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CENTER FOR DRUG AND HEALTH PLAN CHOICE

TO: All Part D Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: 2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions

DATE: April 16, 2010

This memorandum addresses two provisions recently enacted under the Patient Protection and Affordable Care Act (H.R. 3590) (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (H.R. 4872) (HCERA). They include section 1101(b)(3) of the HCERA, which addresses coverage for generic drugs in the coverage gap and section 3314 of PPACA, which addresses costs incurred by AIDS drug assistance programs and Indian Health Service counting toward the annual true out-of-pocket threshold under Part D. Separate guidance will be forthcoming regarding Part D sponsor responsibilities under the new drug discount program enacted under section 3301 of PPACA, and as amended by section 1101 of the HCERA.

In addition to the information about the new legislative provisions, this memorandum also addresses two regulatory provisions that directly affect 2011 bid and benefit package reviews. As sponsors are aware, on April 6, 2010, CMS issued a final regulation that includes a number of revisions for the Medicare Parts C and D programs. The provisions in this final rule that largely take effect for the 2011 Contract Year include regulatory revisions to 1) ensure that Part D sponsors submit meaningfully different PBPs within the same service area, and 2) submit Part D cost sharing designs that are not discriminatory. This memorandum provides additional information on how CMS will implement these provisions. We also include some updates and reminders on formulary and benefit package design and submission requirements to help sponsors ensure accurate bid preparation.

When considering the guidance contained in this memorandum, we remind Part D sponsors that under section 3209 of PPACA, the Secretary has the authority to deny a 2011 Part D sponsor bid if it proposes significant increases in cost sharing or decreases in benefits offered under the plan. CMS will be carefully reviewing bids in light of this new authority as part of our upcoming negotiations with sponsors this summer.

A. New Legislative Provisions in 2011

1. Coverage for Generic Drugs in Coverage Gap

Under section 1101(b)(3) of the HCERA, which amended section 3301 of PPACA, additional coverage of Part D drugs will be phased into the Part D benefit between 2011 and 2020, so that by 2020 the standard benefit will cover 25 percent of the cost of brand drugs and 75 percent of the cost of generic drugs in the gap. As part of the legislation, section 1860D-2(b)(2) of the Social Security Act (the Act) was amended to add new paragraphs (C)(i) and (ii) that provide generic-gap coinsurance percentages for future years under the standard benefit. For 2011, the specified coinsurance percentage is 93% for generic drugs. In the alternative, the coinsurance may be an actuarially equivalent amount determined using processes and methods specified under 1860D-11(c) of the Act. The statute limits this coverage to applicable beneficiaries who are defined as individuals who, on the date of dispensing of a covered Part D generic drug, are 1) enrolled in a prescription drug plan or an MA–PD plan; 2) are not enrolled in a qualified retiree prescription drug plan; 3) are not entitled to an income-related subsidy under section 1860D–14(a) of the Act; and 4) who have reached or exceeded the initial coverage limit under section 1860D–2(b)(3) during the year; and have not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

For the purpose of implementing this provision in 2011, CMS will require that Part D sponsors offering basic Part D plans for the next contract year include as part of the bid 7% coverage in the gap for all generic drugs on the plan's formulary. For alternative plan benefit designs, we clarify that the coverage gap begins for the purpose of applying the 7% coverage based on the plan's initial coverage limit (approved as part of the bid) and ends at the point a beneficiary reaches the catastrophic threshold. While the statute includes reference to actuarially equivalent amounts, we will not be accepting such amounts for 2011 given the high degree of risk associated with defining an appropriate actuarially equivalent benefit structure. Instead, Part D sponsors must submit basic bids reflecting 93% coinsurance in the coverage gap for generic drugs on their formulary. As our understanding of coverage in the gap expands, CMS will work on developing a valid design for determining when coverage is actuarially equivalent. We note that the Summary of Benefits (SB) Statement will display language regarding the mandated 7% generic gap coverage benefit. Although, there is no 2011 PBP data entry on the part of sponsors for this new benefit, Part D sponsors will be required to complete a new BPT data entry.

Please be aware that the regulation at 42 CFR 423.4 defines generic drugs as those drug products for which there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)). The type of application on file with the Food and Drug Administration (FDA) determines whether or not the drug product is considered to be a generic drug. A drug is considered a generic drug if its approval is based upon an abbreviated new drug application (ANDA). This definition applies to the coverage gap regardless of whether the sponsor's formulary includes the same drug on its generic cost-sharing tier or on a higher tier, or how a particular drug product is identified by the major drug listing services. Thus, regardless of tier placement on a plan's formulary, generic drugs (as defined above) that are covered below the plan's ICL, must be available at 93% cost sharing in the coverage gap. We note that this benefit does not apply to Part D Excluded drugs.

Finally, we note that the gap coverage level descriptions determined by CMS for Part D sponsors offering enhanced benefit designs and displayed in the SB will reflect additional coverage above the 7% standard coverage of generics in the gap as mandated under the new legislation. As

described below, these gap coverage level descriptions will continue to be based on the additional percentage of formulary drugs (brand or generic above the 7% standard coverage) covered through the gap.

2. Costs that Count toward a Beneficiary's True Out-of-Pocket (TrOOP) Limit

Section 3314 of PPACA amended 1860D–2(b)(4)(C) of the Act to treat the following costs as incurred costs for the purpose of applying TROOP: 1) costs borne or paid by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or 2) costs borne or paid for under an AIDs Drug Assistance Program (ADAP) under part B of title XXVI of the Public Health Service Act. Part D sponsors must update their systems to ensure that TrOOP accumulators appropriately account for these costs beginning in 2011. We note that sponsors are able to identify these IHS and ADAP costs via existing sources of information; namely, network pharmacy contracting data and identifiers and other health insurance coverage information qualifiers on CMS coordination of benefits (COB) files, respectively.

B. Meaningful Differences in Part D Plan Offerings

In accordance with section 1857(e)(1) of the Social Security Act (the Act), as incorporated in Part D by section 1860D-12(b)(3)(D) of the Act, CMS revised its regulations to ensure that plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. Specifically, effective for contract year 2011, §423.272(b)(3)(i) was revised to stipulate that CMS would only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure was substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. A related change to §423.265(b)(2) also requires that Part D sponsors submit multiple bids in the same area only if the offerings are substantially different from each other. For 2011, CMS will be waiving the meaningful differences requirements of sections 42 CFR 423.272(b)(3)(i) and 423.265(b)(2) to allow sponsors of employer group plans (800 series and direct contract plans) to submit, and seek approval of, employer plan benefit packages that do not meet the meaningful differences requirements. We note that we reserve the right to reconsider this waiver in the future. In addition to the guidance set forth below, CMS will be providing additional guidance under separate cover regarding Medicare Advantage Organization (MAO) and Prescription Drug Plan (PDP) Sponsor Renewal/Non-Renewal Options for CY 2011.

1. Out-of-Pocket Cost Comparisons

CMS does not believe that sponsors can demonstrate meaningful differences based on expected out-of-pocket costs (OOPCs) between two stand-alone basic Part D benefit designs and maintain both statutory actuarial equivalence requirements and fulfill the requirement [in §423.153(b)] to maintain cost-effective drug utilization review programs. Therefore, we believe sponsors should submit only 1 basic offering (where basic offering includes defined standard, actuarial equivalent and basic alternative drug benefit types) for a stand-alone prescription drug plan in a service area. In addition, consistent with prior years' negotiations, we will be negotiating with Part D sponsors to offer no more than 3 stand-alone prescription drug plan offerings in a service area,

resulting in a mix of 1 basic and at most, two enhanced plans—subject to the following qualifications.

To determine if cost sharing and formulary and benefit differences result in meaningful differences for the 2011 Contract Year, CMS will compare plan offerings by the same sponsor in a service area by evaluating expected OOPC amounts under each offering. To do this we will utilize a uniform market basket of drugs from a representative population of Medicare beneficiaries run through each plan's benefit design. Specifically, CMS will calculate an OOPC amount for each 2011 PBP using a market basket of all drugs reported by a nationally representative cohort of 13,531 people with Medicare from the 2004 and 2005 Medicare Current Beneficiary Survey (MCBS file) and 2009 PDE data run under the submitted plan design.

In establishing a target for differentiation among an organization's plan offerings, we will be particularly scrutinizing "low-additional-value" enhanced alternative benefit designs. In consultation with beneficiaries and their advocates we have learned that it has been difficult for beneficiaries to distinguish between plan offerings of the same sponsor when cost-sharing and premiums are similar between the enhanced and basic drug plan offering. We recognize that sponsors may have purposefully established plan benefit designs to address different utilization patterns among sub-groups of beneficiaries and in order to segment risk. However, CMS is concerned that some low-additional-value enhanced offerings are not understood by beneficiaries in terms of expected value and may not be meaningfully different from the basic offering.

Using PDP plan offerings submitted for 2010, CMS evaluated enhanced plans to identify those with a meaningful increase in value over the basic plan offerings. We found that for those plans offering a supplemental enhanced benefit including at least a reduced deductible, as well as coverage in the gap of at least some generics, there was a monthly median difference of $22 between the enhanced plans and the basic plan in the same service area (or in other words, we found there was $22 less in expected out-of-pocket costs for the enhanced plan, exclusive of premium amounts). Based on these findings, for the 2011 bid negotiations CMS expects the OOPC plan differential (exclusive of premium amounts) between a basic benefit offering and an enhanced offering of the same sponsor in the same service area to be least at $22 monthly ($264 annually). Additionally, CMS expects that where two enhanced stand-alone drug plans are offered within the same service area, the second enhanced plan will have a higher value than the first and include coverage of at least some brand drugs in the gap (where some is defined as $\geq$10% - 65% of formulary drug entities labeled as brands, see the CY 2010 Call Letter for more information). Sponsors not meeting our targets will be asked to amend or withdraw their PBPs.

To prepare for negotiations with CMS, Part D sponsors planning to offer multiple plans should calculate and compare the OOPCs for a set basket of drugs and constant group of beneficiaries already enrolled with their organization. Part D sponsors may also want to review their own CMS OOPC calculations and methodology for 2010, which will be made available via HPMS in late April. Technical instructions for accessing the OOPC data in the HPMS Part C and Part D Performance Metrics modules will be sent under separate cover. Based on plan review of prior year OOPC calculations and their own OOPC analysis for 2011, sponsors should target necessary revisions to PBPs prior to uploading them in May or June.

2. Low Enrollment Plans

The Medicare Modernization Act (MMA) set the PDP sponsor minimum [contract-level] enrollment levels at the same levels required under the Medicare Advantage (MA) program: 5,000 individuals (1,500 if the organization primarily serves non-urban areas). This number is to be calculated by adding up the number of individuals who receive prescription drug benefits (Medicare and non-Medicare) from the contracting organization. In addition, in our recently released final rule, CMS-4085-F, we provide that with some exceptions, we will use our authority under section 1857(c)(2)(B) of the Act and codified in 42 CFR §423.507(b)(1)(iii) to non-renew plans [at the benefit-package level] that do not meet minimum enrollment thresholds after a specified length of time. Consistent with that authority we will be scrutinizing low-enrollment plans during the bid review period and will expect that sponsors will have withdrawn or consolidated low-enrollment plans prior to submitting bids for CY 2011. This guidance applies to non-employer stand-alone Part D plans. We note that CMS previously granted a waiver of 42 CFR 423.512(a) (minimum enrollment requirements) for sponsors of employer group plans. We reserve the right to reconsider this waiver in the future.

We expect to particularly examine plans that constitute the lowest quintile (20%) of 2010 plans ranked by enrollment. As of March 2010, the lowest quintile was comprised of 303 plans, with an average of 9 plans per each of the 34 PDP regions. These plans had a total enrollment of 94,000 beneficiaries, with an average of 308 enrollees and a median enrollment of 257.5 per plan. The actual plan enrollments ranged from a low of 1 to a high of 1,133 beneficiaries. While we are particularly concerned about these smallest plans, we urge sponsors to consider withdrawing or consolidating any stand-alone plan with less than 1,000 enrollees. Data on plan enrollment counts can be viewed at: www.cms.hhs.gov/MCRAdvPartDenrolData/.

C. Prevention of Discriminatory Part D Cost Sharing

According to 1860D-11(e) of the Medicare Modernization Act, the Secretary can only approve a plan if the design of the plan and its benefits are not likely to substantially discourage enrollment by certain Part D eligible individuals. Based on this authority, CMS updated its regulations at §423.104(d)(2) by adding a new paragraph (iii) to specify that tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory.

To implement these requirements, CMS will examine PDP and MA-PD bid (benefit package) data for 2011 to determine acceptable cost sharing thresholds. Consistent with prior years' review, we plan to conduct an analysis to identify drug tier cost sharing outliers relative to other sponsors' competing benefit packages submitted. As part of this analysis, we will take into consideration plan type, (basic versus enhanced), the number of drug tiers within a PBP, cost structure (copayment versus coinsurance), and differences between MA-PDs (including cost plans) as well as differences between MA-PDs and PDPs.

Assuming similar benefit designs are submitted for 2011 as they were for 2010, sponsors can expect that CMS will establish 2011 thresholds that are reasonably consistent with the prior year's experience. Therefore, in constructing PBPs, Part D sponsors should consider the

following thresholds that were used as part of the 2010 discrimination review for three tiered drug plans:

Tier 1 over $10
Tier 2 over $45
Tier 3 over $95

It is important to note that in identifying drug tier outliers, CMS will take into consideration specific benefit design aspects that could justify an exception for the purpose of our discrimination review. For instance, we may give allowance to cost sharing thresholds for plan benefit designs in which a particular tier represents the specialty tier or for cost sharing in higher tiers if cost sharing in lower tiers is well below the discriminatory pricing thresholds. Atypical tiering structures, such as a two-tier formulary, will also be taken into account.

New for 2011, CMS will increase scrutiny of the expected cost sharing amounts incurred by beneficiaries under coinsurance tiers, in order to more consistently compare copay and coinsurance cost sharing impacts. We expect to derive average expected cost sharing amounts for a sponsor's 2011 coinsurance tiers using 2009 PDE drug cost data mapped to 2011 formulary tiers. If a sponsor submits coinsurance values (instead of copayment values) for its formulary tiers, CMS may also request documentation from the sponsor on the average expected price for medications on the coinsurance tier(s) in order to better translate the coinsurance value into an average cost sharing amount for the purpose of our discrimination review.

Consistent with the meaningful difference review, CMS will notify plan sponsors whose benefit structures include drug tiers that exceed our discriminatory cost sharing threshold limits and conduct negotiation calls as applicable prior to bid approval. Sponsors not meeting our targets will be asked to amend or withdraw their PBPs.

D. Other Formulary/Benefit Design and Submission Information

The following guidance applies to all Part D plans, except as qualified in a specific section.

1 Formulary Six Tier Limit & Standardization of Tier Labels

CMS has heard from various beneficiary and advocacy stakeholders that a large number of drug tiers and non-standardized labeling of those tiers are confusing to beneficiaries when trying to compare plans. In order to keep drug benefits meaningful to beneficiaries while allowing sponsors adequate flexibility in their Part D benefit design, CMS has revised the PBP and formulary upload software for Contract Year 2011 to accept a maximum of six tiers, which includes any excluded Part D drug tiers. While the tool permits a maximum of six tiers, we encourage sponsors to consider submitting benefit designs with fewer formulary drug tiers, as fewer tiers will simplify beneficiary comparisons across benefit designs.

In addition, to improve the clarity and consistency of drug tier label descriptions for beneficiaries, we have updated the 2011 PBP software to display a pick list of standardized drug tier labels that must be used by sponsors when assigning tier names. These labels were derived in part from the most common drug tier names used by sponsors in the CY2010 bid process. We note that the standardized labels selected by sponsors from the drop-down menu must be

consistent with the drug type designations chosen for each tier as part of the PBP upload process. Thus, for example, the drug tier designated by the plan as the *Specialty* tier must have the tier label name of *Specialty Tier Drugs.* Tiers that only include excluded drugs must have *Supplemental* in their tier label name. We note that the standardized tier labels selected by the sponsor will be populated in the Summary of Benefits.

2. Gap Coverage Level Descriptions

As described in the 2010 Call Letter, CMS implemented the use of standardized gap coverage level descriptions for display in the Summary of Benefits and other marketing or plan disseminated materials. For 2011, we clarify that sponsors will no longer indicate their level of gap coverage in the PBP. Instead, CMS will quantify each plan's gap coverage based upon the percentage of formulary drugs (brand or generic above the 7% standard coverage) covered through the gap and then will assign appropriate descriptions. As noted previously, these gap coverage level descriptions will reflect additional coverage above the mandated 7% coverage of generic drugs in the coverage gap starting in 2011.

We note that supplemental (excluded) drugs will not be factored into the determination of gap coverage. Thus, for example, if a plan will cover both generic Part D and supplemental drugs, only the Part D generic drugs will be used in calculating the percentage of generic formulary drugs covered through the gap. A new HPMS report will be available for sponsors to review the CMS-assigned gap coverage labels for approved 2011 formularies in July or August 2010.

3. Requirement to Offer a Basic Plan or Full Supplemental Premium Buy-down for Enhanced Alternative MA-PD Plans

According to 42 CFR § 423.104(f) of the Part D regulations, each MA organization offering Part D benefits must offer required prescription drug coverage throughout its service area. As stated in 42 CFR § 423.100, "required prescription drug coverage" means coverage of Part D drugs under an MA-PD plan that consists of either (1) Basic prescription drug coverage or (2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the plan. In order to help ensure that this requirement is being met, we have added two new questions in the 2011 PBP software for enhanced alternative plans. Sponsors must indicate that they either have another basic (defined standard, actuarially equivalent or basic alternative) Part D plan or that the enhanced alternative plan being submitted meets this requirement because the sponsor has bought down the supplemental Part D premium to zero using the MA rebate.

4. SNPs Targeting Zero Dollar Cost Sharing

We remind sponsors that if they wish to offer a dual eligible SNP with zero dollar cost sharing under Part D, the sponsor must buy down the entire 25% actuarial equivalent cost sharing amount using MA rebate dollars in the bid. Part D plans do not have the option of only applying the rebate dollars to the statutory patient pay amounts and receiving federal cost sharing subsidies for the remainder. Part D sponsors are also not permitted to waive the LIS cost sharing amounts.

We note that States, using state-only funding, may wrap around the Part D LIS cost sharing. Thus, a dual eligible SNP could submit a Part D plan with the statutory LIS cost sharing amounts

to CMS and then also enter into a contract with the State to fund the LIS cost sharing amounts. Under this arrangement, the dual eligible SNP is reimbursed for the LIS cost sharing by the State and the remainder of the actuarial equivalent cost sharing by Medicare through the low-income cost sharing subsidy. This arrangement would leave the MA rebates available to fund other benefits.

5. Sufficient Administrative Costs

Part D sponsors must ensure that they have projected sufficient administrative costs to adequately address CMS requirements (e.g., grievance, appeal, and call center requirements) and maintain acceptable levels of performance. We believe that there is a positive relationship between plan performance and direct administrative costs. For the purposes of our 2011 bid review, CMS expects to more closely scrutinize proposed direct administrative costs relative to 2009 performance measures to ensure that Part D sponsors are committing sufficient funding to administrative programs and services to maintain compliance with CMS performance standards.

6. Home Infusion (HI) Supplemental Files

Since 2007, MA-PD and 1876 Cost Plans have been able to elect to bundle home infusion Part D drugs under Part C as a mandatory supplemental benefit. Sponsors are reminded that plans electing the bundling option are required to apply this coverage consistently and, for 2011, only those drugs appropriate for home infusion will be accepted on HI supplemental file submissions through HPMS. In addition, home infusion coverage changes are only permitted when submitted and approved in accordance with CMS guidance with regard to formulary changes. Plans found to have made unauthorized changes to their HI files during a formulary submission window will face suppression.

7. Over-the-Counter (OTC) Drugs used in Step Therapy Protocols

Part D sponsors may offer over-the-counter (OTC) drugs either as part of (1) a step therapy (ST) protocol submitted for review and approval by CMS or (2) a general drug utilization management (UM) program. To ensure consistency between PBP and formulary file submissions, sponsors will be required to indicate the type of UM strategy they intend to use to administer coverage of OTCs in both the 2011 PBP and formulary submission module. Sponsors electing to offer OTCs as part of their administrative cost structure must upload an OTC supplemental file, along with their HPMS formulary submissions, identifying which OTCs will be provided as well as the UM strategy applied to each drug. CMS reminds sponsors that the step therapy information submitted on the OTC supplemental file must agree with the step therapy information submitted on the PBP and formulary files. OTC files with conflicting information will be rejected.

8. Part D Rx Notes

The Part D Medicare Rx Notes section in the 2011 PBP software has been reduced to 225 characters. This limitation was added since other information previously transmitted via the notes field (i.e., OTC drugs, Home Infusion drugs and Supplemental drugs) are now submitted on supplemental files. We remind sponsors that the Medicare Rx Notes section should only be used for very rare situations that cannot be described adequately using the PBP software. Information that is general and available elsewhere, or that does not pertain directly to the Part D benefit, is inappropriate for the notes sections. Additionally, the notes must not modify, qualify,

or contradict information entered in the PBP or otherwise limit the benefit, and should not automatically include information from the prior year's notes unless applicable for 2011. CMS will not approve any plans with redundant or inappropriate notes and sponsors will be required to remove any such notes and resubmit before bid approval.

9. Plan Corrections

The plan correction module will be available in HPMS for 2011 PBPs for a limited period, from mid-September until October 1, 2010. Organizations may only request a plan correction after their contract has been approved. This limited timeframe will ensure that correct bid information will be available for review on the Medicare Prescription Drug Plan Finder in time for the open enrollment start date. Only changes to the PBP that are supported by the BPT are allowed during the plan correction period.

CMS expects that sponsors' requests for plan corrections will be very rare. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. Please be advised that an organization requesting a plan correction will receive a corrective action warning letter. An organization that received a warning letter for CY 2010 bid correction issues will receive a corrective action plan (CAP) if it requests a plan correction for CY 2011.

We appreciate your cooperation on these important matters and look forward to productive discussions with Part D sponsors in preparation for the 2011 Contract Year. Please direct any questions on matters addressed in this memo to the following mailbox: PartDBenefits@cms.hhs.gov

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