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November 30, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Center for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

I am writing to you regarding two new Government Accountability Office reports that I am releasing today.[1] The reports analyze the Administration's implementation and oversight of the Medicare drug card program established under the Medicare Modernization Act. These reports — which reveal serious flaws in the implementation of the drug card program — have important implications for the new Medicare drug benefit.

In the first report, GAO finds widespread problems in the administration and enforcement of the Medicare drug card program. According to GAO, the information about the Medicare drug cards posted on the Medicare website was riddled with errors; the private drug card sponsors frequently overbilled Medicare; and the Department of Health and Human Services failed to conduct effective oversight, proposing only one civil penalty despite receiving over 26,000 grievances and complaints. In the second report, GAO finds that HHS failed to provide "clear, accurate, and accessible" information to seniors about the Medicare drug cards and that due to the program's "unfamiliar design," "abundance of choices," and "confusion and misperceptions," only 7% of eligible beneficiaries enrolled themselves in the program.

Although the Medicare drug card program will be replaced by the new Medicare benefit on January 1, 2006, it would be a serious mistake to dismiss the GAO findings. By design, the Medicare drug card program and the Medicare drug benefit share fundamental similarities: each requires seniors to choose a private plan from among dozens of choices; each relies on private entities to negotiate drug savings; each uses a complicated Medicare website to help seniors navigate their choices; and each includes government subsidies paid to private companies on behalf of beneficiaries. Unless they are corrected, the problems identified by GAO will undermine the new Medicare drug benefit, just as they did the Medicare drug card program.

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[1] GAO, *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program* (Nov. 2005); GAO, *Medicare: CMS's Beneficiary Education and Outreach Efforts for the Medicare Prescription Drug Discount Card and Transitional Assistance* (Nov. 2005).

A report I issued last week called into question a central tenet of the new Medicare drug benefit: the ability of decentralized private insurers to negotiate meaningful drug discounts for seniors.[2] The two GAO reports I am releasing today raise doubts about another key issue: whether the Administration is prepared to implement and enforce the vastly complicated new benefit effectively.

The Medicare Drug Card Program

The Medicare Modernization Act of 2003 created a new prescription drug benefit for Medicare beneficiaries that will go into effect on January 1, 2006. Unlike traditional Medicare, which is run by the government, the prescription drug benefit will be provided by competing insurance companies. President Bush and Republican leaders in Congress said that this complicated design would benefit seniors and protect taxpayers because private insurers could negotiate lower drug prices than the federal government.

The Act also established Medicare-approved prescription drug cards that were designed to provide drug savings to seniors in the two years between passage of the Act and the implementation of the full benefit. According to President Bush, the drug cards were intended to "serve as a transition to the reforms that are inherent in the Medicare legislation."[3] Like the drug benefit itself, the premise of the Medicare drug card program was that competition among private drug card sponsors would provide seniors with significant discounts on prescription drugs. Former Secretary of Health and Human Services Tommy Thompson promised that under the drug card program, "[s]eniors will be able to reap the benefits of competition in terms of lower prices."[4]

The Medicare drug card program commenced in June 2004 and terminates on January 1, 2006.[5] In many respects, the program served as a trial run for the new Medicare drug benefit. The structure of the Medicare drug card program closely resembles the structure of the new Medicare drug benefit, except that the drug card program avoided the added complications of providing a universal Medicare benefit. Like the Medicare drug benefit now being offered to

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[2] Minority Staff, House Committee on Government Reform, *New Medicare Drug Plans Fail to Provide Meaningful Drug Discounts* (Nov. 2005) (online at http://www.democrats.reform.house.gov/story.asp?ID=975).

[3] The White House, *President Applauds Congress for Passing Historic Medicare Bill* (Nov. 25, 2003) (online at: http://www.whitehouse.gov/news/releases/2003/11/20031125-5.html).

[4] CMS, *Medicare Drug Discount Cards Continue to Drop Prices and Offer Better Savings* (May 14, 2004).

[5] Medicare beneficiaries can continue to use existing Medicare drug discount cards until May 15, 2006, or until they join a Medicare prescription drug plan, whichever comes first. *See* CMS, *Medicare and You Handbook* (Dec. 2005) (available online at http://www.medicare.gov/publications/pubs/pdf/10050.pdf).

seniors, the Medicare drug card program offered seniors a choice among dozens of competing private drug plans; relied on the competing private drug plans to negotiate significant discounts on prescription drugs; and used a complicated website to guide seniors through their drug plan choices. In addition, like the Medicare drug benefit, the Medicare drug card program was supported by a multi-million dollar publicity campaign and offered federal subsidies to low-income seniors.[6]

Moreover, the private companies involved in the two programs are virtually identical. There are ten private insurers, pharmacy benefit managers, and other organizations that are approved by Medicare to offer nationwide prescription drug benefit plans. Nine of these entities participated in the Medicare drug card program.[7]

The Medicare drug card program did not deliver the drug discounts promised by Administration officials.[8] According to Administration officials, however, the program did provide valuable experience for the Medicare drug benefit. In fact, you testified before Congress in April about some of the ways in which the experience with drug card program would shape the drug benefit:

> [HHS] will draw on our experience in developing the price comparison tool for the Medicare-Approved Prescription Drug Card that was described by sponsors as both a necessary instrument and an important resource for Medicare beneficiaries. ... We have used our expertise and lessons learned from the Medicare-Approved Prescription Drug Card to design the simplest income and asset testing approach ever and the largest low-income outreach campaign ever.[9]

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[6] In the drug card program, federal subsidies of up to $600 were available to certain low-income beneficiaries as "transitional assistance." Under the Medicare drug benefit, many of these same seniors receive "extra help" to pay prescription drug costs. Qualified seniors will pay reduced premiums, deductibles, and copayments. *See* CMS, *Medicare and You Handbook* (Dec. 2005) (available online at http://www.medicare.gov/publications/pubs/pdf/10050.pdf).

[7] The ten national prescription drug plan organizations are Aetna Medicare, CIGNA HealthCare, Coventry AdvantraRX. First Health Premier, Medco Health Solutions, Inc., MEMBERHEALTH, PacifiCare Life and Health Insurance Company, SilverScript, Unicare, United Healthcare, and Wellcare. *See* CMS, *National Prescription Drug Organizations* (Sept. 23, 2005) (available online at http://www.cms.hhs.gov/map/charts/NationalPrescription DrugPlanOrganizations.pdf). All of these organizations except CIGNA HealthCare offered Medicare-approved prescription drug discount cards.

[8] Minority Staff, House Committee on Government Reform, *Prescription Drug Cards Still Provide Few Discounts to Seniors* (June 2004) (online at http://www.democrats.reform.house.gov/story.asp?ID=343).

[9] Senate Homeland Security and Government Affairs Committee, Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia, Testimony of CMS Administrator Dr. Mark B. McClellan, *Monitoring CMS' Vital Signs: Implementation of the Medicare Prescription Drug Benefit* (Apr. 5, 2005).

The GAO Request

On July 6, 2004, Rep. Louise Slaughter and I wrote to Secretary Thompson about what we described as "a serious flaw in the Medicare drug card program": inaccurate information about individual drug cards on the Medicare.gov website. Based on our investigation of drug cards offered in New York State and Washington, D.C., we reported widespread errors in the information about participating pharmacies listed by drug card sponsors.[10]

Secretary Thompson dismissed our concerns as "isolated instances" of errors, and he promised that HHS would "take appropriate actions to protect beneficiaries and to ensure the most accurate information is provided to them." He further stated that if "systemic problems are detected, the offending card sponsor may be subjected to a corrective action plan, sanctioned, or ultimately have its contract terminated."[11]

At my request, GAO examined whether HHS kept Secretary Thompson's commitment to enforce the requirements of the Medicare drug card program. Specifically, I asked GAO to evaluate the Medicare discount drug card program and the effectiveness of the Administration's oversight and enforcement, including whether HHS did in fact take enforcement action against drug sponsors that provided misleading or erroneous information to seniors.[12] The two reports I am releasing today present the results of GAO's investigation. Not only do they confirm the problems Rep. Slaughter and I identified, they disclose many other significant deficiencies in the implementation and enforcement of the Medicare drug card program.

GAO Findings on Implementation and Enforcement

In the first report, GAO examined the implementation and oversight of the Medicare discount drug card program by the Centers for Medicare and Medicaid Services (CMS), the agency within HHS charged with administering Medicare. GAO found "limitations with respect to the timeliness of oversight activities and the guidance provided to sponsors."[13] The multiple problems identified by GAO included:

- Widespread errors in the information posted on the Medicare website;
- Widespread errors in the information sent by drug card sponsors to seniors;
- Overbillings by drug card sponsors;

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[10] Letter from Rep. Henry A. Waxman and Rep. Louise M. Slaughter to HHS Secretary Tommy Thompson (July 6, 2005).

[11] Letter from HHS Secretary Tommy Thompson to Rep Henry A. Waxman (July 21, 2004).

[12] Letter from Rep. Henry A. Waxman to the Honorable David M. Walker (Jan. 10, 2005).

[13] GAO, *Medicare: CMS's Efforts for the Medicare Prescription Drug Discount Card*, *supra* note 1 at 5.

- Virtually nonexistent enforcement by HHS;
- Failure to substantiate drug discounts.

Erroneous Website Information. As in the case of the Medicare drug benefit, the primary vehicle for informing seniors about the Medicare drug card program was the Medicare website (www.Medicare.gov). Seniors could use this website to find detailed information about specific Medicare drug cards, including drug prices and participating pharmacies. GAO found, however, that the website was rife with errors.

According to GAO, one in five pharmacy listings on the Medicare drug card website was inaccurate. And in three states — North Dakota, Iowa, and Missouri — GAO found that two-thirds or more of the pharmacy listings were inaccurate. GAO also found that the prices listed on the Medicare website contained numerous errors, particularly in the early stages of the drug card program.[14]

Erroneous Information from Drug Card Sponsors. Another systematic problem uncovered by GAO was incomplete and inaccurate information provided to seniors by drug card sponsors, many of whom are now offering Medicare drug benefits. A review of enrollment materials provided to beneficiaries by drug card sponsors found that every single mailing examined was "non-compliant with program requirements."[15] GAO also identified problems with the call centers maintained by drug card sponsors, including call centers that provided inappropriate responses to beneficiary complaints, "confusion about enrollment fees" among customer service representatives, and the unavailability of representatives for non-English speakers and the deaf.[16] Although HHS learned of these problems in 2004, GAO found that CMS did not begin follow-up with sponsors on these issues until summer 2005, six months before the program was slated to end.[17]

Overbillings. Under the Medicare drug card program, plan sponsors were required to exclude nine classes of drugs, including barbiturates and benzodiazines, from their drug cards. According to GAO, however, "$1.3 million in [Medicare] funds were inappropriately used by drug card sponsors to pay for excluded drugs" for low-income beneficiaries.[18] In fact, GAO reported that every drug card sponsor audited by the federal government had submitted claims and received payment for improper claims.[19]

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[14] *Id.* at 5.

[15] *Id.* at 6.

[16] *Id.* at 6.

[17] *Id.* at 6-7.

[18] *Id.* at 7.

[19] *Id.* at 50.

GAO also found that "several sponsors had allowed beneficiaries to receive subsidies that exceeded the [maximum] subsidy of up to $600 per year."[20]

Inadequate Oversight and Enforcement. GAO reported that seniors and other beneficiaries filed 26,000 grievances and complaints with the Medicare program and drug card sponsors. These complaints and grievances addressed issues such as problems with enrollment and disenrollment and delays in receiving drug cards.[21]

Yet GAO found that the federal response to these grievances and complaints — as well as to additional problems identified by agency officials — was anemic: HHS took only 23 enforcement actions against drug card sponsors in the first 15 months of the drug card program, proposed only one civil monetary penalty against a drug card sponsor, and did not terminate a single contract.[22]

Failure to Substantiate Drug Discounts. The principal rationale for the Medicare drug card program was that the drug card sponsors would be able to negotiate low drug prices for seniors. But GAO found that the Administration could not substantiate drug discounts. According to GAO, poor data collection efforts prevented HHS from determining the size of discounts obtained by drug card sponsors and the extent to which they were passed on to consumers. GAO concluded that the "overall quality of that data remained questionable."[23]

GAO Findings on the Drug Card Publicity Campaign

In the second report, GAO examined the effectiveness of the Administration's efforts to educate seniors and other Medicare beneficiaries about the drug card program. The total federal spending on the national Medicare publicity campaign was extraordinarily high. In FY 2004 alone, the government spent approximately $65 million.[24] But GAO found that despite the large expenditures, the Administration's education materials did not provide "clear, accurate, and accessible" information to Medicare beneficiaries.[25] GAO reported that the materials that were distributed "collectively fell short of conveying program features."[26] According to GAO, "CMS was effective in raising awareness of the drug card program, but was less effective in its efforts to inform and assist beneficiaries."[27]

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[20] *Id.* at 7.

[21] *Id.* at 52-53.

[22] *Id.* at 54.

[23] *Id.* at 5.

[24] GAO, *Medicare: CMS's Efforts for the Medicare Prescription Drug Discount Card*, *supra* note 1 at 6.

[25] *Id.* at 2.

[26] *Id.* at 2.

[27] *Id.* at 2.

GAO further reported that these problems discouraged seniors from participating in the Medicare drug card program. GAO found that only about 7% of eligible Medicare beneficiaries enrolled themselves in the discount drug card program.[28] According to GAO, the low enrollment was due in part to the program's "unfamiliar design," "abundance of choices," and "confusion and misperceptions about the drug cards."[29]

Conclusion

Last week, I released a report that called into question the complicated design of the Medicare drug benefit. During the congressional debate two years ago, Republican leaders in Congress and Bush Administration officials rejected Democratic proposals to allow Medicare to negotiate directly with drug manufacturers for discounted prices for seniors. The Republican argument was that private insurers could obtain lower drug prices than federal negotiators, benefiting seniors and saving the taxpayers money. In fact, the reverse now appears to be true. According to the report I released last week, the drug prices being offered by the new Medicare drug plans are over 80% higher than federally negotiated prices.[30]

The GAO reports I am releasing this week address a different, but equally important, issue: whether the Administration will be able to implement and enforce the new Medicare drug benefit effectively. The outlook does not appear promising. The Medicare drug card program was in effect a trial run for the new drug benefit. Yet GAO found serious and widespread deficiencies in the Administration's implementation and enforcement of the drug card program. Crucial mistakes were made in virtually every aspect of the program, including in the public education campaign, the accuracy of the information posted on the website and distributed by drug card sponsors, payments to drug sponsors, and oversight and enforcement.

As the enrollment process for the new drug benefit continues, the Administration needs to demonstrate that it will take a fundamentally different approach in administering the Medicare drug benefit than it took in administering the Medicare drug cards. A laissez faire philosophy and continued lax oversight and enforcement will serve neither seniors nor the taxpayers. Denying the existence of serious problems — as the Administration did when it described

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[28] GAO found that 2.3 million people self-enrolled for a drug card. Another four million beneficiaries were automatically enrolled through their Medicare Advantage program, Medicare Savings program, or through a state pharmacy assistance program. *See Id.* at 13. The total eligible Medicare beneficiary population — all Medicare beneficiaries except those who have drug coverage through Medicaid — is approximately 35 million. *See* Kaiser Family Foundation, *The Medicare ChartBook* (Summer 2005)(online at http://www.kff.org/medicare/7284.cfm).

[29] GAO, *Medicare: CMS's Efforts for the Medicare Prescription Drug Discount Card, supra* note 1 at 3.

[30] Minority Staff, House Committee on Government Reform, *New Medicare Drug Plans Fail to Provide Meaningful Drug Discounts* (Nov. 2005) (online at http://www.democrats.reform.house.gov/story.asp?ID=975).

inaccuracies on the Medicare.gov website as "isolated incidents" — will further erode credibility.

I am enclosing copies of the new GAO reports for your review. I request a detailed explanation of the reforms your agency will take to address these issues and to administer and enforce the new Medicare drug benefit effectively.

Sincerely,

Henry A. Waxman
Ranking Minority Member

Enclosure