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POLITICS, POLICY & LAW

PART D SOUR SPOT

BY STEVE USDIN, WASHINGTON EDITOR

A law that comes into effect next year will squeeze profits from moderately priced drugs that treat common, chronic conditions afflicting older Americans, and increase economic incentives to develop high-priced medicines for rare or acute, life-threatening diseases.

The law increases the discounts branded drug manufacturers provide to people in the Medicare Part D donut hole. Manufacturers of drugs to treat common, chronic conditions will be especially hard hit, as these drugs occupy the "sour spot," a zone in which drug prices are high enough to get beneficiaries into the donut hole, but not so high that they quickly become eligible for Part D's catastrophic coverage. Drug companies are not required to discount drugs for patients who reach catastrophic coverage.

The Affordable Care Act created the sour spot by requiring drug companies, starting in 2011, to pay a 50% discount on branded drugs purchased in the donut hole.

Starting in 2013, Part D plans also were also required to provide donut hole discounts. Their liability gradually increased to 15% this year and was slated to grow to 25% in 2020, leaving beneficiaries on the hook for 25% of branded drug costs.

The donut hole does not apply to beneficiaries with incomes less than 150% of the poverty rate, who receive government subsidies for copays and premiums.

The Bipartisan Budget Act of 2018, which President Donald Trump signed into law in February, changed the discount formula. The discount required from drug manufacturers increases to 70% starting in 2019, while the liability of Part D plans shrinks to 5%.

PhRMA and many of its members were taken by surprise by the change, which was unveiled a day before the law was passed. The trade association lobbied furiously — and unsuccessfully — to have the increase dialed back in the 2018 budget bill that Trump signed on March 28.

Industry lobbyists are telling Congress and the White House that the change will cost drug companies $40 billion over a decade. A white paper produced by Milliman Inc., an actuarial consulting company, estimates the cost to pharma at $1.9 billion in 2019.

SQUEEZING CHRONIC CONDITIONS

The increased cost will fall most heavily on manufacturers of drugs that treat common, chronic conditions for two reasons. These conditions affect high percentages of the elderly who make up the majority of Medicare beneficiaries. And drugs to treat these conditions tend to be priced at levels that are high enough to get patients into the donut hole, but not so high that patients quickly become eligible for catastrophic coverage.

"The drugs that will be impacted the most are those used by patients with total prescription drug spending in the range of $500-$1,000 per month," Gabriela Dieguez, principal and consulting actuary at Milliman, told BioCentury.

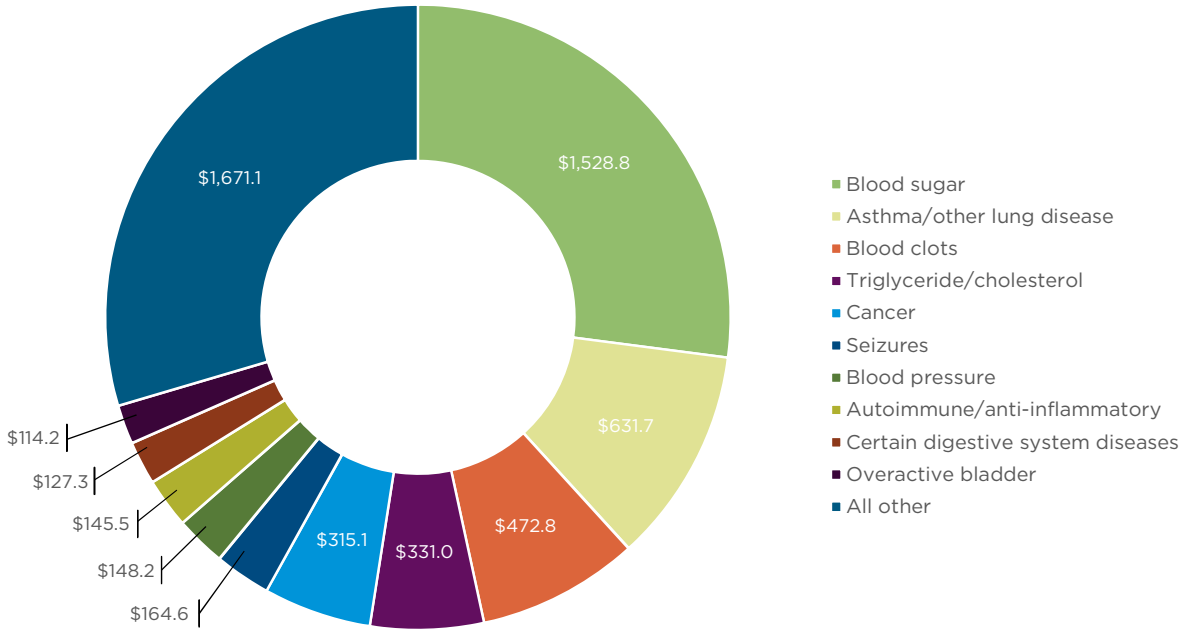
The squeeze will be especially tight for companies that make drugs in therapeutic classes that include generics or multiple branded alternatives, which give plans leverage to demand large rebates (see "Donut Hole Discounts By Therapeutic Class").

A CMS study found that in 2014 Medicare Part D rebates for brand name drugs across all therapeutic classes averaged 17.8%, and approached 30%

DONUT HOLE DISCOUNTS BY THERAPEUTIC CLASS

Manufacturers of drugs that are heavily prescribed to patients who fall into the Medicare Part D donut hole will have the greatest exposure to an increase in discounts mandated by the Bipartisan Budget Act of 2018. The chart shows that in 2016, the total dollar value of manufacturer discounts paid in the donut hole was highest for diabetes, lung disease, blood clots, hyperlipidemia and cancer. While the relative amount of discounts for each category will certainly change as large branded products lose patent protection, the types of categories that are affected should remain the same.

Starting in 2019, the manufacturer discount will increase to 70% from 50%. The spending limits that define the donut hole in 2019 are not published. For 2018, the donut hole begins after a beneficiary's drug costs reach $3,750 and ends when he or she reaches the $5,000 out-of-pocket limit. $M; *Source: Centers for Medicare & Medicaid Services (CMS)*



for two therapeutic classes that treat common, chronic conditions: 26% for cardiovascular drugs and 25% for hormones and synthetic substitutes.

A study by Quintiles IMS Holdings Inc. (now IQVia Holdings Inc.), commissioned by PhRMA, found that Part D discounts and rebates across the 12 therapy classes most commonly used by patients in Medicare Part D averaged 35%.

Donut hole discounts are based on the pharmacy price of drugs, meaning they come on top of rebates manufacturers have already paid to plans and PBMs.

This means that if manufacturers provide plans a rebate of 30% or more and Part D beneficiaries a 70% discount, they could make no revenue on drugs sold to beneficiaries who are in the donut hole.

"Chronic care, popular medicines will be the most challenged because they have the least pricing margins to play with," said Roger Longman, CEO of reimbursement consultancy Real Endpoints LLC. He cited respiratory drugs such as those marketed by GlaxoSmithKline plc and AstraZeneca plc as examples.

Longman also highlighted costs to companies that make diabetes products including sodium-glucose cotransporter 2 (SGLT2) inhibitors and insulin, as well as manufacturers of blood clot treatments such as Eliquis apixaban from Bristol-Myers Squibb Co., Pradaxa dabigatran from Boehringer Ingelheim GmbH, Savaysa edoxaban from Daiichi Sankyo Co. Ltd. and Xarelto rivaroxaban from Johnson & Johnson. Because payers can choose among competitors, they have negotiated high rebates and discounts for these products, Longman said.

The increased donut hole discounts could be bad for public health because they will make it less financially attractive for drug companies to create moderately priced medicines for the most common, chronic diseases. These categories are already burdened with high development costs due to the need for very large, expensive studies, often including outcomes studies.

Manufacturers of more expensive drugs with few therapeutic alternatives would not be as severely affected by the increased discount because payers don't have the leverage to demand large rebates.

Expensive drugs also don't leave beneficiaries in the donut hole for very long. For example, for a drug that costs over $150,000 per year, patients would exit the donut hole with their first script in January and manufacturers would not be required to provide discounts for the rest of the year.

Biologics that are injected or infused in physicians' offices and hospital outpatient facilities, which are reimbursed through Medicare Part B, will not be affected.

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>
> ROGER LONGMAN, REAL ENDPOINTS

NOT BENEFITING BENEFICIARIES

The new discount rate was proposed and implemented quickly, and so far no one has explained its public policy goals, other than closing the donut hole a year earlier than planned.

It is particularly difficult to understand why Congress decided to shift liability from plans to drug companies, rather than using increased discounts to help beneficiaries.

"Instead of reducing beneficiary liability, the new policy is reducing what would have been plan liability," Erin Trish, associate director of health policy at the University of Southern California's Leonard D. Schaeffer Center for Health Policy & Economics, noted. While plans can be expected to reduce premiums, the cost reduction for beneficiaries will be modest, she said, and will do little to help individuals who have large out-of-pocket costs in the donut hole.

Congress "could have applied the additional 25% to beneficiaries. I don't know why they did this," Trish told BioCentury.

Medicare Part D plans already have financial incentives to favor drugs with higher list prices and higher rebates over lower-priced drugs, including generics. These incentives will be increased by reducing plan liability to 5%, according to the Milliman white paper.

Reduced liability will also give plans little incentive to manage costs in the donut hole, which could lead to more beneficiaries becoming eligible for catastrophic coverage.

Once beneficiaries are in the catastrophic phase, plans are liable for only 15% of branded drug costs. The federal government pays 80%, and beneficiaries are responsible for 5%. "There is not much incentive for plans to manage the bulk of the drug spending and the bulk of drug spending growth," said Trish.

According to Milliman, if plans apply savings from reduced discounts to premiums as expected, it would save beneficiaries $1.3 billion in 2019, and government savings from reduced subsidies would be $600 million.

NOT LIKELY TO CHANGE

Pharma lobbyists, who did not want to be identified, told BioCentury they are feeling the heat from drug companies that have large exposure to Medicare Part D.

Their employers and clients are angry that industry lobbyists failed to anticipate or head off the donut hole discount threat, and incensed that they were unable to persuade Congress to mitigate it in the FY18 spending bill enacted in March.

Lobbyists are focusing on a few "must-pass" bills as potential vehicles for dialing back the donut hole discount. These include reauthorization of the Federal Aviation Authority, flood insurance legislation, reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization, and opioid abuse legislation.

The chances of success, pharma lobbyists told BioCentury, are slim. bc

COMPANIES AND INSTITUTIONS MENTIONED

AstraZeneca plc (LSE:AZN; NYSE:AZN), London, U.K.
Boehringer Ingelheim GmbH, Ingelheim, Germany
Bristol-Myers Squibb Co. (NYSE:BMY), New York, N.Y.
Centers for Medicare and Medicaid Services (CMS), Baltimore, Md.
Daiichi Sankyo Co. Ltd. (Tokyo:4568), Tokyo, Japan
GlaxoSmithKline (LSE:GSK; NYSE:GSK), London, U.K.
IQVia Holdings Inc. (NYSE:IQV), Durham, N.C.
Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.
Milliman Inc., Seattle, Wash.
Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.
University of Southern California, Los Angeles, Calif.

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