

Information Pharmacists Can Use on: Closing the Coverage Gap

The Affordable Care Act includes provisions to close the Medicare Part D prescription drug coverage gap (also called the "donut hole") to make prescription drugs more affordable for people with Medicare.

People with Medicare who have Part D but who don't get Extra Help (the low-income subsidy) will pay only 47.5% in 2013 and 2014 for "applicable" drugs at the point-of-sale. Coverage also increases for all other covered Part D drugs (e.g., generic drugs and supplies associated with the delivery of insulin) in the coverage gap.

Prescription drug coverage will continue to increase over the next several years for all covered drugs in the coverage gap, so what people pay during the gap will continue to decrease until it reaches 25% in 2020.

What are "applicable" drugs?

Applicable drugs are Part D prescription drugs approved under new drug applications (NDAs) or licensed under biologics license applications (BLAs). These are generally brand-name Part D drugs, including insulin and Part D vaccines. Applicable drugs also include some Part D prescription drugs that are commonly considered generic drugs, but actually have been FDA approved under NDAs. Applicable drugs must be subject to a signed discount agreement to be covered under Part D. All other covered Part D drugs (e.g. generic drugs approved under abbreviated new drug applications (ANDAs) and supplies associated with the delivery of insulin) may continue to be covered by Part D plans regardless of a signed manufacturer agreement.



How does the Medicare Coverage Gap Discount Program work?

Drug manufacturers must sign an agreement with the Centers for Medicare & Medicaid Services (CMS) to participate in the Medicare Coverage Gap Discount Program. The agreement specifies that all of the manufacturers' applicable drugs will automatically be discounted at the point-of-sale for coverage gap claims. The full cost of the drug will count as out-of-pocket spending for purposes of reaching catastrophic coverage.

Example: Mrs. Anderson reaches the coverage gap. She goes to her pharmacy to fill a prescription for a covered brand-name drug. The price for the drug is \$60 and the dispensing fee is \$2. Mrs. Anderson will pay 47.5% of the plan's cost for the drug and dispensing fee ($62 \times .475 = 29.45). Mrs. Anderson will pay \$29.45 for her prescription, but \$59.45 will be counted as out-of-pocket spending and will help Mrs. Anderson get out of the coverage gap because both the amount that Mrs. Anderson pays (\$29.45) plus the manufacturer discount payment (\$30.00) count as out-of-pocket spending. The remaining \$2.55, which is 2.5% of the drug cost and 52.5% of the dispensing fee paid by the drug plan, isn't counted toward Mrs. Anderson's out-of-pocket spending.

If a drug manufacturer doesn't sign a discount agreement with CMS, its applicable drugs won't be covered under Part D, and Part D sponsors won't be allowed to grant an exception or provide a transition for such drugs. People may still buy the drug at its full price, but the cost won't count toward getting into or out of the coverage gap. Part D plans will review coverage gap claims to determine the person's eligibility and if the drugs are eligible for the discount.

How will I know which manufacturers have signed a Coverage Gap Discount Program agreement with CMS?

CMS publishes a listing of companies that have signed an agreement along with the associated 5-digit labeler codes on its website. The listing of labeler codes and manufacturers can be found at cms.gov/PrescriptionDrugCovGenIn. Select "Part D Information for Pharmaceutical Manufacturers."

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How should pharmacies prepare for the Coverage Gap Discount Program?

- 1. Manage Supply Chain—Pharmacies should work with Part D contractors to review the list of labeler codes on the CMS website to determine if their inventories have applicable drugs. This can be done by comparing inventory against CMS's list of labeler codes that are covered by a signed agreement. Pharmacies can use the Medicare Coverage Gap Discount Program labeler code list to identify which manufacturers' applicable drugs will continue to be covered under Part D.
- 2. Educate Staff—Pharmacies should make staff aware of the Medicare Coverage Gap Discount Program and prepare them to answer patient inquiries about it.

How has Medicare increased its coverage for Part D drugs?

Medicare has increased its standard coverage by paying a certain percent (21% in 2013) of the cost for all non-applicable Part D drugs (e.g., generic drugs and supplies associated with the delivery of insulin) during the coverage gap, including the dispensing fee. Medicare coverage of applicable drugs is 2.5% in 2013 and 2014, and 52.5% of the dispensing fee during the coverage gap. This means people with Medicare who reach the coverage gap will pay 79% of the cost in 2013. Part D coverage will increase each year and the amount people pay **will decrease each year** until 2020, when the amount eligible people pay for drugs in the coverage gap will be 25% of the cost. The standard rules for calculating the person's out-of-pocket costs apply.

Example: Mrs. Anderson reaches the coverage gap. She goes to her pharmacy to fill a prescription for a covered generic drug that's a non-applicable Part D drug. The price for the drug is \$20, and the dispensing fee is \$2. Once the 21% coverage is applied to the \$22, she will pay \$17.38 for the covered generic drug and only \$17.38 will be counted as out-of-pocket spending that'll help Mrs. Anderson get out of the coverage gap.

Who's eligible for the savings while in the coverage gap?

People who meet all of the following criteria are eligible for discounts under the Medicare Coverage Gap Discount Program:

- They're currently enrolled in a Medicare Prescription Drug Plan (including people enrolled in employer group health and waiver plans), or a Medicare Advantage Plan (like an HMO or PPO) that includes prescription drug coverage
- They don't get Extra Help (a Medicare program to help people with limited income and resources pay Medicare prescription drug costs)
- They've reached the coverage gap

Note: Some people are in Medicare drug plans that don't have a coverage gap, but they'll still be eligible to get a discount on brand-name prescriptions once they reach the defined standard initial coverage limit (ICL) unless the gap coverage makes their cost sharing \$0. For 2013, the defined standard ICL is \$2,970.

How will someone know what discounts have been applied?

The Explanation of Benefits (EOB) notice, that people with Medicare get, will show the amount of the monthly prescription drug costs funded by the manufacturers.

How do the discounts work if someone is enrolled in a State Pharmacy Assistance Program (SPAP)?

People with Medicare who are eligible for the discounts and enrolled in a State Pharmacy Assistance Program (SPAP), or any other program that gives coverage or financial assistance for Part D drugs (other than Extra Help), still get the discount on applicable drugs in the coverage gap. The coverage gap discount is applied to the price of the drug before any SPAP or other coverage.

What if someone gets discounts from a drug manufacturer?

Patient assistance programs offered by manufacturers don't have the same rules as SPAPs. People should check with the manufacturer to see if their assistance program will change.

Does the discount apply to people who have enhanced Part D coverage?

Yes. A discount may be applied after their enhanced Part D coverage has been applied to the cost of the drug. The discount will apply to the remaining amount they owe.

Example: Mrs. Anderson is in an enhanced Part D plan. Her plan has an enhanced brand-name drug benefit of 60%. After she reaches the initial coverage limit, she goes to her pharmacy to fill a prescription for a brand-name drug. The negotiated price of the drug is \$100. After the plan's benefits are applied (60% off of \$100 =\$40), Mrs. Anderson pays 50% of the remaining \$40 amount. Mrs. Anderson will pay \$20 for her prescription, but the entire \$40 paid by Mrs. Anderson and the manufacturer will count as out-of-pocket spending and help Mrs. Anderson get out of the coverage gap.

Who's responsible for handling disputes if someone believes they should have received a discount but didn't?

Part D plans must handle inquiries and complaints about the Medicare Coverage Gap Discount Program. Individuals who think they should get a discount need to call their Part D plan. The plan's phone number is located on the individual's plan membership card. If the individual and drug plan disagree on whether a discount is owed, the individual may use the existing coverage determination and appeals process to resolve the dispute.

They can also call 1-800-MEDICARE (1-800-633-4227) to file a complaint. TTY users should call 1-877-486-2048.

Can someone file an exception for a drug if the manufacturer isn't participating in the Medicare Coverage Gap Discount Program?

No. If a manufacturer doesn't have an agreement with CMS to participate in the Discount Program, no applicable drugs labeled by that manufacturer will be covered under Part D. All other covered Part D drugs (e.g. generic drugs and supplies associated with the delivery of insulin) by such manufacturers may continue to be covered by Part D plans. Most manufacturers that produce more than 99% of the brand-name drugs used by people with Medicare participate in this program.

Can retroactive adjustments affect the discount?

Yes, if changes are made to an individual's eligibility or benefit it could affect the discount. These adjustments would be reported on the monthly Explanation of Benefits (EOB) notice that people with Medicare get. It'll show the amount of the monthly prescription drug costs, funded by the manufacturers. People should contact their plan if they think they're eligible for an adjustment.

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What happens if only a portion of the claim is in the gap?

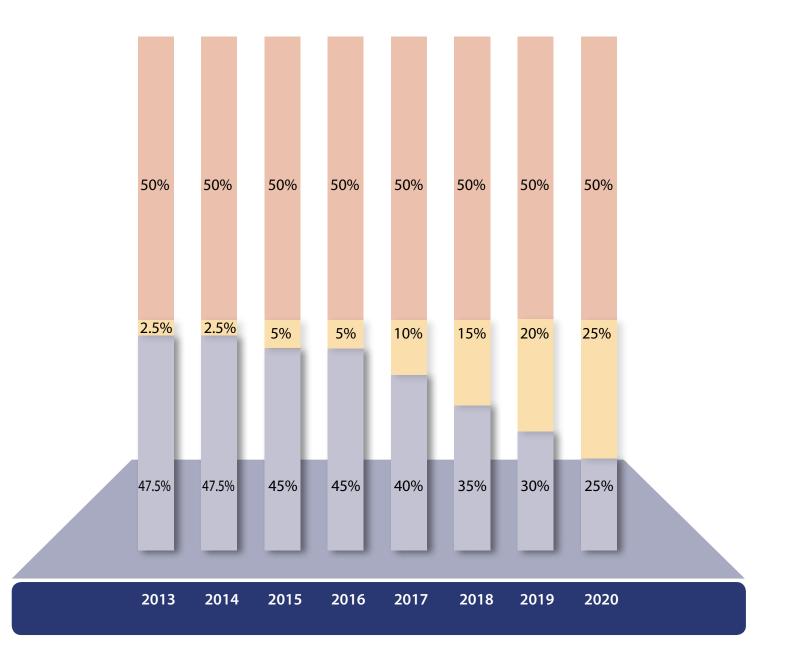
The discount will only apply to the portion of the claim that's in the coverage gap. For example, if someone fills a \$100 prescription when he or she is \$50 away from reaching the coverage gap, only the \$50 in the coverage gap is subject to the discount.

What additional discounts and savings will people with Medicare have over time in the coverage gap?

- Over the next several years, the benefits will increase for all covered drugs so that people with Medicare will pay less in the coverage gap.
- By 2020, the coverage gap will close and people will pay only 25% for covered brand-name and generic drugs from the time they meet the deductible (if applicable) until they reach the out-of-pocket limit.

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Brand-Name Prescription Drug Savings in the Coverage Gap



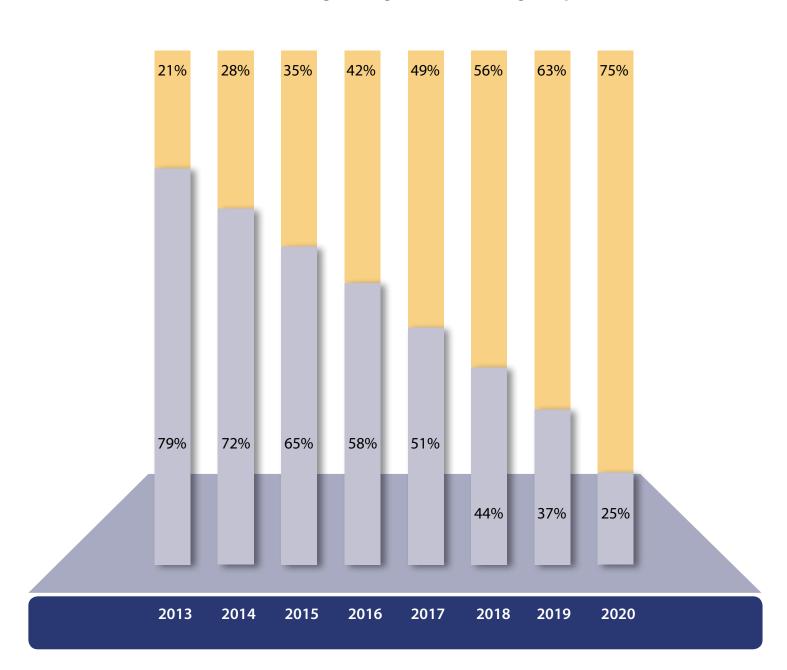
Manufacturer Discount

Plan pays

Beneficiary pays

CLOSING THE COVERAGE GAP

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Generic Drug Savings in the Coverage Gap

Plan pays

Beneficiary pays



CMS Product No. 11522-P