60.4 - Administration of Cost-Sharing Subsidy
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

60.4.1 - Application to Generic and Multiple-Source Drugs
(Rev. *10*, Issued: *10-01-18*, Effective/Implementation Date: *10-01-18*)

When imposing cost sharing on *LIS* eligible individuals, sponsors are required to apply specific copayments for generic drugs as defined by regulation and in section 10 of this chapter. Specifically, 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)). For purposes of Part D, what determines whether a drug is a generic drug is the type of application on file for that drug product with the Food and Drug Administration (FDA). If a drug product approval is based upon an abbreviated new drug application (ANDA), that drug is a generic drug.

This definition applies regardless of whether the brand-name drug is no longer manufactured and there is only one remaining ANDA-approved drug product on the market, whether the sponsor's formulary includes the 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. Consequently, when sponsors by statute are required to apply specific copayments for generic drugs (that is, for generic drugs obtained by *LIS* eligible enrollees and enrollees with spending above the out-of-pocket threshold), they must ensure that the appropriate cost-sharing is applied to

the generic drug as defined under CMS regulations and reflected in this manual.

For example, in accordance with 42 CFR 423.782(a)(2)(iii)(A), non-institutionalized full- benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty level for their family size will pay no more than *the amount listed in the current year's Call Letter* for generic drugs. Consequently, the sponsor must ensure that these individuals pay no more than *the* copayment for generic drugs *as listed in the current year's Annual Call Letter. This holds true for* all drug products approved under an ANDA, even if a Part D sponsor places such a drug product in its preferred cost-sharing tier rather than its generic cost-sharing tier.

A multiple-source drug includes the branded product when the same drug is also available as a generic. A prescription may be filled with the generic version of a drug, or the pharmacy may choose to dispense a branded, multiple- source drug because the pharmacy purchased the branded, multiple-source drug at a better price. Under this scenario, the beneficiary pays the lower copayment for the generic/preferred multiple-source copayment (provided in *the Annual Call Letter*) regardless of whether they received the generic or branded multiple-source drug. Alternatively, the plan may have identified a specific branded multiple-source drug as a preferred product to be used whenever a generic could be dispensed and, therefore, the beneficiary would pay the lower cost sharing in this instance, as well. However, if the pharmacy is required to dispense a branded multiple-source drug (for instance, if a physician requires dispense as written), and that drug is not cheaper for the pharmacy nor identified by the plan as a preferred multiple-source drug, the beneficiary would be required to pay the higher copayment.

60.4.2- Application to *Months'* / Days' Suppl*ies*
(Rev. *10*, Issued: *10-01-18*, **Effective/Implementation Date:** *10-01-18*)

For month's supplies and supplies over a month's supply, Part D sponsors must apply the equivalent of one copayment for LIS eligible beneficiaries to each pharmacy transaction irrespective of days' supply. For example, in 201*8*, a full subsidy eligible individual with incomes over 100% of the FPL who uses mail order to purchase his/her prescription medications may not be charged more than $*3.35* for a 90 day supply of a generic or preferred multiple source drug and more than $*8.35* for a 90 day supply of any other drug. This same policy applies to fills during the catastrophic coverage period.

Supplies less than a month's supply are subject to the daily cost-sharing rule at 42 CFR 423.100 and 423.153 (b)(4). Under this rule, a beneficiary who receives less than the approved month's supply of a solid oral dose drug (except antibiotics and pre-packaged drugs) that is subject to a copayment pays a copayment that is adjusted for the reduced days' supply dispensed. The adjusted amount is calculated by first calculating a daily cost-sharing rate, which is done by taking the applicable monthly copayment under the enrollee's Part D plan and dividing it by the number of days in the plan's applicable approved month's

supply and rounding it to the nearest cent. To calculate the adjusted copayment, the calculated daily cost-sharing rate is then multiplied by the number of days of drug actually dispensed.

LIS individuals are not excluded from the daily cost-sharing rule; however, they must also not pay more than the applicable statutory maximum copayments. We provide the following example for a full subsidy eligible LIS individual with income over 100%: First, the plan must determine what the reduced supply would cost under the plan's applicable copayment. The plan has a $60 copay for a brand drug in question and has a 30 day approved month's supply. A 10 day supply of the brand drug would cost $20 ($60 / 30 = 2.00 x 10 days = $20). This LIS individual would pay the statutory copay of $8.35 in this scenario. However, if the plan has a $5 copay for a generic drug, a 10 day supply would cost $1.70 ($5 / 30 = .17 (rounded to nearest cent) x 10 = $1.70). In such a case, the LIS individual would pay $1.70. The LIS beneficiary pays the lesser of the sponsor's calculated daily cost share amount or the applicable LIS copay.

60.4.3 - Application of Cost Sharing Subsidy When Individual Chooses Enhanced Alternative Coverage (Rev. *14,* Issued: *10-01-18;* Effective Date: ***10-01-18****;* Implementation Date: ***10-01-18***)

Although the cost-sharing subsidy only applies to basic prescription drug coverage, it applies equally to beneficiaries enrolled in both basic and enhanced alternative plans. When a Part D sponsor provides enhanced alternative coverage, thus reducing the cost sharing on a covered Part D drug, the cost-sharing subsidy applies to the beneficiary liability after the plan's supplemental benefit is applied. Supplemental benefits provided under the plan are always applied *before* beneficiary liability and *LIS* amounts are calculated. Therefore, the plan should determine the cost-sharing due under the enhanced alternative coverage after the supplemental benefit is provided, then apply the LIS amount to further reduce the LIS beneficiary's cost-sharing liability.

For example, if the beneficiary qualifies for full subsidy benefits *he/she* is only required to pay a *nominal* maximum. *If a drug cost $100, for example,* under the plan's basic benefit package, the cost sharing for a non-LIS beneficiary would be 25% of $100, or $25. Since the beneficiary qualifies for LIS, the Part D sponsor would receive $21.70 in *low-income-cost-sharing subsidy (*LICS*)* payments ($25 *minus* $3.30) under the basic benefit package. Under the enhanced alternative plan, the cost sharing is supplemented by the plan *with* an additional $10 resulting in a cost share of $15. The Part D sponsor would receive $11.70 in LICS for the LIS beneficiary ($15 *minus* $3.30).

The LIS only applies to covered Part D drugs. For supplemental drugs covered by a Part D plan, the LIS beneficiary pays the same amount of cost-sharing as any other beneficiary under their benefit package.

60.4.4 -Application of Lesser of Cost Sharing Amounts Test (Rev. 9, Issued: 02-05-10-10, Effective/Implementation Date: 01-01-10

Since the cost sharing subsidy is a reduction in beneficiary liability at the point-of-sale (POS), Part D sponsors must perform a calculation that compares the amount due from a non-low income subsidy (non-LIS) individual under the plan, to the statutory cost sharing provisions described in the Annual Call Letter. For each dispensing event, the Part D sponsor must compare the amount of cost-sharing due from a non-LIS beneficiary under the plan's benefit package to the maximum cost-sharing and deductible amounts due from a LIS eligible beneficiary. The LIS beneficiary should be charged the lesser of the two amounts.

60.4.5 - Cost Sharing: When Claims for LIS Individuals Cross Multiple Benefit Phases

(Rev. *14*, Issued: *10-01-18*, Effective Date: *10-01-18*; Implementation Date: *10-01-18*)

When a claim crosses multiple phases of the prescription drug benefit that all have co-payments, Part D sponsors must charge beneficiaries only one co-payment per prescription. Part D sponsors are specifically required to charge all beneficiaries the co-payment applicable to the phase of the benefit in which the claim began. For example, a beneficiary is enrolled in an enhanced alternative plan that has a generic co-payment of $5 in the initial coverage period and a generic co-payment of $15 in the coverage gap. If the beneficiary purchases a generic drug and that purchase moves the beneficiary from the initial coverage period to the coverage gap phase of their prescription drug benefit, the plan must charge the beneficiary a $5 co-payment because the claim started in the initial coverage period. Note that this policy does not apply to claims that cross multiple benefit phases in which any of the benefit phases have coinsurance.

If a claim crosses multiple benefit phases in which any of the benefit phases have coinsurance, the beneficiary is responsible for the applicable cost sharing in each phase that the claim crosses. However, when a claim crosses from the coverage gap to the catastrophic phase of the benefit, Part D sponsors are required to charge the cost sharing applicable to the portion of the claim below the out-of-pocket threshold only. For *the purpose of an example,* a partial subsidy LIS beneficiary is enrolled in a defined standard plan *in 2018* and has *$5,000* in true out-of pocket costs (TrOOP). If the beneficiary purchases a covered Part D brand drug that has a total cost of $150, the plan must charge the beneficiary $2.25 in coinsurance (15%) for the $15 in gross covered drug cost applicable to the coverage gap phase. The plan would not charge the LIS beneficiary the additional $5.60 co-payment for the portion of the drug cost applicable to the catastrophic phase.