



November 4, 2010

Honorable Paul Ryan
Ranking Member
Committee on the Budget
U.S. House of Representatives
Washington, DC 20515

Dear Congressman:

As you requested, this letter describes how the Congressional Budget Office (CBO) analyzed the effects on prescription drug prices of certain provisions of the Patient Protection and Affordable Care Act, or PPACA, (P.L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

That legislation requires manufacturers of brand-name drugs to provide new discounts and rebates for drugs purchased through Medicare and Medicaid, with the amount of those discounts and rebates based on the prices of the drugs. Manufacturers thus have an incentive to raise those prices to offset the costs of providing the new discounts and rebates, although other forces will limit their ability to do so.

For drugs covered by Medicare's drug benefit, CBO estimated that those provisions of the legislation would raise the prices paid by pharmacies less any rebates paid to insurers by manufacturers by about 1 percent, on average. That increase in prices would make federal costs for Medicare's drug benefit and the costs faced by some beneficiaries slightly higher than they would be in the absence of those provisions, while the new discounts would make the costs faced by other beneficiaries substantially lower. For newly introduced drugs purchased through Medicaid, CBO estimated that those provisions would raise the prices paid by pharmacies by about 4 percent, on average. For currently available drugs purchased through Medicaid, which account for the bulk of projected Medicaid drug spending over the next decade, other provisions of law will constrain manufacturers' ability to raise prices to offset the new rebates. The combined effect of the increase in prices and new rebates is that Medicaid would pay less for drugs, on average, than it would in the absence of those provisions.

The legislation contains several other provisions that will affect drug prices as well:

- It establishes an abbreviated pathway for approving “follow-on” biological drugs, and the resulting increase in competition will yield substantially lower prices for certain drugs. However, the affected drugs represent a relatively small share of projected total drug spending over the next decade, so CBO estimated that the average effect on drug prices would be modest—a reduction of about 2 percent in 2019.
- The legislation also imposes an annual fee on manufacturers and importers of brand-name drugs. CBO expects that the fee will probably increase the prices of drugs purchased through Medicare and the prices of newly introduced drugs purchased through Medicaid and other federal programs by about 1 percent. Those increases will be in addition to the ones described above that stem from the new requirements for discounts and rebates.
- Furthermore, the legislation expands drug coverage under the Medicare benefit (by gradually filling in the coverage gap, or “doughnut hole”) and extends insurance coverage to people who would otherwise have been uninsured (more than 30 million non-elderly people by the second half of the decade, according to CBO’s estimates). Both of those expansions in coverage could affect drug prices—but CBO estimated the expansions’ overall effects on insurance premiums and federal spending and not their effects on drug prices in particular.

The various provisions of the legislation will exert competing pressures on drug prices paid by private purchasers. CBO estimated that the overall impact on those prices would be small, on average.

Given the intricacy of the mechanisms for setting drug prices and the numerous features of the health care legislation that affected those prices, CBO’s estimates of the effects of the legislation on drug prices were necessarily uncertain. The actual effects could be larger or smaller than CBO estimated.

Brief Background on Prescription Drug Pricing

Analyzing the effects of any legislation on prescription drug prices is a complex task because the mechanisms for setting those prices are complex. As drugs move from manufacturers to consumers, a series of transactions occur that also involve wholesalers, pharmacies, and insurers. In particular, the price paid by a pharmacy to acquire a brand-name drug is generally not the net cost of obtaining the drug from the manufacturer because manufacturers frequently pay rebates on brand-name drugs to insurers. Although there are many different prices paid along the supply chain, CBO’s analysis has generally focused on two prices—the price paid

by a pharmacy, and the so-called “net price,” which is the price paid by the pharmacy less any rebates paid to insurers by the manufacturer.¹

The rebate amounts vary by payer and by drug and are determined in different ways. Federal law requires manufacturers to pay a statutory rebate for drugs dispensed to Medicaid beneficiaries, whereas in Medicare Part D and in the private sector, insurers negotiate with brand-name drug manufacturers over the rebate amounts.² Manufacturers offer rebates to purchasers who act in ways that increase the market shares of their drugs. For example, health plans can increase the market shares of certain drugs by charging a lower copayment for those preferred drugs than for other (non-preferred) drugs that are therapeutically similar. A purchaser’s bargaining power with manufacturers reflects its ability to influence which drug is purchased from a set of therapeutically similar drugs and, to a lesser extent, depends on its volume of purchases. Because those characteristics vary across purchasers, different purchasers can pay different net prices for the same drug.

Effects of the New Required Medicare Discount

Currently, the standard outpatient prescription drug benefit under Part D of Medicare has the following features: an annual deductible for which the beneficiary is responsible; a dollar range of coverage in which the beneficiary pays 25 percent of the cost of covered drugs; and a catastrophic threshold above which the beneficiary pays about 5 percent of the cost of covered drugs. In the gap between the end of the initial coverage range and the catastrophic threshold—commonly referred to as the doughnut hole—most beneficiaries are liable for all of their drug costs. For Part D insurance coverage, most beneficiaries pay premiums that finance about 25 percent of the cost of the coverage (on average); the federal government pays the remaining 75 percent. Beneficiaries with limited means, however, may enroll in a low-income subsidy (LIS) program, through which the federal government covers a much larger share of their prescription drug costs—including their premiums and most of their spending in the doughnut hole.

Starting in 2011, the health care legislation requires manufacturers to provide a 50 percent discount to Part D beneficiaries who are not enrolled in the LIS program for brand-name drugs they purchase in the doughnut hole. (The legislation also phases in coverage under Part D for both brand-name and generic drugs purchased in that range of spending, increasing the generosity of the Part D benefit.) Under Part D, private plans deliver the drug benefit and negotiate their own prices with drug manufacturers and pharmacies while competing with each other for enrollees. The new discount will be taken as a percentage of those negotiated prices. Although it would not be feasible for manufacturers to increase

¹ For further discussion of drug pricing, see Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* (January 2007).

² In addition, many state Medicaid programs negotiate with manufacturers to obtain supplemental rebates for Medicaid drugs.

net prices only for the people receiving the discount, they will have some latitude to offset at least part of the impact of the new discount by increasing net prices charged to all Part D beneficiaries either by increasing prices charged to pharmacies or by reducing rebates paid to insurers.

Effects on Drug Prices and Federal Costs in Part D. CBO expected that pharmaceutical manufacturers would respond to the discount program by slightly increasing the net prices charged for Part D drugs.

The increase in net prices is expected to be small for two reasons. First, the discount is required for a relatively small share of spending under Part D; CBO estimates that spending on brand-name drugs in the doughnut hole by beneficiaries who were not enrolled in the LIS program constituted about 10 percent of total Part D spending in 2007, and that share is probably similar today. (There will likely be a small increase in spending eligible for the discount because of the increased generosity of the Part D benefit.) Therefore, an increase in net prices for all drugs sold in Part D of roughly 5 percent would fully offset the total costs of the required discount. Second, CBO did not anticipate that manufacturers would completely offset the costs of providing the discount because they would still have to negotiate with drug plans and offer rebates to receive preferred status. Given the pattern of existing rebates described above, CBO expected that the change in net prices would likely differ by drug, with larger increases for drugs with few substitutes and smaller increases for drugs with many competitors.

Overall, CBO expected that net prices of drugs (as defined above, the prices paid by pharmacies less any rebates paid by manufacturers) under Part D would increase by about 1 percent, on average, as a result of the manufacturers' response to the discount program. Thus, CBO expected that federal costs for premium and cost-sharing subsidies would be about 1 percent higher than they would otherwise be.

Effects on Beneficiaries in Part D. The premiums of drug plans will increase along with the increase in net drug prices, so the premiums paid by beneficiaries will increase slightly.³ The effects of higher net drug prices on out-of-pocket spending by Part D beneficiaries will vary depending on whether they are enrolled in the LIS program and, if not, on the amount of their spending:

- Beneficiaries enrolled in the LIS program face little or no cost sharing, so their out-of-pocket spending will be largely unaffected (although some copayments in the LIS program are indexed to spending growth and thus will be slightly higher).

³ The gradual elimination of the coverage gap under the legislation will generate a larger increase in premiums. See Congressional Budget Office, "The Estimated Change in Medicare Part D Premiums from Provisions in H.R. 3200, America's Affordable Health Choices Act of 2009," letter to the Honorable Dave Camp (August 28, 2009).

- Beneficiaries who are not enrolled in the LIS program and have spending below the benefit's initial coverage limit will, on average, pay slightly more toward their deductibles, coinsurance, and copayments.
- Beneficiaries who are not enrolled in the LIS program and reach the coverage gap will pay substantially less for those drugs because the discount will be 50 percent and the average increase in net prices will be much smaller. For most such beneficiaries, this effect will probably outweigh the effect of higher out-of-pocket payments for drugs purchased in the initial coverage range, and thus they will probably pay less for their drugs overall.
- Beneficiaries who reach the catastrophic phase of the benefit will generally pay only a little more for those drugs because their cost sharing is about 5 percent.

Effects of the Increased Rebate under Medicaid

The health care legislation also increases the minimum rebate that manufacturers of brand-name drugs must provide under Medicaid. To see how that requirement is likely to affect drug prices, it is useful to review the key features of Medicaid's rebate program.

The Medicaid Rebate Program. Pharmaceutical manufacturers that participate in the Medicaid program are required to provide a rebate for drugs dispensed to Medicaid beneficiaries, which reduces federal and state Medicaid spending. Medicaid rebates are calculated on the basis of two prices:

- the "best price," which is essentially the lowest price paid by a private purchaser (including some but not all private rebates); and
- the average manufacturer price (AMP), which is the average price paid by retail pharmacies (not counting any rebates to private insurers).

Initially, the Medicaid rebate for brand-name drugs is the greater of a fixed percentage of the AMP that is specified in law, or the difference between the AMP and the best price; as a result, Medicaid pays an amount less than or equal to the best price. An additional rebate for a brand-name drug is required if its price rises faster than overall inflation (as measured by the consumer price index for all urban consumers). The Medicaid rebate for generic drugs is a fixed percentage of the AMP. Some states also negotiate supplementary rebates with manufacturers, and those rebates are shared with the federal government. Such supplementary rebates totaled roughly 10 percent of all rebates collected by Medicaid in fiscal year 2009.⁴

⁴ For a more detailed discussion of the Medicaid rebate program, see Congressional Budget Office, *Prices for Brand-Name Drugs under Selected Federal Programs* (July 2005).

Effects of the Legislation. The health care legislation increased Medicaid’s minimum rebate for most brand-name drugs from 15.1 percent to 23.1 percent of the AMP. CBO expected that manufacturers would offset some of the higher rebates they will pay by charging higher launch prices for new drugs—particularly breakthrough drugs that use new mechanisms to treat illnesses. Additionally, CBO expected manufacturers to reduce slightly the amount of supplementary rebates offered to states.

Manufacturers’ ability to raise prices on drugs that are already on the market is constrained, however, by the additional rebate required for drugs whose prices grow faster than inflation. Moreover, competition from drugs already on the market will probably limit the extent to which manufacturers charge higher prices for certain new drugs, particularly those that are different formulations or strengths of products already on the market. In addition, states’ continuing efforts to negotiate supplemental rebates in return for preferred treatment will tend to limit manufacturers’ ability to reduce such rebates.

Overall, CBO expected that the combination of the higher required Medicaid rebate and the new required Medicare discount would lead manufacturers to increase the average price paid by retail pharmacies for new drugs by about 4 percent. The effect of those higher prices on the average price that Medicaid pays for all drugs would be very small at first but would increase gradually over time as spending on newly introduced drugs becomes a larger share of total drug spending. Even so, CBO expected that the increase in the average price paid by retail pharmacies would not fully offset the increase in the rebate, so that Medicaid would pay a lower price for drugs, on average.

Effects of Establishing a New Approval Process for Biological Drugs

For brand-name drugs that have been approved under the federal Food, Drug, and Cosmetic Act, an abbreviated regulatory process exists for approving generic alternatives once a patent expires. As a result, following the expiration of a patent, a number of lower-priced generic drugs usually become available, generating substantial savings to purchasers. By contrast, such competition has been largely absent in the market for biological drugs (which are much more complex molecules derived from living organisms). Those products are usually licensed under the Public Health Service Act (PHSA), which had no comparable abbreviated regulatory process for licensing “follow-on” products that are similar to—but may not be exact copies of—the original brand-name products. (Such drugs are sometimes called follow-on biologics or “bio-similars.”)

The health legislation established an abbreviated approval pathway for follow-on biologics licensed under the PHSA. The lower cost of obtaining approval under the abbreviated pathway will encourage multiple manufacturers of follow-on biologics to enter the market more quickly, particularly for top-selling products, and the resulting competition will generate savings to purchasers of those drugs.

CBO estimated that follow-on biologics would initially have prices about 25 percent below their brand-name counterparts and after several years of competition would have prices about 40 percent below those counterparts (on an average sales-weighted basis). Biological drugs that will probably face competition from follow-on biologics over the next ten years currently account for roughly 10 percent of total drug spending in the United States. Because follow-on biologics may not be viewed as perfect substitutes for their brand-name counterparts—especially when they first become available—sales of those brand-name versions will probably continue to represent a large share of total sales through 2019. As a result, CBO estimated that the average reduction in prices across all drugs resulting from the abbreviated approval pathway for follow-on biologics would be about 2 percent in 2019.

Effects of Other Provisions of the Legislation

The health care legislation imposes a fee on manufacturers and importers of brand-name prescription drugs, which will be allocated among firms on the basis of drug sales to government programs. Because that fee will not impose an additional cost for drugs sold in the private market, CBO and the staff of the Joint Committee on Taxation expected that it would not result in measurably higher costs for private purchasers. However, CBO expects that prices for drugs purchased through Medicare, and for newly introduced drugs purchased through Medicaid and other federal programs, will probably increase by about 1 percent as a result of the fee. The amount of the fee will vary from year to year over the coming decade, so the impact on prices may vary as well.

Additionally, provisions of the legislation requiring that individuals purchase health insurance and providing subsidies for private health insurance coverage are expected to raise the number of individuals with health insurance. The people who would not otherwise have had insurance to cover part of their drug spending will be less sensitive to the prices of their prescriptions, which would give manufacturers room, all else equal, to raise drug prices slightly. However, entities that administer the expanded coverage might make aggressive use of cost-management tools, some of which could result in substantial price discounts and changes in the mix of drugs prescribed or purchased. Furthermore, CBO estimated that many of the people who become newly insured will be covered by Medicaid, which pays relatively low net prices for drugs. CBO's analysis did not include a separate estimate of such provisions' effects on drug prices; instead, those effects were subsumed in the overall estimate of the cost of expanding insurance coverage.

Effects on Drug Prices in the Private Sector

Although CBO anticipated that the average prices paid by pharmacies for certain Medicare and Medicaid drugs would increase because of the health care legislation, the agency expected that some private purchasers would be affected by those increases and others would not. Uninsured individuals, who do not have health plans negotiating prices on their behalf, would probably face those price

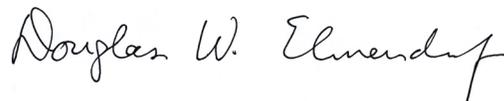
increases—although the effects might be offset in part by existing discount programs offered by manufacturers for uninsured people with lower income.

However, for people covered by employment-based health plans, CBO expected that net prices would probably not increase because those plans would be able to negotiate larger rebates that roughly offset the higher prices paid by pharmacies. Specifically, manufacturers were presumably planning to charge net prices that maximized their profits under prior law, and those calculations would be largely unaffected by the new legislation; thus, the likely outcome of negotiations over prices and rebates under the legislation would be the same net prices. (By contrast, the new discounts and rebates for purchases under Medicare and Medicaid will reduce manufacturers' profits, an effect they will presumably seek to offset subject to the constraints discussed above.)

Certain provisions in the health care legislation will encourage manufacturers to negotiate larger rebates with private purchasers. The best-price formula in Medicaid's rebate program has discouraged manufacturers from offering rebates larger than the minimum Medicaid rebate to certain private purchasers such as health maintenance organizations and mail order pharmacies, because any such rebates would have automatically triggered a larger rebate to Medicaid. However, the provisions in the legislation that increase Medicaid's minimum rebate effectively give manufacturers greater flexibility to offer larger rebates on existing drugs to a subset of private purchasers.

If you have questions about this analysis, please contact me or CBO staff. The CBO staff contacts are Ellen Werble and Rebecca Yip.

Sincerely,



Douglas W. Elmendorf
Director

cc: Honorable John M. Spratt Jr.
Chairman