Congress of the United States
House of Representatives
Washington, D.C. 20515

May 12, 2006

The Honorable David M. Walker
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Comptroller General Walker:

We are very appreciative of the Government Accountability Office's (GAO) efforts to date in oversight and monitoring of the new Part D drug benefit. Given the amount of Federal dollars at stake in this new program and the health consequences for seniors and people with disabilities if the program does not work properly, your oversight role is critical.

We request that the GAO examine how well Part D is working to provide Medicare beneficiaries with their medications. We are particularly concerned that Part D plans may use a number of so-called management techniques designed to prevent patients from getting their medicines. These techniques include:

- Excluding a drug entirely from the list of drugs paid for by the plan;
- Charging higher cost-sharing for certain drugs (by placing it in a higher, unaffordable cost-sharing category) while still claiming that is it "available" on the formulary;
- Requiring approval from the drug plan (prior-authorization) before a beneficiary can get their medicine;
- Requiring patients to try a different medicine from the one they are currently taking to determine if it will work before they are permitted to fill a prescription for their preferred medicine (step-therapy); and
- Placing limits on the quantity of pills that may be received (i.e., only dispensing 30 pills in a month when the patient normally takes 60) or limits on the dosage or strength of the drug that will be covered.

We also ask GAO to explore the following four questions:

First, with respect to appeals:

(a) The total number of beneficiary requests for appeals under Part D that have been filed with private drug plans;

(b) The total number of beneficiary appeals by type including: medicine not included on what the plan will pay for (formulary), requiring a different medicine be tried before accessing the doctor-recommended drug (step-therapy), limits on the quantity or dosage of medicine that is allowed under the plan, denials by plans of a medicine because the plan bureaucrats conclude it is not medically necessary to treat the patient's condition, or denials by plans of payment for a medicine because the beneficiary obtained the medicine through an out-of-network provider, etc.;

(c) The number of appeals by category of beneficiary (elderly, individuals with disabilities, dual eligibles, low-income subsidy, institutionalized individuals);

(d) The drugs most commonly appealed across all of Part D and also for each category of beneficiary;

(e) The disposition of those requests (how many were resolved in favor of the beneficiary, how many in favor of the plan) by type of appeal, category of beneficiary, and by drug;

(f) The number of appeals that are still pending/unresolved, and the number which have not been resolved within CMS's required time frames; and

(g) The number of appeals pursued to the next higher level.

Second, with respect to the instances where prior approval is needed from a plan before accessing a particular medicine, we would like GAO to examine:

(a) A listing of the different medicines (organized by class of drug, e.g., anti-depressants) subject to prior authorization or step therapy (or other restriction) across Part D;

(b) The number of cost-sharing categories used by plans and the placement of medicines in those categories, e.g., how many drugs subject to plan restrictions are charged the highest cost-sharing, how many are charged the next highest cost-sharing, and whether or not there is an alternative in the tier with the lowest cost to the beneficiary;

(c) A summary of the policies used by plans to determine how much cost-sharing is paid by the beneficiary when formulary exception is approved (e.g., do beneficiaries pay the lowest or highest cost-sharing available under the plan, does the plan have discretion for how much to charge, does this vary across plans?)

(d) The number of different prior authorization forms in use in individual plans and across all Part D plans;

(e) The evidence plans require beneficiaries or providers to submit in order to get a prior-authorization request approved and whether such evidence requirements are uniform across all plans or not;

(f) The means for determining whether the request for a medicine should be granted, and whether this standard varies across plans;

(g) The number of beneficiaries taking a medicine in the six "protected categories" of drugs who have been told that their medicine is not covered, or that it is covered, but in a high (and sometimes unaffordable) cost-sharing category, or that it is subject to some other restriction and the number of beneficiaries who have failed to access one of these needed medicines under Part D because of excessive cost-sharing imposed by their plan;

(h) The number of prior authorization requests that have been filed to date pertaining to a drug in one of the six "protected" classes;

(i) Any enforcement actions taken relating to Part D plans failing to comply with CMS guidance on access to medications in one of the six protected classes.

In addition, we would like GAO to examine the frequency with which plans use prior-authorization and other tactics to restrict access to drugs, whether these tactics are used more by some types of plans than by others (e.g., Medicare Advantage versus PDP versus commerical plans), whether the restrictions have adversely affected beneficiaries, and whether plans are adequately informing beneficiaries of restrictions on access to medicines.

Third, there is likely to be wide variation in how plans are performing in terms of appeals. We ask that GAO explore plan performance and rank the top five plans in each State with:

(a) The greatest number of appeals filed (in each plan category);

(b) The fewest number of appeals filed (in each plan category);

(c) The greatest number of appeals resolved in favor of the beneficiary;

(d) The greatest number of appeals resolved in whole or in part in favor of the plan; and

(e) The greatest number of appeals not resolved within CMS-required time frames.

Finally, we are also concerned about the Centers for Medicare and Medicaid Services enforcement activities with respect to poor-performing or bad-acting Part D plans. We would like GAO to examine what actions CMS is taking to monitor and enforce contractual requirements on Part D plans and protect beneficiaries enrolled in those plans. In addition, please answer the following questions:

(a) Has CMS initiated any corrective action, applied any sanction, or otherwise reprimanded any particular plan – including any warning letters – for its practices thus far during the implementation of the Part D benefit program?

(b) How many complaints have been received by CMS (or otherwise passed on to CMS) pertaining to false, fraudulent, or otherwise misleading marketing or enrollment practices? Please provide the number of complaints and nature of each, as well as the general source (beneficiary, State, provider, etc.). How many of these complaints have been resolved?

(c) How many complaints have been received pertaining to other issues regarding plan conduct? What is the nature of those complaints and what action has CMS taken with regard to resolving the complaints and taking action against those responsible for violations?

(d) What are the top five plans in each State with the highest number of complaints and the top five plans in each State with the fewest complaints?

(e) What corrective actions have been taken by the Administration, including any sanctions that have been assessed against plans where such complaints have been filed?

We appreciate your prompt attention to this request and look forward to working with you on this and other Part D matters in the future. For further information, please contact Bridgett Taylor, Amy Hall, or Purvee Kempf of the Committee on Energy and Commerce Democratic staff at 202-226-3400, or Cybele Bjorklund or Chad Shearer of the Committee on Ways and Means Democratic staff at 202-225-4021.

Sincerely,

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