DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

CENTER FOR MEDICARE

TO: All Part D Sponsors

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

Cheri Rice, Director, Medicare Plan Payment Group

SUBJECT: Request for Comments on Part D Benefit Administration and Prescription Drug Event (PDE) Reporting

DATE: December 11, 2012

The purpose of this memorandum is to provide plans an opportunity in advance of the draft CY2014 Call Letter and Advance Notice to comment on potential new policies and policy changes that CMS is considering for CY 2014. These changes are intended to clarify several issues directly affecting Part D benefit administration and PDE reporting. The timing of the annual draft Call letter, when combined with the statutory timing of the Advanced and Final Rate Notices, diminishes the time allowed to fully explore substantive changes suggested by commenters. This Request for Comments allows CMS to have additional time to review and evaluate comments prior to the Final Call Letter and Rate Notice.

We will consider all comments received by December 28, 2012 at 5pm EST in drafting the proposals for CY 2014. Please submit only one set of responses per organization to pdejan2011@cms.hhs.gov. Commenters will have another opportunity to submit comments on any revisions to these proposals resulting from this first set of comments through the Advance Notice and draft Call Letter process.

Our goal is to establish one clear set of rules that all Part D plans can implement so that we can ensure uniform treatment of beneficiary liability across all Part D plans, accurate calculation of the coverage gap discount amount, and consistency of benefit administration across all phases of the benefit. In working with industry to prepare for benefit changes resulting from the Affordable Care Act of 2010 and the upcoming change to the regulatory definition of Part D supplemental benefits, it has become clear that there is a need for additional guidance relating to:

- Applicable Beneficiary and Plan Dispensing/Vaccine Administration Fee Liability on
    - a) Applicable Drug Claims that Straddle the Coverage Gap and
    - b) Applicable Drug Coverage Gap Claims for Enhanced Alternative (EA) Plans offering Part D Supplemental Coverage in the Gap;
- Beneficiary and Plan Negotiated Price Cost Component Liability;
- Other Health Insurance (OHI) and Employer Group Waiver Plans (EGWPs); and
- Enhanced Alternative Plan Mapping Rules.

1. Applicable Beneficiary and Plan Dispensing/Vaccine Administration Fee Liability on a) Applicable Drug Claims that Straddle the Coverage Gap and b) Applicable Drug Coverage Gap Claims under EA Plans offering Part D Supplemental Coverage in the Gap.

In the 2013 Advance and Final Rate Notices, respectively, CMS proposed and adopted the policy that plans and beneficiaries will share dispensing/vaccine administration fee liability on coverage gap claims for applicable drugs. Specifically, the beneficiary liability for such fee(s) on a coverage gap claim will be determined by applying the beneficiary's coverage gap coinsurance to the dispensing fee and the plan liability will be calculated as the balance. In 2013, this means that the beneficiary will pay 47.5% of the dispensing fee and the plan will by 52.5% on coverage gap claims without supplemental coverage in the gap.

However, in working through examples with industry to illustrate how to apply the policy to applicable drug coverage gap straddle claims and coverage gap claims under EA plans with Part D supplemental coverage in the gap, it became clear that more detailed guidance would be needed. Consequently, we delayed implementation of policy changes for applicable drug coverage gap straddle claims and coverage gap claims under EA plans with Part D supplemental coverage in the gap for 2013. We now seek comments on the following potential new policies we are considering for CY2014:

a) Coverage Gap Straddle Claims: We are considering a policy that would always include the dispensing/vaccine administration fee within the negotiated price to the greatest extent possible. This policy would be intended to resolve the issue of having two different definitions of negotiated price apply to a single claim—one definition that includes the dispensing/vaccine administration fee and the other definition in the coverage gap that excludes the dispensing/vaccine administration fee. In effect, this policy would maintain the current policy that the dispensing/vaccine administration fee for any coverage gap straddle claim is included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold to the greatest extent possible.

   The following example demonstrates how this proposed policy would be implemented for PDE reporting.

   When claim adjudication begins, the TGCDC Accumulator is $6,700.00 and the TrOOP Accumulator is $4720.00. The plan offers an enhanced alternative benefit. The claim begins in the coverage gap and ends in the catastrophic coverage phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee. There is a 30% co-insurance in the coverage gap.

PDE Fields	**Claim Total**
Total Gross Covered Drug Cost Accumulator	$6,700.00
True Out of Pocket Accumulator	$4720.00
Beginning Benefit Phase	G
Ending Benefit Phase	C

Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

Distribution of Drug Cost across benefit phases

Benefit Phase	**Drug Cost within each phase**	**Ingredient cost paid**	**Dispensing fee**
Coverage Gap	$100.00	$100.00	$0.00
Catastrophic Coverage Phase	$102.00	$100.00	$2.00
Total	$202.00	$200.00	$2.00

PDE Reporting of Coverage Gap PDEs for EA plans with additional gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $100.00
2. **Determine Plan liability:** $100.00 - $30.00 = $70.00
3. **Determine Discount Eligible Cost:** $100.00 - $70.00 = $30.00
4. **Calculate Gap Discount:** $30.00 * 50% = $15.00
5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $30.00 - $15.00 = $15.00
6. **Determine CPP and NPP amounts:**
   Determine CPP and NPP in the Coverage Gap phase:
   CPP is 2.5% of the ingredient cost and sales tax plus 52.5% of the dispensing fee in the gap
   2.5% * $100.00 = $2.50
   The dispensing fee is outside of the coverage gap.

   NPP in the coverage gap is $100.00 **–** ($15.00 + $15.00 + $2.50) = $67.50

   Determine CPP and NPP for cost falling outside of the Coverage Gap phase:
   The plan amount is the lesser of 95% of the drug cost in the catastrophic phase or Drug cost - $6.60. The CPP amount is $102 - $6.60 = $95.40.
   NPP in the catastrophic phase is $0.00

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:** In this example, the dispensing fee is in the catastrophic phase and will be considered when determining beneficiary liability for cost falling outside of the Coverage Gap.
8. **Determine beneficiary liability for cost falling outside of the Coverage Gap:** In the catastrophic phase, the beneficiary pays the greater of $6.60 or 5% of the drug cost in the catastrophic phase. In this example, the beneficiary pays $6.60.

	Pt. Pay Amount	Reported Gap Discount	CPP	NPP
Coverage Gap	$15.00	$15.00	$2.50	$67.50
Catastrophic Coverage	$6.60	$0.00	$95.40	$0.00

Phase				
PDE Fields	$21.60	$15.00	$97.90	$67.50

b) Coverage Gap Claims under EA plans with Part D supplemental coverage in the gap: We are considering implementing the policy originally adopted in the Final Rate Notice for CY 2013 that specified the dispensing/vaccine administration fee liability on applicable drug coverage gap claims under EA plans with Part D supplemental coverage in the gap would be commensurate with the coinsurance percentage. For example, if the coinsurance percentage under the benefit is 25%, the beneficiary will pay 25% of the dispensing/vaccine administration fee and the plan will pay 75% of the dispensing/vaccine administration fee. The manufacturer discount would be calculated as 50% of the beneficiary coinsurance percentage as applied to the coverage gap negotiated price (as defined in 42 CFR 423.100). However, we are not considering implementing a rule for applicable drug coverage gap claims with copays because under current CMS requirements there will not be any such enhanced benefit designs allowed in 2014. This approach to applicable drug coverage gap claims under EA plans aligns with the shared responsibility approach on applicable drug coverage gap claims under basic benefits.

The following example demonstrates how this proposed policy would be implemented for PDE reporting.

When claim adjudication begins, the TGCDC Accumulator is $3,000.00 and the TrOOP Accumulator is $1,110.00. The plan offers an enhanced alternative benefit. The claim falls in the coverage gap phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee. There is a 30% co-insurance in the coverage gap.

PDE Fields	**Claim Total**
Total Gross Covered Drug Cost Accumulator	$3,000.00
True Out of Pocket Accumulator	$1,100.00
Beginning Benefit Phase	G
Ending Benefit Phase	G
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

PDE Reporting of Coverage Gap PDEs for EA plans with additional gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $202.00
2. **Determine Plan liability:** $202.00 - $60.60 = $141.40
3. **Determine Discount Eligible Cost:** The beneficiary pays 30% of the ingredient cost and 30% of the dispensing fee within the gap. The discount eligible cost is the drug cost in the gap minus plan liability and beneficiary liability for the dispensing fee. In this example, the discount eligible cost is $202 - $141.40 - $0.60 = $60.00
4. **Calculate Gap Discount:** $60.00 * 50% = $30.00

5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $60.00 - $30.00 = $30.00
6. **Determine CPP and NPP amounts:**
   Determine CPP and NPP in the Coverage Gap phase:
   CPP is 2.5% of the ingredient cost and sales tax plus 52.5% of the dispensing fee in the gap
   2.5% * $200.00 = $5.00
   52.5% * $2.00 = $1.05
   NPP is $202.00 – ($30.60 + $30.00 + $6.05) = $135.35

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:**
   The beneficiary pays 30% of the dispensing fee falling within the gap. The beneficiary liability for the dispensing fee is $0.60

	Pt. Pay Amount	Reported Gap Discount	CPP	NPP
PDE Fields	$30.60	$15.00	$6.05	$141.40

2. Beneficiary and Plan Negotiated Price Cost Component Liability

In the Advance Notice for CY 2013, we proposed that plan and beneficiary liability for each cost component of the negotiated price be calculated proportional to plan and beneficiary liability for the entire negotiated price in all phases of the benefit. The reasons for doing do included ensuring a level playing field, uniform treatment of beneficiary liability across all Part D plans, and consistency of benefit administration across all phases of the benefit. In light of technical challenges that have been raised with respect to this policy change and remaining questions that need to be answered, we had announced that we will not be changing the existing policy for CY 2013.

We again are considering a policy for CY 2014 that makes beneficiary and plan liability for each cost component of the negotiated price proportional to the beneficiary and plan liability for the entire negotiated price when the claim falls squarely in one phase of the Part D benefit. For example, if a beneficiary has a 25% coinsurance on a claim in the initial coverage phase with a $100 negotiated price that includes a $2 dispensing fee and $5 sales tax, the beneficiary would be responsible 25% of the ingredient cost, 25% of the dispensing fee and 25% of the sales tax, and the plan would be responsible for the remainder of each cost component.

However, if a claim straddles benefit phases, we are considering adopting one of two options for determining beneficiary and plan negotiated price cost component liability and seek comments on each option:

a) Implement the policy proposed in the Advance Notice for CY 2013 and adopted in the Final Rate Notice for CY 2013 that each cost component of the negotiated price be calculated proportional to beneficiary and plan liability for the entire negotiated price in all phases of the benefit. Under this policy, a plan could either apply programming logic that calculates the proportional liability of each cost component in each phase or alternatively calculate the proportional liability based upon the aggregate beneficiary/plan liability for the claim. Either methodology would take into account the differing proportional liability in each phase of the benefit and would ensure that plan could consistently determine individual negotiated price cost component liability when necessary.

The following example demonstrates how this proposed policy would be implemented for PDE reporting.

When claim adjudication begins, the TGCDC Accumulator is $6,700.00 and the TrOOP Accumulator is $4720.00. The plan offers an enhanced alternative benefit. The claim begins in the coverage gap and ends in the catastrophic coverage phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee and $10.00 sales tax. There is a 30% co-insurance in the coverage gap.

PDE Fields	**Claim Total**
Total Gross Covered Drug Cost Accumulator	$6,700.00
True Out of Pocket Accumulator	$4720.00
Beginning Benefit Phase	G
Ending Benefit Phase	C
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

Distribution of Drug Cost across benefit phases

Benefit Phase	**Drug Cost within each phase**	**Percentage of drug cost (excluding dispensing fee) within each phase**	**Ingredient cost paid**	**Dispensing fee**	**Sales tax**
Coverage Gap	$100.00	50.00%	$95.00	$0.00	$5.00
Catastrophic Coverage Phase	$102.00	50.00%	$95.00	$2.00	$5.00
Total	$202.00	100%	$190.00	$2.00	$10.00

PDE Reporting of Coverage Gap PDEs for EA plans with additional gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $10.00

2. **Determine Plan liability:** $100.00 - $30.00 = $70.00
3. **Determine Discount Eligible Cost:** $100.00 - $70.00 = $30.00. The $30.00 co-insurance contains ($28.50 ingredient cost and $1.50 sales tax)
4. **Calculate Gap Discount:** $30.00 * 50% = $15.00
5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $30.00 - $15.00 = $15.00. The beneficiary pays $14.25 in ingredient cost and $0.75 in sales tax.
6. **Determine CPP and NPP amounts:**
   Determine CPP and NPP in the Coverage Gap phase:
   CPP is 2.5% of the ingredient cost and sales tax plus 52.5% of the dispensing fee in the gap
   2.5% * $100.00 = $2.50
   The dispensing fee is outside of the coverage gap.

   NPP is $100.00 **–** ($15.00 + $15.00 + $2.50) = $67.50

   Determine CPP and NPP for cost falling outside of the Coverage Gap phase:
   The plan amount is the lesser of 95% of the drug cost in the catastrophic phase or Drug cost - $6.60. In this example, the CPP amount is $95.40.
   NPP in the catastrophic phase is $0.00
7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:** In this example, the dispensing fee is in the catastrophic phase and will be considered when determining beneficiary liability for cost falling outside of the Coverage Gap.
8. **Determine beneficiary liability for cost falling outside of the Coverage Gap:** In the catastrophic phase, the beneficiary pays the greater of $6.60 or 5% of the drug cost in the catastrophic phase. In this example, the beneficiary pays $6.60.

	Pt. Pay Amount	Reported Gap Discount	CPP	NPP
Coverage Gap	$15.00	$15.00	$2.50	$67.50
Catastrophic Coverage Phase	$6.60	$0.00	$95.40	$0.00
PDE Fields	$21.60	$15.00	$97.50	$67.50

b) Implement a new policy that each negotiated price cost component must be included entirely in one phase of the benefit to the greatest extent possible. For the dispensing fee, this phase would always be below the ICL or above the annual out-of-pocket threshold to the greatest extent possible. For all other cost components, this phase would be the first phase in which the cost component would be less than the amount remaining in the phase. While this approach does not provide for claim-level proportionate liability for each cost component, it does provide a level playing field, uniform treatment across all Part D plans, and consistency of benefit administration across all phases of the benefit without changing the straddle claim logic presented in the 2011 PDE Participant Guide.

The following example demonstrates how this proposed policy would be implemented for PDE reporting.

When claim adjudication begins, the TGCDC Accumulator is $6,700.00 and the TrOOP Accumulator is $4720.00. The plan offers an enhanced alternative benefit. The claim begins in the coverage gap and ends in the catastrophic coverage phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee and $10.00 sales tax. There is a 30% co-insurance in the coverage gap.

PDE Fields	Claim Total
Total Gross Covered Drug Cost Accumulator	$6,700.00
True Out of Pocket Accumulator	$4720.00
Beginning Benefit Phase	G
Ending Benefit Phase	C
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

Distribution of Drug Cost across benefit phases

Benefit Phase	Drug Cost within each phase	Ingredient cost paid	Dispensing fee	Sales tax
Coverage Gap	$100.00	$90.00	$0.00	$10.00
Catastrophic Coverage Phase	$102.00	$100.00	$2.00	$0.00
Total	$202.00	$190.00	$2.00	$10.00

PDE Reporting of Coverage Gap PDEs for EA plans with additional gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $100.00
2. **Determine Plan liability:** $100.00 - $30.00 = $70.00
3. **Determine Discount Eligible Cost:** $100.00 - $70.00 = $30.00. The $30.00 co-insurance contains $27.00 in ingredient cost and $3.00 in sales tax
4. **Calculate Gap Discount:** $30.00 * 50% = $15.00
5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $30.00 - $15.00 = $15.00. The beneficiary pays $13.50 in ingredient cost and $1.50 in sales tax.
6. **Determine CPP and NPP amounts:**
   Determine CPP and NPP in the Coverage Gap phase:
   CPP is 2.5% of the ingredient cost and sales tax plus 52.5% of the dispensing fee in the gap
   2.5% * $100.00 = $2.50
   The dispensing fee is outside of the coverage gap.

NPP is \$100.00 – (\$15.00 + \$15.00 + \$2.50) = \$67.50

Determine CPP and NPP for cost falling outside of the Coverage Gap phase:
The plan amount is the lesser of 95% of the drug cost in the catastrophic phase or Drug cost - \$6.60. In this example, the CPP amount is \$95.40.
NPP in the catastrophic phase is \$0.00

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:** In this example, the dispensing fee is in the catastrophic phase and will be considered when determining beneficiary liability for cost falling outside of the Coverage Gap.
8. **Determine beneficiary liability for cost falling outside of the Coverage Gap:** In the catastrophic phase, the beneficiary pays the greater of \$6.60 or 5% of the drug cost in the catastrophic phase. In this example, the beneficiary pays \$6.60.

	Pt. Pay Amount	Reported Gap Discount	CPP	NPP
Coverage Gap	\$15.00	\$15.00	\$2.50	\$67.50
Catastrophic Coverage Phase	\$6.60	\$0.00	\$95.40	\$0.00
PDE Fields	\$21.60	\$15.00	\$97.90	\$67.50

3. Other Health Insurance (OHI) and Employer Group Waiver Plans (EGWPs)

EGWPs currently provide additional coverage as either 1) Medicare Part D supplemental benefits, reported on PDEs as Non Covered Plan Paid Amount (NPP) or 2) Non-Medicare OHI, reported on PDEs as patient liability reduced by other payer (PLRO). Beginning in 2014, all additional coverage provided by EGWPs will be considered OHI and reported as PLRO.

It is our understanding that there are two PDE reporting methods currently being used by Part D sponsors when OHI results in beneficiary cost-sharing that is greater than it would be under the Part D plan benefit. Under one method, sponsors cap the patient pay amount, low-income cost-sharing subsidy (LICS) amount, and TrOOP amount based upon their Part D plan benefit and report PLRO as zero. In other words, OHI is not reported on the PDE when it increases beneficiary cost-sharing above the Part D plan benefit.

Under the second method, Part D sponsors apply the LICS formula rules, which are published in our technical assistance training guide. With this method, LICS is calculated and capped based upon the Part D plan benefit and patient pay is adjusted based upon the OHI. For EGWPs providing additional coverage as OHI, LICS is capped based upon the defined standard benefit. If the patient pay amount under the OHI is greater than the Part D plan benefit, PLRO is negative and the patient pay is updated to reflect the patient pay amount under OHI. For example, a low income beneficiary purchases a brand drug in the initial coverage phase. The low income beneficiary is a category two low income beneficiary in which the co-pay for a brand drug is \$3.50. The cost of the drug is \$100.00. In the initial coverage phase, a non-low income beneficiary would pay \$25.00 for this drug.

The LICS amount is the difference between the non-low income beneficiary amount ($25.00) and the category two co-pay amount ($3.50), which is $21.50. The beneficiary has OHI in which the co-pay is $40.00. To determine PLRO, the OHI patient pay amount ($40.00) is subtracted from the original patient pay amount ($3.50). The PLRO amount is -$36.50.

Beginning in 2014, we are considering requiring all Part D sponsors, including EGWP sponsors, use only the second method and apply LICS formula rules. We seek comments to identify questions and issues with implementing this policy.

4. Enhanced Alternative Plan Mapping Rule 4

Curently, under EA Mapping Rule 4, if the YTD Gross Covered Drug cost is greater than the estimated total covered Part D spending at the Out-of-Pocket threshold but True Out-of-Pocket (TrOOP) cost is less than or equal to the Out-of-Pocket (OOP) threshold, the Part D plan maps 15% of the discount eligible cost and any fees falling within this rule (dispensing fee or vaccine administration fee) to covered plan paid amount (CPP).

As a result of the Affordable Care Act changes to the Defined Standard Benefit that began closing the coverage gap for non-applicable drugs in 2011 and begins closing the coverage gap for applicable drugs in 2013, CMS has been asked if EA Mapping Rule 4 will change. After considering these questions and reconsidering the justification for Mapping Rule 4 in light of the coverage gap changes, CMS is considering eliminating EA Mapping Rule 4 beginning in 2014. We believe that EA sponsors are already being paid for the additional 15% through supplemental beneficiary premiums and question why we should continue to credit this amount as CPP. Consequently, EA plans would always use EA Mapping Rule 3 to map to the basic Part D benefit when a beneficiary has drug spend above the initial coverage limit but TrOOP is less than or equal to the OOP threshold. We seek comment on this potential policy change, including justification for maintaining EA Mapping Rule 4.

We will consider all comments received by December 28, 2012 at 5pm EST. Please submit only one set of responses per organization. Please submit all comments to pdejan2011@cms.hhs.gov. Thank you for your participation.