DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

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TO: All Part D Sponsors

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SUBJECT: Additional Guidance concerning Closing the Coverage Gap in 2011

In response to questions we have received since issuing guidance through the May 21, 2010 and June 2, 2010 memoranda, we are issuing this third memorandum so that Part D sponsors have all information necessary to complete their programming in time for January 1, 2011 implementation. This memorandum provides Part D sponsors with additional 2011 guidance specific to:

- Enhanced Alternative Benefits Designs without an initial coverage limit
- Non-Calendar year Employer Group Waiver plans
- Covered Part D drugs that are not Applicable Drugs under the Medicare Coverage Gap Discount Program
- Part D vaccine administration fees
- Discounts on direct member reimbursements for prescriptions filled at out-of-network pharmacies
- Part D compounds
- Brand-only deductibles

Enhanced Alternative Benefit Designs without an initial coverage limit

Part D sponsors, primarily those with employer group waiver plans (EGWPs), have asked CMS about the applicability of discounts under the Medicare Coverage Gap Discount Program (CGDP) if a plan has an enhanced alternative benefit design that does not have an ICL. Under this benefit design, the cost-sharing, after deductible, is uniform all the way through the benefit

until catastrophic. The Affordable Care Act defines an applicable beneficiary as having reached or exceeded the ICL under section 1860D-2(b)(3) during the year and not having 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). In guidance, CMS states that for purposes of determining when the coverage gap begins, Part D plans shall apply their plan specific ICL under basic alternative, actuarially equivalent, or enhanced alternative Part D benefit designs. Therefore, if a Part D plan increased its ICL by $500, the discounts could not begin until the individual exceeds the plan's ICL.

However, under the scenario where there is no ICL, the defined standard ICL must be used for purposes of identifying coverage gap claims for applicable drugs that are subject to discount. Accordingly, the discount would apply to those claims above the defined standard ICL in accordance with the CGDP supplemental coverage rules specified in our guidance. This policy ensures that beneficiaries in enhanced alternative Part D plans that have uniform cost-sharing throughout the benefit have the same access to discounts as beneficiaries in any other enhanced alternative Part D plan that offers supplemental benefits in the coverage gap.

Non-Calendar year Employer Group Waiver plans

Non-calendar year EGWPs must implement the coverage gap changes on a calendar year basis. Therefore, applicable beneficiaries enrolled in non-calendar year EGWPs will begin accessing discounts under the CGDP at the same time as applicable beneficiaries enrolled in individual market plans. Any applicable beneficiaries that have reached the coverage gap during their non-calendar plan year would be eligible for coverage gap discounts beginning January 1, 2011 based upon their existing non-calendar year accumulated drug costs for applicable drugs. The accumulated drug costs would be reset with the beginning of the next non-calendar plan year.

Similarly, non-calendar year EGWPs will implement changes with respect to "generic" coverage gap cost-sharing on a calendar year basis beginning on January 1, 2011 and each January 1st thereafter until 2020. Beginning in 2013, the January 1st changes will include the additional changes to applicable drug cost-sharing in addition to the manufacturer discounts. While the cost-sharing changes will be implemented on a calendar year basis, the accumulated drug costs will be based upon the non-calendar plan year for purposes of establishing when an enrollee has entered or exited the coverage gap.

Covered Part D drugs that are not Applicable Drugs under the CGDP

Medicare Part D only covers drugs that satisfy the definition of a Part D drug. In general, 1860D-2(e)(1) of the Act defines a Part D drug as a FDA-approved prescription drug, biological, or insulin, when used for a medically accepted indication. In addition, the definition includes older prescription drugs that have not been subject to a "new drug" determination by the FDA. Applicable Part D drugs under the CGDP are those drugs that are on a Part D plan's formulary, or treated as if on formulary (e.g. through the exceptions process), and are approved under a new drug application (NDA) under section 505(b) of the Federal Food Drug and Cosmetic Act or in the case of a biological product, the drug is licensed under section 351 of the Public Health Service Act (BLA) (other than a product licensed under subsection (k) of such section 351).

Only those applicable Part D drugs covered by a manufacturer discount agreement will be covered under the Part D program beginning January 1, 2011.

CMS previously issued guidance clarifying that a covered Part D drug approved under an ANDA is not an applicable drug and meets the requirements under 1860D-2(b)(C) for "generic" gap cost-sharing. We want to further clarify that all the categories of Part D drugs that are not applicable drugs will be subject to the "generic" coverage gap cost-sharing in 2011 (e.g. medical supplies associated with the delivery of insulin, Part D compounds (see below)). While other drugs, in addition to medical supplies associated with the delivery of insulin and Part D compounds, that meet the definition of Part D drugs also meet the requirements for "generic" coverage gap cost-sharing, CMS does not believe that many of the older prescription drugs currently on the market meet the definition of a Part D drug and, therefore expects Part D sponsors to carefully make determinations to cover any such drugs.

Part D vaccine administration fees

In a response to a comment in the May 21, 2010 guidance, CMS clarified that vaccine administration fees are included in the negotiated price for purposes of determining the applicable discount. Upon further consideration, CMS believes that vaccine administration fees are analogous to dispensing fees for purposes of the CGDP and, therefore, must be excluded from the definition of negotiated price for purposes of determining the applicable discount. Unlike sales tax, dispensing fees and vaccine administration fees pay for services apart from of the applicable drug itself. This is made clear by the fact that a vaccine administration fee may be billed separately from the dispensing of the vaccine. If the vaccine administration fee is billed separately from the vaccine in the coverage gap, it is subject to neither a discount under the CGDP nor "generic" coverage gap cost-sharing. Sales tax remains included in the definition of negotiated price under the CGDP.

For straddle claims, both the dispensing fee and vaccine administration fee must be included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold. If the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold is less than the sum of the dispensing fee and vaccine administration fee, the dispensing fee must be included first in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold.

Discounts on direct member reimbursements for prescriptions filled at out-of-network pharmacies

For purposes of discounting direct member reimbursement claims, negotiated price shall mean the plan allowance as set forth in 42 CFR 423.124, less any dispensing fee.

Part D compounds

In the previously issued May 21, 2010 guidance, CMS stated that Part D sponsor shall provide a discount on a Part D compound if the NDC submitted on the PDE is for an applicable drug and that such discount shall only be provided on the negotiated price of the applicable drug submitted on the PDE. Upon further consideration, CMS has determined that Part D compounds are not applicable drugs for purposes of the CGDP. While Part D sponsors can cover compounds with at least one Part D drug ingredient for the cost associated with the Part D drug ingredients only, we believe that the applicable drug determination must be made with respect to the compound as a whole. We changed this policy based upon a better understanding of the complexities associated with trying to accurately determine and validate discounts on an ingredient level basis given the information that is available on pharmacy claims transactions and PDEs. Given that a compound as a whole is not approved under an NDA or BLA, a compound does not meet the definition of an applicable drug. Therefore, Part D sponsors will apply the "generic" gap cost-sharing to the Part D drug components of all Part D compounds.

Brand-only deductibles

CMS has not previously provided guidance with respect to deductibles and the effect, if any, that either the ICL or true out-of-pocket (TrOOP) threshold would have on any deductibles. With the implementation of the CGDP, however, CMS finds it necessary to clarify that for purposes of the CGDP only beginning in 2011, a Part D deductible ceases to apply once a beneficiary's total gross covered drug costs exceed the ICL. This means that for a beneficiary enrolled in a Part D plan with a brand-only deductible, applicable (i.e. brand) drugs that would otherwise be subject to the deductible will be eligible for a coverage gap discount once the beneficiary's total gross covered drug costs exceed the ICL even if the beneficiary has not satisfied the deductible.

If you have any questions regarding this guidance, please contact Craig Miner at 410-786-7937 or craig.miner@cms.hhs.gov.