DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244

MEMORANDUM

TO: All Medicare Advantage, Medicare Advantage-Prescription Drug Organizations, Cost-Based Contractors, and Employer/Union Only Sponsored Groups

FROM: Patricia Smith, Director, Medicare Advantage Group
Cynthia Tudor, Acting Director, Medicare Drug Benefit Group

RE: Public Comment Period for Draft 2007 MA, MA-PD and PDP Call Letters

DATE: February 21, 2006

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

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

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

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

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2007 Contract Year Renewal Dates
(Dates are Subject to Change)

NOTE: Employer Group Waiver Plans (EGWPs) are subject to the same timeline as non-group plans.

2006	Item Description
April 7	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 (including Direct Contract EGWPs and PDP Sponsors offering EGWPs) 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) will be available to PDP Sponsors.
September 1	Final date for PDP Sponsors to submit non-model ANOC to regional offices for review.
September 14 - 15	PDP Sponsors preview the 2007 Medicare & You handbook plan data in HPMS prior to printing the CMS publication.
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.

September 16-19	PDP Sponsors preview the CY 2007 "Drug Plan Finder" data in HPMS prior to public release through CMS Web site.
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 non-model ANOCs to CMS regional offices for review.
October 12 (Tentative)	Medicare Drug Plan Finder data released to public through CMS Web site.
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.
October 31	CY 2007 ANOCs (with SBs and abridged or comprehensive formulary) are due to all members. PDP Sponsors must mail the required documents before this date to ensure receipt by members by October 31.
November 1	Final date for PDP Sponsors to submit non-model EOCs to CMS regional offices for review. PDP Sponsors are encouraged to submit all EOCs to CMS in advance of this date to ensure the EOC can be reviewed, approved, printed, and mailed to members by the December 31, 2006 deadline.
November 15	Final date for PDP Sponsors to submit the model EOC without modification to regional offices for review. PDP Sponsors are encouraged to submit all EOCs to CMS in advance of this date to ensure the EOC can be reviewed, approved, printed, and mailed to members by the December 31, 2006 deadline.

November 15 – December 31	Annual Election Period. All PDP Sponsors must hold open enrollment.
December 31	PDP Sponsors must mail CY 2007 EOCs to members with an effective date of 1/1/2006.
January 1, 2007	2007 plan benefit begins.

I. RENEWALS

CMS Renewal Notice to PDP Sponsors

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 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.

Our evaluation will include thorough reviews of Sponsors' performance in such operational areas as customer service (e.g., call center hours of operation, hold times, call abandonment rates), administration of transition policies, and enrollment/disenrollment processing. CMS may consider non-renewing the contracts of Sponsors that fail to demonstrate substantial compliance with all Part D program requirements.

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 it bids submitted on June 5, 2006.

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.) Only employer/union plan bids may cover more than one 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 complete and submit 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 the 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 drug 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

II. BIDDING/PAYMENT

Number of Plans Per Region Per PDP Sponsor Contract

CMS is interested in obtaining industry feedback on ways to simplify PDP options for CY 2007. In addition to considering PDP Sponsor performance throughout the 2006 contract year, the two approaches outlined below are being considered in this context.

CMS is considering limiting the number of PDP benefit designs to no more than two per contract per region. More specifically, we are looking at the feasibility of limiting submissions to one basic benefit (defined standard, basic alternative, or actuarial equivalent) and one enhanced alternative benefit within each region per contract.

CMS expects that benefit designs within contracts, as well as within parent organizations, will have meaningful differences that present substantially different choices for beneficiaries. For 2007, PDP Sponsors must ensure that the array of PDP benefit packages presented in each service area can be reasonably evaluated and compared by beneficiaries in terms of deductibles, tiered benefit designs, cost sharing, mail order availability, coverage in the gap, and other factors.

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. 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.

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

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

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

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

For the purposes of bid submission, PDP Sponsors must report all direct and indirect remuneration to CMS. In order to report the full amount of compensation that a Sponsor is providing to pharmacies for participation in the Part D program, Sponsors shall have a provision in all pharmacy contracts that requires pharmacies to fully disclose any and all discounts and rebates or any other direct or indirect remuneration from drug manufacturers or other parties when such remuneration is designed to directly or indirectly influence or impact utilization of Part D drugs. Such disclosure shall detail the

source of the funds, the purpose and the specific dollar amounts paid to the pharmacy from the manufacturer for these purposes. PDP Sponsors shall require pharmacies to indemnify them for the full amount of any such payments not disclosed to the Sponsor. In the event that pharmacies' information on rebates is not based on claims, pharmacies will develop a per-unit rebate calculation that the plans can use to equate to claims utilization data. PDP Sponsors should assure pharmacies that this information will remain confidential.

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, 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, or if a PDP Sponsor requests suppression of its information on the MPDPF because it was inaccurate, we will not approve marketing materials for that plan until the MPDPF 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 1, 2006. As a result, marketing

materials submitted for that plan will not be approved 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 marketing of 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 Dual Eligible Members in 2007

PDPs with premiums at or below the low-income premium subsidy amount in 2006 and 2007: In this situation, 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 dual eligible members to that PDP. (If there is more than one PDP in that service area 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, and there is no applicable premium subsidy by the State or through an approved charity group, CMS will randomly auto-assign these individuals among PDPs 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 is establishing two new SEPs for the following types of beneficiaries:

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

- Individuals who have Low Income Subsidy (LIS) but do not have Medicaid benefits (i.e., individuals who receive Supplemental Security Income (SSI) and others who apply and are approved for LIS).

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 have LIS but no Medicaid – CMS is establishing an SEP to facilitate on an ongoing basis enrollment of these individuals who have not chosen a plan. Previous guidance had indicated that only those who had not chosen a plan by May 15, 2006, would be facilitated on a one-time basis for a June 1, 2006, effective date. After June 1, 2006, those with SSI only, or who apply for LIS and do not have Medicaid benefits, would be facilitated during the next valid enrollment period, which would likely be the next AEP. The enrollment effective date would not be until January 1, 2007. CMS believes it is important to give those individuals who are eligible and approved for the subsidy the immediate opportunity to enroll in a plan and make use of the subsidy. Therefore, we are establishing this SEP to facilitate immediate 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 will extend through December 31st of that year. Proof of eligibility for this SEP may include the subsidy award letter from SSA or the state, or a notice from CMS informing 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.**

Auto-Assignment process & effective dates for full-benefit dual eligible individuals:

Guidance for the process of auto-assignment had previously been provided in section 30.1.4 of the PDP Enrollment and Disenrollment Guidance. To provide a more even distribution of auto-enrollees to Sponsors, CMS is reiterating that it will first distribute auto-enrollments evenly among the all the PDP Sponsors offering low-income subsidy-eligible Part D plans in each PDP Region. CMS will then assign each PDP Sponsor's auto enrollments evenly among the low-income PBPs offered by the Sponsor in that PDP Region.

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 initial enrollment period. 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; or
(2) Coverage through another type of plan actuarially determined to be creditable prescription drug coverage.

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.]

Sponsors will be required to review creditable coverage documentation and report to CMS information upon which CMS will determine whether a late enrollment penalty applies, and if so, the penalty amount. Specifically, beginning in July 2006, 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, Sponsors must determine if a beneficiary had any gaps of 63 days or more from the end of his 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. If the beneficiary attests that he had creditable coverage, he must submit either

- a copy of a personalized disclosure notice from the covering entity, or
- a copy of a generic creditable coverage disclosure notice from the covering entity, with some sort of proof of beneficiary coverage, such as an identification card, a bill, a summary of plan notice, etc..

However, CMS reserves the right to modify or add to the types of evidence of creditable coverage that PDP Sponsor's must review.

If the beneficiary provides insufficient information with the enrollment form, the Sponsor will be required to notify the beneficiary (a model 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. Unless and until the beneficiary provides acceptable evidence of creditable coverage to the Sponsor within 60 days of the beneficiary's effective date, the Sponsor will default to report to CMS that the beneficiary had no uncovered months. If no creditable coverage evidence is provided by the deadline, the beneficiary will be noted and reported as such by the Sponsor as not having creditable coverage for any months not covered by a Medicare plan that provides prescription drug coverage or a retiree prescription drug plan whose sponsor receives a retiree drug subsidy from Medicare. Upon receipt of acceptable creditable coverage evidence by the deadline, and in conjunction with data from the 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. If an enrollee disagrees with an LEP decision made by CMS, the enrollee 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 decision. Additional specific guidance, model letters, and instructions will be provided in the Medicare Prescription Drug 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 premium is $0. Depending on the beneficiary's income level and low income subsidy qualifying status, CMS may subsidize a portion of a beneficiary's LEP for a period of time. Since the LEP is considered part of the premium, 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.

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 will be able to keep, the portion of the penalty that will be attributable to Sponsors' increased actuarial costs.

Given that August 1, 2006, is the first effective date at least 63 days after May 15, 2006, August 1, 2006, 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 (expected April 2006) 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).

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

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 Sponsor of any development 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 Plans

All PDP Sponsors must cease using public media to market CY 2006 plans beginning October 30, 2006. If the Sponsor begins marketing its CY 2007 plans between October 1 and October 30, 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 and to employer/union group members. 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. 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 2006. 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 except the member identification card, the CMS contract number and a 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). In addition, the member identification card must include the contract number and Plan Benefit Package (PBP) number.

File and Use marketing materials must also include the CMS contract number and a 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 elements of the model language and 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.

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. Sponsors must also send an SB to employer/union group members with the ANOC; however, they are not required to use the standardized SB for these members. 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 Sponsors 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 2006 Evidence of Coverage (EOC)

All PDP Sponsors must mail CY 2007 EOCs and LIS riders to all current plan members no later than December 31, 2006. After these Sponsors have mailed the CY 2007 EOC to all current members, they 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 notice of acceptance of enrollment are contained in the Enrollment and Disenrollment Guidelines.

The model EOCs will be available by July 1, 2006. Use of the model EOC without modification is not mandatory; however, it will facilitate a 10 day review period.

Please refer to the "2007 Contract Year Marketing Dates" (below) for 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 December 31, 2006 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 Drug Plan Finder Data

General Instructions

Tentatively scheduled for October 12, 2006, the CY 2007 health plan data will appear on the "Medicare Personal Plan Finder" and "Medicare Prescription Drug Plan Finder" in the standardized summary of benefits format. In addition, "Medicare Personal Plan Finder" will continue to include charts displaying several HEDIS and CAHPS measures, as well as disenrollment reasons data for the MA plans.

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

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 14 and 15, 2006.

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 Sponsoring. 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.

CMS is proposing the following change in co-branding requirements. 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 be required to include the following language located below all co-branding names and/or logos on the member identification card and other marketing materials:

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

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

Customer and Provider Telephone Contact Standards

CMS has updated for 2007 performance standards for certain customer service and provider contact telephone line operations. Sponsors will be required to operate a toll-free call center for both current and prospective enrollees that operates seven days a week at least from 8:00 A.M. to 8:00 P.M. according to the time zones for the regions in which they operate.

Sponsors must operate a toll-free pharmacy technical help call center that operates during the entire period during which the sponsor's network pharmacies in their plans' service areas are open. Note that sponsors whose pharmacy networks include 24-hour pharmacies must operate their pharmacy technical help call centers 24 hours a day as well.

Sponsors must also operate a toll-free call center to respond to physicians and other providers for information related to exceptions and prior authorizations as well as beneficiary appeals. The call center must operate during normal business hours and never less than 8:00 A.M. to 6:00 P.M. Monday through Friday according to the time zones for the regions in which they operate. Voicemail may be used provided the message 1) indicates that the mailbox is secure, 2) lists the information that must be provided so the case can be worked, 3) articulates and follows a process for resolution within one calendar day of call of expedited exceptions requests (3 calendar days for expedited appeals), and 4) provides and follows a process for immediate access in situations where an enrollee's life or health is in serious jeopardy.

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 **new e-mail address TBD**

HPMS Connectivity: Don Freeburger, 410-786-4586

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

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

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.

Conflict of Interest

Contracts with CMS will be amended to add an organizational conflict of interest provision. This requirement was added to the 2007 PDP applications. Entities will be required to provide financial and organizational conflict of interest reports to CMS, pursuant to instructions to be issued by CMS.

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. A draft of the 2007 Transition Process Guidance will be posted on our web site for comment.

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. Nevertheless, Part D plans may not require network pharmacies to qualify as a "Specialty" pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question. The convenient access standards dictate that "Specialty" pharmacies be used to supplement network pharmacy access when necessary and not otherwise restrict it.

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.

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.

Notices to Enrollees and the Public

Non-renewing PDP Sponsors must issue a written notice to all of its 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.

XIV. EMPLOYER/UNION-ONLY GROUP WAIVER PLANS

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

2007 EGWP Timeline

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

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

2007 EGWP Renewal and Non-Renewal Process
(EGWPs and Direct Contract EGWPs)

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

EGWPs and Direct Contract EGWPs that intend to non-renew their Medicare contracts must provide to CMS notice of their decision on or before June 5, 2006. EGWP

procedures for notification to beneficiaries of non-renewal are the same as that in the non-group market.

If EGWP service area expansions are necessary, this information will need to be submitted to CMS as per the 2007 EGWP Service Area Expansion Process section below.

2007 EGWP Service Area Expansion and Reduction Process

For EGWPs-

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

If current PDP Sponsors should want to reduce their service area, they should notify CMS before the June 5, 2006, deadline.

For Direct Contract EGWPs-

Since all Direct Contract EGWPs had a national service area defined for 2006, no service area expansions or reductions will be necessary for 2007.

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 and retains all of the same plan service area, **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 and retains all of its plan service area from 2006.	**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 a regular ANOC.
3	Consolidated Renewal Plan (combining two or more plans within	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	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	No enrollment election is required.	Beneficiaries are sent a regular 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 PDP Region)	combined plans are offered the same benefits in CY2007, the PDP Sponsor must designate which of the renewal Plan IDs will be retained in CY2007 after consolidation. **Note:** If a PDP Sponsor eliminates a region, the PDP Sponsor must follow the Renewal Plan with SAR rules for handling beneficiaries in the eliminated region.		into the designated renewal plan ID. The PDP Sponsor **does not** submit any transactions.		
4	Renewal Plan with an SAE (applicable only to employer/union plans)		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.	Beneficiaries who wish to enroll in the new region must complete an enrollment election.	Only existing beneficiaries are sent a regular ANOC.

Contract Year 2007 Guidance for PDP Sponsor Renewals						
	Activity	Guidelines	HPMS Plan Crosswalk	System Enrollment Activities Submitted to CMS	Enrollment Procedures	ANOC
		1. The model (modified ANOC) 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 transactions** to enroll the beneficiary in another plan with the PDP Sponsor;	Beneficiaries are required to complete an enrollment election if they choose to enroll in another plan.	Beneficiaries are sent a 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 supersede all such other provisions.

2. Definitions.

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

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

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

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

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

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

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

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

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

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

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

3. Description of Provider.

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

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

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

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

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

4. Deductibles.

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

5. Persons eligible for services of Provider.

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

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

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

9. Employee license.

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

the Part D Plan Sponsor's Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

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

10. Provider eligibility for payments.

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

11. Dispute Resolution.

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

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

12. Governing Law.

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

13. Pharmacy/Dispensary Participation.

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

14. Acquisition of Pharmaceuticals.

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

15. Drug Utilization Review/Generic Equivalent Substitution.

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

16. Claims.

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

17. Payment Rate.

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

18. Information, Outreach, and Enrollment Materials.

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

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

19. Hours of Service.

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

20. Endorsement

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

_____ _____
Signature of Authorized Representative

_____ _____
Printed Name of Authorized Representative

_____ _____
Title of Authorized Representative