DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

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TO: All Part D Plan Sponsors

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

SUBJECT: Additional Guidance on 2011 Coverage for Generic Drugs in the Coverage Gap

This memorandum addresses questions CMS has received concerning 2011 bid submissions and the new provision regarding coverage for generic drugs in the coverage gap 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). We previously provided background for this new provision as well as bid submission instructions in the *2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions* memorandum posted on April 16, 2010. Please review the April 16th memo for more information.

Q1. Does the newly mandated 7% standard coverage of generic drugs in the gap apply to generics drugs residing on non-generic formulary tiers (e.g. brand tier or specialty tier)?

A1. Yes. For 2011, the 7% standard coverage of generic drugs costs in the gap applies to all generics treated as formulary drugs in the pre-initial coverage limit (ICL) phase, regardless of tier placement (this includes generic drugs obtained through the exceptions process). For the purpose of this new standard benefit, a generic is defined by the regulation at 42 CFR 423.4 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; therefore, a drug is considered a generic drug if its approval is based upon an abbreviated new drug application (ANDA). This generic 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 (such as the specialty tier), or how a particular drug product is identified by the major drug listing services (e.g. the 7% reduction does not apply to multisource brands). Thus, regardless of the tier placement on a plan's formulary, generic drugs (as defined above) that are covered below the plan's ICL must be available at no more than 93% cost sharing in the coverage gap.

Q2. Are generic Part D excluded drugs covered through the gap by enhanced alternative plans subject to the new provision for generic gap coverage?

A2. No. The new standard benefit does not apply to Part D excluded drugs. Only those Part D generic drugs treated as formulary drugs (including generics received by beneficiaries through the exceptions process) are subject to the new benefit.

Q3. In 2011, are enhanced alternative plans offering additional gap coverage required to provide supplemental benefits for all pre-ICL generics through the gap?

A3. No. As in years prior, for CY 2011, sponsors may elect to provide additional gap coverage for generic drugs on certain tiers or subsets of tiers, but are not required to provide additional gap coverage for all formulary generics. However, for any pre-ICL covered generic that is not included under the additional gap coverage offered through a supplemental benefit, the 7% reduction in cost sharing must also be covered (in the basic benefit) such that the beneficiary pays no more than 93% coinsurance for these generic drugs. Thus, for all basic plan types (i.e., defined standard, actuarial equivalent, and basic alternative) and enhanced alternative plans with no additional gap coverage, the beneficiary cost share is 93% in the gap for all generic formulary drugs. Likewise, for enhanced alternative plans that only provide additional gap coverage for a subset of formulary generics, those generics that are not subject to the supplemental benefit must also have a beneficiary cost share in the gap of 93%.

Q4. For enhanced alternative plans offering additional gap coverage of generics in the gap, are there limitations in the type of cost sharing that can be applied to these drugs for CY 2011?

A4. No. Enhanced alternative plans offering additional gap coverage of generics may apply copayment or coinsurance cost sharing through the gap, and that cost sharing does not need to be the same type or value as the cost-sharing applied pre-ICL. We remind sponsors that for alternative benefit designs with increased or decreased ICLs, 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. In addition, the 7% reduction must be applied in the coverage gap (i.e., alternative benefit designs cannot use actuarial equivalence to shift this reduction below the ICL such that there is higher cost sharing for generics in the coverage gap).

Q5. To comply with the new legislation, when constructing 2011 bids do enhanced alternative plans need to use lesser of logic when offering additional gap coverage of generics?

A5. No. However, when constructing the 2011 bids, any enhanced benefit for additional gap coverage of generics should be meaningfully different from the new 7% standard coverage of generics in order to reflect a common understanding of supplemental coverage by the beneficiary. An enhanced alternative plan may establish a copayment amount in the gap for pre-ICL covered generics at the tier level without applying lesser of logic at the claim level so long as the enhanced benefit across the gap for generics is actuarially equivalent to significantly more than the required standard coverage. In addition, consistent with our existing regulations, the cost sharing at the point of sale for a generic drug cannot be more than the plan negotiated cost

of the drug. For example, a copayment of $5 for generics in tier 1, which represented an actuarially equivalent benefit to 50% of the generic drug costs for generics in that tier, would clearly demonstrate a more meaningful benefit than the new standard cost share of 93%. In this same example, if at the point of sale the plan negotiated cost of a tier 1 generic was only $4, the beneficiary must be charged the lower amount (i.e., $4 instead of the tier 1 gap copayment of $5). Thus, the beneficiary pays the lesser of the copay or the cost of the generic drugs in tiers subject to an enhanced supplemental gap coverage benefit and pays 93% of the cost of generics in all other "non-enhanced" tiers. Similarly, an enhanced alternative plan may establish a coinsurance amount in the gap for pre-ICL covered generics provided that the beneficiary cost share for the additional gap coverage of generics is significantly less than 93%. For example, CMS would not consider supplemental coverage of 10% of generic drug costs in the gap meaningfully different from the new standard of 7%.

Q6. How does the 7% standard coverage of generic drugs in the gap affect gap coverage level descriptions for enhanced alternative plans with supplemental gap coverage in 2011?

A6. In 2011, any supplemental gap coverage offered by enhanced alternative plans will be above and beyond the mandated 7% standard coverage of generic drug costs in the gap. As in years prior, CMS will evaluate the proportion of formulary drugs covered through an enhanced benefit and assign appropriate gap coverage level descriptions. These gap coverage level descriptions in 2011 will only apply to the additional gap coverage offered through a supplemental benefit by enhanced alternative plans. Thus, these descriptions will not factor in what is being offered as part of the new standard benefit for generic drug cost coverage.

The gap coverage level designations for this supplemental gap coverage will continue to be based on the percentage of formulary drugs (brand or generic) covered in the gap under the supplemental benefit, using the same descriptions and thresholds as in 2010. For example, if an enhanced alternative plan has 1,000 unique drug entities on their formulary and 85% of the unique drug entities labeled as generics are subject to additional gap coverage (across various formulary tiers), then the plan would be described as offering "Many Generics". The 85% of covered generic drug entities in this scenario is not an additive number between the new standard generic gap coverage benefit and the additional gap coverage offering by EA plans and, therefore, does not reflect the 7% standard coverage of generic drug costs. Rather, it reflects the proportion of the plan's generic formulary drugs that are covered through the gap under a supplemental benefit.

Please note that the definition of generic, for purposes of the additional gap coverage level descriptions, is not the same as the definition used for the mandated 7% standard coverage of generic drug costs. For the additional gap coverage level descriptions, the brand or generic drug type labels assigned by the sponsor during formulary submissions are used to identify the formulary brand and generic drugs. The additional gap coverage level descriptions will be calculated by CMS based on formulary, PBP and supplemental file submissions and the resulting additional gap coverage descriptions will be displayed in the Summary of Benefits for 2011.