ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

June 10, 2004

The Honorable Mark McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W., #314-G
Washington, D.C. 20201

Dear Administrator McClellan,

This month, seniors and other Medicare beneficiaries enrolled in the Medicare prescription drug discount card program. With regard to this program, I am concerned about the Centers for Medicare and Medicaid Services' (CMS) ability to do the following:

(1) prohibit "bait and switch" tactics that could change the discounts and the drugs that enrollees expected when they signed up for the program;

(2) oversee and prosecute program fraud, such as illegal cards, quickly to stop further exploitation of seniors and other Medicare beneficiaries; and

(3) maintain and establish access to the drug card and the $600 transitional assistance benefit for the poorest Medicare beneficiaries.

My concern for these issues carries over to the preparations underway for the Medicare drug benefit that will go into effect in 2006.

"Bait and switch" is an age-old tactic used by all types of "snake oil" salesmen to offer one product while actually delivering another. This is not something that should be sanctioned within Medicare. Generally, a senior will pay the enrollment fee for a specific Medicare drug discount card if he or she expects to save money on the drugs they take over the term of the program. As I heard in testimony received by the Committee on Energy and Commerce, Subcommittee on Health, during a hearing entitled "Medicare Prescription Drug Discount Cards: Immediate Savings for Seniors" last month, choosing the right card can take many hours of research because of the differing prices and formularies offered by the numerous cards. If the Medicare drug discount card program permits drug sponsors to change the price of specific drugs

offered or allows sponsors to change the drugs on which a discount is available after a senior has already selected the card, it will undermine that senior's well-researched and thoughtful decision. At a minimum, if CMS wants seniors and other Medicare beneficiaries to actually use these cards, it should ensure security in their choices by guaranteeing the drugs offered and the prices charged remain the same.

I am also troubled by the allegations of unsavory and illegal sales practices I have heard about in the short period of time since marketing and enrollment of the Medicare drug discount cards began. Confusion provides many opportunities for fraud, and as the hearing in the Committee on Energy and Commerce, Subcommittee on Health, highlighted, the marketing and enrollment of the Medicare drug discount card program has been confusing to seniors and other Medicare beneficiaries, particularly the most vulnerable -- those who are poor, uneducated, ill or mentally incapacitated. Notably, just one week into the program, HHS is conducting inquiries into nearly 30 complaints from seniors and other Medicare beneficiaries about fraudulent and deceptive marketing practices.[1] Additionally, many seniors and other Medicare beneficiaries have reported receiving unsolicited phone calls or visits from Medicare drug discount card sponsors. As Medicare regulations do not permit this, the occurrence of these calls and personal visits they are very worrisome. The *Washington Post* reported that crooks may be using the card program to obtain personal information that can be used for identity or credit card theft or may be selling fraudulent cards.[2] In Massachusetts, the attorney general's office has received complaints about mail solicitations for discount cards that appeared to be from the Federal Government but were not.[3] *The Wall Street Journal* reported similar scams in other states.[4] The Kansas Insurance Department is investigating whether seniors and other Medicare beneficiaries were misled into thinking that some discount cards were insurance cards because several providers reported that seniors were presenting discount cards as insurance cards at the time of payment.[5]

CMS has confirmed that Medicare has received complaints about fraudulent activity from around the country. CMS must take strong steps to eliminate and protect our seniors and other Medicare beneficiaries against fraud. So far, I see little evidence of any action that CMS is

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[1] Emily Heil and Marilyn Werber Serafini, *Senators Seek Better Funding for HHS Inspector General's Office*, CONGRESS DAILY AM at page 14 (June 9, 2004).

[2] Michelle Singletary, *Beware of Scams as Medicare Discount Drug Cards Become Available*, WASHINGTON POST at page E03 (May 20, 2004).

[3] *Id.*

[4] Christopher Windham, *Discount Health Cards Rarely Prove Useful, Regulators Warn*, WALL STREET JOURNAL at page D5, (March 16, 2004).

[5] *Id.*

taking. In fact, CMS actually approved 20 cards offered by companies that had previously been named in federal or state fraud cases.[6]

Morever, the Medicare regulations that claim to protect seniors and other Medicare beneficiaries against "bait and switch," fraud, and other problems mentioned above appear to be unusually weak. They only allow for intermediate sanctions, which CMS defines as suspended marketing and enrollment activities, or fines against violators. Additionally, in a very cumbersome enforcement plan, some violations are enforced by CMS and others by the Office of Inspector General (OIG) in the Department of Health and Human Services. There is just as much confusion about what sanctions will be assessed, at what level of violation, for what specific violations, and by whom as there is for a senior choosing one of the 73 cards. My concern is that this confusion in the regulations will result in a lack of enforcement and unending litigation over what is actually impermissible when enforcement is attempted. Unfortunately, seniors and other Medicare beneficiaries will pay the price.

Also, a successful Medicare benefit must not only offer a significant benefit to Medicare beneficiaries in a safe and secure method, but it must successfully enroll in the benefit a majority of the people who are eligible. Since Medicare began in 1965, it has been successful in enrolling 97 percent of all those eligible for the program. I expect nothing less for any specific Medicare benefit, but only 2.87 million people were enrolled in the cards as of the end of May?. Of these, approximately 2.4 million Medicare beneficiaries were auto-enrolled by their managed care plans, so only about 500,000 seniors and other Medicare beneficiaries chose to enroll. That is a mere one percent of the approximately 40 million Medicare beneficiaries in the country. Moreover, enrollment in the $600 transitional assistance program is invaluable to eligible low-income beneficiaries. CMS has said, however, that it is expecting to enroll only 65 percent of those eligible. Considering that the outreach budget for the Medicare prescription drug discount card and Medicare prescription drug benefit is one billion dollars, it would seem that CMS would have the resources to enroll a much larger number of this neediest population for such a critical benefit.

In addition to assistance with enrollment, seniors and other Medicare beneficiaries also need access to benefits through a sufficient and identified pharmacy network. According to some reports, the information provided by Medicare.gov has not accurately reflected which pharmacies are participating.[7] Seniors and other Medicare beneficiaries need to have the ability to easily access the actual benefits for which they have signed up. I would like to know what immediate and concrete steps CMS is taking to ensure accuracy of its information.

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[6] Center for American Progress, *Paying to Play: Health Care Companies, Campaign Contributions and Medicare Drug Discount Cards,* (June 1, 2004).

[7] Lisa Barnett Mann, *Pick a Card! She Thought Choosing Mom's Medicare Drug Card Would Be an Easy Trick. It Turned Into a Real Stumper,* THE WASHINGTON POST at page F01 (May 18, 2004).

The questions and responses will be included in the printed hearing record of the hearing entitled "Medicare Prescription Drug Discount Cards: Immediate Savings for Seniors," held by the Subcommittee on Health on May 20, 2004. Therefore, the responses should be received no later than Friday, June 25, 2004.

Please fax and e-mail the responses. The faxed response should be directed to Eugenia Edwards, Committee on Energy and Commerce, Majority staff, at 202-226-2447, and Voncille Hines, Committee on Energy and Commerce, Minority staff, at 202-225-5288. The e-mail copy of the responses should be directed to Eugenia Edwards (eugenia.edwards@mail.house.gov) and Voncille Hines (voncille.hines@mail.house.gov). Due to the uncertainties of postal deliveries on Capitol Hill, we ask that your responses not be sent through the postal service.

If you have any questions about this request, please have your staff contact Bridgett Taylor, minority professional staff, or Purvee Kempf, minority counsel, at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Michael Bilirakis, Chairman
Subcommittee on Health

The Honorable Sherrod Brown, Ranking Member
Subcommittee on Health

Questions for the Honorable Mark McClellan, M.D., PhD.
Administrator, Centers for Medicare and Medicaid Services

1. "Bait and switch" tactics include those where drug card sponsors advertise lower prices for specific drugs but then increase those prices after Medicare beneficiaries enroll or where drug card sponsors provide a discount on a specified drug and after Medicare beneficiaries enroll the sponsor changes the drug on which they provide a discount. Seniors and other Medicare beneficiaries are locked into the card they select for the remainder of the year putting them at risk of unanticipated price increases under these "bait and switch" tactics. Officials from Centers for Medicare and Medicaid Services (CMS) have claimed on numerous occasions that CMS protects Medicare beneficiaries from changes in overall drug prices to guard against "bait and switch."[8] CMS references its authority to assess intermediate sanctions and civil monetary penalties for a "substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP) and/or an amount proportionate to the changes in the endorsed sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy)."[9] Please answer the following questions regarding this:

   a. Is a Medicare drug discount card sponsor permitted to change their prices for drugs every seven days?

   b. Is a Medicare drug discount card sponsor permitted to change the drugs on which they offer discounts every seven days?

   c. Can a beneficiary change cards once he or she has enrolled in one specific card before the end of the year?

   d. According to its December 15, 2003, interim final regulations, CMS will approve price changes that occur for specified reasons such as a change in the AWP or a change in the drug sponsor's cost structure. AWP is an artificial price changed at the whim of the manufacturer. How will CMS verify that manufacturers are not arbitrarily changing prices as part of a "bait and switch" scheme?

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[8] CMS, *Medicare Implements New Steps to Prevent Drug Card Fraud*, MEDICARE NEWS, April 22, 2004.

[9] 68 Federal Register 69840, 69925-6 (proposed December 15, 2003) (to be codified at 42 CFR 403.820(a)(3)(iv) and 403.820(b)(2)).

e. Did CMS consider prohibiting drug price changes because of a change in the AWP, an artificial index set by the manufacturer, until the next open season? If CMS considered this, why did it choose not to mandate such price stability? If not, why not?

f. Discounts, rebates, or other changes in the sponsor's "cost structure" are a function of the contracts signed between the drug card sponsor and the manufacturer. Did CMS consider mandating that drug card sponsors who enter into any of these "special arrangements" or contracts with a manufacturer keep prices stable throughout the year as opposed to allowing prices changes to affect seniors and other Medicare beneficiaries? If CMS considered this, why did it choose not mandate such price stability? If not, why not?

g. Describe in specific terms what other costs beyond the "material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy"[10] are considered in a drug card sponsor's cost structure?

2. Please answer the following questions concerning fraud and fraudulent actors:

a. What steps is CMS taking to ensure that fraudulent actors do not take advantage of seniors and other Medicare beneficiaries under the guise of selling or utilizing the Medicare drug discount card?

b. How many staff and how much in monetary resources has CMS budgeted to pursue complaints of fraud from seniors and other Medicare beneficiaries?

c. Given the short timeframe of this program, how quickly does CMS expect to issue a penalty once a violation has occurred?

d. Will CMS prohibit participation by the Medicare drug card sponsors or others that receive intermediate sanctions or civil monetary penalties in the full Medicare drug benefit in 2006?

e. When CMS approved Medco Health Solutions, Inc., as a Medicare drug card sponsor, did it know that Medco had recently agreed to pay $29 million to settle allegations by 20 states that it had pressured doctors to switch patients' medications to financially benefit Medco? If so, why was this approval granted?

f. When CMS approved PacifiCare Health Systems, Inc., as a Medicare drug card sponsor for its Secure Horizons Medicare Advantage plan, did it know that PacifiCare had recently paid $87.3 million to the Federal Government to settle alleged violations of the Federal False Claims Act, including submitting inflated claims for insurance payments based on rates that did not conform with

[10] 68 Federal Register at 69925 (to be codified at 42 CFR 403.820(a)(3)(iv)).

regulations for Federal employees, failure to give health care programs the most favorable rates it gave to commercial customers, failure to coordinate Federal health benefits with those provided to participants over age 65 in the Medicare program, and failure to fully disclose rate adjustments in statements it submitted to the Office of Personnel Management? If so, why was this approval granted?

g. When CMS approved Express Scripts, Inc., as a Medicare drug card sponsor, did it know that Express Scripts had recently been subpoenaed by the New York Attorney General for information relating to the company's contacts and business practices to determine the company's compliance with state and federal antitrust and consumer protection statutes? If so, why was this approval granted?

3. Please answer the following questions with regard to access:

a. How many people are enrolled in each of the 73 Medicare-approved drug cards as of the date of your response to this letter? Of these, how many were automatically enrolled through their Medicare Advantage plans or through their State Pharmacy Assistance Programs?

b. How many people are eligible for and have enrolled in the $600 transitional assistance program as of the date of your response to this letter? Of these, how many were automatically enrolled through their Medicare Advantage plans or through their State Pharmacy Assistance Programs?

c. How many people are eligible for a Medicare-approved drug discount card and the $600 transitional assistance program?

d. Is CMS permitting auto-enrollment of the 700,000 Medicare beneficiaries in Medicare Savings Programs that are eligible for the $600 transitional program? If not, why not?

e. Is CMS aware of pharmacies that are listed on the Medicare.gov web site as participating in a Medicare drug discount card program but are not actually participating? If the answer is in the affirmative, please explain how these pharmacies were allowed on the web site by CMS?

f. What steps is CMS taking to ensure that in the future only participating pharmacies are listed on the Medicare.gov web site?

4. CMS issued interim final regulations for the Medicare discount drug card program in the *Federal Register* on December 15, 2003.[11] In a very confusing division of enforcement responsibility, CMS split the authority for imposing civil monetary penalties between itself and the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS).

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[11] 68 Fed. Reg. at 69840 (to be codified at 42 CFR 403 and 408).

a. CMS has the right to impose monetary penalties in those instances "where the endorsed sponsor's conduct constitutes non-compliance with an operational requirement not directly related to beneficiary protection."[12] The OIG has the right to impose civil monetary penalties for violations "that concern misleading or defrauding a beneficiary."[13] However, CMS maintains authority over a number of specific instances that clearly are related to beneficiary protection. The following is a list of such provisions as cited in the regulations:

> (iii) Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor;
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> (iv) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP) and/or an amount proportionate to the changes in the endorsed sponsor's cost structure) including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy);
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> (v) Charging drug card enrollees additional fees beyond a $30 enrollment fee;
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> (vi) Charging transitional assistance enrollees any enrollment fee;
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> (vii) Charging a coinsurance more than five percent for those at or below 100 percent of the poverty line, or 10 percent for those above 100 percent but at or below 135 percent of the poverty line;[14]

1) Please explain why CMS does not view each of these violations as a direct beneficiary protection and therefore give the OIG enforcement authority when, in all cases, violations would result in excess and erroneous monies being paid by beneficiaries for prescription drugs or to drug card sponsors?

2) If CMS is intent on keeping authority over these violations, how much in monetary and staffing resources has CMS budgeted for the investigation of and assessment of civil monetary penalties for such violations? Does CMS have access to that amount of resources currently? If so, within which budget are those resources specifically located? If not, would this require new appropriations or a reduction in the Part A trust fund?

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[12] 68 Fed. Reg. at 69878.

[13] 68 Fed. Reg. at 69878.

[14] 68 Fed. Reg. at 69925 (to be codified at 42 CFR 403.820(a)(3)(iii-vii)).

b. The following is a chart of violations for which CMS and OIG appear to have overlapping jurisdiction in assessing civil monetary penalties:

CMS	OIG
"Charging drug card enrollees additional fees beyond a $30 enrollment fee . . .[c]harging transitional assistance enrollees any enrollment fee. . . [c]harging a coinsurance more than five percent for those at or below 100 percent of the poverty line, or 10 percent for those above 100 percent but at or below 135 percent of the poverty line"[15]	"who knowingly charged a program enrollee in violation of the terms of the endorsement contract"[16]
"Substantial failure to administer properly the transitional assistance funding for transitional assistance enrollees"[17]	"who knowingly used transitional assistance funds of any program enrollee in any manner that is inconsistent with the purpose of the transitional assistance program."[18]
"Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor"[19]	"who knowingly misrepresented or falsified information in outreach material or comparable material provided to a program enrollee or other person."[20]

1) For each row in the chart, who will have primary authority in that type of violation, CMS or OIG?

2) Is it up to the Secretary to resolve jurisdictional disputes between CMS and the OIG? If not, then how will disputes be resolved?

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[15] 68 Fed. Reg. at 69925 (to be codified at 42 CFR 403.820(a)(3)(v)-(vii)).

[16] 69 Fed. Reg. 28842, 28845 (proposed May 19, 2004) (to be codified at 42 CFR 1003.102(b)(18)).

[17] 68 Fed. Reg. at 69925 (to be codified at 42 CFR 403.820(a)(3)(viii)).

[18] 69 Fed. Reg. at 28845 (to be codified at 42 CFR 1003.102(b)(19)).

[19] 68 Fed. Reg. at 69925 (to be codified at 42 CFR 403.820(a)(3)(iii)).

[20] 69 Fed. Reg. at 28845 (to be codified at 42 CFR 1003.102(b)(17)).

5. The interim final regulations require that a "substantial failure" be found prior to assessing both intermediate sanctions and civil monetary penalties for a number of specific violations. Additionally, CMS has the authority to impose intermediate sanctions, which CMS defines as "[S]uspension of enrollment of Medicare beneficiaries...[s]uspension of information and outreach activities to Medicare beneficiaries."[21] or a civil monetary penalty up to $10,000 fine per violation. Please answer the following questions:

   a. How does CMS define "substantial failure"? Do you plan to issue specific guidance on what constitutes "substantial failure" or leave it up to the administrative law judges to interpret?

   b. Would a single inappropriate price change on one drug from a drug sponsor's formulary one time be considered "substantial failure"? If not, what constitutes a "substantial failure" in regards to a price change?

   c. Would CMS attempt to impose an intermediate sanction or a civil monetary penalty for a "substantial failure" for the above type violation? If CMS will impose a civil monetary penalty, how much of a penalty will it impose for the violation noted above if not the full $10,000? Does CMS plan to issue further specific guidance on the use of intermediate sanctions and civil monetary penalties or leave it up to the administrative law judges to interpret?

[21] 68 Fed. Reg. at 69925 (to be codified at 42 CFR 403.820(a)(1)).