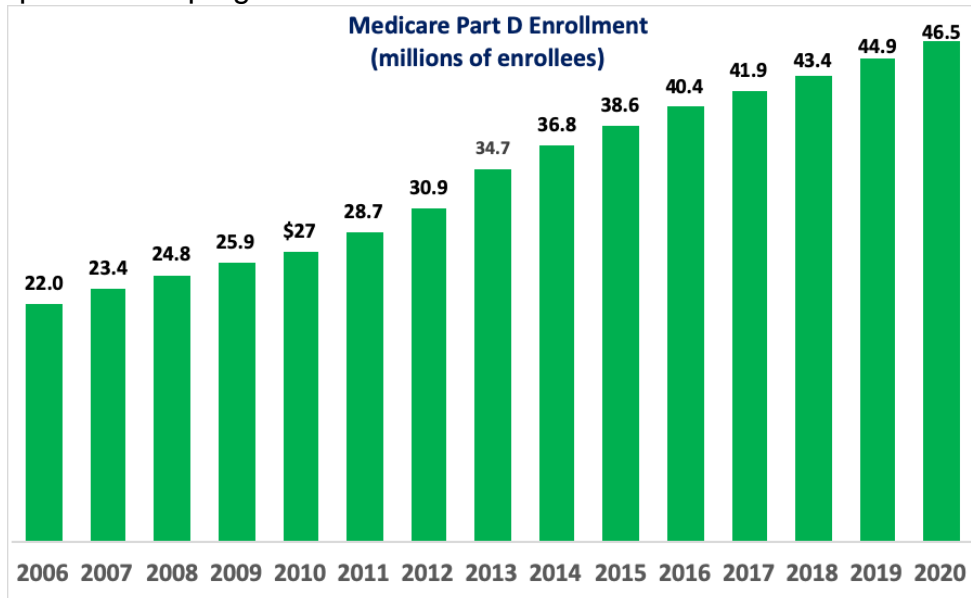


## Impact of Medicare Part D Donut Hole on GTN



We are getting older. Approximately 46 million of the more than 62 million Medicare beneficiaries are enrolled in the Part D federal-government program to help pay for self-administered prescription drugs. The number of enrollees more than doubled since the inception of the program in 2006.







Branded pharma companies are required to pay a government rebate of 70% when the patient enters the Medicare Part D Coverage Gap (“donut hole”) by incurring retail drug costs exceeding \$4,130.





The donut hole rebate applies to 33 million enrollees and excludes the 13 million Part D enrollees receiving premium and cost-sharing assistance through the Low-Income Subsidy (LIS) program.

### Medicare Part D Coverage Gap (Donut Hole) Example

The Medicare Part D coverage stages and percentages paid by each party are as follows (% of retail drug costs):

Who Pays What %	 BENEFICIARY	 PLAN	 DRUG MANUFACTURERS	 GOVERNMENT
<b>Coverage Phase</b>				
Deductible (up to \$445)	100%	-	-	-
Initial Coverage (\$445-\$4,130)	25%	75%	-	-
Donut Hole – Brand	25%	5%	70%	-
Donut Hole – Generic	25%	75%	-	-
Catastrophic (> 10,048 in total drug spend)	5%	15%	-	80%

Assume a Medicare Part D non-LIS enrollee incurs annual retail costs of \$20,000 for several branded and generic prescription drugs. The amounts paid by the patient (beneficiary), health plan, government and **all** of the pharma companies for drugs consumed while the patient is in the donut hole under the standard Medicare Part D prescription drug plan parameters for 2021 are as follows:

	 BENEFICIARY	 PLAN	 DRUG MANUFACTURERS	 GOVERNMENT	True Out-of-Pocket TrOOP
Deductible (\$445)	\$445	-	-	-	\$445
Initial Coverage (\$3,685)	\$921	\$2,764	-	-	\$921
Donut Hole - Brand (\$5,293)	\$1,323	\$265	<b>\$3,705</b>	-	\$5,028
Donut Hole - Generic (\$625)	\$156	\$469	-	-	\$156
<b>Sub-total (\$10,048)</b>	<b>\$2,845</b>	<b>\$3,498</b>	<b>\$3,705</b>	-	<b>\$6,550</b>
Catastrophic (\$9,952)	\$498	\$1,493	-	\$7,962	
<b>Total (\$20,000)</b>	<b>\$3,343</b>	<b>\$4,991</b>	<b>\$3,705</b>	<b>\$7,962</b>	

Total retail drug costs for branded drugs from the time the patient enters the donut hole until the exit into catastrophic (when TrOOP reaches \$6,550) are \$5,293 resulting in a coverage gap rebate to the government of 70% or \$3,705. Note that the \$3,705 rebate is for all banded drugs consumed while the patient is in the donut hole.

The order of patient consumption matters. If the patient consumes drugs manufactured by other pharma companies during the donut hole phase and drugs manufactured by our company while in the catastrophic phase, the donut hole liability is paid in its entirety by the other companies. On the other hand, if only drugs manufactured by our company are consumed first when the patient is in the donut hole phase, our company would be responsible for the donut hole liability of \$3,705 in its entirety (assuming total retail drug costs exceed \$10,048). Order matters.

### Estimating the Medicare Part D Coverage Gap (Donut Hole) Rebate Liability

The percent of Medicare Part D (non-LIS) enrollees entering the donut hole and catastrophic coverage phases approximate 10% and 3%, respectively. Enrollees entering the catastrophic phase generally take high-cost specialty drugs in therapeutic areas such as oncology, rheumatoid arthritis, and multiple sclerosis.

Special consideration should be devoted to the following key areas to estimate the rebate liability for the Medicare Part D Coverage Gap:

- Evaluate the disease state and medications taken by patients. The nature of the disease state dictates the number of drugs consumed to enter and exit the donut hole as well as the timing. Companies with lower cost drugs may not see patients enter the donut hole until the third or fourth quarter. A disease state such as multiple sclerosis will see higher donut hole rebates in the first or second quarter due to the high-cost of the specialty drugs. Note that patients in the catastrophic phase may choose to stockpile toward the end of the year since the patient costs of 5% of the price for the brand name drug resets to 25% in the ensuing year.
- Examine the net gain of price increases. The complex way patients move into, through and out of the coverage gap effects the net impact of list price increases as well as the patient out-of-pocket costs and incentives to fill prescriptions.

- Review the quarterly CMS invoice and utilization trends to estimate the Medicare Part D Coverage Gap liability at the end of the quarter. Note that the liability will include donut hole prescriptions for the current quarter plus anticipated Part D donut hole prescriptions related to product in the pipeline at wholesalers and retailers.
- Consider the order, price and type of prescriptions taken for patients in the therapeutic area.
- Be conservative to avoid unexpected negative gross-to-net true-up adjustments.

I encourage you to register for the upcoming webinar “Impact of Medicare, Medicaid and 340B Rebates on GTN” which includes numerical examples illustrating key government pricing concepts and practical applications.

[Webinar Registration - Impact of Medicare, Medicaid and 340B Rebates on GTN](#)