Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ASSESSMENT OF SPONSORS' MATERIALS UNDER THE TEMPORARY MEDICAREAPPROVED DRUG DISCOUNT CARD PROGRAM



Daniel R. Levinson Inspector General

October 2005 OEI-05-04-00190

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts management and program evaluations (called inspections) that focus on issues of concern to HHS, Congress, and the public. The findings and recommendations contained in the inspections generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs. OEI also oversees State Medicaid Fraud Control Units which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.



Part D of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 added outpatient prescription drug benefits to the Medicare program beginning in 2006. In the interim, the MMA also created the Medicare-Approved Drug Discount Card program (drug card program). The Centers for Medicare & Medicaid Services (CMS) administers the drug card program through private companies (sponsors) it has approved to offer the drug cards. CMS requires these sponsors to develop pre-enrollment packets, which must contain the information beneficiaries need to make informed choices. Sponsors may use pre-enrollment packets in their active outreach and/or may develop advertising materials to attract beneficiaries to their cards. CMS reviews and approves sponsors' materials. Although we assessed sponsors' materials under the drug card program, this report is intended to provide information to assist CMS in preparing for the Part D drug benefit.

There are three sections to this report. First, we provide background information on the drug card program and the Part D drug benefit, as well as a brief description of our methodology. Second, we provide the results of our assessment of sponsors' materials under the drug card program: the materials sponsors used in their outreach to potential enrollees, the compliance of selected sponsors' materials with CMS's requirements, and beneficiary understanding of key aspects of the drug card program based on reading sponsors' materials. Finally, based on our assessment of the drug card program, we offer implications for CMS to consider for the new Part D drug benefit. In return, CMS provided extensive comments demonstrating how its ongoing and planned efforts related to the oversight of sponsors' marketing materials for the drug benefit have incorporated our suggestions.

TABLE OF CONTENTS

S Y N O P S I S
INTRODUCTION 1
DRUG CARD MATERIALS 9 Materials used in outreach 10 Compliance of materials 13 Beneficiary understanding of materials 20
IMPLICATIONS: NEW DRUG BENEFIT
AGENCY COMMENTS
OFFICE OF INSPECTOR GENERAL RESPONSE
ENDNOTES
APPENDIXES
A: Detailed Methodology
B: Noncompliance for All Requirements Assessed and Sources of Error
C: Beneficiary Understanding
D: Agency Comments
A C K N O W L E D G M E N T S



OBJECTIVE

To assess drug card sponsors' materials under the Medicare-Approved Drug Discount Card Program in an effort to assist CMS in preparing for the new Medicare drug benefit under Part D. In particular, to assess whether sponsors' materials promote informed choice for beneficiaries and to review CMS oversight of sponsors' materials.

BACKGROUND

Medicare Coverage of Prescription Drugs

In 2004, Medicare provided health insurance for approximately 41.8 million Americans; this includes more than 35 million seniors and 6.5 million nonelderly people with disabilities. Medicare Part B covers a limited range of drugs, primarily those administered in a physician's office. In 2003, Medicare spent approximately \$4 billion on prescription drugs covered under Part B.²

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108-173, added an outpatient prescription drug benefits to Medicare under Part D. Effective January 2006, all Medicare beneficiaries will be able to enroll in private plans, which will cover a percentage of their drug costs. Assistance with premiums and cost sharing will also be provided to an estimated 11 million low-income beneficiaries.³ Estimates of the Part D drug benefit cost range from \$47 billion to \$58.9 billion for FY 2006.⁴

Medicare-Approved Drug Discount Card Program

While the full Medicare prescription drug benefit will not be implemented until January 2006, the MMA also created the Medicare-Approved Drug Discount Card program (drug card program) to provide immediate access to discounted prescription drugs. All Medicare beneficiaries who are enrolled in Medicare Part A and/or Part B and do not have outpatient prescription drug coverage under Medicaid are eligible. Beneficiaries can enroll in the drug card program at any time from May 3, 2004, through December 31, 2005. Discounts became available in June 2004 and end in January 2006 with the advent of the full prescription drug benefit. The Centers for Medicare & Medicaid Services (CMS) reported in December 2004 that 5.8 million beneficiaries had enrolled in the drug card program.⁵

In early 2004, CMS approved private companies (sponsors), including manufacturers, health insurance companies, drug store groups, and

managed care firms, to provide a total of 73 Medicare-approved drug discount cards. Sponsors offer 40 national drug cards and 33 regional drug cards.⁶ Throughout this report, we use the term "drug card sponsor" when referring to the entity contracted to offer an individual drug card. In some cases, one company actually has several contracts and offers multiple drug cards.

Medicare beneficiaries are allowed to enroll in only one drug card per year. Once beneficiaries are enrolled, they are not allowed to switch to a different drug card until the next open enrollment period. Beneficiaries are expected to consider several program features when deciding which drug card is best for them. Discounts vary between cards and may vary within each card by drug, by pharmacy, and by geographic location; and the discounts may also change over time. Drug card sponsors can offer discounts on all drugs allowed by CMS or may cover only a select list of drugs, and the particular drugs covered by a card may vary throughout the life of the drug card program. Discounts are available only at network pharmacies that have agreed to accept the card. Network pharmacies also vary by drug card. Drug card sponsors may charge an annual enrollment fee of up to \$30 or may offer a card without an enrollment fee.

In addition to the discounts available through the drug cards, the Medicare-Approved Drug Discount Card program provides \$600 in Transitional Assistance credit for beneficiaries with incomes at or below 135 percent of the Federal poverty level and without other drug coverage. Eligible beneficiaries may use the annual \$600 credit toward prescription drug purchases in both 2004 and 2005. Medicare also will pay any drug card enrollment fees for these beneficiaries. According to CMS, 1.5 million drug card enrollees had begun receiving the \$600 Transitional Assistance credit by December 2004. 10

Sponsors and CMS Must Promote Informed Choice

The MMA directs CMS and sponsors to make certain information available to eligible beneficiaries for the purpose of promoting informed choice among drug cards. ¹¹ CMS has conducted an outreach and education campaign and offers beneficiaries several other informational resources. CMS offers a toll-free hotline (1-800-MEDICARE) to help beneficiaries assess their eligibility, find out which drug cards are available in their area, and compare features of available drug cards including discounts on the drugs they take. CMS also offers this

information on its Web site (www.medicare.gov), along with a price comparison feature.

The MMA requires that each sponsor "shall make available to discount card eligible individuals . . . information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs ... "12 CMS has delineated this information in its Information and Outreach Materials Guidelines for sponsors' materials. CMS's regulations incorporate these Information and Outreach Materials Guidelines by reference. 13 Examples of required information include how to become enrolled in a drug card, eligibility qualifications for the \$600 credit, toll-free telephone numbers, enrollment fees, types of contracted pharmacies, types of prescription drugs offered for a negotiated price, how enrollees can obtain more complete information regarding drugs discounted and the pharmacy network, and a notice that drugs and prices may change. Drug card sponsors' materials must explain enrollment rules, some of which imply that multiple drug cards are available (for example, materials must state that enrollees cannot enroll in a new drug card until January 1, 2005). However, materials are not required to explicitly state that beneficiaries have a choice of drug cards.14

Sponsors' Materials: Pre-Enrollment Packets and Advertising Materials CMS classifies sponsors' drug card materials as either explanatory materials or advertising materials.

<u>Pre-Enrollment Packets and Other Explanatory Materials</u>. Explanatory materials include information required by CMS to inform beneficiaries about the program. CMS requires sponsors to make explanatory materials available to beneficiaries upon request prior to enrollment (through pre-enrollment packets), at enrollment (e.g., notification of enrollment status), and after enrollment (e.g., member handbooks, membership cards).¹⁵

Sponsors' pre-enrollment packets must include information CMS has deemed necessary for promoting informed choice prior to enrolling in a sponsors' drug card. These packets contain a cover letter, a program description (called a Summary of Program Features), enrollment instructions, and enrollment forms. According to CMS regulations, sponsors are required to provide pre-enrollment, explanatory information "through the Internet and some other tangible medium (such as a mailing)" to explain the sponsors' drug card to eligible beneficiaries. 16

Advertising Materials. Advertising materials provide general information about a drug card and are intended to generate interest and encourage beneficiaries to get the additional information they need to enroll. Although advertisements are not necessarily intended to provide indepth information about sponsors' drug cards, these materials may affect beneficiary choice by including some key information about program features. Advertising materials are required to include certain disclaimers when topics such as discounts and enrollment fees arise.

Advertising materials cannot include enrollment forms and are not meant to be used to enroll. However, beneficiaries who see sponsors' advertisements may enroll over the phone (through a sponsor's call-in center) and may not have the benefit of reviewing a pre-enrollment packet prior to enrolling.

CMS Oversight of Sponsors' Materials

The MMA requires the Secretary to provide "appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section." CMS uses several mechanisms to ensure that sponsors' materials are in compliance.

In January 2004, CMS issued specific requirements and guidance for sponsors' explanatory and advertising materials in its Information and Outreach Materials Guidelines. These requirements outline the key program information that materials must include, as well as specific disclaimers, specific terminology, and requirements for presenting information clearly such as font size specifications. These guidelines were revised and updated in August 2004. CMS has also provided sponsors with a list of suggested terminology and model materials for member handbooks, enrollment instructions, and enrollment forms that sponsors can choose to adopt.¹⁸

To ensure that materials promote informed choice, drug card sponsors must obtain CMS's approval of all materials before distributing them to beneficiaries. ¹⁹ CMS has hired a contractor (hereinafter referred to as CMS's contractor) to review and approve sponsors' materials. Materials are reviewed within 30 days and approved, disapproved, or approved with stipulations. In the last category, sponsors are expected to make small changes to their materials before distributing them and to submit a copy of the final material to CMS's contractor. CMS's contractor conducts a retrospective review of a portion of these materials to determine whether the stipulated changes are made. Materials that follow CMS models receive a streamlined 10-day review.

Finally, CMS may opt to randomly retrieve and review sponsor materials from the marketplace to ensure that sponsors have not modified these materials without CMS's approval.

Implications for the Full Medicare Prescription Drug Benefit Under Part D

Our assessment of sponsors' materials and CMS oversight under the drug card program has particular relevance for CMS's implementation of the Part D drug benefit. While the drug card program will end with the start of the Part D drug benefit in 2006, prescription drug plan sponsors' materials will play a similar role in informing beneficiaries' choice under the Part D program. Specifically, beneficiaries will rely on information from CMS and prescription drug plan sponsors when enrolling in the Part D program. Prescription drug plan sponsors will be required to produce materials similar to those under the drug card program and submit their materials to a similar review process under Part D. In some cases, drug card sponsors are likely to apply to become prescription drug plan sponsors.

CMS and prescription drug plan sponsors' outreach to beneficiaries needs to be sufficiently thorough and clear to allow beneficiaries to make an informed decision about enrollment. Beneficiaries' understanding of the Part D drug benefit will be even more crucial than their understanding of the drug card program because the choices about enrolling in the Part D drug benefit will be considerably more complex. For example, Part D benefits will vary with beneficiary drug expenditures and with beneficiary income. Further, beneficiaries with private prescription drug coverage will need to compare that coverage to the prescription drug plans available under Part D to determine which program best meets their needs. And, though Part D is voluntary, beneficiaries who delay enrollment will face financial consequences, including increased premiums.

Concurrent OIG Inspections

OIG has conducted two additional studies related to the drug card program. One, Medicare-Approved Drug Discount Card: Beneficiaries' Awareness and Use of Information Resources (OEI-05-04-00200), assesses the extent of beneficiaries' awareness and use of information resources to decide whether to enroll in the drug card program and navigate the enrollment process. The second study, Analysis of Drug Card Sponsors' Drug Prices (OEI-05-05-00020), monitors the prescription drug prices posted by sponsors on the Medicare Web site and determines the extent to which sponsors are changing these prices.

METHODOLOGY

This inspection focuses on sponsors' materials that are likely to inform beneficiary decisions about enrolling in the drug card program: pre-enrollment packets and advertising materials. To assess the extent to which sponsors' materials promote informed choice, we reviewed a selection of materials and conducted interviews with sponsors that administer 62 drug cards. Although there are 73 cards in the program, we excluded 11 drug cards from our study. Some of these 11 drug cards were not available to beneficiaries at the time of our interviews or served only long-term care beneficiaries. See Appendix A for additional information about our methodology.

Assessing Whether Sponsors' Materials Promote Informed Choice

To assess the extent to which pre-enrollment packets and advertising materials promote informed choice, we assessed selected sponsors' materials in two ways: we conducted a structured review of sponsors' materials and conducted cognitive interviews with beneficiaries who read selected materials and answered questions based on their reading.

<u>Selected sponsors' materials</u>. We selected 62 pre-enrollment packets and 20 advertising materials for our review. We selected 1 pre-enrollment packet for each of the 62 drug cards included in our study. Based on our interviews with sponsors, we determined that the 62 drug card sponsors used a total of 80 pre-enrollment packets. We found that 45 sponsors use only 1 pre-enrollment packet. For the 17 sponsors that use 2 or 3 pre-enrollment packets, we selected the packet that sponsors indicated was used to target the most beneficiaries.

For our review, we selected one tangible advertising material from each of 20 drug card sponsors that use tangible advertising materials. Tangible advertising materials include such things as direct mail, print ads, and flyers; they do not include radio or TV ads, posters, presentations, etc. For sponsors that sent tangible advertising materials via direct mail, we selected the direct mail material that targeted the most beneficiaries. Similarly, for sponsors that did not use direct mail to send advertising materials, we selected the tangible advertisement that targeted the most beneficiaries.

<u>Structured review of sponsors' materials.</u> We conducted a structured review of selected sponsors' materials to identify whether CMS-approved materials include required information. We discussed the noncompliance we found in our structured review with CMS and CMS's contractor. Our report includes the results of these discussions.

We selected 25 requirements applicable to pre-enrollment packets and 7 requirements applicable to advertisements.²⁰ Because some requirements are only applicable to certain drug cards or materials, between 20 and 24 requirements are applicable to each selected pre-enrollment packet and 2 to 7 requirements are applicable to each selected advertisement. All selected materials were approved between March and July 2004. Although CMS revised its requirements for sponsors' materials in August 2004, we assessed materials' compliance with requirements applicable at the time the material was approved. As a result, some portion of materials that met all the requirements we assessed may not meet all current CMS requirements.²¹ See Appendix B for a complete list of the requirements we selected for our review.

<u>Cognitive interviews with beneficiaries</u>. To assess whether sponsors' materials are clear and understandable to Medicare beneficiaries, we interviewed 151 Medicare beneficiaries in 5 cities: Chicago, IL, Tucson, AZ, Seattle, WA, Providence, RI, and Jackson, MS. We selected these cities because they vary by population size and geographical region, because more than 10 percent of each city's population is over age 65, and because beneficiaries in these cities' State Pharmacy Assistance Programs were not automatically enrolled in the drug card program.²² We excluded cities that CMS visited to conduct similar beneficiary interviews to test Medicare outreach materials. We conducted interviews at four or five community-based senior centers in each city.

Prior to the interviews, we screened respondents to ensure that they were eligible for the drug card program and that they made their own health care decisions. Further, we only included beneficiaries who reported that they were comfortable reading and discussing materials.

Each respondent was assigned a short 5- to 15-minute reading selection consisting of either an advertising material or a selection from a pre-enrollment packet. Thirty-eight respondents read an advertisement and 113 respondents read a selection from a pre-enrollment packet. Respondents then answered questions about the drug card program based on the material. Although we allowed respondents to take their time and refer back to materials throughout the interview, beneficiaries in a real-world setting may have assistance from others in understanding sponsors' materials, which our respondents did not have during our interview. Overall, individual interviews lasted approximately 20 to 30 minutes. (As previously mentioned, OIG is assessing how beneficiaries made enrollment decisions in real-world

settings in our concurrent inspection on beneficiary use of information resources.)

In cases in which multiple drug card sponsors used the same pre-enrollment packet or advertisement, we included only one copy of the material for beneficiary interviews. Because several sponsors developed identical or "template" materials that were used for multiple drug cards, our original selection of 62 pre-enrollment packets and 20 advertisements was reduced to 35 unique pre-enrollment packets and 12 unique advertisements as reviewed by beneficiaries. Since each beneficiary read 1 material and there were 47 selected materials (35 unique pre-enrollment packets and 12 unique advertisements), each material was read by 3 or 4 beneficiaries, for a total of 151 interviews.

Interviews With Sponsors

We conducted structured telephone interviews with 33 sponsor companies that offer a total of 62 general drug cards. We used these interviews to identify sponsors' materials for our review and to determine how sponsors use pre-enrollment packets and advertising materials in their outreach to beneficiaries. (As indicated previously, we use the term "drug card sponsor" when referring to the entity contracted to offer an individual drug card; thus, there are 62 drug card sponsors included in this study. In some cases, one company actually has several contracts and offers multiple drug cards. Because of this, we use the term "sponsor companies" when referring to the 33 parent companies that administer the 62 drug cards included in this study.)

Limitations

The data in this report are restricted to the 62 pre-enrollment packets and 20 advertisements we assessed and to the sponsors and beneficiaries we interviewed. Although we do not project our results to all sponsors' materials, our data represent the primary outreach materials used to target the largest number of beneficiaries for the vast majority of drug card sponsors.

Standards

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

As mentioned previously, CMS requires sponsors' materials to provide information deemed necessary to promoting beneficiaries' informed choice. When considering the information needed to inform beneficiaries' choice, it is helpful to use the following framework. To make an informed decision about enrolling in the Medicare-Approved Drug Discount Card program (as opposed to other drug coverage options), beneficiaries need to understand:

- Whether the drug card program itself applies to them (their eligibility), and
- The benefits and limitations of the drug card program.

To make an informed decision about enrolling in a <u>particular</u> drug card, beneficiaries need to understand:

- o That there are multiple drug cards to choose from, and
- How drug cards can vary, so they can compare cards and decide which card is best for them.

CMS requires that sponsors' pre-enrollment packets include information relevant to this decision framework, including eligibility requirements; disclaimers on key aspects of program benefits; and information about features that vary among drug cards, such as enrollment fees, drug prices, and pharmacy networks.

Our assessment of whether sponsors' materials promote informed choice for beneficiaries follows in three parts. First, to convey this required information, drug card sponsors distribute information to potential enrollees. Thus we first assessed materials used in outreach, including which materials are used, how they are distributed, how many beneficiaries potentially received them, and barriers to distributing materials through outreach. Second, sponsors' materials must supply potential enrollees with required information. We assessed this by looking at compliance of materials. Third, sponsors' materials must be clear and understandable to potential enrollees who will use the information in making decisions about enrollment. We addressed this topic by assessing whether beneficiaries understand key aspects of the drug card program, as it would apply to them, after reading sponsors' materials.

Materials used in outreach

By the end of July 2004, 47 of the 62 drug card sponsors we

interviewed had engaged in outreach to inform beneficiaries about their drug cards. These efforts were designed to reach out to beneficiaries rather than rely on them to seek out information on sponsors' drug cards. The remaining drug card sponsors made information available to beneficiaries in more passive ways, such as through Web sites or call-in centers. Of the 15 sponsors not conducting outreach activities at the time of our interviews, 9 indicated that they had plans to begin doing so by September 2004.

Nearly all drug card sponsors that engaged in outreach distributed pre-enrollment packets to beneficiaries, rather than relying solely on promotional advertising

Of the 47 drug card sponsors that conducted outreach, 46 used pre-enrollment packets in these efforts. Pre-enrollment packets are required to contain information needed to promote beneficiaries' ability to make informed decisions regarding enrolling in the program and selecting the appropriate drug card. In addition to distributing pre-enrollment packets, many sponsors also engaged in advertising campaigns to encourage beneficiaries to inquire about their drug cards.

Drug card sponsors most commonly distributed pre-enrollment packets through the mail, but many also provided them to beneficiaries in person The majority of drug card sponsors distributed pre-enrollment packets via traditional direct mail campaigns, as noted in Table 1 below.

TABLE 1: Number of Drug Card Sponsors That Distributed Pre Enrollment Packets to Beneficiaries, by Outreach Method			
Sponsors' Outreach Method	Number of Drug Card Sponsors That Used Method to Distribute Pre-Enrollment Packets		
Direct Mail/E-mail	32		
In-Person Outreach to Beneficiaries	21		
Providing Written Material for Distribution	14		
Other	4		
Total (Unduplicated) Drug Card Sponsors That Used Pre- Enrollment Packets in at Least One Outreach Method	46		

Source: Office of Inspector General analysis of drug card sponsor interviews, 2004.

Sponsors used direct mail to deliver their pre-enrollment packets to as few as 2,250 beneficiaries and as many as 4 million beneficiaries. The median number of beneficiaries targeted by a sponsor's direct mail campaign was $270,000.^{23}$

However, the pre-enrollment packet material alone may not be sufficient to explain the program or promote informed choice. Some drug card sponsors noted the difficulty of explaining the program in a written format. One sponsor noted that the complexity of the program was difficult to capture in a "small brochure" and "necessitates face-to-face contact where you can walk the beneficiary through the program."

In fact, many drug card sponsors did engage in in-person outreach to market their drug cards. Some drug card sponsors provided information to beneficiaries at town hall meetings and health fairs. Others made presentations about their drug cards at senior centers, pharmacies, and various other venues. In these settings, drug card sponsors not only distributed pre-enrollment packets, but also provided in-person education about their cards and were available to answer beneficiaries' questions and resolve confusion that may be hindering beneficiaries' decisions about enrolling. However, due to the time-consuming and labor-intensive nature of this approach, fewer beneficiaries received their pre-enrollment packets in this manner than by mail. The number of beneficiaries at these events ranged from a few to 500, with a median of 33 beneficiaries. The median number of events attended or held by a drug card sponsor was 15.

Another method drug card sponsors employed was providing third-party entities with pre-enrollment packets to distribute to beneficiaries on behalf of the sponsor. Typically these third-party entities were participating pharmacies, but they also included physicians' offices, senior centers, and several other health care and government entities. This approach allows beneficiaries to receive information and ask questions about the drug cards from a trusted health-care professional. It also has the potential to reach a broader array of beneficiaries than the face-to-face presentations. The median number of beneficiaries targeted with this approach was 33,750.

While beneficiaries are more likely to have confidence in information received from a trusted health care professional, there is the potential that some may enroll in the drug card offered by the trusted third-party and not receive the benefit of comparison shopping. As one sponsor indicated, "People are pretty tied to their pharmacist and will listen to

their advice." Another sponsor indicated concern about the consequences of pharmacists' promoting their card. They asked, if a pharmacy was promoting one card, "would the beneficiary get information from the pharmacist about what is the best card [for the beneficiary]?"

Finally, four drug card sponsors sought to educate people who would be in a position to educate beneficiaries. This included conducting seminars with local businesses and sending pre-enrollment packets to church leaders and State staff.

Thirty-five of the 47 drug card sponsors that conducted outreach used advertising materials

Although most sponsors indicated that they relied on pre-enrollment packets as their main form of outreach, 35 of the 47 sponsors conducting outreach also used advertising materials. In these cases, an advertisement may be the only outreach material seen by beneficiaries who use the advertisement to decide whether to contact the sponsor or CMS for more information.

As with pre-enrollment packets, drug card sponsors reported that they primarily distributed advertising materials via direct mail campaigns. They also relied on mass media, primarily using print advertisements. Substantially fewer sponsors advertised on radio or television, despite the fact that these offer the potential to reach far broader audiences.

Drug card sponsors also used other, less conventional means to advertise their drug cards. Sixteen drug card sponsors distributed advertisements as part of their in-person outreach and 10 engaged third parties to display or distribute their advertisements.

Sponsors cited a variety of obstacles to informing beneficiaries about their drug cards

According to 29 of the 33 sponsor companies we interviewed, some CMS requirements or processes present barriers to outreach. We did not independently validate sponsor companies' concerns but offer their feedback as we received it, as it provides an important perspective on the topic of promoting informed choice. Twenty-six of these sponsor companies indicated problems with the CMS Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines. Their primary frustration was that the guidelines were constantly changing, often leading to multiple iterations through the approval process. Twenty-two of the 29 sponsor companies also felt that the process for reviewing and approving the

materials presented problems. Twelve of these provided general comments about the process, describing it as "cumbersome," "tedious," and the "most frustrating challenge." Twenty-one of the 22 sponsor companies provided specific issues of concern, including inconsistent review; length of the review process; unresponsiveness of CMS's contractor; and communication between CMS and its contractor, resulting in confusion and inconsistent decisionmaking.

These issues have the potential to negatively affect the information that beneficiaries receive about the program. Some impacts that sponsor companies mentioned included their ability to get information into the market in a timely way, their ability to alter their strategy in response to changes in the market, and their creativity in testing new ideas or options. One sponsor company found the review process so slow that the sponsor was deterred from developing new materials. Another refrained from correcting errors and improving a document because it "didn't have time to wait on the review process."

On the other hand, the concerns mentioned by sponsor companies may be related to the challenges of implementing a new program in a very short timeframe. For example, as time went on, some sponsor companies saw improvements in the review process. One summed up this view, stating, ". . . the review/approval process was pretty rough at the beginning . . . it was a learning stage. It has improved now." In addition, 13 sponsor companies, at the time of our interviews, indicated that they had no problems with CMS's contractor or had positive comments about the process.

Compliance of materials

CMS requires sponsors to include information necessary for

promoting beneficiaries' informed choice in their pre-enrollment packets. These requirements include information that beneficiaries can use to assess whether the program applies to them, whether the program will benefit them, and information for choosing among drug cards.

Of the 62 pre-enrollment packets we reviewed, we found 39 that were missing some information required by CMS

These 39 noncompliant pre-enrollment packets were used in sponsors' outreach to target approximately 8.6 million beneficiaries, primarily through direct mail. These 39 packets represent 20 unique pre-enrollment packets because some sponsor companies developed

identical or "template" pre-enrollment packets that were used by multiple drug cards.²⁴

Of the 39 noncompliant pre-enrollment packets, 32 did not meet 1 or 2 requirements. The remaining 7 did not meet 3 or more requirements; 2 of these pre-enrollment packets did not meet 14 requirements.

The seven most commonly missed requirements relate to eligibility, program disclaimers, choice of cards, and comparative drug card information

Of the 25 requirements we assessed, 7 requirements were missed most often by pre-enrollment packets. Each of these 7 requirements was missed by between 5 and 20 pre-enrollment packets. All other requirements were missed by zero to two pre-enrollment packets. See Appendix B for results for all requirements we assessed.

The seven most commonly missed requirements relate to four categories: eligibility, program disclaimers, required information indicating that beneficiaries have a choice of cards, and information needed to compare the prices/discounts offered by drug cards. (See Table 2.)

TABLE 2: Requirements Missed Most Often in Pre-Enrollment Packets			
Key Program Feature	Requirements	Pre-Enrollment Packets Not in Compliance (of 62)	
Eligibility	Income definition for determining eligibility for Transitional Assistance	7	
	Program description disclaimer: Not intended to replace other drug benefits	18	
Program	Program description disclaimer: Not a Medicare benefit	17	
Disclaimers	Drug prices/discounts disclaimer: Discounts subject to change [over time]	17	
	Pharmacy network disclaimer: Beneficiaries must use network pharmacies for discount and \$600 credit	9	
Choice of Cards	Disclaimer: Beneficiaries may only be enrolled in one card at a time	20	
Comparative Program Information	How to find information on drug prices/discounts, including Medicare price compare Web site	5	
Total (Unduplicated Least One of the Se) Pre-Enrollment Packets Not in Compliance With at even Requirements	39	

Source: Office of Inspector General analysis of selected sponsor materials, 2004.

<u>Eligibility.</u> CMS requires that pre-enrollment packets include eligibility criteria that beneficiaries can use to determine whether they are eligible

for the drug card program and for the Transitional Assistance credit. We found that nearly all pre-enrollment packets included required eligibility criteria for both the drug card program and the credit. For example, all but two pre-enrollment packets stated that beneficiaries may be eligible for the \$600 Transitional Assistance credit if "your income, plus your spouse's income (if married) is no more than . . . Single: \$12,569 or less, Married: \$16,862 or less."²⁵

However, we found that seven pre-enrollment packets did not include the following required definition of what counts as income:

Income includes money that you receive through retirement benefits from Social Security, Railroad, the Federal or State governments, or other sources, and benefits you receive for a disability or as a Veteran, plus any other sources of the type that you would report for tax purposes.²⁶

CMS requires that sponsors' enrollment instructions include a definition of income. In some cases, CMS contractor's reviewers may have assumed that these sponsors included enrollment instructions in their pre-enrollment packets. However, four of the seven noncompliant pre-enrollment packets did not include a separate enrollment instructions document in their pre-enrollment packet.

<u>Program disclaimers</u>. We found four disclaimers that were frequently not included in pre-enrollment packets. These include two disclaimers related to describing the program, one related to discounts, and one related to pharmacy networks. These disclaimers provide important information about the limitations of the program which may help beneficiaries compare this program to other drug coverage options.

The following two disclaimers relate to describing the program:

- [Program name] is not intended to replace prescription drug benefits obtained through participation in insurance plans including a Medicare Advantage plan, a Medigap policy, Medicaid, or an employer or retiree plan.
- [Program name] is a prescription drug discount card program that is approved by Medicare but it is not a Medicare benefit.²⁷

We found that 18 pre-enrollment packets were missing the first disclaimer, and all but 1 of these were also missing the second disclaimer.

The third frequently missed disclaimer is required for materials that include "any discussion of discounts." These materials must include a disclaimer that discounts can change (i.e., over time). We found that 17 pre-enrollment packets did not meet this requirement. This noncompliance is explained by a miscommunication about CMS policy changes. CMS's contractor interpreted a new discount disclaimer to supersede this original disclaimer, although this interpretation was not intended by CMS.²⁸

The fourth frequently missed disclaimer relates to descriptions of pharmacy networks. CMS requires pre-enrollment packets to include the following disclaimer about pharmacy networks:

Enrollees must use [Approved Card Program]'s network pharmacies in [service area] to obtain the prescription discount we offer and to apply Transitional Assistance to the prices of your drug. A network pharmacy is a pharmacy where our discounted drugs can be purchased and Transitional Assistance can be used.²⁹

Although all but one pre-enrollment packet we reviewed indicated that enrollees must use network pharmacies, we found that nine pre-enrollment packets did not include the full information required in the disclaimer—namely, that network pharmacies are also places that Transitional Assistance can be used. This noncompliance is also explained by a miscommunication of CMS policy changes. CMS's contractor interpreted a CMS policy clarification related to describing pharmacy networks to supersede this original disclaimer, although this interpretation was not intended by CMS.³⁰

Choice of cards. The topic of choice of cards is slightly different from the other requirements we examined. Although the MMA notes the importance of promoting beneficiaries' informed choice, drug card sponsors' materials are not required to explicitly state that beneficiaries have a choice of drug cards. Despite this, we found 16 pre-enrollment packets that explicitly state that beneficiaries have a choice of cards. One pre-enrollment packet states, "There is a lot to know before you choose a discount card program We will help you find the program that is right for you." Another pre-enrollment packet indicates, ". . . you can choose any Medicare-approved discount card you want. But you can choose only one."

However, CMS does require that pre-enrollment packets include information that implicitly indicates that beneficiaries have a choice of cards (for example, how to disenroll in one card and enroll in a new one). We assessed whether pre-enrollment packets included the required statement: "you may be enrolled in only one Medicare-Approved [drug discount card] at one time." Twenty pre-enrollment packets did not include this statement.

For 13 of these pre-enrollment packets, CMS contractor's reviewers did not apply the correct review protocol to the material, which accounts for the noncompliance. When submitting materials for review and approval, sponsors are not required to designate whether a material will be included in their pre-enrollment packet. Pre-enrollment packets can contain a variety of different materials, such as a Summary of Program Features, enrollment instructions, and forms. However, some sponsors included simple brochures in their pre-enrollment packets, as opposed to their Summary of Program Features. Because of this, reviewers assumed that materials submitted as "direct mail brochures" were not pre-enrollment packet materials but advertisements. Sponsors that included a brochure in their pre-enrollment packet in place of their standard explanatory materials may have been unclear on CMS's requirements, or may have intended to take advantage of the fact that CMS does not require them to report how they intend to use submitted materials.

Comparative information. Nearly all pre-enrollment packets included required information about some comparative features, including annual enrollment fees, and a description of how to get more information about pharmacies in a drug card's network. In addition, all pre-enrollment packets included sponsor contact information, and most listed the CMS Web site. (See Table 5 in Appendix B for more detail.) However, we found five pre-enrollment packets that did not meet the requirement to describe how to get more complete information about drug prices and/or discounts, including both visiting the Medicare price compare Web site and contacting the drug card sponsor. Referring beneficiaries to Medicare's Web site is especially relevant since beneficiaries can use the site to compare different drug cards' prices on the specific drugs the beneficiary uses.

Of the 20 advertising materials we reviewed, 15 were noncompliant with one or more of the requirements we assessed

Of the 20 advertising materials we reviewed, 15 did not include information related to at least one of the 2 to 7 requirements we assessed. These 15 noncompliant advertisements were used to target

approximately 4.7 million beneficiaries through direct mail and an unknown number of beneficiaries through a print advertisement and a pharmacy flier. These 15 materials represent 7 unique advertising materials, since 1 "template" postcard was used by 9 cards. (See Appendix B for results for all requirements we assessed.)

A communication error between CMS and its contractor accounts for all the noncompliance that we found. All 15 advertisements were missing a description of how to get more complete information about discounts, including visiting the Medicare Web site and contacting the sponsor. Thirteen of these fifteen were also missing the disclaimer that discounts are subject to change.³² Similar to pre-enrollment packets, CMS's contractor considered both of these requirements for advertisements to be superseded by a new requirement.³³

CMS oversight processes did not prevent noncompliance found relatively early in the program

CMS oversight processes, including Information and Outreach Materials Guidelines for sponsors' materials, review and approval of materials, and CMS model documents, did not prevent the noncompliance we found. CMS provided sponsors with some model documents, including a model cover letter for pre-enrollment packets, a model member handbook, and model enrollment instructions and forms. We found evidence that many drug card sponsors were interested in following model documents. Fifty-nine of 62 pre-enrollment packets followed at least some model language offered by the CMS model handbook, model enrollment instructions, or model cover letter. However, CMS staff did not develop a model Summary of Program Features. CMS staff indicated that a model Summary of Program Features may have assisted sponsors in understanding the requirements for their pre-enrollment packets.

All the materials we reviewed were approved by CMS relatively early in the program (between March and July 2004), which was a time characterized by very tight deadlines and by many changes and clarifications regarding requirements for sponsors' materials. These constraints increased the potential for communication problems both with sponsors and with CMS's contractor.

We found three sources of error that explain all noncompliance found in 39 pre-enrollment packets and 15 advertisements: reviewer error, sponsor error, and miscommunication about policy changes. Each source of error is described below. Many of the 39 noncompliant

pre-enrollment packets had more than one source of error, so the following description contains a duplicated count of pre-enrollment packets. (See the final table in Appendix B for an unduplicated accounting of sources of error.)

<u>Reviewer error.</u> Twenty of the thirty-nine noncompliant pre-enrollment packets were noncompliant due, at least in part, to reviewer error. Eleven of these cases relate to two "template" pre-enrollment packets. Some reviewer error may be attributable to challenges CMS's contractor faced in the early implementation of the program, including frequent changes to review policies, high volume of materials for review, and confusing communication from CMS.

Sponsor error. Eighteen of the thirty-nine noncompliant pre-enrollment packets were noncompliant, at least in part, due to sponsor error (such as using an advertising brochure in the pre-enrollment packet as opposed to standard explanatory materials, or failing to include enrollment instructions in their pre-enrollment packet). Sponsors may have failed to include correct materials in their pre-enrollment packets due to unclear standards. For instance, CMS's original Information and Outreach Materials Guidelines do not clearly explain that sponsors are responsible for including all required materials in any packet to be used directly for enrollment. CMS had not used formal methods of communicating to sponsors (for example, a bulletin) to clarify pre-enrollment packet requirements. Although CMS staff indicated that this issue might have been raised during weekly conference calls with sponsors, CMS did not record or distribute minutes for these calls. However, CMS has somewhat clarified this issue in its revised guidelines.

We also found evidence that some sponsors did not follow CMS requirements prior to distributing materials. For instance, some sponsors apparently changed materials after approval and did not notify CMS. In most cases, these changes were minor. In addition, we noted that some sponsors did not revise materials to address stipulations on approval. After reviewing a sample of 105 materials, CMS's contractor found that 61 materials failed to address stipulations. Finally, we found two instances in which it appears that sponsors used unapproved materials. CMS reserved the right to conduct a review of sponsors' materials in the marketplace, but has not conducted this review.

<u>Miscommunication of policy changes.</u> Twenty-three of the thirty-nine noncompliant pre-enrollment packets and all 15 advertisements were

noncompliant due to miscommunication about policy changes. CMS and its contractor developed an "issues matrix" to communicate policy changes and to identify and resolve questions about interpreting requirements for sponsors' materials. When CMS resolved a policy question, the matrix would be updated with the decision and decision date. Reviewers used the issues matrix along with a standard review protocol while reviewing sponsors' materials. Although this system appeared to work effectively to address many policy questions, it apparently failed in relation to disclaimers for discounts and pharmacy networks, as previously discussed. In one case, CMS issued a policy clarification through a brief e-mail, which was outside CMS's typical communication structure.

Beneficiary understanding of materials

Prior to enrolling in a drug card, beneficiaries need to

receive key information that is relevant to making an informed choice. In addition, this information must be understandable. Materials that include required information do not fully inform beneficiaries' decisions unless they can grasp key concepts, including eligibility, benefits and limitations of the card, choice of cards, and comparative information to select the card that best meets their needs. We assessed beneficiary understanding of five key program features related to these decision elements: eligibility, program limitations related to drugs covered, limitations related to drug prices, choice of cards, and comparative enrollment fee information.

Each of five key features was understood by between 54 to 74 percent of beneficiary respondents reading pre-enrollment packets; however, only 21 percent understood all five

We asked 113 beneficiaries to review selected pre-enrollment packets to assess whether they could understand five key program features. In doing so, we found that each individual feature was understood by a majority of respondents. In fact, all but three respondents understood at least one key program feature. Table 3 outlines these results. (In all cases, denominators vary depending on the number of respondents answering each question. See Appendix C for more detail.)

Respondents misunderstood key program features that were particularly complex (such as eligibility), not explicitly stated (such as choice of cards), and discussed only briefly (such as limitations on drugs covered). Nearly 80 percent of beneficiaries we interviewed did not understand all key features of the program.

TABLE 3: Proportion of Respondents Who Understood Key Program Features	
Based on Reading Sponsors' Pre-Enrollment Packets	

Key Program Feature	Proportion of Respondents Who Understood Key Feature	Transitional Assistance- Eligible Respondents	Non-Transitional Assistance- Eligible Respondents*
Eligibility	58%	63%	55%
Program Limitations: Drugs Covered Can Change	59%	44%	64%
Program Limitations: Drug Prices Can Change	74%	67%	78%
Choice of Cards	54%	45%	59%
Comparative Information: Annual Enrollment Fee	58%	50%	62%
All Key Program Features	21%	22%	21%

^{*} This category includes 13 respondents whose eligibility for Transitional Assistance could not be determined. Source: Office of Inspector General analysis of Medicare beneficiary interviews, 2004.

A greater proportion of Transitional Assistance-eligible (TA-eligible) respondents understood eligibility than those not eligible for Transitional Assistance; however, this was not the case for other topics. Sixty-three percent of TA-eligible respondents understood eligibility, compared to 55 percent of non-TA-eligible respondents. (See Appendix C for further results related to beneficiary understanding by eligibility status for Transitional Assistance.)

Eligibility: Fifty-eight percent of respondents correctly assessed their eligibility; most confusion concerned income requirements

Based on the material reviewed, 58 percent of respondents were able to correctly determine their program eligibility.³⁴ Some respondents correctly determined their eligibility despite indicating confusion about eligibility at some point in the interview. Respondents had to take into consideration their Medicare status, income, and other prescription drug coverage to determine their eligibility for both the drug card program and the Transitional Assistance credit.³⁵

A greater proportion of respondents correctly assessed their eligibility for the Transitional Assistance credit than correctly assessed their eligibility for the drug card program. Eighty-four percent of respondents correctly judged whether they were eligible for the Transitional Assistance credit. Of these, the vast majority provided at least one correct reason for their eligibility (for example, low income, lack of other drug coverage). However, only 66 percent of respondents

correctly judged that they were eligible for the drug card program.³⁶ Of these, 15 respondents gave an incorrect reason for their eligibility.

Respondents who did not understand their eligibility for the drug card program most frequently misunderstood the nature of the income requirement described in pre-enrollment packets. Some respondents erroneously believed the drug card program to have income requirements. In addition, many respondents did not understand that the drug card program and the Transitional Assistance credit were two separate programs with distinct eligibility requirements. For instance, some respondents characterized the material as describing a program solely for low-income individuals. Eligibility for the Part D prescription drug benefit will be similarly complex, with low-income beneficiaries eligible for enhanced drug coverage.

In addition to income, respondents expressing confusion about eligibility mentioned specific confusion about the role of existing prescription drug coverage and current prescription drug expenditures. Twelve respondents indicated concern that existing drug coverage (other than Medicaid) disqualified them from the drug card program. Existing prescription drug coverage does exclude beneficiaries from receiving Transitional Assistance but not from enrolling in the drug card program. Nine respondents reported that the amount they spent on drugs either qualified them or made them ineligible for the drug card program. However, prescription drug expenditures are not a factor in assessing eligibility for either the drug card program or the Transitional Assistance credit.

<u>Program limitations:</u> Between 59 and 74 percent of respondents understood key limitations of the drug card program

More respondents understood that drug prices could change than that drugs covered could change. Seventy-four percent of respondents understood that drug prices could change. Most pre-enrollment packet selections read by respondents described discounts or drug prices, and many included a percent discount that beneficiaries could expect.

However, only 59 percent of respondents understood that drugs covered could change, perhaps due to a lack of description of drugs covered in the pre-enrollment packet. Aside from the disclaimer that drugs covered could change, pre-enrollment packet selections tended to mention the topic of drugs covered only briefly. For example, the vast majority of selections read by respondents did not mention specific drugs covered by the drug card.

<u>Choice of cards:</u> Fifty-four percent of respondents understood that they had a choice of Medicare-approved drug discount cards

Overall, 54 percent of respondents interviewed correctly identified that more than one Medicare-approved drug discount card is available, based on the pre-enrollment packet they reviewed.³⁷ Twenty-six percent of respondents incorrectly identified that the card described in the pre-enrollment packet they read was the only one available, and 20 percent did not know if there were other available cards. Although most selections read by beneficiaries implicitly indicated that beneficiaries have a choice of drug cards, CMS does not require sponsors to explicitly state that beneficiaries have a choice of drug cards. Respondents reading pre-enrollment packets understood this topic least often out of all topics we assessed.

Some beneficiaries indicated that they knew from sources other than the material they reviewed that several Medicare-approved drug discount cards were available. Five of these respondents volunteered that, based on the selected material reviewed, they were led to believe there was only one available Medicare-approved drug discount card, but that they knew from outside sources that there were others.³⁸

<u>Comparative information:</u> Fifty-eight percent of respondents correctly determined the annual enrollment fee of the drug card

For the drug card offered by the pre-enrollment packet they reviewed, 58 percent of respondents correctly assessed both the amount and the frequency of the enrollment fee, if applicable.³⁹ For the amount of the enrollment fee alone, 73 percent of respondents reported a correct response, and 75 percent of respondents reported a correct response for the frequency of the enrollment fee alone.

Respondents reading advertisements understood key program features less often than those reading pre-enrollment packets

Overall, respondents reading advertisements answered questions correctly less often than respondents reading pre-enrollment packets. Twenty-seven percent answered the vast majority of test questions correctly, compared with nearly half of respondents who reviewed pre-enrollment packets. In contrast, 57 percent of respondents reading advertisements answered half or fewer test questions correctly. About

one-third of respondents who reviewed pre-enrollment packets answered half or fewer of their questions correctly. 40 (See Table 4 below.)

TABLE 4: Proportion of Key Test Questions Answered Correctly					
Proportion of Test Questions Answered Correctly	Respondents Reviewing Advertisements	Respondents Reviewing Pre-Enrollment Packets			
50% or Less	57%	32%			
51%-79%	16%	22%			
80% or More	27%	46%			

Source: Office of Inspector General analysis of Medicare beneficiary interviews, 2004.

Similar to beneficiaries who read pre-enrollment packets, a greater proportion of respondents who read advertisements correctly assessed their eligibility for the Transitional Assistance credit than correctly assessed their eligibility for the drug card program. Of the 14 respondents who were asked to judge their eligibility for the \$600 Transitional Assistance credit, 11 both understood their eligibility and provided the correct reason for their eligibility. Of the 20 beneficiaries asked to judge their eligibility for the drug card program, 11 understood that they were eligible, and 4 of these gave the correct criteria for their eligibility.

Roughly half of respondents reading advertisements understood choice of cards and enrollment fee. Sixteen of the 34 respondents asked were able to correctly identify that there is more than one Medicare-approved drug discount card available. Of the 14 respondents asked the amount of the enrollment fee, 8 correctly reported the amount of the fee and 6 responded that they did not know the amount.

>

Under Medicare's new Part D prescription drug benefit, beneficiaries will face choices very similar to those they have under the drug card program. They will need complete, accurate, and understandable information about the Part D drug benefit to assess whether the program is appropriate for them and, if so, which prescription drug plan best meets their needs. For instance, beneficiaries will need to understand whether they are eligible for the basic Part D drug benefit or the subsidies available to low-income individuals. They will need to understand the advantages and limitations of the drug benefit, as well as how to compare different plans available to them. While similar, many of the choices facing beneficiaries will be more complex under the Part D drug benefit, and will have greater implications for beneficiaries who delay enrollment.

CMS will play a lead role in providing quality beneficiary education while reaching the number of beneficiaries who need to be informed about the new drug benefit. To do this, CMS will need to first establish effective oversight systems. Second, these oversight systems should ensure that prescription drug plan sponsors' materials provide clear information about their plans. Finally, CMS outreach to beneficiaries must provide key comparative information about prescription drug plans to ensure that all beneficiaries are aware of their options under the Part D drug benefit.

In light of our review of drug card materials, and to promote informed choice for beneficiaries, we believe that CMS should consider the following as it implements oversight of prescription drug plan sponsors' materials and develops outreach for the full prescription drug benefit under Part D.

CMS Management and Communication Systems

CMS should anticipate implementation challenges to ensure that its management and communication systems are consistent, clear, and formalized.

Anticipate implementation challenges. As we found with the drug card program, CMS will likely run into challenges in the early months of implementing the new drug benefit. CMS may find it must make unexpected clarifications to policies or processes and will face high volumes of materials for review as plan sponsors will be eager to begin marketing their programs. CMS may want to anticipate these

implementation challenges by ensuring that there are enough staff and resources to review the high volume of materials likely to be submitted in the few months before prescription drug plan marketing begins. CMS will need to ensure that all reviewers are well trained on reviewer protocols and should consider pretesting review protocols and the review process.

<u>Establish consistent, clear communication.</u> CMS should ensure that it uses consistent and clear communication with prescription drug plan sponsors and with CMS's contractor. Clear communication is especially important given the abbreviated timeframe CMS has to implement the full Part D drug benefit. CMS should ensure that plan sponsors and reviewers receive the same information related to materials and should coordinate instructions to both the CMS contractor and CMS regional staff who will review materials for Medicare Advantage prescription drug plans.

Formalize communication. Further, CMS should formalize communication with prescription drug plan sponsors and reviewers when feasible. While frequent conference calls may be an efficient way to address questions and any unforeseen issues, policy changes, clarifications, and guidance discussed on these calls should be documented and distributed to plan sponsors and reviewers. CMS may want to continue to use an "issues matrix," such as the one used in the drug card program, to track clarifications and instructions to reviewers.

CMS Oversight of Prescription Drug Plans' Materials

CMS oversight of prescription drug plan sponsors' pre-enrollment packets and advertising materials should ensure that beneficiaries have all the information necessary to make informed decisions about participating in the Part D drug benefit. CMS requirements and oversight mechanisms should aim to facilitate the development and distribution of informative pre-enrollment packets and responsible advertisements. In particular, CMS should consider incorporating the following items in its oversight of plan sponsors' materials:

Require development of pre-enrollment materials that contain specified information needed prior to enrollment. CMS should consider requiring that prescription drug plan sponsors develop pre-enrollment packets (or their equivalent) for the Part D drug benefit. Similar to the drug card program, CMS should specify the minimum information that these pre-enrollment materials should contain to ensure that beneficiaries can use them to make an informed decision about enrolling.

CMS may want to keep these requirements as concise as possible. In our interviews, many drug card sponsors reported that pre-enrollment packet requirements and the review and approval process for their materials were burdensome. Prescription drug plan sponsors may also find the review process burdensome, and thus may be unlikely to dedicate the time and resources needed to develop these explanatory materials unless required.

Requirements that result in extensive pre-enrollment packets may discourage prescription drug plan sponsors from using them in their outreach, due to printing and distribution costs.

Identify pre-enrollment packet materials. If CMS decides to require pre-enrollment packets (or their equivalent), it will need to require prescription drug plan sponsors to identify materials they will include in their packets to facilitate correct review. Further, CMS should clearly state that plan sponsors are responsible for including these materials when they distribute enrollment forms. Prescription drug plan sponsors should have no confusion about the information beneficiaries should receive when preparing to enroll.

<u>Provide model materials.</u> To streamline requirements for and facilitate compliance of materials, CMS should consider developing model materials for prescription drug plan sponsors to use. We found evidence that many drug card sponsors were interested in following model documents. Because model materials are likely to be adopted by plan sponsors, CMS should consider pretesting its model materials by conducting focus groups or cognitive interviews with beneficiaries.

Require "choice of plans" statement. To ensure that beneficiaries realize they have a choice when considering the Part D drug benefit, CMS could require that prescription drug plan sponsors' materials clearly state this. Specifically, CMS could require that all materials, including advertisements, include a CMS-sponsored label clearly stating that beneficiaries have a choice of Medicare prescription drug plans, describing the main ways in which plans vary, encouraging beneficiaries to find the best plan to meet their needs, and providing Medicare contact information to compare plans.

<u>Spot check materials.</u> CMS should consider conducting spot checks of prescription drug plan sponsors' materials in the marketplace to determine whether plans are using unapproved outreach materials. If CMS finds that plan sponsors are using such materials, it should take enforcement measures to address noncompliant plan sponsors and

consider focusing more efforts on reviewing final submitted versions of materials that were approved with stipulations.

CMS Outreach to Beneficiaries

different networks of pharmacies.

CMS should enhance its outreach efforts to ensure that beneficiaries have all information necessary to make informed decisions about participating in the Part D drug benefit. Exposure to information about a particular prescription drug plan alone may not provide beneficiaries with a full understanding of the array of choices available. This could result in beneficiaries' signing up for the plan that was marketed to them rather than the plan that best suits their health care needs. For example, they may simply sign up for the plan that their pharmacist has endorsed. Thus, CMS outreach will be a critical component in promoting informed choice by providing comparative information on prescription drug plans. CMS should consider the following steps in its efforts to inform beneficiaries about the Part D drug benefit, to ensure that beneficiaries can make an informed decision about their enrollment.

Distribute regionally tailored letters at the beginning of the new drug benefit. To facilitate beneficiaries' informed choice at the beginning of the Part D drug benefit, CMS could distribute to beneficiaries regionally tailored letters that include a list of all prescription drug plans available in their area. This letter could provide comparative information about these plans, such as premiums and basic plan benefits. The letter could also inform beneficiaries about the benefits and limitations of the program and how to compare plans. For instance, the letter could indicate that premiums vary, that plans' formularies may vary, and that plans use

Provide a short guide to choosing a prescription drug plan. In addition, CMS could produce a short guide to choosing a prescription drug plan and could require it to be included with all pre-enrollment packets. This guide could reduce the burden on plan sponsors for sharing specific information necessary to informing beneficiary choice. Alternatively, CMS could require each pre-enrollment packet to include a section on information "Medicare wants you to know." CMS is a trusted source and could give plan sponsors' materials added credibility, as well as point out the basic factors a beneficiary should consider when choosing a plan.

<u>Facilitate in-person education</u>. Finally, CMS should continue to focus efforts on in-person education and should consider facilitating and

promoting prescription drug plan sponsors' efforts to inform beneficiaries in person about the Part D drug benefit. Explaining the new drug benefit in person provides the greatest opportunity to help individual beneficiaries understand whether the Part D benefit is right for them. Some drug card sponsors found in person outreach to be more effective than relying on written materials alone. Further, only 21 percent of beneficiary respondents were able to understand all key program features after reading sponsors' pre-enrollment packets. In person education allows beneficiaries to ask questions and resolve confusion that may be hindering their decision about enrolling.

As part of CMS's education and outreach efforts, CMS should continue to emphasize local, in-person outreach. CMS currently partners with a variety of community-based organizations to provide local outreach to beneficiary populations that are sometimes difficult to reach. Congress has allotted funds for CMS to enhance its in-person education efforts for the Part D drug benefit (through the State Health Insurance Assistance Program). In addition to these efforts, CMS should continue to promote its toll-free hotline through which CMS representatives can provide quality information and answer beneficiaries' questions.

In addition to its own efforts, CMS should consider how to promote prescription drug plan sponsors' use of in-person outreach to beneficiaries, including providing a forum in which plan sponsors can interact with beneficiaries. For instance, CMS could leverage its partnerships with community-based organizations, departmental grantees, and senior groups to provide such forums and invite prescription drug plan sponsors to provide in-person education to beneficiaries. CMS could also partner with State and local legislators to offer town hall-style meetings and invite regional plan sponsors to participate.

AGENCY COMMENTS

CMS stated that it views the drug card as an important opportunity for using "lessons learned" when implementing the new drug benefit and agreed with most of the implications for the drug benefit that we suggested. In fact, CMS noted that ongoing communications with OIG throughout the course of this project have already allowed it to incorporate some of our suggestions in the development and implementation of the marketing rules, guidelines, and oversight for sponsors' materials and outreach to beneficiaries.

CMS noted that it has had substantially more time to plan for the drug benefit, as compared to the drug card program, and thus has been able to address our suggestions to develop stronger management and communication systems, oversight of marketing materials, and outreach efforts. To ensure consistent, clear, and formalized communications, CMS indicated that it has set up multiple channels for communication with Part D sponsors and industry representatives. These include weekly Part D user group calls, a searchable MMA Question & Answers database, and a "PDP help line" to provide drug benefit sponsors with answers to marketing questions. Finally, a marketing guideline training program has been established.

CMS stated that it has worked with an outside marketing contractor and received extensive public comment to help it develop marketing guidelines, model materials, and a streamlined marketing review to ensure the appropriate oversight of sponsors' materials. Additionally, CMS stated that it has developed an oversight strategy to ensure that sponsors are complying with requirements for the content and distribution of makerting materials. Some components of this strategy include focused audits, routine audits, a complaints tracking system, and spot checks on a wide range of marketing materials.

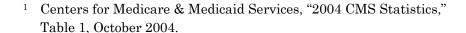
CMS detailed a comprehensive outreach effort with national, regional, and community-based outreach efforts related to our suggestions. The agency described a targeted education effort that incorporates a national multimedia campaign, simple fact sheets, audience-specific outreach materials, direct mail, and community-based grassroots outreach with numerous partners. CMS also highlighted the personalized information available through the Drug Plan Compare Web tool and 1-800-MEDICARE, as well as the one-on-one personalized advice and counseling available from the State Health Insurance Assistance Programs. The complete text of CMS's comments is included in Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

OIG appreciates CMS's response to this report and the detailed descriptions of its ongoing and planned efforts regarding the oversight of sponsors' marketing marterials for the new drug benefit. These descriptions highlight substantial efforts by CMS toward ensuring the appropriate management, guidance, and oversight of sponsors' marketing materials.

We are pleased that CMS found this information to be constructive and is taking actions consistent with our findings and all of our suggestions, with the exception of two. While CMS is not requiring the use of specific pre-enrollment packets as we suggested, it is specifying pre-enrollment materials sponsors should use in the marketing guidelines. This guidance should help ensure that beneficaries receive the information they need prior to enrollment. CMS also disagreed with our suggestion to include a statement informing beneficiaries that they have a choice of plans in sponsors' marketing materials. It indicated that this would not be consistent with industry standards, and that it is using other marketing techniques to inform beneficiaries of their choices. Based on our interviews with beneficiaries, we found that they may not fully understand the range of choices that they have. We encourage CMS to strongly emphasize this in its education and outreach campaigns.

ENDNOTES



- Part B summary data, CMS National Claims History file, calendar year 2003.
- Genters for Medicare & Medicaid Services, "Medicare Fact Sheet: Final Rules Implementing the New Medicare Law: A New Prescription Drug Benefit for All Medicare Beneficiaries, Improvements to Medicare Health Plans and Establishing Options for Retirees," p. 3, January 21, 2005.
- ⁴ Congressional Budget Office, "Comparison of CBO's March 2005 Medicare Prescription Drug Baseline and the CBO Estimate for the MMA," March 4, 2005; and Centers for Medicare & Medicaid Services, "Releasing the HHS Proposed Budget for FY 2006," February 7, 2005.
- Oenters for Medicare & Medicaid Services, "Fact Sheet: Medicare Modernization Benefits in the First Year," December 8, 2004.
- ⁶ Centers for Medicare & Medicaid Services, "Approved General Drug Cards." This list includes all approved general drug cards, including those with special endorsements such as long-term care pharmacies and U.S. Territories; May 17, 2004.
- ⁷ Exceptions are made for beneficiaries under certain circumstances, such as moving outside the area served by their current drug card.
- 8 These program limitations are described in the following documents: Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173, § 101, subpart 4, codified in § 1860D-31(c)(1-2) and § 1860D-31(d)(1-2) of the Social Security Act; and Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," pp. 51-62, revised August 2004.
- ⁹ Low-income beneficiaries who receive Medicaid, TRICARE (military health insurance), the Federal Employees Health Benefit Program, or

- an employer's health plan are not eligible to enroll in the Transitional Assistance program.
- ¹⁰ Centers for Medicare & Medicaid Services, "Fact Sheet: Medicare Modernization Benefits in the First Year," December 8, 2004.
- ¹¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173, § 101, subpart 4, codified in § 1860D-31(d)(1) and § 1860D-31(d)(2)(A) of the Social Security Act.
- ¹² Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173, § 101, subpart 4, codified in § 1860D-31 (d)(2)(A) of the Social Security Act.
- ¹³ 42 CFR § 403.806(g)(5)(i) requires sponsors to "comply with the Information and Outreach Materials Guidelines published by CMS." CMS initially published the "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines" on January 22, 2004, and revised these guidelines in August 2004. Revised guidelines are available on the CMS Web site: www.cms.hhs.gov/discountdrugs.
- ¹⁴ 42 CFR § 403.806(g)(1) and Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," pp. 24-25 and 39-51, January 22, 2004.
- ¹⁵ Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," pp. 24-30, January 22, 2004.
- ¹⁶ Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," pp. 24-30, January 22, 2004. Also, 42 CFR § 403.806(g)(1).
- ¹⁷ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173, § 101, subpart 4, codified in § 1860D-31(i)(2) of the Social Security Act.

OEI-05-04-00190

- Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," January 22, 2004, revised in August 2004. Revised guidelines are available on the CMS Web site: www.cms.hhs.gov/discountdrugs. Also, Centers for Medicare & Medicaid Services, "Drug Discount Card Preferred Terminology for Beneficiaries," February 13, 2004.
- ¹⁹ 42 CFR § 403.806(g)(5)(ii) and 68 FR 69869, December 15, 2003.
- We excluded requirements related to other program features, such as grievance procedures, enrollment/disenrollment rules, and mail order pharmacies.
- 21 CMS updated its Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines in August 2004. Although we assessed compliance with the original Information and Outreach Materials Guidelines, the requirements we assessed continue to be applicable to sponsors' materials in the updated guidelines.
- 22 Some State Pharmacy Assistance Programs automatically enrolled their low-income members in an exclusive drug card. These beneficiaries did not make a decision about enrolling in the program.
- It is important to note that all estimates of the number of beneficiaries targeted by particular outreach methods are based only on the estimations of drug card sponsors willing and able to supply the information. Therefore, these figures are only meant to provide a general sense of the potential of each outreach method and may not represent the actual number of beneficiaries who received information about the drug card program.
- The 39 noncompliant pre-enrollment packets are accounted for by 20 different pre-enrollment packets: 3 "template" pre-enrollment packets that cover a total of 22 drug cards and 17 pre-enrollment packets for individual cards. Of the 23 pre-enrollment packets not found to be noncompliant, 19 were for individual cards and 1 "template" pre-enrollment packet covered the remaining 4 drug cards.

- ²⁵ Centers for Medicare & Medicaid Services, "Model Enrollment Form Instructions," March 9, 2004. Income requirements are accurate for 2004.
- ²⁶ Centers for Medicare & Medicaid Services, "Model Enrollment Form Instructions," March 9, 2004.
- ²⁷ Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," p. 40, January 22, 2004.
- In March 2004, CMS added a requirement that when sponsors' materials specify a percent discount, they must also include the disclaimer: "Discounts vary by drug. Contact [drug card sponsor] to find out . . . the discounted price." CMS's contractor interpreted this policy change to supersede all previous disclaimers for discounts, as opposed to adding this new disclaimer to the existing requirements. This miscommunication about policy changes seems to have occurred despite the formal structure CMS and its contractor had established to handle policy clarification issues.
- ²⁹ Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," p. 43, January 22, 2004.
- In late April 2004, CMS attempted to clarify some of the requirements for sponsors' pre-enrollment packets by listing the key information that must be included in a sponsor's Summary of Program Features. In this listing, CMS indicated that Summaries of Program Features must describe types of pharmacies in a drug card's network (e.g., retail, mail order, etc.). However, this listing omitted several required disclaimers, including the disclaimer about pharmacy networks. CMS's contractor informed us that it interpreted this omission as superseding the original pharmacy network disclaimers. CMS's policy clarification occurred outside the formal structure established to communicate policy changes between CMS and its contractor.

- ³¹ Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Discount Card and Transitional Assistance Program, Information & Outreach Materials Guidelines," p. 47, January 22, 2004.
- Fourteen of our twenty selected advertisements specified a percentage discount. All 14 included the required disclaimer: "Discounts vary by drug. Contact [drug card sponsor] to find out . . . the discounted price." However, this disclaimer does not indicate that discounts are subject to change over time, nor that discounted prices may be found on CMS's Web site.
- 33 See endnote 28 above.
- All 151 respondents interviewed were eligible for the drug card program, and 53 respondents were eligible for the \$600 Transitional Assistance credit according to demographic information they provided. We found that 82 respondents were not eligible for Transitional Assistance and 16 respondents did not provide enough demographic information to determine their eligibility. These 16 respondents are included (with the 82 respondents) in our analysis as not eligible for Transitional Assistance because the majority of Medicare beneficiaries are not eligible for Transitional Assistance. Of the 113 respondents reading pre-enrollment packets, 37 were eligible for Transitional Assistance, 63 were not eligible, and 13 did not provide enough demographic information to determine their eligibility.
- 35 However, this does not account for the reason respondents gave for their eligibility. In some cases, respondents correctly assessed their eligibility but gave an incorrect reason or indicated that they did not know why they were or were not eligible.
- 36 To be included in our interviews, respondents had to be eligible for the drug card program. That is, respondents were Medicare beneficiaries without Medicaid prescription drug coverage.
- Unlike our other key program topics, we did not remove this question from interviews if the material did not explicitly address choice of cards. This question was meant to assess the impression made on respondents by reading sponsors' materials.

- These five responses were included in our analysis as answering "based on the material, there is only one drug card available." We excluded from our quantitative analysis any response clearly based on outside knowledge and not on the material. In addition to the five responses above, seven beneficiaries indicated that they knew from outside knowledge that more than one drug card was available under the Medicare-approved drug discount card program. Eight other beneficiaries responded that they knew from outside knowledge that more than one drug card was available; however, these respondents referenced other, non-Medicare-approved drug cards. All 15 responses were removed from our quantitative analysis.
- ³⁹ Fourteen interviews were about cards that had no enrollment fee. These respondents were not asked to identify the frequency of the fee. In addition, respondents were not asked to identify the frequency of the fee if they incorrectly reported that there was no enrollment fee, or reported that they did not know the amount of the fee based on reading the material.
- 40 Unlike pre-enrollment packets, advertising materials are not expected to provide in-depth information about the drug card program and thus are not required to include information about all key program features. Because we only asked respondents about topics covered in the material they read, the number of beneficiaries responding to each question varied from 3 to 34. We calculated the proportion of correct answers for each respondent by dividing the number of correct answers by the number of test questions included in the interview.



Detailed Methodology

Scope

This inspection focuses on sponsors' materials that are likely to inform beneficiaries' decisions about enrolling in the drug card program. Preenrollment packets are required to include information CMS has designated as necessary to promote informed choice prior to enrollment. Advertising materials are intended to generate interest and encourage beneficiaries to obtain the additional information they need to enroll.

We did not review enrollment forms or postenrollment materials because these do not affect informed choice. Also, our review excludes any materials written in languages other than English as well as any materials specifically designed for persons with disabilities (such as materials in Braille). CMS guidelines encourage, but do not require, sponsors to develop these targeted materials.

Materials from exclusive drug card sponsors were excluded from our review because these sponsors' drug cards are offered exclusively to beneficiaries enrolled in the sponsor's Medicare Advantage program. These beneficiaries choose only whether to enroll in the drug card offered by their Medicare Advantage program and do not have a choice among drug cards.

Assessing Whether Sponsors' Materials Promote Informed Choice

To assess the extent to which sponsors' materials promote informed choice, we reviewed a selection of materials and conducted interviews with sponsors that administer 62 drug cards.

<u>Selection of sponsors' materials.</u> We selected 62 pre-enrollment packets and 20 advertising materials as they were approved by CMS for our review. Because we obtained materials from CMS rather than directly from the sponsors, it is possible that the selected materials could be different from the ones sent to beneficiaries. For example, it is possible that a sponsor could send to beneficiaries materials that have not been reviewed and approved by CMS, or that a sponsor could fail to submit revised material to CMS prior to sending it to beneficiaries.

The 20 advertising materials included 14 direct-mail materials (postcards, letters, brochures), 1 print ad, and 5 other tangible advertisements (brochures, pharmacy fliers) distributed either in person or through a third party. Although 28 drug card sponsors used some tangible advertising in their outreach, 6 used materials not approved by CMS's contractor. Four of these were letters approved by CMS regional

offices to be sent to Medicare Advantage members; the other two should have been submitted for CMS's review but were not. Finally, in two cases we made a sampling error by selecting an alternate version of the sponsor's pre-enrollment packet instead of an advertisement.

<u>Structured Review of Sponsors' Materials.</u> We conducted a structured review of selected sponsors' materials to identify whether approved materials include required information. We also collected some descriptive information about each material. Our review included requirements related to eight key program features: program description, eligibility, choice of cards, discounts/drug prices, enrollment fee, pharmacy network, contact information, and enrollment instructions/forms.

We discussed the noncompliance we found in our structured review with CMS and CMS's contractor. At our request, CMS's contractor reviewed sponsor materials we found to be noncompliant. For most of the noncompliance we found, CMS's contractor agreed that materials were noncompliant and provided an assessment of the source of error that led to noncompliance. In a few cases, CMS's contractor indicated that our interpretation of certain CMS requirements did not match the protocol used in its approval process, and that some materials in question should be considered compliant. We discussed these cases with CMS staff, who clarified these requirements. As part of this discussion, CMS staff indicated that a miscommunication about policy changes between CMS and its contractor was a source of error. Our report includes the results of these discussions.

<u>Cognitive Interviews With Beneficiaries.</u> We conducted interviews at a total of 24 community-based senior centers in five cities (we visited 4 senior centers in 1 city and 5 senior centers in each of the other cities). Within each city we sought to maximize the number of centers located in low-income areas to increase the number of Transitional Assistance-eligible respondents. Respondents volunteered to be interviewed and were not compensated for their time.

To allow beneficiaries to review pre-enrollment packets and answer questions in a relatively short interview, we found it was necessary to provide them with a selection from the pre-enrollment packet as opposed to a complete packet. We used a standard protocol to prepare pre-enrollment packet selections. Our selections included information relevant to the key program topics in the interview and excluded information not relevant to the interview or repetitive information. In

cases in which key information was repeated in the pre-enrollment packet we included the more comprehensive section. Advertising materials were brief enough to be read in 5 to 15 minutes and were used in our cognitive interviews in their entirety.

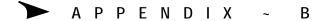
We excluded questions from each interview when the selected material did not contain answers to those questions. In addition, all interview questions were phrased to elicit responses based on the material. We attempted to ascertain if a respondent's response was based on the selected material or on outside information. If it was clear that the respondent was answering a question based on knowledge other than from reading the material, we excluded that response from our analysis of that question.

Key Demographic Information on Our Beneficiary Respondents

Overall, 53 of the 135 respondents who provided information on income, marital status, and other prescription drug coverage were eligible for the \$600 Transitional Assistance credit. The 2004 income limit for Transitional Assistance is \$12,570 for single individuals and \$16,862 for married beneficiaries. Medicare beneficiaries who also have Medicaid. TRICARE for Life, Federal Employees Health Benefit Program, or other employer-sponsored coverage are not eligible for Transitional Assistance. We found that 82 respondents were not eligible for Transitional Assistance and 16 respondents did not provide enough demographic information to determine their eligibility. These 16 respondents are included (with the 82 respondents) in our analysis as not eligible for Transitional Assistance because most Medicare beneficiaries are not eligible for Transitional Assistance.

Following are demographics for the beneficiaries we interviewed:

- 74 percent were single and 76 percent were female.
- 71 percent were Caucasian, 21 percent were African American, 2 percent were Hispanic, 1 percent were Asian, and 5 percent were other races.
- o 79 percent of our respondents were 65 to 84 years old, 14 percent were 85 and over, and 7 percent were under 65.
- 70 percent had less than a college degree (5 percent had some grammar school, 14 percent had some high school, 27 percent were high school graduates, and 24 percent had some college), 15 percent were college graduates, and 15 percent had attended graduate school.



Noncompliance for All Requirements Assessed and Sources of Error

Key Program Feature	Requirements—Pre-Enrollment Packets Must Include the Following Information:*	Pre-Enrollment Packets Not in Compliance (of 62)
	Annual income limits for both single and married beneficiaries	2
Eligibility for	Beneficiary cannot have other prescription drug coverage	2
Transitional Assistance	Definition of income: "Income includes money that you receive through retirement benefits from Social Security, Railroad, the Federal or State governments, or other sources, and benefits you receive for a disability or as a Veteran, plus any other sources of the type that you would report for tax purposes."	7
	Who is eligible for drug card program	0
	Must be a Medicare beneficiary to be eligible for drug card program	0
Eligibility for the Drug Card Program	Must not be receiving drug benefits through Medicaid to be eligible for drug card program	2
	"[Approved Card Sponsor Name] is available to all Medicare beneficiaries in [service area] except for those who have prescription drug coverage under their State's Medicaid."	2
	Program description material (could be Summary of Program Features, Member Handbook, or other type)	0
Pre-Enrollment	Enrollment instructions	2
Information	Enrollment form for the drug card program	1
	Enrollment form for Transitional Assistance	1
Benefits of the Program	IF AN ENROLLMENT FEE IS CHARGED: Must indicate that Medicare will pay the fee if a beneficiary is eligible for Transitional Assistance	0
Program Disclaimers	"[Program name] is not intended to replace prescription drug benefits obtained through participation in insurance plans including a Medicare Advantage plan, a Medigap policy, Medicaid, or an employer or retiree plan."	18
	"[Program name] is a prescription drug discount card program that is approved by Medicare but it is not a Medicare benefit."	17
	WHEN PRE-ENROLLMENT PACKET DISCUSSES DISCOUNTS: Discounts and/or drug prices are subject to change [over time]	17
	Requirement that enrollees must use network pharmacies	1
	"Enrollees must use [Approved Card Program]'s network pharmacies in [service area] to obtain the prescription discount we offer and to apply Transitional Assistance to the prices of your drug. A network pharmacy is a pharmacy where our discounted drugs can be purchased and Transitional Assistance can be used."	9
	IF AN ENROLLMENT FEE IS CHARGED: Must mention that an enrollment fee is charged	2
	WHEN PRE-ENROLLMENT PACKET INDICATES THAT NO ENROLLMENT FEE IS CHARGED: Must indicate that there is a cost for drugs	1

^{*} Drug card sponsors are allowed to paraphrase information in quotes.

Source: Office of Inspector General analysis of selected sponsor materials, 2004.

TABLE 5 (cont.): Requirements Assessed for Pre-Enrollment Packets and Noncompliance Found			
Key Program Feature	Requirements—Pre-Enrollment Packets Must Include the Following Information:*	Pre-Enrollment Packets Not in Compliance (of 62)	
Choice of Cards	"You may be enrolled in only one [Medicare-Approved Rx Discount Approved Card Program] at one time" OR "Medicare beneficiaries may be enrolled in only one [Approved Card Program] at a time."	20	
Comparative Information About Drug Card	IF AN ENROLLMENT FEE IS CHARGED: Must include the (correct) amount	1	
	WHEN PRE-ENROLLMENT PACKET DISCUSSES DISCOUNTS: How to get more complete information about drug prices and/or discounts including both visiting Medicare Price Compare Web site and contacting sponsor	5	
	Drug card sponsor toll-free number	0	
	Medicare toll-free number	0	
	Medicare Web site	2	
Total (Unduplicated)	Pre-Enrollment Packets Not in Compliance With at Least One of the 25 Requirements	39	

^{*} Drug card sponsors are allowed to paraphrase information in quotes.

Source: Office of Inspector General analysis of selected sponsor materials, 2004.

Key Program Feature	Requirements—Advertisements Must Include the Following Information:*	Advertisements Not in Compliance (of 20)
Program Disclaimers	WHEN AD INDICATES THAT NO ENROLLMENT FEE IS CHARGED: Must indicate that there is a cost for drugs	0
	WHEN AD DISCUSSES DISCOUNTS: Must indicate that discounts and/or drug prices are subject to change [over time]	13
	WHEN AD SPECIFIES A PERCENT DISCOUNT: Must state that "Discounts vary by drug. Contact [Program Name] to find out [if your prescription drug is covered and] the discounted price."	0
Choice of Cards	WHEN AD INCLUDES ENROLLMENT INFORMATION: Must include "You may be enrolled in only one [Medicare-Approved Rx Discount Approved Card Program] at one time" OR "Medicare beneficiaries may be enrolled in only one [Approved Card Program] at a time."	0
Comparative Information About Drug Card	WHEN AD INDICATES THAT AN ENROLLMENT FEE IS CHARGED: Must include the (correct) amount	0
	WHEN AD DISCUSSES DISCOUNTS: Must describe how to get more complete information about drug prices and/or discounts including both visiting Medicare price compare Web site and contacting sponsor	15
	Drug card sponsor toll-free number	0
Total (Unduplicated) Advertisements Not in Compliance With at Least One of the Seven Requirements		15

^{*} Drug card sponsors are allowed to paraphrase information in quotes.

OEI-05-04-00190

Source: Office of Inspector General analysis of selected sponsor materials, 2004.

TABLE 7: Sources of Noncompliance for Sponsors' Pre-Enrollment Packets and Advertising Materials			
Source(s) of Error	Pre-Enrollment Packets With Any Noncompliance	Ads With Any Noncompliance	
Reviewer Error Only	13	0	
Sponsor Error Only	3	0	
Miscommunication of Policy Changes Only	3	15	
Reviewer and Sponsor Error	0	0	
Reviewer Error and Policy Miscommunication	5	0	
Sponsor Error and Policy Miscommunication	13	0	
All Types of Error: Reviewer Error, Sponsor Error, and Policy Miscommunication	2	0	
Total With Any Noncompliance	39	15	

Source: Office of Inspector General analysis of CMS verification of selected sponsor materials' noncompliance, 2004.



Beneficiary Understanding

Although this report presents beneficiary interview data primarily using proportions, this appendix provides the actual number of respondents for our key data, as well as respondent understanding by eligibility for Transitional Assistance.

As mentioned previously, the actual number of respondents answering each question varies. In many cases this is because the pre-enrollment packet or advertisement did not contain the information relevant to a particular question. In other cases, beneficiaries were unable to separate their outside knowledge of the program from the material, and so we excluded their response from our quantitative analysis. In all cases, the data in this report are restricted to our respondents and are not projectable to the entire Medicare population.

TABLE 8: Proportion of Respondents Who Understood Key Program Features Based on Reading Sponsors' Pre-Enrollment Packets

Key Program Feature	Proportion of Respondents Who Understood Key Feature	Transitional Assistance- Eligible Respondents	Non-Transitional Assistance- Eligible Respondents*
Eligibility	58% (n=99)	63% (n=35)	55% (n=64)
Program Limitations: Drugs Covered Can Change	59% (n=68)	44% (n=18)	64% (n=50)
Program Limitations: Drug Prices Can Change	74% (n=82)	67% (n=24)	78% (n=58)
Choice of Cards	54% (n=92)	45% (n=29)	59% (n=63)
Comparative Information: Annual Enrollment Fee	58% (n=100)	50% (n=32)	62% (n=68)
All Key Program Features	21% (n=113)	22% (n=37)	21% (n=76)

^{*} This category includes 13 respondents whose eligibility for Transitional Assistance could not be determined. Source: Office of Inspector General analysis of Medicare beneficiary interviews, 2004.

To calculate the proportion of respondents who understood all key program features, we divided the number of correct answers by the number of test questions answered. Although we interviewed 38 beneficiaries who reviewed advertising materials, one respondent reading an advertisement did not provide a response to any test question, although this respondent answered other opinion and descriptive questions in the interview.

TABLE 9: Proportion of Key Test Questions Answered Correctly, by Advertisements vs. Pre-Enrollment Packets			
Proportion of Test Questions Answered Correctly	Proportion of Respondents Reviewing Advertisements (n=37)	Proportion of Respondents Reviewing Pre-Enrollment Packets (n=113)	
50% or Less	57%	32%	
51%-79%	16%	22%	
80% or More	27%	46%	

Source: Office of Inspector General analysis of Medicare beneficiary interviews, 2004.

Respondent Understanding of Pre-Enrollment Packets, by Respondents' Eligibility for Transitional Assistance

Regardless of eligibility status, a greater proportion of respondents understood their eligibility for Transitional Assistance than for the drug card program. Of the TA-eligible respondents who assessed their eligibility, 80 percent understood that they were eligible for Transitional Assistance. However, 74 percent of TA-eligible respondents understood that they were eligible for the drug card program. Of non-TA-eligible, 86 percent understood that they were not eligible for Transitional Assistance, and only 62 percent understood that they were eligible for the drug card program.

More respondents understood that drug prices could change than understood that drugs covered could change. Sixty-seven percent of TA-eligible respondents understood that drug prices could change, as did 78 percent of non-TA-eligible respondents. Forty-four percent of TA-eligible respondents understood that drugs covered could change, as did 64 percent of non-TA-eligible respondents.

Fewer TA-eligible respondents than non-TA-eligible respondents correctly identified that more than one Medicare-approved drug discount card existed. That is, 45 percent of TA-eligible respondents correctly identified that there was more than one available card, compared to 59 percent of non-TA-eligible respondents.

Fewer TA-eligible respondents than non-TA-eligible respondents correctly identified the cost of the enrollment fee and reported that this information was clearly explained. Specifically, 69 percent of TA-eligible respondents correctly reported the amount of the enrollment fee for the material they reviewed, compared to 75 percent of

non-TA-eligible respondents. Similarly, 63 percent of respondents eligible for Transitional Assistance reported that the enrollment fee was clearly explained, compared to 78 percent of non-TA-eligible respondents.



Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Administrator Washington DC 20201

GENERAL

TO:

Daniel R. Levinson Inspector General

Office of Inspector General

FROM:

Mark B. McClellan, M.D., Ph.D.

Administrator MM

SUBJECT:

CMS Response to OIG Draft Report: "Assessment of Sponsors' Materials Under

the Medicare-Approved Drug Discount Card Program", OEI-05-04-00190

We appreciate having the opportunity to review and comment on the Office of Inspector General Draft Report: "Assessment of Sponsors' Materials Under the Medicare-Approved Drug Discount Card Program." We are in complete agreement with the OIG that the value of the report stems from the implications for the Medicare drug benefit that emerged as a result of this work. We also appreciate your early communication of the report findings to us, enabling us to work to incorporate the report's suggestions and ideas into our approach for Part D since early this year.

Altogether, around 6.5 million beneficiaries with no or limited drug coverage have saved billions of dollars on prescription drugs using the card – in line with initial expectations about the drug discount card program. In addition, an independent evaluation has found a high level of satisfaction with the enrollment process for the drug cards (68 percent) and with the discounts obtained on the cards themselves (63 percent) for those who responded to these survey questions. It is important to note that while lessons learned from the drug card can be applied to implementation of the Medicare prescription drug benefit, the time frames and nature of the drug card were very different from that of Part D.

Finally, we are pleased that our oversight has led to only a limited number of beneficiary complaints, all of which we have tracked or are tracking to resolution. In particular, this report has been helpful to us over the course of this year in the development and implementation of the marketing rules and guidelines, marketing oversight, and beneficiary outreach and education for the prescription drug program. We have already been able to incorporate many of the steps the OIG recommended for the drug benefit.

The attachment summarizes our existing implementation approach, which responds to the three sets of OIG recommendations highlighted by your study:

- CMS management and communication systems for reviewing marketing materials and conveying instructions and guidelines to sponsors and contractors;
- CMS oversight of prescription drug plans' materials to ensure the accuracy and usefulness of sponsors' marketing materials; and
- CMS outreach to beneficiaries to ensure beneficiaries have all the information necessary to make informed decisions for participating in the prescription drug benefit.

Using your recommendations, our experience with the drug card, and the additional time and resources available to us for oversight of the drug benefit, we are establishing effective oversight mechanisms to ensure the new Medicare drug benefit plan sponsors' materials provide clear and accurate information to beneficiaries to make informed choices, and especially to ensure that beneficiaries are well informed and get the important help with drug costs that the Medicare drug benefit provides.

We thank you for incorporating this information into your final report, in order to provide a more complete picture of the implementation of the drug benefit. This is the most important new Medicare benefit in forty years, and in part based on our lessons learned from the drug card experience, we are conducting the most extensive oversight of sponsors' materials in the history of the program. Even more importantly, we are incorporating your suggestions and those of many other partner organizations inside and outside of government to give beneficiaries the personalized support they need to save money on drugs, increase their financial security, and help prevent their Medicare benefits from falling so far behind modern medicine ever again.

Attachment

2

Attachment

CMS management and communication systems for reviewing Part D marketing materials and conveying instructions and guidelines to Part D sponsors and contractors

CMS has worked with an outside Marketing contractor and an extensive public comment and input process to develop marketing guidelines, model materials, a streamlined marketing review process, and industry training sessions to ensure that Part D sponsors receive clear, consistent direction. In June, CMS released two installments of draft marketing guidelines for public comment. The final marketing guidelines recently released reflect input and recommendations from consumer, industry, and health professional perspectives.

Sponsors have been involved in the development process as well, being given the opportunities to provide feedback through weekly phone conferences, a help line and a searchable Q&A database. CMS and the contractor are keeping logs tracking issues and sponsor contacts, which are constantly being updated to reflect the most recent operational guidance, thus ensure that all marketing reviewers are receiving consistent direction. There is multiple daily communications with our marketing contractor, both telephonically and in writing, in order to facilitate clear and consistent directions from CMS with regards to any policy or operational changes that may occur. Contractor issues and feedback are also discussed in order to improve and enhance our review processes and facilitate and expedite customer concerns. In turn, we expect this approach plus our enforcement activities based on these guidelines to achieve a high level of compliance.

OIG Suggestion: Anticipate implementation challenges

CMS concurs with OIG recommendations and has already taken many steps to ensure that the Marketing contractor has allocated sufficient resources and staff to accommodate the demand for review of marketing materials in the beginning of the prescription drug program this fall. The reviewers are receiving substantial training on the marketing guidelines, the marketing review process, and the marketing review tracking system used to capture important information about the reviews, to ensure that we have an adequate and effective review capacity.

OIG Suggestion: Establish consistent, clear communication

CMS has set up multiple channels for consistent, clear communications with Part D applicants and industry representatives. First, CMS has established a weekly Part D user group call that discusses and clarifies policies and operational issues for potential Part D sponsors. This call also allows ample time for questions from Part D sponsors. CMS has also established the MMA Q&A Database that allows the general public to research the library of prior questions and responses or submit new questions pertaining to all aspects of the Prescription Drug Benefit, including Marketing. Additionally, and as part of the Marketing Support Contract, the "PDP Help Line" has been established to provide PDP applicants with answers to marketing questions. Finally, a marketing guideline training program has been set up with one session having already occurred in June With the recent release of final marketing guidelines, another session will be held shortly.

OIG Suggestion: Formalize communication

CMS has set up weekly industry "User Group" calls where information, including marketing topics, is communicated to the industry, and marketing questions are addressed by CMS representatives. In addition to CMS staff, the CMS marketing contractor is also present at these calls to address any marketing issues that need further discussion or clarification. CMS reviews with the marketing contractor the questions brought up on these "User Group" calls and other operational issues generated through the "PDP Help Line" and through the review of sponsor marketing materials. These regular communication channels have high levels of participation.

CMS oversight of prescription drug plans' materials to ensure the accuracy and usefulness of sponsors' marketing materials

Title I of the Medicare Modernization Act requires that, where possible, Part D should be consistent with and modeled after Medicare Advantage (MA). There was no such stipulation, however, with respect to the Medicare Prescription Drug Discount Card program. That being said, in the development of the Part D marketing guidelines and model materials, CMS utilized the experiences gained through regulating both programs to ensure the usefulness and appropriateness of plan sponsors' materials.

Based on these experiences and extensive public input, CMS developed final marketing guidelines designed to provide clear and effective governance of marketing activity for stand alone Prescription Drug Plans (PDPs), Medicare Advantage plans, and Medicare Prescription Drug plans (MA-PDs). The standards set forth in the guidelines reflect proven methods and ongoing oversight to protect beneficiaries.

CMS has required plans to convey certain information to beneficiaries prior to enrollment to facilitate the distribution of informative materials. Due to this requirement, CMS is providing training to sponsors and reviewers to ensure that sponsors' materials are accurate.

Additionally, CMS has developed a Part D oversight strategy to ensure that Part D sponsors are complying with our requirements for the content and distribution of marketing materials and other information. Some of the components of this strategy include focused audits, routine audits, and evaluation of customer service, customer satisfaction, and compliance measures through activities such as mystery shopping, website evaluation, and market conduct analysis.

CMS is currently developing a Monitoring Guide for Part D with a chapter on Marketing and Beneficiary Communications that will be a reference tool during plan audits to ensure sponsors are complying with the MMA, Part D regulations, and contractual requirements. The Marketing and Beneficiary Information Chapter focuses on ensuring plan distributed marketing materials have been approved by CMS. It also focuses on ensuring PDPs have full control over the marketing activities of those hired to sell their Part D plans.

Additionally, CMS is instituting a complaints tracking system for the collection, management, and resolution of complaints generated by beneficiaries, caregivers, community organizations, and others. The complaints will be captured, categorized, and analyzed to identify compliance problems across the program or for specific sponsors. CMS will investigate any complaints made by beneficiaries and other organizations. This system as well reflects our experience with the drug card, where timely follow-up on individual complaints resulted in the early detection

4

and resolution of potential problems, keeping the overall complaint rate low and beneficiary satisfaction high.

When compliance problems are identified, CMS will take proactive steps to correct the problem. Under Part D the remedies range from conducting educational calls with the plan, to corrective action plans, to freezing marketing and enrollment, to the imposition of civil monetary penalties and/or termination.

OIG Suggestion: Require development of pre-enrollment materials that contain specified information needed prior to enrollment

While CMS is not requiring the use of a specific pre-enrollment packet per se, we expect that plans will generally be sending pre-enrollment materials to potential beneficiaries. Within the Part D marketing guidelines there is a listing of materials and information which are required to be disseminated to prospective enrollees prior to enrollment. This requirement includes information regarding, for example, enrollment instructions and forms, Summary of Benefits, written explanation of the Plan's exceptions, grievance and appeals processes, as well as other information which the Plan is responsible for making available upon request.

OIG Suggestion: Identify pre-enrollment packet materials

CMS has identified specific pre-enrollment materials in the Marketing Guidelines to Part D plans. The materials listed in the response above would constitute the materials which a plan could use to fill a pre-enrollment packet or "sales kit."

OIG Suggestion: Provide model materials

CMS is currently developing a wide range of model marketing materials for Part D Plans. CMS has also given opportunities for plans and other interested parties to provide feedback to these model materials. There will be about thirty model documents for plans including: Enrollment and Disenrollment letters, Grievance and Appeals letters, Formularies, Pharmacy Directories, Evidence of Coverage, Summary of Benefits, Annual Notices of Change, Explanation of Benefits and others. Under "file and use" when CMS-approved language is utilized "without modification", these models will afford the submitting Part D plan an abbreviated 10-day review period and will streamline the review process for both CMS and the industry while assuring a consistent message to beneficiaries.

OIG Suggestion: Require "choice of plans" statement

CMS has not required a "choice of plans" statement to be placed in plan marketing materials because this practice would not be consistent with industry standards and would be seen as unduly burdensome to plans. Instead, CMS is using approaches that have proven to be effective in the existing Medicare Advantage program as well as other large choice-based programs, such as the Federal Employees Health Benefits program. For example, CMS has conducted extensive outreach campaigns (detailed below) in an effort to ensure beneficiary understanding of the prescription drug options available to them within the marketplace.

OIG Suggestion: Spot check materials

We agree that spot checking materials will be an important activity for the Medicare drug benefit. As described above, we have plans in place to spot check and review a wide range of sponsor marketing materials, including materials submitted for "file and use," websites, information provided via toll-free customer service lines, and information packets distributed by mail.

CMS outreach to beneficiaries to ensure beneficiaries have all the information necessary to make informed decisions for participating in the Part D drug benefit

As you point out, education and outreach to help beneficiaries, their caregivers, and others who assist them in making decisions is a critical issue for the success of the new Medicare prescription drug benefit and other new Medicare benefits.

Consequently, CMS is conducting a comprehensive outreach effort with national, regional and community-based outreach efforts to promote awareness of the new prescription drug benefit at the grassroots level. This outreach involves specific information and tools targeted to particular beneficiaries. For example, beneficiaries with retiree coverage and those with Medicaid drug coverage face different kinds of decisions. CMS is also engaging in broad based federal, state and local government outreach activities to facilitate communication at the grassroots level. Fully coordinated efforts are underway with all sister agencies at HHS including OMH, AoA, HRSA, and SAMSHA. Every federal agency that directly contacts people with Medicare is similarly involved; these agencies include SSA, HUD, DoL, DoD, DoT, and USA Freedom Corps.

In addition to the locally based grassroots efforts, CMS is executing a fully integrated and multimedia campaign. This strategy includes advertising, and the development of audience specific outreach materials, training materials and publications. These materials and publications are being disseminated through national coalitions, regional offices, and community-based grassroots organizations. States, territories, employers, unions, professional health associations, caregivers, patient advocates, and community-based organizations are all participating in this effort. Successfully reaching beneficiaries will provide them with the opportunity to select a plan that meets their needs.

CMS is also supporting non-profit community-based organizations and health care organizations that are helping to educate and assist low-income beneficiaries who may otherwise be hard to reach. CMS is working with the Access to Benefits Coalition (ABC), a coalition of almost 100 beneficiary and patient support organizations to target this hard-to-reach population. CMS is also working with Medicare Today, a partnership of nearly 100 major health care organizations, including providers, advocacy entities, plans and employers to inform beneficiaries about the new drug benefit. Medicare Today is a coast-to-coast grassroots effort that is utilizing the capacities of its various member organizations.

CMS is also enhancing existing programs and partnerships in support of the Part D outreach efforts. CMS has enhanced its partnership with the State Health Insurance Assistance Programs (SHIPs) by increasing SHIP funding in 2004 and providing \$31.7 million to SHIPs in 2005, reflecting the increased emphasis on one-on-one, personalized advice and counseling for Medicare beneficiaries. The SHIPs will use the additional funds to equip their local organizations with the tools needed to answer beneficiaries' questions.

CMS is also utilizing its Regional Education About Choices in Health (REACH) Campaign, a nationally coordinated educational and publicity effort implemented on the local level by the Agency's 10 Regional Offices. The REACH campaign disseminates tailored information to the hard to reach populations and special coverage groups in each region. The campaign is already working with community organizations and ensuring that low-income Medicare beneficiaries, including full-benefit dual eligible beneficiaries, who may not have learned about the new benefit and subsidy program because of barriers of location or literacy, know how and where to get their questions answered, receive culturally and linguistically appropriate information, and receive accurate, reliable and relevant information.

Below are some of the activities CMS is undertaking for the Medicare prescription drug coverage program:

- CMS is working closely with health care information intermediaries, providers, partner organizations, federal/state agencies, and health care stakeholders to ensure they have a clear understanding of Medicare prescription drug coverage and their role in educating people with Medicare. CMS is also working with other community-based organizations to disseminate information through informal community grassroots networks such as grocery stores, banks, and churches to raise awareness and support for Medicare prescription drug coverage, and encourage these groups to highlight important Medicare messages in their interactions with people with Medicare and caregivers.
- CMS is conducting ongoing training focused on plans and partners. National webcasts
 focused on plan sponsor education and web-based training targeted at partners will be made
 available on www.cms.hhs.gov. A comprehensive Train-the-Trainer Toolkit has been
 developed for use by those who train others about Medicare prescription drug plans. A
 listserv and teleconferencing help distribute training information and materials to partners.
- Direct mail communicates specific messages at specific times to particular audiences. Both CMS and SSA are sending direct mail letters to people with Medicare. SSA also has mailed low-income subsidy (LIS) applications to potentially eligible people.
- A wide variety and range of publications and print materials provide standard reference
 material targeted to the specific needs and questions of particular kinds of beneficiaries.
 Materials include a direct mailer, targeted and tailored fact sheets and tip sheets, a larger
 consumer booklet, and the Medicare and You Handbook.
- A national multi-media campaign will raise awareness of Medicare prescription drug
 coverage, highlight important messages, direct people to information resources and
 encourage informed enrollment in Medicare prescription drug plans. Paid media options
 under consideration include targeted advertising placements in physician and clinic waiting
 areas in addition to television, radio, newspaper and Internet at the national and/or local
 level.
- The <u>www.medicare.gov</u> website will be a comprehensive resource providing current, accurate, and relevant information that is can be personalized to the needs of individual beneficiaries. Users can compare benefits and pricing of locally available plans, and then enroll in a plan.
- The 1-800 MEDICARE helpline will provide 24 hour-a-day reference and assistance.
 Customer service representatives will answer questions about the benefits and costs of

locally-available drug plans, take orders for consumer publications, mail out low income subsidy (LIS) applications, let beneficiaries know their LIS-eligibility status, and enable beneficiaries to take advantage of all the personal support tools on www.medicare.gov. For beneficiaries who cannot easily go online, these customer service representatives provide another way to help beneficiaries get the information and support they need to compare and enroll in prescription drug plans.

Medicare's partnerships with the SHIPs, the Area Agencies on Aging, and many other public
and private organizations will also provide ways for beneficiaries to get personalized support
in finding out about and choosing a drug plan, through face-to-face, local help.

OIG Suggestion: Distribute regionally tailored letters at the beginning of the new drug benefit

The 2006 Medicare & You Handbook that will be mailed to all Medicare beneficiaries in October provides a wealth of critical information to Medicare beneficiaries about the new drug benefit, including regionally tailored information on the prescription drug plans and Medicare Advantage plans that will be available. This year's Handbook goes even further to help beneficiaries in particular circumstances to understand their options and make appropriate decisions. For instance, the Handbook provides information specifically devoted to beneficiaries with employer or union health coverage, VA benefits, and so forth.

OIG Suggestion: Provide a short guide to choosing a prescription drug plan

We have developed numerous guides – both short and more detailed – to choosing a prescription drug plan. Some of the titles include:

- Your Guide to Medicare Prescription Drug Coverage, (CMS Pub. No. 11109);
- · Introducing Medicare's New Coverage for Prescription Drugs, (CMS Pub. No. 11103);
- The Facts about Medicare Prescription Drug Plans, (CMS Pub. No. 11065); and
- Quick Facts about Medicare's New Coverage for Prescription Drugs (CMS Pub. No. 11102).

In total, more than 30 different publications have been developed, are in process, or are planned.

All of the publications will be available in Spanish, and many of them are also being translated into Chinese (Mandarin), Vietnamese, Korean, Russian, and Tagalog.

Additionally, the Medicare Drug Plan Finder tool will go live on www.medicare.gov in October to provide people with information on plans in their areas so that they can compare and choose one that meets their needs.

OIG Suggestion: Facilitate in-person education

As described at length above, we recognize the importance of in-person education of Medicare beneficiaries. Working with groups such as SHIPs, other federal agencies, community based organizations, and other partners, we have developed a substantial capacity to reach Medicare beneficiaries and help them take advantage of the Part D program.

ACKNOWLEDGMENTS

This report was prepared under the direction of William C. Moran, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Ann Maxwell, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

Susan Otter, Team Leader

Mara Siler-Price, *Program Analyst*

Nicole Lawhorn, Intern

Emily Melnick, Senior Program Analyst

Laura Torres, Program Analyst

Erin Lemire, Program Analyst

Beth Middendorf, Presidential Management Fellow

Tricia Davis, Director, Medicare and Medicaid Branch

Linda Boone Abbott, Program Specialist

Technical Assistance:

Barbara Tedesco, Mathematical Statistician

Kevin Farber, Mathematical Statistician