CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Peter R. Orszag, Director

April 10, 2007

Honorable Ron Wyden
United States Senate
Washington, DC 20510

Dear Senator:

You asked a number of questions relating to the Medicare drug benefit and options for allowing the Secretary of Health and Human Services (HHS) to negotiate over the prices paid for drugs under that benefit. The Medicare Modernization Act contained a provision that prohibits the Secretary both from interfering in the negotiations between drug manufacturers and the prescription drug plans (PDPs) that deliver the Medicare benefit, and from requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs.

Responses to the questions you raised are below.

Could negotiating by the Secretary over drug prices obtain savings for the Medicare program if those negotiations were limited to selective instances?

As the Congressional Budget Office (CBO) indicated in a previous letter, negotiations limited to a few selected drugs or types of drugs could potentially generate cost savings.[1] For example, negotiations could be focused on drugs with no close substitutes or those with relatively high prices under Medicare. In such cases, CBO assumes that the effect of the Secretary's actions—if he or she took advantage of the new authority—would primarily reflect the use of the "bully pulpit" to pressure drug manufacturers into reducing prices.

Although cost savings might be possible in selective instances, the impact on Medicare's overall drug spending would likely be limited. Bully pulpit strategies would probably be effective only if they were constrained to a small number of drugs; otherwise, the pressure of the spotlight would be dissipated. Consequently, spending on the small number of affected drugs would likely account for only a small fraction of expenditures under the Medicare drug benefit. Furthermore, even if the Secretary focused on a select number of drugs, the effect might be limited because pressure from PDPs and public relations concerns already affect pricing—so the incremental effect of giving HHS additional options for exerting pressure would generally be small. Finally, drug manufacturers could seek to limit the impact of the Secretary's actions by setting higher initial prices for their drugs, to offset any potential price concessions from negotiations with the Secretary. As a result, CBO expects that the overall impact on federal spending from

[1] See Congressional Budget Office, Letter to the Honorable Ron Wyden regarding the authority to negotiate prices for single-source drugs for Medicare beneficiaries (March 3, 2004).

negotiations targeted at selected drugs would be modest. Beyond that general conclusion, the precise effect of any specific proposal would depend importantly on its details.

Recent negotiations over Cipro and FluMist showed significant savings relative to prevailing commercial prices, but several factors substantially limit their relevance to Medicare negotiations. In the case of Cipro, which can be used to treat anthrax, the relevant negotiations were conducted in the climate of a national emergency immediately following the attacks of September 11th and deaths from anthrax-laced letters. Furthermore, Cipro's patent protection was close to expiring and several manufacturers were poised to produce that drug once the patent expired. That set of circumstances gave particular force to the threat issued by Secretary Thompson to seek authority for generic production of Cipro, which was apparently instrumental in bringing the negotiations to a close. FluMist, a nasal form of flu vaccine, was relatively new at the time of the relevant negotiations. The manufacturers of that product apparently overestimated demand for it and therefore had large stockpiles on hand that would have little or no use once the flu season ended. Although HHS was able to negotiate price reductions for FluMist in December 2003, its manufacturer chose soon thereafter to give away a substantial quantity of the vaccine free of charge—and even then demand apparently remained low. The exceptional circumstances associated with those two examples limit their applicability to the case of drugs covered by the Medicare benefit.

If the Secretary were given authority to negotiate by Congress and used that authority, would it be possible to obtain savings to Medicare?

The key factor in determining whether negotiations would lead to price reductions is the leverage that the Secretary would have to secure larger price concessions from drug manufacturers than competing PDPs currently obtain.[2] When several drugs are available to treat the same medical condition, PDPs can secure rebates from selected drug manufacturers by giving their drugs preferred status within formularies. Because enrollees are encouraged to use such preferred drugs (through lower cost-sharing requirements), manufacturers are willing to offer price concessions to the PDPs in order to give their drugs preferred status and thereby increase their market share.

By itself, giving the Secretary broad authority to negotiate drug prices would not provide the leverage necessary to generate lower prices than those obtained by PDPs and thus would have a negligible effect on Medicare drug spending. Negotiation is likely to be effective only if it is accompanied by some source of pressure on drug manufacturers to secure price concessions. The authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions could give the Secretary the ability to obtain significant discounts in negotiations with drug manufacturers. In the absence of such

[2] See Congressional Budget Office, Letter to the Honorable William H. Frist, M.D., regarding CBO's estimate of the effect of striking the "noninterference" provision as added by P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (January 23, 2004); and Congressional Budget Office, cost estimate for H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007 (January 10, 2007).

authority, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited. Broad negotiating authority would not necessarily result in the type of targeted approach that could produce savings. CBO thus estimates that providing broad negotiating authority by itself would likely have a negligible effect on federal spending.

Since 2003, has anything changed—other than the Secretary saying he would not negotiate—that would indicate whether such negotiation would be successful?

Since the enactment of the Medicare Modernization Act, HHS has issued certain regulations to implement the drug benefit that suggest a reluctance to limit the availability of drugs to enrollees, even if the result is somewhat higher drug spending.

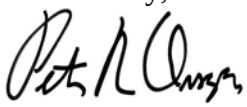
Under the act, PDPs are required to cover at least two drugs in each therapeutic class of drugs that treat the same condition. Because a common definition of therapeutic classes did not exist, the law also provided for U.S. Pharmacopoeia, a private standard-setting entity, to establish a model set of classes, which PDPs were encouraged but not required to follow. In its regulations, HHS required PDPs to cover all or substantially all drugs in several important classes, including antipsychotic medications. (That requirement was established on the grounds that failure to cover such a broad set of medications would discourage individuals from enrolling in the benefit or in a drug plan that provided less extensive coverage.) In addition, those regulations encouraged PDPs to cover at least one drug in each subclass of drugs that U.S. Pharmacopoeia specified, even though that was not required under the legislation. The regulations reduced the rebates that PDPs can secure and raised the cost of the drug benefit.[3] The motivations affecting those regulations would presumably also affect the negotiating stance of the Secretary, limiting the likelihood that the negotiations would yield lower drug prices. At the same time, the regulations have reduced the rebates obtained by PDPs and thus created some potential for additional savings.

The current HHS Secretary has indicated that he would not pursue drug price negotiation if given the authority to do so, and it is difficult for CBO to predict what actions future HHS Secretaries might or might not take. Simply put, it may be difficult through legislation to force a Secretary to pursue negotiations aggressively if he or she is reluctant to do so.

[3] See Congressional Budget Office, *An Analysis of the President's Budgetary Proposals for 2006* (March 2005), Appendix A, and Congressional Budget Office, Letter to the Honorable Joe Barton and the Honorable Jim McCrery regarding potential effects of disclosing price rebates on the Medicare drug benefit (March 12, 2007).

I hope this analysis is helpful to you. If you would like additional information on this subject, CBO would be pleased to provide it. The staff contacts for this analysis are Tom Bradley and Philip Ellis.

Sincerely,



Peter R. Orszag
Director

cc: Honorable Max Baucus
Chairman
Committee on Finance

Honorable Charles E. Grassley
Ranking Member