Estimating the Budgetary Impact of the Patient Health and Real Medication Access Cost Savings Act of 2009

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Since the late 1980s, the vast majority of outpatient prescription drug benefits in the United States have been administered by pharmacy benefit managers (PBMs). In addition to providing the administrative services required to process pharmacy claims, PBMs perform two additional functions. First, they aggregate together the demand of the covered lives enrolled in pharmacy benefits programs in order to increase negotiating leverage with pharmaceutical manufacturers and pharmacies, with the result that they are able to obtain substantial discounts from both the manufacturers who make the drugs, and the pharmacists that dispense them. Second, they conduct a variety of utilization management programs intended to ensure the medical necessity of the drugs being described, and the cost-effectiveness of the drugs chosen to fill each prescription. Taken together, these cost management tools give PBMs the ability to deliver pharmacy benefits at a substantially lower cost than would apply if drugs were obtained on an uninsured retail basis.

The bill H.R. 4199, the "Patient Health and Real Medication Access Cost Savings Act of 2009," contains a variety of changes in the rules governing permissible business practices by PBMs. The policies contained in this bill include the following:

- Establishing a beneficiary "freedom of choice" requirement for pharmacy services.
- Prohibiting PBMs from giving beneficiaries financial incentives to use selectively contracted pharmacy providers.
- Restricting the ability of PBMs to use captive mail order operations in their benefit programs.
- Establishing an "any willing provider" policy for pharmacy network contracts.
- Specifying permissible cost sharing arrangements and dispensing fees.
- Prohibiting PBMs from marking up ingredient costs to plan sponsors.
- Prohibiting PBMs from retaining rebates paid by manufacturers.
- Requiring transmittal of wholesale cost information to physicians.

In addition to containing provisions that would regulate PBMs, the bill contains two additional requirements:

- It would amend the definition of "medical and other health services" under Medicare part B to include "pharmacist services."
- It would require to the Secretary to establish a "pharmaceutical access program," under which supplemental dispensing fees would be paid to pharmacists by non-federal plan sponsors (other than Medicaid).

The Moran Company was engaged by the Pharmaceutical Care Management Association, the trade association of PBM companies, to assess the budgetary implications of this legislation. Specifically, we have been asked to predict how the Congressional Budget Office (CBO) might

"score" this policy if it were to be actively considered in the legislative process. Our findings are as follows:

- As drafted, the bill states various policies, but provides no explicit mechanism to enforce those policies. Hence, as a threshold question, CBO would need to consider the practical effect of this legislation before addressing the question of what its budgetary impact might be.
- Assuming that CBO reached the conclusion that the legislation would, if enacted, impose the bill's policies on all activities conducted by PBMs for any payer, we believe that CBO would conclude that most of the provisions of the bill would have a budgetary effect.
- We believe that CBO will conclude that section 2 of the bill, which contains the beneficiary freedom of choice language, would have no budgetary effect.
- However, if CBO were to conclude that section 2 represented a requirement for PBMs to reimburse out-of-network pharmacies at payment rates greater than their in-network fee schedule, this could increase the costs of the bill overall.
- We believe that CBO will conclude that the PBM regulatory provisions of section 3 would sharply curtail PBMs' ability to reduce pharmacy benefits costs for both public and private plan sponsors.
- We estimate that the combined impact on the Federal budget of section 3's policies would increase outlays and lower federal revenues, increasing the Federal deficit by $198 billion over 2010-2019.
- By comparison, the provisions of section 4, which establish the "pharmaceutical access program," would have a minor budgetary effect, offsetting only $11.8 billion of the impact of the PBM regulatory provisions.
- The provisions of section 4 would also impose significant costs on the private sector. We estimate costs to private health plans would increase by $105.7 billion over the 2010-2019 period.

The rationale for these findings is presented in the sections that follow.

CBO's Approach to Scoring the Effects of Pharmacy Benefits Management

During the 2002-2004 period surrounding the enactment of the Medicare Modernization Act (MMA), CBO produced a number of documents for the Congress that presented, in considerable detail, the methodologies it employed in scoring the MMA provisions implementing the new pharmacy benefit.

Under its announced methods, CBO applied what might be labeled a "top-down" approach to scoring the effects of changes in the way pharmacy benefits were organized and managed. This methodology was premised on the assumption that the "gross" cost of a benefit turns on the availability of tools to manage costs, and the will to use them.[1] Relative to the cost of uninsured retail purchases, CBO posited a "cost management factor (CMF)," which it characterized as the percentage reduction in spending (relative to uninsured retail) that would be achieved by the use of different combinations of tools.[2] Its methodology was premised on the assumption that plans which faced the full insurance risk for the benefit, and which were free to employ the full range of tools available to PBMs, would achieve the maximum amount of savings, which CBO estimated to be a 30% reduction from uninsured retail.[3] Policies that reduced or eliminated risk—or constrained the ability of PBMs to use the full array of tools available—were scored at a discount to this maximum savings. CBO did not make line item adjustments for each departure from its "maximum savings" model. Rather, it characterized different policies as being in the neighborhood of prototypes for which CBO had access to empirical evidence on the cost savings achievable. Hence it scored the Clinton Administration plan from 2000, which ceded no insurance risk and constrained PBM efforts to fully manage benefits, to a CMF of 10%.[4] CBO typified the average employer group health plan as being associated with a CMF of 15%. In its final score of the MMA, CBO's estimates were based on the assumption that the achieved CMF would rise from 20% to 25% over the 2004-2013 period.[5]

CBO'S Likely Analysis of H.R. 4199

Given this backdrop, we would expect CBO's analysis of the provisions of H.R. 4199 to focus on four discrete issues:

- The effects of the "freedom of choice" provisions of section 2;
- The effects of the PBM regulatory provisions of section 3;
- The effects of adding "pharmacist services" to the definition of "medical and other health services" in section 1861(s)(2) of the Social Security Act; and
- The effects of creating the "pharmaceutical access program."

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[1] Holtz-Eakin, D. *Estimating the Cost of the Medicare Modernization Act*. (Congressional Budget Office: March 24, 2003), p. 6.
[2] Congressional Budget Office. *Issues in Designing a Prescription Drug Benefit for Medicare*. October, 2002, p.36.
[3] Congressional Budget Office, *Detailed Description of CBO's Cost Estimates for the Medicare Prescription Drug Benefit.* July, 2004, p. 14.
[4] *Issues in Designing*…,p. 39.
[5] Holtz-Eakin, *op. cit.*, p.6.

Prior to reaching a conclusion about these issues, CBO will need to consider a threshold question: whether the provisions of H.R. 4199 would, if enacted in their present form, have any practical effect on the conduct of the PBM business in the United Sates. We raise this issue because the bill, as drafted, enunciates a variety of different policies regarding permissible PBM conduct, but contains no mechanism to enforce those policies. For purposes of this analysis, we adopt the convention that CBO will score this policy as if it were fully enforceable on all PBM activities in the United States. We note the significant possibility, however, that CBO might reach a different conclusion about the bill as now drafted.

Freedom of Choice

While the sponsors of this legislation may intend this section to confer new rights to those receiving pharmacy benefits, the literal language employed in this section does not explicitly do so. Beneficiaries of pharmacy benefits programs that restrict program benefits to those who use network pharmacies are not, under current law and policy, precluded from filling their prescriptions, at retail, at any pharmacy they choose. Hence we expect CBO to conclude that this policy has no explicit budgetary effects. If, however, they were to conclude that section 2 represented a requirement for PBMs to reimburse out-of-network pharmacies at payment rates greater than their in-network fee schedule, we would expect to CBO to consider section 2 together with the other PBM regulatory requirements in section 3, rather than presenting a separate score for this provision. In that instance, however, we think the CBO's estimate of the overall costs of the bill would increase.

PBM Regulatory Provisions of Section 3

Since the early part of this decade, CBO has consistently taken the position that policies that restrict the flexibility of PBMs to use all available tools to manage benefits would sharply reduce PBMs' ability to control cost. In the instant case, we expect CBO to conclude that the policies of section 3 would have a large dampening effect on a PBM's ability to obtain discounts from both pharmacies and manufacturers.

On the pharmacy side, the bill's policies appear consciously designed to prohibit PBMs from engaging in selective contracting with pharmacies. The inability to exclude pharmacies from their networks, or to incentivize beneficiaries to use pharmacies that offer lower prices will, we believe, induce CBO to conclude that virtually all of the discounts that PBMs now obtain from contract pharmacies would be in jeopardy.

On the manufacturer side, the bill's policies would eliminate all incentives for PBMs to aggregate purchasing power across plan sponsors to motivate manufacturers to offer discounts. While PBMs would be authorized to negotiate rebates "…on behalf of a pharmacy benefit plan sponsor…" PBMs would be unable to retain any of the economic value of such rebates. We believe CBO will conclude that achieved rebates would decline materially under such a regime.

The net effect of the policies of section 3 of H.R. 4199 would be to reduce PBMs to the role of contract claims processors and utilization review managers. While we expect CBO to conclude that some amount of continued cost savings could be achieved under this market model, it is likely that CBO would apply a substantial discount to the cost management factor it applied in its scoring of the MMA. Since the exact discount CBO would apply is uncertain, we believe that a 50% reduction in the CMF assumed in the baseline for each payer type represents a conservative estimate. Our estimates of the budgetary impact of H.R. 4199 presented in the concluding section reflect this assumption.

Adding "Pharmacist Services" to Part B

Paragraph (6) of section 3 amends the Social Security Act definition of "medical and other health services" to add "pharmacist services" to the definition of covered services under Part B of Medicare. While the intent is obviously to authorize separate reimbursement of these services under Part B, the actual effect of this provision is uncertain. Because the phrase "pharmacist services" is not a term of art in Medicare, the Secretary of Health & Human Services would have to define it before payment could be made to pharmacists under §1832(a) of the Act. In fashioning a definition, the Secretary must take into consideration the requirements of §1835(a), which limit reimbursement of "medical and other health services" only to those certified by a physician to be "medically necessary." The Secretary could also be expected to define these services in such a way as to preclude payment for services currently being rendered by pharmacists in the course of filling prescriptions. Therefore, we expect CBO to conclude that this provision, while potentially requiring the Secretary to make limited payments in specific circumstances, would have only a *de minimus* budgetary effect.

Creating a "Pharmaceutical Access Program"

While the language of section 4 contains some ambiguities, two specific activities are authorized.

First, the Secretary is directed to collect fees from each pharmacy ($0.50 for a branded script and $1.00 per script for a generic) for dispensing both branded and generic drugs under Federal drug benefit programs other than the Medicaid program.

Second, the Secretary is required to direct pharmacy benefit plan sponsors that are not federally-supported to direct their PBM contractors to make comparable payments to pharmacies.

While the language indicates that the proceeds of these transactions are to be used to "…provide affordable access to prescription drugs to low-income individuals…", no explicit program to achieve this end is authorized in this section. Hence we expect CBO to conclude that the two transaction streams described above comprise the program established under this section. Our estimates of CBO's score of these provisions, presented in the next section, reflect this assumption.

While our estimates show net savings to the Federal Government from the provisions of section 4, they also reflect increased costs to private health plans of $105.7 billion over the 2010-2019 period, which we estimate would result in a Federal revenue loss of $31.7 billion.

Our Estimates of CBO's Score of H.R. 4199

Based on this analysis, our estimates of CBO's likely score of H.R. 4199 is as follows:

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-2014	2010-2019
Section 2	---	---	---	---	---	---	---	---	---	---	---	---
Section 3												
PBM Regulatory Provisions ($B)	$12.2	$13.5	$15.1	$16.8	$18.2	$20.0	$21.9	$24.2	$26.7	$29.5	$75.8	$198.1
Part B Definition	*	*	*	*	*	*	*	*	*	*	*	*
Section 4	-$1.1	-$1.1	-$1.1	-$1.1	-$1.2	-$1.2	-$1.2	-$1.2	-$1.3	-$1.3	-$5.6	-$11.8
Net Deficit Impact	$11.1	$12.4	$14.0	$15.6	$17.1	$18.8	$20.7	$22.9	$25.4	$28.2	$70.1	$186.2

** = less than $50 M.*

We based these estimates on the projections of prescription drug utilization and financing presented in the National Health Expenditures estimates published annually by the CMS Office of the Actuary. We used these projections to develop our own estimates of drug spending, by payer type, potentially subject to the provisions of H.R. 4199. We then developed estimates of prescription volume using IMS Health prescribing activity data for 2008.[6] We used data from the Medical Expenditure Panel Survey (MEPS) to analyze variations in average cost per prescription across payer types. Our projected scores of both sections 3 and 4 are based on separately estimating the impact of these policies on Federal spending, and also the effects of increasing private spending on Federal tax revenues.

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