Congress of the United States
U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
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June 21, 2006

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20500

Dear Administrator McClellan:

Thank you for appearing before the Committee last week to discuss implementation of the Medicare Part D, and for staying through an entire round of questioning.

A number of us asked for specific data at the hearing or have written letters requesting such information. As we discussed, we are putting these requests in writing in hopes of both clarifying the exact nature of the requested data and expediting the answers.

We request you respond to the attached questions by June 30, 2006. Please answer each question by referring to the corresponding number and letter. Questions requiring answers about the number and type of beneficiaries enrolled or not enrolled should be answered with both national aggregate numbers and by state, with the greatest degree of accuracy possible. If you are unable to provide a complete answer to one or more questions by June 30, please provide the answer or data to the best of your ability, explain why it cannot be answered at this time and provide a timeframe for the provision of the final, complete answer.

If you have any questions or need additional information, please contact Cybele Bjorklund on the Democratic staff of the Committee on Ways and Means at 202-225-4021.

Sincerely,

Pete Stark

The Honorable Pete Stark
Ranking Democrat
Subcommittee on Health

Charles B. Rangel

The Honorable Charles B. Rangel
Ranking Democrat

The Honorable Sander M. Levin
Ranking Democrat
Subcommittee on Social Security

The Honorable Benjamin L. Cardin
Ranking Democrat
Subcommittee on Trade

The Honorable John Lewis
Ranking Democrat
Subcommittee on Oversight

The Honorable Richard Neal
Member

The Honorable Michael McNulty
Ranking Democrat
Subcommittee on Select Revenue Measures

The Honorable John B. Larson
Member

The Honorable Jim McDermott
Ranking Democrat
Subcommittee on Human Resources

The Honorable Rahm Emanuel
Member

The Honorable Xavier Becerra
Member

The Honorable Lloyd Doggett
Member

Questions for Record on June 14 Part D Hearing
Submitted to CMS Administrator Mark McClellan by Democratic Members
Committee on Ways and Means
June 20, 2006

ENROLLMENT AND OTHER DATA

1. **New coverage**. In Q&A, you acknowledged that a large majority of beneficiaries with drug coverage had coverage prior to the start of Part D. You asserted that just 11.6 million beneficiaries – approximately 30 percent of the 38.2 million cited by the Administration as having coverage –have new drug coverage this year.
    a. Please provide an updated version of the first table ("Total Medicare Beneficiaries with Drug Coverage, as of 6-11-06") in your testimony with a new column on the far right showing how many beneficiaries are presumed to be newly covered in each category. Please indicate with an * which categories are funded by Part D (e.g., PDP, MA-PD, Medicare-Medicaid and retiree drug subsidy).
    b. How many PDP enrollees previously had drug coverage through a Medigap plan? How many of those transferred into a PDP offered by their Medigap insurer?

2. **Plan-specific enrollment data.** CMS has refused to release plan-level enrollment data, despite numerous requests from Members of Congress, press, researchers and others. At the hearing, you cited privacy concerns, given apparently low enrollment in some plans. However, this is not an issue since we are not asking for beneficiary or even de-identified demographic information. CMS has the data, or you couldn't be paying the plans or making announcements about the average premiums of enrollees. Thus, please provide plan-specific enrollment data by region and, for the national plans, nationally.

3. **Data on doughnut or coverage gap.**
    a. How many beneficiaries are enrolled in plans with a doughnut hole?
    b. How many beneficiaries are currently in the doughnut hole?
    c. How many do you project will fall into the doughnut hole some time during the 2006 plan year?
    d. How many people do you project will exit the doughnut hole and receive catastrophic coverage? Please provide these answers for both PDP and MA-PD enrollees.

4. **New enrollees.** Even with the closure of the initial enrollment period, there will be on-going outreach, education and enrollment issues for new beneficiaries.
    a. How many beneficiaries are newly eligible each month?
    b. How many are duals?
    c. How many are thought to be eligible for the limited-income subsidy (LIS) or "Extra Help"? Please provide national and, if possible, state-level data.

LIMITED-INCOME SUBSIDY (LIS)

5. **Facilitated enrollment for LIS and Katrina late enrollees.** Regarding the CMS demonstration project that will allow seniors and people with a disability who qualify for the Extra Help or who live in an area affected by Hurricane Katrina to enroll in Part D without penalty through December 31, 2006:

a. Will CMS facilitate enrollment for newly approved LIS beneficiaries or those who live in an area affected by Hurricane Katrina during this demonstration project?
b. If so, how?

6. **Clarification of penalty status for LIS.** You testified that beneficiaries eligible for the low-income subsidy who enroll during the 2006, "will not face a premium penalty for late enrollment," but also that CMS lacks the administrative authority to waive the late enrollment penalty without further Congressional action.

    a. Is CMS "waiving" the penalty for those who sign up for Extra Help during 2006 or is there some other mechanism by which beneficiaries will avoid paying the penalty?
    b. What will CMS policy be on late enrollment penalties for LIS beneficiaries who enroll during 2007?

7. **People denied LIS after May 15.** Regarding beneficiaries who applied for Extra Help before May 15 but were denied LIS status after that deadline:

    a. Since they were awaiting determination of their LIS eligibility on May 15, have you developed a procedure in place to allow these beneficiaries to enroll in a plan before the November open enrollment period?
    b. Will you waive the late enrollment penalty for them if they enroll during the next enrollment period?

8. **Part D enrollees eligible for, but not receiving, Extra Help.** Regarding beneficiaries who enrolled in Part D plans before May 15, unaware of their eligibility for Extra Help, you clarified that they can still apply for the LIS during the demonstration project and receive Extra Help:

    a. Will they be allowed to switch plans after becoming eligible for Extra Help?
    b. Is there a process in place to refund premiums and co-payments to beneficiaries who were always LIS-eligible, but had not previously applied for the subsidy?

9. **Churning among duals.** Every month, tens of thousands of beneficiaries fall in the gap between Medicaid and Medicare drug coverage. These dual-eligibles may go up to eight weeks without prescription drug coverage, and pay hundreds of dollars out of pocket, or worse, go without prescriptions that should be covered by Part D. Regarding low-income Medicare beneficiaries who cycle in and out of the Medicaid program as their expenses reach certain threshold amounts:

    a. What actions is CMS taking to automatically enroll these beneficiaries so that they have Part D (and Extra Help, when applicable) coverage the day their Medicaid coverage ends?
    b. How will CMS treat those who experience periods without creditable coverage because of their inability to pay premiums when their dual-eligible status ends?
    c. How quickly are plans required to reimburse dual-eligibles who have made out of pocket expenditures while in the gap between Medicaid and Part D coverage, and how do beneficiaries pursue such reimbursement?

10. **Treatment of transitional assistance beneficiaries.** Regarding Medicare beneficiaries who received transitional assistance in the Medicare drug discount card program:

    a. How many are still enrolled in Medicare?
        i. Of the answer to 10(a), how many are now enrolled in Part D?
        ii. Of the answer to 10(a), how many are now enrolled in Extra Help?
    b. Please describe CMS' additional outreach efforts, if any, directed specifically to those identified in 10 (a) who are either not signed up for Part D, or are signed up but not receiving Extra Help?

11. **Possible opt-in for LIS screening.**
    a. In order to increase enrollment in Extra Help, will CMS include an "opt-in form" or "check box" in the enrollment materials for new Medicare beneficiaries, which would authorize CMS to screen them for LIS eligibility?
    b. If not, why?
    c. Will CMS require plans to do this for their enrollment and application materials and processes?

12. **Effect of Income and Asset Restrictions.** We are concerned that the current eligibility standards may preclude many truly needy beneficiaries from receiving Extra Help. To help quantify this problem, we request:

    a. Number of people who have applied for the LIS.
    b. Number of people rejected for Extra Help because their assets exceed the applicable limits required by the asset test, the average amount of assets over that limit for those rejected, and the asset or resource category(ies) that caused the disqualification.
    c. Number of people rejected for Extra Help because their income exceeded 150% of the federal poverty limit, and the average amount over that limit for those rejected.

13. **LIS participation among Medicare Savings Plan enrollees.** How many people participating in the Medicare Savings Plans are not enrolled in Extra Help?
    a. Please describe what is being done to reach these beneficiaries.
    b. Please provide copies of any applicable outreach materials.

14. **NCOA materials.** Please provide copies of the grant application, scope of work documents, and all written or electronic communications to and from the National Council on Aging with regard to its "CMS-funded grant to reach and qualify beneficiaries for LIS."

15. **Extra Help communications.** Please provide copies of all communications regarding Extra Help sent to beneficiaries by CMS, the Social Security Administration, and your grantees and subcontractors. For each different communication, please include:
    a. the date(s) sent; and
    b. the number of households to which it was sent.

16. **Future LIS outreach efforts.** On page 13 of your recent written testimony to the Committee, you refer to a new CMS endeavor to "focus future grassroots efforts" in "counties with large numbers of potential LIS-eligibles." Please provide a listing of all

counties (and Metropolitan Statistical Areas and census tracts, if applicable) in which these efforts will occur. For each county or area so identified, please provide:

a. the average per capita income
b. the number of seniors with incomes at or below 150% of the federal poverty limit
c. the number of Medicare beneficiaries
d. the number of Part D enrollees
e. the number of Extra Help enrollees

17. **Outreach to minority beneficiaries and those living in rural areas.** On page 14 of your testimony, you refer to "special initiatives for both minority beneficiaries who live in urban areas and beneficiaries who live in rural areas who may be isolated from community outreach efforts." Please provide a complete description of these "special initiatives" and copies of any printed materials to be used.

MISCELLANEOUS

18. **Customer service data.** Members of this Committee have asked CMS numerous times, including via a letter on April 25, to release data on the customer service provided by Part D plan sponsors, specifically the data collected over the last number of months on plan call centers and other customer service measures. We understand CMS has given this information to the plans on a regular basis. During the Subcommittee hearing on May 3, Dr. McClellan promised to provide the data, yet they still have not been released as of today.
    a. Please provide, by plan sponsor, all of the data that have been collected and any corresponding analyses.
    b. Please explain what specific data will be released to better enable beneficiaries to compare plans based on customer service for the 2007 enrollment period.

19. **Plan quality information.** CMS has been collecting data from the plans on a number of quality measures, including (1) the number of grievances, exceptions and appeals filed per 1,000 enrollees, (2) the resolution of appeals and exceptions, and (3) the number of requests per 1,000 enrollees for prior authorization, step therapy, tier and non-formulary exceptions. We understand that the first quarter information was due to CMS on May 31. Please provide all of the collected information by plan sponsor, and provide the timeline for the public release of data that would allow beneficiaries to compare plans based on these and other non-price (e.g., call center performance) measures.

20. **Rebate information/negotiated prices.** PBMs and insurers make much of their profit by negotiating large rebates with drug manufacturers, often based on the volume of a drug prescribed.

    a. On average, how much of the rebate gets passed onto Medicare Part D beneficiaries in the negotiated price they see at the pharmacy counter?
    b. Given that the law does not require that all of the rebates and discounts be passed on, doesn't this mean that beneficiaries in the coverage gap or donut hole pay more than the lowest negotiated price, while the plan gets a kickback (in the form of the rebate) for their purchases?

c. The law requires that CMS payments be NET of rebates and other negotiations. Is CMS getting the needed information and are you certain that your payments reflect rebates and all other negotiations?

21. **Effects of risk corridor payments.** Please provide both in aggregate terms and specific to plan sponsor or organization whether and how much taxpayers are losing or saving during 2006 through the risk corridor arrangement.
    a. If CMS cannot provide this data by the deadline, when can we get that information?
    b. Do you expect substantial changes for 2007?
    c. If so, why?

22. **Prior authorization problems.** Regarding the numerous stories about beneficiaries being unable to obtain prior authorization for needed drugs that are listed on their plan formularies and doctors being put on hold for hours while attempting to get prior authorization for a particular prescription from plans, what is CMS doing to ensure that plan sponsors meet their obligations to beneficiaries to provide prompt and accurate prior authorization determinations to avoid both health crises and wasted physician and pharmacist time and resources?

23. **MEDICs/fraud and abuse.** In October of 2005 CMS announced a comprehensive project to monitor fraud, waste, and abuse in the Part D program. To date, CMS has contracted with only one Medicare Drug Integrity Contractor (MEDIC) to carry out this work, despite that the Deficit Reduction Act (DRA) provided $100 million specifically for program integrity.
    a. When will the remainder of the MEDICs be in place to monitor fraud, waste and abuse in Part D?
    b. What resources are current being spent on oversight that should be done by the MEDICs?
    c. What specifically is being done with the $100 million from the DRA?

24. **Humana's privacy breaches.** In recent weeks there have reports of two beneficiary data privacy breaches by Humana. In one instance, a widely accessible hotel business center computer was found to contain identifiable data on 17,000 Part D enrollees. In response, you stated, "It is unacceptable when personal information on any beneficiary is put at risk." However, your corrective actions for Humana fail to include any fines for this grave violation.
    a. Why did CMS fail to impose the $10,000 to $100,000 civil monetary penalties available under 42 CFR 423.750(a)(1), if this is so "unacceptable?"
    b. What specific actions have you taken? Why haven't you taken this opportunity to make an example out of a plan that appears to be so careless with these data?

25. **Licensure waivers.** The National Association of Insurance Commissioners has grave concerns about the broad licensure waivers granted by CMS. It appears that in some instances CMS is not even requiring the plans to meet the requirements in the regulations. Please explain.

26. **Price transparency.** The Administration has been advocating for price transparency for certain healthcare providers.
    a. Do you support price transparency and public disclosure of the actual negotiated prices for drugs and the extent to which discounts are passed on?

b. If not, why should this be hidden from the public, especially in light of the public financing?
c. To the extent you are concerned it would undermine the negotiating authority of the plans, why don't you worry that the same holds true for price transparency for physicians and hospitals?
d. Given that a feature of competitive markets is consumer access to information, how will Part D provide the ultimate experiment of the "consumer choice" model if consumers lack significant information?