring documentation within the Notes fields should be entered accurately prior to June 2, 2008. Information entered in Notes fields cannot "take away" from benefits in the PBP.

II. Bidding

A. General Biding Guidance

The pricing in the Bid Pricing Tool (BPT) reflects the benefits submitted in the PBP. To protect the integrity of the bid, once the bid is approved, the pricing cannot be altered. Similarly, after bids are approved, benefits cannot be added if they were not explicitly priced in the BPT and specifically included in the supporting documentation, nor can benefits be taken away. This includes attempts to include or exclude referral and/or prior authorization requirements. After the initial bid is submitted, there is little flexibility in correcting errors in the pricing, and any BPT corrections are subject to pre-approval by CMS. Once BPTs & PBPs are approved, there will be a shorter window for requesting plan corrections in 2009, thus quality control must be an integral part of the PBP and BPT submission process. Please ensure that the documentation in both the PBP and BPT is clear and accurate. See Section III of this Call Letter for more information about plan corrections.

All benefits must be directly health-related (i.e., health care items and services whose primary purpose is to prevent, cure or diminish, actual or future, illness or injury) for which the MA plan incurs a bid-priced cost that is not solely administrative. Items and services that do not meet this definition are not benefits nor are VAIS items - neither of which should be included within the bid (PBP or BPT).

See Section III of this Call Letter for more information about the release of the PBP and BPT software and the HPMS plan crosswalk (Attachment G) that continuing MAOs must complete when uploading their CY 2009 bids.

B. Bidding Instruction Updates

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

C. Late Bid Submissions

The absolute deadline for CMS to receive bids is no later than 11:59 p.m. PDT on Monday, June 2, 2008. CMS will not accept any bids received after that time. If the MAO experiences a technical difficulty when submitting to HPMS, they should contact the HPMS Help Desk at1-800-220-2028 or hpms@cms.hhs.gov before the deadline.

D. Rebate Reallocation

Following CMS' publication in August 2008 of the 2009 Part D national average monthly bid amount, the Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the MA regional benchmarks, MA organizations may reallocate Part C rebate dollars in the MA BPT for certain MA plan bids. Detailed guidance is provided in the CY 2009 Instructions for the MA BPT, to be released in early April.

Please note that no changes may be made to the basic A/B package (benefits or premium) during the rebate reallocation period. Also, no changes are allowed to the allowed costs, administrative costs, or gain/loss margin in the Part D basic and Part D supplemental benefits.

In situations where the amount of rebate allocated to the Part C mandatory supplemental benefit must be reduced (due to "insufficient allocation" resulting in a Part D basic premium larger than the target premium or due to a reduction in the total amount of rebate for a regional plan) MAOs **must** make reallocations that reflect the following priorities. Specifically, there may not be any reduction of rebate allocated to priority (3) unless reductions have first been made priority (1), then priority (2).

1. Reduce or remove non-Medicare covered benefits;
2. Increase cost sharing for widely-used services such as primary care visits; and
3. As a last resort**,** increase cost sharing for more limited-use services such as inpatient, skilled nursing facility (SNF), and home health care.

MA plans that do not adhere to this guidance will be asked to resubmit accordingly.

III. 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. 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.

A. Using HPMS to Submit Bids and Formularies

MAOs use HPMS to electronically upload plan formularies and bids to CMS. Cost 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 previous years, cost 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.

MAOs and cost 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 31, 2008. MAOs and cost plans offering the Part D benefit may upload their formularies one or more times between March 31, 2008 and the formulary deadline of 11:59 p.m. EDT on April 21, 2008. CMS will use the last successfully uploaded and validated formulary version as of 11:59 p.m. EDT on April 21, 2008 as the official formulary submission for CY 2009. 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 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 21, 2008 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. Any formulary not attached to a PBP should be deleted or withdrawn.

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 16, 2008.

MAOs and cost plans may upload their plan bids one or more times between May 16, 2008 and the CY 2009 bid deadline of 11:59 p.m. PDT on June 2, 2008. 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.

B. HPMS Crosswalk

It is extremely important that MAOs and cost plans review the crosswalk (Attachment G) for guidance when determining their plan structures for CY 2009. The crosswalk must be submitted by continuing organizations as they upload their bids. Because the crosswalk designates the relationships between plans offered in 2008 to those being submitted for 2009, indicating enrollment, notification, and other requirements associated with offering a plan, we believe this document will also help you prepare for 2009 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 2009* in HPMS.

C. Instructions for Obtaining HPMS Access

MAOs and cost 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 a T-1 lease line 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 the HPMS access team at HPMS_Access@cms.hhs.gov.

D. Interoperability Standards for Health Information Technology

On August 22, 2006, the President issued Executive Order 13410: "*Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs.*" The Executive Order directs federal agencies that contract with health plans, insurers, and providers to require, to the extent permitted by law, that as health information technology systems are acquired or updated, they include recognized interoperability standards for health information technology. All Part C, Part D, Cost, and Employer/Union-Sponsored Group health plans should take steps to implement the provisions addressed in this Executive Order to the extent consistent with current obligations. We will be providing guidance to plans to assist them in this effort.

IV. Quality and Performance Measures

A. HEDIS Reporting

CMS is conducting analyses to determine whether changes would be appropriate in the current minimum enrollment criteria for MAO submission of HEDIS data. These new criteria would be used to determine which contracts must submit HEDIS in 2009. The current enrollment criteria for HEDIS are for an MA contract to have at least 1,000 enrollees on July 1 of the measurement year. MAOs will be notified of any changes to the minimum enrollment criteria by HPMS memo.

B. Quality Improvement and Chronic Care Improvement

In CY 2008, CMS will issue a list of recommended Quality Improvement (QI) project topics and indicators for MAOs to implement as quality improvement projects. MAOs are required to implement QI projects under federal regulations at 42 CFR §422.152(2). This list of recommended topics may include utilization of preventive services, access to care, and customer service. CMS will also issue a list of recommended populations and conditions for inclusion in Chronic Care Improvement Programs (CCIP). MAOs are required to implement CCIPs under federal regulations at 42 CFR §422.152(1).

In CY 2008, CMS will begin working with low performers on customer service indicators in conducting QI projects on specific CMS-directed topics.

C. HOS Reporting

Cost-based contractors with open enrollment and all MAOs with a minimum of 500 members with six months of continuous enrollment, 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, and Social HMOs (SHMOs) regardless of contract effective date, must comply with the Medicare Health Outcomes Survey (HOS) requirement for current year HEDIS reporting. MAOs comprised of one or more special needs plans (SNPs), regardless of institutionalized, chronically ill, or dual-eligible enrollment, are also included in the HOS requirement. PFFS plans, with a minimum enrollment of 500 members, with Medicare contracts in effect on or before January of the previous year, may voluntarily report HOS.

All Programs of All Inclusive Care for the Elderly (PACE), Minnesota Senior Health Options, Minnesota Disability Health Options, Wisconsin Partnership Programs, and Massachusetts MassHealth Senior Care Options plans with contracts in effect on or before January of the previous year are required by CMS to administer the HOS–Modified (HOS-M) survey for current year HEDIS reporting. A minimum enrollment threshold does not apply to the HOS-M.

D. Part C Reporting Requirements

In order to facilitate Part C program administration, contractor monitoring and oversight, and performance assessment, CMS is developing a set of reporting requirements for Part C contractors. Part C contractors will be required to collect and report information beginning in 2009, most likely using a web-based data entry system. CMS is requesting this self-reported information under regulatory authority of 42 CFR §422.516 (a). Areas of interest to CMS may include, but are not limited to: administrative stability, network stability, claims payment, organizational determinations and denials of coverage, grievances, enrollment, disenrollment, and call center customer service.

V. Compliance and Monitoring

A. Compliance Procedures

As announced in the 2008 Call Letter, we revised several procedures related to the contract determination and sanction processes. These revisions were carried out in 2007 through the formal rulemaking process. The final regulation with comment addresses MA and PDP contract determinations (terminations and non-renewals of contracts), appeal rights for contract determinations, intermediate sanctions, civil money penalties, voluntary self-reporting of fraud and misconduct, and access to records and facilities of contractors. It was published in the *Federal Register* on December 5, 2007 (Vol. 72, No. 233).

Several of these provisions take effect starting January 4, 2008, and others will be effective beginning January 1, 2009 (see Table 1).

Table 1. Implement Dates for Revised Contract Determination and Sanction Processes

Regulation Change	Implementation Date
Incorporation of Fraud, Waste, and Abuse Prevention Measures into Compliance Plan	1/1/2009
Requirement to apply Compliance Plan's training and communication requirements to first tier, downstream, and related entities	1/1/2009
Voluntary procedures for MA organizations for self-reporting potential fraud and misconduct	1/1/2009
Requirement to obtain access to Part D sponsor's first tier, downstream, and related entity's books and records through contractual arrangements	1/1/2009
Elimination of CMS' requirement to inform organization of renewal	1/4/2008
Change date of CMS' notification of non-renewal from May 1 to August 1	1/4/2008
Provide for same administrative appeal rights (including Corrective Action Plans (CAPs)) for all contract determinations (non-renewal, expedited termination, termination)	1/4/2008
Change regarding CAP process may be provided prior to notification of termination, and the imposition of time limits on Corrective Action Plans	1/4/2008
Change immediate termination to expedited termination with CMS setting the effective date of termination	1/4/2008
Elimination of Reconsideration Step for contract determination appeals	1/4/2008
Implementation of Burden of Proof for contract determinations	1/4/2008
Ability for a hearing officer to issue summary judgment	1/4/2008
Request for Administrator review, submission of information, and timeframe associated with Administrator review	1/4/2008
Settlement of Civil Money Penalties	1/4/2008
Appeal procedures for Civil Money Penalties	1/4/2008

Comments will still be considered on the mandatory self-reporting provisions until February 4, 2008. For more information please refer to: http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-5946.htm.

B. Audit Assistance Contractor

During 2007, we utilized private contractors to conduct Part C, Part D, and PACE compliance audits. CMS will continue to employ contractors for the foreseeable future to perform these audit services along with regional and central office staff.

C. Analytic-Driven Compliance Requirements

CMS is currently developing an analytic-driven compliance approach for MA and MA-PD contracts in order for CMS to assess compliance in meeting CMS requirements. CMS will use this analytic approach to produce a performance profile of MAOs based upon either pre-established performance thresholds or by measuring contractors against the mean performance of like contracts. As part of this approach, CMS will continue to pursue and conduct widespread surveillance activities across all contracts while over-sampling and performing additional scrutiny on outliers. Some examples of future surveillance activities include, but are not limited to: secret shopping marketing events and conducting outbound calls to enrollees. CMS will also continue to make use of performance-related data presently available, including CAHPS and HOS survey results, complaints and appeals data.

The analytic driven tool will not replace any of the current or existing CMS auditing and monitoring procedures, but will help target those auditing and monitoring activities. MA and MA-PD organizations may be requested to meet additional reporting requirements as deemed necessary by CMS.

VI. Enrollment

A. MA enrollment guidance for Contract year 2009

All MAOs must follow the eligibility, enrollment and disenrollment requirements issued by CMS for accepting & 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, 2009, later in 2008.

VII. Beneficiary Transition in the Event of MA/MA-PD Contract Termination

CMS must periodically terminate (either through mutual agreement or at its own initiative to protect beneficiaries) an entity's MA/MA-PD contract. When this occurs, CMS' primary concern is to protect the impacted beneficiaries. Any actions which may be taken are done so to consider beneficiary choice while recognizing that a situation may compel CMS to assign a member to another plan. When we make an assignment, we aim to move beneficiaries to a plan in which their best interests are primary. CMS will implement a beneficiary transition plan based upon the particular circumstances involved and local conditions, so the elements of these plans can vary. However, all beneficiary transition plans will follow these guiding principles:

- Beneficiary Choice: Members of terminating MAOs always have a choice to join other MAOs in the service area. Impacted members are granted a Special Election Period during which they can join another MAO or Original Medicare and a stand alone

Prescription Drug Plan. (Beneficiaries may be transitioned to Original FFS and a stand alone PDP or another MAO depending on the circumstances of the termination).

- Beneficiary Education: Terminating plans must send a notice to beneficiaries that informs them of the termination and includes a full discussion of their rights under the transition (including Special Election Periods as appropriate) and information on other MAOs in the service area. Unique scripts will be developed for 1-800 MEDICARE. CMS may also require the terminating plan to take one or more of the following steps: conduct media advertising & outreach; issue notices to providers, outreach community organizations, and state and local governments; and conduct additional mailings or phone calls to impacted members.
- Assuring Continuity of Care: If members of the terminating MAO do not make an alternate election or the need for immediate termination does not allow time for beneficiaries to make an advance election, CMS may choose to establish a default option, including moving those members to another MAO (or stand alone PDP, depending on the nature of the termination). In such circumstances, CMS will select a receiving MAO(s) or PDP that:
    1. Operates in the same service area as the terminating plan;
    2. Has a plan product similar to that of the terminating plan (benefits, cost sharing, premiums, and formulary [if Part D coverage is affected]);
    3. Has the capacity to absorb additional members;
    4. Has a compliance and performance history that gives CMS confidence that the selected MAO can serve the potential new members.
    5. Agrees to and signs terms and conditions with respect to how it will conduct the transition, including strict requirements around promoting beneficiary choice, conducting beneficiary education, and ensuring continuity of care for affected beneficiaries.

VIII. Payment

A. Submittal of Medicare Secondary Payer (MSP) Data for Computation of the MSP Reduction Factor

We are providing clarifications on whom to survey for MSP and what survey results to report to CMS. We are also providing a required record layout for the submittal of this data. Further details on the method and location to submit this data will be provided in a future HPMS letter.

This task is to be completed by MA, MA-PD, Social Health Maintenance Organizations (SHMOs), Special Needs Plans (SNPs) and PACE plans. It is <u>not</u> to be completed by Prescription Drug Plans (PDPs), cost plans, or plans that will be non-renewing at the end of 2008.

<u>Whom to Report</u>

Plans will survey the non-ESRD/non-Hospice aged and disabled members contained on the March 2008 monthly membership report (MMR). CMS requires that plans submit data for:
(1) members that report that Medicare is secondary, and

(2) members that fail to respond to the survey.

Plans do not report members that responded that Medicare is primary. Non-MSP members are derived by CMS based on the other data that plans submit.

What to Report

Plans are to provide the data exactly as it is defined in the format described below (see Table 3). Failure to comply with the format will prevent a plan's data from being processed. CMS will then consider the plan's entire membership to be Non-respondent. In this situation, the MSP status on the MBD will be used to determine the MSP reduction factor for your plan.

- The data must be submitted in a TXT file (per the format defined below).
- Only one TXT file is to be submitted for each contract number.
- The TXT file must contain records for both MSP and Non-respondent members. Do not separate the MSP and Non-respondent members into different files.
- The naming convention to be followed is **MSPPROCESS.2008.HXXXX.TXT**; where X is the numeric portion of the plan's contract number.
- The TXT file can only be password-protected; no other encryption techniques are acceptable. Compressing the file using WINZIP or PKZIP is allowed.

Table 2. Required Record Layout of the TXT File

	Field	Field Length	Positions	Description
1	Contract Number	5	1 – 5	The plan's contract number; i.e., HXXXX, where X is the numeric portion of your contract number.
2	Member's Health Insurance Claim Number (HICN).	12	6 – 17	The member's Medicare number including the CAN and the BIC.
3	Member's Full Last Name	30	18 – 47	Self-explanatory; unused positions must be blank
4	Member's Full First Name	18	48 – 65	Self-explanatory; unused positions must be blank
5	Member's Middle Name Initial	1	66	Self-explanatory – optional If not provided, the field must be blank.
6	Member's Date of Birth	8	67 – 74	The date of birth must be in **CCYYMMDD** format.
7			75	

	MSP Status Flag	1		The status flag must be either: **W = for MSP or** **N = for non-respondent**

There can only be one record per member (per HICN) on the TXT file. The data values reported MUST be submitted exactly as stated and in the correct positions per the layout above. No exceptions are allowed.

Note that the date of birth format is CCYYMMDD, that only records for one contract number can be on one TXT file and that the MSP status flag values are W and N (not Y and N).

Failure to comply with these requirements will result in CMS rejecting your data. Your entire membership will be considered as Non-respondent, and their MSP status will be checked on the MBD.

How and Where to Report

Information related to the submittal process is not yet final. Do not submit any data until you receive final guidance in an upcoming HPMS letter. This year, the due date for the data is September 15, 2008.

If you have any questions, please contact your Division of Payment Operations (DPO) representative as specified below.

Boston and New York	John Campbell (410) 786-0542 John.Campbell2@cms.hhs.gov
Philadelphia	James Krall (410) 786-6999 James.Krall@cms.hhs.gov
Atlanta	Gloria Webster (410) 786-7655 Gloria.Webster@cms.hhs.gov
Chicago	Janice Bailey (410) 786-7603 Janice.Bailey@cms.hhs.gov or Louise Matthews (410) 786-6903 Louise.Matthews@cms.hhs.gov

Dallas	Joanne Weller (410) 786-5111 Joanne.Weller@cms.hhs.gov
Kansas City	Terry Williams (410) 786-0705 Terry.Williams@cms.hhs.gov
Denver	Francine Jordan (410) 786-6505 Francine.Jordan@cms.hhs.gov
San Francisco	Kim Miegel (410) 786-3311 Kim.Miegel@cms.hhs.gov
Seattle	David Evans (410) 786-0412 David.Evans2@cms.hhs.gov
PACE	William Bucksten (410) 786-7477 William.Bucksten@cms.hhs.gov

B. Payment Changes

All payment-related changes will appear in the *Announcement of CY 2009 MA Capitation Rates and Payment Policies & CY 2009 Part D Payment Notification*, which will be released in HPMS and posted on the CMS website on April 7, 2008.

C. Risk Adjustment

Changes in payment methodology for 2009, including Part C and Part D payment and risk adjustment, are described in the February 22, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2009 Medicare Advantage Payment Rates* and the April 7, 2009, *Announcement of Calendar Year (CY) 2009 Medicare Advantage Payment Rates* (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).

In addition, it is essential for all providers to review *Attachment A—Risk Adjustment Implementation—*of *Section D, Appendices*. In *Attachment A*, we furnish updated requirements for risk adjustment implementation, data submission and data validation. Among other topics, we provide information on Part A risk adjustment factor options, risk adjustment IT Technical Assistance Outreach, the National Provider Identifier, and hospital acquired conditions.

IX. Grievances, Organization 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 Medicare Managed Care Manual.

B. New Privacy Requirements Related to IRE Correspondence to Beneficiaries

As part of CMS' ongoing efforts to safeguard the privacy and security of beneficiaries' protected health information (PHI), the Part C independent review entity (IRE) will be implementing a new format for all correspondence sent to Medicare beneficiaries. As of January 1, 2009, the IRE will only include the first initial of the beneficiary's first name, the beneficiary's full last name, and the last four digits of the beneficiary's health insurance claim number (HICN). A complete HICN will no longer be used in IRE correspondence sent to beneficiaries. This new format will further safeguard Medicare beneficiaries' PHI and prevent inappropriate disclosures of PHI and is similar to the new version of the Medicare Summary Notice (MSN).

MAOs and cost plans must ensure that their systems and operations can accommodate this new correspondence format for purposes of tracking and processing grievances, organization determinations, and appeals, including complying with effectuation and other regulatory requirements.

X. Special Needs Plans

For the 2009 MA contracting year, CMS is not accepting any Special Needs Plans (SNP) proposals. On December 29, 2007, the President signed into law the "Medicare, Medicaid, and SCHIP Extension Act of 2007. Section 108 of the statute extended the SNP enrollment authority to December 31, 2009. However, section 108(b)(1) imposed a moratorium on the approval of "disproportionate" SNP plans under the authority of section 231(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Section 108(b)(2) also precludes the enrollment of a beneficiary in *any* SNP in an area in which that SNP was not available for enrollment on January 1, 2008. The statute precludes a MA plan from being designated as a disproportionate share SNP, except those plans that were designated as such prior to January 1, 2008. MA Organizations may continue to offer existing CMS approved SNPs through December 31, 2009 Further guidance will be provided to contracting MAs with SNPs.

Applicants, who submitted a Notice of Intent (NOI) to file a MA application and were planning to **exclusively** offer SNP(s) and no other MA plan(s) for contract year 2009, should contact CMS to withdraw the NOI. Please send an email to Kateisha Martin at Kateisha.martin@cms.hhs.gov to withdraw your NOI request, stating the NOI is being withdrawn because of the SNP moratorium.

Although CMS previously permitted MAOs to target marketing to a special needs population under a non-SNP MA plan, this was prior to the enactment of the authority to provide SNPs. Given that Congress has spoken on this issue, marketing targeted to a special needs population may only be done in the case of a SNP serving that population. In addition, while we permitted non-SNPs to be redesignated as SNPs at the inception of the implementation of SNP authority, we will not permit an existing MA plan to be redesignated as a SNP.

A. Medicare and Medicaid Integrated Care

CMS has a web location that serves as a resource for States, health plans, and providers to facilitate the design and development of Medicare and Medicaid integrated care delivery systems. The website contains an overview page and a road map that provides a summary of, and a link to, Medicare and Medicaid documents and tools instrumental to building integrated models of care for dually eligible beneficiaries. It includes recently released CMS guidance on an integrated Medicare and Medicaid appeals process for SNPs. There is also a mail-box for submitting questions or comments to CMS. CMS will continue to update this site with new materials as they are developed and approved. The site can be accessed directly using the following URL: www.cms.hhs.gov/integratedcareint/. On the left-hand side of the page, click on "Integrated Care Roadmap" where you will find a list of documents available for downloading and a short explanation applicable to each download. The site can also be accessed through a link from the Medicare home page at www.cms.hhs.gov/SpecialNeedsPlans/ and click on "Integrated Care Initiatives".

B. Model of Care

The term "specialized MA plans" in the statute clearly signifies that the SNP product provides "specialized" benefits that are focused to meet the needs of the targeted SNP population. As indicated in the ensuing discussion, CMS has expectations that SNP plans develop and execute an appropriate model of care for all SNPs including institutional, dual-eligible, and chronic SNPs. MAOs offering existing SNPs must demonstrate how they meet the model of care requirements. The audit guide is being updated to accommodate these items.

1. Description of Model of Care

In the 2008 SNP applications we have reviewed, MAOs offering SNPs demonstrated a great degree of variability in designing their model of care. While CMS directed that the model of care focus on the unique needs of the SNP-defined population (e.g., full benefit dual eligibles, beneficiaries living in the community but requiring an institutional level of care, beneficiaries with congestive heart failure, etc.), we also gave MAOs wide flexibility to develop a care model that pinpointed the population's specialized needs. In addition, CMS expected MAOs to meet the needs of vulnerable subpopulations (beneficiaries who were frail/disabled, had multiple chronic illnesses, or were near the end of life) for each targeted population since these subsets were likely to be more prevalent among the special needs populations.

What CMS observed in reviewing the 2008 applications was that SNP applicants did not consistently articulate elements of a model of care that differentiated the specialized needs of the

target population nor the corresponding extra benefits and services to ameliorate those identified needs. For example, any MA eligible population should have health assessments to effectively manage preventive services, diagnostic testing, and therapies. Special needs beneficiaries, by contrast, require comprehensive risk-based assessment that accounts for their already-compromised health status and delivery of coordinated care that assures collaborative rather than parallel services. Specific model of care components to consider are:

1) Goals and objectives pertinent to the plan's targeted special needs beneficiaries
2) Comprehensive risk assessment (including a sample risk assessment tool)
3) Specialized provider network
4) Coordinated care and case management
5) Service delivery system (including protocols and out-of-network specialists)
6) Communication and accountability system
7) SNP training for network resources
8) Performance measurement and improvement activities

An appropriate SNP model of care is focused on pertinent clinical expertise with corresponding staff structures, value-added benefits and services, and evidence-based processes and protocols that reflect the special needs of the target population. For example, pertinent clinical expertise is evidenced when a network of licensed and/or certified mental health clinicians are contracted by a SNP that is targeting beneficiaries having mental illness. Care coordination is demonstrated by the use of nurse practitioners and case managers having specialized HIV management training to coordinate care for beneficiaries having AIDS. An appropriate communication network is exemplified when a system for direct collaboration exists between nursing home staff and SNP staff to implement comprehensive risk assessment and care management for a frail/disabled beneficiary who is institutionalized. For auditing purposes, all existing SNP plans must implement a model of care that unequivocally addresses the plan's special needs beneficiaries.

C. Dual Eligible SNPs

We continue to field questions regarding the categories of dual-eligible SNPs. The four categories are:

1. All dual eligible
2. Full dual eligible
3. Zero cost sharing (minimally QMB and QMB Plus duals)
4. Medicaid subsets.

All dual eligibles - A SNP that enrolls all Medicare beneficiaries who are also entitled to Medical Assistance under a State Plan under Title XIX (Medicaid) and includes all categories of Medicaid eligibility. The categories include: Qualified Medicare Beneficiary (QMB only); QMB+; Specified Low-Income Medicare Beneficiary (SLMB only); SLMB+; Qualifying Individual (QI); other full benefit dual eligible (FBDE); Qualified Disabled and Working Individual (QDWI). Note: The "+" refers to the full State Medicaid benefit.

Full dual eligibles **-** A full or full-benefit dual eligible is a Medicare beneficiary who is determined eligible by the State for full benefits under Title XIX of the Social Security Act (medical assistance) under any eligibility category for the month covered under the State plan. This includes individuals eligible for Medicaid either categorically or through optional coverage groups such as medically needy or special income levels for institutionalized or home and community-based waivers. The full-benefit is usually referred to by the "+", e.g., QMB+ or SLMB+.

Zero cost sharing dual **-** This category includes Qualified Medicare Beneficiaries (QMB) and QMB pluses, the two categories of dual eligible beneficiaries that have all Medicare cost sharing (except Part D) paid by Medicaid, and may include any other dual eligible beneficiaries for which the State holds harmless for Part A and Part B cost sharing. Please note that Medicaid may not pay for the LIS cost sharing under Part D.

Medicaid Subset based on coordination with State Medicaid programs **-** A dual eligible SNP that targets a more narrow population than would otherwise be allowable in order to coordinate services between the Medicare and Medicaid programs. Any enrollment limitations for Medicare beneficiaries under this SNP must parallel any enrollment limitations under the Medicaid program, including the structure and care delivery patterns of the Medicaid program. For example, if a State Medicaid Agency contracts with a plan for a Medicaid wraparound package for certain dual eligibles (such as disabled individuals), an MA organization may establish a SNP that limits enrollment to that same subset of dual eligibles. Further, the SNP must provide documentation to CMS regarding their contract and/or agreement with the State Medicaid agency.

For 2008, a number of the Medicaid subset arrangements with the State included zero cost sharing for Medicare Parts A and B of the SNP. It was determined that CMS' system would not show the SNP as zero cost sharing in the public domain. As an interim work around solution for 2008, CMS changed these Medicaid subset SNPs to zero cost share SNPs. CMS is in the process of making the necessary system changes to allow Medicaid subset SNPs to show as zero cost sharing in the public domain for 2009. The impact of this change will not affect the 2008 SNPs. CMS will take the necessary action to make the 2008 Medicaid subset SNPs that were changed to zero cost share SNPs to Medicaid subset SNPs for 2009. No action will be needed by the SNP. CMS will communicate directly with the impacted SNPs with follow-up instructions and guidance.

The system changes described in the preceding paragraph will not affect the pricing in the bid. Cost sharing, whether paid by the enrollee or a state Medicaid agency, must be fully reflected in the Bid Pricing Tool. The full level of plan cost sharing must be included in the PBP and the BPT.

A complete breakdown of dual eligible categories is located at the following website: http://www.cms.hhs.gov/DualEligible/02_DualEligibleCategories.asp. An additional resource for dual eligible information is the HPMS website.

D. Institutional SNPs

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.

E. Chronic Condition SNPs

In light of the SNP moratorium, CMS will not approve any additional chronic conditions in calendar years 2008 and 2009. However, chronic condition SNPs approved prior to January 1, 2008, may continue to enroll eligible beneficiaries for whom the chronic condition is appropriately verified as outlined in the guidance below. The list of chronic conditions CMS has approved for existing chronic condition SNPs is shown in Table 5. The ensuing discussion relates to chronic condition SNPs that existed prior to January 1, 2008.

In addition to the dual eligible and institutionalized SNP plan types, the MMA legislation stipulated that persons with severe or disabling chronic conditions were eligible for a SNP plan. In 2007, approximately 150 plans developed chronic condition SNPs. In the past, CMS required that SNPs serving beneficiaries with severe or disabling chronic conditions verify with a provider or the provider's office that a potential enrollee had the condition for which the chronic care SNP was targeted. SNPs reported, however, that some providers or their office staff were not readily accessible to obtain verification of chronic condition in a timely manner. Therefore, effective May 31, 2007, MAOs were permitted to submit a Pre-enrollment Qualification Assessment tool to be approved on a case-by-case basis as an alternative to the existing pre-enrollment verification processes.

CMS has approved the use of a Pre-enrollment Qualification Assessment tool under the following conditions:

1) The Pre-enrollment Qualification tool provides for each applicable condition a clinically appropriate set of questions relevant to the specific condition(s) that cover the potential enrollee's past medical history, current signs and/or symptoms, and medication regimen that serve as a reliable indicator that the beneficiary has the condition. An example of a pre-qualification questionnaire is displayed as an attachment. CMS worked with industry experts to develop several pre-qualification question sets that may be used by organizations seeking approval to use this alternative verification process.

2) The MAO maintained a record of the results of the Qualification Tool, such as documentation of a phone call. This record must include a date and time that establishes the

verification occurred in accordance with the timeframes for completing an MA enrollment request, pursuant to CMS Enrollment and Disenrollment Guidance for Medicare Advantage Organizations.

3) The MAO conducted a post-enrollment confirmation of each enrollee's information and eligibility based on medical information provided by the enrollee's physician or other provider.

4) The MAO ensured that for all enrollments conducted by an agent or broker, if applicable, any commission or payment associated with that enrollment would be forfeited in the event the condition cannot be confirmed post-enrollment.

5) If the enrollee was accepted into the SNP, but was later determined not to have had the targeted condition, the enrollee would remain in the SNP until the end of the calendar year and would be disenrolled at that time. The MAO must notify the enrollee of this disenrollment by October 1 of each year. The beneficiary would have a Special Enrollment Period (SEP) beginning on October 1 and ending on March 31 of the following year. For CY 2009, the individual will be disenrolled as of the first of the month following the month it was determined he or she did not have the targeted condition and therefore was not eligible to enroll. The MAO must provide prospective notice of this disenrollment. Individuals will have a Special Enrollment Period beginning with the month they are notified of the prospective disenrollment ending 2 months following the disenrollment.

6) The MAO tracked the total number enrollees and the number and percent by condition whose post enrollment verification matched the pre-enrollment verification. These data and the supporting documentation would be available upon request by CMS and would be audited.

7) All information gathered in the pre-enrollment Qualification Tool would be held confidential and in accordance with the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA). This requirement applies to plan employees as well as the plan's business associates.

A request for approval to use a Pre-enrollment Qualification Assessment tool must be submitted by mail to:

Director, Division of Special Programs
7500 Security Blvd.
Mail Stop C4-22-04
Baltimore, MD 21244

The request must include the assessment tool for approval by CMS and an attestation that states the MAO agrees to implement the policy provided in items 1 through 7 above. CMS expects that a SNP plan implementing an approved Pre-enrollment Qualification Assessment tool obtain provider verification (from any licensed provider) within 30 days of enrollment. If a plan identifies extenuating circumstances that preclude provider verification within 30 days, a letter documenting the problem should be sent to the address noted above, and CMS will work with the plan toward a reasonable resolution.

In the coming year, CMS will continue to work with industry experts to help SNP plans meet the statutory caveat "severe or disabling chronic condition" by further defining these terms. The list of the chronic conditions CMS has approved for existing chronic condition SNPs is exhibited in Table 5.

Table 5. List of CMS-approved chronic conditions for existing chronic condition SNPs

2008 Chronic Condition LIST	2009 Chronic Condition Crosswalk List
Chronic cardiomyopathy	CVD: Chronic Heart Failure
Coronary artery disease	CVD: Coronary Artery Disease
Hypertension	CVD: Hypertension
Asthma	COPD: Asthma
Chronic obstructive pulmonary disease	COPD: Asthma
Chronic obstructive pulmonary disease	COPD: Chronic bronchitis
Chronic obstructive pulmonary disease	COPD: Emphysema
Diabetes	Endocrine/Metabolic: Diabetes
Hypercholesteremia	Endocrine/Metabolic: Dyslipidemia
Obesity	Endocrine/Metabolic: Obesity
HIV	Immune Disorders: HIV infection
Arthritis	Joint Disorders: Osteoarthritis
Ischemic Stroke	Neurologic Disorders: Ischemic stroke
Dementia	Neurologic Disorders: Dementia
Chronic kidney disease	Renal Disorders: Chronic renal failure
Renal failure	Renal Disorders: Chronic renal failure
Renal failure (pre-End Stage Renal Disease)	Renal Disorders: Chronic renal failure
End-stage renal disease	Renal Disorders: End-stage renal disease (ESRD)
Post-kidney transplant	Status-post kidney transplantation
Cardiovascular disease	CVD: Chronic Heart Failure
Cardiovascular disease	CVD: Coronary Artery Disease
Cardiovascular disease	CVD: Hypertension
Cardiovascular disease	CVD: Peripheral Vascular Disease
Heart Disease	CVD: Chronic Heart Failure
Heart Disease	CVD: Coronary Artery Disease
Heart Disease	CVD: Hypertension
Heart Disease	CVD: Peripheral Vascular Disease
Mental illness	Psychiatric Disorders: Alcoholism
Mental illness	Psychiatric Disorders: Bipolar disorder
Mental illness	Psychiatric Disorders: Drug dependency
Mental illness	Psychiatric Disorders: Major depression
Mental illness	Psychiatric Disorders: Schizophrenia
Neurological condition	Neurologic Disorders: Dementia

Neurological condition	Neurologic Disorders: Ischemic stroke
Psychiatric disorders	Psychiatric Disorders: Alcoholism
Psychiatric disorders	Psychiatric Disorders: Bipolar disorder
Psychiatric disorders	Psychiatric Disorders: Drug dependency
Psychiatric disorders	Psychiatric Disorders: Major depression
Psychiatric disorders	Psychiatric Disorders: Schizophrenia
Rheumatologic disease	Immune Disorders: Rheumatoid arthritis
Alzheimer's disease	Neurologic Disorders: Dementia
Vascular dementia	Neurologic Disorders: Dementia
Pick's disease	Neurologic Disorders: Dementia
Creutzfeldt-Jakob disease	Neurologic Disorders: Dementia
Parkinson's disease	Neurologic Disorders: Parkinson's disease
Lewy Body Disease	Neurologic Disorders: Dementia
Schizoaffective disorder	Psychiatric Disorders: Schizophrenia
Arteriovascular disease	CVD: Peripheral Vascular Disease
Degenerative joint disease	Joint Disorders: Degenerative joint disease

Key: CVD is cardiovascular disease; COPD is chronic obstructive pulmonary disease

F. SNP Enrollment and Disenrollment

1. Deemed Enrollment Periods

MA enrollment guidance for a "deemed" enrollment period for dual eligibles (a period during which a dual eligible enrolled in a dual eligible SNP loses Medicaid eligibility, but is deemed temporarily to remain eligible for the plan because he or she may re-gain Medicaid eligibility) is provided in the *MA Enrollment Guidance Update*, June 2007, Section 50.2.5. This past year, plans asked a number of questions about how benefits and beneficiary out-of-pocket expenses were affected during the deemed enrollment period. Our policy has not changed from prior years that a deeming period is set by the plan within a range of 30 days to six months. However, we want to reiterate that, during the deemed eligibility period, the MAO must continue to provide all plan benefits, must charge the deemed-eligible member the same premium and cost-sharing that was stipulated in the original enrollment agreement, and must continue coverage of any supplemental benefits (e.g., vision, dental, etc.) during the projected temporary loss of eligibility for the SNP.

For example, if a dual SNP has advertised or described that members of the SNP pay $0 cost sharing at the doctor's office, then any individuals in the period of deemed continued eligibility pay $0 cost sharing during that period. It is the SNPs responsibility to protect members in the period of deemed continued eligibility by either:

- informing contracting providers to look to the SNP for payment of any co-pays (now due because of loss of Medicaid eligibility), or
- informing contracting providers to forgo the co-pays during this period. SNPs must have language to support this in its contracts with providers.

If SNP plans encounter individual situations that raise additional questions, contact CMS for a case-specific interpretation.

2. Disenrollment of Ineligible Beneficiaries during Enrollment Verification Process

If, during the SNP enrollment eligibility verification process for a chronic condition SNP, it is determined that the beneficiary does not meet the SNP eligibility criteria, the plan may not retain that beneficiary as a member through the end of the calendar year and must disenroll the beneficiary per the guidance provided in item E of this section of the Call Letter.

G. Audit Protocols for SNPs

1. SNP Section of MA Audit Guide

Recently, the Medicare Advantage Audit Guide was updated to insert a section specifically designed to review critical aspects of a special need plan. The revised guide monitors enrollment, disenrollment and marketing of the SNP. The review determines if the MAO adequately described the eligibility requirements in the marketing materials and provided 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 includes 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 the review of LTC facility contracts for institutional SNPs.

H. SNP Quality Measures

SNPs are currently subject to the same quality improvement as all other Medicare Advantage plans including the reporting of performance measures for the Healthcare Effectiveness Data and Information Set (HEDIS), Medicare Health Outcome Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS).

Starting in April of 1997, CMS contracted with the National Committee for Quality Assurance (NCQA) to develop performance measures to assess Medicare Advantage Plans. To develop

these performance measures, NCQA was funded to convene and manage the Geriatric Measurement Advisory Panel (GMAP). The GMAP is a committee of twenty-two leading national geriatric, measurement, and clinical experts that develops and tests quality measures.

Since January of 2007, the GMAP developed recommendations for evaluating SNPs. In March of 2007, NCQA proposed a potential list of evaluation measures for SNPs which were approved by the GMAP in November 2007. These recommendations included thirteen HEDIS measures and a set of Structure and Process measures. On December 12, 2007, NCQA posted the measures and supporting documents to their website for public comment. The public comment period ended on January 18, 2008. Public comments were considered by the GMAP and used to inform revisions to the measures. The measures were finalized in March/April 2008. Starting in April 2008, NCQA will collect HEDIS measures from every SNP at the plan benefit package level. Note that HOS and CAHPS will continue to collect survey data at the contract level for all participating organizations, including SNPs, in 2008. SNP information collection and submissions will be completed by June 30, 2008. Through July and August 2008, NCQA will assess and validate SNP responses. NCQA will deliver SNP performance data to CMS by September 30, 2008.

The quality measures program for this year is part of a three-year strategy. In Phase 1 (FY 2008), thirteen HEDIS measures and Structure and Process Measures will be utilized to evaluate the SNPs. In Phase 2 (FY 2009), the HEDIS measures will be expanded to twenty-eight (including measures that focus on the care for older adults), and Structure and Process measures will be expanded. Benchmark measures will be tested as well and CAHPS and HOS will be collected by each SNP benefit package. If the SNP legislation is extended beyond its projected December 31, 2009 sunset, the third year strategy, Phase 3 (FY 2010), may expand the HEDIS measures to include access/availability of care, service utilization, and cost of care. The Benchmark measures will also be refined.

I. Renewing 2008 Dual Eligible Medicaid Subset SNP for 2009

MAs who were approved and offered a dual eligible Medicaid subset SNP in 2008 must have a signed contract/agreement with the State in order to offer the SNP in 2009. In circumstances when an MAO has been approved by CMS 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 or agreement effective for the next year with the State Medicaid agency to continue offering the subset SNP. Specifically, the contract must be signed by October 1 of the year preceding the effective date of January 1 for the new contract year.

XI. Private Fee-For-Service Plans

Private fee-for-service (PFFS) plans are a growing segment of the MA program. On May 25, 2007, CMS released guidance to PFFS plans titled “Ensuring Beneficiary Understanding of Private Fee-for-Service Plans, Actions and Best Practices”. We provided additional model documents and required new outreach processes to ensure beneficiaries and providers are informed about the distinctive features of PFFS plans.

A. Compliance and Oversight of PFFS Plans

PFFS was originally authorized in the Balanced Budget Act of 1997. For many years, PFFS plans were a small component of the MA program. Between August 2006 and June 2007, however, the number of PFFS plans and the number of PFFS enrollees have nearly doubled. While this rapid growth served some useful purposes, such as bringing MA into rural areas where beneficiaries did not have a plan choice before, it has also contributed to some misunderstanding about PFFS plans among sales agents and beneficiaries, as well as providers who furnish services to those in Medicare.

In CY 2008, CMS will be increasing its focus on compliance and oversight activities with respect to PFFS plans. We strongly encourage PFFS plans to be proactive, not reactive, in addressing problems by mining their own data and analyzing complaints. Plans need to have operational procedures and infrastructure in place to identify critical emerging issues early. Plans need to also take responsibility for expanding their self-monitoring efforts through self-audits and internal mystery shopping. Furthermore, plans should increase oversight of agents and brokers and call centers, and education and outreach to beneficiaries and providers in the community.

Much public attention has already been focused on marketing problems with PFFS plans; however, issues related to provider outreach, payment, and access are of equal importance to us. PFFS plans should strive to ensure that their terms and conditions of payment are easily accessible and that providers are being paid correctly and timely. See item E below about the requirements for the terms and conditions of payment. Plans should take every step possible to encourage providers to accept PFFS plans – lack of provider participation directly affects beneficiaries enrolled in these plans. Along with increased provider education, it is essential that beneficiaries get accurate, clear, and concise printed and oral information about PFFS products, and that they are able to make informed and educated decisions. No materials provided to beneficiaries should confuse or mislead them.

B. Training and Testing of Agents/brokers Selling PFFS Plans

We are reminding MAOs that all agents and brokers (employed and contracted) selling the PFFS product to beneficiaries on behalf of the MAO are required to be trained, and they must pass a written test that demonstrates their thorough familiarity with both the Medicare program and the product they are selling. See Section C of this Call Letter for more information on training and testing requirements for agents and brokers.

C. Provider Education and Outreach

All PFFS plans should have a provider education and outreach program in place to encourage a wide range of providers to accept PFFS enrollees. PFFS plans need to develop provider relation strategies, a provider education process, and educational materials that include establishing relationships with and educating providers in the PFFS plan service area. PFFS plans must conduct effective outreach to providers to help them understand how PFFS plans work and to

overcome any resistance that may be particularly caused by concerns about the timeliness and accuracy of payments. In order to address these issues, PFFS plans must ensure that they clearly inform providers about how to obtain their terms and conditions of payment, how to get payment or coverage questions quickly answered, and how to appeal payment decisions. As indicated in the May 25, 2007 memo, PFFS plans are required to have staff available to assist providers with questions concerning plan payment and payment accuracy.
To ensure that a PFFS plan's provider outreach program will be approved by CMS, the plan should address each of the following:

- Develop a process to obtain current provider information from new enrollees and proactively contact and educate each enrollee's current providers.
- Use the sales force to educate providers in the plan service area and state provider associations (e.g., medical and hospital associations).
- Furnish a new provider package upon receipt of the first claim from a new provider.
- Make the beneficiary/provider education leaflet (see Attachment 2 of May 25, 2007 memo) widely available to enrollees, so that they may in turn furnish it to their providers.
- Additionally, non-network PFFS plans have the option of establishing direct contracts under which providers agree in advance to treat plan members and accept its terms & conditions of payment. Under the PFFS access rules at 42 CFR §422.114, PFFS plans that establish payment rates less than Original Medicare must have direct contracts with sufficient providers to meet Medicare access requirements under federal regulations at 42 CFR §422.114(a)(2)(ii) or (a)(3)(iii). However, as noted above, PFFS plans that have met Medicare access requirements by establishing payment rates at or above Original Medicare may also establish direct contracts with providers. In this case, the plan establishes provider contracts not to meet Medicare access requirements, but rather to assure enrollees that they will have access to providers who have already agreed to accept the plan's terms and conditions of payment. Note that such contracted providers must be paid under the PFFS plan's CMS-approved terms & conditions of payment. These payment rates must be identical to the rates paid to deemed providers.

Adequate participation by providers is critical to the success of the PFFS program, thus plans should focus on increasing outreach to providers and educating them about how PFFS plans work. To encourage provider participation, plans must ensure that providers have reasonable access to their terms and conditions of payment and that providers are being paid correctly and timely. The large number of beneficiaries enrolled in PFFS plans makes provider access and participation a top priority for CMS. The provider component is under close scrutiny similar to marketing in 2007. We will be closely monitoring beneficiary and provider complaints and other marketplace-based information to determine whether compliance and/or enforcement actions are warranted.

D. Correction of Disclaimer Language

CMS has revised the disclaimer language that was included the May 25, 2007 memo to PFFS plans. As stated in this memo, MAOs offering PFFS plans are required to prominently display this disclaimer in all materials including, but not limited to, advertisements, enrollment-related materials, web-based information, materials used at sales presentations by agents and brokers

(employed and contracted) of the MAO in public venues, and private meetings with beneficiaries.

> *A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your doctor or hospital is not required to agree to accept the plan's terms and conditions, and thus may choose not to treat you, with the exception of emergencies. If your doctor or hospital does not agree to accept our payment terms and conditions, or otherwise agree to treat you, you will not be able to receive covered services from them under this plan. Providers can find the plan's terms and conditions on our website at: [insert link to PFFS terms and conditions].*

Immediate use of the revised disclaimer language is recommended; however, plans must begin the use of this disclaimer prior to marketing CY 2009 PFFS plans.

E. Terms and Conditions of Payment Requirements

PFFS plans' terms and conditions of payment are the primary means for providers to obtain complete information regarding a PFFS organization's payment arrangements and provider requirements. It is essential that all plans' terms and conditions of payment are accurate, information is presented clearly, and provider contact information is appropriate in order to allow providers to make a confident decision as to whether or not they will agree to accept the terms and conditions of payment. In general, making PFFS terms and conditions more explicit will help providers gain a greater understanding of the PFFS Program and increase provider participation.

Requirement

Federal regulations at 42 CFR §422.216 requires PFFS organizations to make information on its payments rates and provider requirements available to providers that furnish services to its enrollees. PFFS organizations are expected to include the following components in their terms and conditions of payment:

1. Explanation of deeming,
2. How providers will be paid,
3. Prompt payment requirements,
4. Providers and physician requirements,
5. Appeal requirements including provider dispute process, and
6. Billing Requirements

Each component should contain sufficient information and instructions as to how additional information can be located if necessary. In addition, PFFS organization must make terms and conditions easy to accessible to providers. Terms and conditions of payment should not be changed without CMS approval.

We anticipate revising the review and approval process for terms and conditions of payment and developing a model template for PPFS terms and conditions of payment later in 2008. In the

interim, we are requiring PFFS organizations to: (1) conduct quality checks of their terms and conditions of payment; (2) ensure their terms and conditions of payment are approved by CMS; (3) ensure CMS' approval, including the approval date, is promptly displayed on their terms and conditions; and (4) ensure the plan's provider dispute process is effectively addressing provider payment disputes.

CMS has posting on its website contact information for all MAOs offering PFFS plans that would allow providers to easily access the plan terms and conditions of payment. The contact information for all MA PFFS contracts is posted on http://www.cms.hhs.gov/PrivateFeeforServicePlans/.

F. Model Process for Resolving Provider Payment Disputes

Under its contract with CMS, PFFS plans are required to have a process in place to resolve provider payment disputes (see Article III.D.3(e) of the CMS/PFFS Contract). In the coming months, CMS will be reviewing the provider payment dispute process of PFFS plans to ensure that the dispute process is responsive to providers who question the amount they are paid by the PFFS plan. CMS considers an effective provider payment dispute process a critical part of a PFFS plan since it will encourage provider participation in the plan.

When reviewing a provider dispute process, CMS will also review the plan's Terms and Conditions of Payment and the rate at which it rejects provider claims. Specifically, the plan's Terms and Conditions of Payment must furnish clear instructions telling providers how to bill the plan for services furnished to its members. As part of this review, CMS will pay particular attention to PFFS plans that reject a large percentage of claims because they are not clean (i.e., claims not paid because they were not billed according to plan instructions). The MA regulation at 42 CFR §422.520(a)(1) require that PFFS plans pay clean claims from deemed providers within 30 days. CMS will review the Terms and Conditions of Payment of PFFS plans to ensure that it clearly informs providers how they can appeal to the plan if the provider believes the amount paid by the plan is less than what is described in its Terms and Conditions of Payment.

There are a number of ways a provider dispute resolution process could be implemented. However, in its review, CMS will pay particular attention to how the plan documents its process and if it appropriately responds to provider appeals in a timely manner. The following guidelines identify some optimal features of a provider payment dispute process, which CMS encourages all PFFS plans to implement.

Model Features of a Provider Payment Dispute Process

1. The PFFS plan has a system for receiving provider payment disputes (e.g., dedicated phone line, e-mail address) and establishes a specific and reasonable timeline for resolution/adjudication of disputes. [CMS recommends 30 days.]

2. The PFFS plan maintains a record of provider payment disputes and resolution and has the capacity to report this information to CMS upon request - including documentation of any corrective actions taken to prevent future payment errors.

3. The PFFS plan furnishes the provider with a written notice explaining how the provider payment was determined. The provider should be told to submit appropriate documentation to the plan to demonstrate that the plan paid the provider less then required under the PFFS plan's terms & conditions of payment. The plan is required to ensure that providers are being paid according to its terms and conditions of payment.

4. If the PFFS plan finds for the provider,(i.e., it agrees that it initially underpaid the provider) in addition to paying the provider the additional amount due, the plan should correct its payment system going forward, and identify similar claims for that contract year to ensure that it has paid them correctly.

5. PFFS plan documents its final decisions regarding provider payment disputes and informs the provider in writing of its decision.

G. Medical Record Requests

CMS is providing guidance to PFFS plans on how they can appropriately request medical records from providers and how the plans may utilize these medical records. CMS is concerned that many PFFS plans are expecting providers to furnish beneficiary medical records without first informing them of the requirement through the plans' terms and conditions of payment.

<u>When the regulations expressly require providers to submit medical records</u>

The MA regulation at 42 CFR § 422.310(e) requires providers to submit medical records so that CMS can validate an MA plan's risk adjustment data. This process occurs annually and is limited to specific beneficiaries in a subset of MA plans. Generally, CMS will direct the MA organization sponsoring the plan chosen for a sample to secure medical records on its behalf. For the specific purpose of CMS-initiated risk adjustment validation audits per 42 CFR § 422.310(e), providers are legally required to provide medical records to CMS, regardless of whether they have been informed of this requirement through the plan's terms and conditions of payment. Nonetheless, a PFFS plan *should* inform providers in its terms and conditions of payment that they may be required to provide medical records, if beneficiaries for which they have been paid by the MAO are selected for CMS audit. Note that when medical records are obtained for this purpose, MAOs cannot use them for other purposes.

<u>When the regulations do not expressly require providers to submit medical records, but such records are required for compliance with regulations</u>

In addition, PFFS plans will need to obtain medical records in instances where the beneficiary or the provider requests an advance determination of coverage from the PFFS plan.
PFFS plans may also want to obtain additional medical records from providers in order to determine if (1) the service furnished by a provider to a beneficiary is covered by the plan; (2) the service was reasonable and medically necessary; or (3) the plan was billed correctly for the service that was furnished to the beneficiary. If a PFFS plan intends to obtain medical records from providers for any of these purposes, then the plan should inform providers in its terms and

conditions of payment that they may be required to submit medical records for these additional reasons. If not, the PFFS plan may have difficulty in meeting its obligation under the regulations to make an advance determination.

Although PFFS plans may perform medical record reviews to make coverage and medical necessity determinations, PFFS plans cannot use medical record reviews to *inappropriately* down-code submitted claims or to create artificial barriers that would delay payments to providers. Note that PFFS plans are required to pay 'clean' claims within the time specified in the terms and conditions of payment. Creating unreasonable delays in payment, or paying providers incorrect amounts, will result in the PFFS plan not paying in accordance with its published terms and conditions of payment and therefore not being in compliance with its contract with CMS.

CMS is taking this opportunity to remind PFFS plans that they should not rely solely on post-payment claims' review. Instead, PFFS plans should, as part of a pre-payment review, adopt claims payment systems that have sufficient sophistication to identify aberrant and error-prone claims. MAOs are encouraged to investigate suspicious claims prior to payment where there is a bona fide reason for concern.

To encourage provider participation, PFFS plans may choose to (1) compensate providers for the time and expense incurred in copying and forwarding requested medical records, and (2) sending plan staff on-site to obtain copies of the desired records (after first securing beneficiary and provider permission). CMS is aware of cases where PFFS plans have chosen this path and has no objection to plans pursuing this course.

CMS strongly urges PFFS plans to include clear and detailed information in terms and conditions of payment as to why medical records are needed, including the expected administrative burden this will place on providers – with mitigating factors such as additional payment from the plan. It is also important to consider that PFFS plans that impose too significant a burden are in danger of causing providers to refuse access to plan members. PFFS plans must notify their Regional Office Plan Manager of all changes made to their terms and conditions of payment.

Until PFFS plans are able to update their terms and conditions of payment, plans that need access to beneficiary medical records, for making advance determination of coverage or post-payment coverage/medical necessity determinations, or when investigating plan-initiated fraud and abuse cases, can submit a written request to their CMS Regional Office asking for permission to obtain a sample of beneficiary medical records. PFFS plans that need access to medical records for the limited purpose of performing CMS-initiated risk adjustment validation audits can obtain these records from their providers without prior CMS approval. However, these plans should also update their terms and conditions of payment.

H. PFFS Prior Authorization Rules

PFFS plans are required to have a system for furnishing an advance determination of coverage upon request of an enrollee or provider. The advance determination of coverage is a beneficiary protection, so that the beneficiary (or provider) can confirm in advance of furnishing a service

that the service is covered by the plan and is being furnished consistent with Medicare coverage requirements. The advance determination of coverage requirement is discussed in the *Federal Register* at Vol.63, No.123 published on June 26, 1998.

PFFS plans can perform retrospective review of claims for the purpose of verifying medical necessity and that the service furnished is a covered service. However, PFFS plans cannot require enrollees or providers to obtain prior authorization from the plan as a condition of coverage. We would view prospective utilization management requirements as analogous to a prior authorization requirement – both of which are prohibited.

PFFS plans can establish a prior notification requirement. Under the prior notification requirement, the plan may impose higher cost sharing for a service (subject to CMS review and approval) if the enrollee or provider does not notify the plan prior to obtaining services. If the member or provider does not prior notify, the plan must still cover the service as long as it is medically necessary and a covered service although the plan would be permitted to impose higher cost sharing."

J. Performance Data

CMS strongly encourages PFFS plans to participate in HEDIS and Medicare Health Outcomes Survey (HOS), if they meet the minimum reporting requirements for these measurement sets. PFFS contractors who have been determined to meet these minimum reporting requirements will receive additional information regarding how to report these measurement sets. PFFS plans that participate in HEDIS and HOS will be advantaged by having their data posted in Medicare.gov Plan Ratings for 2009 open enrollment.

XII. Medical Savings Account Plans

A Medicare Medical Savings Account (MSA) plan is a type of MA plan that combines a high-deductible health plan with a medical savings account. Enrollees of MSA plans can initially use their savings account to help pay for health care and then will have coverage through a high-deductible insurance plan once they have reached their deductible. Medicare Advantage MSA plans provide Medicare beneficiaries with added freedom to exercise control over health care utilization while still providing coverage against catastrophic health care expenses.

MSAs were first proposed as a limited demonstration program in the Balanced Budget Act of 1997. In 2003, the Medicare Modernization Act made this plan type permanent. 2007 was the first year that MSAs were actually available to Medicare beneficiaries for enrollment. Demonstration MSA plans are more like the popular consumer-directed health savings accounts (HSAs) available in the private sector.

Enrollees cannot get Medicare Part D prescription drug coverage from an MSA plan, however, MSA plan enrollees can join a stand-alone Medicare prescription drug plan (PDP). MSA savings account withdrawals can be used for Part D drug plan co-pays that will count towards TROOP.

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

Further information:

- For more information on MSA plans, see CMS publication Your Guide to Medicare Medical Savings Account Plans www.medicare.gov/Publications/Pubs/pdf/11206.pdf.
- For information on MSA plans open for enrollment in 2008, see www.medicare.gov.
- We will be updating the MSA webpage www.cms.hhs.gov/MSA/ with frequently asked questions, applications, payment guidance, and enrollment information and forms. CMS is also in the process of developing an audit guide for MSAs and a checklist to facilitate the development and review of draft MSA marketing materials.

One item that will change in contract year 2009 is that for MSA demonstration plans the minimum difference between the deductible and the deposit will be set at $1,000 (in 2008 it is $530). With increases in cost sharing requirements in Private Fee-for-Service and coordinated care plans, it is necessary to increase the minimum difference between the deductible and the deposit in order to maintain a clear distinction between MSA demonstration plans, which are supposed to be "high-deductible" health plans, and other types of Medicare Advantage plans.

XIII. 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 plan (EGWP) program 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 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. 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 2009 contract year for MAOs offering employer or union-sponsored group plans and/or clarifications on certain topics.

A. Permitting Employer/Union Sponsors to Enroll Beneficiaries in Both an "800 Series" Local MA-Only Coordinated Care Plan and an "800 Series" Standalone PDP

Beginning with CY 2009, all employer and union group plan sponsors will be allowed to enroll their members in both an "800 series" local coordinated care MA-Only plan (i.e., HMO, HMO/POS, Local PPO) and an "800 series" standalone PDP. As a condition for providing this waiver, CMS will require the separate medical and prescription drug vendors to work closely with each other and the employer sponsor to provide coordinated care and disease management services between the MA and PD portions of the benefit. This coordination is similar to the kind that would be offered if the employer purchased the medical coverage and the drug coverage from a single local MA-PD vendor.

B. Formularies for Non-Calendar Year Plans Offered by MAOs

CMS allows entities offering Part D EGWPs to offer prescription drug benefits on a calendar year and on a non-calendar year basis (if entities are approved to offer non-calendar year Part D EGWP plan benefit packages). In accordance with existing employer group policy, entities offering Part D EGWPs can add new drugs to their formulary or change the cost sharing to a lower cost share without submitting a new formulary for CMS approval. However, as with individual Medicare plans, these formularies may only be modified to remove drugs from the drug list, increase cost-share tiers, or add restrictions or limitations by following the established negative formulary change process for all Part D sponsors. Negative formulary change requests for non-calendar year Part D EGWPs are required to follow the same review and approval process as calendar year plans. Negative formulary change requests are not permitted after July 31st for any Part D sponsor. Thus, the time frame for non-calendar year Part D EGWPs to make negative changes is the same as calendar year plans.

However, in order to accommodate non-calendar year Part D EGWPs, CMS is clarifying that non-calendar year Part D EGWPs may elect to convert to the conditionally approved formulary for the next calendar year on January 1st. Any entities offering non-calendar year EGWPs that choose this option must provide appropriate beneficiary notice as specified in 423.120(b)(5). Alternatively, entities offering non-calendar year Part D EGWPs whose plan start date occurs after conditional approval of the formulary for the following calendar year may elect to use that formulary for the entire non-calendar plan year. Any further changes for the rest of the non-calendar year would have to be consistent with the process for updating CY 2008 formularies and requesting negative formulary changes as described in the November 28, 2007 HPMS memo – Updating CY 2008 formularies.

The following example illustrates the above-stated policy:

A non-calendar year Part D EGWP with a start date of October 1, 2008 could either:

1. Use its CY 2008 conditionally approved formulary throughout the employer group sponsor's plan year (October 1, 2008 –September 30, 2009) and make no negative changes;

2. Use its CY 2008 conditionally approved formulary from October 1, 2008 – December 31, 2008 and its CY 2009 conditionally approved formulary from January 1, 2009 – September 30, 2009) and request negative changes through July 31, 2009 in accordance with the above-stated policy; or

3. Use its CY 2009 conditionally approved formulary throughout the employer group sponsor's plan year (October 1, 2008 – September 30, 2009) and request negative changes through July 31, 2009 in accordance with the above-stated policy.

C. Clarification of Network Access Submission Requirements for MAOs Applying to Offer EGWPs

1. MAOs Applying to Offer Both Individual and "800 Series" Plans

Consistent with prior contract year requirements, MAOs applying to offer both individual plans and "800 series" plans under a single contract in CY 2009 will not initially be required to have Part C or Part D networks in place for those designated EGWP service areas outside of their individual plan service areas. Accordingly, these MAO applicants will also not be initially required to submit Part D GeoNetworks® retail pharmacy reports and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) for those designated EGWP service areas outside of their individual plan service areas. However, Part C and Part D access sufficient to meet the needs of employer group enrollees must be in place once the MAO enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area. Also, CMS may review the adequacy of its Part C and D networks and potentially require expanded access in the event of beneficiary complaints or for other reasons in order to ensure that the plan's network is sufficient to meet the needs of its enrollee population.

2. MAOs Applying to Only Offer "800 Series" Non-Network PFFS Plans (i.e., "800 Series Only" Contracts)

The elimination of the "nexus test", effective January, 2008, made it possible for MAOs to apply to offer non-network PFFS plans to employer groups through separate "800 Series Only" contracts without offering them to individual beneficiaries. MAOs applying to offer "800 Series Only" non-network PFFS contracts in CY 2009 are required to submit GeoNetworks® retail pharmacy reports and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) for their entire designated EGWP service areas. The same rules apply to Employer/Union Direct Contract MAOs.

D. Designation of Service Area in HPMS for "800 Series" Plans

In order for a beneficiary to be eligible to enroll in an employer-sponsored individual MA plan or an EGWP plan, he/she must permanently reside in the defined service area of the individual MA plan or EGWP. MAOs offering EGWPs are eligible for extended geographic service areas (outside of their individual plan service areas) for certain kinds of MA plans under several service area waivers issued by CMS. Therefore, MAOs offering EGWPs should ensure that their EGWP defined service area includes all geographic areas in which employer/union sponsored group health plan Medicare eligibles may permanently reside (e.g., national service area) during the contract year. No mid-year service area expansions will be permitted to address situations where MAOs have failed to define their service area broadly enough and later wish to enroll employer group beneficiaries that permanently reside out of their EGWP defined service area.

E. Service Area Expansion for EGWPs ("800 Series" Plans, Employer/Union Direct Contract and "800 Series Only" Contracts)

CMS does not require MAOs to submit a service area expansion application for EGWPs. However, MAOs are required to submit the following service area expansion and reduction requests to the Employer Policy & Operations Group in writing:

1. Request to expand an EGWP service area to include states/counties that were not previously included in the service area for the contract.

2. Request to reduce an EGWP service area to eliminate employer-only states/counties.

These service area expansion and reduction requests should be made to the Director of the Employer Policy & Operations Group on the Organization's letterhead and should be signed by an authorized representative. The request should include the contract number and list the states/counties that should be added to or deleted from the EGWP service area. This request should be submitted by April 30, 2008. CMS will make the necessary changes in HPMS after reviewing the request. Submit this request via hard copy to:

Centers for Medicare & Medicaid Services
Employer Policy & Operations Group
Mail Stop: C1-22-06
Attn: 2009 Service Area Expansion/Reduction Request
7500 Security Blvd.
Baltimore, MD 21244-1850

Section B – 2009 Prescription Drug Plan Sections

Table of Contents

Introductory Note: Most of the information in Section B of the 2009 Call Letter applies to all types of Medicare Part D sponsors (i.e., prescription drug plan (PDP) sponsors, Medicare Advantage organizations (MAOs), and Cost Plan sponsors). The applicability of the information in each subsection is indicated in brackets next to the heading for that subsection. MAOs and Cost Plan sponsors offering Part D benefit plans must review both the Part C and Part D sections of the Call Letter to obtain complete information concerning their Medicare contract obligations for 2009. Section C contains marketing-related information that applies to MAOs, Cost plans, and PDP sponsors.

CALENDAR – PREPARATION FOR 2009

2009 Contract Year Renewal Dates [PDP sponsors only]

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).

2009 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
2008	
March 15, 2008	CMS releases 2009 Call Letter. Attachments include 2009 standardized combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), pharmacy directory, provider directory, transition notice, and abridged and comprehensive formulary marketing models.
Late February/Early March 2008	Conference call to discuss 2009 Call Letter.
March 25, 2008	Industry training on ANOC/EOC and other standardized marketing models.
March 31, 2008	Release of Health Plan Management System (HPMS) formulary submissions module.
April 10, 2008	CMS Bid Conference (tentative).
April 11, 2008	Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) available on HPMS.
April 21, 2008	Final day to submit 2009 formularies via HPMS (11:59 PM EDT). Transition Policies and Procedures for new contracts due to CMS.
May 15, 2008	Model Low Income Subsidy (LIS) riders will be available for all organizations.

2009 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
May 16, 2008	CMS begins accepting CY2009 bids via HPMS.
Late May 2008	CMS sends PDP sponsor contract eligibility determinations to Applicants based on review of the 2009 applications.
June 2, 2008	Final day for PDP sponsors to submit CY2009 bids via HPMS (11:59 PM PDT). Non-Renewal: Deadline for MAOs, PDP sponsors to submit a non-renewal or service area reduction notice to CMS for CY2009.
June 9, 2008	CMS begins accepting supplemental formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS. CMS begins accepting CY2009 Actuarial Certifications in HPMS.
June 16, 2008	CMS begins accepting CY2009 marketing material for review via HPMS Marketing Module.
June 30, 2008	Final date for PDP sponsors to submit CY2009 marketing materials for CMS' review and approval. NOTE: This date does not apply to CY2008 file & use materials since PDP sponsors may file these materials with the CMS regional office five calendar days prior to their use.
August 1, 2008	PDP sponsors are expected to submit non-model Low Income Subsidy (LIS) riders to the CMS regional office for review. Non-Renewal: CMS to post the beneficiary model final non-renewal notification letter.
By August 1, 2008	CMS issues contract non-renewal notices to those PDP sponsors CMS finds not qualified to offer Part D benefit plans in 2009.
Early August 2008	CMS publishes national average Part D premium, national average monthly bid amount, and base beneficiary premium for 2009.
Late August 2008	Submission of attestations, contracts, and final actuarial certifications.

2009 Part D Calendar ***(All dates, unless identified as statutory, are subject to change)***	
Early September 2008	CMS completes review and approval of 2009 bid data. Part D contracting materials due to CMS.
September 8 – 10, 2008	PDP sponsors preview the 2009 Medicare & You handbook plan data in HPMS prior to printing the CMS publication (not applicable to EGWPs).
October 1, 2008	PDP sponsors submit model Low Income Subsidy (LIS) riders for review.
October 1, 2008	PDP sponsors may begin CY2009 marketing activities.
October 1, 2008	Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.
October 1, 2008	PDP sponsors are required to include information in CY2008 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2009.
October 9, 2008	Tentative date for 2009 prescription drug benefit information to be displayed on the Medicare Prescription Drug Plan Finder on Medicare.gov (not applicable to EGWPs).
October 15 - 30, 2008	Medicare & You handbooks are mailed to Medicare beneficiaries.
October 31, 2008	PDP sponsors must cease marketing CY2008 plans through public media. CY2009 standardized combined ANOC/EOC is due to all PDP members. PDP sponsors must mail the combined ANOC/EOCs before this date to ensure receipt by members by October 31. All PDP sponsors must mail their Low Income Subsidy (LIS) riders and abridged or comprehensive formularies in the same package as the combined ANOC/EOC. Package must be mailed before this date to ensure receipt by members by October 31.
November 15, 2008	Marketing guidelines require that PDP sponsors mail a CY 2009 EOC to each new member no later than when they notify the new member of acceptance of enrollment. PDP sponsors must mail their low income subsidy (LIS) riders

2009 Part D Calendar *(All dates, unless identified as statutory, are subject to change)*	
	and abridged or comprehensive formularies in the same package with the EOCs for new members.
November 15 - December 31, 2008	Annual Election Period: All PDP sponsors must hold open enrollment (EGWPs see Section 20.3.8 of the PDP Guidance: Eligibility, Enrollment and Disenrollment).
Early December 2008	Potential New PDP sponsors and existing sponsors seeking to expand currently contracted service areas must submit Notices of Intent to Apply for the 2010 contract year.
Late December 2008	CMS issues pending HPMS contract numbers to new PDP sponsors for the 2010 contract year.
2009	
January 1, 2009	2009 plan benefit begins.
Mid January 2009	Final 2010 PDP sponsors contract applications are posted to the CMS website and HPMS.
Mid January 2009	Automated applications released for organizations seeking new Part D contracts or service area expansions.
Late January 2009	Industry training on contract applications for 2010 contract year.
Early March 2009	Applications due for organizations seeking new Part D sponsor contracts or service area expansions in 2010.

I. CONTRACTING PROCESS

[All Part D sponsors]

The contracting process is a critical requirement for all sponsors that intend to participate in the Medicare Part D program in CY2009. All Part D sponsors, including new and renewing sponsors, are required to participate in the contracting process.

CMS will release official guidance in the summer of 2008 on the contracting submission process, which will include a description of the required documentation for each contract type, as well as all relevant deadlines. CMS currently estimates that sponsors will be required to submit all required CY2009 contracting documents to CMS by early September 2008. The specific documents an organization must submit will depend on the organization type. For example, *new* applicants for CY2009 are required to submit signed contracts to CMS, while *renewing* organizations are not. However, all Part D sponsors will be required to submit benefit attestations to CMS. Sponsors will be unable to download their benefit attestation from HPMS until all plan bids, including formularies, under the contract number are approved.

It is imperative that all Part D sponsors comply with all aspects of the contracting instructions, including submitting the correct contracting materials by the required deadline. Sponsors that fail to submit all required contracting documents by the required deadline may be at risk for exclusion from the Medicare & You Handbook.

II. BIDDING/PAYMENT

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

All updates for bidding will appear in the 2009 Bid Pricing Tool instructions.

B. Advanced and Final Payment Notices [All Part D sponsors]

All payment-related changes will appear in the *Announcement of CY2009 MA Capitation Rates and Payment Policies & CY2009 Part D Payment Notification*, which will be released in HPMS and posted on the CMS website on April 7, 2008.

C. Ensuring Significant Differences in Approved Bids

(For more information please refer to the benefits section later in this call letter.)

D. Risk Adjustment

Changes in payment methodology for 2009, including Part C and Part D payment and risk adjustment, are described in the February 22, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2009 Medicare Advantage Payment Rates* and the April 7, 2009, *Announcement of Calendar Year (CY) 2009 Medicare Advantage Payment Rates* (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).

In addition, it is essential for all providers to review *Attachment A—Risk Adjustment Implementation*—of the *Appendices*. In *Attachment A*, we furnish updated requirements for risk adjustment implementation, data submission and data validation. Among other topics, we provide information on Part A risk adjustment factor options, risk adjustment IT Technical Assistance Outreach, the National Provider Identifier, and hospital acquired conditions.

III. FORMULARY

A. Six Classes of Clinical Concern

With the exception of the following modification, there will be no change in our six classes of clinical concern policy for contract year 2009.

Given our experience to date with the Part D program, we believe HIV/AIDS prescribers should be provided wide discretion in initiating antiretroviral therapy. Consequently we are removing the exception in our six classes of clinical concern (Section 30.2.5 of Chapter 6 of the Prescription Drug Benefit Manual) that allowed for the potential application of prior authorization to the HIV drug, Fuzeon. As a result, Part D sponsors must list on their formulary "all or substantially all" antiretrovirals and should not generally employ any utilization management tools for these drugs.

We also clarify that new drugs or newly approved uses for drugs within the six classes that come onto the market after April 21, 2008 will be subject to an expedited Pharmacy and Therapeutic (P&T) committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement. At the end of the 90 day period, these drugs must be added to Part D plan formularies subsequent to P&T Committee review.

B. Prior Authorization

In our ongoing efforts to improve Part D formulary review processes, CMS is standardizing the submission of Part D plan prior authorization (PA) requirements for the 2009 review cycle. We believe this standardization will further streamline the CMS formulary review and provide a uniform format that will allow greater transparency when comparing Part D plan formularies.

As previously announced on the December 19, 2007 Part C and D User Group Call, Part D sponsors will be required to compile their PA criteria into a 2009 CMS standardized PA format. Each drug identified in the Part D plan's formulary flat file as having PA must have corresponding criteria uploaded into our Health Plan Management System (HPMS) using the standardized PA format. Operational details associated with the location and completion of this 2009 CMS standardized PA file will be released as part of the CY2009 Formulary Submission Module and Reports Technical Manual in March 2008.

CMS also is establishing a new requirement that Part D sponsors post their approved PA criteria on Part D plan websites. In a previous HPMS memorandum, CMS indicated that Part D sponsors must provide current and prospective enrollees (or their physician or authorized representative) with information regarding specific PA criteria in a timely manner. Given the uniformity that will result from Part D sponsor utilization of the 2009 CMS standardized file, we believe that webpage posting of this information will augment the Part D sponsor's ability to rapidly provide this information, improve transparency and allow Part D plan comparison during enrollment. Accordingly, for CY2009, Part D sponsors will need to ensure that approved PA criteria are available on their Part D plans' formulary websites for display on November 15, 2008. CMS expects Part D sponsors to make these criteria available for beneficiary viewing either from a link when the drug identified with PA is displayed or from a general link on the formulary page. Part D sponsors will be expected to display all of the PA criteria contained within the HPMS-PA file.

C. Formulary Submission Timeline

Part D sponsors that fail to meet formulary submission and re-submission deadlines during the 2009 contract year formulary approval process may face a CMS determination that we cannot approve their 2009 Part D bids. For most Part D sponsors, a failure to obtain bid approvals will result in the termination of their Part D sponsor or MA organization contracts effective December 31, 2008. In the case of an initial Part D sponsor or MA organization contract applicant, CMS would decline to enter into a contract with the organization for 2009.

According to the Part D regulations at 42 C.F.R. § 423.272(b)(2)(i), a bid consists of pricing and plan design, including a formulary or tiered formulary structure. Also, pursuant to 42 C.F.R. § 423.265(c), Part D sponsors are required to submit bids and supplemental information for CMS

review. CMS is required to review each formulary to ensure that it would not have the effect of discouraging enrollment by certain Medicare beneficiaries.

To ensure the timely review of thousands of bid submissions each year, CMS established a process by which we conduct the formulary review process in stages. Specific formulary elements are examined in each stage, which builds upon the prior stage. Corrections to the formulary requested in one stage must be made in order for the formulary to continue to the next stage. The Stage 1 review mainly involves the review of the drug list and formulary categories and classes. The Stage 2 review examines the utilization management tools and drug tiering. Reviewing the formularies in stages, rather than looking at all elements at once, fosters consistency among formulary review results.

Part D sponsors that fail to meet the 2009 formulary submission deadlines adversely impact CMS' review of all remaining Part D formularies. CMS cannot jeopardize completion of the annual formulary reviews by making exceptions to deadlines to accommodate Part D sponsors that are not attentive to formulary submission requirements. Therefore, since a formulary is a necessary element of a bid, CMS has determined that a Part D sponsor's failure to make timely formulary submissions for the 2009 contract year will have the same impact on its bid approval status as would a failure to submit other elements of the bid in a timely manner. That is, CMS may determine that Part D sponsors failing to meet one of the formulary submission deadlines for the 2009 contract year have not submitted a timely bid which CMS can approve. As a result, the affected Part D sponsors will not be eligible to offer Part D benefits during that year.

All Part D sponsors and most MAOs facing this situation would be precluded from entering into a contract with CMS for 2009 (Note: MAOs that are not required to offer a Part D benefit plan, such as those administering private fee-for-service plans, would not be precluded from contracting with CMS during 2009). Such a determination would be made on the basis that the organization had failed to submit a bid which CMS could approve, a determination that would not be subject to a request for appeal under Subpart N of 42 C.F.R. Part423 (for Part D sponsors) and Part422 (for MA organizations).

The 2009 formulary upload functionality will be available on March 31, 2008. The deadline for 2009 formulary submission to CMS is 11:59 PM EDT on April 21, 2008. CMS will use the last successfully uploaded and validated formulary version as of 11:59 PM EDT on April 21, 2008 as the official formulary submission for CY2009.

For each Part D plan being offered, Part D sponsors will also use the Plan Benefit Package (PBP) software to describe the detailed structure of their Part D benefit and the Bid Pricing Tool (BPT) software to define their bid pricing information. The formulary must accurately crosswalk to the PBP. Once the PBP and BPT software has been completed for each Part D plan being offered, Part D sponsors will upload their bids to HPMS. Part D sponsors will be able to submit bid uploads to HPMS on their PBP or BPT one or more times between May 16, 2008 and the CY2009 bid deadline of June 2, 2008. CMS will only use the last successful upload received for a Part D plan as the official bid submission.

D. Specialty Tiers

We continue to analyze and evaluate the specialty formulary tier for very high cost and unique items that are exempt from tiered cost-sharing exceptions. Based upon current analysis, CMS will maintain a $600 dollar threshold for a Part D sponsor's specialty formulary tier for

CY2009. Therefore, only Part D drugs with Part D sponsor negotiated prices that exceed $600 per month may be placed in the specialty tier.

We also clarify that Part D sponsors will need to evaluate the negotiated prices at the drug product strength, package size, and formulation level in order to determine appropriate inclusion of the drug in the Part D plan's specialty tier. If a Part D drug product is available in multiple strengths, package sizes and formulations, CMS will only allow inclusion on the specialty tier of those strengths, package sizes and formulations that would reasonably exceed the monthly dollar threshold.

E. Limited Access Drugs

As outlined in section 50.3 of Chapter 5 of the Prescription Drug Benefit Manual, we remind Part D sponsors that they may not restrict certain Part D drugs to "specialty" pharmacies. In line with this guidance, Part D sponsors may only restrict access to Part D drugs to a subset of their network pharmacies for the following reasons:

1. The FDA has restricted distribution of the drug to certain facilities or physicians, or
2. Appropriate dispensing of the Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.

We note that additional education or counseling alone does not qualify a drug for limited distribution within the overall pharmacy network.

If a Part D sponsor finds it necessary to restrict access to a Part D drug for either of the two reasons listed above, it must indicate those Part D drugs on its formulary upload for CY2009. Additionally, Part D sponsors must be prepared to provide CMS with documentation substantiating the limited access drug criteria.

F. Supplemental Formulary File Submissions

To streamline CMS' benefit review and to provide beneficiaries with additional information regarding their 2009 benefit, we will be implementing a new process for Part D sponsors with respect to supplemental formulary file submissions. For CY2009, we will require the submission of the following supplemental files:

1. An excluded drug file for Part D plan offerings for enhanced alternative coverage of excluded drugs.
2. An over-the-counter (OTC) drug file for Part D plan offerings indicating payment for OTCs as part of a utilization management program.
3. A Part D home infusion drug file for MA-PD plan offerings indicating coverage of Part D home infusion drugs as part of a bundled service as a supplemental benefit under Part C according to guidance given in the CY2008 Call Letter.

Operational details associated with the format and submission of these 2009 supplemental drug files will be released as part of the CY2009 Formulary Submission Module and Reports Technical Manual in March 2008.

The excluded drug file will enable the Part D sponsor to specify both quantity limits on drugs and "capped benefit limits." The quantity limit fields should be utilized when the limit is based on clinical criteria, such as dosage limitations supported by FDA labeling, which could also be

appealed by the beneficiary. Alternatively, the "capped benefit limit" should be utilized when the Part D sponsor is indicating a hard edit that limits coverage of the supplemental benefit up to a particular threshold, which cannot be appealed by the beneficiary. The "capped benefit limit" is an option only for excluded drugs. For CY2009, Part D sponsors will be required to identify drugs with a capped limit on their supplemental excluded drug file. We have updated the 2009 model formulary marketing document to reflect this change. Thus, a Part D sponsor may submit a supplemental excluded drug file that reflects a quantity limit of 30 capsules/tablets per 30 days for a sedative/hypnotic (*e.g.* benzodiazepine) based on clinical criteria supporting a maximum dose of 1 capsule/tablet per day. This quantity limit could be appealed by the beneficiary. Alternatively, the Part D sponsor may indicate a capped benefit that may not be appealed by the beneficiary.

G. E-Prescribing

CMS and HHS have both worked to encourage and support the utilization of electronic prescribing within the Part D program. We continue to believe the migration to electronic prescribing will not only result in programmatic cost savings through the reduction of administrative inefficiencies involved in handwritten prescriptions but also result in improved outcomes for beneficiaries through the reduction of adverse drug events that occur in our current prescribing environment.

While Part D sponsors already are required to support final Part D electronic prescribing standards, we also understand that Part D formulary information provided in the CMS Public Use File (PUF) is relied upon by vendors that support electronic prescribing. Accordingly, we are seeking industry input on additional Part D formulary information that CMS could obtain from Part D sponsors that would be reflected in the FRF. This information would then be available for display on the PUF that would be useful for supporting and promoting the use of electronic prescribing. For example, CMS would like to know if we should request that Part D sponsors provide a Formulary Status identifier, such as the Formulary Status identifier specified in the NCPDP Formulary and Benefit Standard Version 1.0, to be reflected in the FRF. We would appreciate comments on this specific example as well as other types of Part D formulary information that could be used to improve electronic prescribing for the Part D program.

Additionally, we are considering adding additional reporting requirements on the part of Part D sponsors that will assist CMS in evaluating electronic prescribing under the Part D program (see the changes in reporting requirements outlined later in this call letter). To support this reporting, we advise Part D sponsors that they will need to require language within their existing network pharmacy contracts mandating use of NCPDP 5.1 optional field 419 DJ – Prescription Origin Code, so they can adequately identify and report on the source of origin for prescriptions filled among all the claims processed within the applicable quarter. By reporting on the source of prescriptions filled, CMS will be able to evaluate the increase in electronic prescribing within the Part D program, identify those plans that have found innovative methods increasing uptake and potentially share innovation across the industry. We refer Part D sponsors to Chapter 7 of the Prescription Drug Benefit Manual for more information regarding e-prescribing and e-prescribing programs.

We are also considering adding a new field to the PDE record in 2009 that would capture the Prescription Origin Code. We request comments on these efforts and how else we may support e-prescribing.

H. RxNorm

CMS will continue to utilize a Formulary Reference File (FRF) and proxy National Drug Codes (NDCs) for HPMS submission of Part D formularies. For CY2009, CMS also will introduce the RxNorm nomenclature for the FRF drugs because we are exploring RXNorm as a potential alternative to proxy NDCs for formulary submissions in future years.

RxNorm is a standardized nomenclature for clinical drugs produced by the National Library of Medicine (http://www.nlm.nih.gov/research/umls/rxnorm/index.html). CMS is working with the National Library of Medicine to evaluate whether RxNorm would provide a more effective means of drug product identification for the FRF. CMS recognizes the value of a standardized nomenclature system for the purpose of Part D formulary submission and review and for its potential application as electronic prescribing evolves. For each CY2009 FRF proxy code, the RxNorm semantic names and RxNorm concept unique identifier (RXCUI) code (when available) will be included. Part D sponsors should be aware that FRF format changes will be forthcoming.

I. HPMS Negative Formulary Change Module

Consistent with our HPMS announcement on December 12, 2007, CMS modified the process by which Part D sponsors submit negative formulary change requests for CY2008 formularies. These requests are now submitted directly to the Health Plan Management System (HPMS) in order to streamline the submission and review processes. Automation built into the module assures Part D sponsors that the submitted change requests are valid upon submission. The HPMS module also affords Part D sponsors real-time access to CMS determinations on previously submitted change requests. This HPMS module will be utilized for CY2009 negative formulary changes.

J. Employer Group Formulary

For formulary guidance specific to entities offering Part D employer/union-only group waiver plans (EGWPs), please see the Employer/Union-Sponsored Group Health Plans section of this Call Letter.

K. Steps to Complete when a Part D Sponsor Changes its PBM

Below are the steps a Part D sponsor needs to complete when changing its pharmacy benefit manger (PBM) either at the start of a new benefit year or mid-year.

1. General Requirements

- Sponsors must notify Central Office account manager (PDP sponsors) or Regional Office Plan Manager (MA-PDs) (Prescription Drug Benefit Manual, Chapter 5, Section 50)
- Part D sponsors should be aware that any decision to change PBMs during the last quarter of the contract year may cause disruption to beneficiary access and services. As a result, Part D sponsors should ensure that a decision to change PBMs includes an internal transition time period.
- Sponsors should be prepared to submit appropriate documentation, upon request, to CMS Central Office at any time after the date the contract takes effect (targeted audit). Such documentation may include but not be limited to:

- Executed PBM contract
- Retail Pharmacy contract template
- Mail Order Pharmacy contract template
- Home Infusion Pharmacy contract template
- Long-Term Care Pharmacy contract template
- ITU Pharmacy contract template
- Up-to-date Part D Pharmacy network listings
- Up-to-date Part D Geo-Access Reports

2. 4Rx Data

- The Part D sponsor's internal transition plan should include the appropriate amount of leeway to properly transition new 4Rx data (CMS guidance issued 10/29/2007 and 11/20/2007).
- We expect that one week prior to the transition all new 4Rx data is submitted and all rejections are resolved.

3. HPMS Requirements

- As of the date the new PBM contract takes effect (CMS guidance issued 02/15/2007) sponsors must:
    - Update the P&T Committee information in HPMS/Contract Management/Basic Contract Management/Part D Data (if applicable)
    - Update the Subcontractor function chart in HPMS/Contract Management/Basic Contract Management/Part D Data

4. Reporting Requirements

- For the annual pharmacy network reporting requirement, Part D sponsors must report on the required data elements related to retail, home infusion and long-term care pharmacy access. (Draft 2008 Reporting Requirements) Note: This applies to all sponsors not just those changing PBMs.
    - 2008 Reporting Requirement due date in HPMS is as follows:

Collection Period	**Reporting Due Date**
January 1 – March 31	May 31

        - Network information should be for the point in time as of March 31
- For the next quarterly due date of the reporting requirements, sponsors must appropriately respond to all subcontractor and P&T reporting requirement questions (Draft 2008 Reporting Requirements) Note: This applies to all sponsors not just those changing PBMs.
    - 2008 Reporting Requirements have quarterly due dates in HPMS as follows:

Collection Period	Reporting Due Date
January 1 – March 31	May 31
April 1 – June 30	August 31
July 1 – September 30	November 30
October 1 –December 31	February 28

5. Marketing Requirements

- In accordance with CMS Marketing Guidelines, Part D sponsors must reissue ID cards to all enrollees in advance of changing the PBM. To the extent the Part D sponsor's PBM is the benefit administrator and/or processor, the guidelines specify that the front of the ID card have the PBM's name or logo. In addition, the correct electronic transaction routing information must be on all the reissued ID cards sent to enrollees. This includes the correct International Identification Number (RxBIN) and the Processor Control (RxPCN) and Group Numbers (RxGrp) when required by the benefit administrator to electronically route a prescription claim. (CMS Medicare Marketing Guidelines for MA, MA-PDs, PDPs and 1876 Cost Plans, pages 52-53, 2nd revision July 25, 2006 (August 5, 2005))

A special mailing of the pharmacy directory must be sent to all enrollees (CMS Medicare Marketing Guidelines for MA, MA-PDs, PDPs and 1876 Cost Plans, page 58, 2nd revision July 25, 2006 (August 5, 2005)) in those instances where the PBM is maintaining the Part D pharmacy network on behalf of the Part D sponsor and the Part D sponsor determines the network has significantly changed.

- In addition, new payer sheets must be sent to all switches and network pharmacies in advance of the PBM change (CMS guidance issued 11/20/2007).
- Where the Part D sponsor is changing its PBM midyear, all claims history and balances must be transferred to the new PBM.

6. Formulary and Benefit Requirements

- Part D sponsors may continue to make enhancements to the formulary and may submit negative formulary changes per 42 C.F.R. § 423.120(b)(4)-(6).
    - For those Part D sponsors changing PBMs mid-year, the formulary and benefits must be administered as approved for the current contract year. Formulary category/class changes are not permitted.
    - For those Part D sponsors changing PBMs for January 1, 2009, the formulary and benefits must be administered as approved for the 2009 contract year.

IV. PART D BENEFITS

A. Limiting Copayments to a Part D Plan's Negotiated Price

In previous operational guidance, Part D sponsors were advised that it was optional when administering a Part D plan's benefit to apply either a copayment (if the sponsor elected to charge a flat copayment in lieu of coinsurance) or the actual negotiated price of the drug when that amount was lower than the copayment as outlined in the plan benefit package. Although we expected that very few Part D sponsors would choose to impose a cost sharing charge higher than the negotiated price of the drug, we allowed the option consistent with commercial practices.

The statute at section 1860D-2(d)(1) of the Act requires Part D sponsors to offer their enrollees access to negotiated prices used for payment for covered Part D drugs. Therefore, for CY2009, we are revising our policy such that Part D sponsors be required to revise their payment systems to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount. For example, a beneficiary who is subject to a $5 copayment during the coverage gap cannot be required to pay more than the negotiated price of the covered Part D drug, if the negotiated price is less than $5.

B. Ensuring Significant Differences in Approved Bids [PDP Sponsors only]

While we support the concept of a wide variety of prescription drug coverage choices for Medicare beneficiaries, we believe it is necessary to ensure that those choices represent substantially different options in order to simplify beneficiaries' enrollment decision-making process. Ensuring that PDP sponsors offer substantially different plan options in each region will maximize opportunities for beneficiaries to select the most appropriate plan for their needs and reduce beneficiary confusion with respect to choices offered by the same Part D sponsor.

Similar to our process for CY2008, we intend to review PDP sponsors' CY2009 bids and negotiate with PDP sponsors to ensure sufficient differentiation among PDP sponsors' approved bids. This negotiation will be based on analysis that considers key benefit characteristics such as differences in deductibles, formularies, and expected out-of-pocket costs. To determine whether there were significant differences between basic prescription drug coverage options (which includes defined standard, actuarially equivalent standard, and basic alternative benefit designs) offered by the same PDP sponsor in a region, our analysis will focus on whether there are significant differences in proposed deductible amounts and/or formularies. It is important to note that, even though a sponsor may submit different formularies for different Part D offerings, all submitted formularies must be sufficiently robust to pass our rigorous formulary reviews and checks and be determined not to discourage enrollment by certain types of beneficiaries. Based on our experience and given statutory actuarial equivalency requirements, we do not expect that – absent substantial differences in approved formularies – PDP sponsors can demonstrate substantial differences between plans offering basic prescription drug coverage.

As for CY2008, we also intend to determine whether there are substantial differences in enhanced alternative benefit designs submitted by the same PDP sponsor based on expected out-of-pocket costs for prospective enrollees. We will request that PDP sponsors with plan benefit packages that are not substantially different from each other either withdraw or enhance a bid in order to ensure that all offerings are, in fact, substantially different. It is our experience, based

on this analysis that PDP sponsors typically must offer substantive coverage in the coverage gap as a supplemental benefit in order to demonstrate that one enhanced alternative plan design is substantially different from another.

We intend to build on "lessons learned" as we continue to accumulate program experience in order to further refine our current analyses and identify additional methods for determining whether there are substantial differences in benefit packages. We are also interested in building additional checks into our process to ensure that, in structuring bids that are sufficiently different from any other bid they may propose, PDP sponsors do not design benefit packages that have the effect of discriminating against certain types of Medicare beneficiaries.

Additionally, consistent with the policy we adopted in the CY2008 Call Letter, PDP sponsors or parent organizations with new acquisitions will be afforded a period of 3 years to transition their plan offerings to meet the goal of ensuring that the Part D sponsor's offerings are substantially different from one another. For example, a Part D sponsor (or its parent organization) completing an acquisition of another Part D sponsor in November 2008 would not be subject to requirements for offering substantially different bids until the 2013 contract year (that is, bids would be due in June 2009 for the 2010 program year; transition would occur during 2010, 2011, and 2012; and the Part D sponsor or parent would need to ensure that in June 2012, when it submits its bids for program year 2013, all of its bids are for substantially different plans). PDP sponsors that have completed a new acquisition will be expected to submit to CMS a plan that details how the three-year transition will take place.

C. Prohibition of Limiting Coverage to Mail Order Only Drugs in the Coverage Gap

We clarify that Part D sponsors offering enhanced alternative coverage that includes coverage in the gap as a supplemental benefit may not limit access to drugs for which they provide coverage in the gap to mail-order pharmacies. Section 1860D-4(b)(1)(D) of the Social Security Act (the Act) provides that a Part D sponsor must permit "enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy)." This prohibition applies to all "benefits" available through mail order pharmacies, and not simply to extended day supplies of Part D drugs or benefits under the basic portion of a Part D sponsor's plan. Therefore, if a plan provides coverage of drugs in the coverage gap when obtained from mail order pharmacies, the plan also must provide coverage of those drugs when obtained from retail pharmacies.

However, as provided in section 50.10 of Chapter 5 of the Prescription Drug Benefit Manual, the plan need not cover such drugs at every network retail pharmacy. Rather, the plan: (1) must cover these drugs when obtained from a retail pharmacy that agrees to provide such drugs at the same price, reimbursement rate, and cost-sharing as the plan's mail order pharmacy or pharmacies; and (2) may cover these drugs when obtained from a retail pharmacy with a higher contracted reimbursement rate, provided the beneficiary pays any differential in charge. The Part D sponsor would be expected to contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to coverage in the gap through retail pharmacies.

D. Cost Sharing Guidance

Cost sharing amounts approved for CY2008 will not automatically be "acceptable" for CY2009. Each benefit year is a separate and distinct review from prior years.

E. Best Available Evidence (BAE) to Correct a Beneficiary's Low-Income Subsidy Status

The regulations at 42 CFR § 423.800 specify the requirements of Part D sponsors in the administration of the low-income subsidy program, including the reduction of cost sharing for subsidy-eligible individuals. In certain cases, due to time lags associated with monthly reporting by the States and SSA and subsequent CMS systems updates, CMS systems do not reflect a beneficiary's correct low-income subsidy (LIS) status at a particular point in time. As a result, the most up-to-date and accurate subsidy information has not been communicated to the Part D plan. To address these situations, CMS created the best available evidence (BAE) policy in 2006. This policy requires sponsors to establish the appropriate cost-sharing for low-income beneficiaries when presented with evidence that the beneficiary's information is not accurate.

Under existing BAE policy, sponsors are required accept specified forms of documentation of a beneficiary's correct LIS status, to change the beneficiary's cost-sharing levels in the sponsor's system based on that documentation, and to submit to CMS requests for correction of these data in our system if the changes do not occur as a result of the routine State reporting. Although we have directed sponsors to update their systems within timeframes that reflect the immediacy of the beneficiary's need in these BAE cases, we have not mandated a specific timeframe. In 2009, we will be directing sponsors to accept BAE at point-of-sale and update their systems within 48-72 hours of their receipt of the documentation. Further, in cases involving immediate need (i.e., when the beneficiary has less than 3 days of medication available), sponsors must have a process in place to permit the beneficiary to receive an emergency supply of medication. Sponsors must then update their systems within 48-72 hours to allow the pharmacy to re-submit claims at the correct cost-sharing level.

CMS will be creating a BAE page on our website containing our policy guidance. In 2009, we expect Part D sponsors to establish a link to this page on their websites affording greater accessibility to the policy for interested parties.

F. Benefit Structure in the Coverage Gap

As part of an enhanced alternative benefit design, Part D sponsors may include coverage of a subset of drugs throughout the coverage gap. The Part D sponsor may elect to cover 1) an entire drug tier, 2) a subset of a drug tier, or 3) a capped dollar amount of drugs within a tier or across the entire benefit. CMS will review the Part D sponsor's plan offering to ensure that it does not violate the non-discrimination provisions in statute and regulation. CMS will also review the breadth of drugs covered through the gap be it 1) an entire drug tier, 2) a subset of a drug tier, or 3) a capped dollar amount of drugs to ensure that the coverage is sufficient to be labeled as either gap coverage or limited gap coverage. We are considering methodologies for determining what is sufficient gap coverage or limited gap coverage, including an analysis of the percentage of beneficiaries who potentially would benefit from a proposed benefit offering in the coverage gap.

We believe that it is important that beneficiaries do not confuse plans offering limited gap coverage with plans offering more robust supplemental coverage. We are considering additional ways to ensure appropriate language of plan offerings with limited gap coverage in CMS materials. An insignificant amount of coverage after the initial coverage limit (ICL) will not be labeled either gap or limited gap coverage.

G. Notes Changes

Notes fields should only be used within the PBP when they are needed to specifically clarify information that cannot otherwise be entered into the standard variables of the PBP. Notes limiting Medicare covered benefits must be removed from the PBP. Once bids are approved, additions to the Notes fields during the Plan Correction process will not be accepted. Benefits information requiring documentation within the Notes fields should be entered accurately prior to June 2, 2008. Information entered in Notes fields cannot take away from benefits in the PBP.

H. Plan Corrections for 2009

Consistent with marketing and open enrollment coordination, Part D sponsors will not be able to request plan corrections for CY2009 benefits packages any later than October 1, 2008. This will ensure that correct bid information will be available for review on Plan Finder for the open enrollment start date of November 15, 2008. Expectations are that with the experience gained over the last three years of bid submissions, requests for plan corrections will be minimal. However, even though we expect Part D sponsors to ensure that the original PBP submission is a true representation of the benefits package being offered, the plan corrections module will be available in HPMS for CY2009 benefits for a limited period, from early September until October 1, 2008. It is important to note that only changes to the PBP that are supported by the BPT are allowed during the plan correction period. We note that CMS is considering measuring sponsor performance on the number of PBP changes for 2009.

V. PHARMACY ACCESS

A. Preferred and Non-Preferred Network Pharmacies

It has recently come to our attention that some Part D sponsors may be incorrectly designating some of their network pharmacies as preferred pharmacies when they submit their network pharmacy information to CMS for the Medicare Prescription Drug Plan Finder (MPDPF), as well as in their PBP uploads. We remind sponsors that, as provided in section 10.2 of Chapter 5 of the Prescription Drug Benefit Manual, preferred and non-preferred pharmacies must meet the following definitions:

- Preferred pharmacy – A network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D sponsor.
- Non-preferred pharmacy – A network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

In other words, sponsors cannot designate certain network pharmacies as preferred without designating its other network pharmacies as non-preferred. We also clarify that a pharmacy can only be designated as preferred if it offers enrollees a lower level of cost-sharing than a non-preferred pharmacy. This means that the differences in cost-sharing must be based on the designated cost-sharing levels, and not on the actual cost to the enrollee. Thus, for example, a sponsor with a benefit design based on coinsurance could offer 20% coinsurance at preferred pharmacies and 25% coinsurance at non-preferred pharmacies. A sponsor with a benefit design based on copayments could offer a $20 copayment at preferred pharmacies and a $25 copayment

at non-preferred pharmacies. We will make changes to the PBP and MPDPF for CY2009 that should help address problems we have experienced with the incorrect designation of preferred pharmacies in sponsors' networks.

We are exploring whether, for marketing purposes, we will allow Part D sponsor to refer to their non-preferred pharmacies as "other network pharmacies" rather than "non-preferred pharmacies" in CY2009. We will provide further guidance on this, including how Part D sponsors with plans with preferred and non-preferred network pharmacies can modify their terminology with regard to non-preferred pharmacies (*e.g.*, automatic hard copy changes to marketing model materials).

B. Timely Delivery of Home Infusion Drugs

CMS expects to finalize a Part D policy and technical corrections regulation in Spring 2008 that will require Part D sponsors to ensure that their network home infusion pharmacies provide delivery of home infusion drugs within 24 hours of discharge from an acute setting, or later if so prescribed. Sponsors should consider this expected new requirement as they contract (or modify their contracts) with home infusion pharmacies for participation in their pharmacy networks.

VI. ENROLLMENT

All PDP sponsors must follow the eligibility, enrollment and disenrollment requirements issued by CMS for accepting and processing beneficiary requests. We expect to issue an update to this guidance in 2008.

VII. LOW-INCOME SUBSIDY POLICY

A. Reassignment of Low-Income Subsidy Eligible Individuals [PDP sponsors only]

In the fall of 2008, CMS will again reassign certain low-income subsidy eligible beneficiaries with full premium subsidy into different Medicare Prescription Drug Plans effective January 1, 2009.

B. Auto-enrollment Process

Beginning in 2009, all auto-enrollment effective dates for full benefit dual eligibles individuals will be prospective. CMS will eliminate the current need for auto-enrollments with retroactive dates by paying all claims for retroactive periods under a separate contract.

VIII. GRIEVANCES/COVERAGE DETERMINATION, AND APPEALS

A. New Privacy Requirements Related to IRE Correspondence to Beneficiaries [All Part D sponsors]

As part of CMS' ongoing efforts to safeguard the privacy and security of beneficiaries' protected health information (PHI), the Part D independent review entity (IRE) will be implementing a new format for all correspondence sent to Medicare beneficiaries. As of January 1, 2009, the IRE will only include the first initial of the beneficiary's first name, the beneficiary's full last name, and the last four digits of the beneficiary's health insurance claim number (HICN). A complete HICN will no longer be used in IRE correspondence sent to beneficiaries. This new

format will further safeguard Medicare beneficiaries' PHI and prevent inappropriate disclosures of PHI and is similar to the new version of the Medicare Summary Notice (MSN).

Part D sponsors must ensure that their systems and operations can accommodate this new correspondence format for purposes of tracking and processing grievances, coverage determinations, and appeals, including complying with effectuation and other regulatory requirements.

IX. CLAIMS PROCESSING

A. 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 2008, the Part D COB user fee was $1.36 per enrollee per year. Upon review of the anticipated costs of COB activities in 2009, the Part D COB user fee will increase to $2.52 per enrollee per year for contract year 2009. This COB user fee will be collected at a monthly rate of $0.28 for the first 9 months of the coverage year (for an annual rate of $0.21 per enrollee per month) for a total user fee of $2.52 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2009 bids.

B. Coordination Fees

Under our current regulation at 42 C.F.R. § 423.464(f)(3), Part D sponsors can impose user (coordination) fees on State pharmaceutical assistance programs (SPAPs) and entities offering other prescription drug coverage as long as they are related to the cost of the coordination of benefits. We further explain in our preamble to the final Part D rule that any user fees imposed must be reasonable and related to the Part D sponsor's actual coordination of benefit costs.

While it is allowable for Part D sponsors to impose user fees for plan coordination, we remind Part D sponsors that the user fee imposed must be reasonably related to the Part D sponsor's cost of coordinating benefits with the SPAP or other payer. An example of what costs could be included in a Part D sponsor's user fee is if an SPAP or another payer requests that their specific formulary or enrollment files be uploaded to the Part D sponsor for coordination purposes. The Part D sponsor may include its cost(s) of updating its systems to accept these files in a user fee charged to the SPAP/other payer. A Part D sponsor cannot impose user fees based upon its aggregate average cost of doing business with all SPAPs or other payers. Each SPAP/other payer has a different benefit structure requiring different approaches to coordination. Therefore, the Part D sponsor's user fees should reflect the variation in costs from SPAP to SPAP. Part D sponsors should also be aware that States may adopt coordinating criteria when selecting plans for facilitated enrollment which could exclude plans of Part D sponsors that charge coordination fees.

C. Premium Coordination

CMS reminds Part D sponsors that they are required by statute to coordinate premium payments. Section 1860D-23(a)(1)(A) of the Social Security Act specifically requires CMS to establish requirements for Part D sponsors to ensure the effective coordination between a Part D sponsor's

plan and a State pharmaceutical assistance program with respect to payment of premiums and coverage. These guidelines regarding coordination of premiums are included in Chapter 14 of the Prescription Drug Benefit Manual.

X. SYSTEMS/HPMS

A. Using HPMS to Submit Bids and Formularies

All Part D sponsors use HPMS to electronically upload plan formularies and bids to CMS. Part D sponsors 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 31, 2008. Part D sponsors offering the Part D benefit may upload their formularies one or more times between March 31, 2008 and the formulary deadline of 11:59 PM EDT on April 21, 2008. CMS will use the last successfully uploaded and validated formulary version as of 11:59 PM EDT on April 21, 2008 as the official formulary submission for CY2009. We 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 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 21, 2008 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. Any formulary not attached to a PBP should be deleted or withdrawn. (Part D sponsors should note that in the context of the contracting process for 2009, a "bid" consists of a CMS-approved PBP, BPT, and formulary. Sponsors missing any of these three elements in September 2008 may not receive a Medicare contract for 2009.)

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 16, 2008.

Part D sponsors may upload their plan bids one or more times between May 16, 2008, and the CY2009 bid deadline of 11:59 PM PDT on June 2, 2008. 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.

B. Instructions for Obtaining HPMS Access

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 a T-1 lease line 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 the HPMS access team at HPMS_Access@cms.hhs.gov.

C. Additional HPMS Contacts

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: hpms_access@cms.hhs.gov

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

D. Interoperability Standards for Health Information Technology

On August 22, 2006, the President issued Executive Order 13410: "*Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs."* The executive Order directs federal agencies that contract with health plans, insurers, and providers to require, to the extent permitted by law, that as health information technology systems are acquired or updated, they include recognized interoperability standards for health information technology. CMS is asking that all Part C, Part D, Cost, and Employer/Union-Sponsored Group Health Plans take steps to implement the provisions addressed in this executive Order to the extent consistent with current obligations. We will be providing guidance to plans to assist them in this effort.

E. System Design Improvements in the MARx System

CMS is considering significant system design improvements in the MARx system as early as possible in 2009 related to delinking of the Parts C & D enrollment and payment processes. Further information is not yet available but will be conveyed as soon as possible. In the meantime plans should budget for additional programming resources in their 2009 bids.

XI. COMPLIANCE/MONITORING

A. Compliance Procedures

We have revised several procedures related to the contract determination and sanction processes. These revisions were carried out in 2007 through the rulemaking process. The final regulation with comment addresses Medicare Advantage and prescription drug plan sponsor contract determinations (terminations and non-renewals of contracts), appeal rights for contract determinations, intermediate sanctions, civil money penalties, voluntary self-reporting of fraud and misconduct, and access to records and facilities of contractors. It was published in the Federal Register on December 5, 2007 (Fed. Reg. 68,700 (Dec. 5, 2007)).

Several of these provisions take effect starting January 4, 2008 and others will be effective beginning January 1, 2009 (see chart below).

Regulation Change	Implementation Date
Incorporation of fraud, waste, and abuse prevention measures into compliance plan	1/1/2009
Requirement to apply compliance plan's training and communication requirements to first tier, downstream, and related entities	1/1/2009
Voluntary procedures for MAOs and Part D sponsors for self-reporting potential fraud and misconduct	1/1/2009
Requirement to obtain access to Part D sponsor's first tier, downstream, and related entity's books and records through contractual arrangements	1/1/2009
Elimination of CMS' requirement to inform organization of contract renewal	1/4/2008
Change date of CMS' notification of contract non-renewal from May 1 to August 1	1/4/2008
Provide for same administrative appeal rights (including corrective action plans (CAPs)) for all contract determinations (non-renewal, expedited termination, termination)	1/4/2008
Change regarding CAP process may be provided prior to notification of termination, and the imposition of time limits on Corrective Action Plans	1/4/2008
Change immediate termination to expedited termination with CMS setting the effective date of termination	1/4/2008
Elimination of reconsideration step for contract determination appeals	1/4/2008
Implementation of burden of proof for contract determinations	1/4/2008
Ability for a hearing officer to issue summary judgment	1/4/2008
Request for Administrator review, submission of information, and timeframe associated with Administrator review	1/4/2008

Regulation Change	Implementation Date
Settlement of civil money penalties	1/4/2008
Appeal procedures for civil money penalties	1/4/2008

Comments will still be considered on the mandatory self-reporting provisions until February 4, 2008. For more information please refer to:

http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-5946.htm

B. Plan Ratings/Quality and Performance Metrics

CMS will continue development of Part D Plan Ratings that incorporate quality measures to enhance the current performance metrics displayed on the Medicare Prescription Drug Plan Finder.

The new areas of the proposed quality measures may include, but are not limited to, the following: Medication Therapy Management services, prescription drug utilization, and patient safety. The measures to be included will come from multiple data sources, most of which are already currently collected by CMS. Part D sponsors will be expected to comply with any other requests by CMS for additional data necessary to support quality improvement activities in Part D. In addition to Plan Ratings, these data may be incorporated into CMS' existing compliance monitoring and contract renewal processes.

C. Sponsors with One and Two-Star Plan Performance Ratings May Be Subject to Monitoring Actions

Since fall 2006, CMS has posted Part D plan performance ratings on the Medicare Prescription Drug Plan Finder (MPDPF) tool. CMS rates Part D sponsors' performance in three broad categories: drug plan customer service, using your plan to get prescriptions filled, and drug pricing information. In 2006, in preparation for the 2007 annual election period, CMS assigned ratings based on a three-star scale, while in 2007, for the 2008 annual election period, we used a 5-star scale. In 2006, a one-star rating indicated poor performance. In 2007, one star indicated poor performance and two stars indicated fair performance.

These ratings have been useful in helping beneficiaries make informed choices about their Part D plan coverage. In addition to serving as a consumer information tool, the rating scale also serves as a monitoring tool. CMS has an obligation to ensure that beneficiaries receive their Part D benefits only from sponsors that demonstrate that they are fully capable of meeting all operational requirements of the program. CMS maintains that only sponsors receiving "good" ratings (*i.e.*, two stars in 2006, three stars in 2007) or better can provide the quality of services needed to ensure beneficiary satisfaction with their Part D benefits.

It is expected that all sponsors, regardless of their CMS ratings, are continually working to improve their Part D operations. However, sponsors with less than "good" ratings in any performance category should expect to be the subject of CMS monitoring and compliance actions. These sponsors will be afforded a reasonable opportunity to bring their performance up to a three-star rating or better. In instances where sponsors do not take advantage of that

opportunity, and CMS determines that a sponsor's continued rating of less than three stars is indicative of its failure to substantially carry out the terms of its Medicare contract, CMS may impose intermediate sanctions (*e.g.*, suspension of marketing and enrollment activities) or pursue contract termination.

D. Impact of Current MA or PDP Sponsor Contract Performance on Applications for New Contracts and Service Area Expansions

Since the start of the Medicare Part D prescription drug benefit program, CMS has received a substantial number of applications for additional contracts (either PDP sponsor or MA-PD organization) or for service area expansions of existing contracts. CMS reminds sponsors that we may consider their performance under their existing contract(s) when determining whether the organization is qualified to offer a new contract or expand its existing service area. In particular, the Part D regulations at 42 C.F.R. § 423.503(b) authorize CMS to deny an application if the applicant fails to comply with the terms of a previous year's contract or fails to complete a corrective action plan during the term of the contract. CMS may deny the application even if the applicant has demonstrated that it otherwise meets all of the other application requirements.

CMS is committed to ensuring that only fully qualified organizations are permitted to offer Part D coverage to Medicare beneficiaries. Only sponsors that are currently meeting Part D program requirements can be expected to serve additional beneficiaries adequately. Accordingly, CMS will scrutinize carefully the monitoring and compliance records of all current Part D sponsors that submit applications for new or expanded Part D sponsor contracts for 2009 and beyond. This information will be incorporated into our review of an organization's qualification for a new or expanded service area contract.

E. Self-Assessments and Monitoring Tools [All Part D sponsors]

The self-assessment requests (*e.g.*, the annual Part D Readiness Checklist) that CMS issues to Part D sponsors are integral to CMS' monitoring efforts and a useful tool for sponsors to ensure they are meeting Part D requirements. We will continue to periodically request that sponsors complete formal self-assessments and report the results back to CMS. We expect that sponsors will respond promptly and thoroughly to future self-assessment and progress report requests.

F. Auto-Enrollment Readiness Audits [PDP sponsors only]

Based on our experience with autoenrollments in the first three years of the Part D program, we have identified several requirements that are critical to making sure that a plan's autoenrolled dual eligible population receives effective drug coverage. To adequately protect Medicare beneficiaries, we are obligated to ensure that PDP sponsors receiving reassignees, autoenrollees, and facilitated enrollees are fully prepared to accept these enrollments. To that end, we will conduct Auto-Enrollment Readiness Audits in late August and early September of 2008. Sponsors will be selected for audits based on a variety of factors, including whether they will qualify for auto-enrollments for the first time in 2009, whether they will be expanding the number of regions in which they will qualify to receive these enrollees in 2009, or whether the sponsor is operating under an existing corrective action plan or is experiencing performance problems.

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

CMS may audit these functions through either an on-site audit or a self-audit request. Based on the results of these audits, any organization that is not fully prepared to undertake this important role will be excluded from receiving reassignees and/or auto and facilitated enrollments. Also, CMS will require the sponsor to complete a corrective action plan (CAP) through which it must demonstrate that it meets the requirements associated with the autoenrollment process. CMS will close the CAP only after the sponsor meets the requirements and has begun to accept autoenrollments.

G. Audit Assistance Contractor

During 2007 we utilized private contractors to conduct Parts C, D and PACE compliance audits. CMS will continue to employ contractors for the foreseeable future to perform these audit services along with regional and central office staff.

H. Part D Sponsor Subcontracting Requirements

There are several new elements which Part D sponsors must include in their contracts with organizations to whom they have delegated Part D-related functions. Effective January 1, 2009, sponsors must have all of their Part D-related subcontractors agree that CMS and its designees may inspect any books or records, including rebate and other price concessions information, related to the operation of the sponsors' Part D contracts. Sponsors also must have in their subcontracting agreements language that indicates that the subcontractor agrees that it will produce upon request from CMS or its designees all books and records related to the operation of the sponsors' Part D benefit operations. The agreement must also state whether the subcontractor is to provide the materials directly to CMS or through the sponsor.

I. 2009 Reporting Requirements

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 CY2009 reporting requirements document. The document is projected to be released upon OMB's grant of final approval. The following changes are anticipated from the CY2008 Reporting Requirements:

Part D sponsors will be required to report on the number and source of prescriptions processed by network pharmacies on a quarterly basis. This will allow CMS to evaluate the increase of electronic prescribing under the Part D program, the source of prescriptions more generally, and ensure Part D sponsor compliance with 42 C.F.R. § 423.159. (For more information please refer to the claims processing section earlier in this call letter.)

Part D sponsors will also be required to report on the number of prescriptions that are immediately filled at point of sale versus the number of prescriptions that are delayed due to the need for the beneficiary to request coverage exceptions or meet prior authorization requirements, etc. Part D sponsors will report on these measures for both existing members and for new members. This information will allow CMS to evaluate our transition policy with respect to new members (under which we would expect that the majority of prescriptions would be filled at

point of sale) and to assess in general how many prescriptions are delayed as a result of formulary coverage issues and drug utilization management procedures.

XII. LICENSURE AND SOLVENCY

A. Expiring Licensure Waivers [PDP sponsors only]

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

These PDP sponsors will also be notified that they should begin to prepare to issue notices to beneficiaries, the public and network providers by October 1st (42 C.F.R. §§ 423.507(b)(2)(i), 423.642(d)).

Specific reporting requirements and deadlines related to the PDP sponsor's actions taken to obtain state licensure are specified in *Attachment I*.

In situations where the state cannot approve a license before the waiver expires because of state requirements that are beyond the PDP sponsor's ability to meet (*e.g.*, a "seasoning" requirement or the need for a state to conduct an audit report and the state has not scheduled an audit), CMS will allow the PDP sponsor to apply for a new waiver, based on the grounds available to an applicant in March of the year that the current licensure waiver expires. To qualify for such a waiver, the Part D sponsor will need to submit a new license application to the state before December 1st of the year preceding the year in which the current waiver expires. If the PDP sponsor has contributed to the state's inability to approve the license application submitted to a state during the current licensure waiver period, then a new CMS waiver will not be granted.

XIII. SECURITY AND PRIVACY STANDARDS

A. Mitigating the Risk of Identity Theft in the Event of a Data Loss or Breach

Loss of control over personal information may present a risk for identity theft. Sponsors should notify CMS immediately upon discovery of any security breach compromising beneficiary personally identifiable information (Prescription Drug Benefit Manual, Chapter 5, Section 80). A security breach could result from records or hardware being lost, misplaced, stolen, improperly stored or improperly disposed of; unauthorized access; unencrypted emails; or inappropriate disclosure or release of information.

CMS will conduct a risk assessment to determine the plausibility of identity theft when a data loss or breach occurs. If the data includes a social security number; or the name, address, or telephone number along with an identification number, an account number, or any additional specific factor that could lead to the personal identifying profile of an individual then there is a reasonable risk for identity theft.

A Part D sponsor may be required to offer one year of credit monitoring services at no cost to the beneficiary if a security breach occurs. The decision to require credit monitoring services and the duration of those services is dependent upon whether or not the data was protected or encrypted, the ability of the Part D sponsor to prevent or mitigate the risk of identity theft, the means by which the loss or breach occurred, evidence of whether the data is being use to commit identity theft, and the ability to prevent or mitigate the risk of harm by offering credit monitoring services.

XIV. PDP RENEWAL/NON-RENEWAL PROCESS

Consistent with the recent revisions to the regulations governing contracts with Part D sponsors, there will be substantial changes to the PDP Renewal/Non-Renewal Process for the 2009 contract period.

A. CMS Renewal Notice to PDP Sponsors [PDP sponsors only]

In accordance with the recent regulatory revisions to 42 C.F.R. § 423.506 and 42 C.F.R. § 423.507, CMS will not issue contract renewal notices for CY2009. Therefore, PDP sponsors that CMS determines are eligible to continue to hold a contract during 2009 will not receive any type of renewal notice from CMS. As in past years, 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.

B. CMS Non-Renewal Notice to PDP Sponsors [PDP sponsors only]

In accordance with the recent regulatory revisions to 42 C.F.R. § 423.507 (b)(2), CMS will provide PDP sponsors determined no longer qualified to operate as a PDP sponsor with a notice of its decision not to authorize renewal of a contract by August 1, 2008. Pursuant to the revised 42 C.F.R. § 423.507 (b)(3) before providing a non-renewal notice CMS will grant the PDP sponsor a reasonable opportunity to develop and submit a corrective action plan (CAP) in accordance with the timeline provided in 42 C.F.R. § 423.507 (b)(3).

C. PDP Sponsor Notice to CMS [PDP sponsors only]

PDP sponsors that elect to non-renew their contract for 2009 must notify CMS of their decision in writing by June 2, 2008. PDP sponsors that submit neither a 2009 bid nor a notice of non-renewal by June 2, 2008, will be considered by CMS to have non-renewed their PDP sponsor contracts. The PDP account manager will provide detailed instructions about the non-renewal process, including the format and timing of the required beneficiary notice, during the summer of 2008.

D. Non-Renewal of All Plans in a PDP Region (Service Area Reduction) [PDP sponsors only]

PDP sponsors that renew their PDP sponsor contract but elect not to offer any plans in a given PDP region (service area reduction) must provide notice to CMS and enrollees residing in the affected region(s) on the same schedule and in the same manner as required of PDP sponsors that non-renew their contracts. The PDP account manager will provide detailed instructions about

this process, including the format and timing of the required beneficiary notice, during the summer of 2008.

E. Appeals of Contract Determinations

On December 5, 2007, CMS issued a set of revisions to the Part D regulations (Federal Register, Vol. 72, No. 233, p. 68700). The Part D regulations now place the burden of proof at a contract determination hearing on the sponsor/applicant to show it was in substantial compliance with the Part D program requirements at the earliest of 1) the date the sponsor received notice of CMS' contract determination, b) the date of the most recent on-site audit conducted as the basis of termination, or c) the date of the alleged breach of the current contract or past substantial non-compliance, as determined by CMS.

Accordingly, organizations that submit new contract applications or service area expansion applications should be aware that they will not be afforded opportunities beyond the period following denial notice to cure their applications. Therefore, it is even more imperative than in past years for organizations to make the effort to submit applications which are complete and accurate on the date they are due to CMS. Also, when a sponsor appeals a CMS-initiated contract termination or non-renewal, the hearing officer will not consider evidence of the sponsor's efforts to come into compliance with Part D program requirements made after the date of the most recent on-site audit CMS used to support the termination or non-renewal or after the date of the alleged breach of the Part D sponsor contract.

XV. CHANGE OF OWNERSHIP

A. Sale of Sets of Beneficiaries Prohibited

During the first two years of the Part D program, CMS has been approached by several PDP sponsors seeking CMS approval of a novation agreement (pursuant to 42 C.F.R. Part 423, Subpart L) under which some portion of that sponsor's PDP membership would be acquired by a second PDP sponsor and enrolled in plans offered by that second sponsor. CMS has consistently disapproved such proposed transactions and will continue to do so in compliance with Part D requirements.

This restriction on the sale of beneficiaries is based on two CMS determinations. First, in the preamble to the current Part D rule, CMS stated that we would recognize the sale of PDP lines of business as asset transfers that constitute a change ownership which CMS may recognize through the execution of an agreement to novate the selling sponsor's PDP sponsor contract to a second qualified sponsor. Using a common understanding of the phrase "line of business" as referring to a company's set of products or services, CMS maintains that a "PDP line of business" includes a PBP as well as the beneficiaries enrolled in that PBP. Therefore, there can be no sale of a line of business consisting solely of a set of beneficiaries without the accompanying transfer to the succeeding sponsor of the obligation to continue to provide the PBP services the beneficiaries have already elected.

Second, the sale of individual beneficiaries would allow PDP sponsors effectively to make enrollment elections on behalf of beneficiaries when the Part D statute grants that authority exclusively to beneficiaries (see section 1860D-1(a)(1)(A) of the Social Security Act) and, in the case of full-benefit dual eligible beneficiaries, CMS (see section 1860D-1(b)(1)(C) of the Act).

The change of ownership provisions of Subpart L may not be read as a grant of enrollment election authority to PDP sponsors.

XVI. Beneficiary Transition in the Event of PDP Sponsor Termination

[PDP Sponsors only]

CMS must periodically terminate (either through mutual agreement or at its own initiative to protect beneficiaries) an organization's PDP sponsor contract. When this occurs, CMS' primary concern is to protect the impacted beneficiaries. Any actions are taken with the intent that beneficiaries are left in the best possible circumstances. CMS will implement a beneficiary transition plan based upon the particular circumstances involved and local conditions, so the elements of these plans can vary. However, all beneficiary transition plans will follow these guiding principles:

- Beneficiary Choice: Members of terminating PDP plans will be afforded a special election period (SEP) during which they may choose to join another PDP or MA-PD plan in the service area.
- Beneficiary Education: Terminating sponsors must send a notice to beneficiaries that informs them of the termination and includes a full discussion of their rights under the transition (including special election periods when appropriate) and information on other Part D plans in the service area. Unique scripts will be developed for 1-800 MEDICARE. CMS may also require the terminating plan to take one or more of the following steps: conduct media advertising & outreach; issue notices to providers, outreach community organizations, and state and local governments; and conduct additional mailings or phone calls to impacted members.
- Assuring Continuity of Care: If members of the terminating PDP sponsor do not make an alternate election or the need for immediate termination does not allow time for beneficiaries to make an advance election, CMS will establish a default option where CMS will move those members to another PDP. In such circumstances, CMS will select a receiving PDP sponsor that:
    1. Operates in the same PDP region as the terminating plan;
    2. Has a plan product similar to that of the terminating plan (benefits, cost sharing, premiums, and formulary);
    3. Has the capacity to absorb additional members;
    4. Has a compliance and performance history that gives CMS confidence that the selected PDP sponsor can serve the potential new members.
    5. Agrees to and signs terms and conditions with respect to how it will conduct the transition, including strict requirements around promoting beneficiary choice, conducting beneficiary education, and administering the CMS-approved formulary transition period for affected beneficiaries.

XVII. EMPLOYER AND UNION-SPONSORED GROUP PLANS

Employer and union group plan sponsors may choose to enroll their members in individual PDPs open to general enrollment. 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 PDP sponsors 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 2009 contract year for PDP sponsors offering employer or union-sponsored group plans and/or clarifications on certain topics.

A. Permitting Employer/Union Sponsors to Enroll Beneficiaries in Both an "800 Series" Local MA-Only Coordinated Care Plan and an "800 Series" Standalone PDP

Beginning with CY2009, all employer and union group plan sponsors will be allowed to enroll their members in both an "800 series" local coordinated care MA-Only plan (*i.e.*, HMO, HMO/POS, Local PPO) and an "800 series" standalone PDP. As a condition for providing this waiver, CMS will require the separate medical and prescription drug vendors to work closely with each other and the employer sponsor to provide coordinated care and disease management services between the MA and PD portions of the benefit. This coordination is similar to the kind that would be offered if the employer purchased the medical coverage and the drug coverage from a single local MA-PD vendor.

B. Clarification of Network Access Submission Requirements for PDP Sponsors Applying to Offer EGWPs

1. PDP Sponsors Applying to Offer Both Individual and "800 Series" Plans

Consistent with prior contract year requirements, PDP sponsors applying to offer both individual plans and "800 series" plans under a single contract in CY2009 will not initially be required to have Part D networks in place for those designated EGWP service areas outside of their individual plan service areas. Accordingly, these PDP sponsor applicants will also not be initially required to submit Part D GeoNetworks® retail pharmacy reports and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) for those designated EGWP service areas outside of their individual plan service areas. However, Part D access sufficient to meet the needs of employer group enrollees must be in place once the PDP sponsor enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area. Also, CMS may review the adequacy of the pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons in order to ensure that the plan's network is sufficient to meet the needs of its enrollee population.

2. PDP Sponsors Applying to Only Offer "800 Series" Plans (i.e., "800 Series Only" Contracts)

The elimination of the "nexus test", effective January, 2008, made it possible for PDP sponsors to apply to offer plans to employer groups through separate "800 Series Only" contracts without offering them to individual beneficiaries. PDP sponsors applying to offer "800 Series Only" contracts in CY2009 are required to submit GeoNetworks® retail pharmacy reports and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) for their entire designated EGWP service areas. The same rules apply to Employer/Union Direct Contract PDP sponsors.

C. Formularies for Non-Calendar Year Plans Offered by PDP Sponsors

CMS allows entities offering Part D EGWPs to offer prescription drug benefits on a calendar year and on a non-calendar year basis (if entities are approved to offer non-calendar year Part D EGWP plan benefit packages). In accordance with existing employer group policy, entities offering Part D EGWPs can add new drugs to their formulary or change the cost sharing to a lower cost share without submitting a new formulary for CMS approval. However, as with individual Medicare plans, these formularies may only be modified to remove drugs from the drug list, increase cost-share tiers, or add restrictions or limitations by following the established negative formulary change process for all PDP sponsors. Negative formulary change requests for non-calendar year Part D EGWPs are required to follow the same review and approval process as calendar year plans. Negative formulary change requests are not permitted after July 31st for any Part D sponsor. Thus, the time frame for non-calendar year Part D EGWPs to make negative changes is the same as calendar year plans.

However, in order to accommodate non-calendar year Part D EGWPs, CMS is clarifying that non-calendar year Part D EGWPs may elect to convert to the conditionally approved formulary for the next calendar year on January 1st. Any entities offering non-calendar year EGWPs that choose this option must provide appropriate beneficiary notice as specified in 42 C.F.R. § 423.120(b)(5). Alternatively, entities offering non-calendar year Part D EGWPs whose plan start date occurs after conditional approval of the formulary for the following calendar year may elect to use that formulary for the entire non-calendar plan year. Any further changes for the rest of the non-calendar year would have to be consistent with the process for updating CY2008 formularies and requesting negative formulary changes as described in the November 28, 2007 HPMS memo – Updating CY2008 formularies.

The following example illustrates the above-stated policy:

A non-calendar year Part D EGWP with a start date of October 1, 2008 could either:

1. use its CY2008 conditionally approved formulary throughout the employer group sponsor's plan year (October 1, 2008 –September 30, 2009) and make no negative changes;
2. use its CY2008 conditionally approved formulary from October 1, 2008 – December 31, 2008 and its CY2009 conditionally approved formulary from January 1, 2009 – September 30, 2009) and request negative changes through July 31, 2009 in accordance with the above-stated policy; or
3. use its CY2009 conditionally approved formulary throughout the employer group sponsor's plan year (October 1, 2008 – September 30, 2009) and request negative changes through July 31, 2009 in accordance with the above-stated policy.

D. Designation of Service Area in HPMS for "800 Series" Plans

In order for a beneficiary to be eligible to enroll in an employer-sponsored individual PDP or an EGWP plan, he/she must permanently reside in the defined service area of the individual PDP or EGWP. PDP sponsors offering EGWPs are eligible for extended geographic service areas (outside of their individual plan service areas) under service area waivers issued by CMS. Therefore, PDP sponsors offering EGWPs should ensure that their EGWP defined service area includes all geographic areas in which employer/union sponsored group health plan Part D eligibles may permanently reside (*e.g.*, national service area) during the contract year. No mid-

year service area expansions will be permitted to address situations where PDP sponsors have failed to define their service area broadly enough and later wish to enroll employer group beneficiaries that permanently reside out of their EGWP defined service area.

E. Service Area Expansion for EGWPs ("800 Series" Plans, Employer/Union Direct Contracts and "800 Series Only" Contracts)

CMS does not require PDP sponsors to submit a service area expansion application for EGWPs. However, PDP sponsors are required to submit the following service area expansion and reduction requests to the Employer Policy & Operations Group in writing:

1. Request to expand an EGWP service area to include regions that were not previously included in the service area for the contract.
2. Request to reduce an EGWP service area to eliminate employer-only regions.

These service area expansion and reduction requests should be made to the Director of the Employer Policy & Operations Group on the Organization's letterhead and should be signed by an authorized representative. The request should include the contract number and list the regions that should be added to or deleted from the EGWP service area. This request should be submitted by April 30, 2008. CMS will make the necessary changes in HPMS after reviewing the request. Submit this request via hard copy to:

Centers for Medicare & Medicaid Services

Employer Policy & Operations Group

Mail Stop: C1-22-06

Attn: 2009 Service Area Expansion/Reduction Request

7500 Security Blvd.

Baltimore, MD 21244-1850

Section C - MARKETING/BENEFICIARY COMMUNICATIONS

This section applies to both MAOs and PDP Sponsors

A. Marketing Guidelines Update

We intend to update our current Medicare Marketing Guidelines for MAOs, MA-PD plans, PDP sponsors, and 1876 cost plans for CY2009. These revisions will capture recent policy changes and clarifications to plan marketing requirements, as well as clarify areas that have been of particular concern or focus since the last revision. More generally, our goal is to streamline and consolidate the guidelines in order to improve the consistency of marketing review processes and materials submission, as well as to promote maximum clarity with respect to marketing requirements.

B. Required Use of Standardized Model Materials

Marketing information that describes a plan's benefits is critical to ensure beneficiaries make the best health care decisions according to their needs. Over the past year, we have undertaken a comprehensive examination of our marketing material review processes. As part of this examination, we found that the Evidence of Coverage (EOC), Summary of Benefits (SB), and Annual Notice of Change (ANOC) were more likely to contain errors than other documents submitted to CMS for marketing material review. Given that these marketing documents communicate the most crucial and comprehensive benefit and plan information to both current and prospective enrollees, we are instituting changes in our processes to achieve more efficiencies and greater consistency in our review protocols and processes.

Our current process encourages plans to use model materials to expedite the marketing material review process. The model marketing documents contain language provided by us that is optional (or can be modified) for plan use. Given this flexibility, MAOs and PDP sponsors submit customized marketing materials that reflect preferred word choices or phrasing tied to corporate messaging.

To reduce variability and to ensure documents are more understandable and free of errors, we will be moving towards more standardization of information in plan materials. Standardized language is language provided by CMS that must be included in plan material without modification. In CY2009, we will require plans to use the combined standardized ANOC/EOC containing standardized language that is consistent with the Federal Employees Health Benefits (FEHB) program's standardized model materials. In addition, plans will be required to send the combined standardized ANOC/EOC earlier so beneficiaries have comprehensive plan information prior to the annual election period.

The first standardized models will be the EOC and ANOC (the SB is already standardized) included as Attachment J Certain other models such as the explanation of benefits (EOB), the pharmacy directory, provider directory, plan formulary document, and transition notice will be considered standardization in 2010 While the ANOC/EOC will contain standardized language that must be used, there will be sections within these documents that contain plan specific information that plans will need to fill and customize with respect to their specific plan benefit

package. We believe that using standardized language will reduce the number of errors and provide beneficiaries with familiar and consistent materials. In addition, a standardized ANOC/EOC should significantly shorten the amount of time required for CMS review.

As a result of the standardization we are making to these models, MAOs and PDP sponsors will be able to submit these documents under the File and Use process. We will provide more detailed instructions in later guidance.

C. Quality Control Processes for Marketing Material Development

Our recent experience with marketing materials review indicates that MAOs and PDP sponsors are submitting a significant number of inaccurate and incomplete marketing materials. This has resulted in longer CMS review times, which in some cases has had implications for plans' marketing materials production schedules.

To address this problem, we will establish processes for CY2009 aimed at improving plans' accountability for the accuracy and completeness of their marketing materials. For example, we are exploring building a quality control checklist into HPMS that would require plans to ensure that they have included all necessary information and have undertaken a thorough quality control review prior to submission of marketing materials for CMS review. This quality control checklist would include both content and editorial review items. In addition, we will require plans to attest to the accuracy and completeness of their submissions in HPMS.

We remind MAOs and PDP sponsors that accurate data entry in the bid pricing tool (BPT) and plan benefit package (PBP) are critical to a streamlined review process. It has increasingly been our experience that sponsors do not correctly populate some of the fields in these tools, which necessitates both plan corrections and hard copy change requests. CMS has made a number of improvements to the system – particularly for Special Needs Plans (SNPs) – that should reduce the need for hard copy change requests. However, hard copy change requests may jeopardize sponsors' ability to produce their marketing materials before the beginning of the Annual Coordinated Election Period (AEP).

D. File & Use

CMS currently allows plans to submit qualified marketing materials for distribution under "File & Use Eligibility" or "File & Use Certification." While plans are permitted to utilize either process, creating one standardized "File & Use" process will allow for consistency and reduce duplication. Therefore, CMS is considering adopting File & Use Certification as the standard process for all plans to submit marketing materials that qualify.

Organizations that currently use File and Use Eligibility will be required to submit an attestation to CMS in order to submit materials through File & Use Certification. CMS will establish a date by which all attestations must be submitted and will continue to allow plans to submit qualified materials through File & Use Eligibility until a deadline for use of File & Use Certification has been established.

E. Marketing versus Call Center Activities Clarification

Since the implementation of both the Medicare Advantage and the Medicare Prescription Drug program, CMS has increasingly been asked to clarify the boundaries between marketing by sales agents and brokers, versus the provision of factual information by plan call center customer

service representatives. We continue to field questions about the nature of these activities and the appropriate role of customer service parties in offering information and providing assistance with enrollment activities.

In order to clarify these gray areas, CMS is clarifying for CY2009 that direct marketing activities constitute contact with an eligible Medicare beneficiary or individual acting on behalf of the beneficiary that serves to promote the choice of a Part D sponsor's or MAO's benefit plans through advice and counseling, but does not include the provision of actual information that is available publicly on plan characteristics, the fulfillment of a request for plan materials, or the taking of demographic information. Moreover, direct marketing would be conducted through an MAO or a Part D sponsor's State licensed marketing representative; however, a plan customer service representative that provides factual information or takes demographic information would not be conducting direct marketing.

Based on this clarification, MAOs and PDP sponsors may not require potential enrollees to interact with a licensed agent in order to obtain plan materials or to enroll in a plan. A Customer Service Representative may fulfill a request for plan materials, including an enrollment form, and accept enrollments on behalf of enrollees who have decided to enroll in a particular plan offered by an organization.

F. Agent and Broker Requirements

As marketing is the primary means for organizations to attract people with Medicare to their products, providing accurate and reliable information is essential to helping inform beneficiaries of their choices. To ensure beneficiaries are getting the information necessary to make informed decisions and agents understand the plans they are marketing and are prepared to provide plan recommendations to them, it is critical that agents receive training. MAOs and PDP sponsors are responsible for providing agents and brokers with training on Medicare rules, regulations and compliance-related information on the plan products they intend to sell. In addition to training, MAOs and PDP sponsors must administer a written test to all agents and brokers selling Medicare products. Agents and brokers must successfully complete the test(s) with a minimum score of 80 percent in order to demonstrate their knowledge of the Medicare program and the plan specific products they intend to sell. These requirements apply to both employed and contracted agents and brokers. CMS will provide continued oversight of all marketing activities; at CMS' request plans must provide to CMS any information necessary to conduct such oversight.

G. Cooling-off Period

We remind organizations that marketing representatives must clearly identify the types of products that will be discussed before marketing to a potential enrollee. To ensure beneficiaries have accurate information to make an informed choice about their Medicare benefits without being pressured, marketing representatives initially meeting with a beneficiary to discuss specific lines of plan business (*e.g.*, Medigap) must schedule a separate appointment to discuss other lines of business (*e.g.*, MA or PDP) plan information. Appointments may not be re-scheduled until 48 hours after the initial appointment. Marketing representatives may leave plan brochures regarding the other lines of business but may not discuss or conduct marketing activities related to the product. Enrollment applications may not be included in any materials provided to the beneficiary during the initial appointment.

H. Increased Emphasis on Monitoring Activities

Due to the number of errors we have identified in plan marketing materials, as well as the increasing number of requests for marketing material reviews, beginning this year, we will be more closely monitoring plans' compliance with the Medicare Marketing Guidelines. We plan on establishing a multi-pronged approach that will include the following elements:

- Improvements to HPMS that will document all revisions to submitted marketing materials;
- Rejection of marketing materials that contain substantive grammatical errors;
- Retraining of CMS reviewers;
- Retrospective reviews of file and use materials;
- Secret shopping of sales events;
- Reviews of Complaints Tracking Module (CTM) marketing complaints;
- Reviews of materials currently in the marketplace; and
- Compliance actions for significant violations of CMS marketing requirements.

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

1. General

On or about October 9, 2008, the CY2009 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, plan ratings information, and disenrollment reasons data for the MAOs. 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 MAOs through the MOC and to MA-PD plans and PDP sponsors through MPDF. This year, the enrollment function will be available for 2008 plans through November 30, 2008, and for 2009 plans beginning November 15. 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 2009. 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 2009. Failure to conduct these QA checks may result in suppression of the MA-PD and PDP sponsors' pricing data from the website.

J. Licensing of Marketing Representatives and Confirmation of Marketing Resources

In response to continued questions from the Part D industry regarding state licensure of marketing representatives, we are reaffirming our requirement that MAOs and PDP sponsors that conduct marketing do so through independent agents that are state-licensed, certified, or registered individuals, if a state licenses such agents. This policy was previously contained within our Marketing Guidelines. The use of only state-licensed marketing representatives helps ensure that the marketing representatives meet minimum standards of integrity and professionalism in order to market to Medicare-eligible beneficiaries.

Consistent with these guidelines, we are asking in 2009 that MAOs and PDP sponsors report to States that they are using such agents, in a manner consistent with their state licensing requirements. This request would permit Medicare to benefit from State efforts to deny licensure to under-educated, unscrupulous or otherwise substandard individuals, and helps ensure that Medicare beneficiaries are not the victims of substandard or inappropriate marketing activities.

K. LIS Rider

MAOs and PDP sponsors must mail the Low Income Subsidy (LIS) rider at the same time as the EOC, regardless of when the EOC is mailed. Part D plans must also send an LIS rider at other times of the year if an enrollee becomes newly LIS eligible, or experiences a change in the level of LIS for which he/she qualifies. Part D plans have the option to send an LIS termination letter when an enrollee's LIS terminates entirely. For contract year 2009, CMS proposes to require Part D plans to send the LIS termination letter when an enrollee's LIS terminates.

L. Beneficiary Materials in the Spanish Language

CMS understands that there are many variations of the Spanish language because of the different spoken dialects. To ensure that beneficiaries understand materials translated into the Spanish language, we ask that plans use the standardized Spanish language in all their materials to target the Hispanic population. As a resource, we recommend that plans consult with "Real Academia Española" (Royal Spanish Academy), the most widely-recognized institution responsible for regulating the Spanish language, when creating their materials in Spanish.

M. Summary of Benefits Place Holder Sentences [MAOs only]

To assist MAOs in meeting the requirement that enrollees have current plan information 15 days prior to the Annual Enrollment Period, CMS is providing organizations with the option to use the prior year's Medicare premium and deductible amounts instead of waiting for CMS to release the new year's amounts. MAOs that apply the Medicare-defined cost sharing for Inpatient Hospital Acute, Inpatient Hospital Psychiatric and Skilled Nursing Facility may also use the prior year's Medicare cost sharing amounts.

Based on this new option, for example, this year the SB will print both the 2008 Medicare cost sharing amounts and a place holder sentence for the 2009 Medicare cost sharing amounts. Organizations that need to go to production prior to CMS' release of the 2009 Medicare cost sharing may use the 2008 Medicare cost sharing amounts and sentences and delete the 2009 placeholder sentences. Organizations that can wait until CMS releases the 2009 Medicare cost sharing should use the 2009 placeholder sentences and manually update the SB with the Medicare cost sharing when the amounts are released. In addition, these organizations should

delete the 2008 Medicare cost sharing amounts and sentences. Medicare Options Compare will not display 2008 Medicare cost sharing amounts.

N. Summary of Benefits Hard Copy Changes [MAOs and PDP sponsors]

We remind organizations that hard copy changes are only permitted to correct inaccurate or misleading information or errors generated from the SB/PBP software. Requests for changes in which the existing sentences are accurate will not be permitted. CMS will not permit changes in wording based on individual preferences. While CMS allows MAOs and PDP sponsors to make changes to the hard copy SB on a very limited basis, organizations are reminded of their responsibility to have the SB available for inclusion in marketing materials. A pending or delayed review of a hard copy change request is not an acceptable excuse for the SB to be delayed. Plans should consider the timing of getting the SB to members before submitting a hard copy change request. Hard copy change requests related to the description of benefits will not be reviewed until CMS has approved all bids. However, plans, may submit administrative hard copy requests (*e.g.*, changes to the local phone number or website location). Plans are reminded that prior to submitting a hard copy request, they should validate the data entered in the PBP as well as reference the SB crosswalk to ensure the correct sentences are generated for the specific benefit being described. Last year, many of the requests received were resolved by entering the appropriate data in the PBP or HPMS.

A hard copy change request permitted in previous years does not guarantee approval this year.

All changes to the SB must be requested by the organization and approved by CMS. Approved hard copy changes will not result in changes in Medicare Options Compare, nor will they result to changes in the Plan Benefit Package (PBP).

As we continue to integrate and streamline materials that include information on Medicare and Medicaid, SNPs that enroll Medicaid subsets are permitted to make hard copy changes requested by the State. Hard copy requests made by the State must be submitted to the CMS Regional Office plan manager for review.

O. 2009 Medicare & You

The 2009 *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 2008 *Medicare & You* handbook released last fall. One CAHPS measure will be included in the 2009 *Medicare & You* handbook. Plans will be able to preview their handbook plan data September 8 through 10.

Section D - Appendices

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ATTACHMENT A – Risk Adjustment Implementation

1. Risk Adjustment Data Submission Schedule

Table 1. Risk Adjustment Implementation Calendar (below) provides the updated submission schedule for all diagnosis data submitted for all risk adjustment models. This includes data for both the Part C CMS-HCC and ESRD models and the Part D Drug risk adjuster model.

Table 1. Risk Adjustment Implementation Calendar

CY	Dates of Service	Initial Submission Deadline*	First Payment Date	Final Submission Deadline
2008	July 1, 2006 through June 30, 2007	September 7, 2007	January 1, 2008	N/A**
2008	January 1, 2007 through December 31, 2007	March 7, 2008	July 1, 2008	January 31, 2009
2009	July 1, 2007 through June 30, 2008	September 5, 2008	January 1, 2009	N/A**
2009	January 1, 2008 through December 31, 2008	March 6, 2009	July 1, 2009	January 31, 2010
2010	July 1, 2008 through June 30, 2009	September 4, 2009	January 1, 2010	N/A**
2010	January 1, 2009 through December 31, 2009	March 5, 2010	July 1, 2010	January 31, 2011
2011	July 1, 2009 through June 30, 2010	September 3, 2010	January 1, 2011	N/A**
2011	January 1, 2010 through December 31, 2010	March 4, 2011	July 1, 2011	January 31, 2012

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

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

Changes in payment methodology for 2009, including Part C and Part D payment and risk adjustment, are described in the February 22, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2009 Medicare Advantage Payment Rates* and the April 7, 2009, *Announcement of Calendar Year (CY) 2009 Medicare Advantage Payment Rates* (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).

2. Part A Risk Adjustment Factor Options

- ***Determinations of Risk Status***

As stated in the April 3, 2006 *Announcement of Calendar Year (CY) 2007 Medicare Advantage Payment Rates* (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/), plans

subject to risk adjusted payments have an option for how to treat beneficiaries with 12 months of Part A data but less than 12 months of Part B enrollment in a data collection year.

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

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

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

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

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

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

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

Effective as of 2006 payments, organizations may elect to have CMS determine payments for all "Part A-only" enrollees using either new enrollee factors or full risk adjustment factors. If an organization elects to have CMS determine payment factors (i.e., new enrollee factors or full risk adjustment factors) for all "Part-A only" enrollees, then -

- The decision will be applied to all "Part-A" only enrollees in the plan; and
- 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 for 2009 must contact: Henry Thomas, CMS, at henry.thomas@cms.hhs.gov by August 31, 2008.

3. Risk Adjustment Implementation

MA organizations must review the following:

- Changes in payment methodology for 2009, including Part C and Part D payment and risk adjustment, are described in the February 22, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2009 Medicare Advantage Payment Rates and Part D Payment Policies* and the April 7, 2009, *Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Payment Policies and CY 2009 Part D Payment Notification* (available at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/).

- Two important risk adjustment memoranda dated November 27, 2007, which were published via HPMS on November 28, 2007 -
    - CMS implementation of ICD-9 diagnosis codes for 2009 CMS implementation of ICD-9 diagnosis codes for 2009
    - Medicaid status for Part C and D risk adjustment and Part D cost sharing; and

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

4. Inpatient Prospective Payment System (Hospital Acquired Conditions)

In the FY 2007 Inpatient Prospective Payment System final rule, CMS implements a provision of the Deficit Reduction Act of 2005 which precludes the Medicare program from making additional payments for certain hospital acquired conditions beginning with discharges occurring on or after October 1, 2008. Effective for discharges on or after October 1, 2007, acute care hospitals are required to begin reporting all diagnoses that are present on admission of patients. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment under the Inpatient Prospective Payment System for cases in which one of the eight selected conditions (including surgical site infections, blood incompatibility, air embolism, object left in surgery, catheter associated urinary tract infections, pressure ulcers, hospital acquired injuries, vascular catheter associated infection) was not present on admission.

For purposes of risk adjustment, only discharge diagnoses are used for payment. To the extent that any ICD-9 codes attributable to the eight selected hospital acquired conditions appear in the discharge diagnoses, these codes can be submitted for risk adjustment payment.

5. National Provider Identifier (NPI)

The January 23, 2004 final rule (69 FR 3434*), HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers*, established the standard for a unique identifier for health care providers and adopted the National Provider Identifier (NPI) number as that standard. The National Provider System (NPS) was established to assign unique NPI numbers to health care providers. The NPS was designed to be used by other Federal and state Agencies as well as by private health plans, if deemed appropriate, to enumerate their health care

providers that did not participate in Medicare. Consequently, the NPI can not be used to determine whether a provider is a Medicare certified provider.

On May 23, 2007, the CMS implemented the use of the NPI, for claims submitted to Fee-For-Service (Original) Medicare and discontinued issuing the Medicare Provider Identifier Numbers (legacy or OSCAR numbers). In the past, Medicare plans could use the legacy number to verify that a provider was a Medicare provider and that the provider was an acceptable source for diagnosis data for the CMS risk adjustment process.

Implementation of the NPI necessitates that Medicare plans that had been using the legacy Medicare provider numbers to verify the source of diagnoses submitted for risk adjustment purposes establish new methodologies for determining: 1) that providers are Medicare certified and 2) that diagnosis sources are acceptable. Implementation of the NPI does not change the requirement for Medicare plans to verify that the diagnosis data submitted to the CMS for risk adjustment are from Medicare certified providers and from acceptable data sources.

6. Testing Requirements

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

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

7. Acceptable Provider Types and Physician Data Sources

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

- Hospital inpatient facilities
- Hospital outpatient facilities
- Physician.

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

MA organizations are responsible for ensuring that the data they collect and submit to CMS for payment comes from acceptable provider types and physician data sources. The collection of physician data relevant for risk adjustment is associated with the physician's specialty. That is,

all ICD-9-CM diagnoses that are in the risk adjustment model and rendered as a result of a visit to a physician must be collected by the MA organization. This includes data collected from non-network as well as network providers. Therefore, CMS requires MA organizations to filter and submit risk adjustment data in accordance with the appropriate provider types and acceptable physician data sources as approved by CMS.

8. Integrity of RAPS Submissions

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

9. IT Technical Assistance Outreach

The purpose of the IT Technical Assistance Outreach program is to provide Part C and Part D contracted organizations with the IT support to perform the required Risk Adjustment, Prescription Data Event and Enrollment/Payment data submissions skills and to understand the roles data play in relationship to enrollment and payment. This outreach will enable these organizations to collect and submit the appropriate data in accordance with CMS requirements; thereby, this assistance's expected outcome seeks to provide a positive impact on "the correct payment." CMS offers Monthly Risk Adjustment and Enrollment/Payment outreach sessions at its Baltimore headquarters. We anticipate conducting our regional outreach sessions in August and September of 2008.

The specific dates for the monthly and regional outreach sessions will be announced during the Risk Adjustment (i.e., Part C) User Group sessions, and will be listed on our contractor's web site. For additional information or to register for the outreach sessions and the User Group sessions, please visit our contractor's web site at http://www.TARSC.info.

10. 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 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 *2007 Risk Adjustment Data Training For Medicare Advantage Organizations, Participant Guide* available on our contractor's web site at http://www.csscoperations.com/new/usergroup/2007raps/ra-particpantguide_120607.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/ftpserv/ftpicd9/icdguide07.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 the *2007 Risk Adjustment Data Training For Medicare Advantage Organizations, Participant Guide* available on our contractor's web site at http://www.csscoperations.com/new/usergroup/2007raps/ra-particpantguide_120607.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.

ATTACHMENT B – Model MA Provider Directory

[Note: For 2009 the Provider Directory has been streamlined to better explain your list of plan providers]

[Instructions: All variable fields are denoted by gray text and brackets. These fields must be populated with Plan-specific information. Adjust Section numbers throughout, if applicable]

[Distribution Note:

For Annual Mailings - Plans have the option of mailing one directory to every member – or – one directory to every address where up to four members reside.

Enrollment - Plans must provide a directory to each member upon enrollment. Please refer to the Marketing Guidelines for more detailed instructions.]

[Name of Plan]
[HMO / Cost / PPO] Plan
Provider Directory

This directory provides a list of [Plan Name]'s plan providers.

This directory is for [provide a description of the plan's service area, including a list of cities and towns].

This directory is current as of [date of publication]. Some plan providers may have been added or removed from the list after this directory was printed. To get the most up-to-date information about [Plan Name] plan providers in your area, you can visit [Web address] or call our Customer Service Department at [phone number], [days and hours of operation]. TTY users should call [TTY number].

[CMS approval date]

[Material ID]

Section 1 – Introduction

This directory provides a list of [Plan Name]'s plan providers. To get detailed information about your health care coverage, please see your Evidence of Coverage.

Use this introduction section to describe how members should use this directory for example to select PCP if your plan uses PCP, explain sub networks, referral circles if applicable, and which types of providers require referral. Use, delete or modify the following based on plan arrangement.

[Insert this paragraph if applicable, depending on plan arrangement: You will have to choose one of our plan providers that are listed in this directory to be your **P**rimary **C**are {**P**hysician/**P**rovider} (PCP). The term "PCP" will be used throughout this directory. Generally, you must get your health care coverage from your PCP.] [Explain PCP in the context of your plan type.]

The "plan providers" listed in this directory have agreed to provide you with your health care coverage. You may go to any of our plan providers listed in this directory; [Insert if applicable: however some services may require a referral.] If you have been going to one plan provider, you are not required to continue going to that same provider. In some cases, you may get covered services from non-plan providers. [Note: Modify the discussion in this section to reflect your own contractual circumstances, such as open access panels, formal referral circles or sub networks, etc. If you don't require referrals but do require prior authorizations, or if you treat prior authorization differently than referrals, adjust the language appropriately.]

What is the service area for [Plan Name]?

The [For PPOs only: States or] counties [and parts of counties] in our service area are listed below. [Optional: You may include a map of the area (in addition to listing the service area), and modify the prior sentence to refer readers to the map.]

[Insert plan service area listing. Use county name only if approved for the entire county. For partially approved counties, use county name plus zip code, (e.g., "County name, the following zip codes only: {xxxxx}…")]

How do you find [Plan Name] providers in your area?

[Plans should describe how an enrollee can find a plan provider nearest his or her home relative to the organizational format used in the provider directory.]

If you have questions about [Plan Name], please call our Customer Service Department at [phone number], [days and hours of operation]. TTY users should call [TTY number]. Or, visit [Web address].

Section 2 – List of Plan Providers

[Note: Identifying Medicare providers in the directory that accept Medicaid will assist dual eligible enrollees in obtaining access to providers and covered services.]

[Recommended organization:

Type of Provider (PCP, Specialty, Skilled Nursing Facilities, Hospitals, Outpatient mental health providers, and pharmacies, where outpatient prescription drugs are offered by the Medicare Advantage plan.)

State (Include only if directory includes multiple states)

County (Listed alphabetically)

City (Listed alphabetically)

Neighborhood/Zip Code (Optional; For larger cities, providers may be further subdivided by zip code or neighborhood)

Provider (Listed alphabetically)

Note: Plans must indicate how types of providers can be identified and located relative to organization of the provider directory. For example plans identifying Medicare providers that participate in Medicaid can include language similar to the following when listing providers: providers identified with an asterisk also accept Medicaid.

(e.g. type of provider, state, city, address, zip code, provider name*]

Primary Care Physicians

[State]

[County]

[City]

[Zip Code]

[Physician Name]

[Physician Street Address, City, State, Zip Code]

[Phone number]

[WEB AND E-MAIL ADDRESSES ARE OPTIONAL]

Specialists

[Specialty Type]

[State]

[County]

[City]

[Zip Code]

[Physician Name]

[Physician Street Address, City, State, Zip Code]

[Phone number]

[WEB AND E-MAIL ADDRESSES ARE OPTIONAL]

Hospitals

[State]

[County]

[City]

[Zip Code]

[Hospital Name]

[Hospital Street Address, City, State, Zip Code]

[Phone number]

[WEB AND E-MAIL ADDRESSES ARE OPTIONAL]

Skilled Nursing Facilities (SNF)

[State]

[County]

[City]

[Zip Code]

[SNF Name]

[SNF Street Address, City, State, Zip Code]

[Phone number]

[WEB AND E-MAIL ADDRESSES ARE OPTIONAL]

Outpatient Mental Health Providers

[State]

[County]

[City]

[Zip Code]

[Physician Name]

[Physician Street Address, City, State, Zip Code]

[Phone number]

[WEB AND E-MAIL ADDRESSES ARE OPTIONAL]

Pharmacies

[State]

[County]

[City]

[Zip Code]

[Pharmacy Name]

[Pharmacy Street Address, City, State, Zip Code]

[Phone number]

[WEB AND E-MAIL ADDRESSES ARE OPTIONAL]

ATTACHMENT C – Model Part D Pharmacy Directory

*[**Note**: Optional language and guidance is provided in bracketed and italicized text. All variable, required fields are denoted by carets and must be populated with Plan-specific information].*

*[**Note**: All references to Member Services and Pharmacy Directory can be changed to the appropriate name your plan uses.]*

<Plan Name>

Pharmacy Directory

This booklet provides a list of <Plan Name>'s network pharmacies. [***Optional:*** *If this directory is a subset of a service area, Plans must include the following disclaimer:* "This directory is for <geographic area>".] [We also list pharmacies that are in our network but are outside <geographic area>. Please contact <Plan Name> at <phone number>, <days and hours of operation>, for additional information.] All network pharmacies may not be listed in this directory. Pharmacies may have been added or removed from the list after this directory was printed. To get current information about <Plan Name> network pharmacies in your area, please visit our Web site at <Web address> or call our Member Services at <phone number>, <days and hours of operation>. (TTY/TDD Users should call <TTY/TDD number>.)

<Material ID>

[<CMS approval date>]

Introduction

This booklet provides a list of <Plan Name>'s network pharmacies. To get a complete description of your prescription coverage, including how to fill your prescriptions, please review the Evidence of Coverage and <Plan Name>'s formulary. If you have additional questions, please call our Member Services at <phone number>, <days and hours of operation>. TTY/TDD Users should call <TTY/TDD number>. Or, visit <Web address>.

We call the pharmacies on this list our "network pharmacies" because we have made arrangements with them to provide prescription drugs to Plan members. A network pharmacy is a pharmacy where beneficiaries obtain prescription drug benefits provided by <Plan Name>. In most cases, your prescriptions are covered under <Plan Name> only if they are filled at a network pharmacy [or through our mail order pharmacy service]. Once you go to one, you are not required to continue going to the same pharmacy to fill your prescription. You can go to any of our network pharmacies. We will fill prescriptions at non-network pharmacies under certain circumstances as described in your Evidence of Coverage.

<Plan Name>'s Network Pharmacies

[Recommended organization:

Type of Pharmacy *(Retail, Mail Order, Home Infusion, LTC, I/T/U)*

State *(Include only if directory includes multiple states)*

County *(Listed alphabetically)*

City *(Listed alphabetically)*

Neighborhood/Zip Code *(Optional; For larger cities, pharmacies may be further subdivided by zip code or neighborhood)*

Pharmacy *(Listed alphabetically)*

*[**Note:** Plans must indicate how types of pharmacies can be identified and located relative to organizational format.*]

[***Note:*** *Plans must indicate when a pharmacy is not available to all members. If symbols are used, a legend must be provided.]*

[***Note:*** *Plans must indicate when a pharmacy is a preferred pharmacy. If symbols are used, a legend must be provided.]*

[Retail Pharmacies

<Pharmacy Name>

<Pharmacy Street Address, City, State, Zip Code>

<Phone Number>

*[**Optional:** <Web and e-mail addresses>]*

*[**Optional:** <Special Services:>] [**Note:** Examples of special services include: Home Delivery, Drive Thru, Compounds Prepared.]*

***[Note:** Indicate whether the pharmacy provides an extended day supply of medications]*

***[Optional:** <Days/Hours of Operation>] [**Note:** You may also indicate if a pharmacy is open 7 days per week and/or 24 hours per day.]*

*[**Note:** You may indicate special services/hours of operation with symbols, although text is preferred. If symbols are used, a legend must be provided. For example, you may use a clock to indicate that a pharmacy is open 24 hours per day, however, it is easier for readers if the directory simply states, "Open 24 hours."*]

[Chain Pharmacies

In lieu of providing addresses for all locations, chains may provide a toll-free customer service number and a TTY/TDD number that an enrollee can call to get the locations and phone numbers of the chain pharmacies nearest their home. If the chain pharmacy does not have a toll-free number, plans should include a central number for the pharmacy chain. If the chain pharmacy does not have a central number for enrollees to call, then plans must list each plan's chain pharmacy and phone number in the directory. If the chain pharmacy does not have a TTY/TDD number, plans are instructed to list the TRS Relay number 711. Plans should not list their own Member Services number as a pharmacy phone number or TTY/TDD number.

<Chain Pharmacy Name>

<Toll-free number/central number for the pharmacy chain and TTY/TDD number/TRS Relay number 711>

***[Note:** Indicate whether the pharmacy provides an extended day supply of medications]*

***[Optional:** <Web and e-mail addresses>]]*

[Mail Order Pharmacy[ies]

<Pharmacy Name>

< Toll-free number and toll-free TTY/TDD number>

***[Optional:** Web and e-mail address >*]]

Home Infusion Pharmacies

*<**Note:** Plans should provide any additional information on home infusion pharmacy services in their network and how enrollees can get more information. >*

<Pharmacy Name>

<Pharmacy Street Address, City, State, Zip Code>

<Phone Number>

***[Optional:** <Web and e-mail address>*]

Long-Term Care Pharmacies

Residents of a long-term care facility may access their prescription drugs covered under <Plan Name> through the facility's long-term care pharmacy or another network long-term care pharmacy.

*<**Note:** Plans should provide any additional information on long-term care pharmacy services in their network and how enrollees can get more information. >*

<Pharmacy/Long-Term Facility Name>

<Pharmacy Street Address, City, State, Zip Code>

<Phone Number>

***[Optional:** <Web and e-mail address>*]

[Indian Health Service / Tribal / Urban Indian Health Program (I/T/U) Pharmacies

Only Native Americans and Alaska Natives have access to Indian Health Service / Tribal / Urban Indian Health Program (I/T/U) Pharmacies through <Plan Name>'s pharmacy network. Those other than Native Americans and Alaskan Natives may be able to access these pharmacies under limited circumstances (e.g., emergencies).

*<**Note:** Plans should provide any additional information on I/T/U pharmacy services in their network and how enrollees can get more information>*

<Pharmacy Name>

<Pharmacy Street Address, City, State, Zip Code>

<Phone Number>

[Optional: *<Web and e-mail address>*]

[Optional: *<Special Services:>] [**Note:** This field is optional. Examples of special services include: Home Delivery, Drive Thru, Compounds Prepared].*

[Optional: *<Days/Hours of Operation>] [**Note:** You may also indicate if a pharmacy is open 24 hours a day and/or 7 days per week.*]

[Network Pharmacies outside the <Geographic Area>]

[We have network pharmacies outside of the service area where you can get your drugs covered as a member of our plan.]

<Pharmacy Name>

<Pharmacy Street Address, City, State, Zip Code>

<Phone Number>

*[**Optional:** <Web and e-mail addresses >]]*

ATTACHMENT D – Model Part D Abridged Formulary

***[Note**: Instructions for Plans are provided within italicized text. Text in square brackets must be included if the text accurately describes the plan's benefit structure. Carets are placeholders for variable information and must be filled in appropriately].*

***[Note:** All references to Member Services and Pharmacy Directory can be changed to the appropriate name your plan uses.].*

<Plan Name>

<Year> Formulary

(List of Covered Drugs)

PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN

Note to existing members: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take.

This document includes <Plan Name's> partial formulary as of <formulary date>. For a complete, updated formulary, please visit our Web site at <Web site address> or call <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

<Material ID>

[<CMS Approval Date >]

Last Updated <Date>

What is the <Plan Name> Formulary?

A formulary is a list of covered drugs selected by <plan name> in consultation with a team of health care providers, which represents the prescription therapies believed to be a necessary part of a quality treatment program. <Plan Name> will generally cover the drugs listed in our formulary as long as the drug is medically necessary, the prescription is filled at a <Plan Name> network pharmacy, and other plan rules are followed. For more information on how to fill your prescriptions, please review your Evidence of Coverage.

This document is a partial formulary and includes only some of the drugs covered by <Plan Name>. For a complete listing of all prescription drugs covered by <Plan Name>, please visit our Web site at <Web site address> or call <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Can the Formulary change?

Generally, if you are taking a drug on our <contract year> formulary that was covered at the beginning of the year, we will not discontinue or reduce coverage of the drug during the < contract year> coverage year except when a new, less expensive generic drug becomes available or when new adverse information about the safety or effectiveness of a drug is released. Other types of formulary changes, such as removing a drug from our formulary, will not affect members who are currently taking the drug. It will remain available at the same cost-sharing for those members taking it for the remainder of the coverage year. We feel it is important that you have continued access for the remainder of the coverage year to the formulary drugs that were available when you chose our plan, except for cases in which you can save additional money or we can ensure your safety.

If we remove drugs from our formulary, [or] add prior authorization, quantity limits and/or step therapy restrictions on a drug [or move a drug to a higher cost-sharing tier], we must notify affected members of the change at least 60 days before the change becomes effective, or at the time the member requests a refill of the drug, at which time the member will receive a 60-day supply of the drug. If the Food and Drug Administration deems a drug on our formulary to be unsafe or the drug's manufacturer removes the drug from the market, we will immediately remove the drug from our formulary and provide notice to members who take the drug. The enclosed formulary is current as of <formulary date>. To get updated information about the drugs covered by <plan name>, please visit our Web site at <Web site address> or call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

How do I use the Formulary?

There are two ways to find your drug within the formulary:

Medical Condition

The formulary begins on page <table page number>. The drugs in this formulary are grouped into categories depending on the type of medical conditions that they are used to treat. For example, drugs used to treat a heart condition are listed under the category, <"category name example">. If you know what your drug is used for, look for the category name in the list that begins < on page number / below / on the next page >. Then look under the category name for your drug.

Alphabetical Listing

If you are not sure what category to look under, you should look for your drug in the Index that begins on page <index page number>. The Index provides an alphabetical list of all of the drugs included in this document. Both brand-name drugs and generic drugs are listed in the Index. Look in the Index and find your drug. Next to your drug, you will see the page number where you can find coverage information. Turn to the page listed in the Index and find the name of your drug in the first column of the list.

What are generic drugs?

<Plan Name> covers both brand-name drugs and generic drugs. A generic drug has the same active-ingredient as the brand name drug. Generally, generic drugs cost less than brand name drugs and are approved by the Food and Drug Administration (FDA).

Are there any restrictions on my coverage?

Some covered drugs may have additional requirements or limits on coverage. These requirements and limits may include: ***[Note:*** *Plans may omit bullets as needed in order to describe all utilization management procedures used by the plan.]*

- **Prior Authorization:** <Plan Name> requires you [or your physician] to get prior authorization for certain drugs. This means that you will need to get approval from <Plan Name> before you fill your prescriptions. If you don't get approval, <Plan Name> may not cover the drug.

- **Quantity Limits:** For certain drugs, <Plan Name> limits the amount of the drug that <Plan Name> will cover. For example, <Plan Name> provides <number of units> per prescription for <drug name>. This may be in addition to a standard one month or three month supply.

- **Step Therapy:** In some cases, <Plan Name> requires you to first try certain drugs to treat your medical condition before we will cover another drug for that condition. For example, if Drug A and Drug B both treat your medical condition, <Plan Name> may not

cover drug B unless you try Drug A first. If Drug A does not work for you, <Plan Name> will then cover Drug B.

You can find out if your drug has any additional requirements or limits by looking in the formulary that begins on page <table page number>.

You can ask <Plan Name> to make an exception to these restrictions or limits. See the section, "How do I request an exception to the <Plan Name's> formulary?" on page <exception page number> for information about how to request an exception.

What if my drug is not on the Formulary?

If your drug is not included in this list of covered drugs, you should first contact Member Services and ask if your drug is covered. This document includes only a partial list of covered drugs, so <Plan Name> may cover your drug. You can contact Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

f you learn that <Plan Name> does not cover your drug, you have two options:

- You can ask Member Services for a list of similar drugs that are covered by <Plan Name>. When you receive the list, show it to your doctor and ask him or her to prescribe a similar drug that is covered by <Plan Name>.

- You can ask <Plan Name> to make an exception and cover your drug. See below for information about how to request an exception.

How do I request an exception to the <Plan Name's> Formulary?

You can ask <Plan Name> to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary.

- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, <Plan Name> limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover more.

- [You can ask us to provide a higher level of coverage for your drug. If your drug is contained in our [non-preferred/highest tier subject to the tiering exceptions process] tier, you can ask us to cover it at the cost-sharing amount that applies to drugs in the

[preferred/lowest tier subject to the tiering exceptions process] tier instead. This would lower the amount you must pay for your drug. Please note, if we grant your request to cover a drug that is not on our formulary, you may not ask us to provide a higher level of coverage for the drug. [**Note:** *If the plan designated one of its tiers as a "high-cost/unique drug tier" and is exempting that tier from the exceptions process, include the following language*: "Also, you may not ask us to provide a higher level of coverage for drugs that are in the [tier designated as the high-cost/unique drug tier."]

Generally, <Plan Name> will only approve your request for an exception if the alternative drugs included on the plan's formulary, [the lower-tiered drug] or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, [tiering] or utilization restriction exception. When you are requesting a formulary, [tiering] or utilization restriction exception you should submit a statement from your physician supporting your request. Generally, we must make our decision within 72 hours of getting your prescribing physician's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get your prescribing physician's supporting statement.

What do I do before I can talk to my doctor about changing my drugs or requesting an exception?

As a new or continuing member in our plan you may be taking drugs that are not on our formulary. Or, you may be taking a drug that is on our formulary but your ability to get it is limited. For example, you may need a prior authorization from us before you can fill your prescription. You should talk to your doctor to decide if you should switch to an appropriate drug that we cover or request a formulary exception so that we will cover the drug you take. While you talk to your doctor to determine the right course of action for you, we may cover your drug in certain cases during the first <*must be at least 90*> days you are a member of our plan.

For each of your drugs that is not on our formulary or if your ability to get your drugs is limited, we will cover a temporary <*must be at least 30*>-day supply (unless you have a prescription written for fewer days) when you go to a network pharmacy. After your first <*must be a least 30*>-day supply, we will not pay for these drugs, even if you have been a member of the plan less than <*must be at least 90*> days.

If you are a resident of a long-term care facility, we will cover a temporary <*must be at least 31*>-day transition supply (unless you have a prescription written for fewer days). We will cover more than one refill of these drugs for the first <*must be at least 90*> days you are a member of our plan. If you need a drug that is not on our formulary or if your ability to get your drugs is limited, but you are past the first <*must be at least 90*> days of membership in our plan, we will

cover a <*must be at least 31*>-day emergency supply of that drug (unless you have a prescription for fewer days) while you pursue a formulary exception.

<***Note:*** *Plans must insert their transition policy for current enrollees with level of care changes, if applicable.*>

For more information

For more detailed information about your <Plan Name> prescription drug coverage, please review your Evidence of Coverage and other plan materials.

If you have questions about <Plan Name>, please call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.) Or visit <Web site address>.

If you have general questions about Medicare prescription drug coverage, please call Medicare at 1-800-MEDICARE (1-800-633-4227) 24 hours a day/7 days a week. TTY/TDD users should call 1-877-486-2048. Or, visit www.medicare.gov.

<Plan Name's> Formulary

The abridged formulary <below/that begins on the next page> provides coverage information about some of the drugs covered by <Plan Name>. If you have trouble finding your drug in the list, turn to the Index that begins on page <index page number>. Remember: This is only a partial list of drugs covered by <Plan Name>. If you prescription is not in this partial formulary, please visit our Web site at <Web site address> or call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number> for additional help.

The first column of the chart lists the drug name. Brand-name drugs are capitalized (e.g., <BRAND NAME EXAMPLE>) and generic drugs are listed in lower-case italics (e.g., <*generic example*>).

The information in the Notes column tells you if <Plan Name> has any special requirements for coverage of your drug.

***[Note:** Plan must explain any symbols or abbreviations used to indicate utilization management restrictions, drugs that are available via mail-order, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only)]*

- *Plans that cover excluded Part D drugs must use this column to indicate that certain drugs are available only through their benefit. Plans may indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states:* "This prescription drug is not normally covered in a Medicare Prescription Drug Plan. The amount you pay when you fill a prescription for this drug does not count towards your total drug costs (that is, the amount you pay does not help you qualify for catastrophic coverage). In addition, if you are receiving extra help to pay for your prescriptions, you will not get any extra help to pay for this drug. ***[Note**: Plans must insert any additional restrictions on this coverage, including any capped benefit limit.]"*

- *Plans that offer generic-use incentive programs permitting zero (or reduced) cost-sharing on first generic fills when a member agrees to use the generic rather than the brand-name version of a medication must indicate the drugs to which this program applies. Plans may indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states:* "This prescription drug will be provided at <zero>/<reduced> cost-sharing the first time you fill it."

- *Plans that restrict access to any drugs by limiting distribution to a subset of network pharmacies must indicate these drugs. Plans may indicate this with an asterisk/other symbol or footnote at the bottom of the page that states:* "This prescription may be available only at certain pharmacies. For more information consult your Pharmacy Directory or call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>."

- *Plans that cover only certain drugs in the coverage gap must indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states*, "We provide coverage of this prescription drug in the coverage gap. Please refer to our Evidence of Coverage for more information about this coverage."

- *MA-PD or cost plans choosing to provide coverage for any Part D home infusion drugs as part of a bundled payment under a Part C supplemental benefit should indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states,* "This prescription drug <is>/<may be> covered under our medical benefit. For more information, call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>."

Drug Table - Option 1

Drug Name	Drug Tier	Notes
<Therapeutic Category Name 1> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>
<Therapeutic Category Name 2> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>

Drug Table - Option 2

Drug Name	Drug Tier	Notes
<Therapeutic Category Name 1> - [Optional: <Plain Language Description>]		
<Therapeutic Class Name 1> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>
<Therapeutic Class Name 2> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>
<Therapeutic Category Name 2> - [Optional: <Plain Language Description>]		
<Therapeutic Class Name 1> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>

General Drug Table instructions:

Column headings should be repeated on each page of the table.

For table sub-headings, plans have the option to use either the therapeutic category only (Table Option 1) or both the therapeutic category and therapeutic class (Table Option 2).

Plans have the option of including a "plain-language" description of the therapeutic category/class next to the name of each category/class. For example, instead of only including the category, "Dermatological Agents," Plans may include "Dermatological Agents – Drugs to treat skin conditions."

For Table Option 1, the therapeutic categories should be listed alphabetically within the table. The drugs should then be listed alphabetically under the appropriate therapeutic category; they should not be sorted by therapeutic class. For Table Option 2, the therapeutic categories should be listed alphabetically and the therapeutic classes listed alphabetically under the appropriate category. The drugs should then be listed alphabetically under the appropriate therapeutic class.

The chart must include at least two covered drugs for each therapeutic category/class except when only one drug exists in the category or class or when two drugs exist in the category or class but one is clinically superior to the other as per your CMS-approved formulary.

Drug Name column instructions:

Brand-name drugs should be capitalized, e.g., DRUG A. Generic drugs should be lower-case and italicized, e.g., penicillin. Plans may include the generic name of a drug next to the brand name.

If a drug has a different tier placement depending on the dosage (e.g., 20 mg has a $20 copayment and 40 mg has a $30 copayment), plans may include the drug twice within the table with the varying dosage listed next to the drug name (e.g., DRUG A, 20 mg and DRUG A, 40 mg). The drug will be counted as a single drug when determining whether the plan has included two drugs within each therapeutic category/class.

Drug Tier column instructions:

Part D Plans that provide different levels of cost sharing for drugs depending on their tier must include a column indicating the drug's tier placement.

Plans may choose from several methods to indicate the tier placement including tier numbers (e.g., 1/ 2/ 3), tier names (e.g., generic/ preferred brand/ other brand), copayment amounts (e.g., $10/$20/$35), or co-insurance percentages (e.g., 10%/25%). The latter two methods are preferred since they are generally easier for members to understand. If one of the two former methods is used, plans must provide an explanation before the table explaining the copayment amount or co-insurance percentage associated with each tier number or tier name.

Plans that have different copayment amounts or co-insurance percentages for retail and mail-order prescriptions may include both retail and mail order amounts within the same column or include separate columns for retail and mail order prescriptions.

Requirements/Limits column instructions:

Part D Plans must indicate any applicable utilization management procedures (e.g., prior authorization, step therapy, quantity limits, etc.), special coverage rules, and/or mail-order procedures for each drug within the Requirement/Limits column.

Plans may include abbreviations within this column (e.g., QL for quantity limits) but must include an explanation at the beginning of the formulary table explaining each abbreviation.

Index of Drugs

Plans must include an alphabetical listing of all drugs included in the abridged formulary that indicates the page where members can find coverage information for that drug. Plans may use more than one column for the index listing.

ATTACHMENT E – Model Part D Comprehensive Formulary

[Note: *Instructions for Plans are provided within italicized text. Text in square brackets must be included if the text accurately describes the plan's benefit structure. Carets are placeholders for variable fields that must be filled in accurately]*

[Note: *All references to Member Services and Pharmacy Directory can be changed to the appropriate name your plan uses.]*.

<plan name>

<Year> Formulary

(List of Covered Drugs)

PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN

Note to existing members: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take.

<Material ID>

[<CMS Approval Date Last Updated <Date>

What is the <plan name> Formulary?

A formulary is a list of covered drugs selected by <plan name> in consultation with a team of health care providers, which represents the prescription therapies believed to be a necessary part of a quality treatment program. <Plan name> will generally cover the drugs listed in our formulary as long as the drug is medically necessary, the prescription is filled at a <plan name> network pharmacy, and other plan rules are followed. For more information on how to fill your prescriptions, please review your Evidence of Coverage.

Can the Formulary change?

Generally, if you are taking a drug on our <contract year> formulary that was covered at the beginning of the year, we will not discontinue or reduce coverage of the drug during the <contract year> coverage year except when a new, less expensive generic drug becomes available or when new adverse information about the safety or effectiveness of a drug is released. Other types of formulary changes, such as removing a drug from our formulary, will not affect members who are currently taking the drug. It will remain available at the same cost-sharing for those members taking it for the remainder of the coverage year. We feel it is important that you have continued access for the remainder of the coverage year to the formulary drugs that were available when you chose our plan, except for cases in which you can save additional money or we can ensure your safety.

If we remove drugs from our formulary, [or] add prior authorization, quantity limits and/or step therapy restrictions on a drug [or move a drug to a higher cost-sharing tier], we must notify affected members of the change at least 60 days before the change becomes effective, or at the time the member requests a refill of the drug, at which time the member will receive a 60-day supply of the drug. If the Food and Drug Administration deems a drug on our formulary to be unsafe or the drug's manufacturer removes the drug from the market, we will immediately remove the drug from our formulary and provide notice to members who take the drug. The enclosed formulary is current as of <formulary date>. To get updated information about the drugs covered by <plan name>, please visit our Web site at <Web site address> or call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

How do I use the Formulary?

There are two ways to find your drug within the formulary:

Medical Condition

The formulary begins on page <table page number>. The drugs in this formulary are grouped into categories depending on the type of medical conditions that they are used to treat. For example, drugs used to treat a heart condition are listed under the category, < "category name example" >. If you know what your drug is used for, look for the category name in the list that begins < on page number / below / on the next page >. Then look under the category name for your drug.

Alphabetical Listing

If you are not sure what category to look under, you should look for your drug in the Index that begins on page <index page number>. The Index provides an alphabetical list of all of the drugs included in this document. Both brand-name drugs and generic drugs are listed in the Index. Look in the Index and find your drug. Next to your drug, you will see the page number where you can find coverage information. Turn to the page listed in the Index and find the name of your drug in the first column of the list.

What are generic drugs?

<Plan name> covers both brand-name drugs and generic drugs. *A generic drug has the same active-ingredient as the brand name drug. Generally, generic drugs cost less than brand name drugs and are approved by the Food and Drug Administration (FDA).*

Are there any restrictions on my coverage?

Some covered drugs may have additional requirements or limits on coverage. These requirements and limits may include: ***[Note:*** *Plans should omit bullets as needed in order to describe all utilization management procedures used by the plan.]*

- **Prior Authorization:** <Plan name> requires you [or your physician] to get prior authorization for certain drugs. This means that you will need to get approval from <plan name> before you fill your prescriptions. If you don't get approval, <plan name> may not cover the drug.

- **Quantity Limits:** For certain drugs, <plan name> limits the amount of the drug that <plan name> will cover. For example, <plan name> provides <number of units> per prescription for <drug name>. This may be in addition to a standard one month or three month supply.

- **Step Therapy:** In some cases, <plan name> requires you to first try certain drugs to treat your medical condition before we will cover another drug for that condition. For example, if Drug A and Drug B both treat your medical condition, <plan name> may not cover drug B unless you try Drug A first. If Drug A does not work for you, <plan name> will then cover Drug B.

You can find out if your drug has any additional requirements or limits by looking in the formulary that begins on page <table page number>.

You can ask <plan name> to make an exception to these restrictions or limits. See the section, "How do I request an exception to the <Plan Name's> formulary?" on page <exception page number> for information about how to request an exception.

What if my drug is not on the Formulary?

If your drug is not included in this formulary, you should first contact Member Services and confirm that your drug is not covered. If you learn that <plan name> does not cover your drug, you have two options:

- You can ask Member Services for a list of similar drugs that are covered by <plan name>. When you receive the list, show it to your doctor and ask him or her to prescribe a similar drug that is covered by <plan name>.

- You can ask <plan name> to make an exception and cover your drug. See below for information about how to request an exception.

How do I request an exception to the <Plan Name's> Formulary?

You can ask <plan name> to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary.

- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, <plan name> limit the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover more.

- [You can ask us to provide a higher level of coverage for your drug. If your drug is contained in our [non-preferred/highest tier subject to the tiering exceptions process] tier, you can ask us to cover it at the cost-sharing amount that applies to drugs in the [preferred/lowest tier subject to the tiering exceptions process] tier instead. This would lower the amount you must pay for your drug. Please note, if we grant your request to cover a drug that is not on our formulary, you may not ask us to provide a higher level of coverage for the drug. *[**Note:** If the plan designated one of its tiers as a "high-cost/unique drug tier" and is exempting that tier from the exceptions process, include the following language*: "Also, you may not ask us to provide a higher level of coverage for drugs that are in the [tier designated as the high-cost/unique drug tier] tier."]

Generally, <plan name> will only approve your request for an exception if the alternative drugs included on the plan's formulary, [the lower-tiered drug] or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, [tiering] or utilization restriction exception. When you are requesting a formulary, [tiering] or utilization restriction exception you should submit a statement from your physician supporting your request. Generally, we must make our decision within 72 hours of getting your prescribing physician's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get your prescribing physician's supporting statement.

What do I do before I can talk to my doctor about changing my drugs or requesting an exception?

As a new or continuing member in our plan you may be taking drugs that are not on our formulary. Or, you may be taking a drug that is on our formulary but your ability to get it is limited. For example, you may need a prior authorization from us before you can fill your prescription. You should talk to your doctor to decide if you should switch to an appropriate drug that we cover or request a formulary exception so that we will cover the drug you take. While you talk to your doctor to determine the right course of action for you, we may cover your drug in certain cases during the first <*must be at least 90*> days you are a member of our plan.

For each of your drugs that is not on our formulary or if your ability to get your drugs is limited, we will cover a temporary <*must be at least 30*>-day supply (unless you have a prescription written for fewer days) when you go to a network pharmacy. <After your first <*must be a least 30*>-day supply, we will not pay for these drugs, even if you have been a member of the plan less than <*must be at least 90*> days.

If you are a resident of a long-term care facility, we will cover a temporary <*must be at least 31*>-day transition supply (unless you have a prescription written for fewer days). We will cover more than one refill of these drugs for the first <*must be at least 90*> days you are a member of our plan. If you need a drug that is not on our formulary or if your ability to get your drugs is limited, but you are past the first <*must be at least 90*> days of membership in our plan, we will cover a <*must be at least 31*>-day emergency supply of that drug (unless you have a prescription for fewer days) while you pursue a formulary exception.

<***Note:*** *Plans must insert their transition policy for current enrollees with level of care changes, if applicable.*>

For more information

For more detailed information about your <plan name> prescription drug coverage, please review your Evidence of Coverage and other plan materials.

If you have questions about <plan name>, please call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.) Or visit <Web site address>.

If you have general questions about Medicare prescription drug coverage, please call Medicare at 1-800-MEDICARE (1-800-633-4227) 24 hours a day/7 days a week. TTY/TDD users should call 1-877-486-2048. Or, visit www.medicare.gov.

<Plan Name's> Formulary

The formulary <below/that begins on the next page> provides coverage information about some of the drugs covered by <plan name>. If you have trouble finding your drug in the list, turn to the Index that begins on page <index page number>.

The first column of the chart lists the drug name. Brand-name drugs are capitalized (e.g., <BRAND NAME EXAMPLE>) and generic drugs are listed in lower-case italics (e.g., <*generic example*>).

The information in the Notes column tells you if <plan name> has any special requirements for coverage of your drug.

***[Note:** Plan must explain any symbols or abbreviations used to indicate utilization management restrictions, drugs that are available via mail-order, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only)]*

- *Plans that cover excluded Part D drugs must use this column to indicate that certain drugs are available only through their benefit. Plans may indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states:* "This prescription drug is not normally covered in a Medicare Prescription Drug Plan. The amount you pay when you fill a prescription for this drug does not count towards your total drug costs (that is, the amount you pay does not help you qualify for catastrophic coverage). In addition, if you are receiving extra help to pay for your prescriptions, you will not get any extra help to pay for this drug. ***[Note**: Plans must insert any additional restrictions on this coverage, including any capped benefit limit.]"*

- *Plans that offer generic-use incentive programs permitting zero (or reduced) cost-sharing on first generic fills when a member agrees to use the generic rather than the brand-name version of a medication must indicate the drugs to which this program applies. Plans may indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states:* "This prescription drug will be provided at <zero>/<reduced> cost-sharing the first time you fill it."

- *Plans that restrict access to any drugs by limiting distribution to a subset of network pharmacies must indicate these drugs. Plans may indicate this with an asterisk/other*

symbol or footnote at the bottom of the page that states: "This prescription may be available only at certain pharmacies. For more information consult your Pharmacy Directory or call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>."

- *Plans that cover only certain drugs in the coverage gap must indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states*, "We provide coverage of this prescription drug in the coverage gap. Please refer to our Evidence of Coverage for more information about this coverage."

- *MA-PD or cost plans choosing to provide coverage for any Part D home infusion drugs as part of a bundled payment under a Part C supplemental benefit should indicate this with an asterisk/other symbol and a footnote at the bottom of the page that states,* "This prescription drug <is>/<may be> covered under our medical benefit. For more information, call Member Services at <toll-free number>, <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>."

Drug Table - Option 1

Drug Name	Drug Tier	Notes
<Therapeutic Category Name 1> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>
<Therapeutic Category Name 2> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>

Drug Table - Option 2

Drug Name	Drug Tier	Notes
<Therapeutic Category Name 1> - [Optional: <Plain Language Description>]		
<Therapeutic Class Name 1> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>
<Therapeutic Class Name 2> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>
<Therapeutic Category Name 2> - [Optional: <Plain Language Description>]		
<Therapeutic Class Name 1> - [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier>	<Util. Mgmt.>
<Drug Name 2>	<Tier>	<Util. Mgmt.>

General Drug Table instructions:

Column headings should be repeated on each page of the table.

For table sub-headings, plans have the option to use either the therapeutic category only (Table Option 1) or both the therapeutic category and therapeutic class (Table Option 2).

Plans have the option of including a "plain-language" description of the therapeutic category/class next to the name of each category/class. For example, instead of only including the category, "Dermatological Agents," Plans may include "Dermatological Agents – Drugs to treat skin conditions."

For Table Option 1, the therapeutic categories should be listed alphabetically within the table. The drugs should then be listed alphabetically under the appropriate therapeutic category; they should not be sorted by therapeutic class. For Table Option 2, the therapeutic categories should be listed alphabetically and the therapeutic classes listed

alphabetically under the appropriate category. The drugs should then be listed alphabetically under the appropriate therapeutic class.

The chart must include at least two covered drugs for each therapeutic category/class except when only one drug exists in the category or class or when two drugs exist in the category or class but one is clinically superior to the other as per your CMS-approved formulary.

Drug Name column instructions:

> *Brand-name drugs should be capitalized, e.g.,* DRUG A. *Generic drugs should be lower-case and italicized, e.g., penicillin. Plans may include the generic name of a drug next to the brand name.*
>
> *If a drug has a different tier placement depending on the dosage (e.g., 20 mg has a $20 copayment and 40 mg has a $30 copayment), plans may include the drug twice within the table with the varying dosage listed next to the drug name (e.g.,* DRUG A, 20 mg *and* DRUG A, 40 mg*). The drug will be counted as a single drug when determining whether the plan has included two drugs within each therapeutic category/class.*

Drug Tier column instructions:

> *Part D Plans that provide different levels of cost sharing for drugs depending on their tier must include a column indicating the drug's tier placement.*
>
> *Plans may choose from several methods to indicate the tier placement including tier numbers (e.g., 1/ 2/ 3), tier names (e.g., generic/ preferred brand/ other brand), copayment amounts (e.g., $10/$20/$35), or co-insurance percentages (e.g., 10%/25%). The latter two methods are preferred since they are generally easier for members to understand. If one of the two former methods is used, plans must provide an explanation before the table explaining the copayment amount or co-insurance percentage associated with each tier number or tier name.*
>
> *Plans that have different copayment amounts or co-insurance percentages for retail and mail-order prescriptions may include both retail and mail order amounts within the same column or include separate columns for retail and mail order prescriptions.*

Requirements/Limits column instructions:

> *Part D Plans must indicate any applicable utilization management procedures (e.g., prior authorization, step therapy, quantity limits, etc.), special coverage rules, and/or mail-order procedures for each drug within the Requirement/Limits column.*

Plans may include abbreviations within this column (e.g., QL for quantity limits) but must include an explanation at the beginning of the formulary table explaining each abbreviation.

Index of Drugs

Plans must include an alphabetical listing of all drugs included in the formulary that indicates the page where members can find coverage information for that drug. Plans may use more than one column for the index listing.

ATTACHMENT F – CY2009 Model Transition Letter

<DATE>

<MEMBER NAME>

<ADDRESS>

<CITY, STATE ZIP>

Dear <MEMBER NAME>:

This letter is to inform you that we have provided you with a temporary supply of the following prescription[s]:

*[**Note:** Plans may include information about multiple transition supplies on the same notice.]*

[**Name of Drug**: *<name of drug>*

Date Filled: *<date filled>*

Reason for Notification: This drug is not on covered on our formulary. We have provided you with a <must be at least 30> day supply, but we will not pay for an additional fill unless you obtain a formulary exception from <Plan Name>.]

[**Name of Drug**: *<name of drug>*

Date Filled: *<date filled>*

Reason for Notification: This drug is not on covered on our formulary. In addition, we could not provide the full amount that was prescribed because of quantity limits for safety reasons. We will allow you to refill your *<name of drug>* prescription until we have provided you with a *<must be at least 30>* day supply, but we will not pay for it after that unless you obtain a formulary exception from <Plan Name>.]

[**Name of Drug**: *<name of drug>*

Date Filled: *<date filled>*

Reason for Notification: This drug requires prior authorization. We have provided you with a *<must be at least 30>* day supply, but we will not pay for an additional fill unless you obtain <Plan Name>'s prior authorization or you obtain an exception to the prior authorization from <Plan Name>.]

[**Name of Drug**: *<name of drug>*

Date Filled: *<date filled>*

Reason for Notification: This drug will be covered only if you try other drugs on our formulary first, as part of a step therapy program. We have provided you with a *<must be at least 30>* day supply, but we will not pay for an additional fill unless you try other drugs on our formulary first or you obtain an exception to the step therapy requirement from <Plan Name>.]

*[**Note**: The following notice requirement is optional, as it technically falls outside the definition of a transition fill. However, we encourage plans to include this in their transition notifications.]*

[**Name of Drug**: *<name of drug>*

Date Filled: *<date filled>*

Reason for Notification: This drug is covered on our formulary. However, we could not provide the full amount that was prescribed because of plan quantity limits. We will not provide more than our quantity limits permit unless you obtain a formulary exception from <Plan Name>.]

How do I change my prescription?

If your drug is not covered on our formulary or is covered on our formulary but we have placed a prior authorization, quantity limit, or other limit on it, you can ask us if we cover another drug used to treat your medical condition. If we cover another drug for your condition, we strongly encourage you to ask your doctor if any of these drugs is an option for you. If your doctor tells you that none of the drugs we cover for treating your condition is medically appropriate for treating your condition, you have the right to request a formulary exception from us. You also have the right to request a formulary exception if your doctor tells you that a prior authorization, quantity limit, or other limit we have placed on a drug you are taking is not medically appropriate for treating your condition.

How do I request an exception?

The first step in requesting an exception is for you or your prescribing doctor to contact us. <Provide the necessary address, fax number, and phone number>.

Your doctor must submit a statement supporting your request. The doctor's statement must indicate that the requested drug is medically necessary for treating your condition because none of the drugs we cover for treating your condition would be as effective as the requested drug or would have adverse effects for you. If the exception involves a prior authorization, quantity limit, or other limit we have placed on a drug you are taking, the doctor's statement must

indicate that the prior authorization or limit would not be appropriate given your condition or would have adverse effects for you.

Once the physician's statement is submitted, we must notify you of our decision no later than 24 or 72 hours, depending on whether the request is an expedited request or a standard request. Your request will be expedited if we determine, or your doctor tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard request.

What if my request is denied?

If your request is denied, you have the right to appeal by asking us to review our decision. You must request this appeal within 60 calendar days from the date of our first decision. <You must file a standard request in writing/we accept standard requests by telephone and in writing. We accept expedited requests by telephone and in writing. Provide the necessary address, fax number, and phone number>.

If you need help to ask for a formulary exception or for more information about our transition policy, please call <Customer/Member> Service at <phone number>. TTY/TDD users should call <TTY/TDD number>. We are available from <hours of operations>.

Sincerely,

<Plan Representative>

ATTACHMENT G – Contract Year 2009 Guidance for Medicare Advantage and Medicare Advantage Prescription Drug Plan Renewals

CY 2009 Guidance for MA and MA-PD Plan Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Beneficiary Enrollment Procedures	Beneficiary Notification
1	New Plan Added	An MA organization creates a new plan benefit package.	A new 2009 plan with no link to a 2008 plan.	The MA organization must submit enrollment transactions for 2009 members.	Beneficiaries are required to complete an enrollment request.	N/A
2	Renewal Plan	An MA organization continues to offer a CY 2008 MA plan in CY 2009 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 2009.	A 2009 plan that links to a 2008 plan and retains all of its plan service area from 2008.	**The renewal plan ID must remain the same** so that beneficiaries will remain in the same plan ID. The MA organization **does not** submit enrollment transactions for existing plan members.	Beneficiaries do not need to complete enrollment requests to remain enrolled.	Beneficiaries are sent a regular ANOC.
3	Consolidated Renewal Plan	An MA organization ***combines*** two or more MA plans offered in CY 2008 into a single renewal plan so that all beneficiaries in the combined plans are offered the same benefits in CY 2009. The MA organization must designate which of the renewal plan IDs will be retained in CY 2009 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 2008 plans that consolidate into one 2009 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 enrollment transactions.	Beneficiaries do not need to complete enrollment requests to remain enrolled.	All beneficiaries are sent a regular ANOC.

CY 2009 Guidance for MA and MA-PD Plan Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Beneficiary Enrollment Procedures	Beneficiary Notification
4	Renewal Plan with an SAE	An MA organization continues to offer a CY 2008 MA plan in CY 2009 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 2009. **This option is available to local MA plans only.**	A 2009 plan that links to a 2008 plan and retains all of its plan service area from 2008, 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 enrollment transactions for these members.	Beneficiaries do not need to complete enrollment requests to remain enrolled.	Current beneficiaries are sent a regular ANOC.

CY 2009 Guidance for MA and MA-PD Plan Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Beneficiary Enrollment Procedures	Beneficiary Notification
5	Renewal Plan with a SAR	An MA organization ***reduces the service area*** of a CY 2008 MA plan and makes the reduced area part of a new or renewal MA plan service area in CY 2009. The MA organization must offer passive elections in CY 2009 to all of the current enrollees who reside in the reduced service area. **This option is available to local MA plans only.** ***Note:** When the reduced service area is not contained in another MA plan (i.e., contract-level SAR), the MA organization must submit disenrollment 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 **TBD**.	A 2009 plan that links to a 2008 plan and retains only a portion of its plan service area.	**The renewal plan ID must remain the same** so that beneficiaries in the renewal portion of the service area will remain in the same plan ID. The MA organization **does not** submit enrollment transactions for these members. When the reduced service area is contained in another plan, and "passive enrollment" is required, the MA organization **must submit enrollment transactions** to enroll the beneficiaries into the other plan. When the reduced service area is NOT contained in another plan, the MA organization must submit disenrollment transactions for affected beneficiaries	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 who will be disenrolled need not request disenrollment.	Beneficiaries continuing in the same plan that were not impacted by the SAR are sent a regular ANOC. Beneficiaries impacted by the plan SAR when the reduced area is part of a new or renewal plan are sent a modified ANOC, which will explain their enrollment in the new plan and receive guaranteed issue Medigap rights. Beneficiaries who will be disenrollment must be sent a termination notice.

CY 2009 Guidance for MA and MA-PD Plan Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Beneficiary Enrollment Procedures	Beneficiary Notification
6	Renewal Plan Split Based on Provider Groups	One CY 2008 MA plan splits into two or more CY 2009 MA plans in order to reflect the beneficiary's provider group choice. Both CY 2009 MA plans must have the same service area. The CY 2008 MA plan ID must be designated as the renewal plan in CY 2009. **Provider-specific plan splits require prior approval from CMS.** MA organizations wishing to offer provider-specific plans effective January 1, 2009 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 8, 2008.** CMS will review such requests on a case-by-case basis and make its determination based upon information that the MA organization submits as part of its proposal. For further information and format requirements, refer to the Health Plans section of the CMS website.	Two or more 2009 plans that are created from one 2008 plan with membership determined by provider choice.	No enrollment transactions will be required for beneficiaries whose appropriate plan based on provider group choice is the renewal plan ID. The MA organization **must submit enrollment transactions** to enroll beneficiaries associated with the other provider group(s).	Beneficiaries in the renewal plan need do nothing. Beneficiaries who will be associated with the other provider group(s) and associated plan will receive information on how their enrollment into the new plan offered by the organization will occur.	Beneficiaries continuing in the renewal plan receive the regular ANOC. Beneficiaries enrolled in the new plan are sent the regular ANOC with special instructions.
7	Terminated Plan	An MA organization terminates the offering a plan benefit package.	A 2008 plan that is no longer offered in 2009.	The MA organization does not need to submit disenrollment transactions.	Beneficiaries do not need to request disenrollment. To enroll in another plan, beneficiaries must complete an enrollment request.	Beneficiaries are sent a termination notice and receive guaranteed issue Medigap rights.

ATTACHMENT H – Contract Year 2009 Guidance for PDP Sponsor Renewals/HPMS Plan Crosswalk

Contract Year 2009 Guidance for PDP Sponsor Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Beneficiary Enrollment Procedures	Notice
1	New Plan Added		A new 2009 plan with no link to a 2008 plan.	The PDP Sponsor must submit enrollment transactions.	Beneficiaries must complete an enrollment request.	None.
2	Renewal Plan	If a PDP Sponsor continues to offer a CY2008 prescription drug plan in CY2009, **it must retain the same Plan ID number** in order for all currently enrolled beneficiaries to remain in the same prescription drug plan in CY2009.	A 2009 plan that links to a 2008 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 enrollment transactions. **Sponsors may need to submit 4Rx data*	No enrollment request is required to remain enrolled.	Beneficiaries are sent an ANOC.

Contract Year 2009 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Beneficiary Enrollment Procedures	Notice
3	Consolidated Renewal Plan	If a PDP Sponsor **combines** two or more prescription drug plans offered in CY2008 into a single renewal plan so that all beneficiaries in the combined plans are offered the same benefits in CY2009, the PDP Sponsor must designate which of the renewal Plan IDs will be retained in CY2009 after consolidation.	Two or more 2008 prescription drug plans that consolidate into one 2009 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 enrollment transactions. **Sponsors may need to submit 4Rx data*	No enrollment request is required to remain enrolled.	Beneficiaries are sent an ANOC.
4	Renewal Plan with an SAE (applicable only to employer/union -only group waiver plans (EGWPs))	If a PDP Sponsor continues to offer a CY 2008 prescription drug plan in CY 2009 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 2009.	A 2009 prescription drug plan that links to a 2008 plan and retains all of its plan service area from 2008, 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 enrollment transactions for these members. However, the PDP Sponsor must submit election transactions for new enrollees.	No enrollment request is required to remain enrolled.	Existing member beneficiaries are sent an ANOC.
Model ANOC/EOC will be available on the CMS Web site at**: TBD**						

Contract Year 2009 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Beneficiary Enrollment Procedures	Notice
5	Terminated Plan		A 2008 plan that is no longer offered in 2009.	PDP sponsors do not need to submit disenrollment transactions.	Beneficiaries do not need to request disenrollment. Beneficiaries must complete an enrollment request to enroll in another plan.	Beneficiaries are sent a termination notice and receive a written description of options for obtaining prescription drug coverage in the service area.

ATTACHMENT I – Part D Licensure Waivers-Reporting and Filing Deadlines

For PDP Sponsors With Licensure Waivers Expiring on December 31, 2008

Deadline	Action
4/1/2008	CMS will notify Part D sponsors that they are not qualified to offer Part D benefits during 2009 in the Part D sponsor regions where a licensure waiver will expire on 12/31/08. Part D Sponsors will be afforded an opportunity to complete a corrective action plan, either by obtaining licenses from all states for which a waiver will expire 12/31/2008 or reducing their service area.
4/1/2008	Part D sponsor will be requested to submit an exit plan* for each region which contains an unlicensed (waivered) state where the waiver will expire on 12/31/2008.
7/31/2008	Last day for Part D sponsors to obtain state licensure in states for which they have 2008 expiring waivers or to reduce their service areas, and not receive a notice of non-renewal from CMS.
8/1/2008	Non-renewals for contract year 2009 issued as appropriate
9/1/2008	Part D sponsor implements service area exit plans as appropriate.
12/31/08	Contract non-renewal or service area reduction becomes effective.

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

For Sponsors With Licensure Waivers Expiring on December 31, 2009

Deadline	Action
4/15/2008	Part D sponsor must submit confirmation from each state for which its licensure waiver will expire in 2009, that the state is in possession of a substantially complete application and expects to be able to approve or disapprove before 4/1/2009, or the state provides the earliest date on which it will accept an application if seasoning is an issue.
12/1/2008	Part D sponsor must submit an updated status report concerning each state for which its licensure waiver will expire in 2009.
3/9/2009	CMS will accept new licensure waiver applications from Part D sponsors with expiring state licensure waivers on 12/31/2009 that were unable to become licensed because of state requirements that are beyond the Part D sponsor's ability to meet.
4/1/2009	CMS will notify Part D sponsors that they are not qualified to offer Part D benefits during 2010 in the Part D sponsor regions where a licensure waiver will expire on 12/31/09. Part D sponsors will be afforded an opportunity to complete a corrective action plan, either by obtaining licenses from all states for which a waiver will expire 12/31/2009 or reducing their service area.
4/1/2009	Part D sponsor will be requested to submit an exit plan* for each region which contains an unlicensed (waivered) state where the waiver will expire on 12/31/2009
7/31/2009	Last day for Part D sponsors to obtain state licensure for states with 2009 expiring waivers or to reduce their service area, and not receive a notice of non-renewal.
8/1/2009	Non-renewals for contract year 2010 issued as appropriate
9/1/2009	Part D sponsor implements service area exit plans as appropriate.
12/31/09	Contract non-renewal or service area reduction becomes effective.

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

ATTACHMENT J - 2009 Draft Standardized Model Combined ANOC/EOC

The Standardized Model Combined ANOC/EOC is for use by Medicare Advantage Plans (MAs), Medicare Advantage Prescription Drug Plans (MA-PDs), Medicare Prescription Drug Plans (PDPs), and Medicare Cost plans. The information in this booklet is color-coded to help you find your plan information. When developing the Combined ANOC/EOC booklet, plan staff needs to identify all of the categories their plan can be classified under and use the language in those sections.

All Plan Types	Black
All plan types except PDP	Indigo Blue
MA-PD and PDP Plans	Red
MA-only plans	Brown
HMO Plans	Green
PPO Plans	Sky Blue
PFFS Plans	Violet
Cost Plans	Orange
SNP Plans	Bright Blue
MSA Plans	Dark Pink
Regional PPOs (RPPOs)	Dark Yellow
Point of Service Plans	Bright Green

Unless otherwise noted, Cost plans should include sections addressed to MA plans. (Cost plans that do not offer Part D should include sections addressed to MA-only plans, and Cost plans that offer Part D as Cost-PD plans should include sections addressed to MA-PD plans.)

Special instructions:

1) Plans using an open access model: modify or delete, as necessary for your plan, all references to PCP, referrals, etc.
2) Plans should modify or delete, as necessary for your plan, all references under "all Plan Types" not relevant to your plan.
3) Plans not offering a Part D benefit package: modify or delete, as necessary for your plan, all references to Part D benefits.
4) All references to Member Services, Pharmacy Directory, and Provider Directory can be changed to the appropriate name your plan uses.
5) After editing plan-specific document per color-coding above, document should be provided to members in black and white print.

Information that needs inserted/chosen by plans: [in brackets]
Instructions to Plans: [***Note:*** xxx]
Instructions to specific plan types: [***Note to PFFS plans:*** xxx]
Instructions including specific text to be added: [***Note:*** insert "xxx"]
Add if applicable information: [***Add if applicable:*** xxx]
Optional information: [***Optional:*** xxx]

[Cover of Booklet]

2009 Annual Notice of Change and Evidence of Coverage

Your Medicare [Health Benefits and Services/Prescription Drug Coverage] as a Member of [Organization Name/Name of Plan]

January 1 – December 31, 2009

This booklet gives the details about your Medicare [health and/or prescription drug] coverage [including information about how our Plan has changed since last year in the Annual Notice of Change] and explains how to get the [health care and/or prescription drugs] you need. This booklet is an important legal document. Please keep it in a safe place.

[Name of organization] Member Services:
For help or information, please call Member Services or go to our Plan Web site at [insert url].

[1-XXX-XXX-XXXX] (Calls to these numbers are free)
[TTY; TTD] users call: [1-XXX-XXX-XXXX]

Hours of Operation:

[Material ID number]
[mm/yyyy]

If you need this booklet in a different format (Spanish, large print, audio tapes), please call Member Services at the number listed above. If you need plan information in another language, please call Member Services.

Table of Contents

Throughout the remainder of this document, we refer to [plan name] as "Plan" or "our Plan."

2009 Annual Notice of Change

[***Note:*** Only incorporate guidance based on your plan type, i.e. leave Prescription Drug sections out if you are not offering Part D.] [***Note:*** This notice must also be sent to all new members who enroll in a plan between October 31 and November 30.]

How our Plan Will Change for 2009

[***Note***: The organization may modify this introductory paragraph to tailor to its needs, as long as the paragraph is kept brief.] This is the time of year when we like to thank you for your membership and let you know of new plan changes for the upcoming year. Beginning January 1, 2009, there will be some changes to [plan name]. [***Note to PDPs rolling members into new plan or consolidating:*** insert "We want to take this opportunity to let you know of our new plan name for the upcoming year.]

We are sending this Annual Notice of Change (ANOC) so you can review the 2009 coverage offered through this plan. [***Note to Cost Plans:*** insert "Since [plan] is a type of Medicare plan called a Medicare Cost Plan, you may leave this plan at anytime and return to the Original Medicare plan. However, while you may leave our Plan at any time, you are generally limited to certain times of the year when you may join other Medicare plans."] Each year from November 15 through December 31, you may make a change to your Medicare plan and Medicare prescription drug coverage, with your new plan beginning on January 1. **If you don't want to change your coverage, you don't need to do anything. You will still be a member of [insert plan name] for the coming year.**

[***Note to Cost Plans that offer Part D:*** include "As a member of our plan, you may choose the Medicare prescription drug coverage [plan name] offers you or you may join any Medicare Prescription Drug Plan that is offered in your area.] [***Note to Cost Plans:*** include "Should you leave our plan and want to rejoin during the year, [insert "call Member Services" or "you may join during [insert open enrollment period]."]

All plan types

How will my plan change for 2009?

Refer to the table below to see how your plan coverage and costs may change for 2009. All changes will be effective January 1, 2009.

	2008	2009
Premium	$[current premium]	$[new premium]
Benefit changes	[***Note to MA and MA-PD Plans:*** list below all benefit changes as applicable to their plan, including changes in cost-sharing, current benefits that will no longer be offered, and new benefits, including any new optional supplemental benefits and the premiums for those benefits. For consistency, list changes in same order as EOC. See examples below.]	
[***Example:*** Visit to primary care physician]	[***Example:*** $10 co-payment]	[***Example:*** $15 co-payment]

[***Example:*** Annual physical]	[***Example:*** Not covered]	[***Example:*** Covered]
Changes to Part D prescription drug benefits	[***Note to PDP and MA-PD Plans:*** list below all benefit changes as applicable to their plan, including changes in cost-sharing, covered drugs, tier structure, types of drugs in each tier, or addition or removal of utilization management tools. For consistency, list changes in same order as EOC. See examples below.]	
[***Example:*** Deductible]	[***Example:*** $0 deductible]	[***Example:*** $100 deductible]
[***Example:*** Tier 1 co-pays for generic drugs]	[***Example:*** $4 co-payment for one month (31-day) supply at retail pharmacy $10 co-payment for three-month (90-day) supply from mail-order pharmacy]	[***Example:*** $6 co-payment for one month (31-day) supply at retail pharmacy $12 co-payment for three-month (90-day) supply from mail-order pharmacy]

This is just a brief summary of the changes in [plan name] for 2009. With this notice, you also received a 2009 Evidence of Coverage and a new formulary that will be effective January 1, 2009. Medicare has reviewed and approved the [benefits described and/or covered drugs listed in the formulary]. Please see [Section 4 and/or Section 5] for more information about the [benefits and or drug coverage] described in the table above.

MA-PDs and PDPs

What if my drugs are not on the formulary or are in a more expensive cost-sharing tier?

[We have changed our formulary.] [The formulary for [plan name] may be different from the one you are using.] [We have added, removed, or placed more limitations on some of the drugs we cover.] Please review the formulary to see if we still cover the drugs that you currently take. [*If including a complete formulary, use the following language:* "The enclosed formulary can also be found on our [formulary Web site] or you may call Member Services if you need any help locating a certain drug."] [*If including an abridged formulary, use the following language:* "To get a complete listing of all the drugs we cover, you may visit our [formulary Web site] or call Member Services.

[***Note:*** Insert the following language if you allow enrollees to request exceptions for the upcoming plan year before the upcoming plan year begins "If a drug we currently cover for you is not on our new formulary, you will need to talk with your doctor about taking an alternative drug that is available on our new formulary. If you wish to continue coverage of your current drug, you or your doctor can request a formulary exception. [If a drug we currently cover for you is on our new formulary but has been moved to a higher non-preferred cost-sharing tier, you can talk with your doctor about taking an alternative drug that is available in a lower cost-sharing tier. If you wish to pay the lower preferred cost-sharing amount for your current drug, you or your doctor can request a tiering exception.] If you or your doctor would like to request an exception, the request should be made by [insert date]. If a formulary exception request is approved, we will continue covering your current drug on January 1. [If a tiering exception

request is approved, we will cover your current drug at the preferred cost-sharing amount on January 1.]"]

[***Note:*** Insert the following language if you do not allow enrollees to request exceptions for the upcoming plan year before the upcoming plan year beings "If a drug we currently cover for you is not on our new formulary, you will need to talk to your doctor about taking an alternative drug that is available on our new formulary. If you wish to continue coverage of your current drug, you or your doctor can request a formulary exception on or after January 1. Beginning January 1, you will get a temporary supply of the drug we currently cover for you that is not on our new formulary. You will need to talk to your doctor about switching to a covered drug, or request a formulary exception before your temporary supply runs out. [If a drug we currently cover for you is on our new formulary but has been moved to a higher non-preferred cost-sharing tier, you can talk with your doctor about taking an alternative drug that is available in a lower cost-sharing tier. If you wish to pay the lower preferred cost-sharing amount for your current drug, you or your doctor can request a tiering exception on or after January 1.]"] Please refer to Section 9 in the Evidence of Coverage for instructions on how to file an exception.

MA-PDs and PDPs

What do I need to know if I qualify for extra help from Medicare to pay for my prescription drugs?

If you qualify for extra help, please refer to the **Evidence of Coverage Rider for those who Receive Extra Help Paying for their Prescription Drugs** that came with this booklet for information on your premiums and cost-sharing in 2009.

[***Note to existing PDPs that will lose certain LIS beneficiaries to re-assignment to a plan within the same PDP sponsoring organization:*** insert "Because the premium for the plan you had in 2008 is increasing in 2009, Medicare has told us to move you to [insert 2009 plan name] where you won't have to pay any monthly premium in 2009. If you want to stay with [insert 2008 plan name], the plan you have in 2008, please call Member Services. If you choose to stay with [insert 2008 plan name], you will be responsible for paying a premium.]

[***Note to existing PDPs that will lose certain LIS beneficiaries to re-assignment to a different PDP sponsoring organization:*** insert*:* "If you qualify for extra help, you will get a blue letter from Medicare by early November. This letter explains that Medicare will enroll you in a new Medicare drug plan to lower your monthly premium cost in 2009. If you want to stay with our Plan instead, please call Member Services. Staying in our Plan will cost you more in premiums than moving to the new plan."]

MA-only plans

What if I don't have drug coverage that is at least as good as Medicare's standard prescription drug coverage?

[Plan] does not include Medicare prescription drug coverage. If you haven't had other prescription drug coverage that was at least as good as Medicare's standard prescription drug coverage ("creditable coverage") you may have to pay a late enrollment penalty when you sign up for Medicare prescription drug coverage. You will pay the penalty if you go without

creditable coverage for a continuous period of 63 days or more. The longer you wait to enroll in a Medicare drug plan, the higher the penalty may be. If you have had prescription drug coverage as good as Medicare's, each year your employer/union will notify you if it continues to be creditable coverage. If you received a notice this year that you no longer have creditable coverage, consider joining a Medicare prescription drug plan. [***Note to Cost plans and PFFS plans not offering prescription drug coverage:*** insert "If you are a member of this plan and want to get Medicare prescription drug coverage, you may join a Medicare Prescription Drug Plan."] [***Note to Cost plans offering a Part D plan:*** insert "If you are a member of this plan and want to get Medicare prescription drug coverage, you may join a Medicare prescription drug plan offered by our organization or buy a separate Medicare prescription drug plan.] [***Note to organizations that offer a Medicare Prescription Drug Plan:*** insert "Our organization offers the following plans:" and list Medicare Prescription Drug plan(s) available in the service area & Member Services contact]. To find other plans available in your area, visit www.medicare.gov and under "Search Tools" select "Compare Medicare Prescription Drug Plans." Or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

If you join another Medicare Health Plan or a Medicare Prescription Drug Plan [***Note to PFFS plans not offering prescription drug coverage:*** do not include phrase "or a Medicare Prescription Drug Plan"] you will be disenrolled from our Plan when your enrollment in the new plan begins.

All Plan Types

Where can I get more information?

The Evidence of Coverage on the following pages has more information on our Plan's coverage, including information on how to make changes to your membership in Section 10. [***Note to MA-PDs and PDPs:*** if the organization offers multiple plans in the service area, the ANOC must notify people with Medicare that more plans are available and include specific information on how to get more information.]

Please call Member Services if you have any questions. You can also get information about the Medicare program and other Medicare plans available by visiting www.medicare.gov or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

We look forward to serving you now and in the future.

Sincerely,
[Plan Representative]

Enclosures: [Summary of Benefits/Evidence of Coverage]
[Formulary]

[Material ID number]
[mm/yyyy]

[Insert Plan Name Here]
2009 Evidence of Coverage
1. Introduction

All Plan Types

Thank you for being a member of [insert plan name]!

This is your Evidence of Coverage, which explains how to get your Medicare [health care and/or drug coverage] through our Plan. We are pleased that you've chosen our Plan, a [insert plan type]; [***Note to all plan types except PDP:*** include "You are still covered by Medicare, but"] you are getting your [health care and/or Medicare prescription drug coverage] through our Plan. [SNPs with an arrangement with the State may revise this language to reflect, when applicable, that the organization is providing both Medicaid and Medicare covered benefits.]
This Evidence of Coverage, together with your enrollment form, riders [including optional supplemental benefit brochures], [formulary,] and amendments that we send to you, is our contract with you. The Evidence of Coverage explains your rights, benefits, and responsibilities as a member of our Plan and is in effect from January 1, 2009 - December 31, 2009. [***Note to organizations that list more than one plan offering in Evidence of Coverage:*** you must clearly identify the specific plan in which the member is enrolled effective January 1, 2009.]

This Evidence of Coverage will explain to you:
[***Note to MA-only plans:*** Do not include references to prescriptions.]

- What is covered by our Plan and what isn't covered.
- How to get [the care you need or your prescriptions filled] including some rules you must follow.
- What you will have to pay for your [health care or prescriptions].
- What to do if you are unhappy about something related to getting your [covered services or prescriptions filled].
- How to leave our Plan, [and other Medicare options that are available, including your options for continuing Medicare prescription drug coverage].

PFFS plans

[Plan name] is a Medicare Advantage Private-Fee-for-Service plan. A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your doctor or hospital is not required to agree to accept the plan's terms and conditions, and thus may choose not to treat you, with the exception of emergencies. If your doctor or hospital does not agree to accept our payment terms and conditions, or otherwise agree to treat you, you will not be able to receive covered services from them under this plan. Providers can find the plan's terms and conditions on our website at: [insert link to PFFS terms and conditions].

All Plan Types except MSA

Eligibility Requirements

To be a member of our Plan, you must live in our service area, be entitled to Medicare Part A, and [***Note to PDP-only plans***: replace this "and" with "or"] enrolled in Medicare Part B [***Note to***

Cost plans: add "or enrolled in Medicare Part B only"]. If you currently pay a premium for Medicare Part A and/or Medicare Part B, you must continue paying your premium in order to keep your Medicare Part A and/or Medicare Part B and remain a member of this plan.

[Note to MSA Plans: insert following section]
You are not eligible for our plan if you:

- Have health coverage that would cover the Medicare MSA plan deductible, including benefits under an employer or union group health plan.
- Get benefits from the Department of Defense (TRICARE) or the Department of Veterans Affairs.
- Are a retired Federal government employee and part of the Federal Employees Health Benefits Program (FEHBP).
- Are eligible for Medicaid (a joint Federal and state program that helps with medical costs for some people with limited income and resources).
- Have end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).
- Are currently getting hospice care.
- Live outside the United States more than 183 days a year.

[*Note to SNPs:* insert following paragraph if applicable to your plan type]

Special Eligibility Requirements for this Plan

Our Plan is designed to meet the needs of people who [insert type of SNP category, such as: "are eligible for both Medicare and Medicaid," "live in [type of institution]," "have [chronic or disabling condition."]]. If you no longer meet this special condition, your membership in this plan will end after [insert applicable grace period]. You will receive a notice from us informing you of the end of your membership and your options.

Materials that you will receive from our Plan

All Plan Types

Plan membership card

Now that you are a member of our Plan, you must use our membership card for [services covered by this plan [*and/or]* prescription drug coverage at network pharmacies]. While you are a member of our Plan you *must not* use your red, white, and blue Medicare card to get covered [services, items [and/or] drugs]. Keep your red, white, and blue Medicare card in a safe place in case you need it later. If you get covered services using your red, white, and blue Medicare card instead of using our membership card while you are a plan member, the Medicare Program won't pay for these services and you may have to pay the full cost yourself. **[*Note:*** Medicare cost plans should change the language in this section to indicate that members are free to use their Medicare card and receive services under the original Medicare program, and pay original Medicare cost-sharing.]

[*Note to SNPs:* Plans may revise this language to reflect, when applicable, that the members will use the plan card exclusively or the plan card and a Medicaid card.]

Please carry your membership card that we gave you at all times and remember to show your card when you get covered [services, items [and/or] drugs]. If your membership card is damaged, lost, or stolen, call Member Services right away and we will send you a new card. Here is a sample card to show you what it looks like: [***Note:*** Insert Membership Card Diagram here – front and back. Mark it as a sample card (for example, by superimposing the word "sample" on the image of the card)]

The Provider Directory gives you a list of network providers

[Note: plans without a provider directory exclude following paragraph.]
Every year that you are a member of our Plan, we will send you either a Provider Directory or an update to your Provider Directory, which lists our network providers. If you don't have the Provider Directory, you can get a copy from Member Services. You may ask Member Services for more information about our network providers, including their qualifications and experience. [Note: It is optional to add more detail to this paragraph that describes what information is available in your provider directory, on your Web site, or from Member Services such as, "Member Services can give you the most up-to-date information about changes in our network providers and about which ones are accepting new patients." You may also note that a complete list of network providers is available on your Web site (give Web site address).]

HMO Plans

You [may be required to use; must use] network providers for services to be covered, except in emergencies, for certain urgently needed services, and for out of the area dialysis services. [***Note to Plans with Point –of-Service (POS) option***: briefly describe POS option here. The details of POS should be addressed in Section 3 How to Get Care.]

PPO Plans

You may pay more for services if you do not use a network provider, except in emergencies, for certain urgently needed services, and for out of area dialysis services.
[***Note to regional PPOs:*** RPPOs that CMS has granted permission to use the exception in § 422.112(a) (1) (ii) to meet access requirements should insert: "Because our Plan is a Regional Preferred Provider Organization, if no contracted network provider is readily available you can access care at in-network cost-sharing from an out-of-network provider. You can call [insert toll-free number] to get help finding an out-of-network provider.]

Network PFFS Plans

[***Note to PFFS plans:*** When this document uses the term "network PFFS plan," it is referring to a PFFS plan that has some or all categories of providers under direct contract in order to (1) meet Medicare access requirement under 42 CFR §422.114(a)(2)(ii) or (a)(3)(iii) because the plan has established payment rates that are less than the Original Medicare Plan, or (2) to ensure that its enrollees have access to providers who have agreed in advance to accept the plan's terms and conditions of payment. In the latter case, the plan has established payment rates that are same or higher than the Original Medicare Plan.]

This directory contains the names of providers who contract with our plan. You may pay more for services if you do not use one of these providers, except in emergencies, for certain urgently needed services, and for out-of-area dialysis services. [***Note:*** describe here what category or

categories of providers Plan has under direct contract in order to meet Medicare access requirements and if the plan has established any higher cost-sharing requirements if the member obtains a covered service from a deemed provider].

Except in emergencies, providers who do not have a contract with our plan have the right to decide if they will accept our plan's terms and conditions of payment each time they see you. In emergency situations you simply seek care from the nearest available provider, the provider does not have to accept our Plan. See "Rules about using out-of-network providers to get your covered services" in Section 3 for a complete description of using out-of-network providers in a PFFS plan.

PDP and MA-PD

The Pharmacy Directory gives you a list of Plan network pharmacies.

[***Optional:*** Add detail to this paragraph that describes more information about pharmacies in your Pharmacy Directory, on your Web site, or from Member Services.]
As a member of our Plan we will send you a complete Pharmacy Directory, which gives you a list of our network pharmacies, at least every three years, and an update of our Pharmacy Directory every year that we don't send you a complete Pharmacy Directory. You can use it to find the network pharmacy closest to you. If you don't have the Pharmacy Directory, you can get a copy from Member Services. They can also give you the most up-to-date information about changes in this Plan's pharmacy network, which can change during the year. You can also find this information on our Website.

MA-PD and PDP

Explanation of Benefits

What is the Explanation of Benefits?

The Explanation of Benefits (EOB) is a document you will get for each month you use your prescription drug coverage. The EOB will tell you the total amount you have spent on your prescription drugs and the total amount we have paid for your prescription drugs. [***Note:*** Plans may insert other methods for receiving an EOB besides receiving it in the mail.] An Explanation of Benefits is also available upon request. To get a copy, please contact Member Services.

What information is included in the Explanation of Benefits?

Your Explanation of Benefits will contain the following information:

- A list of prescriptions you filled during the month, as well as the amount paid for each prescription;
- A list of prescriptions you filled during the month, as well as the amount paid for each prescription;
- Information about how to request an exception and appeal our coverage decisions;
- A description of changes to the formulary that will occur at least 60 days in the future and affect the prescriptions you have gotten filled;
- A summary of your coverage this year, including information about:
    - [**Annual Deductible-**The amount paid before you start getting prescription coverage.]

- **Amount Paid For Prescriptions-**The amounts paid that count towards your initial coverage limit.
- **Total Out-Of-Pocket Costs that count toward Catastrophic Coverage-**The total amount you and/or others have spent on prescription drugs that count towards you qualifying for catastrophic coverage. This total includes the amounts spent for your [deductible,] [***Note:*** Plan insert either "coinsurance" *OR* "co-payments" *OR* "coinsurance or co-payments"], and payments made on covered Part D drugs after you reach the initial coverage limit. (This amount doesn't include payments made by your current or former employer/union, another insurance plan or policy, a government-funded health program or other excluded parties.)

All Plan Types except PDPs

How do I keep my membership record up to date?

[Note: In the heading and in this paragraph, substitute the name you use for this file if different from "membership record."]

We have a membership record about you. Your membership record has information from your enrollment form, including your address and telephone number. It shows your specific Plan coverage [***Note:*** Insert as appropriate] The [Primary Care Physician/Medical Group/IPA] you chose when you enrolled], and other information. Doctors, hospitals, [pharmacists], and other network providers use your membership record to know what services [or drugs] are covered for you. Section 6 tells how we protect the privacy of your personal health information.

Please help us keep your membership record up to date by telling Member Services if there are changes to your name, address, or phone number, or if you go into a nursing home. Also, tell Member Services about any changes in other health insurance coverage you have, such as from your employer, your spouse's employer, workers' compensation, Medicaid, or liability claims such as claims from an automobile accident.

All Plan Types

The geographic service area for our Plan.

The [state(s) and counties [and parts of counties] or Regions] in our service area are listed below.

[***Optional info:*** You may include a map of the area (in addition to listing the service area), and modify the prior sentence to refer readers to the map.]

[***Note:*** Insert plan service area listing. Use county name only if approved for entire county. For partially approved counties, use county name plus zip code, e.g., "county name, the following zip codes only: [xxxxx]"]

[***Optional info:*** National/multi-state plans may include the following: The Plan offers coverage in [several/all] states [and territories]. If you move out of the state where you live into a state listed above, you must call Member Services in order to update your information. If you don't, you may be disenrolled from our Plan. If you move into a state not listed above, please call Member Services to find out if we have a plan in your new state.]

2. Your Costs for This Plan

All Plan Types except PDPs

Paying your monthly plan premium

As a member of our Plan, you pay:

1) Your monthly Medicare Part B premium. Most people will pay the standard premium amount, which is [$96.40] in [2008]. (Your Part B premium is typically deducted from your Social Security payment.)

   Your monthly premium will be higher if you are single (file an individual tax return) and your yearly income is more than $82,000, or if you are married (file a joint tax return) and your yearly income is more than $164,000.) [***Note to plans with Part B premium reduction benefits:*** insert "Under our Plan, your premium is lower than the amount you would have to pay if you were not enrolled." Plans should adjust numbers in chart accordingly.]

If your Yearly Income in 2008 is		**In 2008, you pay**
File individual tax return	File joint tax return	
$82,000 or below	$164,000 or below	$96.40*
$82,001-$102,000	$164,001-$204,000	$122.20*
$102,001-$153,000	$204,001-$306,000	$160.90*
$153,001-$205,000	$306,001-$410,000	$199.70*
Above $205,000	Above $410,000	$238.40*

*If you pay a late-enrollment penalty, this amount is higher.

[***Note to Cost plans***: Cost plan sponsors may not include statements about Part B premium reduction in the materials sent to Cost plan enrollees.]

2) Your monthly Medicare Part A premium, if necessary (most people don't have to pay this premium).

[***Note:*** If the plan has no premium and/or no supplemental coverage with a premium, delete parts of this subsection that don't apply and delete or edit the main heading and subheadings as needed for accuracy. Mention additional billing options other than monthly (e.g. quarterly.)]

3) Your monthly premium for our Plan

[***Note***: You may use "method" or "program" to refer to payment plans, as shown in the model language, or you may substitute whatever name or label is used by the Plan.]

As a member of our Plan, **your monthly plan premium is [$___] each month**. If you signed up for extra benefits, also called "optional supplemental benefits", then you pay an additional premium each month for these extra benefits. Your total premium reflects [both] basic [and

extra] benefits. If you have any questions about your Plan premiums or the payment programs, please call Member Services.

MA-PDs and PDPs

Paying your monthly plan premium

[***Note:*** Plans that don't have a monthly premium can delete this section.]
As a member of our Plan, you pay a monthly premium. (Unless you qualify for full extra help from Medicare.)

[Monthly Plan Premium: $___.] OR [The table below shows the monthly premium amount for each region we serve.] [**Note**: Insert a list of or table with the state/region and monthly premium amount for each area included within the EOC]

If you get your benefits from your current or former employer, or from your spouse's current or former employer, call the employer's benefits administrator for information about your Plan premium.

Note: If you are getting extra help with paying for your drug coverage, the premium amount that you pay as a member of this Plan is listed in your "Evidence of Coverage Rider for those who Receive Extra Help for their Prescription Drugs". Or, if you are a member of a State Pharmacy Assistance Program (SPAP), you may get help paying your premiums. Please contact your SPAP to determine what benefits are available to you.

Paying the premium for your coverage as a member of our Plan

There are two ways to pay your monthly plan premium. [***Note:*** Indicate how the member can inform the plan of their premium payment option choice and the procedure for changing that choice.]

Option one: Pay your plan premium directly to our Plan.
You may decide to pay your premium directly to our Plan.
[***Note:*** Insert plan specifics regarding premium payment intervals (e.g., monthly, quarterly- please note that beneficiaries must have the option to pay their premiums monthly), how they can pay by check, including an address, whether they can drop off a check in person, and by what day the check must be received (e.g., the 5th of each month). If the Plan uses coupon books, explain when they will receive it and to call Member Services for a new one if they run out or lose it. In addition, include information if you charge for bounced checks.]

Instead of paying by check, you can have your premium [Note: include all relevant choices: automatically withdrawn from your bank account, charged directly to your credit card, charged directly to your debit card]. [***Note:*** Insert plan specific information on the frequency of automatic deductions (e.g., monthly, quarterly – please note that beneficiaries must have the option to pay their premiums monthly), the approximate day of the month the deduction will be made, and how this can be set up.]

Option two: **You may have your monthly plan premium directly deducted from your monthly Social Security check.**

You may choose this option if you can pay for the entire premium with your Social Security check. Contact Member Services for more information on how to pay your premium this way.

Note: We don't recommend this option if you are getting extra help for your premium payment from another payer, like a State Pharmaceutical Assistance Program (SPAP). Social Security can only withhold the full amount of the premium and will not recognize any premium payments made by other payers as part of this process.

MA-PDs and PDPs

Can your Plan premiums change during the year?

[***Note to MA-PD Plans***: Plans that don't have a monthly premium can delete this section.]
The premium associated with this plan cannot change during the year. However, the amount you pay could change, depending on whether you become eligible for, or lose, extra help for your prescription drug costs. If our plan premium changes for next year we will tell you in October and the change will take effect on January 1.

What is the Medicare Prescription Drug Plan late enrollment penalty?

If you don't join a Medicare drug plan when you are first eligible, and you go without creditable prescription drug coverage for a continuous period of 63 days or more, you may have to pay a late enrollment penalty when you enroll in a plan later. This penalty amount changes every year, and you have to pay it as long as you have Medicare prescription drug coverage. However, if you qualified for extra help in 2006, 2007, or 2008, you may not have to pay a penalty.

If you must pay a late enrollment penalty, your penalty is calculated when you first join a Medicare drug plan. To estimate your penalty, take 1% of the national base beneficiary premium for the year you join (in 2009, the national base beneficiary premium is [insert amount]). Multiply it by the number of full months you were eligible to join a Medicare drug plan but didn't, and then round that amount to the nearest ten cents. This is your estimated penalty amount, which is added each month to your Medicare drug plan's premium for as long as you are in that plan.
If you disagree with your late enrollment penalty, you may be eligible to have it reconsidered (reviewed). Call Member Services to find out more about the late enrollment penalty reconsideration process and how to ask for such a review.

You won't have to pay a late enrollment penalty if:

- You had creditable prescription drug coverage (other coverage as good as Medicare's)
- Any period of time that you didn't have creditable prescription drug coverage was less than 63 continuous days
- You can demonstrate that you were not informed that your prescription drug coverage was not creditable
- You lived in an area affected by Hurricane Katrina AND you signed up for a Medicare prescription drug plan by December 31, 2006, AND you stay in a Medicare prescription drug plan
- You received or are receiving extra help AND you join a Medicare prescription drug plan by December 31, 2008, AND you stay in a Medicare prescription drug plan

All Plan Types

[***Note:*** MA and MA-PD plans that don't have a monthly premium can delete this section.]
[***Note:*** Delete this subsection if the Plan doesn't take action by discontinuing or disenrolling members who fail to pay basic and optional supplemental premiums.]

What happens if you don't pay or are late with your plan premiums?

If your plan premiums are late [***Cost plans insert***: "or you have not been paying your [insert as appropriate: co-payments, coinsurance, or deductibles]"], we will tell you in writing that if you don't pay your premium [***Cost plans insert***: "or [insert as appropriate: co-payments, coinsurance, or deductibles]"] by [Insert plan grace period] we will end your membership in our Plan." [***Note to PDPs:*** do not include next sentence.] If we end your membership, you will have Original Medicare Plan coverage.

[Add if applicable: "Should you decide later to re-enroll in our Plan, or to enroll in another plan that we offer, you will have to pay any late plan premiums that you didn't pay from your previous enrollment in our Plan."]

[Note: If you elect to discontinue offering optional supplemental benefits for members who fail to pay the premium for these benefits, insert "If you signed up for extra benefits ("optional supplemental benefits"), and you don't pay the additional premium for these extra benefits on time, we will tell you in writing that if you don't pay the premium for these extra benefits within [insert plan grace period] we will end coverage for the extra benefits."]

MA-PDs and PDPs

What extra help is available to help pay my plan costs?

[***Note to organizations offering plans in the U.S. Territories*:** revise this section as needed to reflect the LIS program available in their service areas.]

Medicare provides "extra help" to pay prescription drug costs for people who have limited income and resources. Resources include your savings and stocks, but not your home or car. If you qualify, you will get help paying for any Medicare drug plan's monthly premium, yearly deductible, and prescription co-payments. If you qualify, this extra help will count toward your out-of-pocket costs.

Do you qualify for extra help?

People with limited income and resources may qualify for extra help one of two ways. The amount of extra help you get will depend on your income and resources.

1. **You automatically qualify for extra help and don't need to apply.** If you have full coverage from a state Medicaid program, get help from Medicaid paying your Medicare premiums (belong to a Medicare Savings Program), or get Supplemental Security Income benefits, you automatically qualify for extra help and do not have to apply for it. Medicare mails letters monthly to people who automatically qualify for extra help.

2 **You apply and qualify.** You may qualify if your yearly income in 2008 is less than $[insert 2008 income amount] (single with no dependents) or $[insert 2008 income amount] (married and living with your spouse with no dependents), and your resources are less than $11,990 (single) or $23,970 (married and living with your spouse). These resource amounts include $1,500 per person for burial expenses. Resources include your savings and stocks but not your home or car. **If you think you may qualify, call Social Security at 1-800-772-1213, visit www.socialsecurity.gov on the Web, or apply at your State Medical Assistance (Medicaid) office.** TTY users should call 1-800-325-0778. After you apply, you will get a letter in the mail letting you know if you qualify and what you need to do next.

The above income and resource amounts are for 2008 and will change in 2009. If you live in Alaska or Hawaii, or pay at least half of the living expenses of dependent family members, income limits are higher.

How do costs change when you qualify for extra help?

If you qualify for extra help, we will send you by mail an "Evidence of Coverage Rider for those who Receive Extra Help Paying for their Prescription Drugs" that explains your costs as a member of our Plan. If the amount of your extra help changes during the year, we will also mail you an updated "Evidence of Coverage Rider for those who Receive Extra Help Paying for their Prescription Drugs".

What if you believe you have qualified for extra help and you believe that you are paying an incorrect co-payment amount?

If you believe you have qualified for extra help and you believe that you are paying an incorrect co-payment amount when you get your prescription at a pharmacy, our Plan has established a process that will allow you to either request our assistance in obtaining evidence of your proper co-payment level or, if you already have the evidence, to provide this evidence to us. [***Note:*** Insert plan's process for allowing beneficiaries to request assistance with obtaining best available evidence, and for providing this evidence, including the time limitation for receiving supporting documentation.]

When we obtain the evidence substantiating your copay level, we will update our system or implement other procedures so that you can pay the correct co-payment when you get your next prescription at the pharmacy. Please be assured that if you overpay your co-payment, we will generally reimburse you. Either we will forward a check to you in the amount of your overpayment or we will offset future co-payments. Of course, if the pharmacy hasn't collected a co-payment from you and is carrying your co-payment as a debt owed by you, we may make the payment directly to the pharmacy. If a state paid on your behalf, we may make payment directly to the state. Please contact Member Services if you have questions.

Important Information about Medicare Prescription Drug Coverage

We will send you [***Note:*** Insert name of COB Survey] so that we can know what other drug coverage you have besides our Plan. Medicare requires us to collect this information from you, so when you get the survey, please fill it out and send it back. If you have additional drug

coverage, you must provide that information to our Plan. The information you provide helps us calculate how much you and others have paid for your prescription drugs. In addition, if you lose or gain additional prescription drug coverage, please call Member Services to update your membership records.

3. How You Get Care and Prescription Drugs

[***Note to PDPs*:** Change the section heading to "How You Get Prescription Drugs"]
[***Note to MA-only plans*:** Delete the words "and Prescription Drugs" from the above section heading.]

All Plan Types except PDP [PDP info is at the end of this section]

How You Get Care

What are "providers"?

"Providers" is the term we use for doctors, other health care professionals, hospitals, and other health care facilities that are licensed or certified by Medicare and by the state to provide health care services.

What are "network providers"?

[***Note to HMOs, PPOs, Cost plans, and PFFS and MSA plans with a network:*** insert "A provider is a "network provider" when they participate in our Plan. When we say that network providers "participate in our Plan," this means that we have arranged with them to coordinate or provide covered services to members in our Plan. Network providers may also be referred to as "plan providers." **You [may/will] pay more if you get care from out-of-network providers.]**
[***Note***: Dual eligible SNPs should indicate in their provider directory which providers are Medicaid providers. Institutionalized SNPs should indicate in their provider directory which providers also serve people in the community.]

What are "covered services"?

"Covered services" is the term we use for all the medical care, health care services, supplies, and equipment that are covered by our Plan. Covered services are listed in the Benefits Chart in Section 4.

What do you pay for covered [services or drugs]?

The amount you pay for covered [services or drugs] is listed in [Section 4 and/or Section 5].

All plan types except PDPs

Providers you can use to get services covered by our Plan

HMO plans

While you are a member of our Plan, you must use our network providers to get your covered services except in limited cases such as emergency care, urgently needed care when our network is not available, or out of service area dialysis. We list the providers that participate with our Plan in our provider directory. If you get non-emergency care from non-plan (out-of-network) providers without prior authorization, you must pay the entire cost yourself. If an out-of-network provider sends you a bill that you think we should pay, please contact Member Services or send the bill to us for payment. We will pay your doctor for our share of the bill and will let you know what, if anything, you must pay. You won't have to pay an out-of-network provider any more

than what he or she would have gotten if you had been covered with the Original Medicare Plan. It is best to ask an out-of-network provider to bill us first, but if you have already paid for the covered services, we will reimburse you for our share of the cost.

HMO Plans with a Point-of-Service (POS) option

[Describe POS option here. Tell members under what circumstances they may obtain services from out-of-network providers and what restrictions apply. General information (no specific dollar amounts) about cost-sharing applicable to use of out-of-network providers in HMO/POS plans should be inserted here, with reference to benefits chart where detailed information can be found.]

All PPO Plans

We list the providers that participate with our Plan in our provider directory. While you are a member of our Plan you may use either network providers or out-of-network providers. However, your out-of-pocket costs may be higher if you use out-of-network providers, except for emergency care. See Section 4 for the costs when you get services from network providers. You don't need to get a referral or prior authorization when you get care from out-of-network providers, however, before getting services from out-of-network providers you may want to confirm with us that the services you are getting are covered by us and are medically necessary. If an out-of-network provider sends you a bill that you think we should pay, please contact Member Services or send the bill to us for payment. We will pay your doctor for our share of the bill and will let you know what, if anything, you must pay. You won't have to pay an out-of-network provider any more than what he or she would have gotten if you had been covered with the Original Medicare Plan. It is best to ask an out-of-network provider to bill us first, but if you have already paid for the covered services, we will reimburse you for our share of the cost. [If we later determine that the services are not covered or were not medically necessary, we may deny coverage and you will be responsible for the entire cost.] [***Include if applicable:*** "In addition, we offer a reduction in cost-sharing if you voluntarily notify us about the use of out-of-network providers."]

[***Note to regional PPOs:*** RPPOs that CMS has granted permission to use the exception in § 422.112(a) (1) (ii) to meet access requirements should insert: "Because our Plan is a Regional Preferred Provider Organization, if no contracted network provider is readily available you can access care at in-network cost-sharing from an out-of-network provider. You can call [insert toll-free number] to get help finding an out-of-network provider.]

All PFFS Plans

As a member of our Plan, you may get healthcare services in the United States from any Medicare-approved provider who, before treating you, agrees to accept our plan's terms and conditions of payment. Not all providers may accept our plan's payment terms or agree to treat you. Therefore, you must show your plan membership ID card every time you visit a health care provider so that the provider is aware of your membership in a PFFS plan. There is a telephone number or website on the card for the provider to find out about our plan's terms and conditions of payment. This gives your provider the right to choose whether to accept our plan's terms and conditions of payment before treating you. The provider cannot change his/her mind about

accepting the Plan's terms and conditions of payment after furnishing services. If you need emergency care, it is covered whether the provider accepts the plan's payment terms or not.

If your provider agrees to accept our plan, then the provider must follow the plan's terms and conditions for payment, and bill the plan for the services they provide for you. You are only required to pay the copayment or coinsurance amount allowed by our plan at the time of the visit. A provider can decide at every visit whether or not to accept our plan's payment terms and agree to treat you.

As soon as you have told your provider that you are a member of our Plan (for example, by showing them your plan ID card) and they agree to treat you, your provider is bound by the terms and conditions of payment of the Plan even if they don't explicitly accept them. We call these providers "deemed providers".

If your provider doesn't agree to our plan's terms and conditions of payment, then the provider shouldn't provide services to you, except for emergencies. In this case, you will need to find another provider that will accept our plan's payment terms. If the provider chooses to treat you, then they may not bill you. They must bill the plan for your covered health care services. You are only required to pay the copayment or coinsurance amount allowed by the plan and listed in Section 4 at the time of the service.

[***Note to Network PFFS***: adapt the following language for the network PFFS plan that is being offered: "Our Plan has direct contracts with some providers to provide you with health care services."] [***Note:*** Plan should describe what category or categories of providers it has under direct contract that were approved by CMS and whether or not the Plan has established any higher cost-sharing requirement if the member obtains a covered service from a deemed provider. Insert the following sentence if the plan includes such differential cost-sharing: "Note that the amount of cost-sharing you pay a non-contracted provider may be more than the cost-sharing you pay a contracted provider."]

What should you do with your provider bills?

You should only pay the provider the cost-sharing allowed by our Plan and listed in Section 4. You should ask your provider to bill us for the rest of the fee and we will pay the provider according to our Plan terms and conditions of payment. If the provider asks you to pay the full amount of the bill, and have you get paid back by the Plan, tell the provider that you only have to pay the cost-sharing amount. Your enrollment card in our Plan will indicate how the provider can contact us for information on our terms and conditions of payment. If the provider wants further information on payment for covered services, please have them contact us at [***Note:*** insert instructions that include a phone number and mailing address].

If you get a bill for the services, you may send the bill to us for payment. We will pay your provider for our share of the bill and will let you know if you must pay any cost-sharing. However, if you have already paid for the covered services we will reimburse you for our share of the cost.

If you have any questions about whether our plan will pay for a certain health care service, you can ask us for a written advance coverage decision before you get the service. We will let you know if our plan will pay for the service.

[***Note to MSA Plans:*** insert "You are free to use any Medicare-qualified provider who agrees to provide you with services, both before and after you meet the deductible. Prior to meeting your deductible, if you receive covered services from out-of-network providers for care that is not emergency care or urgently needed care, and you pay your bill at the time of service, you must submit a claim to our Plan so that we can count it towards your deductible and your Plan maximum out-of-pocket limit. After you meet the deductible, we will pay for services."]

All Cost Plans

If you get original Medicare services from an out-of-network provider then you must pay the original Medicare cost-sharing amounts - except in an emergency or if the services were urgently needed. You can find the original Medicare cost-sharing amounts in the *Medicare & You* handbook or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. [***Note:*** insert this sentence if your plan offers supplemental benefits: "If you get covered supplemental benefits, such as [include examples of supplemental benefits], from an out-of-network provider then you must pay the entire cost of the service."] If an out-of-network provider sends you a bill that you think we should pay, please contact Member Services. Generally, it is best to ask an out-of-network provider to bill the Original Medicare Plan first, and then to bill us for the remaining amount." We may require the out-of-network provider to bill the Original Medicare Plan. We will then pay any applicable Medicare coinsurance and deductibles minus your co-payments on your behalf. Note: If we do not cover services furnished by an out-of-network provider, the services will be covered by Original Medicare if they are Medicare-covered services. In this case you would be responsible for Original Medicare cost-sharing amounts."

All plans except PDP

Choosing Your Primary Care Physician (PCP)

[***Note***: Insert this section only if plan uses PCPs. If plan uses PCPs, explain PCP in context of your plan type by including at least the following:

- What is a PCP?
- What types of providers may act as a PCP?
- How do you choose/change a PCP if member desires or when PCP leaves plan?
- Explain the role of a PCP in your plan.
- What services does the PCP furnish (e.g. routine medical care) and what services can members get on their own? Be sure to include the following services that Medicare beneficiaries can get on their own without approval in advance:
    - Routine women's health care, which include breast exams, mammograms (x-rays of the breast), Pap tests, and pelvic exams.
    - Flu shots [***Note*:** insert if appropriate: "and pneumonia vaccinations"] [***Note*:** insert if appropriate: "as long as you get them from a network provider"].
    - Emergency services, whether you get these services from network providers or out-of-network providers

- Urgently needed care that you get from out-of-network providers when you are temporarily outside the Plan's service area or when you are in the service area but, because of unusual or extraordinary circumstances, the Network providers are temporarily unavailable or inaccessible.
- Dialysis (kidney) services that you get when you are temporarily outside the Plan's service area. [***Note:*** You may insert requests here, e.g., if possible, please let us know before you leave the service area where you are going to be so we can help arrange for you to have maintenance dialysis while outside the service area.] [***Note to Cost plans***: delete this bullet.]

- What is the role of the PCP in coordinating covered services?
- For what services will the PCP need to get prior authorization from the plan?
- Explain if the selection of a PCP results in being limited to specific specialists or hospitals to which that PCP refers, i.e. sub-network, referral circles.

All MA plans except non-network PFFS

What if your doctor or other provider leaves your plan?

Sometimes a network provider you are using might leave the Plan. If this happens, you will have to switch to another provider who is part of our Plan. Member Services can assist you in finding and selecting another provider.

[***Note to SNP Plans:*** Organizations offering dual eligible SNPs that are obligated under state Medicaid programs to have a transition benefit when a doctor leaves a plan, may discuss that benefit here.]

All Plan Types except PDP

Getting care if you have a medical emergency or an urgent need for care

[***Note***: Throughout this section plans can change "notify plan" to provider, medical group or any other specific area the member should call after an emergency.]

What is a "medical emergency"?

A "medical emergency" is when you believe that your health is in serious danger. A medical emergency includes severe pain, a bad injury, a sudden illness, or an illness that is quickly getting much worse.

If you have a medical emergency:

- Get medical help as quickly as possible. Call 911 for help or go to the nearest emergency room, hospital, or urgent care center. You don't need to get approval or a referral first from your PCP or other network provider. [***Note to PFFS plans*:** Do not include previous sentence.]
- As soon as possible, make sure that we know about your emergency, because we need to be involved in following up on your emergency care. [***Note to HMO and Cost Plans:*** insert **"**You or someone else should call to tell us about your emergency care,

usually within 48 hours."] [*Note*: Insert instructions – either give the number to call or explain where to get the number to call (e.g., the back of the membership card)].]

[***Note to all plan types except PDPs, PFFS and MSAs*:** include next paragraph and modify accordingly to address post-stabilization care for your plan type.]
We will talk with the doctors who are giving you emergency care to help manage and follow up on your care. When the doctors who are giving you emergency care say that your condition is stable and the medical emergency is over. Your follow-up care will be covered according to Medicare guidelines. In general, we will try to arrange for network providers to take over your care as soon as your medical condition and the circumstances allow.

What is covered if you have a medical emergency?

- You may get covered emergency medical care whenever you need it, anywhere in the United States. [***Note to MA-PD*:** insert "We discuss filling prescriptions when you cannot access a network pharmacy later in this section."]
- **Ambulance** services are covered in situations where other means of transportation in the United States would endanger your health.
- [***Note*:** If the plan offers emergency coverage benefit or ambulance services outside of the country, then describe the benefit here.

What if it wasn't a medical emergency?

HMOs, PPOs, and Cost Plans

Sometimes it can be hard to know if you have a medical emergency. For example, you might go in for emergency care – thinking that your health is in serious danger – and the doctor may say that it wasn't a medical emergency after all. If this happens, you are still covered for the care you got to determine what was wrong, as long as you thought your health was in serious danger, as explained in "What is a 'medical emergency'" above. [***HMO and Cost plans*:** include "If you get any extra care after the doctor says it wasn't a medical emergency, the Plan will pay its portion of the covered additional care **only if you get it from a network provider."** [***HMO plans:*** include "We will pay our portion of the covered additional care from an out-of-network provider if you are out of our service area, as long as the additional care you get meets the definition of "urgently needed care" that is given below."][***Cost plans:*** include "If you get any extra care from an *out-of-network provider* after the doctor says it wasn't a medical emergency, you will normally have to pay the Original Medicare Plan cost-sharing. "] [***PPO plans:*** include "If you get any extra care after the doctor says it wasn't a medical emergency, the amount of cost-sharing that you pay will depend on whether you get the care from network providers. If you get the care from network providers, your costs will usually be lower than if you get the care from out-of-network providers."]

All PFFS Plans

Sometimes it can be hard to know if you have a medical emergency. For example, you might go in for emergency care—thinking that your health is in serious danger—and the doctor may say that it was not a medical emergency after all. If you decide to get follow-up care from the provider treating you, then you should advise them of your plan enrollment as soon as possible. The plan will pay for all medically necessary plan covered services furnished by the provider and

non-emergency care that you get from any provider in the United States to whom you have informed, by showing your member ID card, that you are a plan member, and who agrees to accept our plan's terms and conditions of payment. (There is more information later in this section on filling your prescription drugs when you are getting urgently needed care and when you are outside the Plan's service area.)

HMOs, PPOs, and Cost Plans

What is urgently needed care?

Urgently needed care refers to a non-emergency situation where you are

- Inside the United States
- Temporarily absent from the Plan's authorized service area
- In need of medical attention right away for an unforeseen illness, injury, or condition, and
- It isn't reasonable given the situation for you to obtain medical care through the Plan's participating provider network.

Under unusual and extraordinary circumstances, care may be considered urgently needed and paid for by our Plan when the member is in the service area, but the provider network of the Plan is temporarily unavailable or inaccessible.

What is the difference between a "medical emergency" and "urgently needed care"?

The two main differences between urgently needed care and a medical emergency are in the danger to your health and your location. A "medical emergency" occurs when you reasonably believe that your health is in serious danger, whether you are in or outside of the service area. "Urgently needed care" is when you need medical help for an unforeseen illness, injury, or condition, but your health is not in serious danger and you are generally outside of the service area.

How to get urgently needed care

If, while temporarily outside the Plan's service area, you require urgently needed care, then you may get this care from any provider. The plan is obligated to cover all urgently needed care at the same cost-sharing levels that apply to care received within the Plan network.

Note: If you have a pressing, non-emergency medical need while in the service area, you generally must obtain services from the Plan according to its procedures and requirements as outlined earlier in this section.

PFFS Plans

What is urgently needed care?

Urgent care refers to non-emergency care received outside the service area of the Plan. However, as discussed in detail earlier in this section, a PFFS plan allows enrollees to access care from any Medicare-approved provider in the United States who agrees to accept our plan's terms and conditions of payment prior to treating you. Consequently, the concept of urgent care does not

apply, since you may always obtain care outside of the service area. Non-emergency care obtained at an urgent-care center may have different cost-sharing than for other providers.

MA-PDs and PDPs

How you get prescription drugs

What do you pay for covered [services or drugs]?

The amount you pay for covered [services or drugs] is listed in [Section 4 and/or Section 5].

If you have Medicare and Medicaid

Medicare, not Medicaid, will pay for most of your prescription drugs. You will continue to get your health coverage under both Medicare and Medicaid as long as you qualify for Medicaid benefits.

If you are a member of a State Pharmacy Assistance Program (SPAP)

If you are currently enrolled in an SPAP, you may get help paying your [premiums,] [deductibles,] [and] [or] [cost-sharing]. Please contact your SPAP to determine what benefits are available to you. Please see the Contacts section for more information.

If you have a Medigap (Medicare Supplement Insurance) policy with prescription drug coverage

If you currently have a Medigap policy that includes coverage for prescription drugs, you must contact your Medigap issuer and tell them you have enrolled in our Plan. If you decide to keep your current Medigap policy, your Medigap issuer will remove the prescription drug coverage portion of your Medigap policy and adjust your premium.

Each year (prior to November 15), your Medigap insurance company must send you a letter explaining your options and how the removal of drug coverage from your Medigap policy will affect your premiums. If you didn't get this letter or can't find it, you have the right to get a copy from your Medigap insurance company.

If you are a member of an employer or retiree group

If you currently have prescription drug coverage through your (or your spouse's) employer or retiree group, please contact your benefits administrator to determine how your current prescription drug coverage will work with this Plan. In general, if you are currently employed, the prescription drug coverage you get from us will be secondary to your employer or retiree group coverage.

Each year prior to November 15, your employer or retiree group should provide a disclosure notice to you that indicates if your prescription drug coverage is creditable (meaning it is at least as good as standard Medicare prescription drug coverage) and the options available to you. You should keep the disclosure notices that you get each year in your personal records to present to a Part D plan when you enroll to show that you have maintained creditable coverage. If you didn't

get this disclosure notice, you may get a copy from the employer's or retiree group's benefits administrator or employer/union.

Using network pharmacies to get your prescription drugs

With few exceptions, **you must use network pharmacies to get your prescription drugs covered.** A network pharmacy is a pharmacy that has a contract with us to provide your covered prescription drugs. The term "covered drugs" means all of the outpatient prescription drugs that are covered by our Plan. Covered drugs are listed in our formulary.

In most cases, your prescriptions are covered only if they are filled at one of our network pharmacies. You aren't required to always go to the same pharmacy to fill your prescription; you may go to any of our network pharmacies. However, if you switch to a different network pharmacy than the one you have previously used, you must either have a new prescription written by a doctor or have the previous pharmacy transfer the existing prescription to the new pharmacy if any refills remain. To find a network pharmacy in your area, please review your Pharmacy Directory. You can also visit our Web site at [insert URL] or call Member Services.

What is a Preferred Pharmacy?

[***Note:*** Delete this section if plan does not have preferred and non-preferred pharmacies in its network.]

Preferred pharmacies are pharmacies in our network in which our Plan has negotiated lower cost-sharing for its plan members for covered prescription drugs than at non-preferred pharmacies. However, you will still have access to lower drug prices at non-preferred pharmacies in our network than at out-of-network pharmacies. You may go to either of these types of pharmacies to receive your covered prescription drugs. [***Note:*** Describe restrictions imposed on members that use non-preferred pharmacies.] Please refer to your Pharmacy Directory or call Member Services to locate a preferred network pharmacy.

What if a pharmacy is no longer a network pharmacy?

Sometimes a pharmacy might leave the Plan's network. If this happens, you will have to get your prescriptions filled at another Plan network pharmacy. Please refer to your Pharmacy Directory or call Member Services to find another network pharmacy in your area.

How do you fill a prescription at a network pharmacy?

To fill your prescription, you must show your Plan membership card at one of our network pharmacies. If you don't have your membership card with you when you fill your prescription, you may have the pharmacy call [network pharmacy contact information] to obtain the necessary information. If you pay the full cost of the prescription (rather than paying just your [Note: plan insert either "coinsurance" OR "co-payment" OR "coinsurance or co-payment"]) you may ask us to reimburse you for our share of the cost by submitting a claim to us. To learn how to submit a paper claim, please refer to the paper claims process described in the subsection below called "How do you submit a paper claim?"

How do you fill a prescription through our Plan's network mail-order-pharmacy service?

[***Note:*** delete this section if plan does not offer mail-order pharmacy service.]

To get [order forms and] information about filling your prescriptions by mail, [insert instructions]. Please note that you must use the [Plan Name] mail order service[s]. Prescription drugs that you get through any other mail order service are not covered.

[***Note:*** Include the following language only if your mail order service is limited to a subset of all formulary drugs, adapting terminology as needed: "You can use [Plan name] mail order service[s] to fill prescriptions for some drugs. [These drugs are marked as [***Note:*** Insert either "maintenance" *OR* "mail order"] drugs on the formulary list.] [These are drugs that you take on a regular basis, for a chronic or long-term medical condition.] The formulary list tells you which drugs are available through our mail order service[s]."]

When you order prescription drugs through our network mail-order-pharmacy service, you [***Note:*** Plan insert either "must order at least a [xx]-day supply, and no more than a [xx]-day supply" *OR* "may order up to a [xx] day supply"] of the drug.

Generally, it takes the mail-order pharmacy [xx] days to process your order and ship it to you. However, sometimes your mail-order may be delayed. ***[Note:*** Insert Plan's process for members to get a prescription if the mail-order is delayed.]

You are not required to use mail order prescription drug services to obtain an extended supply of [maintenance]/[mail order] medications. Instead, you have the option of using a [***Note:*** Plan insert either "preferred retail pharmacy" OR "non-preferred retail pharmacy" OR "retail pharmacy"] in our network to obtain a supply of [maintenance/mail order] medications. Some of these retail pharmacies may agree to accept the mail order reimbursement rate for an extended supply of [maintenance/mail order] medications, which may result in no out-of-pocket payment difference to you. Other retail pharmacies may not agree to accept the mail order reimbursement rate for an extended supply of [maintenance/mail order] medications. In this case, you will be responsible for the difference in price. Your Pharmacy Directory contains information about retail pharmacies in our network at which you can obtain an extended supply of [maintenance/mail order] medications. You can also call Member Services for more information.

How do you fill prescriptions outside the network?

[We have network pharmacies outside of the service area where you can get your drugs covered as a member of our Plan.] Generally, we only cover drugs filled at an out-of-network pharmacy in limited circumstances when a network pharmacy is not available. Below are some circumstances when we would cover prescriptions filled at an out-of-network pharmacy. Before you fill your prescription in these situations, call Member Services to see if there is a network pharmacy in your area where you can fill your prescription. If you do go to an out-of-network pharmacy for the reasons listed below, you may have to pay the full cost (rather than paying just [Note: plans insert either "coinsurance" OR "co-payment" OR "coinsurance OR co-payment"]) when you fill your prescription. You may ask us to reimburse you for our share of the cost by

submitting a claim form. You should submit a claim to us if you fill a prescription at an out-of-network pharmacy, as any amount you pay will help you qualify for catastrophic coverage. To learn how to submit a paper claim, please refer to the paper claims process described in the subsection below called "How do you submit a paper claim?" [***Note***: If we do pay for the drugs you get at an out-of-network pharmacy, you may still pay more for your drugs than what you would have paid if you had gone to an in-network pharmacy.]

[Note: Plans should insert a list of situations when they will cover prescriptions out of the network and any limits on their out-of-network policies (e.g., day supply limits, use of mail-order during extended out of area travel, authorization or plan notification.)]

How do you submit a paper claim?

When you go to a network pharmacy and use our membership card, your claim is automatically submitted to us by the pharmacy. However, if you go to an out-of-network pharmacy and attempt to use our membership card for one of the reasons listed above, the pharmacy may not be able to submit the claim directly to us. When that happens, you will have to pay the full cost of your prescription. [Note: Insert how a member should submit a paper claim including plan-established time frames for submission of paper claims]

If you submit a paper claim asking us to reimburse you for a prescription drug that is not on our formulary or is subject to coverage requirements or limits, your doctor may need to submit additional documentation supporting your request. See Section 9 to learn more about requesting coverage determinations.

In rare circumstances when you are in a coverage gap or deductible period and have bought a covered Part D drug at a network pharmacy under a special price or discount card that is outside the Plan's benefit, you may submit documentation and have it count towards qualifying you for catastrophic coverage. Additionally, if you get help from, and pay co-payments under, a drug manufacturer patient assistance program outside our Plan's benefit, you may submit documentation for the amount you paid and have it count towards qualifying you for catastrophic coverage. Please call Member Services for more information.

Reimbursing Plan Members for Coverage During Retroactive Periods

PDP

If you were automatically enrolled in our Plan because you were Medicaid eligible, your enrollment in our Plan may be retroactive back to when you became eligible for Medicaid. Your enrollment date may even have occurred last year. In order to be reimbursed for expenses you had during this time period (and that were not reimbursed by other insurance), you must submit a paper claim to us. (See "How do you submit a paper claim") We have a seven-month special transition period that allows us to cover most of your claims from the effective date of your enrollment to the current time; however, depending upon your situation, you or Medicare may be responsible for any out-of-network or price differences. You may also be responsible for some claims outside of the seven-month special transition period if the claims are for drugs not on our formulary. For more information, please call Member Services.

How does your prescription drug coverage work if you go to a hospital or skilled nursing facility?

If you are admitted to a hospital for a Medicare-covered stay, [***Note:*** Insert if plan is a PDP **"**Medicare Part A"] [***Note:*** Insert if plan is an MA-PD "our Plan's medical (Part C) benefit"] should generally cover the cost of your prescription drugs while you are in the hospital. [***Note:*** Insert if plan is a PDP: "Once you are released from the hospital, we will cover your prescription drugs as long as the drugs meet all coverage requirements (such as the drugs being on our formulary, filled at a network pharmacy, etc.) and they aren't covered by Medicare Part A or Part B."] [***Note:*** Insert if plan is an MA-PD "Once you are released from the hospital, our plan's Part D benefit will cover your prescription drugs as long as the drugs meet all coverage requirements (such as the drugs being on our formulary, filled at a network pharmacy, etc.) and they aren't covered by our medical benefit (Part C)."] We will also cover your prescription drugs if they are approved under the Part D coverage determination, exceptions, or appeals process.

If you are admitted to a skilled nursing facility for a Medicare-covered stay: [***Note:*** Insert if plan is a PDP "After Medicare Part A stops paying for your prescription drug costs as part of skilled nursing facility Medicare-covered stay, we will cover your prescription drugs as long as the drug meets all of our coverage requirements (including the requirement that the skilled nursing facility pharmacy be in our pharmacy network and that the drugs aren't otherwise covered by Medicare Part B."] [***Note:*** Insert if plan is an MA-PD "After our plan's medical benefit (Part C) stops paying for your prescription drug costs as part of a skilled nursing facility Medicare-covered stay, our plan's Part D benefit will cover your prescription drugs as long as the drug meets all of our coverage requirements (including the requirement that the skilled nursing facility pharmacy be in our pharmacy network, unless you meet standards for out-of–network care, and that the drugs aren't otherwise covered by our plan's medical benefit (Part C)."] When you enter, live in, or leave a skilled nursing facility, you are entitled to a special enrollment period, during which time you will be able to leave this Plan and join a new Medicare Advantage or Prescription Drug Plan. See Section 10 of this booklet for more information about leaving this Plan and joining a new Medicare Prescription Drug Plan.

Long-term care (LTC) pharmacies

Generally, residents of a long-term-care facility (like a nursing home) may get their prescription drugs through the facility's LTC pharmacy or another network LTC pharmacy. Please refer to your Pharmacy Directory to find out if your LTC pharmacy is part of our network. If it isn't, or for more information, contact Member Services. [***Note:*** Insert any additional information on Long-term Care pharmacy services in Plan's network.]

[***Note:*** Insert the following section if the service area and the network contain I/T/U Pharmacies.]

Indian Health Service / Tribal / Urban Indian Health Program (I/T/U) Pharmacies

Only Native Americans and Alaska Natives have access to Indian Health Service / Tribal / Urban Indian Health Program (I/T/U) Pharmacies through our Plan's pharmacy network. Others may be able to use these pharmacies under limited circumstances (e.g., emergencies). [*Note*: Insert any additional information on I/T/U pharmacy services in Plan's network.] Please refer to your

Pharmacy Directory to find an I/T/U pharmacy in your area. For more information, contact Member Services.

Home infusion pharmacies

[***Note:*** Plans may provide information on home infusion pharmacy services in their network.] Please refer to your Pharmacy Directory to find a home infusion pharmacy provider in your area. For more information, contact Member Services.

Some vaccines and drugs may be administered in your doctor's office

We may cover vaccines that are preventive in nature and aren't already covered by [Medicare Part B/our Plan's medical benefit (Part C)]. This coverage includes the cost of vaccine administration. See Section 5 for more information about your costs for covered vaccinations.

4. Part C Medical Benefits and How Much You Pay

[***Note*:** The requirement to include a list of covered benefits applies to all plan types.] [***Note to SNPs*:** SNP plans may add a discussion to this section if they cover benefits under Medicaid. This may include adding new language to the benefit chart itself as well as language to the related text in this section. This may be done in an additional column or additional rows or within the existing cells of the chart or grouped together at the end and labeled Medicaid benefits.]

All Plan Types except PDPs

This section has a Benefits Chart that gives a list of your covered services and tells what you must pay for each covered service. These are the benefits and coverage you get as a member of our Plan. Section 7 tells about services that are not covered (these are called "exclusions"). [***Add if applicable:*** Section 7 also tells about limitations on certain services.] [***Note***: If applicable, you may mention other places where benefits, limitations, and exclusions are described, such as optional additional benefits, or addenda.]

Some general requirements apply to all covered services.

The covered services listed in the Benefits Chart in this section are covered only when all requirements listed below are met:

- Services must be provided according to the Medicare coverage guidelines established by the Medicare Program.
- The medical care, services, supplies, and equipment that are listed as covered services must be medically necessary. Certain preventive care and screening tests are also covered.

See Section 3 for information on requirements for using network providers.

HMO and PPO Plans

Some of the covered services listed in the Benefits Chart in this section are covered only if your doctor or other network provider gets "prior authorization" (approval in advance) from our Plan. Covered services that need prior authorization are marked in the Benefits Chart by [an asterisk/footnote, in bold, in italics, etc.]. [***Note to PPO plans with network providers and prior authorization requirements***: insert "Prior authorization is only required for services obtained from a network provider. You never need prior authorization for out-of-network services from out-of-network providers (but your cost-sharing may be higher)."]

All Plan Types except PDPs – include if applicable

What do you pay for covered [services or drugs]?

[***Note:*** include reference to all applicable cost-sharing types your plan uses]

"Deductibles," "co-payments," and "coinsurance" are the amounts you pay for covered services.

- [***Note***: Include if applicable] The **"deductible"** is the amount you must pay for the [health care services or drugs] you receive before our Plan begins to pay its share of your covered [services or drugs].
- A **"co-payment"** is a payment you make for your share of the cost of certain covered

[services or drugs] you get. A co-payment is a set amount per [service or drug]. You pay it when you get the [service or drug].

- **"Coinsurance"** is a payment you make for your share of the cost of certain covered [services or drugs] you receive. Coinsurance is a percentage of the cost of the [service or drug]. You pay your coinsurance when you get the [service or drug].
- [***MA and MA-PD plans add if applicable***: "Depending on your Medicaid benefit, you may not have to pay out-of-pocket costs for premiums, [***Note to MA-only plans with no Part C premium:*** delete "premiums,"] deductibles, co-payments and coinsurances. These costs may be covered by Medicaid, as long as you qualify for Medicaid benefits and the provider accepts Medicaid. The only exception is that you are responsible for [Part D prescription drug [Note: Plan insert either: "coinsurance" OR "co-payment" OR "coinsurance or co-payment"] co-payments and] your Medicaid co-payments, if applicable.]

What is the maximum amount you will pay for covered services?

There is a limit to how much you have to pay out-of-pocket for your covered health care services each year. [***Note to Plans with out-of-pocket limited:*** describe, including dollar amounts]

[***Note to MSA plans:*** plans must disclose their deductible amounts and any out-of-pocket maximums if applicable. If there is any cost-sharing between the deductible and the out-of-pocket maximum (demonstration plans only), that must also be disclosed. For demonstration plans if there is a network, any differential cost-sharing must be disclosed. Standard MSA plans that have a network should indicate that there is no differential cost-sharing for in-network vs. out-of-network costs.

[***Note to MA and MAPD plans:*** include "Once the total costs for your Part D drugs, including your [deductible,] co-payments, [and coinsurance], reaches $[insert annual out-of-pocket maximum amount], then you won't have to continue paying for these expenses for the remainder of the year.]

[***Note to Regional PPOs***: Regional PPO Plans must disclose their in-network and total (inclusive of in and out of network) catastrophic cap on member cost-sharing for A and B services (see § 422.101(d)(2) and (d)(3).]

All plan types except PDPs

Benefits Chart

The benefits chart on the following pages list the services our Plan covers and what you pay for each service.

[***Instructions to All Plan Types except PDPs on completing benefits chart:***

- When preparing this Benefits Chart, please refer to any instructions contained in the cover memorandum for this Model EOC.
- All plans with networks should clearly indicate for each service applicable the difference in cost-sharing at network and out-of-network providers and facilities.

- [SNPs may modify the language, as applicable, to address billing and cost-sharing for its dual eligible population.]]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Inpatient Services	
Inpatient hospital care [List days covered and any restrictions that apply.] Covered services include: • Semiprivate room (or a private room if medically necessary) • Meals including special diets • Regular nursing services • Costs of special care units (such as intensive or coronary care units) • Drugs and medications • Lab tests • X-rays and other radiology services • Necessary surgical and medical supplies • Use of appliances, such as wheelchairs • Operating and recovery room costs • Physical, occupational, and speech therapy • Under certain conditions, the following types of transplants are covered: corneal, kidney, kidney-pancreatic, heart, liver, lung, heart/lung, bone marrow, stem cell, and intestinal/multivisceral. If you need a transplant, we will arrange to have your case reviewed by a Medicare-approved transplant center that will decide whether you are a candidate for a transplant. [***Note to Network plans:*** insert "If you are sent outside of your community for a transplant, we may arrange or pay for appropriate lodging and transportation costs for you and a companion.] • Blood - including storage and administration. Coverage of whole blood and packed red cells begins only with the fourth pint of blood that you need - you pay for the first 3 pints of unreplaced blood. All other components of blood are covered beginning with the first pint used. [Modify as necessary if the Plan begins coverage with an earlier pint.] • Physician Services	[List co-payments/coinsurance. If cost-sharing is based on benefit period, include definition/ explanation of BID approved benefit period here. Also, plans that use a per-admission deductible, include the following sentence: A per admission deductible is applied once during a benefit period.] If you get inpatient care at a non-plan hospital after your emergency condition is stabilized, your cost is the [***Insert if applicable:*** highest] cost-sharing you would pay at a plan hospital. [***Note to Cost plans:*** insert instead of last sentence "If you get inpatient care at a non-plan hospital after an emergency admission, your cost is the cost-sharing you would pay at a plan hospital."]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Inpatient mental health care Covered services include mental health care services that require a hospital stay. [List days covered, restrictions such as 190-day lifetime limit for inpatient services in a psychiatric hospital. The 190-day limit does not apply to Mental Health services provided in a psychiatric unit of a general hospital.]	[List co-pays / coinsurance]
Skilled nursing facility (SNF) care [List days covered and any restrictions that apply, including whether any prior hospital stay is required.] Covered services include: • Semiprivate room (or a private room if medically necessary) • Meals, including special diets • Regular nursing services • Physical therapy, occupational therapy, and speech therapy • Drugs (This includes substances that are naturally present in the body, such as blood clotting factors) • Blood - including storage and administration. Coverage of whole blood and packed red cells begins only with the fourth pint of blood that you need - you pay for the first 3 pints of unreplaced blood. All other components of blood are covered beginning with the first pint used. [Modify as necessary if the Plan begins coverage with an earlier pint.] • Medical and surgical supplies • Laboratory tests • X-rays and other radiology services • Use of appliances such as wheelchairs • Physician services	[List co-pays/ coinsurance. If cost-sharing is based on benefit period, include definition/explanation of BID approved benefit period here.] [***Note to HMO and PPO plans***: insert "Generally, you will get your SNF care from plan facilities. However, under certain conditions listed below, you may be able to pay in-network cost-sharing for a facility that isn't a plan provider, if the facility accepts our Plan's amounts for payment. • A nursing home or continuing care retirement community where you were living right before you went to the hospital (as long as it provides skilled nursing facility care). • A SNF where your spouse is living at the time you leave the hospital.

Benefits chart – your covered services	**What you must pay** when you get these covered services
Inpatient services (when the hospital or SNF days aren't, or are no longer, covered) Covered services include: • Physician services • Tests (like X-ray or lab tests) • X-ray, radium, and isotope therapy including technician materials and services • Surgical dressings, splints, casts and other devices used to reduce fractures and dislocations • Prosthetics and Orthotics devices (other than dental) that replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices • Leg, arm, back, and neck braces; trusses, and artificial legs, arms, and eyes including adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient's physical condition • Physical therapy, speech therapy, and occupational therapy	[List co-pays / coinsurance]
Home health agency care Covered services include: • Part-time or intermittent skilled nursing and home health aide services • Physical therapy, occupational therapy, and speech therapy • Medical social services • Medical equipment and supplies	[List co-pays / coinsurance]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Hospice care You may receive care from any Medicare-certified hospice program. The Original Medicare Plan (rather than our Plan) will pay the hospice provider for the services you receive. Your hospice doctor can be a network provider or an out-of-network provider. You will still be a plan member and will continue to get the rest of your care that is unrelated to your terminal condition through our Plan. Covered services include: • Drugs for symptom control and pain relief, short-term respite care, and other services not otherwise covered by Medicare • Home care Our Plan covers hospice consultation services (one time only) for a terminally ill person who hasn't elected the hospice benefit. [***Note***: Include information about cost-sharing if applicable.]	When you enroll in a Medicare-certified Hospice program, your hospice services are paid for by Medicare, not your Medicare Advantage plan.
Outpatient Services	
Physician services, including doctor office visits Covered services include: • Office visits, including medical and surgical care in a physician's office or certified ambulatory surgical center • Consultation, diagnosis, and treatment by a specialist • Second opinion [Insert in appropriate: by another network provider] prior to surgery • Outpatient hospital services • Non-routine dental care (covered services are limited to surgery of the jaw or related structures, setting fractures of the jaw or facial bones, extraction of teeth to prepare the jaw for radiation treatments of neoplastic cancer disease, or services that would be covered when provided by a doctor) [Also list any additional benefits offered]	[List co-pays / coinsurance]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Chiropractic services Covered services include: • Manual manipulation of the spine to correct subluxation [Also list any additional benefits offered]	[List co-pays / coinsurance]
Podiatry services Covered services include: • Treatment of injuries and diseases of the feet (such as hammer toe or heel spurs). • Routine foot care for members with certain medical conditions affecting the lower limbs. [Also list any additional benefits offered]	[List co-pays / coinsurance]
Outpatient mental health care (including Partial Hospitalization Services) Covered services include: • Mental health services provided by a doctor, clinical psychologist, clinical social worker, clinical nurse specialist, nurse practitioner, physician assistant, or other Medicare-qualified mental health care professional as allowed under applicable state laws. "Partial hospitalization" is a structured program of active treatment that is more intense than the care received in your doctor's or therapist's office and is an alternative to inpatient hospitalization.	[List co-pays / coinsurance]
Outpatient substance abuse services	[List co-pays / coinsurance]
Outpatient surgery	[List co-pays / coinsurance]
Ambulance services Covered services include ambulance services to an institution (like a hospital or SNF), from an institution to another institution, from an institution to your home, and services dispatched through 911, where other means of transportation could endanger your health.	[List co-pays / coinsurance. Specify whether cost-sharing applies one way or for round trips.]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Emergency care [Identify whether this coverage is within the U.S. or world-wide.]	[List co-pays / coinsurance. Explain (if appropriate) that cost-sharing is waived if member admitted to hospital.] If you get inpatient care at a non-plan hospital after your emergency condition is stabilized, your cost is the [***Insert if applicable:*** highest] cost-sharing you would pay at a plan hospital. [Cost plans use this in lieu of last sentence: "If you get inpatient care at a non-plan hospital after an emergency admission, your cost is the cost-sharing you would pay at a plan hospital."]
Urgently needed care [Identify whether this coverage is within the U.S. or world-wide.]	[List co-pays / coinsurance]
Outpatient rehabilitation services Covered services include: physical therapy, occupational therapy, and speech and language therapy	[List co-pays / coinsurance]
Durable medical equipment and related supplies Covered items include: wheelchairs, crutches, hospital bed, IV infusion pump, oxygen equipment, nebulizer, and walker. (See definition of "durable medical equipment" in Section 13)	[List co-pays / coinsurance]
Prosthetic devices and related supplies – (other than dental) that replace a body part or function. These include colostomy bags and supplies directly related to colostomy care, pacemakers, braces, prosthetic shoes, artificial limbs, and breast prostheses (including a surgical brassiere after a mastectomy). Includes certain supplies related to prosthetic devices, and repair and/or replacement of prosthetic devices. Also includes some coverage following cataract removal or cataract surgery – see "Vision Care" on page [x] for more detail.	[List co-pays / coinsurance]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Diabetes self-monitoring, training and supplies – for all people who have diabetes (insulin and non-insulin users). Covered services include: • Blood glucose monitor, blood glucose test strips, lancet devices and lancets, and glucose-control solutions for checking the accuracy of test strips and monitors • One pair per calendar year of therapeutic shoes for people with diabetes who have severe diabetic foot disease, including fitting of shoes or inserts • Self-management training is covered under certain conditions. • For persons at risk of diabetes: Fasting plasma glucose tests. [Insert frequency] [Also list any additional benefits offered]	[List co-pays / coinsurance]
Medical nutrition therapy – for people with diabetes, renal (kidney) disease (but not on dialysis), and after a transplant when referred by your doctor.	[List co-pays / coinsurance]
Outpatient diagnostic tests and therapeutic services and supplies Covered services include: • X-rays • Radiation therapy [***Note***: list separately any services for which a separate co-pay/coinsurance applies over and above the outpatient radiation therapy co-pay/coinsurance.] • Surgical supplies, such as dressings • Supplies, such as splints and casts • Laboratory tests • Blood - Coverage begins with the fourth pint of blood that you need – you pay for the first 3 pints of unreplaced blood. [Modify as necessary if the Plan begins coverage with an earlier pint]. Coverage of storage and administration begins with the first pint of blood that you need.	[List co-pays / coinsurance]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Preventive Care and Screening Tests	
Bone-mass measurements For qualified individuals (generally, this means people at risk of losing bone mass or at risk of osteoporosis), the following services are covered every 2 years or more frequently if medically necessary: procedures to identify bone mass, detect bone loss, or determine bone quality, including a physician's interpretation of the results. [Also list any additional benefits offered.]	[List co-pays / coinsurance.]
Colorectal screening For people 50 and older, the following are covered: • Flexible sigmoidoscopy (or screening barium enema as an alternative) every 48 months • Fecal occult blood test, every 12 months For people at high risk of colorectal cancer, we cover: • Screening colonoscopy (or screening barium enema as an alternative) every 24 months For people not at high risk of colorectal cancer, we cover: • Screening colonoscopy every 10 years, but not within 48 months of a screening sigmoidoscopy [Also list any additional benefits offered.]	[List co-pays / coinsurance]
Immunizations Covered services include: • Pneumonia vaccine • Flu shots, once a year in the fall or winter • If you are at high or intermediate risk of getting Hepatitis B: Hepatitis B vaccine • Other vaccines if you are at risk [***Note to Plans offered Part D:*** include "We also cover some vaccines under our outpatient prescription drug benefit**."**] [***Note:*** Also list any additional benefits offered.]	[List co-pays / coinsurance]
Mammography screening Covered services include: • One baseline exam between the ages of 35 and 39 • One screening every 12 months for women age 40 and older [Also list any additional benefits offered.]	[List co-pays / coinsurance]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Pap tests, pelvic exams, and clinical breast exam Covered services include: • For all women, Pap tests, pelvic exams, and clinical breast exams are covered once every 24 months • If you are at high risk of cervical cancer or have had an abnormal Pap test and are of childbearing age: one Pap test every 12 months [Also list any additional benefits offered.]	[List co-pays / coinsurance]
Prostate cancer screening exams For men age 50 and older, covered services include the following - once every 12 months: • Digital rectal exam • Prostate Specific Antigen (PSA) test [Also list any additional benefits offered.]	[List co-pays / coinsurance]
Cardiovascular disease testing Blood tests for the detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease). [Insert frequency.]	[List co-pays / coinsurance]
Physical exams [***Note to any Plan that covers only what the Original Medicare covers:*** include "A one-time physical exam for members within the first 6 months that they have Medicare Part B. Includes measurement of height, weight and blood pressure; an electrocardiogram; education, counseling and referral with respect to covered screening and preventive services. Doesn't include lab tests."] [Plans that cover a richer physical exam benefit than Original Medicare Plan don't include above description and instead describe plan benefit.]	[List co-pays / coinsurance]

Benefits chart – your covered services	**What you must pay** when you get these covered services
Other Services	
Dialysis (Kidney) Covered services include: • Outpatient dialysis treatments (including dialysis treatments when temporarily out of the service area, as explained in Section 3) • Inpatient dialysis treatments (if you are admitted to a hospital for special care) • Self-dialysis training (includes training for you and anyone helping you with your home dialysis treatments) • Home dialysis equipment and supplies • Certain home support services (such as, when necessary, visits by trained dialysis workers to check on your home dialysis, to help in emergencies, and check your dialysis equipment and water supply)	[List co-pays / coinsurance]
Prescription Drugs These drugs are covered under Part B of the Original Medicare Plan. Members of our plan receive coverage for these drugs through our plan. Covered drugs include: • Drugs that usually aren't self-administered by the patient and are injected while you are getting physician services • Drugs you take using durable medical equipment (such as nebulizers) that was authorized by the plan • Clotting factors you give yourself by injection if you have hemophilia • Immunosuppressive drugs, if you have had an organ transplant that was covered by Medicare • Injectable osteoporosis drugs, if you are homebound, have a bone fracture that a doctor certifies was related to post-menopausal osteoporosis, and cannot self-administer the drug • Antigens • Certain oral anti-cancer drugs and anti-nausea drugs • Certain drugs for home dialysis, including heparin, the antidote for heparin when medically necessary, topical anesthetics, Erythropoietin (Epogen®) or Epoetin alfa, and Darboetin Alfa (Aranesp®)	[List co-pays / coinsurance]

Benefits chart – your covered services	**What you must pay** when you get these covered services
• Intravenous Immune Globulin for the treatment of primary immune deficiency diseases in your home [***MA-PD plans insert:*** Section 5 explains the Part D prescription drug benefit, including rules you must follow to have prescriptions covered.]	
Additional Benefits	
[***Note:*** Include if applicable] Dental Services [List any additional benefits offered, such as routine dental care.]	[List co-pays / coinsurance]
[***Note:*** Include if applicable] Hearing Services [List any additional benefits offered, such as routine dental care.]	[List co-pays / coinsurance]
[***Note:*** Include if applicable] Vision care Covered services include: • Outpatient physician services for eye care. • For people who are at high risk of glaucoma, such as people with a family history of glaucoma, people with diabetes, and African-Americans who are age 50 and older: glaucoma screening once per year • [Adapt this description if the Plan offers more than is covered by the Original Medicare Plan] One pair of eyeglasses or contact lenses after each cataract surgery that includes insertion of an intraocular lens. Corrective lenses/frames (and replacements) needed after a cataract removal without a lens implant. [Also list any additional benefits offered, such as routine vision exams or glasses.]	[List co-pays / coinsurance]
[***Note:*** Include if applicable] Health and wellness education programs [These are programs focused on clinical health conditions such as hypertension, cholesterol, asthma, and special diets. Programs designed to enrich the health and lifestyles of members include weight management, smoking cessation, fitness, and stress management. Describe the nature of the programs here.]	[List co-pays / coinsurance]

All plans except PDP

Extra "optional supplemental" benefits you can buy

[***Note:*** Include this section if you offer optional supplemental benefits in the Plan. (You may include this section either in the EOC or as an insert to the EOC.)]

Our Plan offers some extra benefits that are not covered by the Original Medicare Plan and not included in your benefits package as a Plan member. These extra benefits are called ["**Optional Supplemental Benefits"].** If you want these optional supplemental benefits, you must sign up for them [and you may have to pay an additional premium for them]. The optional supplemental benefits included in this section are subject to the same appeals process as any other benefits.

[***Note:*** Insert plan specific optional benefits, premiums, deductible, co-pays and coinsurance and rules using a chart like the Benefits Chart above. Insert plan specific procedures on how to elect optional supplemental coverage, including application process and effective dates and on how to discontinue optional supplemental coverage, including refund of premiums. Also insert any restrictions on members' re-applying for optional supplemental coverage (e.g., must wait until next annual enrollment period).]

All plans except PDP and PFFS

[Getting care using our Plan's traveler benefit]

[**Note:** If your plan offers traveler benefits to members who are out of your service area, adapt and expand the following paragraphs as needed to describe the traveler benefits and rules related to receiving the out-of-area coverage.]

You may get care when you are outside the service area. You will usually pay higher costs for the care because you will get your care from out-of-network providers, but you won't pay extra if you are getting care for a medical emergency. If you have questions about your medical costs when you travel, please call Member Services.

Problems getting medical care or services you believe are covered for you?

If you have any concerns or problems getting the medical care or services you believe are covered for you as a member, we want to help. Please call Member Services. You have the right to ask for a decision about getting services or payment for services that you believe are covered as a member. See Section 9 for information.

Can your benefits change during the year?

The Medicare Program doesn't allow us to decrease your benefits during the calendar year. The only time your benefits may decrease is at the beginning of the next calendar year. The Medicare Program must approve any decreases we make in your benefits. We will tell you in October if there are going to be any increases or decreases in your benefits for the next calendar year that begins on January 1.

At any time during the year, the Medicare Program can change its national coverage. Since we cover what the Original Medicare Plan covers, we would have to make any change that the Medicare Program makes. [***Note to Cost plans:*** delete the following section.] If your benefits increase, the Original Medicare Plan will pay for the benefit for the rest of the calendar year. In those cases, you will have to pay the Original Medicare Plan out-of-pocket amounts for those services. We will let you know in advance if you will have to pay the Original Medicare Plan out-of-pocket costs for an increased benefit.]

All MA Plan Types except Cost plans

What is your cost for services that aren't covered by our Plan?

You are responsible to pay the full cost of care and services that aren't covered by our Plan. Other sections of this booklet describe the services that are covered under our Plan and the rules that apply to getting your care as a plan member.

If you have any questions about whether our Plan will pay for a service or item, including inpatient hospital services, you have the right to have an organization determination [or a coverage determination] made for the service. You may call Member Services and tell us you would like a decision on whether the service will be covered.

For covered services that have a benefit limitation, you pay the full cost of any services you get after you have used up your benefit for that type of covered service [***Note*:** Explain whether paying for costs once a benefit limit has been reached will count toward an out-of-pocket maximum.] You can call Members Services when you want to know how much of your benefit limit you have already used.

Cost Plans

What is your cost for services that are not covered by Medicare or our Plan

You are responsible for paying for the full cost of care and services that aren't covered by the Original Medicare Plan or our Plan. Other sections of this booklet describe the services that are covered by our Plan and the rules that apply to getting your care as a plan member. You also have the right to seek care from any provider that is qualified to treat Medicare members. However, in that case it will be the original Medicare program that pays your claims and you will owe the Original Medicare Plan cost-sharing amounts.

If you have any question whether Medicare or our Plan will pay for a service, including inpatient hospital services, you have the right under law to have a written/binding advance coverage determination made for the service. Call our Plan and tell us you would like a decision if the service or item will be covered.

For covered services that have a benefit limitation, you pay the full cost of any services you get after you have used up your benefit for that type of covered service, unless your plan offers, as a covered supplemental benefit, coverage beyond the Original Medicare Plan limits. [Explain whether paying for costs once a benefit limit has been reached will count toward an out-of-pocket maximum.]

You can call Member Services when you want to know how much of your benefit limit you have already used.

How can you participate in a clinical trial?

A "clinical trial" is a way of testing new types of medical care, like how well a new cancer drug works. A clinical trial is one of the final stages of a research process that helps doctors and researchers see if a new approach works and if it is safe.

Medicare pays for routine costs if you take part in a clinical trial that meets Medicare requirements. Routine costs include costs like room and board for a hospital stay that Medicare would pay for even if you weren't in a trial, an operation to implant an item that is being tested, and items and services to treat side effects and complications arising from the new care. Generally, Medicare will not cover the costs of experimental care, such as the drugs or devices being tested in a clinical trial.

There are certain requirements for Medicare coverage of clinical trials. If you participate as a patient in a clinical trial that meets Medicare requirements, the Original Medicare Plan (and not our Plan) pays the clinical trial doctors and other providers for the covered services you get that are related to the clinical trial. When you are in a clinical trial, you may stay enrolled in our Plan and continue to get the rest of your care that is unrelated to the clinical trial through our Plan.

[***Note:*** If your plan charges the Original Medicare cost-sharing amounts for clinical trial services, use this language: "You will have to pay the same coinsurance amounts charged under Original Medicare for the services you receive when participating in a qualifying clinical trial, but you do not have to pay the Original Medicare Part A or Part B deductibles because you are enrolled in our Plan."]

[***Note:*** If you will cover all or a portion of the FFS coinsurance for your members participating in a clinical trial, say so here and/or modify the previous sentences. Also, specify the conditions (if any) under which such additional coverage is available (e.g., if the member participates in a clinical trial sponsored by one of your contracting providers.)]

You don't need to get a referral (approval in advance) from a network provider to join a clinical trial, and the clinical trial providers don't need to be network providers. However, please be sure to **tell us before you start participation in a clinical trial** so that we can keep track of your health care services. When you tell us about starting participation in a clinical trial, we can let you know what services you will get from clinical trial providers and the cost for those services. You may view or download the publication "Medicare and Clinical Trials" At www.medicare.gov under "Search Tools" select "Find a Medicare Publication." Or, call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

How to access care in Religious Non-medical Health Care Institutions

Care in a Medicare-certified Religious Non-medical Health Care Institution (RNHCI) is covered by our Plan under certain conditions. Covered services in an RNHCI are limited to non-religious aspects of care. To be eligible for covered services in a RNHCI, you must have a medical

condition that would allow you to receive inpatient hospital or skilled nursing facility care. You may get services furnished in the home, but only items and services ordinarily furnished by home health agencies that are not RNHCIs. In addition, you must sign a legal document that says you are conscientiously opposed to the acceptance of "non-excepted" medical treatment. ("Excepted" medical treatment is medical care or treatment that you receive involuntarily or that is required under federal, state or local law. "Non-excepted" medical treatment is any other medical care or treatment.) [***Note***: Plans that do not require authorization, delete the following sentence.] Your stay in the RNHCI is not covered by our Plan unless you obtain authorization (approval) in advance from our Plan. [***Note:*** Explain whether Medicare Inpatient Hospital coverage limits apply (reference Benefits Chart) or whether there is unlimited coverage for this benefit.]

5. Part D Prescription Drug Benefits and How Much You Pay

PDP and MA-PD Plans

This section describes how your drug coverage from our Plan works, and has a chart that tells you what you must pay for covered drugs. These are the benefits you get as a member of our Plan. Section 7 tells about drugs that are not covered (these are called "exclusions").

How much do you pay for drugs covered by this Plan?

If you qualify for extra help with your drug costs, your costs for your drugs may be different from those described below. For more information, see the "Evidence of Coverage Rider for those who Receive Extra Help Paying for their Prescription Drugs" that you received with this Evidence of Coverage. If you do not already qualify for extra help, see "Do you qualify for extra help?" in Section 2 for more information.

When you fill a prescription for a covered drug, you may pay part of the costs for your drug. The amount you pay for your drug depends on what coverage level you are in (i.e., [deductible,] initial coverage period, the period after you reach your initial coverage limit, and catastrophic level), the type of drug it is, and whether you are filling your prescription at an in-network or out-of-network pharmacy. Each phase of the benefit is described below. Refer to your plan formulary to see what drugs we cover [and what tier they are on]. (More information on the formulary is included later in this section.)

[Deductible]

[***Note to Plans with a deductible:*** insert "You will pay a yearly deductible of $[deductible amount]. OR [***Note to plans with a deductible on only a subset of drugs:*** insert "You will pay a yearly deductible of $[deductible amount] on [list of applicable drug tiers] drugs. For these drugs you will not have to pay any deductible and will start receiving coverage immediately."] [After you meet the deductible, you will reach the initial coverage period.]

Initial Coverage Period

During the **initial coverage period**, we will pay part of the costs for your covered drugs and you will pay the other part. The amount you pay when you fill a covered prescription is called the [***Note:*** Plans insert either "coinsurance" OR "co-payment" OR "coinsurance or co-payment"]. Your [coinsurance/co-payment/coinsurance or copayment] will vary depending on the drug and where the prescription is filled.

You will pay the following for your covered prescription drugs*:

*[**Note:** If plan has any preferred pharmacies, the chart must be modified to reflect the appropriate member cost-sharing for preferred and non-preferred pharmacies. The Plan may also add tiers to the chart as necessary.]*

[Drug Tier]	**Retail Co-pay/ Coinsurance (30 day Supply)**	**Retail Co-pay/ Coinsurance (90 day Supply)**	**[Mail-Order Co-pay/ Coinsurance (30-day supply)]**	**Mail-Order Co-pay/ Coinsurance (90-day supply)**	**Out of Network Co-pay/ Coinsurance***
[Tier Name 1]	[Co-pay/	[Co-pay/	[Co-pay/	[Co-pay/	[Co-pay/

	Coinsurance]	Coinsurance]	Coinsurance]	Coinsurance]	Coinsurance]
[Tier Name 2]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]
[Tier Name 3]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]	[Co-pay/ Coinsurance]

* Amounts in this chart may vary according to your individual out-of-network cost-sharing responsibility.

Once your total drug costs reach $[ICL], you will reach your **initial coverage limit**. Your initial coverage limit is calculated by adding payments made by this Plan and you. If other individuals, organizations, current or former employer/union, and another insurance plan or policy help pay for your drugs under this Plan, the amount they spend may count towards your initial coverage limit.

[We offer additional coverage on some prescription drugs that are not normally covered in a Medicare Prescription Drug Plan. Payments made for these drugs will not count towards your initial coverage limit or total out-of-pocket costs. [***Note:*** insert only if plan pays for OTC drugs as part of its administrative costs: "We also provide some over-the-counter medications exclusively for your use. These over-the-counter drugs are provided at no cost to you."] To find out which drugs our plan covers, refer to your formulary.]

Coverage Gap

[***Note:*** Insert either "After your total drug costs reach $[ICL] you, or others on your behalf, will pay 100% for your drugs until your total out-of-pocket costs reach $[TrOOP Amount], and you qualify for catastrophic coverage." OR "After your total drug costs reach $[ICL], we will continue to provide some prescription drug coverage until your total out-of-pocket costs reach $[TrOOP Amount." [***Note:*** Plans offering coverage in the coverage gap must describe that coverage, noting that cost-sharing for coverage in the coverage gap does not count toward the TrOOP amount.] Once your total out-of-pocket costs reach $[TrOOP amount], you will qualify for catastrophic coverage."]

Catastrophic Coverage

All Medicare Prescription Drug Plans include catastrophic coverage for people with high drug costs. In order to qualify for catastrophic coverage, you must spend $[TrOOP amount] out-of-pocket for the year. When the total amount you have paid toward [your deductible,] [***Note:*** *Plan insert either:* "coinsurance" *OR* "co-payment" *OR* "coinsurance or co-payment",] and the cost for covered Part D drugs after you reach the initial coverage limit reaches $[TrOOP], you will qualify for catastrophic coverage. During catastrophic coverage you will pay: [the greater of 5% coinsurance or $[*Insert 2009 catastrophic cost-sharing amount for generics/preferred multisource drugs*] for generics or drugs that are treated like generics and $[*Insert 2009 catastrophic cost-sharing amount for all other drugs*] for all other drugs] *OR* [*Insert appropriate tiered cost-sharing amounts*] We will pay the rest.

[***Note***: As mentioned earlier we offer additional coverage on some prescription drugs not normally covered in a Medicare Prescription Drug Plan. The amount you pay when you fill a prescription for these drugs does not count towards your [deductible], initial coverage limit, or

total out-of-pocket costs (that is, the amount you pay does not help you move through the benefit or qualify for catastrophic coverage).]

How is your out-of-pocket cost calculated?

What type of prescription drug payments count toward your out-of-pocket costs?

The following types of payments for prescription drugs may count toward your out-of-pocket costs and help you qualify for catastrophic coverage as long as the drug you are paying for is a Part D drug or transition drug, on the formulary (or if you get a favorable decision on a coverage-determination request, exception request or appeal), obtained at a network pharmacy (or you have an approved claim from an out-of-network pharmacy), and otherwise meets our coverage requirements:

- [Your annual deductible];
- Your [coinsurance/co-payment coinsurance or co-payment];
- Payments you make after the initial coverage limit.

When you have spent a total of $[TrOOP amount] for these items, you will reach the catastrophic coverage level.

What type of prescription drug payments will not count toward your out-of-pocket costs?

[The amount you pay for your monthly premium doesn't count toward reaching the catastrophic coverage level. In addition,] [T/t]he following types of payments for prescription drugs **do not count** toward your out-of-pocket costs:

- Prescription drugs purchased outside the United States and its territories
- Prescription drugs not covered by the Plan
- Prescription drugs obtained at an out-of-network pharmacy when that purchase does not meet our requirements for out-of-network coverage
- [***Note:*** Insert only if plan does not provide coverage for excluded drugs as a supplemental benefit "Non-Part D drugs, including prescription drugs covered by Part A or Part B and other drugs excluded from coverage by Medicare"]

[***Note:*** Insert next two bullets only if plan provides coverage for excluded drugs as a supplemental benefit.]

- [Prescription drugs covered by Part A or Part B]
- [Non-Part D drugs that are covered under our additional coverage but are not normally covered in a Medicare Prescription Drug Plan. Payments made for these drugs will also not count towards your initial coverage limit. See Section 7 for more information on the excluded non-Part D drugs we may cover as part of our additional coverage."]

Who can pay for your prescription drugs, and how do these payments apply to your out-of-pocket costs?

[Except for your premium payments,] any payments you make for Part D drugs covered by us count toward your out-of-pocket costs and will help you qualify for catastrophic coverage. In addition, when the following individuals or organizations pay your costs for such drugs, these

payments will count toward your out-of-pocket costs and will help you qualify for catastrophic coverage:

- Family members or other individuals;
- [Qualified State Pharmacy Assistance Programs (SPAPs);]
- Medicare programs that provide extra help with prescription drug coverage; and
- Most charities or charitable organizations that pay cost-sharing on your behalf. Please note that if the charity is established, run or controlled by your current or former employer or union, the payments usually will not count toward your out-of-pocket costs.

Payments made by the following don't count toward your out-of-pocket costs:

- Group Health Plans;
- Insurance plans and government funded health programs (e.g., TRICARE, the VA, the Indian Health Service, AIDS Drug Assistance Programs); and
- Third party arrangements with a legal obligation to pay for prescription costs (e.g., Workers Compensation).

If you have coverage from a third party such as those listed above that pays a part of or all of your out-of-pocket costs, you must let us know.

We will be responsible for keeping track of your out-of-pocket expenses and will let you know when you have qualified for catastrophic coverage. If you are in a coverage gap or deductible period and have purchased a covered Part D drug at a network pharmacy under a special price or discount card that is outside the Plan's benefit, you may submit documentation and have it count towards qualifying you for catastrophic coverage. In addition, for every month in which you purchase covered prescription drugs through us, you will get an Explanation of Benefits that shows your out-of-pocket cost amount to date.

What drugs are covered by this Plan?

What is a formulary?

A formulary is a list of the drugs that we cover. We will generally cover the drugs listed in our formulary as long as the drug is medically necessary, the prescription is filled at a network pharmacy and other coverage rules are followed. For certain prescription drugs, we have additional requirements for coverage or limits on our coverage. These requirements and limits are described later in this section under "Utilization Management."

The drugs on the formulary are selected by our Plan with the help of a team of health care providers. Both brand-name drugs and generic drugs are included on the formulary. A generic drug has the same active ingredient as the brand-name drug, usually costs less than brand-name drug, and is rated by the Food and Drug Administration (FDA) to be as safe and as effective as the brand-name drug.

Not all drugs are covered by our plan. In some cases, the law prohibits Medicare coverage of certain types of drugs. (See Section 7 for more information about the types of drugs that are not normally covered under a Medicare Prescription Drug Plan.) In other cases, we have decided not to include a particular drug on our formulary.

In certain situations, prescriptions filled at an out-of-network pharmacy may also be covered. See Section 3 for more information about filling a prescription at an out-of-network pharmacy.

How do you find out what drugs are on the formulary?

You may call Member Services to find out if your drug is on the formulary or to request a copy of our formulary. You may also get updated information about the drugs our Plan covers by visiting our Website [***Note:*** Insert formulary Web site URL].

[What are drug tiers?

Drugs on our formulary are organized into different drug tiers, or groups of different drug types. Your [***Note*:** Plan insert either: "coinsurance" *OR* "co-payment" *OR* "coinsurance or co-payment"] depends on which drug tier your drug is in.
You may ask us to make an exception (which is a type of coverage determination) to your drug's tier placement. See Section 9 to learn more about how to request an exception.]

Can the formulary change?

We may make certain changes to our formulary during the year. Changes in the formulary may affect which drugs are covered and how much you will pay when filling your prescription. The kinds of formulary changes we may make include:

- Adding or removing drugs from the formulary
- Adding prior authorizations, quantity limits, and/or step-therapy restrictions on a drug
- [Moving a drug to a higher or lower cost-sharing tier]

If we remove drugs from the formulary, [or add prior authorizations, quantity limits and/or step therapy restrictions on a drug] [or move a drug to a higher cost-sharing tier] and you are taking the drug affected by the change, you will be permitted to continue taking that drug [at the same level of cost-sharing] for the remainder of the Plan year. However, if a brand name drug is replaced with a new generic drug, or our formulary is changed as a result of new information on a drug's safety or effectiveness, you may be affected by this change. We will notify you of the change at least 60 days before the date that the change becomes effective or provide you with a 60 day supply at the pharmacy. This will give you an opportunity to work with your physician to switch to a different drug that we cover or request an exception. (If a drug is removed from our formulary because the drug has been recalled from the pharmacies, we will not give 60 days notice before removing the drug from the formulary. Instead, we will remove the drug immediately and notify members taking the drug about the change as soon as possible.)

What if your drug isn't on the formulary?

If your prescription isn't listed on the formulary, you should first contact Member Services to be sure it isn't covered. If Member Services confirms that we don't cover your drug, you have two options:

1. You may ask your doctor if you can switch to another drug that is covered by us. If you would like to give your doctor a list of covered drugs that are used to treat similar medical conditions, please contact Member Services or go to our formulary [***Note:*** Insert URL] on our Web site.

2. You may ask us to make an exception (a type of coverage determination) to cover your drug. If you pay out-of-pocket for the drug and request an exception that we approve, the Plan will reimburse you. If the exception isn't approved, you may appeal the Plan's denial. See Section 9 for more information on how to request an exception or appeal.

In some cases, we will contact you if you are taking a drug that isn't on our formulary. We can give you the names of covered drugs that also are used to treat your condition so you can ask your doctor if any of these drugs are an option for your treatment.

If you recently joined this Plan, you may be able to get a temporary supply of a drug you were taking when you joined our Plan if it isn't on our formulary.

Transition Policy

New members in our Plan may be taking drugs that aren't on our formulary or that are subject to certain restrictions, such as prior authorization or step therapy. Current members may also be affected by changes in our formulary from one year to the next. Members should talk to their doctors to decide if they should switch to a different drug that we cover or request a formulary exception in order to get coverage for the drug. See Section 9 under "What is an exception?" to learn more about how to request an exception. Please contact Member Services if your drug is not on our formulary, is subject to certain restrictions, such as prior authorization or step therapy, or will no longer be on our formulary next year and you need help switching to a different drug that we cover or requesting a formulary exception.

During the period of time members are talking to their doctors to determine the right course of action, we may provide a temporary supply of the non-formulary drug if those members need a refill for the drug during the first [must be at least 90] days of new membership in our Plan. If you are a current member affected by a formulary change from one year to the next, we will [***Note:*** Plan insert either "provide a temporary supply of the non-formulary drug if you need a refill for the drug during the first [must be at least 90] days of the new plan year" OR "provide you with the opportunity to request a formulary exception in advance for the following year"].

When a member goes to a network pharmacy and we provide a temporary supply of a drug that isn't on our formulary, or that has coverage restrictions or limits (but is otherwise considered a "Part D drug"), we will cover a [must be at least 30]-day supply (unless the prescription is written for fewer days). After we cover the temporary [must be a least 30]-day supply, we generally will not pay for these drugs as part of our transition policy again. We will provide you with a written notice after we cover your temporary supply. This notice will explain the steps you can take to request an exception and how to work with your doctor to decide if you should switch to an appropriate drug that we cover.

If a new member is a resident of a long-term-care facility (like a nursing home), we will cover a temporary [must be at least 31]-day transition supply (unless the prescription is written for fewer days). If necessary, we will cover more than one refill of these drugs during the first [must be at least 90] days a new member is enrolled in our Plan. If the resident has been enrolled in our Plan for more than [must be at least 90] days and needs a drug that isn't on our formulary [or is subject to other restrictions, such as step therapy or dosage limits,] we will cover a temporary

[must be at least 31]-day emergency supply of that drug (unless the prescription is for fewer days) while the new member pursues a formulary exception.

[***If applicable***: Plans must insert their transition policy for current members with level of care changes.]

Please note that our transition policy applies only to those drugs that are "Part D drugs" and bought at a network pharmacy. The transition policy can't be used to buy a non-Part D drug or a drug out of network, unless you qualify for out of network access. See Section 7 for information about non-Part D drugs.

Vaccines (including administration)

Our Plan's prescription drug benefit covers a number of vaccines, including vaccine administration. The amount you will be responsible for will depend on how the vaccine is dispensed and who administers it. Also, please note that in some situations, the vaccine and its administration will be billed separately. When this happens, you may pay separate cost-sharing amounts for the vaccine and for the vaccine administration.

The following chart describes some of these scenarios. Note that in some cases, you will be receiving the vaccine from someone who is not part of our pharmacy network and that you may have to pay for the entire cost of the vaccine and its administration in advance. You will need to mail us the receipts, following our out-of-network paper claims policy (see Section 3), and then you will be reimbursed up to our normal [coinsurance/co-payment/coinsurance or copayment] for that vaccine. In some cases you will be responsible for the difference between what we pay and what the out-of-network provider charges you. The following chart provides examples of how much it might cost to obtain a vaccine (including its administration) under our Plan. Actual vaccine costs will vary by vaccine type and by whether your vaccine is administered by a pharmacist or by another provider.

Remember you are responsible for all of the costs associated with vaccines (including their administration) during the [deductible or] [coverage gap] phase[(s)] of your benefit.

If you obtain the vaccine at:	**And get it administered by:**	**You pay (and/or are reimbursed)**
The Pharmacy	The Pharmacy (not possible in all States)	You pay our normal [coinsurance/co-payment/coinsurance or co-payment] for the vaccine.
Your Doctor	Your Doctor	You pay up-front for the entire cost of the vaccine and its administration. You are reimbursed this amount less our normal [coinsurance/co-payment/ coinsurance or co-payment] for the vaccine (including administration) [***Note:*** insert the following only if an out-of-network differential is charged "less any difference between the amount the Doctor charges and

		what we normally pay.”*]
The Pharmacy	Your Doctor	You pay our normal [coinsurance/co-payment/coinsurance or co-payment] for the vaccine at the pharmacy and the full amount charged by the doctor for administering the vaccine. You are reimbursed the amount charged by the doctor less any applicable in-network charge for administering the vaccine [***Note:*** insert the following only if an out-of-network differential is charged “less any difference between what the Doctor charges for administering the vaccine and what we normally pay.”*]

* If you receive extra help, we will reimburse you for this difference.

We can help you understand the costs associated with vaccines (including administration) available under our Plan before you go to your doctor. For more information, please contact Member Services.

Drug Management Programs

[***Note:*** Section below applies to all plans except PFFS plans that do not have utilization management programs.]

Utilization management

For certain prescription drugs, we have additional requirements for coverage or limits on our coverage. These requirements and limits ensure that our members use these drugs in the most effective way and also help us control drug plan costs. A team of doctors and/or pharmacists developed these requirements and limits for our Plan to help us provide quality coverage to our members.

The requirements for coverage or limits on certain drugs are listed as follows:

[**Prior Authorization**: We require you to get prior authorization (prior approval) for certain drugs. This means that your provider will need to contact us before you fill your prescription. If we don’t get the necessary information to satisfy the prior authorization, we may not cover the drug.]

[**Quantity Limits**: For certain drugs, we limit the amount of the drug that we will cover per prescription or for a defined period of time. For example, we will provide up to [number of units] per [defined prescription period (i.e., per 30-day period)] for [drug name].]

[**Step Therapy**: In some cases, we require you to first try one drug to treat your medical condition before we will cover another drug for that condition. For example, if Drug A and Drug

B both treat your medical condition, we may require your doctor to prescribe Drug A first. If Drug A does not work for you, then we will cover Drug B.]

[**Generic Substitution**: When there is a generic version of a brand-name drug available, our network pharmacies may recommend and/or provide you the generic version, unless your doctor has told us that you must take the brand-name drug and we have approved this request.]

You can find out if the drug you take is subject to these additional requirements or limits by looking in the formulary or on our formulary Web site ([Insert URL]), or by calling Member Services. If your drug is subject to one of these additional restrictions or limits and your physician determines that you aren't able to meet the additional restriction or limit for medical necessity reasons, you or your physician may request an exception (which is a type of coverage determination). See Section 9 for more information about how to request an exception.

Drug utilization review

We conduct drug utilization reviews for all of our members to make sure that they are getting safe and appropriate care. These reviews are especially important for members who have more than one doctor who prescribes their medications. We conduct drug utilization reviews each time you fill a prescription and on a regular basis by reviewing our records. During these reviews, we look for medication problems such as:

- Possible medication errors
- Duplicate drugs that are unnecessary because you are taking another drug to treat the same medical condition
- Drugs that are inappropriate because of your age or gender
- Possible harmful interactions between drugs you are taking
- Drug allergies
- Drug dosage errors

If we identify a medication problem during our drug utilization review, we will work with your doctor to correct the problem.

Medication therapy management programs

[***Note:*** Section below applies to all plans except PFFS plans that do not have MTM programs.]
We offer medication therapy management programs at no additional cost to members who have multiple medical conditions, who are taking many prescription drugs, and who have high drug costs. These programs were developed for us by a team of pharmacists and doctors. We use these medication therapy management programs to help us provide better coverage for our members. For example, these programs help us make sure that our members are using appropriate drugs to treat their medical conditions and help us identify possible medication errors.

We may contact members who qualify for these programs. If we contact you, we hope you will join so that we can help you manage your medications. Remember, you don't need to pay anything extra to participate.

If you are selected to join a medication therapy management program we will send you information about the specific program, including information about how to access the program.

How does your enrollment in this Plan affect coverage for the drugs covered under Medicare Part A or Part B?

PDP Only

Your enrollment in this Plan doesn't affect Medicare coverage for drugs covered under Medicare Part A or Part B. If you meet Medicare's coverage requirements, your drug will still be covered under Medicare Part A or Part B even though you are enrolled in this Plan. In addition, if your drug would be covered by Medicare Part A or Part B, it can't be covered by us even if you choose not to participate in Part A or Part B. Some drugs may be covered under Medicare Part B in some cases and through this Plan (Medicare Part D) in other cases but never both at the same time. In general, your pharmacist or provider will determine whether to bill Medicare Part B or us for the drug in question.

See your *Medicare & You* handbook for more information about drugs that are covered by Medicare Part A and Part B.

MA-PDs

Your enrollment in this Plan doesn't affect Medicare coverage for drugs that would normally be covered under Medicare Part A or Part B. Depending on where you may receive your drugs, for example in the doctor's office versus from a network pharmacy, there may be a difference in your cost-sharing for those drugs. You may contact our Plan about different costs associated with drugs available in different settings and situations.

6. Your rights and responsibilities as a member of our Plan

All Plan Types

Introduction to your rights and protections

Since you have Medicare, you have certain rights to help protect you. In this section, we explain your Medicare rights and protections as a member of our Plan and we explain what you can do if you think you are being treated unfairly or your rights are not being respected. If you have any questions whether our Plan will pay for a service, including inpatient hospital services, and including services obtained from providers not affiliated with our Plan, you have the right under law to have a written/binding advance coverage determination made for the service. Call us and tell us you would like a decision if the service or item will be covered.

Your right to be treated with dignity, respect and fairness

You have the right to be treated with dignity, respect, and fairness at all times. Our Plan must obey laws that protect you from discrimination or unfair treatment. We don't discriminate based on a person's race, disability, religion, sex, sexual orientation, health, ethnicity, creed, age, or national origin. If you need help with communication, such as help from a language interpreter, please call Member Services. Member Services can also help if you need to file a complaint about access (such as wheel chair access). You may also call the Office for Civil Rights at 1-800-368-1019 or TTY/TDD 1-800-537-7697, or your local Office for Civil Rights.

Your right to the privacy of your medical records and personal health information

There are federal and state laws that protect the privacy of your medical records and personal health information. We protect your personal health information under these laws. Any personal information that you give us when you enroll in this plan is protected. We will make sure that unauthorized people don't see or change your records. Generally, we must get written permission from you (or from someone you have given legal power to make decisions for you) before we can give your health information to anyone who isn't providing your care or paying for your care. There are exceptions allowed or required by law, such as release of health information to government agencies that are checking on quality of care. [***Note to MA-PDs and PDPs***: include "The Plan will release your information, including your prescription drug event data, to Medicare, which may release it for research and other purposes that follow all applicable Federal statutes and regulations."]

The laws that protect your privacy give you rights related to getting information and controlling how your health information is used. We are required to provide you with a notice that tells about these rights and explains how we protect the privacy of your health information. You have the right to look at medical records held at the Plan, and to get a copy of your records (there may be a fee charged for making copies). You also have the right to ask us to make additions or corrections to your medical records (if you ask us to do this, we will review your request and figure out whether the changes are appropriate). You have the right to know how your health information has been given out and used for non-routine purposes. If you have questions or

concerns about privacy of your personal information and medical records, please call Member Services.

Your right to see network providers, get covered services, and get your prescriptions filled within a reasonable period of time

[***Note to HMO and Cost Plans***: insert "As explained in this booklet, you will get most or all of your care from network providers, that is, from doctors and other health providers who are part of our Plan.][***Note to PPO plans:*** insert "As explained in this booklet, you can get your care from plan doctors and other health providers who are part of our Plan. You can also get most or all of your care from non-plan doctors and other health providers who are not part of our Plan.] [***Note to PPOs:*** If your plan does not require any referrals or prior authorization within the preferred network, delete the next two sentences and instead state "You have the right to choose a provider for your care."] You have the right to choose a network provider (we will tell you which doctors are accepting new patients). You have the right to go to a women's health specialist (such as a gynecologist) without a referral [***Note to PPO plans:*** insert "and still pay in-plan cost-sharing"]. You have the right to timely access to your providers and to see specialists when care from a specialist is needed. "Timely access" means that you can get appointments and services within a reasonable amount of time. [***Note to Regional PPO plans***: explain how members will obtain care at in-plan rates in any areas of its region where the plan has a limited contracted provider network.]

All PFFS Plans

As explained in this booklet, you will get most or all of your care from licensed providers who have agreed accept our plan's terms and conditions of payment and treat you. You have the right to seek care from any provider in the U.S. who is eligible to be paid by Medicare and agrees to accept our Plan terms and conditions of payment. "Timely access" means that you can get services within a reasonable amount of time.

PDP & MA-PD Plans

You have the right to timely access to your prescriptions at any network pharmacy.

All Plan Types except PDP

Your right to know your treatment options and participate in decisions about your health care

You have the right to get full information from your providers when you go for medical care, and the right to participate fully in decisions about your health care. Your providers must explain things in a way that you can understand. Your rights include knowing about all of the treatment options that are recommended for your condition, no matter what they cost or whether they are covered by our Plan. [***Insert if applicable:*** "This includes the right to know about the different Medication Management Treatment Programs we offer and in which you may participate."] You have the right to be told about any risks involved in your care. You must be told in advance if any proposed medical care or treatment is part of a research experiment, and be given the choice of refusing experimental treatments.

You have the right to receive a detailed explanation from us if you believe that a provider has denied care that you believe you were entitled to receive or care you believe you should continue to receive. In these cases, you must request an initial decision called an organization determination [or a coverage determination]. Organization determinations [and coverage determinations] are discussed in Section 9.

You have the right to refuse treatment. This includes the right to leave a hospital or other medical facility, even if your doctor advises you not to leave. This includes the right to stop taking your medication. If you refuse treatment, you accept responsibility for what happens as a result of your refusing treatment.

All Plan Types except PDPs

Your right to use advance directives (such as a living will or a power of attorney)

You have the right to ask someone such as a family member or friend to help you with decisions about your health care. Sometimes, people become unable to make health care decisions for themselves due to accidents or serious illness. If you want to, you can use a special form to give someone the legal authority to make decisions for you if you ever become unable to make decisions for yourself. You also have the right to give your doctors written instructions about how you want them to handle your medical care if you become unable to make decisions for yourself. The legal documents that you can use to give your directions in advance in these situations are called "advance directives." There are different types of advance directives and different names for them. Documents called "living will" and "power of attorney for health care" are examples of advance directives.

If you want to have an advance directive, you can get a form from your lawyer, from a social worker, or from some office supply stores. You can sometimes get advance directive forms from organizations that give people information about Medicare. [***Note:*** You can list your organization as a contact if they provide these forms]. Regardless of where you get this form, keep in mind that it is a legal document. You should consider having a lawyer help you prepare it. It is important to sign this form and keep a copy at home. You should give a copy of the form to your doctor and to the person you name on the form as the one to make decisions for you if you can't. You may want to give copies to close friends or family members as well.

If you know ahead of time that you are going to be hospitalized, and you have signed an advance directive, take a copy with you to the hospital. If you are admitted to the hospital, they will ask you whether you have signed an advance directive form and whether you have it with you. If you have *not* signed an advance directive form, the hospital has forms available and will ask if you want to sign one.

Remember, it is *your choice* whether you want to fill out an advance directive (including whether you want to sign one if you are in the hospital). According to law, no one can deny you care or discriminate against you based on whether or not you have signed an advance directive. If you *have* signed an advance directive, and you believe that a doctor or hospital hasn't followed the instructions in it, you may file a complaint with [***Note:*** List appropriate state-specific agency here, such as State Department of Health. Provide contact information.]

Your right to get information about our Plan, network providers, [drugs], health care coverage, and costs

[***Note to non-network PFFS plans and MSA plans:*** delete all references to network providers from this section.]

This booklet tells you what medical services are covered for you as a plan member and what you have to pay. If you need more information, please call Member Services. You have the right to an explanation from us about any bills you may get for services not covered by our Plan. We must tell you in writing why we will not pay for or approve a service, and how you can file an appeal to ask us to change this decision. See Section 9 for more information about filing an appeal.

You also have the right to get information from us about our Plan. This includes information about our financial condition, about our Plan health care providers and their qualifications, about information on our network pharmacies, and how our Plan compares to other health plans. You have the right to find out from us how we pay our doctors. To get any of this information, call Member Services. You have the right under law to have a written/binding advance coverage determination made for the service, even if you obtain this service from a provider not affiliated with our organization.

All Plan Types

Your right to make complaints

You have the right to make a complaint if you have concerns or problems related to your [coverage or care.] A complaint can be called a grievance, an organization determination, or a coverage determination depending on the situation. See Section 8 for more information about complaints. If you make a complaint, we must treat you fairly (i.e., not retaliate against you) because you made a complaint. You have the right to get a summary of information about the appeals and grievances that members have filed against our Plan in the past. To get this information, call Member Services.

How to get more information about your rights

If you have questions or concerns about your rights and protections, you can

1. Call Member Services at the number on the cover of this booklet.
2. Get free help and information from your SHIP (contact information for your SHIP is in the Contacts section of this booklet).
3. Visit www.medicare.gov to view or download the publication "Your Medicare Rights & Protections."
4. Call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

What can you do if you think you have been treated unfairly or your rights are not being respected?

If you think you have been treated unfairly or your rights have not been respected, you may call Member Services or:

- If you think you have been treated unfairly due to your race, color, national origin, disability, age, or religion, you can call the Office for Civil Rights at 1-800-368-1019 or TTY/TDD 1-800-537-7697, or call your local Office for Civil Rights.
- If you have any other kind of concern or problem related to your Medicare rights and protections described in this section, you can also get help from your SHIP.

All Plan Types except PDPs

Your responsibilities as a member of our Plan

Your responsibilities include the following:

- Getting familiar with your coverage and the rules you must follow to get care as a member. You can use this booklet to learn about your coverage, what you have to pay, and the rules you need to follow. Call Member Services if you have questions.
- Using all of your insurance coverage. If you have additional [health insurance coverage *OR* prescription drug coverage] besides our Plan, it is important that you use your other coverage in combination with your coverage as a member of our Plan to pay your [health care *OR* prescription drug] expenses. This is called "coordination of benefits" because it involves coordinating all of the [health *OR* drug] benefits that are available to you.
- **You are required to tell our Plan if you have additional [health insurance or drug coverage]. Call Member Services.**
- Notifying providers when seeking care (unless it is an emergency) that you are enrolled in our Plan and you must present your plan enrollment card to the provider. [***Note to Cost plans:*** use "Notifying out-of-network providers when seeking care (unless it is an emergency) that although you are enrolled in our Plan, the provider should bill original Medicare. You should present your plan enrollment card and your Medicare card."]
- Giving your doctor and other providers the information they need to care for you, and following the treatment plans and instructions that you and your doctors agree upon. Be sure to ask your doctors and other providers if you have any questions and have them explain your treatment in a way you can understand.
- Acting in a way that supports the care given to other patients and helps the smooth running of your doctor's office, hospitals, and other offices.
- Paying your [plan premiums and] [coinsurance/co-payment/coinsurance or co-payment] for your covered services. You must pay for services that aren't covered.
- Letting us know if you have any questions, concerns, problems, or suggestions. If you do, please call Member Services.

MA-PDs and PDPs

Your right to get information about your drug coverage and costs

This EOC tells you what you have to pay for prescription drugs as a member of our Plan. If you need more information, please call Member Services. You have the right to an explanation from us about any bills you may get for drugs not covered by our Plan. We must tell you in writing why we will not pay for a drug, and how you can file an appeal to ask us to change this decision. See Section 9 for more information about filing an appeal. You also have the right to receive an explanation from us of any utilization-management requirements, such as step therapy or prior authorization that may apply to your plan. If you have any questions please review our formulary Web site or call Member Services.

Your right to get information about our Plan and our network pharmacies

You have the right to get information about our Plan. This includes information about our financial condition and about our network pharmacies. To get any of this information, call Member Services.

Your responsibilities as a member of our Plan

Your responsibilities include the following:

- Getting familiar with your coverage and the rules you must follow to get care as a member. You can use this booklet to learn about your coverage, what you have to pay, and the rules you need to follow. Call Member Services if you have questions.
- Using all of your insurance coverage. If you have additional prescription drug coverage besides our Plan, it is important that you use your other coverage in combination with your coverage as a member of our Plan to pay your prescription drug expenses. This is called "coordination of benefits" because it involves coordinating all of the drug benefits that are available to you.
- **You are required to tell our Plan if you have additional drug coverage. Call Member Services.**

What can you do if you think you have been treated unfairly or your rights aren't being respected?

For concerns or problems related to your Medicare rights and protections described in this section, you may call Member Services. You can also get help from your State Health Insurance Assistance Program, or SHIP.

MSA Plans

Special tax-reporting responsibilities of members of a Medicare Medical Savings Account (MSA)

[Plan name] is a Medicare Medical Savings Account plan. MSA enrollees must file Form 1040, U.S. Individual Income Tax Return, along with Form 8853, "Archer MSAs and Long-Term Care Insurance Contracts," to the Internal Revenue Service (IRS) for any year distributions are made from their Medicare MSA account to ensure that they are not taxed on their MSA account withdrawals. These tax forms must be filed for any year in which a MSA account withdrawal is made even if the enrollee has no taxable income or any other reason for filing Form 1040. Note that MSA account withdrawals for qualified medical expenses are tax-free, while account withdrawals for non-medical expenses are subject to both income tax and a 50% tax penalty.

- You will receive a statement (Form 1099-SA) from your MSA bank trustee reporting your MSA savings account distributions by January 31 each year. The bank trustee is also required to report this information to the IRS.
- You must file tax forms 1040 and 8853 even if you are not otherwise required to file an income tax return in order to avoid owing taxes on MSA account withdrawals.

- You must file by April 15 of the following year, unless you request an extension on your tax return.

Important reminder: Information reported to the IRS on MSA account withdrawals for qualified medical expenses is NOT the same expense information that will count towards your MSA plan deductible. Remember that only Medicare Part A and Part B expenses will count towards your MSA plan deductible. Therefore, you will also want to keep track of your qualified medical expenses that are also Part A and Part B expenses and that will count towards your MSA plan deductible.

More information on MSA tax-reporting requirements

There are two IRS Publications relevant to Medicare MSAs.

- IRS Publication 969, titled "Health Savings Accounts and Other Tax-Favored Health Plans", includes information on medical savings accounts, including Medicare MSAs. Publication 969 has information on what are qualified medical expenses for MSAs, which adds to medical expense information in Publication 502. (*See below for information from Publication 969 on qualified medical expenses. You generally cannot use your MSA account to pay for health insurance premiums, including drug plan premiums. You can, however, use your MSA account to purchase non-prescription drugs.)
- IRS Publication 502, titled "Medical and Dental Expenses", defines what types of services generally count as qualified medical expenses for IRS tax purposes.

These publications are available on the web at www.irs.gov or from 1-800-TAX-FORM (1-800-829-3676). On the web, look up publications by number at "Publications".

Form 1040, U.S. Individual Income Tax Return, and Form 8853 must be filed in order to avoid owing taxes on MSA account withdrawals.

- Form 8853, "Archer MSAs and Long-Term Care Insurance Contracts", Section B, is the place to report both on Medicare MSA account withdrawals (which the IRS calls distributions) and on the enrollee's qualified medical expenses for the year.

Form 8853 and Form 8853 Instructions are available at www.irs.gov or from 1-800-TAX-FORM (1-800-829-3676). On the web, look up forms by number at "Forms". (Note: IRS tax code considers Medicare MSAs a type of "Archer" MSA, therefore, IRS references to "Archer" MSAs include Medicare MSAs.)

* More details on qualified medical expenses discussed in Publication 969:

- You generally cannot use your MSA account to pay for health insurance premiums. Health insurance premiums, including drug plan premiums, are not a qualified medical expense when you pay for them with money from your MSA account (while these are included in Publication 502). Other insurance premiums, such as for long-term care, are qualified medical expenses for purposes of both Publication 969 and Publication 502.

- You can use your MSA account to purchase non-prescription drugs. Non-prescription drugs are qualified medical expenses in MSAs. (Note that insulin is the only non-prescription drug included in Publication 502).

Who to call for more information or for help in preparing your tax return

You may call the IRS toll-free for live telephone assistance from Monday – Friday, 7 a.m. – 10 p.m. local time, or you may visit your local IRS office.

- For individuals: 1-800-829-1040
- For people with hearing impairments: 1-800-829-4059 (TDD)
- Face-to-Face Assistance -- In certain areas, IRS also has local offices. Find your local office at www.irs.gov/localcontacts/index.html on the web.

7. General Exclusions

All MA & MA-PD Plan Types

Introduction

The purpose of this section is to tell you about [medical care and services,] [items,] [and] [drugs] that aren't covered ("are excluded") or are limited by our Plan. The list below tells about these exclusions and limitations. The list describes [services,] [items,] [and] [drugs] that aren't covered under any conditions, [and some services that are covered only under specific conditions.] (The Benefits Chart in Section 4 also explains about some restrictions or limitations that apply to certain services).

If you get [services, items AND/OR drugs] that are not covered, you must pay for them yourself

We won't pay for the exclusions that are listed in this section (or elsewhere in this booklet), and neither will the Original Medicare Plan, unless they are found upon appeal to be [services,] [items,] [and] [drugs] that we should have paid or covered (appeals are discussed in Section 9).

All MA Plan Types and Cost Plans

What services are not covered or are limited by our Plan?

[***Note:*** You may add references to optional supplemental benefits where applicable, using the following format: However, [this item / these items] are available under Optional Supplemental Benefits.] [***Note to SNPs:*** Plans may, as appropriate, remove or modify language regarding benefit exclusions when the benefits are covered by the Plan under the Medicaid program, e.g., excluded drugs.]

In addition to any exclusions or limitations described in the Benefits Chart in Section 4, or anywhere else in this booklet [Add mention of other places where exclusions are given, such as addenda], **the following items and services aren't covered under the Original Medicare Plan or by our plan:**

[***Note:*** The services listed in the remaining bullets are excluded from the Original Medicare benefit package. If any services below are covered supplemental benefits, delete them from this list. When plans partially exclude services excluded by Medicare they need not delete the item completely from the list of excluded services but may revise the text accordingly to describe the extent of the exclusion]

1. Services that aren't reasonable and necessary, according to the standards of the Original Medicare Plan, unless these services are otherwise listed by our Plan as a covered service.
2. Experimental or investigational medical and surgical procedures, equipment and medications, unless covered by the Original Medicare Plan or unless, for certain services, the procedures are covered under an approved clinical trial. CMS will continue to pay through Original Medicare for clinical trial items and services covered under the September 2000 National Coverage Determination that are provided to MA plan members. Experimental

procedures and items are those items and procedures determined by our Plan and the Original Medicare Plan to not be generally accepted by the medical community.

3. Surgical treatment of morbid obesity *unless* medically necessary and covered under the Original Medicare plan.
4. Private room in a hospital, *unless* medically necessary.
5. Private duty nurses.
6. Personal convenience items, such as a telephone or television in your room at a hospital or skilled nursing facility.
7. Nursing care on a full-time basis in your home.
8. Custodial care unless it is provided in conjunction with skilled nursing care and/or skilled rehabilitation services. This includes care that helps people with activities of daily living like walking, getting in and out of bed, bathing, dressing, eating and using the bathroom, preparation of special diets, and supervision of medication that is usually self-administered.
9. Homemaker services.
10. Charges imposed by immediate relatives or members of your household.
11. Meals delivered to your home.
12. Elective or voluntary enhancement procedures, services, supplies and medications including but not limited to: Weight loss, hair growth, sexual performance, athletic performance, cosmetic purposes, anti-aging and mental performance unless medically necessary.
13. Cosmetic surgery or procedures, unless needed because of accidental injury or to improve the function of a malformed part of the body. All stages of reconstruction are covered for a breast after a mastectomy, as well as for the unaffected breast to produce a symmetrical appearance.
14. Routine dental care (such as cleanings, fillings, or dentures) or other dental services. However, non-routine dental services received at a hospital may be covered.
15. Chiropractic care is generally not covered under the Plan, (with the exception of manual manipulation of the spine,) and is limited according to Medicare guidelines.
16. Routine foot care is generally not covered under the Plan and is limited according to Medicare guidelines.
17. Orthopedic shoes unless they are part of a leg brace and are included in the cost of the brace. Exception: Orthopedic or therapeutic shoes are covered for people with diabetic foot disease.
18. Supportive devices for the feet. Exception: Orthopedic or therapeutic shoes are covered for people with diabetic foot disease.
19. Hearing aids and routine hearing examinations.
20. Eyeglasses (except after cataract surgery), routine eye examinations, radial keratotomy, LASIK surgery, vision therapy and other low vision aids and services.
21. Self-administered prescription medication for the treatment of sexual dysfunction, including erectile dysfunction, impotence, and anorgasmy or hyporgasmy.
22. Reversal of sterilization procedures, sex change operations, and non-prescription contraceptive supplies and devices.
23. Acupuncture.
24. Naturopath services.

[***Note:*** If you get a waiver from Medicare to exclude the limited abortion services covered by the Original Medicare Plan, you must provide the disclaimer in the bullet point below. List the specific services you won't provide and an alternative method (telephone number) for getting information on the covered services a member won't get based on moral or religious grounds.]

25. [Counseling or referral services that our Plan objects to based on moral or religious grounds. In the case of our Plan, we won't give counseling or referral services related to [enter the benefits for which you will not provide counseling or referral services, e.g., advance directives related to withholding nutrition/treatment, etc.]. To the extent these services are covered by Medicare, they will be covered under the Original Medicare Plan.]
26. Services provided to veterans in Veterans Affairs (VA) facilities. However, in the case of emergency services received at a VA hospital, if the VA cost-sharing is more than the cost-sharing required under our Plan, we will reimburse veterans for the difference. Members are still responsible for our Plan cost-sharing amount.
27. Any of the services listed above that aren't covered will remain not covered even if received at an emergency facility. For example, non-authorized, routine conditions that do not appear to a reasonable person to be based on a medical emergency are not covered if received at an emergency facility.

PDP and MA-PD Plans

Excluded Drugs

[***Note to Enhanced Alternative Plans and SNPs:*** plans may revise language under this heading to reflect their coverage of Part D excluded drugs.]

This section talks about drugs that are "excluded," meaning they aren't normally covered by a Medicare Prescription Drug Plan. If you get drugs that are excluded, you must pay for them yourself. We won't pay for the exclusions that are listed in this section (or elsewhere in this booklet), and neither will the Original Medicare Plan, unless they are found upon appeal to be drugs that we should have paid or covered (appeals are discussed in Section 9).

- A Medicare Prescription Drug Plan can't cover a drug that would be covered under Medicare Part A or Part B.
- A Medicare Prescription Drug Plan can cover off-label uses (meaning for uses other than those indicated on a drug's label as approved by the Food and Drug Administration) of a prescription drug only in cases where the use is supported by certain reference-book citations. Congress specifically listed the reference books that list whether the off-label use would be permitted. (These reference books are: American Hospital Formulary Service Drug Information, the DRUGDEX Information System, and USPDI or its successor.) If the use is not supported by one of these reference books, known as compendia, then the drug is considered a non-Part D drug and cannot be covered by our Plan.
- By law, certain types of drugs or categories of drugs are not normally covered by Medicare Prescription Drug Plans. These drugs are not considered Part D drugs and may be referred to as "exclusions" or "non-Part D drugs." These drugs include:

Non-prescription drugs (or over-the counter drugs)	Drugs when used for treatment of anorexia, weight loss, or weight gain
Drugs when used to promote fertility	Drugs when used for cosmetic purposes or to promote hair growth
Drugs when used for the symptomatic relief of cough or colds	Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations

Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer as a condition of sale	Barbiturates and Benzodiazepines
Drugs, such as Viagra, Cialis, Levitra, and Caverject, when used for the treatment of sexual or erectile dysfunction	

[We offer additional coverage of some prescription drugs not normally covered in a Medicare Prescription Drug Plan. [*Note*: Insert details about the excluded drugs your plan does cover, including whether you place any limits on that coverage.] The amount you pay when you fill a prescription for these drugs does not count towards qualifying you for catastrophic coverage. In addition, if you are receiving extra help from Medicare to pay for your prescriptions, the extra help will not pay for these drugs. Please refer to your formulary or call Member Services for more information.]

8. How to file a Grievance

[***Note to all plans:*** If this EOC is for a single state, replace the references to the QIO with the actual name of the QIO in that state throughout the document, adapting any wording as needed to accommodate this substitution.]
[***Note to SNPs***: Revise the following language, as appropriate, to incorporate information about the process available to beneficiaries to pursue grievances related to Medicaid-covered services.]

All plan types

What is a Grievance?

A grievance is any complaint, other than one that involves a request for an initial determination as described in Section 9 of this manual.

Grievances do not involve problems related to approving or paying for [***Note to MA-PDs and PDPs:*** insert "Part D drugs,"] [***Note to all plan types except PDPs:*** insert "medical care or services, problems about having to leave the hospital too soon, and problems about having Skilled Nursing Facility (SNF), Home Health Agency (HHA), or Comprehensive Outpatient Rehabilitation Facility (CORF) services ending too soon].

If we will not give you the [***Note to all plan types except PDPs:*** insert "medical care or services"] [***Note to MA-PDs and PDPs:*** insert "or Part D drugs"] you want, [***Note to all plan types except PDPs:*** insert "you believe that you are being released from the hospital or SNF too soon, or your HHA or CORF services are ending too soon,"] you must follow the rules outlined in Section 9.

What types of problems might lead to your filing a grievance?

- Problems with the service you receive from Member Services.
- If you feel that you are being encouraged to leave (disenroll from) the Plan.
- If you disagree with our decision not to give you a "fast" decision or a "fast" appeal. We discuss these fast decisions and appeals in more detail in Section 9.
- We don't give you a decision within the required time frame.
- We don't give you required notices.
- You believe our notices and other written materials are hard to understand.
- [***MA-PDs and PDPs*:** insert bullet] Waiting too long for prescriptions to be filled.
- [***MA-PDs and PDPs*:** insert bullet] Rude behavior by network pharmacists or other staff.
- [***MA-PDs and PDPs*:** insert bullet] We don't forward your case to the Independent Review Entity if we do not give you a decision on time.
- [***All plan types except PDPs:*** insert bullet] Problems with the quality of the medical care or services you receive, including quality of care during a hospital stay.
- [***All plan types except PDPs:*** insert bullet] Problems with how long you have to wait on the phone, in the waiting room, or in the exam room.
- [***All plan types except PDPs:*** insert bullet] Problems getting appointments when you need them, or waiting too long for them.
- [***All plan types except PDPs:*** insert bullet] Rude behavior by doctors, nurses, receptionists, or other staff.

- [***All plan types except PDPs:*** insert bullet] Cleanliness or condition of doctor's offices, clinics, or hospitals.

If you have one of these types of problems and want to make a complaint, it is called "filing a grievance." In certain cases, you have the right to ask for a "fast grievance," meaning we will answer your grievance within 24 hours. We discuss fast grievances in more detail in Section 9.

Filing a grievance with our Plan

If you have a complaint, please call the phone number for [***Note to all plan types except PDPs:*** insert "**Part C Grievances** (for complaints about medical care or services)"] [and/or] [***Note to MA-PDs and PDPs:*** insert "**Part D Grievances** (for complaints about Part D drugs)"] in Section 12 of this booklet. We will try to resolve your complaint over the phone. If you ask for a written response, we will respond in writing to you. **If we cannot resolve your complaint over the phone, we have a formal procedure to review your complaints. We call this** [***Note to all plans:*** insert name of your grievance procedure, then insert description of the procedures (including time frames) and instructions about what members need to do if they want to use it. Be sure to describe expedited grievance time frames for grievances about decisions to not conduct expedited organization/coverage determinations or reconsiderations/redeterminations.]

We must address your grievance as quickly as your case requires based on your health status, but no later than 30 days after receiving your complaint. We may extend the time frame by up to 14 days if you ask for the extension, or if we justify a need for additional information and the delay is in your best interest.

[***Note to all plan types except PDPs*:** Describe expedited grievance time frames for grievances about decisions to take extensions on initial decisions or appeals.]

For quality of care problems, you may also complain to the QIO

You may complain about the quality of care received under Medicare, including care during a hospital stay. You may complain to us using the grievance process, to an independent review organization called the Quality Improvement Organization QIO, or both. If you file with the QIO, we must help the QIO resolve the complaint. See Section 12 for more information about the QIO.

9. Getting the [Part D Prescription Drugs and/or Part C Medical Care and Services] You Need

[*Note to all plans:* If this EOC is for a single state, replace the references to the QIO with the actual name of the QIO in that state throughout the document, adapting any wording as needed to accommodate this substitution.]

Introduction

This section explains how you ask for your [***Note:*** plans insert either "Part D drugs" AND/OR "medical care or services" as applicable to your plan type] or payments in different situations. [***Note to all plan types except PDPs:*** insert "This section also explains how to make complaints when you think you are being asked to leave the hospital too soon, or you think your skilled nursing facility (SNF), home health (HHA) or comprehensive outpatient rehabilitation facility (CORF) services are ending too soon."] These types of requests and complaints are discussed below in Part 1[***Note to all plan types except PDPs:*** insert ", Part 2, or Part 3"].

Other complaints that do not involve the types of requests or complaints discussed below in Part 1[***Note to all plan types except PDPs:*** insert ", Part 2, or Part 3"] are considered **grievances**. You would file a grievance if you have any type of problem with us or one of our network providers that does not relate to coverage for [Part D drugs and/or medical care or services]. For more information about grievances, see Section 8.

[***Note to Cost Plans***: Cost plans may adapt the wording of this paragraph to reflect how the plan is structured.] As stated in Section 3, you may use out-of-network providers. However, if you use out-of-network providers for care that is not emergent or urgently needed care, you will usually have to pay Original Medicare cost-sharing amounts for your care. If you have a complaint about a bill when you receive care from an out-of-network provider, the appeals process in Section 9 will not apply (unless you were directed to go to that out-of-network provider by the Plan or one of the network providers). Instead, please refer to the notice of the service you receive from Original Medicare. It is called a Medicare Summary Notice (MSN). The MSN will provide information on how to appeal a decision made by Original Medicare.

[***Note: All Cost Plans except HCPPs***: add.] If you have a complaint regarding a service provided by a hospital or skilled nursing facility that is not part of the Plan network, you will follow Original Medicare rules as provided in your 2009 *Medicare & You* Handbook. However, if you have a complaint involving a plan network hospital or skilled nursing facility (or you were directed to go to a non-plan network hospital or skilled nursing facility by the Plan or one of the network providers), you will follow the instructions contained in this section. This is true even if you received a Medicare Summary Notice (MSN) indicating that a claim was processed but not covered by Original Medicare. Furthermore, if you have a complaint regarding an emergency service or urgently needed care, or the cost-sharing for hospital or skilled nursing facility services, you will follow the instructions contained in this section. See Section 3 for guidance on what is emergency or urgently needed care.

Part 1. Requests for [Part D drugs and/or medical care or services] **or payments.**

[***Note to Cost-Plans***: insert "Please note that if you have complaints about optional supplemental benefits, you file an appeal."]

[***Note to MSAs***: insert "This includes complaints about our decisions regarding whether your expenses, paid for with money from your MSA bank account or paid for out-of-pocket, constitute Medicare expenses that count towards the deductible."]

Part 2. Complaints if you think you are asked to leave the hospital too soon.

Part 3. Complaints if you think your skilled nursing facility (SNF), home health (HHA) or comprehensive outpatient rehabilitation facility (CORF) services are ending too soon.

PART 1. Requests for [Part D drugs and/or medical care or services] or payment

This part explains what you can do if you have problems getting the [Part D drugs and/or medical care or service] you request, or payment for a [Part D drugs and/or medical care or service] you already received.

If you have problems getting the [Part D drugs and/or medical care or services] you need, or payment for a [Part D drug and/or service] you already received, you must request an initial determination with the plan.

Initial Determinations

The initial determination we make is the starting point for dealing with requests you may have about covering a [Part D drug and/or medical care or service] you need, or paying for a [Part D drug and/or medical care or service] you already received. [***Note to MA-PDs and PDPs:*** insert: "Initial decisions about Part D drugs are also called "**coverage determinations**.""] [***Note to all plan types except PDPs:*** insert: "Initial decisions about medical care or services are also called "**organization determinations**.""] With this decision, we explain whether we will provide the [Part D drug and/or medical care or service] you are requesting, or pay for the [Part D drug and/or medical care or service] you already received. [***Note to MSAs***: insert "Initial determinations also include decisions regarding whether your expenses, paid for with money from your MSA bank account or paid for out-of-pocket, constitute Medicare expenses that count towards the deductible."]

The following are examples of requests for initial determinations:

- [***MA-PDs and PDPs*:** insert bullet] You ask us to pay for a prescription drug you have received.
- [***MA-PDs and PDPs*:** insert bullet] You ask for a Part D drug that is not on your plan sponsor's list of covered drugs (called a "formulary"). This is a request for a "formulary exception." **See "What is an exception" below for more information about the exceptions process.**

- [***MA-PDs and PDPs*:** insert bullet] You ask for an exception to our utilization management tools - such as [***Note:*** insert examples, such as prior authorization, dosage limits, quantity limits, or step therapy requirements]. Requesting an exception to a utilization management tool is a type of formulary exception. **See "What is an exception" below for more information about the exceptions process.**
- [***MA-PDs and PDPs*:** insert bullet] You ask for a non-preferred Part D drug at the preferred cost-sharing level. This is a request for a "tiering exception." **See "What is an exception" below for more information about the exceptions process.**
- [***MA-PDs and PDPs*:** insert bullet] You ask us to pay you back for the cost of a drug you bought at an out-of-network pharmacy. In certain circumstances, out-of-network purchases, including drugs provided to you in a physician's office, will be covered by the Plan. See "Filling Prescriptions Outside of Network" in Section 3 for a description of these circumstances.
- [***All plan types except PDPs:*** insert bullet] You are not getting medical care or services you want, and you believe that this care is covered by the Plan.
- [***All plan types except PDPs:*** insert bullet] We will not approve the medical treatment your doctor or other medical provider wants to give you, and you believe that this treatment is covered by the Plan.
- [***All plan types except PDPs:*** insert bullet] You are being told that a medical treatment or service you have been getting will be reduced or stopped, and you believe that this could harm your health.
- [***All plan types except PDPs:*** insert bullet] You have received medical care or services that you believe should be covered by the Plan, but we have refused to pay for this care.
- [***MSAs*:** insert bullet] We make a decision regarding whether your expenses, paid for with money from your MSA Bank Account or paid for out of pocket, constitute Medicare expenses that count towards the deductible.
- [*MSAs*: insert bullet] You believe that, prior to meeting the deductible, you have been required to pay more for a service than the Medicare allowable amount.

MA-PDs and PDPs

What is an exception?

An exception is a type of initial determination (also called a "coverage determination"). You may ask us to make an exception to our coverage rules in a number of situations.

- You may ask us to cover your drug even if it is not on our formulary. Excluded drugs cannot be covered by a Part D plan unless coverage is through an enhanced plan that covers those excluded drugs.
- You may ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, we limit the amount of the drug that we will cover. If your drug has a quantity limit, you may ask us to waive the limit and cover more. See Section 5 ("Utilization Management") to learn more about our additional coverage restrictions or limits on certain drugs."
- [***Note: If the plan uses cost-sharing tiers to manage its formulary, insert the following language:*** You may ask us to provide a higher level of coverage for your drug. If your drug is contained in our [non-preferred/highest tier subject to the tiering exceptions process] tier, you may ask us to cover it at the cost-sharing amount that applies to drugs

in the [preferred/lowest tier subject to the tiering exceptions process] tier instead. This would lower the [coinsurance/co-payment] amount you must pay for your drug. Please note, if we grant your request to cover a drug that is not on our formulary, you may not ask us to provide a higher level of coverage for the drug.] [Note: If the Plan designated one of its tiers as a "high-cost/unique drug tier" and is exempting that tier from the exceptions process, include the following language: "Also, you may not ask us to provide a higher level of coverage for drugs that are in the [tier designated as the high-cost/unique drug tier] tier."]

Generally, we will only approve your request for an exception if the alternative drugs included on the Plan formulary [***Note:*** If the plan uses cost-sharing tiers to manage its formulary, insert "or the drug in the preferred tier"] would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

Your doctor must submit a statement supporting your exception request. In order to help us make a decision more quickly, the supporting medical information from your doctor should be sent to us with the exception request.

If we approve your exception request, our approval is valid for the remainder of the Plan year, so long as your doctor continues to prescribe the drug for you and it continues to be safe for treating your condition. If we deny your exception request, you may appeal our decision.

Note: If we approve your exception request for a non-formulary drug, you cannot request an exception to the co-payment or coinsurance amount we require you to pay for the drug.

You may call us at the phone number shown under **Part D Coverage Determinations** in Section 12 of this booklet to ask for any of these requests.

All plan types

Who may ask for an initial determination?

You, your prescribing physician, or someone you name may ask us for an initial determination. The person you name would be your "representative." You may name a relative, friend, advocate, doctor, or anyone else to act for you. Other persons may already be authorized under State law to act for you. If you want someone to act for you who is not already authorized under State law, then you and that person must sign and date a statement that gives the person legal permission to be your representative. [***Note to all plan types except PDPs:*** insert: "If you are requesting medical care or services, this statement must be sent to us at the address listed under "**Part C Organization Determinations**" in Section 12 of this booklet."] [***Note to MA-PDs and PDPs:*** insert "If you are requesting Part D drugs, this statement must be sent to us at the address listed under "**Part D Coverage Determinations**" in Section 12 of this booklet."] To learn how to name your representative, you may call Member Services.

You also have the right to have a lawyer act for you. You may contact your own lawyer, or get the name of a lawyer from your local bar association or other referral service. There are also groups that will give you free legal services if you qualify.

Asking for a “standard" or "fast" initial determination

A decision about whether we will give you, or pay for, the medical care or service you are requesting can be a “standard" decision that is made within the standard time frame, or it can be a “fast" decision that is made more quickly. A fast decision is also called an “expedited" decision.

Asking for a standard decision

To ask for a standard decision for a [Part D drug and/or medical care or service] you, your doctor, or your representative should [***Note:*** If the plan accepts standard requests by telephone, insert "call,"] fax, or write us at the numbers or address listed under [***Note to MA-PDs and PDPs:*** insert: "**Part D Coverage Determinations** (for appeals about Part D drugs)"] [***Note to all plan types except PDPs:*** insert: "**Part C Organization Determinations** (for appeals about medical care or services)"] in Section 12 of this booklet.
[***Note***: Specify instructions for delivering requests that are made outside of regular weekday business hours if the Plan has a different process for doing so.]

Asking for a fast decision

You may ask for a fast decision **only** if you or your doctor believe that waiting for a standard decision could seriously harm your health or your ability to function. (Fast decisions apply only to requests for benefits that you have not yet received. You cannot get a fast decision if you are asking us to pay you back for a benefit that you already received.)

If you are requesting a [Part D drug and/or medical care or service] that you have not yet received, you, your doctor, or your representative may ask us to give you a fast decision by calling, faxing, or writing us at the numbers or address listed under [**Part D Coverage Determinations** (for appeals about Part D drugs) and/or **Part C Organization Determinations** (for appeals about medical care or services)] in Section 12 of this booklet.

[***Note***: Specify instructions for delivering requests that are made outside of regular weekday business hours if the Plan has a different process for doing so.]

Be sure to ask for a “fast,” or “expedited” review. If your doctor asks for a fast decision for you, or supports you in asking for one, and the doctor indicates that waiting for a standard decision could seriously harm your health or your ability to function, we will automatically give you a fast decision.

If you ask for a fast decision without support from a doctor, we will decide if your health requires a fast decision. If we decide that your medical condition does not meet the requirements for a fast decision, we will send you a letter informing you that if you get a doctor’s support for a fast review, we will automatically give you a fast decision. The letter will also tell you how to file a “grievance” if you disagree with our decision to deny your request for a fast review (for more information about grievances, see Section 8). If we deny your request for a fast initial determination, we will give you a standard decision.

What happens when you request an initial determination?

- [***MA-PDs and PDPs*:** insert bullet] For a standard initial determination about a Part D drug (including a request to pay you back for a Part D drug that you have already received).

  Generally, we must give you our decision no later than 72 hours after we receive your request, but we will make it sooner if your health condition requires us to. However, if your request involves a request for an exception (including a formulary exception, tiering exception, or an exception from utilization management rules – such as [***Note:*** insert examples, such as prior authorization, dosage limits, quantity limits, or step therapy requirements], we must give you our decision no later than 72 hours after we receive your physician's "supporting statement" explaining why the drug you are asking for is medically necessary.

  If you have not received an answer from us within 72 hours after we receive your request, your request will automatically go to Appeal Level 2.

- [***MA-PDs and PDPs*:** insert bullet] For a fast initial determination about a Part D drug that you have not yet received.

  If we give you a fast review, we will give you our decision within 24 hours after you or your doctor ask for a fast review. We will give you the decision sooner if your health condition requires us to. If your request involves a request for an exception, we will give you our decision no later than 24 hours after we have received your physician's "supporting statement," which explains why the drug you are asking for is medically necessary.

  If we decide you are eligible for a fast review and you have not received an answer from us within 24 hours after receiving your request, your request will automatically go to Appeal Level 2.

- [***All plan types except PDPs:*** insert bullet] For a decision about payment for medical care or services you already received.

  If we do not need more information to make a decision, we have up to 30 days to make a decision after we receive your request, although a small number of decisions may take longer. However, if we need more information in order to make a decision, we have up to 60 days from the date of the receipt of your request to make a decision. You will be told in writing when we make a decision.

  In either case, if we do not approve your request for payment, we must tell you why, and tell you how you can appeal this decision. If you have not received an answer from us within 60 days of your request, you can **appeal** this decision. (An appeal is also called a "reconsideration.")

- [***All plan types except PDPs:*** insert bullet] For a standard decision about medical care or

services you have not yet received.

We have 14 days to make a decision after we receive your request. However, we can take up to 14 more days if you ask for additional time, or if we need more information (such as medical records) that may benefit you. If we take additional days, we will notify you in writing. If you believe that we should not take additional days, you can make a specific type of complaint called a "fast grievance". If we do not approve your request, we must explain why in writing, and tell you of your right to appeal our decision. If you have not received an answer from us within 14 days of your request (or by the end of any extended time period), you have the right to appeal.

- [***All plan types except PDPs:*** insert bullet] For a fast decision about medical care or services you have not yet received.

  If you receive a "fast" decision, we will give you our decision about your requested medical care or services within 72 hours after you or your doctor ask for it. However, we can take up to 14 more days if we find that some information is missing that may benefit you, or if you need more time to prepare for this review. If you believe that we should not take any extra days, you can file a fast grievance.

  We will call you as soon as we make the decision. If we deny any part of your request, we will send you a letter that explains the decision within 3 days of calling you. If we do not tell you about our decision within 72 hours (or by the end of any extended time period), this is the same as denying your request and you have the right to appeal. If we deny your request for a fast decision, you may file a fast grievance.

What happens if we decide completely in your favor?

- [***MA-PDs and PDPs*:** insert bullet] For a standard decision about a Part D drug (including a request to pay you back for a Part D drug that you have already received).

  We must give you the Part D drug you requested as quickly as your health requires, but no later than 72 hours after we receive the request. If your request involves a request for an exception, we must give you the Part D drug you requested no later than 72 hours after we receive your physician's "supporting statement." If you are asking us to pay you back for a Part D drug that you already paid for and received, we must send payment to you no later than 30 calendar days after we receive the request.

- [***MA-PDs and PDPs*:** insert bullet] For a fast decision about a Part D drug that you have not yet received.

  We must give you the Part D drug you requested no later than 24 hours after we receive your request. If your request involves a request for an exception, we must give you the Part D drug you requested no later than 24 hours after we receive your physician's "supporting statement."

- [***All plan types except PDPs:*** insert bullet] For a decision about payment for medical care

or services you already received.
If we do not need more information to make a decision, we have up to 30 days to make a decision after we receive your request, although a small number of decisions may take longer. However, if we need more information in order to make a decision, we have up to 60 days from the date of the receipt of your request to make a decision. You will be told in writing when we make a decision.

- [***All plan types except PDPs:*** insert bullet] For a standard decision about medical care or services.
  We must authorize or provide your requested care within 30 days of receiving your request. If we extended the time needed to decide your appeal, we will authorize or provide your medical care immediately.

- [***All plan types except PDPs:*** insert bullet] For a fast decision about medical care or services.
  We must authorize or provide your requested care within 72 hours of receiving your request. If we extended the time needed to decide your appeal, we will authorize or provide your medical care immediately.

What happens if we decide against you?

If we decide against you, we will send you a written decision explaining why we denied your request. If an initial determination does not give you all that you requested, you have the right to appeal the decision. (See Appeal Level 1.)

Appeal Level 1: Appeal to the Plan

You may ask us to review our initial determination, even if only part of our decision is not what you requested. [***Note to MA-PDs and PDPs:*** insert "An appeal to the plan about a Part D drug is also called a plan "**redetermination**."] [***Note to all plan types except PDPs:*** insert: "An appeal to the plan about medical care or services is also called a plan "**reconsideration**."] When we receive your request to review the initial determination, we give the request to people at our organization who were not involved in making the initial determination. This helps ensure that we will give your request a fresh look.

Who may file your appeal of the initial determination?

[***MA-PDs and PDPs*:** insert] If you are appealing an initial decision about a Part D drug, you or your representative may file a **standard appeal** request, or you, your representative, or your doctor may file a **fast appeal** request.

[***All plan types except PDPs:*** insert] If you are appealing an initial decision about medical care or services, the rules about who may file an appeal are the same as the rules about who may ask for an organization determination. Follow the instructions under "Who may ask for an initial determination?" However, providers who do not have a contract with the Plan must sign a "waiver of payment" statement that says that they will not ask you to pay for the medical care or service under review, regardless of the outcome of the appeal.

How soon must you file your appeal?

You must file the appeal request within 60 calendar days from the date included on the notice of our initial determination. We may give you more time if you have a good reason for missing the deadline.

How to file your appeal

1. Asking for a standard appeal

To ask for a standard appeal about a [Part D drug and/or medical care or service] a written appeal request must be sent to the address listed under [**Part D Appeals** (for appeals about Part D drugs) and/or **Part C Appeals** (for appeals about medical care or services)] in Section 12 of this booklet.

[***Note:*** If the plan accepts oral requests for standard appeals, insert "You may also ask for a standard appeal by calling us at the phone number shown under [**Part D Appeals** (for appeals about Part D drugs) and/or **Part C Appeals** (for appeals about medical care or services)] in Section 12 of this booklet."]

2. Asking for a fast appeal

If you are appealing a decision we made about giving you a [Part D drug and/or medical care or service] that you have not received yet, you and/or your doctor will need to decide if you need a fast appeal. The rules about asking for a fast appeal are the same as the rules about asking for a fast initial determination. You, your doctor, or your representative may ask us for a fast appeal by calling, faxing, or writing us at the numbers or address listed under [**Part D Appeals** (for appeals about Part D drugs) and/or **Part C Appeals** (for appeals about medical care or services)] in Section 12 of this booklet.

[***Note***: Specify instructions for delivering requests that are made outside of regular weekday business hours if the Plan has a different process for doing so.]

Be sure to ask for a "fast," "expedited" review. Remember, if your doctor provides a written or oral supporting statement explaining that you need the fast appeal, we will automatically give you a fast appeal.

[***Note***: If you have appeals sent to a different office than where your initial determinations are sent, you should mention that while the process for deciding on a standard or fast appeal is the same as the process at the initial determination level, the place where the appeal is sent is different; also include instructions for where to send appeal requests.]

Getting information to support your appeal

We must gather all the information we need to make a decision about your appeal. If we need your assistance in gathering this information, we will contact you. You have the right to obtain and include additional information as part of your appeal. For example, you may already have documents related to your request, or you may want to get your doctor's records or opinion to help support your request. You may need to give the doctor a written request to get information.

You may give us your additional information to support your appeal by calling, faxing, or writing us at the numbers or address listed under [**Part D Appeals** (for appeals about Part D drugs) and/or **Part C Appeals** (for appeals about medical care or services)] in Section 12 of this booklet.

You may also deliver additional information in person to the address listed under [**Part D Appeals** (for appeals about Part D drugs) and/or **Part C Appeals** (for appeals about medical care or services)] in Section 12 of this booklet.

You also have the right to ask us for a copy of information regarding your appeal. You may call or write us at the phone number or address listed under [**Part D Appeals** (for appeals about Part D drugs) and/or **Part C Appeals** (for appeals about medical care or services)] in Section 12 of this booklet. [*Note: If a fee is charged, insert* "We are allowed to charge a fee for copying and sending this information to you."]

How soon must we decide on your appeal?

- [***MA-PDs and PDPs*:** insert bullet] For a standard decision about a Part D drug that includes a request to pay you back for a Part D drug you have already paid for and received.

  We will give you our decision within seven calendar days of receiving the appeal request. We will give you the decision sooner if your health condition requires us to. If we do not give you our decision within seven calendar days, your request will automatically go to Appeal Level 2.

- [***MA-PDs and PDPs*:** insert bullet] For a fast decision about a Part D drug that you have not yet received.

  We will give you our decision within 72 hours after we receive the appeal request. We will give you the decision sooner if your health condition requires us to. If we do not give you our decision within 72 hours, your request will automatically go to Appeal Level 2.

- [***All plan types except PDPs:*** insert bullet] For a decision about payment for medical care or services you already received
  After we receive your appeal request, we have 60 days to decide. If we do not decide within 60 days, your appeal automatically goes to Appeal Level 2.

- [***All plan types except PDPs:*** insert bullet] For a standard decision about medical care or services you have not yet received
  After we receive your appeal, we have 30 days to decide, but will decide sooner if your health condition requires. However, if you ask for more time, or if we find that helpful information is missing, we can take up to 14 more days to make our decision. If we do not tell you our decision within 30 days (or by the end of the extended time period), your request will automatically go to Appeal Level 2.

- [***All plan types except PDPs:*** insert bullet] For a fast decision about medical care or services you have not yet received
  After we receive your appeal, we have 72 hours to decide, but will decide sooner if your health condition requires. However, if you ask for more time, or if we find that helpful information is missing, we can take up to 14 more days to make our decision. If we do not decide within 72 hours (or by the end of the extended time period), your request will automatically go to Appeal Level 2 within 24 hours of our decision.

What happens if we decide completely in your favor?

- [***MA-PDs and PDPs*:** insert bullet] For a standard decision about a Part D drug (including a request to pay you back for a Part D drug that you have already received).

  We must give you the Part D drug you requested as quickly as your health requires, but no later than 72 hours after we receive the request. If your request involves a request for an exception, we must give you the Part D drug you requested no later than 72 hours after we receive your physician's "supporting statement." If you are asking us to pay you back for a Part D drug that you already paid for and received, we must send payment to you no later than 30 calendar days after we receive the request.

- [***MA-PDs and PDPs*:** insert bullet] For a fast decision about a Part D drug that you have not yet received.

  We must give you the Part D drug you requested no later than 24 hours after we receive your request. If your request involves a request for an exception, we must give you the Part D drug you requested no later than 24 hours after we receive your physician's "supporting statement."

- [***All plan types except PDPs:*** insert bullet] For a decision about payment for medical care or services you already received.
  We must pay within 60 days of the day we received your appeal request.

- [***All plan types except PDPs:*** insert bullet] For a standard decision about medical care or services you have not yet received.
  We must authorize or provide your requested care within 30 days of receiving your appeal request. If we extended the time needed to decide your appeal, we will authorize or provide your medical care immediately.

- [***All plan types except PDPs:*** insert bullet] For a fast decision about medical care or services you have not yet received.
  We must authorize or provide your requested care within 72 hours of receiving your appeal request. If we extended the time needed to decide your appeal, we will authorize or provide your medical care immediately.

Appeal Level 2: Independent Review Entity (IRE)

At the second level of appeal, your appeal is reviewed by an outside, Independent Review Entity (IRE) that has a contract with the Centers for Medicare & Medicaid Services (CMS), the government agency that runs the Medicare program. The IRE has no connection to us. You have the right to ask us for a copy of your case file that we sent to this entity. [*Note: If a fee is charged, insert*: We are allowed to charge you a fee for copying and sending this information to you.]

How to file your appeal

[***MA-PDs and PDPs*:** insert] If you asked for Part D drugs or payment for Part D drugs and we did not rule completely in your favor at Appeal Level 1, you must send an appeal request to the IRE. The decision you receive from the plan (Appeal Level 1) will tell you how to file this appeal, including who can file the appeal and how soon it must be filed.

[***All plan types except PDPs*:** insert] If you asked for medical care or services, or payment for medical care or services, and we did not rule completely in your favor at Appeal Level 1, your appeal is automatically sent to the IRE.

How soon must the IRE decide?

The IRE has the same amount of time to make its decision as the plan had at **Appeal Level 1**.

If the IRE decides completely in your favor:

The IRE will tell you in writing about its decision and the reasons for it.

- [***MA-PDs and PDPs*:** insert bullet] For a decision to pay you back for a Part D drug you already paid for and received, we must send payment to you within 30 calendar days from the date we receive notice reversing our initial determination.

- [***MA-PDs and PDPs*:** insert bullet] For a standard decision about a Part D drug you have not yet received, we must give you the Part D drug you asked for within 72 hours after we receive notice reversing our initial determination.

- [***MA-PDs and PDPs*:** insert bullet] For a fast decision about a Part D drug you have not yet received, we must give you the Part D drug you asked for within 24 hours after we receive notice reversing our initial determination.

- [***All plan types except PDPs:*** insert bullet] For a decision about payment for medical care or services you already received.
  We must pay within 30 days after we receive notice reversing our initial determination.

- [***All plan types except PDPs:*** insert bullet] For a standard decision about medical care or services you have not yet received.
  We must authorize your requested medical care or service within 72 hours, or provide it to you within 14 days after we receive notice reversing our initial determination. If we extended the time needed to decide your appeal, we will authorize or provide your medical care or service immediately.

- [***All plan types except PDPs:*** insert bullet] For a fast decision about medical care or services.
  We must authorize or provide your requested medical care or services within 72 hours after we receive notice reversing our initial determination. If we extended the time needed to decide your appeal, we will authorize or provide your medical care or services immediately.

Appeal Level 3: Administrative Law Judge (ALJ)

If the IRE does not rule completely in your favor, you or your representative may ask for a review by an Administrative Law Judge (ALJ) if the dollar value of the [Part D drug and/or medical care or service] you asked for meets the minimum requirement provided in the IRE's decision. During the ALJ review, you may present evidence, review the record (by either receiving a copy of the file or accessing the file in person when feasible), and be represented by counsel.

How to file your appeal

The request must be filed with an ALJ within 60 calendar days of the date you were notified of the decision made by the IRE (Appeal Level 2). The ALJ may give you more time if you have a good reason for missing the deadline. The decision you receive from the IRE will tell you how to file this appeal, including who can file it.
The ALJ will not review your appeal if the dollar value of the requested [Part D drug and/or medical care or service] does not meet the minimum requirement specified in the IRE's decision. If the dollar value is less than the minimum requirement, you may not appeal any further.

How soon will the Judge make a decision?

The ALJ will hear your case, weigh all of the evidence, and make a decision as soon as possible.

If the Judge decides in your favor:

See the section "**Favorable Decisions**" below for information about what we must do if our initial decision denying what you asked for is reversed by an ALJ.

Appeal Level 4: Medicare Appeals Council (MAC)

If the ALJ does not rule completely in your favor, you may ask for a review by the Medicare Appeals Council (MAC).

How to file your appeal

The request must be filed with the MAC within 60 calendar days of the date you were notified of the decision made by the ALJ (Appeal Level 3). The MAC may give you more time if you have a good reason for missing the deadline. The decision you receive from the ALJ will tell you how to file this appeal, including who can file it.

How soon will the Council make a decision?

The MAC will first decide whether to review your case (it does not review every case it receives). If the MAC reviews your case, it will make a decision as soon as possible. If it decides not to review your case, you may request a review by a Federal Court Judge (see Appeal Level 5). The MAC will issue a written notice explaining any decision it makes. The notice will tell you how to request a review by a Federal Court Judge.

If the Council decides in your favor:

See the section "**Favorable Decisions**" below for information about what we must do if our initial decision denying what you asked for is reversed by the MAC.

Appeal Level 5: Federal Court

You have the right to continue your appeal by asking a Federal Court Judge to review your case if the amount involved meets the minimum requirement specified in the Medicare Appeals Council's decision, you received a decision from the Medicare Appeals Council (Appeal Level 4), and:

- The decision is not completely favorable to you, or
- The decision tells you that the MAC decided not to review your appeal request.

How to file your appeal

In order to request judicial review of your case, you must file a civil action in a United States district court within 60 calendar days after the date you were notified of the decision made by the Medicare Appeals Council (Appeal Level 4). The letter you get from the Medicare Appeals Council will tell you how to request this review, including who can file the appeal.

Your appeal request will not be reviewed by a Federal Court if the dollar value of the requested [Part D drug and/or medical care or service] does not meet the minimum requirement specified in the MAC's decision.

How soon will the Judge make a decision?

The Federal Court Judge will first decide whether to review your case. If it reviews your case, a decision will be made according to the rules established by the Federal judiciary.

If the Judge decides in your favor:

See the section "**Favorable Decisions**" below for information about what we must do if our initial decision denying what you asked for is reversed by a Federal Court Judge.

If the Judge decides against you:

The Judge's decision is final and you may not take the appeal any further.

Favorable Decisions

This section explains what we must do if our initial decision denying what you asked for is reversed by the ALJ, MAC, or a Federal Court Judge.

- [***MA-PDs and PDPs*:** insert bullet] For a decision to pay you back for a Part D drug you already paid for and received, we must send payment to you within 30 calendar days from the date we receive notice reversing our initial determination.

- [***MA-PDs and PDPs*:** insert bullet] For a standard decision about a Part D drug you have not yet received, we must give you the Part D drug you asked for within 72 hours after we receive notice reversing our initial determination.

- [***MA-PDs and PDPs*:** insert bullet] For a fast decision about a Part D drug you have not yet received, we must give you the Part D drug you asked for within 24 hours after we receive notice reversing our initial determination.

- [***All plan types except PDPs:*** insert bullet] For a decision about medical care or services, we must pay for, authorize, or provide the medical care or service you have asked for within 60 days of the date we receive the decision.

[***Note to all plan types except PDPs*:** Add the following language for a plan serving members who are dually eligible for Medicare and Medicaid if that plan does not already have a model in place: "As a plan member, some of your plan services may also be covered by Medicaid. Therefore, if you believe that we improperly denied you a service or payment for a service, you may also have the right to appeal this decision to Medicaid. We will let you know in writing if you have the right to appeal our decision to Medicaid."] [***Note***: Add Medicaid process here.]

All plans except PDPs

PART 2. Complaints (appeals) if you think you are being discharged from the hospital too soon

When you are admitted to the hospital, you have the right to get all the hospital care covered by the Plan that is necessary to diagnose and treat your illness or injury. The day you leave the hospital (your discharge date) is based on when your stay in the hospital is no longer medically necessary. This part explains what to do if you believe that you are being discharged too soon.

Information you should receive during your hospital stay

Within two days of admission as an inpatient or during pre-admission, someone at the hospital must give you a notice called the Important Message from Medicare (call Member Services or 1-800 MEDICARE (1-800-633-4227) to get a sample notice or see it online at http://www.cms.hhs.gov/BNI). This notice explains:

- Your right to get all medically necessary hospital services paid for by the Plan (except for any applicable co-payments or deductibles).
- Your right to be involved in any decisions that the hospital, your doctor, or anyone else makes about your hospital services and who will pay for them.

- Your right to get services you need after you leave the hospital.
- Your right to appeal a discharge decision and have your hospital services paid for by us during the appeal (except for any applicable co-payments or deductibles).

You (or your representative) will be asked to sign the Important Message from Medicare to show that you received and understood this notice. **Signing the notice does not mean that you agree that the coverage for your services should end – only that you received and understand the notice.** If the hospital gives you the Important Message from Medicare more than 2 days before your discharge day, it must give you a copy of your signed Important Message from Medicare before you are scheduled to be discharged.

Review of your hospital discharge by the Quality Improvement Organization

You have the right to request a review of your discharge. You may ask a Quality Improvement Organization to review whether you are being discharged too soon.

What is the "Quality Improvement Organization"?

[***Note*:** If EOC is for a single state, adapt this subsection to use the actual name of the QIO] "QIO" stands for Quality Improvement Organization. The QIO is a group of doctors and other health care experts paid by the federal government to check on and help improve the care given to Medicare patients. They are not part of the Plan or the hospital. There is one QIO in each state. QIOs have different names, depending on which state they are in. The doctors and other health experts in the QIO review certain types of complaints made by Medicare patients. These include complaints from Medicare patients who think their hospital stay is ending too soon.

Getting the QIO to review your hospital discharge

You must quickly contact the QIO. The Important Message from Medicare gives the name and telephone number of the QIO and tells you what you must do.

- You must ask the QIO for a **"fast review"** of your discharge. This "fast review" is also called an "immediate review."
- You must request a review from the QIO no later than the day you are scheduled to be discharged from the hospital. **If you meet this deadline, you may stay in the hospital after your discharge date without paying for it while you wait to get the decision from the QIO.**
- The QIO will look at your medical information provided to the QIO by us and the hospital.
- During this process, you will get a notice giving our reasons why we believe that your discharge date is medically appropriate.
- The QIO will decide, within one day after receiving the medical information it needs, whether it is medically appropriate for you to be discharged on the date that has been set for you.

What happens if the QIO decides in your favor?

We will continue to cover your hospital stay for as long as it is medically necessary (except for any applicable co-payments or deductibles).

What happens if the QIO agrees with the discharge?

You will not be responsible for paying the hospital charges until noon of the day after the QIO gives you its decision. However, you could be financially liable for any inpatient hospital services provided after noon of the day after the QIO gives you its decision. You may leave the hospital on or before that time and avoid any possible financial liability.

If you remain in the hospital, you may still ask the QIO to review its first decision if you make the request within 60 days of receiving the QIO's first denial of your request. However, you could be financially liable for any inpatient hospital services provided after noon of the day after the QIO gave you its first decision.

What happens if you appeal the QIO decision?

The QIO has 14 days to decide whether to uphold its original decision or agree that you should continue to receive inpatient care. If the QIO agrees that your care should continue, we must pay for or reimburse you for any care you have received since the discharge date on the Important Message from Medicare, and provide you with inpatient care as long as it is medically necessary (except for any applicable co-payments or deductibles).

If the QIO upholds its original decision, you may be able to appeal its decision to an Administrative Law Judge (ALJ). Please see Appeal Level 3 in Part 1 of this section for guidance on the ALJ appeal. If the ALJ upholds the decision, you may also be able to ask for a review by the Medicare Appeals Council (MAC) or a Federal court. If any of these decision makers agree that your stay should continue, we must pay for or reimburse you for any care you have received since the discharge date, and provide you with inpatient care as long as it is medically necessary (except for any applicable co-payments or deductibles).

What if you do not ask the QIO for a review by the deadline?

If you do not ask the QIO for a fast review of your discharge by the deadline, you may ask us for a "fast appeal" of your discharge, which is discussed in Part 1 of this section. If you ask us for a fast appeal of your discharge and you stay in the hospital past your discharge date, you may have to pay for the hospital care you receive past your discharge date. Whether you have to pay or not depends on the decision we make.

- If we decide, based on the fast appeal, that you need to stay in the hospital, we will continue to cover your hospital care for as long as it is medically necessary (except for any applicable co-payments or deductibles).
- If we decide that you should not have stayed in the hospital beyond your discharge date, we will not cover any hospital care you received after the discharge date.

If we uphold our original decision, we will forward our decision and case file to the Independent Review Entity (IRE) within 24 hours. Please see Appeal Level 2 in Part 1 of this section for guidance on the IRE appeal. If the IRE upholds our decision, you may also be able to ask for a review by an ALJ, MAC, or a Federal court. If any of these decision makers agree that your stay

should continue, we must pay for or reimburse you for any care you have received since the discharge date on the notice you got from your provider, and provide you with any services you asked for as long as they are medically necessary (except for any applicable co-payments or deductibles).

PART 3. Complaints (appeals) if you think coverage for your skilled nursing facility, home health agency, or comprehensive outpatient rehabilitation facility services, is ending too soon

When you are a patient in a Skilled Nursing Facility (SNF), Home Health Agency (HHA), or Comprehensive Outpatient Rehabilitation Facility (CORF), you have the right to get all the SNF, HHA or CORF care covered by the Plan that is necessary to diagnose and treat your illness or injury. The day we end coverage for your SNF, HHA or CORF services is based on when these services are no longer medically necessary. This part explains what to do if you believe that coverage for your services is ending too soon.

Information you will receive during your SNF, HHA or CORF stay

Your provider will give you written notice called the Notice of Medicare Non-Coverage at least 2 days before coverage for your services ends (call Member Services or 1-800 MEDICARE (1-800-633-4227) to get a sample notice or see it online at http://www.cms.hhs.gov/BNI/). You (or your representative) will be asked to sign and date this notice to show that you received it. **Signing the notice does not mean that you agree that coverage for your services should end – only that you received and understood the notice.**

Getting QIO review of our decision to end coverage

You have the right to appeal our decision to end coverage for your services. As explained in the notice you get from your provider, you may ask the Quality Improvement Organization (the "QIO") to do an independent review of whether it is medically appropriate to end coverage for your services.

How soon do you have to ask for QIO review?

You must quickly contact the QIO. The written notice you got from your provider gives the name and telephone number of your QIO and tells you what you must do.

- If you get the notice 2 days before your coverage ends, you must contact the QIO no later than noon of the day after you get the notice.
- If you get the notice more than 2 days before your coverage ends, you must make your request no later than noon of the day before the date that your Medicare coverage ends.

What will happen during the QIO's review?

The QIO will ask why you believe coverage for the services should continue. You don't have to prepare anything in writing, but you may do so if you wish. The QIO will also look at your medical information, talk to your doctor, and review information that we have given to the QIO. During this process, you will get a notice called the Detailed Explanation of Non-Coverage giving the reasons why we believe coverage for your services should end. Call Member Services

or 1-800-MEDICARE (1-800-633-4227 - TTY users should call 1-877-486-2048) to get a sample notice or see it online at http://www.cms.hhs.gov/BNI/).

The QIO will make a decision within one full day after it receives all the information it needs.

What happens if the QIO decides in your favor?

We will continue to cover your SNF, HHA or CORF services for as long as they are medically necessary (except for any applicable co-payments or deductibles).

What happens if the QIO agrees that your coverage should end?

You will not be responsible for paying for any SNF, HHA, or CORF services provided before the termination date on the notice you get from your provider. You may stop getting services on or before the date given on the notice and avoid any possible financial liability. If you continue receiving services, you may still ask the QIO to review its first decision if you make the request within 60 days of receiving the QIOs first denial of your request.

What happens if you appeal the QIO decision?

The QIO has 14 days to decide whether to uphold its original decision or agree that you should continue to receive services. If the QIO agrees that your services should continue, we must pay for or reimburse you for any care you have received since the termination date on the notice you got from your provider, and provide you with any services you asked for as long as they are medically necessary (except for any applicable co-payments or deductibles).

If the QIO upholds its original decision, you may be able to appeal its decision to an Administrative Law Judge (ALJ). Please see Appeal Level 3 in Part 1 of this section for guidance on the ALJ appeal. If the ALJ upholds our decision, you may also be able to ask for a review by the Medicare Appeals Council (MAC) or a Federal Court. If either the MAC or Federal Court agrees that your stay should continue, we must pay for or reimburse you for any care you have received since the termination date on the notice you got from your provider, and provide you with any services you asked for as long as they are medically necessary (except for any applicable co-payments or deductibles).

What if you do not ask the QIO for a review by the deadline?

If you do not ask the QIO for a review by the deadline, you may ask us for a fast appeal, which is discussed in Part 1 of this section.

If you ask us for a fast appeal of your coverage ending and you continue getting services from the SNF, HHA, or CORF, you may have to pay for the care you get after your termination date. Whether you have to pay or not depends on the decision we make.

- If we decide, based on the fast appeal, that coverage for your services should continue, we will continue to cover your SNF, HHA, or CORF services for as long as they are medically necessary.
- If we decide that you should not have continued getting services, we will not cover any services you received after the termination date.

If we uphold our original decision, we will forward our decision and case file to the Independent Review Entity (IRE) within 24 hours. Please see Appeal Level 2 in Part 1 of this section for guidance on the IRE appeal. If the IRE upholds our decision, you may also be able to ask for a review by an ALJ, MAC, or a Federal court. If any of these decision makers agree that your stay should continue, we must pay for or reimburse you for any care you have received since the discharge date on the notice you got from your provider, and provide you with any services you asked for as long as they are medically necessary (except for any applicable co-payments or deductibles).

10. Ending your Membership

All Plan Types

Ending your membership in our Plan may be **voluntary** (your own choice) or **involuntary** (not your own choice):

- You might leave our Plan because you have decided that you *want* to leave.
- There are also limited situations where we are required to end your membership. For example, if you move permanently out of our geographic service area.

Voluntarily ending your membership

MA and MA-PD (but not PFFS)

There are only certain times during the year when you may voluntarily end your membership in our Plan. The key time to make changes is the Medicare fall open enrollment period, which occurs every year from November 15 through December 31 This is the time to review your health care and drug coverage for the following year and make changes to your Medicare health or prescription drug coverage. Any changes you make during this time will be effective January 1st.

If you want to end your membership in our plan during this time, this is what you need to do:

- **If you are planning on enrolling in a new Medicare Advantage plan**: Simply join the new plan. You will be disenrolled from our plan when your new plan's coverage begins on January 1.
- **If you are planning on switching to the Original Medicare Plan and joining a Medicare Prescription drug plan:** Simply join the new Medicare Prescription drug plan. You will be disenrolled automatically from our plan when your new coverage begins on January 1.
- **If you are planning on switching to the Original Medicare Plan without a Medicare Prescription drug plan:** Contact Member Services or call 1-800-MEDICARE (1-800-633-4227) to request disenrollment from our plan. TTY users should call 1-877-486-2048. Your enrollment in Original Medicare will be effective January 1.

[***Note to MA-PD plans:*** insert "You can also make changes during the Medicare Advantage open enrollment period that occurs from January 1 – March 31, however, you can't drop Medicare prescription drug coverage during this time. For example, you can join another Medicare Advantage plan that has prescription drug coverage or go to Original Medicare and join a Medicare prescription drug plan."]

[***Note to MA-only plans:*** insert "You can also make changes during the Medicare Advantage open enrollment period that occurs from January 1 – March 31, however, you cannot add Medicare prescription drug coverage during this time. For example, you can join another Medicare Advantage plan that does not have prescription drug coverage or go to Original Medicare."]

Outside of these time periods, you generally can't make other changes during the year unless you meet special exceptions, such as if you move, if you have Medicaid coverage, or if you get extra help paying for your drugs.

PFFS plans

There are only certain times during the year when you may voluntarily end your membership in our Plan. The key time to make changes is the Medicare fall open enrollment period, which occurs every year from November 15 through December 31. This is the time to review your health care and drug coverage for the following year and make changes to your Medicare health or prescription drug coverage. Any changes you make during this time will be effective January 1st.

If you want to end your membership in our plan during this time, this is what you need to do:

- **If you are planning on enrolling in a new Medicare Advantage plan**: Simply join the new plan. You will be disenrolled from our plan when your new plan's coverage begins on January 1.

[***Note to PFFS plans with drug coverage:*** insert bullet below]

- **If you want to switch to the Original Medicare Plan and join a Medicare prescription drug plan:** Simply join the new plan. You will be disenrolled from our plan and enrolled in Original Medicare when your new plan's coverage begins on January 1.

[***Note to PFFS plans without drug coverage:*** **insert bullet below]**

- **If you want to switch to Original Medicare Plan:** You must contact us or call 1-800-MEDICARE (1-800-633-4227) to request disenrollment from our plan. TTY users should call 1-877-486-2048. Your enrollment in Original Medicare will be effective January 1.

  If you are already enrolled in a Medicare prescription drug plan, you will continue to be enrolled in your current plan -- disenrollment from our plan will not affect your enrollment. However, if you want to join a new Medicare prescription drug plan, you must request enrollment in the plan of your choice. Enrollment in the new drug plan will not automatically disenroll you from our plan. Your coverage will be effective January 1.

You can also make changes during the Medicare Advantage open enrollment period that occurs from January 1 – March 31, however, you cannot add or drop Medicare prescription drug coverage during this time. [Note: if plan offers drug coverage, use this sentence "For example, you can join another Medicare Advantage plan that has prescription drug coverage or go to Original Medicare and join a Medicare prescription drug plan."]

[Note: if plan does not offer drug coverage, use this sentence: "For example, if you do not have Medicare prescription drug coverage with another plan, you can join another Medicare Advantage plan that does not offer drug coverage or you can switch to the Original Medicare plan."]

Outside of these time periods, you generally can't make other changes during the year unless you meet special exceptions, such as if you move, if you have Medicaid coverage, or if you get extra help paying for your drugs.

PDP plans

There are only certain times during the year when you may voluntarily end your membership in our Plan. The key time to make changes is the Medicare Fall open enrollment period, which occurs every year from November 15 through December 31. This is the time to review your health care and drug coverage for the following year and make changes to your Medicare health or prescription drug coverage. Any changes you make during this time will be effective January 1st.

During the fall open enrollment period, if you want to end your membership in our plan, this is what you need to do:

- **If you are planning on joining another Medicare Prescription drug plan:** Simply join the new Medicare Prescription drug plan. You will be disenrolled automatically from our plan when your new coverage begins on January 1.

- **If you are planning on enrolling in a Medicare Advantage plan**: Request enrollment in the new plan. In most cases, you will be disenrolled automatically when your new plan's coverage begins on January 1.

  EXCEPTION -- If you are joining a Medicare Advantage "Private Fee-for-Service" plan and that plan does not offer drug coverage, enrollment will not automatically disenroll you from our plan. Therefore, you will need to do the following:

  - To join a new Medicare prescription drug plan, simply join the new Medicare prescription drug plan, or
  - If you do not want Medicare prescription drug coverage, request disenrollment from our plan by contacting us or calling 1-800-MEDICARE (1-800-633-4227) to request disenrollment from our plan. TTY users should call 1-877-486-2048.

- **If you would like to end your membership without joining any other Medicare health or prescription drug plan:** Contact us or call 1-800-MEDICARE (1-800-633-4227) to request disenrollment from our plan. TTY users should call 1-877-486-2048. Your enrollment in Original Medicare will be effective January 1.

IMPORTANT -- If you disenroll from Medicare prescription drug coverage and do not have coverage that is at least as good as Medicare drug coverage, you will pay a penalty later if you join.

If you meet the additional eligibility requirements for a Medicare Advantage plan, you will also have the ability to join one during the Medicare Advantage open enrollment period that occurs from January 1 – March 31, however, you cannot add or drop Medicare prescription drug coverage during this time. For example, you can join a Medicare Advantage plan that has

prescription drug coverage or go to Original Medicare and join a Medicare prescription drug plan.

Outside of these time periods, you generally can't make other changes during the year unless you meet special exceptions, such as if you move, if you have Medicaid coverage, or if you get extra help paying for your drugs.

All plans insert chart below

Enrollment Period	When?	Effective Date
Fall Open Enrollment Time to review health and drug coverage and make changes.	Every year from November 15 to December 31	January 1
Medicare Advantage (MA) Open Enrollment Cannot use this period to [***MA-PDs insert*** "drop"/***MA-only plans insert*** "add"/PFFS plans insert "add or drop"] Medicare prescription drug coverage Examples: If you are in a MA, can switch to another Medicare Advantage plan or go to Original Medicare If in Original Medicare Plan and have a Medicare prescription drug plan, can join an MA-PD If in an MA-PD, can leave and join Original Medicare Plan and a Medicare prescription drug plan	Every year from January 1 to March 31	First day of next month after plan receives your enrollment request
Limited Special Exceptions, such as: • Change in residence • Medicaid • Extra help with Medicare prescriptions • Live in institution	Determined by exception.	Generally, first day of next month after plan receives your enrollment request

For more information about these times and the options available to you, please call Member Services or contact Medicare at 1-800-MEDICARE (1-800-633-4227. TTY users should call 1-877-486-2048.

Cost Plans

Voluntarily ending your membership

You may end your membership in our Plan at any time during the year and go to the Original Medicare Plan. Your membership will end on the first of the month following your request to our Plan. To end your membership, you must make this request in writing to us. Contact us if you need more information on how to do this. [***Note to Cost plans with drug coverage:*** insert "If you have drug coverage through our plan and you leave our plan during the year, you will have the opportunity to join another Medicare prescription drug plan when you leave."]

If you want to end your membership and join another Medicare health plan or prescription drug coverage, there are limited times when you may join such plans. The Medicare Fall open enrollment period occurs every year from November 15 through December 31. This is the key time to review your health care and drug coverage and change your Medicare health or prescription drug coverage for the following year. Any changes you make during this time will be effective January 1st.

For more information about the options available to you during the fall open enrollment period, contact Medicare at 1-800-MEDICARE (1-800-633-4227.) TTY users should call 1-877-486-2048. Additional information can also be found in the *"Medicare & You"* handbook. This handbook is mailed to everyone with Medicare each fall. You may view or download a copy from www.medicare.gov - under "Search Tools," select "Find a Medicare Publication."

Until your membership ends, you must keep getting your Medicare [services and/or prescription drug coverage] through our Plan

All plan types

If you leave our Plan, it may take some time for your membership to end and your new way of getting Medicare to take effect (we discuss when the change takes effect later in this section). While you are waiting for your membership to end, you are still a member and must continue to get your [care and/or prescription drugs] as usual through our Plan. [***All plans except PDPs:*** insert: "If you happen to be hospitalized on the day your membership ends, call Member Services to find out if your hospital care will be covered by our Plan.]

Cost Plans

If you see out-of-network providers to obtain medical services, the services are covered under Original Medicare. You will be responsible for the Original Medicare cost-sharing for such services, with the exception of emergent and urgently needed services. If you get prescription drugs from an out-of-network provider, you will be responsible for the cost of the drug.

MA-PDs and PDPs

Until your prescription drug coverage with our Plan ends, use our network pharmacies to fill your prescriptions. While you are waiting for your membership to end, you are still a member and must continue to get your prescription drugs as usual through our Plan's network pharmacies. In most cases, your prescriptions are covered only if they are filled at a network pharmacy [or through our mail-order-pharmacy service], are listed on our formulary, and you follow other coverage rules.

MSA Plans

What happens to the money in your account if you leave our Plan?

If you leave our Plan in the middle of the year, part of the most recent deposit (based on the number of months left in the current calendar year) may have to be refunded to Medicare. If you are disenrolled from a Medicare Saving Account Plan mid-year, the amount deposited into your account for the remaining months in the year may be recovered from you and returned to Medicare after your disenrollment is confirmed. Funds remaining in your account from the previous year belong to you. Recovery applies only to funds deposited into your account for the current year. Example: If you get a $1,200 deposit in your account in January and disenroll in March, we may recover $900 to return to Medicare. If you have any questions about this, please contact Member Services at the number on the first page of this document.

All Plan Types except MA chronic Care SNPs

We cannot ask you to leave the Plan because of your health.

We *cannot* ask you to leave your health plan for any health-related reasons. If you ever feel that you are being encouraged or asked to leave our Plan because of your health, you should call 1-800-MEDICARE (1-800-633-4227), which is the national Medicare help line. TTY users should call 1-877-486-2048. You may call 24 hours a day, 7 days a week.

All Plan Types (plans should modify as appropriate to plan options)

Involuntarily ending your membership

If any of the following situations occur, we will end your membership in our Plan.

- If you do *not* stay continuously enrolled in [MA use "Medicare A and B"; PDP use "Medicare A or B (or both) [***Note to Cost plans and plans with Part B -only grandfathered members*:** mention that these members need to stay continuously enrolled in Medicare Part B].
- [***Note to SNPs***: include]If you no longer are [insert SNP category].
- [***Note to MSAs:*** include] If you no longer meet the additional MSA eligibility requirements, as outlined in Section 1.
- If you move out of the service area or are away from the service area for more than [***Note to MA without visitor/traveler:*** insert "6 months"; MA with visitor/traveler insert "[# up to 12] months"/Cost plans insert "90 days"] in a row. If you plan to move or take a long trip, please call Member Services to find out if the place you are moving to or traveling to is in our Plan's service area.
  If you move permanently out of our geographic service area, or if you are away from our service area for more than six months in a row [***Note:*** MA plans that currently offer a visitor/traveler benefit: insert "[# up to 12]"/ Cost plans insert "90 days" or another period up to one year if plan offers an extended absence option], you cannot

remain a member of our Plan. In these situations, if you do not leave on your own, we must end your membership ("disenroll" you). [***Note to plans with visitor/traveler benefits:*** insert "Section 3 gives more information about getting care when you are away from the service area."]

- [***Note to MA-PD, PDP, and Cost Plans with Part D***: include] If you knowingly falsify or withhold information about other parties that provide reimbursement for your prescription drug coverage.
- [***Note:*** delete bullet if not applicable] If you intentionally give us incorrect information on your enrollment request that would affect your eligibility to enroll in our Plan.
- [***Note:*** delete bullet if not applicable] If you behave in a way that is [***Note to Cost plans:*** insert "unruly, uncooperative, abusive, or"] disruptive, to the extent that you continued enrollment seriously impairs our ability to arrange or provide medical care for you or for others who are members of our Plan. We cannot make you leave our Plan for this reason unless we get permission first from Medicare.
- [***Note:*** delete bullet if not applicable] If you let someone else use your plan membership card to get medical care. If you are disenrolled for this reason, CMS may refer your case to the Inspector General for additional investigation.
- [***Note***: this bullet for all plans except Cost plans - delete bullet if not applicable] If you do not pay the Plan premiums, we will tell you in writing that you have a [insert time frame] grace period during which you may pay the Plan premiums before your membership ends.
- [***Note:*** this bullet for Cost plans only – delete bullet if not applicable] If you do not pay the basic plan premiums or cost-sharing, we will tell you in writing before you are required to leave our Plan.

All Plan Types

You have the right to make a complaint if we end your membership in our Plan

If we end your membership in our Plan we will tell you our reasons in writing and explain how you may file a complaint against us if you want to.

11. Legal Notices

Notice about governing law

Many laws apply to this Evidence of Coverage and some additional provisions may apply because they are required by law. This may affect your rights and responsibilities even if the laws are not included or explained in this document. The principal law that applies to this document is Title XVIII of the Social Security Act and the regulations created under the Social Security Act by the Centers for Medicare & Medicaid Services, or CMS. In addition, other Federal laws may apply and, under certain circumstances, the laws of the State(s) of [insert name or names of states] may apply.

Notice about nondiscrimination

We don't discriminate based on a person's race, disability, religion, sex, sexual orientation, health, ethnicity, creed, age, or national origin. All organizations that provide [Medicare Advantage Plans or Medicare Prescription Drug Plans], like our Plan, must obey federal laws against discrimination, including Title VI of the Civil Rights Act of 1964, the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act, all other laws that apply to organizations that get Federal funding, and any other laws and rules that apply for any other reason.

[***Note:*** You may include other legal notices, such as a notice of member non-liability or a notice about third party liability. These notices may only be added if they conform to Medicare laws and regulations.]

12. Helpful Phone Numbers and Resources

All Plan Types

How to contact our Plan Member Services

If you have any questions or concerns, please call or write to our Plan Member Services. We will be happy to help you.

CALL	[Insert phone number]. This number is also on the cover of this booklet for easy reference. [***Add if applicable:*** "Calls to this number are free.] [Insert hours of operation] [***Note to dual eligible SNPs:*** as appropriate, add additional phone numbers that members may use to access specific services covered under the Medicaid program.]
TTY	[Insert TTY number]. This number requires special telephone equipment. It is on the cover of this booklet for easy reference. [***Add if applicable:*** "Calls to this number are free."]
[FAX]	[Insert fax number.]
WRITE	[Insert address. You may also include e-mail addresses here]
[VISIT]	[Insert street address]
WEBSITE	[insert URL]

How to contact [MSA Bank] Member Services

CALL	[Insert number]. This number is also on the cover of this booklet for easy reference. [***Add if applicable:*** "Calls to this number are free."] [You may also include reference to 24-hour lines here]
TTY	[Insert number] This number requires special telephone equipment. It is on the cover of this booklet for easy reference. [*Add if applicable:* "Calls to this number are free."]

Contact Information for Grievances, [Organizations Determinations, Coverage Determinations] and Appeals

[***Note:*** If your plan uses the same contact information for Part C and Part D issues indicated below, you may combine these contact information sections.]

[***Note to PDPs:*** Omit Part C contact information.]

Part C Organization Determinations

CALL [Insert phone number]. [**Add if applicable:** Calls to this number are free.] [You may also include reference to 24-hour lines here.] [If you have a different phone number for accepting expedited organization determinations, also include that number here.]

TTY [Insert TTY number]. This number requires special telephone equipment. [***Add if applicable*:** Calls to this number are free.] [If you have a different TTY number for accepting expedited organization determinations, also include that number here.]

[FAX] [***Optional:*** Insert fax number.] [If you have a different fax number for accepting expedited organization determinations, also include that number here.]

WRITE [Insert address.] [If you have a different address for accepting expedited organization determinations, also include that address here.]

For information about Part C organization determinations, see Section 9.

Part C Grievances

CALL [Insert phone number]. [***Add if applicable*:** Calls to this number are free.] [You may also include reference to 24-hour lines here.] [If you have a different phone number for accepting expedited grievances, also include that number here.]

TTY [Insert TTY number]. This number requires special telephone equipment. [***Add if applicable*:** Calls to this number are free.] [If you have a different TTY number for accepting expedited grievances, also include that number here.]

[FAX] [***Optional:*** Insert fax number.] [If you have a different fax number for accepting expedited grievances, also include that number here.]

WRITE [Insert address.] [If you have a different address for accepting expedited grievances, also include that address here.]

For information about Part C grievances, see Section 8.

Part C Appeals

CALL [Insert phone number]. [***Add if applicable*:** Calls to this number are free.] [You may also include reference to 24-hour lines here.] [If you have a different phone number for accepting expedited appeals, also include that number here.]

TTY [Insert TTY number]. This number requires special telephone equipment. [***Add if applicable*:** Calls to this number are free.] [If you have a different TTY number for accepting expedited appeals, also include that number here.]

[FAX] [***Optional:*** Insert fax number.] [If you have a different fax number for accepting expedited appeals, also include that number here.]

WRITE [Insert address.] [If you have a different address for accepting expedited appeals, also include that address here.]

For information about Part C appeals, see Section 9.

[***Note to MA-only plans:*** Omit Part D contact information.]

Part D Coverage Determinations

CALL [Insert phone number]. [***Add if applicable*:** Calls to this number are free.] [You may also include reference to 24-hour lines here.] [If you have a different phone number for accepting expedited coverage determinations, also include that number here.]

TTY [Insert TTY number]. This number requires special telephone equipment. [***Add if applicable*:** Calls to this number are free.] [If you have a different TTY number for accepting expedited coverage determinations, also include that number here.]

[FAX] [***Optional:*** Insert fax number.] [If you have a different fax number for accepting expedited coverage determinations, also include that number here.]

WRITE [Insert address.] [If you have a different address for accepting expedited coverage determinations, also include that address here.]

For information about Part D coverage determinations, see Section 9.

Part D Grievances

CALL [Insert phone number]. [***Add if applicable*:** Calls to this number are free.] [You may also include reference to 24-hour lines here.] [If you have a different phone number for accepting expedited grievances, also include that number here.]

TTY [Insert TTY number]. This number requires special telephone equipment. [***Add if applicable*:** Calls to this number are free.] [If you have a different TTY number for accepting expedited grievances, also include that number here.]

[FAX] [***Optional:*** Insert fax number.] [If you have a different fax number for accepting expedited grievances, also include that number here.]

WRITE [Insert address.] [If you have a different address for accepting expedited grievances, also include that address here.]

For information about Part D grievances, see Section 8.

Part D Appeals

CALL [Insert phone number]. [***Add if applicable*:** Calls to this number are free.] [You may also include reference to 24-hour lines here.] [If you have a different phone number for accepting expedited appeals, also include that number here.]

TTY [Insert TTY number]. This number requires special telephone equipment. [***Add if applicable*:** Calls to this number are free.] [If you have a different TTY number for accepting expedited appeals, also include that number here.]

[FAX] [***Optional:*** Insert fax number.] [If you have a different fax number for accepting expedited appeals, also include that number here.]

WRITE [Insert address.] [If you have a different address for accepting expedited appeals, also include that address here.]

For information about Part D appeals, see Section 9.

Other important contacts

Below is a list of other important contact. For the most up-to-date contact information, check your *Medicare & You* Handbook, visit www.medicare.gov and choose "Find Helpful Phone Numbers and Resources," or call 1-800-Medicare (1-800-633-4227). TTY users should call 1-877-486-2048. or

[***Note to organizations offering plans in multiple states:*** use generic organization name (SHIP, QIO, etc) when necessary, and include a list of names and phone numbers for all organizations in your service area.]

[State-specific name of State Health Insurance Assistance Program (SHIP)]

[State-specific name of SHIP or SHIPs] is a state program that gets money from the Federal government to give free local health insurance counseling to people with Medicare. [State-specific name of SHIP or your SHIP] can explain your Medicare rights and protections, help you make complaints about care or treatment, and help straighten out problems with Medicare bills. [State-specific name of SHIP or your SHIP] has information about Medicare Advantage Plans, Medicare Prescription Drug Plans, [Note: include only if offered in your plan area: "Medicare Cost Plans"], and about Medigap (Medicare supplement insurance) policies. This includes information about whether to drop your Medigap policy while enrolled in a Medicare Advantage Plan and special Medigap rights for people who have tried a Medicare Advantage Plan for the first time.

You may contact [state-specific name of SHIP or the SHIP in your state] at [Insert name, address, and telephone number for all applicable SHIPS]. You may also find the Web site for [state-specific name of SHIP or your local SHIP] at www.medicare.gov under "Search Tools" by selecting "Helpful Phone Numbers and Websites."

[State-specific name of QIO or Quality Improvement Organization]

"QIO" stands for Quality Improvement Organization. The QIO is a group of doctors and health professionals in your state that reviews medical care and handles certain types of complaints from patients with Medicare, and is paid by the federal government to check on and help improve the care given to Medicare patients. There is a QIO in each state. QIOs have different names, depending on which state they are in. The doctors and other health experts in the QIO review certain types of complaints made by Medicare patients. These include complaints about quality of care and appeals filed by Medicare patients who think the coverage for their hospital, skilled nursing facility, home health agency, or comprehensive outpatient rehabilitation stay is ending too soon. See Section 9 for more information about complaints, appeals and grievances.

You may contact [name of QIO] at [name, address, and number for all applicable QIOs].

How to contact the Medicare program

- Call 1-800-MEDICARE (1-800-633-4227) to ask questions or get free information booklets from Medicare. TTY users should call 1-877-486-2048. Customer service representatives are available 24 hours a day, including weekends.
- Visit www.medicare.gov for information. This is the official government Web site for Medicare**.** This Web site gives you up-to-date information about Medicare and nursing homes and other current Medicare issues. It includes booklets you can print directly from your computer. It has tools to help you compare Medicare Advantage Plans and Medicare Prescription Drug Plans in your area. You can also search under "Search Tools" for Medicare contacts in your state. Select "Helpful Phone Numbers and Web sites." If you don't have a computer, your local library or senior center may be able to help you visit this Web site using its computer.

Medicaid

[***Note:*** You may adapt this generic discussion of Medicaid to reflect the name and features of the Medicaid program in your state or states.]

[***Note:*** SNPs may describe the Medicaid managed care program under which the organization contracts with the state Medicaid agency.]

[***Note:*** SNPs must, as appropriate, include additional telephone numbers for Medicaid program assistance, e.g., the telephone number for the state Ombudsman.]

Medicaid is a state government program that helps with medical costs for some people with limited incomes and resources. Some people with Medicare are also eligible for Medicaid. Medicaid has programs that can help pay for your Medicare premiums and other costs, if you qualify. To find out more about Medicaid and its programs, contact [***Note:*** Insert name, address, and telephone number for all applicable state Medicaid agencies/state departments of health and social services. You may also add your [member services] contact information.]

Social Security

Social Security programs include retirement benefits, disability benefits, family benefits, survivors' benefits, and benefits for the aged and blind. You may call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You may also visit **www.ssa.gov** on the Web.

[State-specific name of State Pharmacy Assistance Program (SPAP)]

[State-specific name of SPAP or SPAPs] are state organizations that provide limited -income and medically needy senior citizens and individuals with disabilities financial help for prescription drugs. You may contact [state-specific name of SPAP or the SPAP in your state] at [Insert name, address, and telephone number for all applicable SPAPs]. You can also find the Web site for [state-specific name of SPAP or your local SPAP and Web site].

[***Note:*** SNPs may, as appropriate, include additional telephone numbers for Medicaid program assistance, e.g., the telephone number for the state Ombudsman.]

Railroad Retirement Board

If you get benefits from the Railroad Retirement Board, you may call your local Railroad Retirement Board office or 1-800-808-0772. TTY users should call 312-751-4701. You may also visit www.rrb.gov on the Web.

Employer (or "Group") Coverage

[***Note:*** SNPs may, as appropriate, delete this language since beneficiaries covered under employer groups are not eligible to participate in dual eligible SNPs in some states.]

If you get or your spouse gets your benefits from your current or former employer or union, or from your spouse's current or former employer or union, call your employer/union benefits administrator or Member Services if you have any questions about your employer/union benefits, plan premiums, or the open enrollment season. Important Note: You (or your spouse's) employer/union benefits may change, or you (or your spouse) may lose the benefits, if you enroll in Medicare Part D. Call your employer/union benefits administrator or Member Services to find out whether the benefits will change or be terminated if you or your spouse enrolls in Part D.

13. Definition of Some Words Used in This Book

[***Note to all plans:*** Insert definitions as appropriate to the plan type described in the EOC. You may insert definitions not included in this model and exclude model definitions not applicable to your plan, or to your contractual obligations with CMS or enrolled Medicare beneficiaries.]

[***Note to all plan types except PDPs***: If you use any of the following terms in your EOC, you must add a definition of the term to the first section where you use it and here in Section 13 with a reference from the section where you use it: IPA, network, PHO, plan medical group, Point of Service [If the plan offers a POS option, also provide definitions of: allowed amount, balance billing, coinsurance and maximum charge], and prescription drug benefit manager.]

Appeal – An appeal is a special kind of complaint you make if you disagree with a decision to deny a request for [health care services and/or prescription drugs] or payment for [services and/or prescription drugs] you already received. [***Note to all plans except PDPs:*** insert "You may also make a complaint if you disagree with a decision to stop services that you are receiving."] For example, you may ask for an appeal if our Plan doesn't pay for a [drug/item/service] you think you should be able to get. Section 9 explains appeals, including the process involved in making an appeal.

Benefit period – For both our Plan and the Original Medicare Plan, a benefit period is used to determine coverage for inpatient stays in hospitals and skilled nursing facilities. [***Note:*** If you offer a more generous benefit period, revise the following sentences to reflect the Plan's benefit period] A benefit period begins on the first day you go to a Medicare-covered inpatient hospital or a skilled nursing facility. The benefit period ends when you haven't been an inpatient at any hospital or SNF for 60 days in a row. If you go to the hospital (or SNF) after one benefit period has ended, a new benefit period begins. There is no limit to the number of benefit periods you can have.

The type of care that is covered depends on whether you are considered an inpatient for hospital and SNF stays. You must be admitted to the hospital as an inpatient, not just under observation. You are an inpatient in a SNF only if your care in the SNF meets certain standards for skilled level of care. Specifically, in order to be an inpatient in a SNF, you must need daily skilled-nursing or skilled-rehabilitation care, or both. (Section 4 tells what is meant by skilled care.)

Brand-Name Drug – A prescription drug that is manufactured and sold by the pharmaceutical company that originally researched and developed the drug. Brand name drugs have the same active-ingredient formula as the generic version of the drug. However, generic drugs are manufactured and sold by other drug manufacturers and are generally not available until after the patent on the brand name drug has expired.

Catastrophic Coverage - The phase in the Part D Drug Benefit where you pay a low co-payment or coinsurance for your drugs after you or other qualified parties on your behalf have spent [Insert TrOOP amount] in covered drugs during the covered year. Please see Section 5 of this document.

Centers for Medicare & Medicaid Services (CMS) – The Federal agency that runs the Medicare program. Section 12 explains how to contact CMS.

Cost-sharing - Cost-sharing refers to amounts that a member has to pay when [drugs/services] are received. It includes any combination of the following three types of payments: (1) any deductible amount the plan may impose before [drugs/services] are covered; (2) any fixed "co-payment" amounts that a plan may require be paid when specific [drugs/services] are received; or (3) any "coinsurance" amount that must be paid as a percentage of the total amount paid for a [drug/service].

Coverage Determination –A decision from your Medicare drug plan about whether a drug prescribed for you is covered by the Plan and the amount, if any, you are required to pay for the prescription. In general, if you bring your prescription to a pharmacy and the pharmacy tells you the prescription isn't covered under your plan, that isn't a coverage determination. You need to call or write to your plan to ask for a formal decision about the coverage if you disagree.

Covered Drugs – The term we use to mean all of the prescription drugs covered by our Plan.

Covered services – The general term we use in this booklet to mean all of the health care services and supplies that are covered by our Plan.

Creditable Prescription Drug Coverage – Coverage (for example, from an employer or union) that is at least as good as Medicare's prescription drug coverage.

Custodial care -- care for personal needs rather than medically necessary needs. Custodial care is care that can be provided by people who don't have professional skills or training. This care includes help with walking, dressing, bathing, eating, preparation of special diets, and taking medication. Medicare does not cover custodial care unless it is provided as other care you are getting in addition to daily skilled nursing care and/or skilled rehabilitation services.

Deductible -- the amount you must pay for the [health care services or drugs] you receive before our Plan begins to pay its share of your covered [services or drugs].
Disenroll or **Disenrollment** – The process of ending your membership in our Plan. Disenrollment may be voluntary (your own choice) or involuntary (not your own choice). Section 10 discusses disenrollment.

Durable medical equipment – Equipment needed for medical reasons, which is sturdy enough to be used many times without wearing out. A person normally needs this kind of equipment only when ill or injured. It can be used in the home. Examples of durable medical equipment are wheelchairs, hospital beds, and equipment that supplies a person with oxygen.

Emergency care – Covered services that are: 1) rendered by a provider qualified to furnish emergency services; and 2) needed to evaluate or stabilize an emergency medical condition. Section 3 and Section 4 discuss emergency services.

Evidence of Coverage (EOC) and Disclosure Information – This document, along with your enrollment form [and any other attachments, riders, or other optional coverage selected], which explains your coverage, what we must do, your rights, and what you have to do as a member of our Plan.

Exception – A type of coverage determination that, if approved, allows you to get a drug that is not on your plan sponsor's formulary (a formulary exception), or get a non-preferred drug at the preferred cost-sharing level (a tiering exception). You may also request an exception if your plan sponsor requires you to try another drug before receiving the drug you are requesting, or the Plan limits the quantity or dosage of the drug you are requesting (a formulary exception).

Formulary – A list of covered drugs provided by the Plan.

Generic Drug – A prescription drug that has the same active-ingredient formula as a brand-name drug. Generally, generic drugs cost less than brand-name drugs and are rated by the Food and Drug Administration (FDA) to be as safe and effective as brand-name drugs.

Grievance - A type of complaint you make about us or one of our network [providers/pharmacies], including a complaint concerning the quality of your care. This type of complaint does not involve coverage or payment disputes. See Section 8 for more information about grievances.

Home health aide – A home health aide provides services that don't need the skills of a licensed nurse or therapist, such as help with personal care (e.g., bathing, using the toilet, dressing, or carrying out the prescribed exercises). Home health aides do not have a nursing license or provide therapy.

Home health care -- Skilled nursing care and certain other health care services that you get in your home for the treatment of an illness or injury. Covered services are listed in the Benefits Chart in Section 4 under the heading "Home health care." If you need home health care services, our Plan will cover these services for you provided the Medicare coverage requirements are met. Home health care can include services from a **home health aide** if the services are part of the home health plan of care for your illness or injury. They aren't covered unless you are also getting a covered skilled service. Home health services don't include the services of housekeepers, food service arrangements, or full-time nursing care at home.

Hospice care -- a special way of caring for people who are terminally ill and providing counseling for their families. Hospice care is physical care and counseling that is given by a team of people who are part of a Medicare-certified public agency or private company. Depending on the situation, this care may be given in the home, a hospice facility, a hospital, or a nursing home. Care from a hospice is meant to help patients in the last months of life by giving comfort and relief from pain. The focus is on care, not cure. For more information on hospice care visit www.medicare.gov and under "Search Tools" choose "Find a Medicare Publication" to view or download the publication "Medicare Hospice Benefits." Or, call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048)

Inpatient Care – Health care that you get when you are admitted to a hospital.

Initial Coverage Limit – The maximum limit of coverage under the initial coverage period.

Initial Coverage Period – This is the period after you have met your deductible (if you have one) and before your total drug expenses, have reached $[insert 2009 initial coverage limit amount], including amounts you've paid and what our Plan has paid on your behalf.

Late Enrollment Penalty – An amount added to your monthly premium for Medicare drug coverage if you go without creditable prescription drug coverage for a continuous period of 63 days or more. You pay this higher amount as long as you have a Medicare drug plan. There are some exceptions.

Medically necessary – Services or supplies that: are proper and needed for the diagnosis or treatment of your medical condition; are used for the diagnosis, direct care, and treatment of your medical condition; meet the standards of good medical practice in the local community; and are not mainly for your convenience or that of your doctor.

Medicare – The Federal health insurance program for people 65 years of age or older, some people under age 65 with certain disabilities, and people with End-Stage Renal Disease (generally those with permanent kidney failure who need dialysis or a kidney transplant).

Medicare Advantage (MA) Plan– Sometimes called Medicare Part C. A plan offered by a private company that contracts with Medicare to provide you with all your Medicare Part A (Hospital) and Part B (Medical) benefits. A MA plan offers a specific set of health benefits at the same premium and level of cost-sharing to all people with Medicare who live in the service area covered by the Plan. Medicare Advantage Organizations can offer one or more Medicare Advantage plan in the same service area. A Medicare Advantage Plan can be an HMO, PPO, a Private Fee-for-Service (PFFS) Plan, or a Medicare Medical Savings Account (MSA) plan. In most cases, Medicare Advantage Plans also offer Medicare Part D (prescription drug coverage). These plans are called **Medicare Advantage Plans with Prescription Drug Coverage**. Everyone who has Medicare Part A and Part B is eligible to join any Medicare Health Plans that are offered in their area, except people with End-Stage Renal Disease (unless certain exceptions apply).

[***Note*:** Insert Cost plan definition only if you are a Medicare Cost plan or there is one in your service area.] **Medicare Cost Plan** – Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursed contract under section 1876(h) of the Act.

Medicare Prescription Drug Coverage (Medicare Part D) – Insurance to help pay for outpatient prescription drugs, vaccines, biologicals, and some supplies not covered by Medicare Part A or Part B.

"Medigap" (Medicare supplement insurance) policy – Medicare supplement insurance sold by private insurance companies to fill "gaps" in the Original Medicare Plan coverage. Medigap

policies only work with the Original Medicare Plan. (A Medicare Advantage plan is not a Medigap policy.)

Member (member of our Plan, or "plan member") – A person with Medicare who is eligible to get covered services, who has enrolled in our Plan and whose enrollment has been confirmed by the Centers for Medicare & Medicaid Services (CMS).

Member Services – A department within our Plan responsible for answering your questions about your membership, benefits, grievances, and appeals. See Section 12 for information about how to contact Member Services.

Network pharmacy – A network pharmacy is a pharmacy where members of our Plan can get their prescription drug benefits. We call them "network pharmacies" because they contract with our Plan. In most cases, your prescriptions are covered only if they are filled at one of our network pharmacies.

Network provider – "Provider" is the general term we use for doctors, other health care professionals, hospitals, and other health care facilities that are licensed or certified by Medicare and by the State to provide health care services. We call them "**network providers**" when they [have an agreement with our Plan to] accept our payment as payment in full, and in some cases to coordinate as well as provide covered services to members of our Plan. Our Plan pays network providers based on the agreements it has with the providers or if the providers agree to provide you with plan-covered services. Network providers may also be referred to as "plan providers."

[***Note***: Include this definition only if plan has preferred and non-preferred pharmacies] **Non-Preferred Network Pharmacy** – A network pharmacy that offers covered drugs to members of our Plan at higher cost-sharing levels than apply at a preferred network pharmacy.

[***Include if applicable:*** **Optional supplemental benefits** – Non-Medicare-covered benefits that can be purchased for an additional premium and are not included in your package of benefits. If you choose to have optional supplemental benefits, you may have to pay an additional premium. You must voluntarily elect Optional Supplemental Benefits in order to get them.]

Organization Determination - The MA organization has made an organization determination when it, or one of its providers, makes a decision about MA services or payment that you believe you should receive.

Original Medicare Plan – ("Traditional Medicare" or "Fee-for-service" Medicare) The Original Medicare Plan is the way many people get their health care coverage. It is the national pay-per-visit program that lets you go to any doctor, hospital, or other health care provider that accepts Medicare. You must pay the deductible. Medicare pays its share of the Medicare-approved amount, and you pay your share. Original Medicare has two parts: Part A (Hospital Insurance) and Part B (Medical Insurance) and is available everywhere in the United States.

Out-of-network provider or out-of network facility – A provider or facility with which we have not arranged to coordinate or provide covered services to members of our Plan. Out-of-

network providers are providers that are not employed, owned, or operated by our Plan or are not under contract to deliver covered services to you. Using out-of-network providers or facilities is explained in this booklet in Section 3.

Out-of-network pharmacy – A pharmacy that doesn't have a contract with our Plan to coordinate or provide covered drugs to members of our Plan. As explained in this Evidence of Coverage, most drugs you get from out-of-network pharmacies are not covered by our Plan unless certain conditions apply. See Section 3.

Part D – The voluntary Medicare Prescription Drug Benefit Program. (For ease of reference, we will refer to the prescription drug benefit program as Part D.)

Part D Drugs – Drugs that Congress permitted our Plan to offer as part of a standard Medicare prescription drug benefit. We may or may not offer all Part D drugs. (See your formulary for a specific list of covered drugs.) Certain categories of drugs, such as benzodiazepines, barbiturates, and over-the-counter drugs were specifically excluded by Congress from the standard prescription drug package (see Section 7 for a listing of these drugs). These drugs are not considered Part D drugs.

[***Note***: Include this definition only if plan has preferred and non-preferred pharmacies]
Preferred Network Pharmacy – A network pharmacy that offers covered drugs to members of our Plan at lower cost-sharing levels than apply at a non-preferred network pharmacy.

Primary Care [Physician] (PCP) – A health care professional you select to coordinate your health care. Your PCP is responsible for providing or authorizing covered services while you are a plan member. Section 3 tells more about PCPs.

Preferred Provider Organization Plan – A Preferred Provider Organization plan is an MA plan that has a network of contracted providers that have agreed to treat plan members for a specified payment amount. A PPO plan must cover all plan benefits whether they are received from network or out-of-network providers. Member cost-sharing may be higher when plan benefits are received from out-of-network providers.

Prior authorization – Approval in advance to get [services AND/OR certain drugs that may or may not be on our formulary]. [***Note to plans:*** include example as appropriate to your plan type: "In an [HMO with a referral model and in the network portion of a PPO], some in-network services are covered only if your doctor or other network provider gets "prior authorization" from our Plan. Covered services that need prior authorization are marked in the Benefits Chart in Section 4." AND/OR "In a [PPO or PFFS] plan you do not need prior authorization to obtain out-of-network services. However, you may want to check with your plan before obtaining services out-of-network to confirm that the service is covered by your plan and what your cost share responsibility is. Covered services that need prior authorization are marked in the Benefits Chart in Section 4." AND/OR "Some drugs are covered only if your doctor or other network provider gets "prior authorization" from us. Covered drugs that need prior authorization are marked in the formulary."]

Quality Improvement Organization (QIO) – Groups of practicing doctors and other health care experts that are paid by the federal government to check and improve the care given to Medicare patients. They must review your complaints about the quality of care given by Medicare Providers. See Section 12 for information about how to contact the QIO in your state and Section 9 for information about making complaints to the QIO.

Rehabilitation services – These services include physical therapy, cardiac rehabilitation, speech and language therapy, and occupational therapy that are provided under the direction of a network provider.

Quantity Limits - A management tool that is designed to limit the use of selected drugs for quality, safety, or utilization reasons. Limits may be on the amount of the drug that we cover per prescription or for a defined period of time.

Service area – Section 1 tells about our Plan's service area. "Service area" is the geographic area approved by the Centers for Medicare & Medicaid Services (CMS) within which an eligible individual may enroll in a certain plan.

Skilled nursing facility (SNF) care - a level of care in a SNF ordered by a doctor that must be given or supervised by licensed health care professionals. It may be skilled nursing care, or skilled rehabilitation services, or both. Skilled nursing care includes services that require the skills of a licensed nurse to perform or supervise. Skilled rehabilitation services are physical therapy, speech therapy, and occupational therapy. Physical therapy includes exercise to improve the movement and strength of an area of the body, and training on how to use special equipment, such as how to use a walker or get in and out of a wheelchair. Speech therapy includes exercise to regain and strengthen speech and/or swallowing skills. Occupational therapy helps you learn how to perform usual daily activities, such as eating and dressing by yourself.

Step Therapy - A utilization tool that requires you to first try another drug to treat your medical condition before we will cover the drug your physician may have initially prescribed.

Supplemental Security Income (SSI) – A monthly benefit paid by the Social Security Administration to people with limited income and resources who are disabled, blind, or age 65 and older. SSI benefits are not the same as Social Security benefits.

Urgently needed care – Section 3 explains about "urgently needed" services. These are different from emergency services.

Index

[***Note:*** Paginate a word and phrase index so members can find specific content easily.]