CHAIRMAN'S MARK
AMENDMENT TO S. 3 – MEDICARE PRESCRIPTION DRUG PRICE NEGOTIATION ACT OF 2007

Section 1. Short title.

Current Law

No Provision

Explanation of Mark

This bill may be cited as the "Medicare Fair Prescription Drug Price Act of 2007."

Section 2. Repeal of Prohibition.

Current Law

Section 1860D-11(i) of the Social Security Act prohibits the Secretary of Health and Human Services (HHS) from interfering with the negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173) conference report (108-391) adds that conferees expect PDPs to negotiate price concessions directly with manufacturers. Section 1860D-11(ii) of the Social Security Act prohibits the Secretary of HHS from requiring a particular formulary to institute a price structure for the reimbursement of covered Part D drugs.

Explanation of Mark

The Chairman's Mark would repeal Section 1860D-11(i), thus the Secretary would no longer be prohibited from interfering with the negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors. Section 1860D-11(ii) would remain intact, and the Secretary would still be prohibited from requiring a particular formulary to institute a price structure for the reimbursement of covered Part D drugs. Nothing in this Mark does any of the following: (1) prevents a PDP or Medicare Advantage Prescription Drug Plan (MA-PD) from obtaining a discount or reduction in price for a covered Part D drug; (2) affects the Secretary's authority to ensure appropriate and adequate access to covered Part D drugs under PDPs and MA-PDs, including compliance with existing formulary requirements; or (3) limits access by individuals enrolled in PDPs and MA-PDs to community pharmacies.

The Mark would require the Secretary to submit an annual report on activities conducted to promote and ensure access to fair prices for Part D prescription drugs.

The amendments would take effect on the date of the enactment of the Act.

Section 3. Greater Transparency of Part D Prices and Information

Current Law

The use and disclosure of most of the information collected by the Centers for Medicare and Medicaid Services (CMS) about PDPs and MA-PDs is restricted by section 1860D–15(f)(2) of the Social Security Act which states, "Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section." The section referred to by this statement addresses payment issues under Medicare Part D including the overall subsidy to plans, reinsurance, risk adjustment, risk corridors and other topics.

The law does not currently allow any other parties, including Congressional support agencies or other researchers, to have access to the data. CMS's interpretation of this statute is that it limits the ability of the agency to use the information for purposes other than those stated in the preceding paragraph, including "for research, internal analysis, oversight, and public health purposes… evaluating the new prescription drug benefit, including its effectiveness and impact on health outcomes, performing Congressionally mandated or other demonstration projects and studies, reporting to Congress and the public regarding expenditures and other statistics involving the new Medicare prescription drug benefit, studying and reporting on the Medicare program as a whole, and creating a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs." As a result of this perceived restriction on its use of the data, CMS has issued a proposed rule clarifying the ability of the Secretary to collect the same information under a different authority (section 1857(e)(1) as incorporated into Part D through section 1860D–12(b)(3)(D)), thus allowing the agency to use the data for the purposes described in this paragraph. To date, no final rule has been issued. [Federal Register / Vol. 71, No. 201 / Wednesday, October 18, 2006 / Proposed Rules 61445-61455.]

Some of the information is currently available to the public. For example, the prices of individual drugs covered by each plan can be obtained from CMS web sites if identified individually and entered on web page forms in the process of researching and comparing plans. However, CMS has not made the entire data set of prescription drug prices by plan available to outside parties such as private researchers.

Explanation of Mark

Data collected by the Secretary on PDP and MA-PD plans would be made available to Congressional support agencies to fulfill their duties. The Congressional support agencies are the Congressional Budget Office (CBO), the Congressional Research Service (CRS), the Government Accountability Office (GAO), and the Medicare Payment Advisory Commission (MedPAC).

Upon request, the Secretary would make available to any of the Congressional support agencies the following Part D data: (1) aggregate information on negotiated price concessions, (2) drug claims data, (3) the amount of reinsurance payments paid to plans, and (4) the amount of adjustments of payments to plans as a result of the risk corridors established under MMA. In addition, CBO would be able to obtain non-aggregated data on negotiated rebates, discounts, and other price concessions by drug and by contract or plan in order to permit analyses at the PDP or MA-PD level.

In the course of performing its activities, each of the Congressional support agencies would be prohibited from disclosing the information where such disclosure by the Secretary would be prohibited under applicable Federal law, where such disclosure would result in the disclosure of trade secrets, and where the disclosure, report, or release of the information by the agency would permit the identification of a specific prescription drug plan, MA–PD plan, pharmacy benefit manager, drug manufacturer, drug wholesaler, drug, or individual enrolled in a prescription drug plan or an MA–PD plan.

The Congressional support agencies would be required to adopt and maintain reasonable safeguards to protect against the unauthorized disclosure of data. The Congressional support agencies would be able to disclose the data to another agency or entity only if the agency or entity were under a subcontract with the Congressional support agency to support any analysis conducted by the Congressional support agency and if the subcontractor were subject to the same data disclosure provisions and safeguards as the Congressional support agency. Data provided under this provision would be exempt from disclosure under the Freedom of Information Act.

The CBO would be required to study the effect of market competition on prices for part D drugs. The study would examine the number and extent of discounts and other price concessions received by PDP and MA–PD plans, the relationship between all price concessions and drug utilization, the extent to which the efforts made by the Secretary, as allowed under the Mark, would have an effect upon payers in non-Medicare markets. A report on this study would be due a year after enactment. The Mark also requires CBO to compare discounts and price concessions under Part with those obtained under the Medicaid program.

GAO and MedPAC would also report to Congress on the limitations of the Part D data, made available by the Mark, in evaluating the drug prices under the Medicare Part D program. These reports would be due no later than 180 days after the date of enactment.

The Secretary would also be required to make public the data on the actual prices charged for each covered part D drug by each PDP and MA–PD plan to individuals enrolled in the plan. The data would reflect the prices posted on the Internet website of the Centers for Medicare & Medicaid Services and would be made available in a manner that permits linkage to other data sources. This information would be provided upon request and in an electronic form determined appropriate by the Secretary for a nominal fee based on the cost of preparing and providing the data.

Section 4. Prioritizing Studies of Comparative Clinical Effectiveness of Covered Part D Drugs

Current Law

Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) instructed the Agency for Healthcare Research and Quality (AHRQ) to conduct research on outcomes of health care items and services. In order to guide this research, AHRQ developed a list of 10 health conditions that were considered to be a priority for Medicare beneficiaries.

Explanation of Mark

This Mark would instruct the Secretary of HHS to develop a new prioritized list of comparative clinical effectiveness studies, which would include the comparison of one Part D drug to any drug, biological product, item, or service covered under the Medicare program. The prioritized list would specify the items and services to be evaluated and the general methodology to be used to conduct each study. The Secretary would be required to consider all methodologies available, from systematic reviews to clinical trials.

In addition, the Secretary would be instructed to list studies deemed most critical to advancing value-based purchasing of covered Part D drugs. In doing so, the Secretary would be instructed to take into account certain factors, such as the clinical areas AHRQ has identified as having insufficient clinical evidence, the original list of priority medical conditions developed for AHRQ's comparative effectiveness studies, clinical areas with the greatest need for information, and advice provided by a new advisory committee.

The Mark would instruct the Secretary to establish an advisory committee to provide advice on setting priorities for comparative clinical effectiveness studies across all agencies of the Department of HHS. Members of the advisory committee would include a diverse range of public and private experts, stakeholders, and interests from medical and pharmaceutical industries, patients and representatives of patients, researchers, and government. The Mark instructs the Secretary to ensure that the committee does not have a majority of members from any one of these groups. Any advice provided to the Secretary by the advisory committee would be required to be made publicly available.

Within one year of the enactment of the Act, the Secretary would be required to submit a report to Congress that would include the prioritized list of comparative clinical effectiveness studies and plans for the conduct of the studies, as well as a summary of the factors the Secretary would be required to take into account in constructing the list. The Secretary would be required to make the report publicly available.

Nothing in this Mark limits the authority of the Secretary to prioritize comparative effectiveness research needs for procedures, devices, diagnostics, or other medical interventions. This Mark also does not limit the authority of the Secretary to conduct any study determined appropriate by the Secretary.

The provision authorizes the appropriation of funds necessary to carry out this section.

Section 5. Authorizing consideration of comparative clinical effectiveness studies in developing and reviewing formularies under the Medicare prescription drug program

Current Law

A formulary is a list of preferred drugs for which a Part D drug plan, or other health insurer, has stipulated that it will pay a portion of the costs. A formulary may also specify contingencies for payment. Medicare prescription drug plan sponsors' formularies must be constructed by a pharmacy and therapeutic (P&T) committee, composed of practicing physicians or practicing pharmacists.

Current law provides some guidance for P&T committees on constructing Part D formularies. Medicare Part D drug plans are required to include two drugs in each therapeutic class, except if only one drug is available. The CMS requires coverage of "all or substantially all" drugs for some mental illnesses, including antidepressants, antipsychotics, and anticonvulsants. Anticancer drugs, immunosuppressants, and HIV/AIDS drugs are also included in the "all or substantially all" list of formulary drug classes. Plans can neither change their formularies without CMS approval, nor drop coverage for persons currently using the drug, except at the beginning of the calendar year.

In deciding which drugs in a therapeutic class should be included or excluded in a formulary, a plan's P&T committee is required to base their clinical decisions on the peer-reviewed medical literature (including randomized clinical trials, pharmacoeconomic studies, outcomes research data, and other information the committee deems appropriate) and the relative safety and efficacy of drugs.

Explanation of Mark

In deciding which drugs in a therapeutic class should be included or excluded from a formulary, the provision would instruct P&T committees to take relevant comparative clinical effectiveness studies into account. The comparative clinical effectiveness studies are to be taken into account in conjunction with the other information already required to be considered, under current law – the peer-reviewed medical literature and the relative safety and efficacy of drugs.

The Mark would leave the other formulary requirements for Part D plans intact.