

Congress of the United States
Washington, DC 20515

December 18, 2006

The Honorable Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS-4119-P

Dear Ms. Norwalk:

As the Chairmen-elect of the Committees on Energy and Commerce, Government Reform and Ways and Means with jurisdiction over Part D, we respectfully submit the following comments on the proposed rules (CMS-4119- P) entitled "Medicare Program; Medicare Part D Data," issued October 18, 2006.

We applaud your effort to clarify CMS's statutory authority to collect Part D data necessary to evaluate the program and its overall effectiveness. We urge you in the final rule to collect all data necessary from all available sources consistent with the authority granted under 1860D-12(b)(3)(D) of the Medicare Modernization Act (MMA). We look forward to using this information in making future policy decisions about the program and welcome the opportunity to work with CMS in the event any additional legislative authority is needed to ensure adequate information is available for these purposes.

Information to be collected

The proposed rule allows claims data, now collected for payment purposes, to be used for research, analysis, reporting and other public health functions. The statute is clear that CMS can use claims data for these purposes. Moreover, we urge CMS to access all the Prescription Drug Event (PDE) data necessary, and to clarify your ability to add elements to the PDE claims data. Specifically we request you require plans to report the net price (after all discounts and rebates) paid by the plan for the drug dispensed.

Purpose of CMS Collecting Information

While we think it is appropriate in the regulations posted by CMS to highlight for what purposes CMS might collect PDE data, CMS should in no way limit its use to only the purposes stated in the rule. Moreover, the list of purposes for which the data would be used for should be expanded to include program integrity. While CMS staff has assured us that program integrity is always an allowable purpose, it is important to clarify in the final rule that PDE data can be used at anytime to protect the program. It

is impossible to properly monitor the program and ferret out waste, fraud, and abuse if the agents charged with program integrity do not have immediate and unfettered access to the claims data.

Sharing Data with Entities Outside of CMS

Many entities, both inside and outside the government, will need and want access to the Part D claims data. Some of these entities deserve broad access with few restrictions, while others should be denied access altogether. We urge CMS to use the final rule to implement a tiered system of access to PDE data taking into account the need for data and opportunity for abuse among: 1) other government entities; 2) contractors and researchers under direct contract with CMS or a government entity; and 3) outside researchers.

The proposed rule must construct a more robust system of deciding who has access to PDE data under what circumstances. The final rule should clearly state that all applicable government agencies, including Congressional support agencies such as the Congressional Budget Office (CBO), Medicare Payment Advisory Commission (MedPAC), Government Accountability Office (GAO) and Congressional Research Service (CRS), will be allowed broad access to claims data in a timely fashion without submitting requests for multiple data use agreements. Data use agreements with government agencies must not be limited to individual investigators, or specific research purposes.

This data should also be made available to state Medicaid Directors, for purposes of monitoring and researching the dual-eligible population. With the transfer of the dual eligibles from Medicaid to Medicare, neither the beneficiary's Medicare Part D plan nor Medicaid now possess a complete profile of a patient's drug regimen. This is likely to lead to increasing instances of adverse interactions and inappropriate care, further complicating recent state efforts improve care coordination. Therefore, we request that CMS amend the proposed rule to provide states with access to the drug utilization and spending data collected by the Medicare Part D prescription drug plans, as well as any other data necessary for states to effectively coordinate the care of the dual eligibles.

There are many contractors "outside of CMS" that should be granted access to Part D claims data. Consistent with our request that claims data be used for program integrity purposes, the final rule should clarify that Medicare Drug Integrity Contractors (MEDICs) can obtain PDE data where necessary to fully investigate complaints and fraudulent claims. Other contractors conducting research funded by CMS, and other government agencies should also enjoy broad access to the data, but data use agreements must be strictly enforced to ensure contractors do not share data with other parties.

Another concern with the proposed rule is the use of PDE data by outside researchers that may attempt to use the information for dubious purposes. Organizations with strong proprietary interests should not have access to the PDE data. For example, pharmaceutical manufacturers hoping to use the data to sell particular drugs to

prescribing physicians should not be allowed to use the data for that purpose. We believe the final rule should strike an appropriate balance between giving bona fide researchers access to data while denying access to proprietary interests. The final rule should specifically deny PDE data access to drug plan sponsors, pharmaceutical manufacturers, and other industry data collection entities (e.g. IMS Health) that sell market research and sales data.

Limitations

The final rule should continue to make clear that CMS has the ability to collect any data otherwise allowed by statute, as well as any data if deems necessary to manage Part D.

Sincerely,



John D. Dingell
Chairman-elect
Committee on Energy & Commerce



Charles B. Rangel
Chairman-elect
Committee on Ways & Means



Henry A. Waxman
Chairman-elect
Committee on Government Reform