HEALTH CARE REFORM CHANGES TO MEDICARE PART D "DONUT HOLE"

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The Medicare Part D coverage gap (the "donut hole"), is the difference between the initial coverage limit ($2,840 in 2011) and the catastrophic coverage threshold ($6,447.50 in 2011). Starting in 2011, under the health care reform law, beneficiaries will pay an increasingly smaller share of costs within the donut hole until the donut hole is phased out in 2020. At that point beneficiaries will only be responsible for the standard 25% of their drug costs until they reach the threshold for catastrophic coverage, when their copayments drop to 5%. In 2020, for generics, the plans pay 75% of the drug costs. For brands, plans will pay 25% of costs; manufacturers will pay 50%. The tables below outline the beneficiary shares and the gradual closing of the donut hole.

Coverage Gap Changes Under the Health Care Reform Law:

- Beginning January 1, 2011, beneficiaries will automatically receive a 50% discount off the negotiated price (not including the dispensing fee) for brand-name drugs, including insulin. Beneficiaries can also count 100% of the negotiated price of discounted drugs toward the coverage gap.
- Beginning January 1, 2011, beneficiaries will automatically receive a 7% discount off the negotiated price (including the dispensing fee) for generic drugs that are covered under their Part D plan's formulary. Whatever is left after you deduct the 7% discount counts towards the coverage gap.

Beneficiary responsibility in each category over time

Category/year	**2011 – 2020 Standard Benefit Design**
Deductible	100% out of pocket *(in 2011, up to $310)*
Initial coverage	25% *(in 2011, over $310 to $2,840)*
Coverage gap ("Donut hole")	**See chart below – reaching 25% in 2020** (*in 2011, begins at $2,840 and will continue until reaching $6,447.50)*
Catastrophic coverage	5% *(in 2011, of amount over $6,447.50)*

Filling the Part D Donut Hole Percent of Negotiated Price Beneficiary Pays		
Brand manufacturers always pay 50% discount, Part D plan and beneficiary pay the remainder		
Year	Brand Drugs	Generic Drugs
2011	50%	93%
2012	50%	86%
2013	47.5%	79%
2014	47.5%	72%
2015	45%	65%
2016	45%	58%
2017	40%	51%
2018	35%	44%
2019	30%	37%
2020	25%	25%

Important Information on the Coverage Gap Discount Program Starting in January, 2011

- All Part D drug manufacturers have signed discount agreements with CMS.
- The coverage gap discount for the beneficiary will occur at the point of sale, so that the pharmacy will initially provide the discount to the beneficiary. Part D sponsors will reimburse the pharmacy for the applicable discount within 14 days for clean claims submitted electronically and 30 days for clean claims submitted otherwise.
- Only applicable Part D brand name drugs that are marketed under labeler codes specified by manufacturers in the discount agreement will be subject to the 50% manufacturer discount. Click the following link for a listing of approved labeler codes: http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage. Pharmacies should review the list of labeler codes to determine if their inventories have applicable Part D drugs.
- Part D sponsors shall use the "date of dispensing" for purposes of providing a discount at the point of sale and determining the amount of such discount.
    - Even if information obtained after the "date of dispensing" affects eligibility back to the date of service, Part D sponsors should not adjust claims that initially showed a "paid response."
    - If Part D sponsor error causes a discount claim to be incorrectly adjudicated, the corrections that the sponsor makes to retroactively adjust for the error should not negatively impact the pharmacy.
- **Who is Eligible? Medicare beneficiaries that:**
        - Are Enrolled in a prescription drug plan or MA-PD plan;
        - Are NOT enrolled in a qualified retiree prescription drug plan;
        - Are NOT entitled to an income-related subsidy;
        - Have reached or exceeded the initial coverage limit; and
        - Have NOT incurred costs of covered Part D drugs in the year equal to the annual out-of-pocket threshold
    - **Applicable discount:** Means 50% of the portion of the ingredient cost component of the negotiated price of the applicable drug of a manufacturer that falls within the coverage gap and that remains after the negotiated price is reduced by any Part D supplemental benefits that are available. The dispensing fee is not included in the negotiated price.
    - **Applicable drug:** means a covered Part D drug that is
        - Approved under a NDA or in the case of a biological product licensed under BLAs
        - If the PDP sponsor uses a formulary, the applicable drug must be on such formulary, OR
        - If the PDP sponsor does not use a formulary, applicable drug means a covered Part D drug for which benefits are available under the plan OR
        - The covered Part D drug is treated as if on formulary, when provided through an exception or appeal
- **Brand vs. Generic Cost Sharing**
    - Drugs approved under an ANDA, Part D drugs that are not applicable drugs, including medical supplies associated with the delivery of insulin, and Part D compounds are subject to the 7% "generic" gap cost-sharing.
    - Many older prescription drugs currently on the market do not meet the definition of a Part D drug and will not be subject to coverage gap cost-sharing of any kind. Part D plan sponsors will subjectively determine which older prescription drugs do not meet the definition of a Part D drug.
    - Vaccine administration fees will be excluded from determining the brand name or generic discount.