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CENTER FOR BENEFICIARY CHOICES

DATE: April 3, 2006

TO: Medicare Prescription Drug Plan (PDP) Sponsors

FROM: Cynthia G. Tudor, Ph.D.
Acting Director, Medicare Drug Benefit Group

SUBJECT: Instructions for 2007 Contract Year

I am pleased to send you these instructions for the 2007 contract year. The guidance in this 2007 "Call Letter" applies to all Prescription Drug Plan (PDP) Sponsors, including those that are currently applying to enter the program. This letter also provides guidance for Employer/Union-Only Group Waiver Plans (EGWPs). A separate letter (including applicable Part D information) has been issued for Medicare Advantage Organizations, Section 1876 Cost-based contractors, and Demonstrations.

This call letter is a key element of the guidance that CMS is providing to help organizations bid and contract for the upcoming contract year. Please note, however, that while we have tried to capture the most significant Part D policy updates for 2007, a complete understanding of the program's operational requirements can only be acquired through an in-depth familiarity with our regulations and the information posted on our web site at www.cms.hhs.gov.

We at CMS appreciate the efforts your organizations have made in addressing the issues that have arisen during the implementation of the Part D program. All of us dedicated significant resources to meeting aggressive deadlines in preparation for delivering Part D services to Medicare beneficiaries, and we continue to respond quickly to issues that inevitably arise as part of such a significant program implementation.

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

Thank you for your continued service to Medicare beneficiaries. If you have specific questions about any of these instructions, please contact Scott Nelson at Scott.Nelson2@cms.hhs.gov. He will distribute your inquiry to the appropriate contact person for a response.

We look forward to your continued participation in the Medicare prescription drug benefit program.

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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).

2006	Item Description
April 10	CY 2007 Bid Software Package (bid pricing tool and PBP), and technical instructions available for download from the Health Plan Management System (HPMS).
April 17	Final day to submit formularies via HPMS.
Early April	Conference call to discuss 2007 Call Letter.
May 1	CMS issues renewal/non-renewal notices to PDP Sponsors.
May 19	CMS begins accepting CY 2007 Bids via HPMS.
June 1	The CY 2007 Model Annual Notice of Change (ANOC) will be available to PDP Sponsors.
June 5	Final day for PDP Sponsors to submit CY 2007 Bids via HPMS
June 6	CMS begins accepting CY 2007 marketing material for review via HPMS Marketing Module.
June 30	Final date for PDP Sponsors to submit **CY 2006** marketing materials for CMS's review and approval. NOTE: This date does not apply to CY 2007 file & use materials since PDP Sponsors may file these materials with the regional office five calendar days prior to their use.
July 1	The CY 2007 Model Evidence of Coverage (EOCs) and Model Low Income Subsidy (LIS) Rider will be available to PDP Sponsors.
September 1	Final date for PDP Sponsors to submit non-model ANOC to regional offices for review.
September 8 - 11	PDP Sponsors preview the 2007 Medicare & You handbook plan data in HPMS prior to printing the CMS publication (not applicable to EGWPs).
September 15	PDP Sponsors are expected to submit final CY 2007 ANOCs and SBs to the regional offices for review, based on their CMS approved benefit bid. NOTE: If a PDP Sponsor's bid is approved earlier than 9/14 (as noted in HPMS), submit the CY 2007 ANOC and SB within 72 working hours of approval.

October 1	• PDP Sponsors may begin marketing CY 2007 benefits to Medicare beneficiaries using CMS-approved and CMS-File & Use accepted marketing materials. All PDP Sponsors must cease marketing CY 2006 plans through public media when they begin marketing 2007 benefits. • IMPORTANT ENROLLMENT NOTE: While marketing of CY2007 benefits can begin on 10/1/06, NO enrollment requests for the 11/15/06-12/31/06 Annual Coordinated Election Period can be received by PDP Sponsors prior to 11/15/06. • PDP Sponsors are required to include information in CY 2006 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2007.
October 12	Final day for PDP Sponsors to submit <u>model</u> ANOCs to CMS regional offices for review.
October 12 (Tentative)	Medicare Prescription Drug Plan Finder data released to public through CMS Web site (not applicable to EGWPs).
October 15 - 30	Medicare & You handbooks are mailed to all people with Medicare.
October 31	• All PDP Sponsors must cease marketing CY 2006 plans through public media. • CY 2007 ANOCs (with SBs and abridged or comprehensive formulary) are due to all members. PDP Sponsors must mail the required documents <u>before</u> this date to ensure receipt by members by October 31.
November 15 – December 31	Annual Election Period. All PDP Sponsors must hold open enrollment. (for EGWPs, *see* Section 20.3.8 of the PDP Guidance: Eligibility, Enrollment and Disenrollment)
December 1	Final date for PDP Sponsors to submit <u>non-model</u> EOCs and LIS Riders to CMS regional offices for review. PDP Sponsors are encouraged to submit all EOCs and LIS Riders to CMS in advance of this date to ensure the EOC and LIS Rider can be reviewed, approved, printed, and mailed to members by the January 31, 2007 deadline.
December 15	Final date for PDP Sponsors to submit the model EOC and model LIS Rider without modification to regional offices for review. PDP Sponsors are encouraged to submit all EOCs and LIS Riders to CMS in advance of this date to ensure the EOC and LIS Rider can be reviewed, approved,

	printed, and mailed to members by the January 31, 2007 deadline.
January 1, 2007	2007 plan benefit begins.
January 31, 2007	PDP Sponsors must mail CY 2007 EOCs to members with an effective date of 1/1/2007.

I. RENEWALS

CMS Renewal Notice to PDP Sponsors

As noted in our regulation, CMS will issue Prescription Drug Plan (PDP) Sponsor contract renewal notices to Sponsors on or before May 1, 2006, to those Sponsors we have determined, based on information available at that time, to continue to be qualified to hold a contract during 2007. 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.

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

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

CMS Evaluation Criteria

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

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

Effective Data Systems

Determining a beneficiary's correct enrollment status, including copayment status, lies at the heart of ensuring his or her access to the Part D benefit. Because enrollment data are updated much more frequently than previously in the Medicare+Choice program, and timely and accurate data processing by plans is essential, CMS expects sponsors to develop and maintain information systems that accurately process updated enrollment information at least weekly, following recommended processing procedures to avoid significant delays or inaccuracies in processing enrollments. These requirements are particularly important for sponsors serving substantial numbers of beneficiaries, particularly those serving auto-enrolled dual eligible beneficiaries. In particular,

Sponsors serving auto-enrolled dual eligible beneficiaries will continue to be expected to process enrollments and updated copayment information timely, and to verify enrollment and copayment status on a biweekly basis using enrollment files provided by CMS. Sponsors are also expected to establish business processes for quickly resolving urgent issues affecting particular beneficiaries, such as late changes in enrollment or copay status, in collaboration with CMS caseworkers. Sponsors are also expected to work with CMS to minimize data submissions that are rejected, and to provide timely and complete 4Rx information on their beneficiaries. We are refining measures related to the effectiveness of PDP Sponsors' information systems interactions with CMS to be used as part of our ongoing monitoring efforts.

Effective Customer Service

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

Follow Transition Guidance

CMS expects PDP Sponsors to follow both our transition guidance and their approved transition processes. All PDP Sponsors have committed to the provision of a temporary supply of non-formulary drugs of at least 30 days in the retail setting. PDP Sponsors should provide enrollees receiving a transition supply with instructions explaining:
(1) That the transitional supply is temporary,
(2) That the beneficiary needs to work with the Sponsor and his or her physician to identify appropriate drug substitutions, and
(3) That the member has a right to request a formulary exception.
(4) The Sponsor's form should also provide the procedures for requesting such an exception.

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

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

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

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

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

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

PDP Sponsor Notice of Renewal to CMS

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

HPMS/Enrollment Crosswalk for PDP Sponsor Renewals for 2007

Current PDP Sponsors will be required to complete the HPMS plan crosswalk when uploading their Contract Year 2007 bids. PDP Sponsors use the HPMS plan crosswalk to designate the relationships between plans offered in 2006 to those being submitted for 2007.

The crosswalk chart (Attachment 1) outlines the PDP Sponsor renewal guidelines and describes the relationships that can be established between CY 2006 and 2007 plans and how each one relates to the HPMS plan crosswalk, the enrollment system actions to be performed by either the PDP Sponsor or CMS, whether and which type of enrollment application is required, and the requirements for beneficiary notifications. It is extremely important that PDP Sponsors review this chart for guidance when determining their plan structures for CY 2007. Technical instructions for completing the HPMS plan crosswalk

for each type of relationship will be provided to PDP Sponsors in the *Bid Submission User's Manual for Contract Year 2007.*

Assumptions:

- Regions are defined by CMS and consist of one or more states.
- Each of a PDP Sponsor's prescription drug plans (PDPs) must be offered throughout at least an entire region or regions. A PDP cannot be offered in only part of a region. Please note that the PDP bidding rules require PDP Sponsors to submit bids for plans that cover only one PDP region at a time. Therefore, HPMS only allows a PDP Sponsor plans to cover one PDP region at a time. (i.e., A Sponsor offering a "national" PDP would, for purposes of bidding, be said to be offering 34 plans, one in each PDP region.)
- PDP Sponsors may offer plans in more than one region.
- A PDP Sponsor may expand the service area of its offerings by submitting additional bids in the PDP regions the Sponsor expects to enter in CY 2007. Such Sponsors must also have completed and submitted to CMS by March 20, 2006, a PDP Service Area Expansion application. CMS must approve the Service Area Expansion application before it will approve a PDP Sponsor's bids for the new regions.
- A PDP Sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. (Note that PDP Sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with CMS' PDP Eligibility, Enrollment, and Disenrollment Guidance.)
- Guaranteed issue Medigap rights do not apply in the context of the Part D benefit but rather the right to obtain qualified RX coverage in the region applies.

Variations to be captured in the crosswalk:

- New plans
- Renewed plans

  + No changes
  + Consolidation of two or more plans into a single plan
- Terminated plans
- Service Area Expansion (employer/union-only group waiver plans (EGWPs) only)

II. BIDDING/PAYMENT

Number of Plans Per Region Per PDP Sponsor Contract

CMS intends to negotiate with PDP Sponsors to ensure that each bid they submit represents a meaningful variation based on plan characteristics that will provide

beneficiaries with substantially different options. Key plan characteristics we would look at include deductibles versus no deductibles, use of flat copays versus coinsurance, coverage in the gap versus no coverage, premiums, and substantial 2006 enrollment versus limited interest. We expect that organizations will take steps to ensure that the array of PDP benefit packages submitted can be reasonably understood and compared by beneficiaries in terms of key plan characteristics.

In general, we expect that more than two bids from a sponsoring organization would not provide meaningful variation, unless one of the bids is an enhanced alternative plan that provides coverage in the coverage gap.

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

Reporting of Manufacturer Rebates

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

Under 42 C.F.R. 423.329(c), a Part D enrollee who incurs costs above the annual out-of-pocket threshold will pay minimal coinsurance or copayments. CMS subsidizes a portion of the increased cost to the PDP Sponsor through reinsurance payments equal to 80 percent of "allowable reinsurance costs" attributable to the "gross covered prescription drugs costs" incurred above the out-of-pocket threshold. The definitions at 42 C.F.R. 423.308 specify that incurred costs are only allowable if they are "actually paid." The definition of gross covered costs excludes administrative costs. The definition of "actually paid" includes only actually incurred costs that are net of "any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source."

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

purposes of calculating allowable reinsurance costs that the value of this price concession equals the portion of the manufacturer rebates retained by the PBM.

Because the calculation of gross covered prescription costs requires the Part D sponsor to deduct from its costs both administrative costs and any price concessions it receives, the Part D sponsor should have the same gross covered prescription drug costs, and thus allowable reinsurance costs, regardless of what proportion of the PBM services are paid for directly by the sponsor (an administrative cost) and what proportion of services are compensated through manufacturer rebates retained by the PBM (a price concession).

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

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

Disclosure of Rebates to Long-Term Care Pharmacies

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

In order to create a cost-effective Medicare prescription drug benefit, the Medicare Modernization Act (MMA) relies on the ability of Part D sponsors to negotiate maximum price concessions from pharmaceutical manufacturers on behalf of Medicare beneficiaries, and to provide beneficiaries access to the negotiated prices. Negotiated

prices must reflect price concessions for covered part D drugs, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remuneration. Section 1860D-2(d)(1)(B). The MMA requires Part D sponsors to disclose to the Secretary the aggregate negotiated price concessions "made available to" the sponsor "by a manufacturer." Section 1860D-2(d)(2).

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

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

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

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

Section 423.153(b) of the Final Rule requires Plan Sponsors to establish a reasonable and appropriate drug utilization management program that (1) Includes incentives to reduce cost when medically appropriate: (2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and (3) Provides CMS with information concerning the procedures and performance of its drug utilization management program according to guidelines specified by CMS.

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

Plan Corrections

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

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

The most important step to reduce the need for plan corrections must be strengthened quality control by PDP Sponsors. Quality control must be an integral part of each PBP and BPT submission. The tight timeframes during the bid season and in preparation for the enrollment period require significant upfront efforts. CMS expects PDP Sponsor requests for plan corrections will be dramatically reduced for 2007. Benefit attestations must reflect accurate benefit packages that require no further corrections. Further, PDP

Sponsors must ensure that their marketing materials, such as the Summary of Benefits and Evidence of Coverage, reflect the accurate data that is submitted on the PBP/BPT.

We believe that beneficiaries have a reasonable expectation that when they receive marketing materials on a PDP, they will be able to access accurate information on the benefits under that plan through the MPDPF. We believe that marketing a plan that does not have such information available is inherently misleading. Accordingly, if we become aware that MPDPF information is inaccurate because the PBP is inaccurate, or if a PDP Sponsor requests suppression of its information on the MPDPF because it was inaccurate due to the PBP being inaccurate, we will not approve marketing materials for that plan until the PBP contains accurate information on the plan. If a PDP Sponsor requests suppression of its MPDPF data during the MPDPF preview period in September due to the PBP being incorrect, we will not be able to ensure that corrected information is included on the MPDPF until November 2006. As a result, all or certain marketing materials submitted for that plan will not be approved or accepted under File & Use for use prior to November 1, 2006. Similarly, if a PDP Sponsor requests suppression of its MPDPF data after the MPDPF preview period in October due to the PBP being incorrect, we will not approve or accept under File & Use all or certain marketing materials for the plan prior to November 15, 2006. We believe these actions are the best way to support competition and reward PDP Sponsors that submit accurate PBPs and ensure that inaccurate materials are not disseminated.

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

III. ENROLLMENT AND ELIGIBILITY

Overview of Enrollment Periods

Details on the enrollment periods and for PDPs are outlined in the PDP Enrollment and Disenrollment Guidance. CMS would like to take this opportunity to emphasize the following enrollment periods:

a. Annual Coordinated Election Period (AEP): Generally, this is the only period in which individuals can join or change Medicare prescription drug plans. In 2007, the AEP is from November 15, 2006 through December 31, 2006. Enrollments made during the AEP are effective January 1, 2007.

b. Coordinating Special Enrollment Period (SEP) for MA-PD enrollees using the MA Open Enrollment Period (OEP) to disenroll to Original Medicare and a PDP. PDPs must accept enrollments for individuals enrolled in an MA-PD plan and who choose to elect Original Medicare during the MA OEP that occurs from January 1, 2007 through March 31, 2007. Since MA rules require these individuals to maintain prescription drug coverage, they MUST enroll in a PDP to accompany Original Medicare. This SEP allows MA-PD enrollees to enroll in a PDP and is limited to 1 enrollment**.** This SEP, and others that coordinate with MA elections, are outlined in Section 20 of the PDP Enrollment and Disenrollment Guidance.

Instructions for Maintaining Full Benefit Dual Eligible Members in 2007

CMS will provide additional guidance on the regional low-income subsidy benchmark calculation for 2007 in the weeks ahead, with the goal of providing continuity of coverage while limiting Federal costs. Sponsors that bid aggressively, while meeting Medicare's performance standards for quality coverage for dual-eligible beneficiaries, will be successful in this process.

PDPs with premiums at or below the low-income premium subsidy amount in 2006 and 2007: In this situation, full-benefit dual eligible members of a PDP will remain members of that PDP. These members will be informed of plan changes in the annual notice of change (ANOC). The ANOC for these members will also include a list of other plans offered by the PDP Sponsor in that service area with a premium at or below the low-income premium subsidy amount.

PDPs with premiums at or below the low-income premium subsidy amount in 2006 that renew in 2007 with a premium above the low-income premium subsidy amount:

If the PDP sponsor offers another PDP in the same service area with a premium at or below the low-income premium subsidy amount, the PDP sponsor will re-assign full-benefit dual eligible members to that PDP. (If there is more than one PDP in that region with a premium at or below the low-income premium subsidy amount, the Sponsor must randomly assign individuals among those PDPs.) These members will be informed of plan changes in the annual notice of change (ANOC). The ANOC for these members will also include a list of other plans offered by the PDP Sponsor in that service area with a premium at or below the low-income premium subsidy amount.

If the PDP sponsor does NOT offer another PDP in the same service area with a premium at or below the low-income premium subsidy amount, CMS will randomly auto-assign these full-benefit dual eligible individuals among PDP sponsors in the service area with PDPs at or below the low-income premium subsidy amount.

More details on this process (including system and notice requirements) will be provided by CMS as soon as possible.

New Special Enrollment Periods (SEP):

CMS has established the following two new SEPs for the following types of beneficiaries, effective immediately:

- Individuals who are enrolled into a PDP by a State Pharmaceutical Assistance Program (SPAP); and

- Individuals who qualify for the Low Income Subsidy because they have Supplemental Security Income (SSI) or applied for LIS at SSA.

a. Individuals who are enrolled into a PDP by a State Pharmaceutical Assistance Program (SPAP) – SPAPs may have authority under state law to make enrollment

decisions on behalf of their members. Individuals enrolled in a plan by their SPAP have an SEP to make one change to enroll in a different PDP at any time through the end of the calendar year.

b. SEP for individuals who qualify for the Low Income Subsidy because they have SSI or applied for LIS at SSA – CMS is establishing an SEP to facilitate on an ongoing basis enrollment of low-income subsidy eligible individuals who have not chosen a plan. Our current guidance specifies that CMS will facilitate enrollment in a PDP effective May 1, 2006 for individuals who qualify for the low-income subsidy because they receive Supplemental Security Income (SSI) benefits or get help from their State paying their Medicare premium (belong to a Medicare Savings Program), or apply and qualify. However, after May 15, 2006, CMS could not facilitate enrollment of individuals who receive SSI benefits or who apply and qualify for the low-income subsidy until their next valid enrollment period, which in most cases would not occur until the next AEP with enrollment effective January 1, 2007. CMS believes it is important to give those individuals who qualify for the low-income subsidy the immediate opportunity to be enrolled in a plan and make use of this assistance. Therefore, we are establishing this SEP to facilitate ongoing enrollment into a PDP.

This SEP will allow the individual to choose a PDP plan on his/her own. If no choice is made, CMS will facilitate his/her enrollment into a PDP. If CMS facilitates the enrollment, the beneficiary will have an SEP to change plans.

The SEP will begin upon notification to the individual of his/her LIS status or the effective date of facilitated enrollment (whichever occurs first), and ends either when the individual enrolls in a PDP or MA-PD, or upon CMS facilitation of enrollment into a PDP. Proof of eligibility for this SEP may include the subsidy award letter from SSA or the state, or a notice from CMS informing the beneficiary that he/she has been deemed eligible for the subsidy and enrolled in a plan. The effective date for this SEP will be either the effective date of the facilitated enrollment, or, if the beneficiary makes a choice, the first day of the month following receipt of the enrollment request by the sponsor. **Note that this SEP changes the effective dates as outlined in section 30.1.5 of the PDP Enrollment and Disenrollment Guidance.**

Creditable Coverage & Late Enrollment Penalty

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

(1) Medicare prescription drug coverage (i.e., coverage through a Medicare plan that provides prescription drug coverage or coverage through a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare; or

(2) Coverage through another type of plan actuarially determined to be creditable prescription drug coverage.

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

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

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

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

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

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

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

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

Upon notifying a beneficiary of any LEP determination, Sponsors will advise the beneficiary of the right to ask for a review of CMS' LEP decision. CMS intends to have LEP-related appeals reviewed by an independent review entity, with final decisions issued by the Secretary or his or her designee. If the beneficiary disagrees with an LEP decision made by CMS, or believes that he/she was not adequately informed of the creditable coverage status pursuant to 42 CFR §423.56(g), the beneficiary may request reconsideration of that decision under a process established by CMS through operational guidance. Sponsors must assist beneficiaries, for example, by making relevant documentation available to support the individual's case, such as notices or other materials related to the initial LEP decision. Additional specific guidance, model letters, and instructions will be provided in the Medicare Prescription Drug Benefit Manual.

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

All Sponsors will be required to collect LEPs through the beneficiary's payment of premium unless the premium is paid through Social Security withholding. A Sponsor will be required to collect LEPs even if its plan premium is $0. Depending on the beneficiary's income level and low income subsidy qualifying status, CMS may subsidize a portion of the beneficiary's LEP for a period of time. Since the LEP is considered part of the premium, Sponsors must bill the LEP at the same time as the premium. Sponsors will have the option, however, to bill zero premium plan enrollees for the late enrollment penalty on an other-than-monthly schedule with the beneficiary's consent. CMS believes that most beneficiaries with zero premium plans will choose to have any late enrollment

penalties deducted from their Social Security checks; however, CMS will not allow sponsors to require such deductions.

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

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

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

Encouraging Early-in-Month Enrollments

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

Enrollments later in the month make it far less likely that all of the information needed to file the claim correctly will be available at the pharmacy or the PDP Sponsor. In those instances, the PDP Sponsor should provide the enrollee with some extra information to help manage expectations and help the beneficiary successfully fill prescriptions. This information includes instructions on appropriate documentation to bring to the pharmacy (e.g., acknowledgement letter, plan welcome letter, enrollment confirmation number, a Medicare or Medicaid card, or other information about the plan in which the beneficiary has enrolled).

Expedited Enrollment Processing

CMS is encouraging PDP Sponsors to implement enrollment systems that will allow for the processing of enrollments as quickly as possible. By acting on daily rather than monthly or weekly batch status reports, PDP Sponsors can ensure that their enrollees are assigned timely the appropriate low-income subsidy status, reducing delays in beneficiaries' access to their proper benefit.

IV. LOW INCOME SUBSIDY

Full Benefit Dual Eligible Beneficiaries Residing in Long-Term Care Facilities

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

V. MARKETING/ BENEFICIARY COMMUNICATIONS

Plan Submission and CMS Review of Marketing Materials

PDP Sponsors may begin submitting 2007 marketing materials (e.g., Summary of Benefits and Annual Notice of Change) on June 6, 2006, in accordance with the marketing guidelines via the HPMS Marketing Module. The relevant CMS Regional Office will either disapprove or conditionally approve the materials. PDP Sponsors that do not have a final CMS contract approval will receive a "conditional approval" on marketing materials. If the materials are conditionally approved, CMS is indicating to the Sponsor that the materials are approvable based on the current, not yet approved, bid. The PDP Sponsor may not use conditionally approved marketing materials in the market. If the materials are disapproved, the Sponsor must revise the materials and continue to work with the regional office until it receives a conditional approval on the materials.

After CMS approves the PDP Sponsor's bid, any necessary changes to conditionally approved materials must be resubmitted to CMS, based on the CMS-approved bid/PBP. The Sponsor must clearly highlight anything in the conditionally approved material that has changed since the material was conditionally approved. This step will help ensure a timely review of the final materials.

PDP Sponsors must follow the marketing review process according to the marketing guidelines to market its plans. If a PDP Sponsor fails to submit materials in a timely manner or to clearly highlight changes in the submitted materials, then it is at risk of not being able to market by October 1, 2006.

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

Marketing Contract Year 2006

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

Renewing PDP Sponsors must maintain their CY2006 Web site content and can continue to send and orally present CY 2006 plan information to individuals who specifically ask for it. PDP Sponsors may continue to enroll individuals for effective dates before January 2007, based on an individual's election period and on other requirements of the law, regulations, and previously issued guidance. If a prospective enrollee inquires about the 2006 plan, the PDP Sponsor should provide the individual with both 2006 and 2007 plan information so that the individual is fully informed about changes that will take place on January 1, 2007.

In general, PDP Sponsors must submit all remaining CY 2006 marketing materials to CMS by no later than June 30, 2006. This deadline will allow CMS to begin focusing resources on the review of CY 2007 marketing materials. In unique and very limited circumstances, a PDP Sponsor may need to have CY 2006 marketing materials reviewed after June 30, 2006. In those cases, the Sponsor should contact its CMS Regional Office to discuss the possibility of an exception.

Effective October 1, 2006, all PDP Sponsors must include disclaimers in CY 2006 marketing materials whenever they advertise a CY 2006 benefit, formulary, pharmacy network, premium, or copayment that may or will change effective January 1, 2007, or whenever it accepts an election form for an effective date in 2006 on or after November 1, 2006. The disclaimer must be in the form of an attachment or an addendum to all marketing materials, including advertisements and election forms, and must alert potential members that changes will occur on January 1, 2007. PDP Sponsors are not required to use the disclaimer for Plans that will not change in 2007.

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

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

Marketing Material Identification Systems

Beginning in CY 2007, all PDP Sponsors will be required to place on all marketing materials the CMS contract number as part of their unique material identification number. For non-File and Use materials, the identification number developed must include a place holder for the CMS material approval date (the date that appears on the CMS approval notice). The contract number and unique material identification number must be printed on the front page of the Summary of Benefits (SB), and the Evidence of Coverage (EOC).

Organizations must include the contract number and Plan Benefit Package (PBP) number on the membership identification card as well as other required information as outlined in the Medicare marketing guidelines.

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

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

Use of Model Documents

For certain pre- and post-enrollment documents, CMS has drafted optional model language that will entitle the PDP Sponsor to a ten-day marketing review period. PDP Sponsors that submit model marketing materials (e.g., EOC, ANOC) to CMS for review must use the model language without modification except in bracketed areas. However, if the PDP Sponsor chooses not to use the model language, it will receive a 45-day review and must include all required elements as outlined in the Medicare Marketing Guidelines. Sponsors are strongly encouraged to use model documents in order to receive an expedited review.

Marketing of Contract Year (CY) 2007 Plans

Beginning October 1, 2006, all PDP Sponsors may begin using approved or File and Use accepted CY 2007 marketing materials. Sponsors must have an approved bid and executed PDP Sponsor contract prior to marketing CY 2007 plans. At a minimum, the following materials (if applicable) must be reviewed and approved and/or appropriately submitted and accepted under File & Use Certification, in accordance with the marketing guidelines by October 1, 2006: Web site content, summary of benefits, comprehensive formulary, and pharmacy directory, and an Annual Notice of Change (if applicable).

While marketing can begin on October 1, 2006, PDP Sponsors will not be allowed to accept any annual coordinated election period (AEP) requests prior to 11/15/06. Per section 20 of the PDP Enrollment and Disenrollment Guidance, in order for a PDP Sponsor to accept an enrollment request, a valid request must be made during an available enrollment period. As a result, any request received outside of a valid election

period must be denied. Therefore, CMS encourages all plans to be explicit about this information in all plan marketing materials.

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

CY 2007 Annual Notice of Change (ANOC)

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

All PDP Sponsors must ensure that members receive the ANOC with the SB and abridged or comprehensive formulary by October 31, 2006.

Please refer to the "2007 Contract Year Marketing Dates" for timeframes related to submitting SBs and abridged or comprehensive formularies to the regional offices for review. The timeframes were established to ensure that PDP Sponsors submit ANOCs, SBs, and formulary documents in time to have them reviewed, approved, printed, and received by members by the October 31, 2006, deadline.

CY 2007 Summary of Benefits (SB)

All PDP Sponsors must send a standardized SB to individual members with the ANOC. General instructions for the SB are included in the Marketing Guidelines.

Please refer to the "2007 Contract Year Marketing Dates" for timeframes related to submitting SBs to the regional offices for review. The timeframes were established to ensure that PDP Sponsors submit ANOCs and SBs in time to have them reviewed, approved, printed, and received by members by the October 31 deadline.

Under unique circumstances, a PDP Sponsor may need to make a hard copy change to its standardized SB. The Marketing Guidelines summarize the process for requesting such changes.

Any changes to PDP Sponsor organization and plan information (e.g., customer service number, plan name, or other plan information) must be changed through HPMS by the PDP Sponsor.

If a PDP Sponsor submits the standardized SB without section 3, plan specific features, it will be treated as a model so the 10 day timeframe will apply. The full three sections standardized SB is reviewed in the 45 days timeframe.

CY 2007 Evidence of Coverage (EOC)

All PDP Sponsors must mail CY 2007 EOCs and LIS riders to all current plan members no later than January 31, 2007. In addition, PDP Sponsors, PDP Sponsors must mail CY 2007 EOCs to new members no later than when they notify the member of acceptance (confirmation) of enrollment. The timeframe requirements for sending notices of acceptance of enrollment are contained in the Enrollment and Disenrollment Guidelines.

The model EOCs will be available by July 1, 2006. Sponsors choosing to utilize the model EOC without modification will receive a 10 day review period.

Please refer to the "2007 Contract Year Marketing Dates" (below) for the timeframes related to submitting EOCs to the regional offices for review. The timeframes were established to ensure that PDP Sponsors submit EOCs in time to have them reviewed, approved, printed, and mailed to members by the January 31, 2007 deadline.

Web Site Content

PDP Sponsors are required to provide certain CY2006 information on a Web site for members and prospective enrollees as defined in the Marketing Guidelines. Renewing contractors will be required to also provide CY2007 Web site content for members and prospective enrollees by October 1, 2006. Information for both CY2006 and CY2007 must be easily accessible and organized in a way that is easily understood by the beneficiary. Additional guidance related to this issue is forthcoming. Web site content is considered marketing material and must be submitted to CMS prior to use in accordance with the Marketing Guidelines.

Medicare Prescription Drug Plan Finder Data

General Instructions

Tentatively scheduled for October 12, 2006, the CY 2007 health plan data will appear on the "Medicare Prescription Drug Plan Finder" in the standardized summary of benefits format. As noted on the timeline, EGWPs will not be included in Medicare Prescription Drug Plan Finder as these employer-only group plans are not open to general enrollment.

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

Quality Checks

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

As noted in the "Plan Corrections" section of this Call Letter, quality control must be an integral part of the Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) submissions. Data entered into the PBP (and subsequently uploaded to HPMS) is the basis for the MPDPF. Therefore, early and strong quality control of the bid submission at the PDP Sponsor level on all submissions is imperative. Previewing the MPDPF is another opportunity for the Sponsor to confirm that the data it submitted is correct. CMS will link approval of a PDP Sponsor's marketing and advertising with the Sponsor's submission of accurate PBPs. PDP Sponsors must further ensure that attestations reflect the benefits they intend to offer in the manner they intend to offer them.

Medicare & You 2007

The *Medicare & You 2007* handbook will contain health plan benefit and Medicare prescription drug plan comparison information. This information may be similar to the information provided in the *Medicare & You 2006* handbook released last fall. Sponsors will be able to preview their handbook plan data September 8 through 11, 2006. As noted on the timeline, EGWPs will not be included in the Medicare & You 2007 handbook as these employer-only group plans are not open to general enrollment.

Co-Branding Requirements for CY 2007

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

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

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

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

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

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

Customer and Provider Telephone Contact Standards

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

Current and Prospective Enrollee Call Center:

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

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

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

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

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

The call center must meet the following operating standards:

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

Pharmacy Technical Help Call Center

Sponsors must operate a toll-free pharmacy technical help call center to respond to inquiries from pharmacies and providers regarding the applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission and claims payment. The call center must operate during the entire period during which the sponsor's network pharmacies in their plans' service areas are open. Note that sponsors whose pharmacy networks include 24-hour pharmacies must operate their pharmacy technical help call centers 24 hours a day as well.

The call center must meet the following operating standards:

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

Exceptions and Appeals Call Center

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

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

VI. SYSTEMS/HPMS

Using HPMS to Submit Bids and Formularies

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

In order to prepare plan bids, PDP 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, PDP Sponsors will use the PBP software to describe the detailed structure of their benefit packages and the BPT software to define their bid pricing information. Each formulary submitted by April 17, 2006, must accurately crosswalk to a plan (or set of plans) defined during the bid process. The combination of the PBP and BPT for a plan comprises a bid.

Once the PBP and BPT software have been completed for each plan being offered, PDP Sponsors will upload their bids to HPMS. CMS anticipates releasing the PBP and BPT bid upload functionality on **May 19, 2006**. PDP Sponsors may upload their plan bids one or more times between May 19, 2006, and the CY 2007 bid deadline of **12:00 midnight PDT on June 5, 2006**. CMS will accept the last successful bid upload received for a plan by this deadline as the official bid submission for that plan.

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

Instructions for Obtaining HPMS Access

PDP Sponsors have three alternatives for accessing HPMS:

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

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

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

Additional HPMS Contacts

*General HPMS Information***:** Tim Hoogerwerf, 410-786-9962; Kristin Finch 410-786-2873

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

HPMS Connectivity: Don Freeburger, 410-786-4586

HPMS User IDs and Passwords: Neetu Jhagwani, 410-786-2548

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

VII. COMPLIANCE/MONITORING

Compliance Plan Requirements

All PDP Sponsors are required to have a compliance plan in place as a condition of participation in the Medicare program. CMS, beginning in January 2007, will begin specifying key elements that must be included within the required components of the compliance plan described in 42 CFR § 423.504(b)(4)(vi). Compliance plans will be reviewed for these requirements as part of the regular monitoring/auditing of PDPs.

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

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

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

Designation of compliance officer and committee accountable to senior management.

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

Effective lines of communication between the compliance officer and organization's employees, contractors, agents, directors, and members of the compliance committee.

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

Effective training and education between the compliance officer and organizations employees, contractors, agents, and directors.

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

Procedures for effective internal monitoring and auditing.

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

Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's contract.

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

Enforcement of standards through well-publicized disciplinary guidelines

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

Comprehensive program to detect, correct, and prevent fraud, waste and abuse.

PDP Sponsors are required to have a program to detect, correct, and prevent fraud, waste and abuse as an element of their compliance plan. This program must articulate the PDP's commitment to detecting, correcting and preventing fraud, waste and abuse. CMS plans to issue additional guidance in April 2006 to assist PDP Sponsors in the development of their fraud, waste and abuse plans.

Part D Audit Guide

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

Conflict of Interest

PDP Sponsors will be required to provide financial and organizational conflict of interest reports to CMS, pursuant to instructions to be issued by CMS. CMS will make draft instructions available for public comment prior to final posting in late 2006.

VIII. FORMULARY

Formulary Submission

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

Transition Process

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

IX. LICENSURE AND SOLVENCY

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

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

Sponsors with CMS-approved licensure waivers must continue to meet CMS' Federal Solvency Standards and must notify CMS when licensure has been obtained in at least one state.

X. PHARMACY ACCESS

Specialty Pharmacy

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

Part D plans may specify, on a drug by drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. We believe that only a limited number of drugs would qualify as needing special attention. Further, Part D plans may not require network pharmacies to qualify as a "Specialty" pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question. The convenient access standards dictate that "Specialty" pharmacies be used to supplement network pharmacy access when necessary and not otherwise restrict it.

I/T/U Addendum

CMS has developed a new addendum for PDP Sponsor contracts with Indian Health Services, Indian Tribes and Tribal Organizations, and Urban Indian Organization (I/T/U) pharmacies (see Attachment 2) to replace the separate IHS and Tribal addenda. All PDP Sponsors that contract with I/T/U pharmacies will be expected to have contracts with these providers incorporating the new addendum in place beginning January 1, 2007.

XI. GRIEVANCES/EXCEPTIONS AND APPEALS

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

XII. CLAIMS PROCESSING

National Provider Identifier

The HIPAA Regulation, 42 CFR Part 162, subpart D, requires all health plans and providers to use the National Provider Identifier (NPI) as the only provider identifier on standard electronic transactions by May 23, 2007. Accordingly, PDP Sponsors will be expected to comply with the NPI requirement on or before that date.

XIII. NON-RENEWALS

CMS Notice to PDP Sponsor

CMS will issue on or before May 1, 2006, notices to all PDP Sponsors indicating whether CMS has elected to renew each Sponsor's contract. Such a notice is a determination that

the Sponsor is qualified to continue participation in the Part D program during 2007. However, PDP Sponsors can enter into a binding contract for the next year only after CMS has approved the Sponsor's bids for 2007. Also, as in the "Renewal" section, above, CMS will continue to evaluate Sponsor compliance with Part requirements throughout 2006. We will focus in particular on those areas that impact beneficiaries' satisfaction with their benefit plans. Where Sponsors are determined to be significantly out of compliance with Part D requirements, CMS may initiate enforcement actions that could include contract termination.

PDP Sponsor Notice to CMS

PDP Sponsors that elect to non-renew their PDP Sponsor contract for 2007 must notify CMS of their decision in writing by June 5, 2006. Pursuant to 42 CFR §423.507(a)(3), Sponsors that non-renew their contracts cannot enter into a contract with CMS for two years unless there are special circumstances that warrant special consideration, as determined by CMS. PDP Sponsors that submit neither a 2007 bid nor a notice of non-renewal by June 5, 2006, will be considered by CMS to have non-renewed their PDP Sponsor contracts. Please keep in mind that failure to meet either of these criteria (non-renewal notice or bid submission) will result in being considered a de facto non-renewal by the Sponsor and thus will trigger the rules included in 42 CFR §§423.507(a)(2)(ii) and (iii), (3), and (4).

Notices to Enrollees and the Public

Non-renewing PDP Sponsors must issue a written notice to all of their PDP enrollees of the non-renewal by October 1, 2006. Such a notice must be approved by CMS and must include a written description of the alternatives available for obtaining qualified prescription drug coverage within the PDP region, including MA-PD plans, and other PDPs.

Non-renewing PDP Sponsors must provide notice to the general public by October 1, 2006, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP Sponsor's service area. Such notice must be approved by CMS prior to publication.

Non-Renewal of All Plans in a PDP Region

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

Impact of Minimum Enrollment Requirements for 2008 Contract Renewals

CMS reminds PDP Sponsors that, pursuant to 42 CFR §423.512, they will be required to meet minimum enrollment standards during 2007. When CMS considers the renewal of PDP Sponsor contracts in the spring of 2007, we will non-renew the contracts of those Sponsors that do not have a minimum enrollment of 5,000 individuals (1,500 individuals for those Sponsors that primarily serve individuals residing outside of urbanized areas).

XIV. EMPLOYER/UNION-ONLY GROUP WAIVER PLANS (EGWPS)

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

CY 2007 Timeline

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

Renewals

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

Bidding/Payment

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

Service area restrictions have been automatically waived for all Direct Contract EGWPs. These plans have national service areas so they may cover retirees nationally. For all other EGWPs (800 series plans), the CY 2006 service area extension waiver granted to plans that are eligible (i.e., plans that are able to meet the "nexus" test) will be available for CY 2007.

Please note that in order to allow coverage for retirees nationally in either Direct Contract and 800 series plans, CMS intends to automatically set all EGWP service areas for CY 2007 to national service areas in HPMS in order to operationally allow these plans to cover retirees wherever they reside.

Unlike non-group plans, EGWP bids may cover more than one PDP region. In order to cover retirees wherever they reside, plans must bid nationally as they did in CY 2006. With regard to providing sufficient pharmacy access throughout the plan's service area, networks to cover these retirees must be in place prior to enrolling retirees.

For CY 2007, EGWP bids will continue to be excluded from the calculation of the Part D national average monthly bid amount and the low-income regional benchmark premium amounts.

Low-Income Subsidy

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

Marketing/Beneficiary Communications

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

Formulary

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

Pharmacy Access

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

Non-Renewals

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

Attachment 1 - Contract Year 2007 Guidance for PDP Sponsor Renewals/HPMS Plan Crosswalk

Contract Year 2007 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC
1	New Plan Added		A new 2007 plan with no link to a 2006 plan.	The PDP Sponsor must submit election transactions.	Beneficiaries are required to complete an enrollment form. Beneficiaries who are already enrolled in another plan with the same PDP Sponsor can complete the short enrollment form.	None.
2	Renewal Plan	If a PDP Sponsor continues to offer a CY2006 prescription drug plan in CY2007, **it must retain the same Plan ID number** in order for all currently enrolled beneficiaries to remain in the same prescription drug plan in CY2007.	A 2007 plan that links to a 2006 plan.	**The renewal plan ID must remain the same** so that beneficiaries will remain in the same plan ID. The plan sponsor **does not** submit any transactions.	No enrollment election is required.	Beneficiaries are sent an ANOC.
3	Consolidated Renewal Plan	If a PDP Sponsor **combines** two or more prescription drug plans offered in CY2006 into a single renewal plan so that all beneficiaries in the combined plans are offered	Two or more 2006 prescription drug plans that consolidate into one 2007 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	No enrollment election is required.	Beneficiaries are sent an ANOC.

Contract Year 2007 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC
		the same benefits in CY2007, the PDP Sponsor must designate which of the renewal Plan IDs will be retained in CY2007 after consolidation.		plan ID. The PDP Sponsor **does not** submit any transactions.		
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 2006 prescription drug plan in CY 2007 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 2007.	A 2007 prescription drug plan that links to a 2006 plan and retains all of its plan service area from 2006, but also adds one or more new regions.	**The renewal plan ID must remain the same** so that beneficiaries in the current service area will remain in the same plan ID. The PDP Sponsor **does not** submit any transactions for these members. However, the PDP Sponsor must submit election transactions for new enrollees.	Employers/unions who wish to enroll their retirees in a PDP EGWP have the option of group enrolling its beneficiaries (*see* PDP Eligibility, Enrollment and Disenrollment Guidance) or having its retirees complete an individual enrollment election.	Only existing beneficiaries are sent an ANOC.
		Model ANOCs will be available on the CMS Web site at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/07_RxContracting_Marketing.asp#TopOfPage..				
5	Terminated Plan		A 2006 plan that is no longer offered in 2007.	If the beneficiary elects to enroll in another plan with the same plan sponsor, the PDP Sponsor **must submit**	Beneficiaries are required to complete an enrollment election if they choose to enroll in	No ANOC sent. Beneficiaries are sent a

Contract Year 2007 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC
				transactions to enroll the beneficiary in another plan with the PDP Sponsor;	another plan.	termination notice and receive a written description of options for obtaining prescription drug coverage in the service area.

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

Attachment 2

INDIAN HEALTH ADDENDUM TO
MEDICARE PART D PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

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

2. Definitions.

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

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

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

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

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

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

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

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

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

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

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

3. Description of Provider.

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

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

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

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

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

4. Deductibles.

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

5. Persons eligible for services of Provider.

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

(b) The parties agree that the persons eligible for services of the Provider who is an Indian tribe or a tribal organization or a Provider who is an urban Indian organization shall be governed by the following authorities: (1) Title XVIII, Part D of the Social Security Act and 42 C.F.R. Part 423;

(2) Sec. 813(a) and Sec. 813(c) of the Indian Health Care Improvement Act, 25 USC §1680c (a) and (c);

(3) Part 136 of Title 42, Code of Federal Regulations; and

(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program.

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

6. Applicability of other Federal laws.

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

(a) An IHS provider:

(1) The Anti-Deficiency Act 31 U.S.C. § 1341;

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

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

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

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

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

7. Non-taxable entity.

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

8. Insurance and indemnification.

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

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

9. Employee license.

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

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

10. Provider eligibility for payments.

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

11. Dispute Resolution.

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

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

12. Governing Law.

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

13. Pharmacy/Dispensary Participation.

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

14. Acquisition of Pharmaceuticals.

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

15. Drug Utilization Review/Generic Equivalent Substitution.

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

16. Claims.

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

17. Payment Rate.

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

18. Information, Outreach, and Enrollment Materials.

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

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

19. Hours of Service.

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

20. Endorsement

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

_____ _____
Signature of Authorized Representative

_____ _____
Printed Name of Authorized Representative

_____ _____
Title of Authorized Representative