Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MARKETING MATERIALS FOR MEDICARE PRESCRIPTION DRUG PLANS

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OBJECTIVES

1. To assess the Centers for Medicare & Medicaid Services' (CMS) oversight of marketing materials for stand-alone Medicare prescription drug plans (PDP).

2. To determine the extent to which marketing materials for PDPs meet CMS guidelines.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added voluntary outpatient prescription drug coverage to Medicare. Private health insurance organizations (hereafter referred to as sponsors) contract with CMS to offer PDPs. Sponsors distribute marketing materials, which CMS defines as materials that promote a PDP; provide enrollment information; or explain its benefits, rules, and covered services. Marketing materials include advertisements, comprehensive formularies, enrollment forms, pharmacy directories, and summaries of benefits.

CMS's Medicare Marketing Guidelines (hereafter referred to as the guidelines) specify what marketing materials must include when describing PDP coverage. To help ensure accuracy and expedite the review process for certain marketing materials, CMS created model documents, which are uniform texts that contain pertinent information. CMS also requires PDP sponsors to use standardized language for the summary of benefits. Before PDP sponsors distribute marketing materials, they must submit them to CMS under one of two review processes. Under the standard review process, CMS staff manually review marketing materials. Under the file & use process, CMS staff do not review materials; rather, PDP sponsors attest that the marketing materials comply with CMS guidelines. The guidelines also outline other oversight activities for CMS to monitor marketing materials, such as requiring identification numbers on materials.

We assessed CMS's oversight of PDP materials based on the oversight strategies outlined in its guidelines. We used CMS's guidelines, regulations, responses to oral and written questions, and data from CMS's Health Plan Management System (HPMS) to assess its oversight of the materials. To determine whether marketing materials met CMS's guidelines, we reviewed marketing materials from a stratified simple random sample of 115 PDPs offered in 2007. All estimates in our

report are projectable to the population of PDPs for each type of material. We also reviewed model documents using these same review guides.

FINDINGS

CMS's oversight for PDP marketing materials is limited. CMS promotes its file & use process but did not complete a retrospective review of the 2006 file & use marketing materials until April 2008. Although CMS completed standard reviews of marketing materials on a timely basis, the reviews lack consistency across regions. None of the performance audits that CMS had conducted at the time of our review examined elements pertaining to marketing materials. We were unable to determine whether CMS has conducted marketplace reviews. Additionally, identification numbers from 45 percent of the materials we reviewed failed to match the numbers in the HPMS. Because the identification numbers do not uniformly identify which materials are written in non-English languages or alternative formats, CMS lacks a systematic way to track them.

CMS's model documents are not consistent with its guidelines, resulting in problems with PDP marketing materials. The standardized language for summaries of benefits omits aspects of required information on the low income subsidy; accordingly, nearly all summaries of benefits lack this information. The model enrollment form also lacks key information required by the guidelines. Consequently, almost all enrollment forms fail to include this key information. Most enrollment forms also lack the required statement on the availability of the form in alternative formats, which is also missing on the model enrollment form. In addition, many marketing materials lack hours of operation and phone numbers for deaf persons (TTY/TDD) where model documents omit these elements. Lastly, the guidelines and model documents do not match in other aspects.

Overall, PDP marketing materials did not meet CMS guidelines. Eighty-five percent of marketing materials failed to meet at least one element of CMS's guidelines. These elements reflected the array of requirements in the guidelines, which ranged from details about PDP benefits and rules to requirements for font size for footnotes. In addition to problems with marketing materials that stem from model documents, 79 percent of advertisements with pharmacy cobranding failed to include a required statement that other pharmacies are also available. Forty-two percent of pharmacy directories did not describe

the process for a beneficiary to obtain a prescription if mail order service is delayed, as required. Seventeen percent of comprehensive formularies, which are organized by therapeutic class, failed to include an alphabetical index of drugs, as required, potentially hindering beneficiaries' ability to find information about their drugs.

RECOMMENDATIONS

To improve CMS oversight and ensure that PDPs provide accurate marketing materials, we recommend that CMS:

Revise model documents to ensure consistency between model documents and guidelines. By ensuring that the model materials and the standardized language for summaries of benefits follow CMS guidelines, CMS would provide more accurate guidance to plans and ultimately beneficiaries.

Develop protocols for the review of marketing materials. These protocols would assist CMS's reviewers in ensuring that marketing materials include all required elements.

Conduct and complete more frequent retrospective reviews of file & use materials to monitor these materials. Performing retrospective reviews on a more frequent basis would provide CMS with more timely information to ensure that file & use materials meet the guidelines.

Enforce the use of the current tracking system and enhance it to include an identifier for marketing materials written in non-English languages and alternative formats. These steps would increase CMS's ability to track specific materials, which would help CMS oversee them and respond to complaints about them.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all four of our recommendations. In its comments, CMS noted that it had implemented steps to improve its oversight of marketing materials and identified seven areas for improving the review process for marketing materials.

CMS also noted that it had made corrections to its model enrollment form in June 2007 and had completed its first retrospective review of file & use materials. We amended the report to indicate that CMS had

completed these tasks but that both were outside the period of our review.

In addition, CMS noted that it focuses its review of marketing materials on elements it considers most critical to beneficiary understanding, and not on all elements contained in the guidelines. However, CMS's guidelines do not distinguish between critical and noncritical elements. Therefore, we reviewed marketing materials based on the requirements for each type of material detailed in CMS's marketing and enrollment guidelines.

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2. To determine the extent to which marketing materials for PDPs meet CMS guidelines.

BACKGROUND

Medicare Prescription Drug Plans

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. No. 108-173) added voluntary outpatient prescription drug coverage to Medicare, known as Medicare Part D. Private health insurance organizations (hereafter referred to as sponsors) contract with CMS to offer Part D benefits. Beneficiaries may obtain prescription drug coverage through PDPs or Medicare Advantage-prescription drug plans (MA-PD) that offer integrated coverage for both prescription drugs and other health care. This evaluation focuses on PDPs only.

PDP Marketing Materials

CMS defines marketing materials as informational materials that promote a PDP, provide enrollment information, explain its benefits, describe its rules, explain how services are covered, or communicate with an individual regarding various membership policies, procedures, and rules.[1] Regulations require that materials provide beneficiaries with an "[a]dequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges" and "[a]ny other information necessary to enable beneficiaries to make an informed decision about enrollment."[2] (See Table 1 on page 2 for a description of the selected marketing materials reviewed in this evaluation.)

[1] 42 CFR § 423.50(b).

[2] 42 CFR §§ 423.50(d)(1)(i) & (iii).

TABLE 1
Description of Types of PDP Marketing Materials Reviewed in This Evaluation

Type of Material	Purpose
Advertisements	Used to attract potential enrollees. Includes materials such as newspaper advertisements, marketing posters, and fliers
Summary of Benefits	Provides general information on PDP guidelines and benefits
Comprehensive Formulary	Conveys details about covered drugs and the level of coverage
Enrollment Form	Used by beneficiaries to enroll in PDPs
Pharmacy Directory	Lists pharmacies where enrollees can have their prescriptions filled

Source: CMS Medicare Marketing Guidelines, 2007.

Guidelines for PDP Marketing Materials

The Medicare Marketing Guidelines (hereafter referred to as the Medicare Marketing Guidelines or guidelines) represent "CMS's current, official position on marketing policy and operational instructions" for PDPs.[3] The guidelines include sections on marketing material content, including disclaimers and formatting requirements. They also outline the process for CMS's review of marketing materials.

The guidelines specify the language, definitions, and explanations that marketing materials must include when describing plan coverage. Materials must include some of these elements verbatim. Among these, the guidelines detail specific information for preenrollment and postenrollment materials. Preenrollment materials refer to marketing materials used by beneficiaries before enrolling in a PDP, and postenrollment materials refer to marketing materials that provide information to beneficiaries enrolled in a PDP.

Furthermore, CMS includes additional guidelines for enrollment forms in "PDP Guidance—Eligibility, Enrollment, and Disenrollment" (hereafter referred to as Enrollment Guidelines). The Enrollment Guidelines include statements that the beneficiary consents to upon enrolling in the PDP.[4] The Enrollment Guidelines also provide a list of

[3] CMS, "Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plans, and 1876 Cost Plans" (2nd Revision: July 25, 2006), (hereafter referred to as "Medicare Marketing Guidelines"), p. 1.

[4] CMS, "PDP Guidance—Eligibility, Enrollment, and Disenrollment" (hereafter referred to as "Enrollment Guidelines"), section 30.1. In June 2007, CMS issued a revised version of the Enrollment Guidelines. We reference the version that was available in March 2007 because we used this iteration during our review.

data elements that must be collected to complete the beneficiary's enrollment into the PDP.

Model Marketing Materials

To help ensure accuracy and expedite the review process for certain marketing materials, CMS created model documents, which are uniform texts that contain pertinent information. To qualify for an expedited review, sponsors may modify the model document only with specifics about the individual PDP's benefits and plan information. CMS offers models for the enrollment form, comprehensive formulary, and pharmacy directory, among other types of marketing materials. CMS does not offer models for advertisements.

In addition to offering model documents, CMS requires PDP sponsors to use standardized language for the summary of benefits (hereafter referred to as the standardized SB).[5] Sponsors can automatically generate a standardized SB for their PDPs through CMS's Health Plan Management System (HPMS). The HPMS combines boilerplate language with specific information from a PDP's plan benefit package to create an individual summary of benefits.

In this report, we use the term "model documents" to refer to the available model materials and the standardized SB. We will refer to each individual document specifically when needed throughout the report.

CMS Oversight for Marketing Materials: Review Processes

CMS has two types of review processes, described below. The type of review process for a material depends on the type of material and whether the material uses unmodified model documents (see Figure 1 on page 5).

Standard Review. Under the standard review process, CMS regional office staff manually review PDP marketing materials. The standard review period may be either 10 days or 45 days:

- *10-day standard review period*. Sponsors may submit marketing materials for the 10-day review period if the sponsor uses CMS's model documents and does not modify the language or sequence

[5] CMS, "Medicare Marketing Guidelines," pp. 15 and 35.

used in the model documents (other than specifics about the individual PDP's benefits and plan information).[6]

- *45-day standard review period*. Sponsors must use this period for marketing materials if they modify the language used in model documents or if they do not use model documents for materials.[7]

After the 10- or 45-day period has passed, a sponsor may distribute the material unless CMS notifies the sponsor that it has disapproved the material.[8] Marketing materials that CMS has neither approved nor disapproved by the close of the review period are deemed approved.[9]

File & Use. CMS's file & use certification system (hereafter, referred to as file & use) streamlines the process for PDP sponsors to submit and distribute certain types of materials.[10] Eligible materials include all forms of advertising, pharmacy directories, and formularies, among others.[11] To submit materials as file & use, PDP sponsors may modify the model document only with specifics about the individual PDP's benefits and plan information. Sponsors must attest, when submitting materials, that they comply with the guidelines.[12] Under file & use, PDP sponsors must submit materials to CMS 5 days before disseminating them. CMS regional office staff do not review file & use materials at the time of submission. Rather, CMS reviews the materials retrospectively.

CMS strongly encourages PDP sponsors to use file & use for qualified materials.[13] PDP sponsors may choose to have CMS review marketing materials under the standard review process. However, CMS requires

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[6] CMS, "Medicare Marketing Guidelines," p. 97.

[7] CMS, "Medicare Marketing Guidelines," p. 96.

[8] Ibid.

[9] Ibid.

[10] CMS also offers an additional review process called file & use eligibility, which further streamlines the review of marketing materials. To qualify for this process, PDP sponsors "must have submitted at least eighteen months of reviewable marketing materials," among other criteria. Because Part D had been in existence for fewer than 18 months at the time that we initiated this evaluation, no PDP sponsor was qualified for this process. See CMS, "Medicare Marketing Guidelines," p. 103.

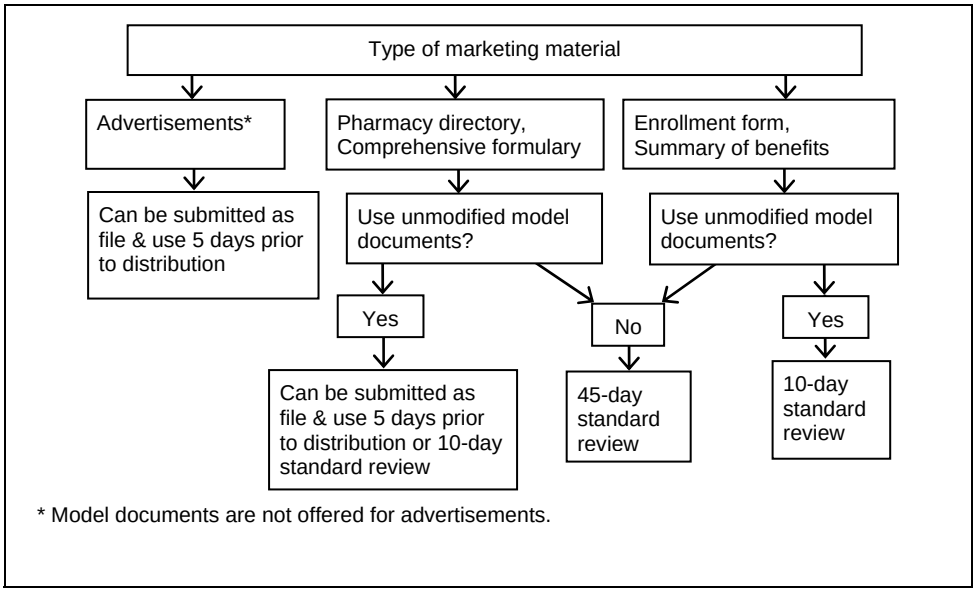
[11] PDP sponsors may provide beneficiaries with either abridged or comprehensive formularies. See CMS, "Medicare Marketing Guidelines," p. 59.

[12] CMS, "Medicare Marketing Guidelines," pp. 100–101.

[13] CMS, "Medicare Marketing Guidelines," p. 98.

PDP sponsors to use file & use for at least 90 percent of materials that qualify for this process.[14]

FIGURE 1
Flow Chart of the Review Process for Selected PDP Marketing Materials



Source: Office of Inspector General analysis of the PDP marketing material review process, 2007.

CMS Oversight for Marketing Materials: Additional Activities

The guidelines outline additional oversight activities used by CMS to monitor marketing materials. These activities include:

Retrospective review. CMS oversees file & use materials through retrospective reviews, which may be conducted semiannually.[15]

Marketplace review. CMS may review marketing materials under three circumstances: use by or in the media; as part of complaint investigations; and during scheduled onsite visits to sponsors for contract compliance monitoring.[16]

Audits. CMS conducts periodic compliance audits of sponsors' operations. CMS's "PDP Sponsor Audit Guide Version 1.0," April 10, 2006 (hereafter referred to as the PDP Sponsor Audit Guide) details the elements that may be covered in the audits. Six elements

[14] CMS, "Medicare Marketing Guidelines," p. 99.

[15] CMS, "Medicare Marketing Guidelines," pp. 98–99.

[16] CMS, "Medicare Marketing Guidelines," p. 109.

within the "Marketing and Beneficiary Information" chapter pertain to marketing materials.[17]

Oversight of materials in other languages and alternative formats. Sponsors that offer marketing materials in non-English languages and alternative formats (such as Braille) must base them on approved marketing materials written in English.[18] After CMS approves the English version of a marketing material, sponsors submit the non-English or alternative format material to CMS along with a letter attesting that the material includes the same content as the English version.[19]

To oversee materials in non-English languages and alternative formats, CMS conducts a verification review of the materials and also reviews these materials on an "as needed basis."[20]

Marketing Material Identification System. CMS requires plan sponsors to include a unique identification number (hereafter referred to as material ID) on each piece of marketing material.[21] The material ID includes the sponsor's contract number, a series of digits of the sponsor's choosing, and the date of its approval, if applicable.[22] The material ID enables CMS to track each piece of marketing material in the marketplace and in the HPMS.

Previous Office of Inspector General Work on Medicare Marketing Materials

In 2000, we found that few approved marketing materials for Medicare + Choice plans were in full compliance with the guidelines and almost half of the materials were not consumer friendly.[23] We recommended that CMS update the marketing guidelines, provide accurate model

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[17] CMS, "PDP Sponsor Audit Guide," Chapter 3. These elements, MR01, 02, 03, 07, 08, and 10, pertain to submission and distribution of marketing materials, file & use marketing materials, requirements for preenrollment materials, marketing materials for significant non-English-speaking populations, marketing to people with disabilities, and requirements for postenrollment materials.

[18] CMS, "Medicare Marketing Guidelines," p. 115.

[19] Ibid.

[20] CMS, "Medicare Marketing Guidelines," p. 93.

[21] CMS, "Medicare Marketing Guidelines," p. 107.

[22] CMS does not require an approval date for file & use materials. See CMS, "Medicare Marketing Guidelines," p. 108.

[23] Department of Health and Human Services (HHS), Office of the Inspector General (OIG), "Medicare Managed Care—1998 Marketing Materials," OEI-03-98-00271, February 2000. Medicare + Choice was the previous name for Medicare Advantage plans.

documents, develop protocols for CMS staff to use when reviewing marketing materials, and track reviews consistently across regions.

In 2005, we found that 39 of 62 marketing materials for the temporary Medicare drug discount card lacked required information.[24] Missing information concerned eligibility, program disclaimers, choice of cards, and comparative drug card information.

In 2006, we found that although marketing materials for Medicare Advantage (MA) plans generally met CMS requirements, materials lacked some required information.[25] The missing information included CMS requirements concerning limitations to prescription drug benefits, most notably language concerning prescription drug formularies.

METHODOLOGY

Scope

We assessed CMS's oversight of PDP materials based on the oversight strategies outlined in its guidelines. We also determined whether five types of marketing materials from a sample of PDPs offered in calendar year 2007 met CMS's guidelines. These materials include selected advertising materials (newspaper advertisements, marketing posters, and fliers), summaries of benefits, comprehensive formularies, enrollment forms, and pharmacy directories. These represent materials that would be used by beneficiaries prior to and after enrolling in a PDP.

Data Sources and Analysis

Our evaluation relied on four sources: CMS marketing guidelines, Enrollment Guidelines, and regulations; information from CMS officials; data from the HPMS; and 2007 PDP marketing materials. We used CMS's guidelines, regulations, responses to oral and written questions, and data from the HPMS to assess its oversight of the materials. We also used the HPMS data to assess timeframes for marketing material reviews and material ID numbers.

[24] HHS, OIG, "Assessment of Sponsors' Materials Under the Temporary Medicare-Approved Drug Discount Card Program," OEI-05-04-00190, October 2005. The temporary Medicare-Approved drug discount card program provided Medicare beneficiaries with access to discounted prescription drugs from June 2004–December 2005 while CMS implemented Medicare Part D.

[25] HHS, OIG, "Medicare Advantage Marketing Materials for Calendar Year 2005," OEI-01-05-00130, August 2006.

To determine whether marketing materials met CMS's guidelines, we reviewed materials from a stratified simple random sample of 115 PDPs. All estimates in our report are projectable to the population of PDPs for each type of material. We created and used review guides based on CMS marketing guidelines and regulations. The review guides divided CMS's guidelines into separate elements for each material. The number of elements in each review guide varied by type of material because the number of specific guidelines varied for each material. We also reviewed model documents using these same review guides.

Lastly, we received training in March 2007 from staff in CMS's New York regional office. This training covered an overview of the marketing guidelines, guidelines for specific types of marketing materials, and the region's process for reviewing marketing materials.

For a detailed methodology, see Appendix A.

Limitations

This study did not assess CMS's oversight of marketing practices, such as tactics used by insurance brokers when enrolling beneficiaries in PDPs and MA plans. Nor did it review the oversight or marketing materials for Special Needs Plans or MA-PDs. We did not assess all requirements in the guidelines because some requirements, such as Internet marketing, were outside the scope of the study. Furthermore, we did not analyze certain elements because we were unable to clearly interpret the guidelines for these elements.

Standards

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

CMS's oversight for PDP marketing materials is limited

CMS's guidelines outline numerous strategies to oversee marketing materials. These include model documents, retrospective reviews of file & use materials, marketplace reviews, audits, use of material ID numbers, and reviews of materials in alternative formats or non-English languages.

CMS promotes file & use but has yet to complete a retrospective review of file & use marketing materials

Sponsors "are strongly encouraged to use file & use for all marketing materials qualified under this process."[26] Indeed, of the materials that sponsors used for calendar year 2007, 53 percent were submitted under file & use.[27]

However, at the time of our review, CMS had not yet completed a retrospective review to determine whether any file & use materials followed the guidelines. In early 2007, CMS began such a retrospective review for file & use marketing materials used in 2006 by both PDPs and MA plans. CMS did not complete this review until April 2008.[28]

CMS may terminate a sponsor's file & use privileges if it determines that the file & use materials do not meet the guidelines.[29] Because CMS did not complete its first retrospective review until April 2008, it was unable to determine whether any sponsors should have their file & use privileges revoked until more than 2 years after Medicare Part D began.

CMS completed standard reviews of marketing materials on a timely basis but those reviews lack consistency across regions

Under CMS's standard review process, CMS regional office staff must review marketing materials within either a 10-day or 45-day timeframe, depending on the material. Reviewers met these timeframes 96 percent of the time for 10-day reviews and 99.7 percent of the time for 45-day

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[26] CMS, "Medicare Marketing Guidelines," p. 98.

[27] OIG analysis of CMS data from PDP marketing material reviews downloaded from the HPMS on November 14, 2007. This figure refers to all types of marketing materials submitted to CMS for PDPs offered in calendar year 2007. The percentage of materials submitted as file & use is based on the number of marketing materials with a status of accepted, approved, deemed, or populated template. This percentage excludes disapproved, pending, or withdrawn materials.

[28] CMS provided OIG with the results of the 2006 retrospective review, dated April 2008, in May 2008.

[29] CMS, "Medicare Marketing Guidelines," p. 100.

reviews.[30] Of the 11,791 materials reviewed, just 47 were not reviewed in the appropriate timeframes and were deemed approved.[31]

Although CMS reviews almost all PDP marketing materials submitted for standard review within the established timeframes, CMS has not reviewed materials consistently. In 2000, an OIG report recommended that CMS use protocols for reviewing marketing materials.[32] However, CMS still lacks standardized protocols for reviewers to follow, even though its staff in nine regional offices review PDP marketing materials. A study completed by a CMS contractor in January 2008 found inconsistencies in the reviews of marketing materials from 2006 and recommended that CMS use protocols to ensure consistent and efficient reviews of marketing materials.[33]

CMS has rarely used audits and marketplace reviews to oversee marketing materials

None of the performance audits that CMS had conducted at the time of our review included audit elements pertaining to marketing materials. When CMS schedules the audits, it selects the chapters from the PDP Sponsor Audit Guide that it will cover. As of September 2007, CMS had conducted 11 audits that reviewed elements from the chapter on Marketing and Beneficiary Information. These audits covered only those elements concerning sales brokers and notifying beneficiaries of formulary changes, but not elements concerning marketing materials.[34]

In addition, even though CMS describes three different types of marketplace reviews in its guidelines, we were unable to determine how many of these reviews it had conducted based on information that CMS officials provided.[35] According to CMS officials, the guidelines included

[30] OIG analysis of CMS data from PDP marketing material reviews downloaded from HPMS on November 14, 2007.

[31] OIG analysis of CMS data from PDP marketing material reviews downloaded from HPMS on November 14, 2007. This figure refers to all types of marketing materials submitted to CMS for PDPs offered in calendar year 2007. Numbers do not include pending or withdrawn materials.

[32] HHS, OIG, "Medicare Managed Care—1998 Marketing Materials," OEI-03-98-00271, February 2000.

[33] CMS, internal study, January 31, 2008.

[34] Audits covered three elements: MR05 - No Engagement in Activities that Mislead, Confuse, or Misrepresent, MR06 - Plan Responsibility for Persons Employed or Contracted to Perform Marketing, MR09 - Provision of Notices Regarding Formulary Changes. Source: Data from audits provided by CMS, September 2007.

[35] CMS, "Medicare Marketing Guidelines," p. 109.

marketplace reviews to show the breadth of options available to oversee marketing materials. However, CMS has yet to implement these options. For example, CMS officials told us that it has not conducted any onsite reviews because "to date there has been no need to do it."[36] Additionally, CMS officials could not identify any instances in which they reviewed marketing materials as a part of complaint investigations.

Even though CMS did not use audits and marketplace reviews to oversee marketing materials, CMS views reports from sponsors that monitor the materials of competing PDPs as an effective method of oversight. CMS officials informed us that monitoring by sponsors helps them to oversee file & use materials, such as advertisements, and told us that "follow through on these complaints [from sponsors] has enabled CMS to further reinforce [its] guidance."[37] However, CMS officials could not provide us with the number or type of complaints received from sponsors monitoring each other.

The tracking system for marketing materials has shortcomings

The guidelines require all marketing materials to include a material ID and state that it "must be entered into HPMS in the same manner that it appears on the material."[38] CMS uses this unique number to track the material and to locate it in the HPMS. CMS officials told us that the material ID enables beneficiaries to identify materials when they have complaints or questions. If CMS is unable to locate the material based on its material ID, it cannot easily access the material for oversight purposes.

Material IDs from 45 percent of the materials we reviewed failed to match material IDs in the HPMS. If the material ID number present on the material does not match the material ID number in the HPMS, CMS cannot readily locate the material. In addition, 21 percent of all material IDs did not follow the proper format (see Table 2 on page 12; also see Appendix B for point estimates and confidence intervals).

[36] CMS, written response to OIG's request for information on oversight of PDP marketing materials, September 20, 2007.

[37] Ibid.

[38] CMS, "Medicare Marketing Guidelines," p. 107.

TABLE 2
Percentage of Material IDs Not Matching the HPMS and Not Following Proper Format

Material	Percentage of Material IDs That Did Not Match Material IDs in the HPMS	Percentage of Material IDs That Did Not Follow Proper Format
Advertisements	42%	14%
Comprehensive Formulary	53%	32%
Enrollment Form	40%	18%
Pharmacy Directory	48%	40%
Summary of Benefits	51%	19%
All materials	**45%**	**21%**

Source: OIG analysis of PDP marketing materials, 2007.

Finally, the material ID system does not uniformly identify which materials are written in non-English languages or alternative formats. CMS does not specify how a plan should indicate a non-English language material or a material in an alternative format. According to CMS officials, some regional offices request that sponsors use a suffix on their material ID numbers to indicate that a material is written in Spanish. Except for these regional offices' requests, CMS lacks a systematic way to track materials in non-English languages or alternative formats.

Without a specific means to identify the materials, CMS is unable to readily identify materials available in non-English and alternative formats. Lacking the ability to easily identify these materials impedes CMS's ability to monitor the content of the materials through a verification review.

CMS's model documents are not consistent with its guidelines, resulting in problems with PDP marketing materials

CMS created model documents to streamline the process for PDP sponsors to create marketing materials and for CMS to review these materials. These model documents include models for the enrollment form, comprehensive formulary, and pharmacy directory, as well as the standardized SB.

Low Income Subsidy information is less comprehensive than required

Beneficiaries with limited income and assets are eligible to receive assistance to pay for the out-of-pocket costs associated with their Medicare Part D coverage through the Low Income Subsidy (LIS).[39] The guidelines

[39] 42 U.S.C. § 1395w-114.

require the summary of benefits to include specific information to help beneficiaries determine whether they qualify for the LIS. This information directs beneficiaries to 1-800-MEDICARE, the Social Security Administration (SSA), or their State Medicaid office.[40] To qualify for the LIS based on income and assets, beneficiaries must apply through SSA or their State Medicaid office.[41]

However, the standardized SB directs beneficiaries to 1-800-MEDICARE only (see Table 3). Consequently, 95 percent of summaries of benefits omit the language in the guidelines directing beneficiaries to SSA or their State Medicaid Office. A 2006 OIG study found that CMS had significant difficulties in identifying beneficiaries who qualify for the LIS.[42] By omitting the two agencies that can determine whether beneficiaries qualify for the LIS based on income and assets, CMS misses an opportunity to convey this information to beneficiaries.

TABLE 3
Comparison of CMS Marketing Guidelines and Standardized SB Language for LIS

Required Language From CMS Marketing Guidelines	Language From CMS's Standardized SB
All Part D plan preenrollment marketing materials detailing eligibility requirements, monthly premiums and other member costs for Part D benefits must include the following language in paragraph or bullet form: "You may be able to get extra help to pay for your prescription drug premiums and costs. To see if you qualify for getting extra help, call: ◆ 1-800-MEDICARE (1-800-633-4227). TTY/TDD users should call 1-877-486-2048, 24 hours a day/7days a week); ◆ The Social Security Administration at 1-800-772-1213 between 7 a.m. and 7 p.m., Monday through Friday. TTY/TDD users should call, 1-800-325-0778; or ◆ Your State Medicaid Office"	"If you qualify for extra help with your Medicare prescription drug plan costs, your premium and costs at the pharmacy will be lower. When you join [PDP name], Medicare will tell us how much extra help you are getting. Then we will let you know the amount you will pay. If you are not getting this extra help you can see if you qualify by calling 1-800-Medicare (1-800-633-4227). TTY/TTD users should call 1-877-486-2048."

Source: CMS Medicare Marketing Guidelines, p. 35, and standardized SB.

[40] CMS, "Medicare Marketing Guidelines," p. 35.

[41] 42 U.S.C. § 1395w-114(a)(3)(B). Beneficiaries who receive full Medicaid benefits, Supplemental Security Income benefits, or who are enrolled in a Medicare Savings Program automatically qualify for the Low Income Subsidy. See CMS, "Medicare & You 2008," p. 76.

[42] HHS, OIG, "Identifying Beneficiaries Eligible for the Medicare Part D Low-Income Subsidy," OEI-03-06-00120, November 2006.

Enrollment information lacks some required elements

According to the Enrollment Guidelines, "[t]he PDP sponsor's enrollment vehicle(s) must include information that the individual acknowledges" when enrolling in a PDP.[43] These acknowledgments include agreeing to follow the rules of the PDP and acknowledging the PDP's appeals process, among others.[44] The absence of this information can result in beneficiaries being unaware of situations that could lead to a lack of coverage or enrollment in the wrong plan.

However, the model enrollment form does not include all of the elements listed in the Enrollment Guidelines, which likely led to their absence in enrollment forms.[45] Most notably, all of the enrollment forms lacked the required information explaining that if the beneficiary enrolls in more than one plan, the last form signed will be the plan to take effect.[46] Further, 88 percent of enrollment forms for calendar year 2007 did not explain that enrollment in a PDP automatically disenrolls the beneficiary from any other PDP, MA plan, or PACE plan in which the beneficiary is enrolled.[47] [48] Likewise, 88 percent of enrollment forms do not explain the expected effective date of enrollment in the PDP.[49]

Additionally, the guidelines require all preenrollment materials to include a statement informing beneficiaries that the PDP contracts with the Federal Government.[50] Yet, this statement is missing on the model enrollment form. Consequently, 69 percent of enrollment forms failed to include this statement.

Alternative format statements are missing

The guidelines require both the enrollment form and the summary of benefits to include a statement that the material is available in

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[43] CMS, "Enrollment Guidelines," section 30.1.

[44] Ibid.

[45] Because we were unable to match all material ID numbers from marketing materials to HPMS data, we cannot determine whether sponsors used CMS's model to create their enrollment forms.

[46] CMS, "Enrollment Guidelines," sections 20 and 30.1.

[47] CMS, "Enrollment Guidelines," section 30.1. PACE stands for Program of All Inclusive Care for the Elderly, which provides both social and medical services for the elderly.

[48] In June 2007, CMS released a revised model enrollment form. The revised model now includes the statement "I can only be in one Medicare prescription drug plan at a time – if I am currently in a Medicare prescription drug plan, my enrollment in <PDP Name> will end that enrollment."

[49] CMS, "Enrollment Guidelines," section 30.1.

[50] CMS, "Medicare Marketing Guidelines," p. 33.

alternative formats, such as Braille or audio tape.[51] However, the model enrollment form lacks this statement, as do 85 percent of enrollment forms. In contrast, the standardized SB includes a statement concerning the availability of alternative formats, and more than 99 percent of summaries of benefits include the statement.

Hours of operation and telephone numbers are missing

Generally, the guidelines require that marketing materials include operating hours and TTY/TDD numbers where all phone numbers are present.[52] These requirements apply to all PDP customer service numbers, as well as to 1-800-MEDICARE. Providing this contact information ensures that beneficiaries with hearing difficulties know how to obtain additional information that they may need.

However, CMS's model documents omit the hours of operation and TTY/TDD phone numbers.[53] Our previous work also identified these same problems with MA marketing materials.[54] Table 4 on page 16 shows that the model enrollment form and the standardized SB did not include the hours of operation for 1-800-MEDICARE in each place where the material listed the number. As a result, 85 percent of enrollment forms for calendar year 2007 and 86 percent of summaries of benefits did not include the hours of operation in all places where 1-800-MEDICARE is listed.

Likewise, the model enrollment form failed to include the Medicare TTY/TDD number in each place where 1-800-MEDICARE is listed, and 37 percent of enrollment forms lacked this number where required. On the other hand, the model comprehensive formulary included TTY/TDD numbers in conjunction with all other telephone numbers and less than 1 percent of comprehensive formularies lacked those numbers.

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[51] CMS, "Medicare Marketing Guidelines," p. 92.

[52] TTY and TDD numbers are telecommunications devices for deaf persons. CMS does not require certain advertisements, such as outdoor advertising, to follow these requirements. See CMS, "Medicare Marketing Guidelines," p. 21.

[53] In June 2007, CMS released a revised model enrollment form. The revised model now includes the hours of operation and TTY/TDD phone number for 1-800-MEDICARE.

[54] HHS, OIG, "Medicare Advantage Marketing Materials for Calendar Year 2005," OEI-01-05-00130, August 2006.

TABLE 4
Comparison of Guidelines, Materials, and Required Information

Guidelines	Type of Material	Included in Model?	Percentage Missing From Marketing Materials
Organizations must also list the hours of operation for 1-800-MEDICARE anytime the organization lists the 1-800-MEDICARE number	Enrollment Form	No	85%
	Summary of Benefits	No	86%
	Comprehensive Formulary	Yes	0%
The Medicare TTY/TDD number must appear in conjunction with 1-800-MEDICARE	Enrollment Form	No	37%
TTY/TDD numbers must appear in conjunction with all other phone numbers	Comprehensive Formulary	Yes	< 1%

Source: OIG review of PDP marketing materials, 2007.

Guidelines and model documents do not match in other aspects

The guidelines require that some preenrollment materials, such as summaries of benefits and enrollment forms, inform beneficiaries who have drug coverage through MA plans that they may not duplicate Medicare drug coverage with PDPs. Those beneficiaries would have to disenroll from their MA plan before enrolling in a PDP. As Table 5 on page 17 shows, the standardized SB language fails to explain this potential duplication in the same detail as the guidelines.

In addition, the standardized SB language assumes that beneficiaries have already determined whether they qualify for the LIS, rather than informing them that they "may be able to get extra help to pay for [their] prescription drug premiums and costs" as required by the guidelines.[55] (See Table 3 on page 13.) Accordingly, 98 percent of summaries of benefits lack that statement. As previously noted, a 2006 OIG study found that CMS had significant difficulties in identifying beneficiaries who qualify for the LIS.[56] By using the language in the standardized SB, CMS misses an opportunity to explicitly convey the availability of the LIS.

[55] CMS, "Medicare Marketing Guidelines," pp. 34–35.

[56] HHS, OIG, "Identifying Beneficiaries Eligible for the Medicare Part D Low-Income Subsidy," OEI-03-06-00120, November 2006.

TABLE 5
Comparison of CMS Marketing Guidelines and Standardized SB Language for Enrollment Information

Required Elements From CMS Marketing Guidelines	Language From CMS's Standardized SB
"If enrolled in an MA coordinated care (HMO or PPO) plan or an MA PFFS plan that includes Medicare prescription drugs, the enrollee may not enroll in a PDP unless they disenroll from the HMO, PPO or MA PFFS plan." "Enrollees in a private fee-for-service plan (PFFS) that does not provide Medicare prescription drug coverage, or an MA Medical Savings Account (MSA) plan may enroll in a PDP. Enrollees in an 1876 Cost plan may enroll in a PDP."	"Eligible individuals may only enroll in one Medicare Prescription Drug Plan at a time and may not be enrolled in a Medicare Advantage Plan (HMO, PPO), unless they are a member of Medicare Private-Fee-For Services plan or are enrolled in an 1876 Cost Plan."

Source: CMS Medicare Marketing Guidelines, p. 37, and standardized SB.

Overall, PDP marketing materials did not consistently meet CMS guidelines

Most marketing materials did not meet all elements of CMS's guidelines. The elements not met comprise the omissions from the model documents, as discussed above, as well as problems with the language created by sponsors. We identified an array of problems that reflect the range of requirements included in the guidelines. This range covers details about PDP benefits and rules to requirements for font size for footnotes. Below, we discuss the extent and nature of these problems.

Most marketing materials did not follow the guidelines for one or more elements

Overall, 85 percent of marketing materials failed to meet at least one element of the guidelines. This includes the aforementioned problems that stem from the model documents, as well as other problems that we found (see Table 6).

TABLE 6
Percentage of PDP Marketing Materials That Fail To Meet CMS Guidelines for One or More Elements

Material	Percentage of Materials Not Following CMS Guidelines for One or More Elements
Enrollment Form	100%
Summary of Benefits	100%
Comprehensive Formulary	96%
Pharmacy Directory	86%
Advertisements	73%
All materials	**85%**

Source: OIG analysis of PDP marketing materials, 2007.

Enrollment forms and summaries of benefits had the highest average percentage of elements that did not meet the guidelines.[57] On average, enrollment forms did not meet 10 of the 60 elements we reviewed, and summaries of benefits did not meet 9 of the 51 elements. CMS identifies these two materials, as well as other materials that do not qualify for file & use, as posing a greater risk to beneficiaries if they contain information "inaccurate in any way."[58] In contrast, comprehensive formularies, pharmacy directories, and advertisements had fewer problems, with an average of one or two elements that did not meet the guidelines (see Table 7; also see Appendix C for ranges of elements not met for each type of material).

TABLE 7
Average Number and Percentage of Elements of CMS Guidelines That PDP Marketing Materials Fail To Meet

Material	Average Number of Elements Not Meeting CMS Guidelines	Number of Elements Reviewed for Each Type of Material	Average Percentage of Elements Not Meeting CMS Guidelines
Enrollment Form	10	60	17%
Summary of Benefits	9	51	18%
Comprehensive Formulary	2	39	5%
Pharmacy Directory	2	27	8%
Advertisements	1	23	5%

Source: OIG analysis of PDP marketing materials, 2007.

Although all elements of the guidelines are important, some can have a greater impact on the accuracy of information disseminated to beneficiaries than others. For example, missing information about obtaining prescriptions at network pharmacies could affect beneficiaries more than footnote placement. Below, we describe three common problems found in PDP marketing materials.

Cobranding requirements were often unmet

CMS defines cobranding as a business relationship between the sponsor of a Medicare plan and another entity, such as a pharmacy.[59] The guidelines require that when cobranding is present on a marketing material, it must note that other pharmacies are available in the

[57] Statistically significant at the 95-percent confidence level in a two-tailed multiple comparison test employing a Bonferroni adjustment.

[58] CMS, "Medicare Marketing Guidelines," p. 99.

[59] CMS, "Medicare Marketing Guidelines," p. 6.

sponsor's network.[60] Yet, 79 percent of advertisements with cobranding did not include this statement. Without this statement, beneficiaries might believe that they may use only those pharmacies whose logos are present on the marketing material.

Processes for mail order delays are frequently missing

The guidelines require that pharmacy directories describe the process for a beneficiary to obtain a prescription if the mail order service is delayed.[61] However, 42 percent of pharmacy directories did not describe this process. Of these, 85 percent stated that the sponsor would call the beneficiaries in the case of a delay rather than informing them of a specific action they could take. This may hinder beneficiaries' ability to obtain prescriptions on time. Additionally, when describing mail order services, 31 percent of pharmacy directories did not include a toll-free number and TTY/TDD number to call with questions as required by the guidelines.[62]

Some indexes required by CMS are missing

Comprehensive formularies must include an alphabetical index that directs the beneficiary to the page containing complete information for a drug. Yet, 17 percent of comprehensive formularies lacked an index. Because the comprehensive formulary organizes all covered drugs by therapeutic class (such as cardiovascular agents), an index may help beneficiaries find information about their drugs. Its omission could hinder beneficiaries' ability to find the appropriate drug.[63]

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[60] CMS, "Medicare Marketing Guidelines," p. 12.

[61] CMS, "Medicare Marketing Guidelines," p. 55.

[62] CMS, "Medicare Marketing Guidelines," p. 56.

[63] CMS, "Medicare Marketing Guidelines," pp. 60–61.

RECOMMENDATIONS

Despite establishing numerous strategies to oversee PDP marketing materials, CMS has conducted limited oversight for these materials. Failure to effectively oversee PDP marketing materials has likely contributed to the problems that we found with the materials. These problems occurred in specific areas, which corresponded largely with discrepancies between CMS's model documents and its guidelines. Information inaccurately conveyed in or omitted from the materials may affect a beneficiary's ability to make an informed decision about enrollment or to access resources, services, or drugs. We also found problems with language created by sponsors.

We recognize that Part D is a new and complex program; however, CMS has had years of experience with the marketing materials for its managed care program. We identified similar problems with marketing materials for Medicare + Choice and MA plans in 2000 and 2006.

To improve CMS oversight and ensure that PDPs provide accurate marketing materials, we recommend that CMS:

Revise model documents to ensure consistency between its model documents and guidelines

This reiterates our recommendation from 2000, when we called for CMS to provide accurate model documents to Medicare + Choice sponsors.[64] By ensuring that the model materials and the standardized SB follow its guidelines, CMS would provide more accurate guidance to plans and ultimately beneficiaries. Since the time of this review, CMS has made some progress toward this end. We recommend that it continue this effort.

Develop protocols for the review of marketing materials

Our 2000 report called for developing standard review instruments for Medicare managed care marketing materials, which CMS has not yet implemented.[65] We continue to recommend that CMS create such protocols to use for the review of all marketing materials. These protocols would assist CMS's reviewers in ensuring that marketing materials include all required elements, such as processes for beneficiaries to follow when using mail-order pharmacies. Additionally,

[64] HHS, OIG, "Medicare Managed Care—1998 Marketing Materials," OEI-03-98-00271, February 2000.

[65] Ibid.

these protocols could be included in the guidelines so that PDP sponsors may use them to ensure their materials include all required elements.

Conduct and complete more frequent retrospective reviews of file & use materials to monitor these materials

In the three cycles of marketing materials since the implementation of the Part D program, CMS had yet to complete quality monitoring activities for file & use materials as of April 1, 2008. Performing retrospective reviews on a more frequent basis (such as the every 6-month timeframe outlined in the guidelines) would provide CMS with more timely information to ensure that file & use materials meet the guidelines.

Enforce the use of the current tracking system and enhance it to include an identifier for marketing materials written in non-English languages and alternative formats

These steps would increase CMS's ability to track specific materials, which would help CMS oversee them and respond to complaints about them. CMS officials told us that the agency will consider developing a system to identify non-English materials. We recommend that the agency proceed with this effort.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all four of our recommendations. In its comments on the draft report, CMS noted that it had implemented steps to improve its oversight of marketing materials and identified seven areas for improving the review process for marketing materials. These areas include developing standardized review protocols, piloting a national retrospective review process, updating model documents to include all requirements from the guidelines, focusing reviews on marketing materials that are most critical to beneficiary understanding, developing checklists for PDP sponsors to use when creating marketing materials, developing electronic attestations of material accuracy, and enhancing HPMS.

CMS also noted that it had made corrections to its model enrollment form in June 2007 and had completed its first retrospective review of file & use materials. We amended the report to indicate that CMS had completed these tasks but that both were outside the period of our review.

In addition, CMS noted that it focuses its review of marketing materials on elements it considers most critical to beneficiary understanding, and not all elements contained in the guidelines. However, CMS's guidelines do not distinguish between critical and noncritical elements. Therefore, we reviewed marketing materials based on the requirements for each type of material detailed in CMS's marketing and enrollment guidelines.

The complete text of CMS's comments can be found in Appendix D.

APPENDIX ~ A

METHODOLOGY

Scope

We assessed the Centers for Medicare & Medicaid Services' (CMS) oversight of Prescription Drug Plan (PDP) materials based on the oversight strategies outlined in its guidelines. We also determined whether five types of marketing materials from a sample of PDPs offered in calendar year 2007 met CMS's guidelines. These materials included selected advertising materials (newspaper advertisements, marketing posters, and fliers), summaries of benefits, comprehensive formularies, enrollment forms, and pharmacy directories. These represent materials that would be used by beneficiaries prior to and after enrolling in a PDP.

Data Sources and Analysis

Our evaluation relied on four sources: CMS guidelines and regulations, information from CMS officials, data from the Health Plan Management System (HPMS), and 2007 PDP marketing materials.

CMS Oversight of Marketing Materials

We assessed CMS's oversight of PDP marketing materials through its guidance, information from CMS officials, and data from the HPMS.

CMS guidelines. We reviewed CMS documents that outline its oversight strategy for marketing materials. These documents included the marketing guidelines, as well as relevant memoranda and guidance CMS issued, the Enrollment Guidelines, and the "PDP Sponsor Audit Guide Version 1.0," April 10, 2006.

Information from CMS officials. To supplement the data analysis, we conducted structured interviews with CMS officials concerning the agency's oversight activities to date. Additionally, in August 2007, we sent a written request to CMS officials regarding details on file & use retrospective reviews, marketplace reviews, audits, and non-English or alternative format materials. In this request, we asked for documents that provided specific details on oversight activities, including their dates, the PDP sponsors examined, and their outcomes.

Data from the HPMS. We obtained data from the HPMS on reviews of marketing materials for calendar year 2007. We used SAS® to match the unique identification number (hereafter referred to as material ID) on the marketing materials we reviewed to the material IDs of

marketing materials reviewed by CMS. We also used SAS® to assess timeframes for marketing material reviews. Additionally, we examined data from the HPMS concerning the scheduling of audits.

Review of Marketing Materials

Sample design. In calendar year 2007, sponsors offered 1,866 PDPs in the 50 States and the District of Columbia. After consulting with other components of the Office of Inspector General (OIG), we reduced the number of PDPs under consideration to 1,763. We stratified the PDPs into two strata based on the total number of PDPs offered by each sponsor. We selected 35 PDPs from the stratum of sponsors offering 4 or fewer PDPs, and 80 from the stratum of sponsors offering more than 4 PDPs (see Table 8 for breakdown of strata).

TABLE 8
Strata Characteristics

Stratum Definitions	Number of Plans in Population	Number of Sponsors in Population	Number of Plans in Sample	Number of Sponsors in Sample
Plans from sponsors offering total of four plans or fewer	92	40	35	25
Plans from sponsors offering total of five or more plans	1,671	25	80	20
Total	**1,763**	**65**	**115**	**45**

Source: OIG collection of PDP marketing materials, 2007.

Marketing materials collection. In April 2007, we contacted the PDPs in our sample and requested the five types of marketing materials listed in the Scope section for each PDP offered in 2007. We received at least one type of marketing material from each of the 115 PDPs in our sample (see Table 9 on page 24). Some sponsors sent multiple materials for a PDP, and we included all of the materials in our review. Each type of material had a different response rate and sample size. We estimated proportions for various characteristics of the materials. We expressed these proportions as percentages and projected them to the population of materials for all plans with an expected absolute precision no greater than 10 percent at the 95-percent confidence level assuming a 90-percent plan response rate.

TABLE 9
Response Rates and Total Number of Materials in Sample

Type of Material	Number of PDPs That Responded	Response Rate	Sample Size of Materials
Summary of Benefits	115	100%	122
Pharmacy Directories	112	97%	144
Comprehensive Formularies	115	100%	122
Enrollment Forms	113	100%*	121
Advertisements	71	84%**	507

*Response rate is based on 113 PDPs because 2 PDP responded that enrollment forms were not produced for calendar year 2007.

**Response rate is based on 85 PDPs because 30 sponsors responded that they did not produce advertisements.

Source: OIG collection of PDP marketing materials, 2007.

Material review. We received training in March 2007 from staff in CMS's New York regional office. This training covered an overview of the marketing guidelines, guidelines for specific types of marketing materials, and the region's process for reviewing marketing materials.

After the training, we developed and used five review guides, one for each type of marketing material. We divided CMS's guidelines into separate elements for each material. The review guides included all requirements for each type of material based on the marketing guidelines and the Enrollment Guidelines. During the course of our review and analysis, we eliminated certain elements because we were unable to clearly interpret the guidelines for these elements.

Four analysts reviewed the marketing materials. We reviewed each type of marketing material three or more times using the elements in the appropriate review guide. We entered the results into a Microsoft Access® database and used SAS® and SAS®-callable SUDAAN to analyze data from this review. During our review process, we performed quality assurance reviews to ensure uniform interpretation of the elements. These analyses included consistency checks by date of review, reviewer, and type of material.

We also reviewed the standardized SB, as well as model documents for the enrollment form, the comprehensive formulary, and the pharmacy directory. We assessed them against the guidelines by using the review guides.

APPENDIX ~ B

Estimates and Confidence Intervals

Estimate Description	Point Estimates	95-Percent Confidence Intervals
Estimates Discussed in Finding 1: Centers for Medicare & Medicaid Services' (CMS) Oversight for PDP Marketing Materials Is Limited		
The unique identification numbers (material IDs) on materials did not match the material ID in the Health Plan Management System (HPMS).	45.4%	40.0%–50.8%
Material IDs did not follow the proper format.	21.1%	14.8%–27.3%
The material ID on the advertisements directory did not match a material ID in the HPMS.	42.3%	36.8%–47.8%
The material ID on the comprehensive formulary did not match a material ID in the HPMS.	53.2%	43.0%–-63.5%
The material ID on the enrollment form did not match a material ID in the HPMS.	39.6%	29.6%–49.7%
The material ID on the pharmacy directory did not match a material ID in the HPMS.	47.7%	36.8%–-58.7%
The material ID on the summary of benefits did not match a material ID in the HPMS.	51.3%	41.1%–61.5%
The material ID on the advertisements did not follow the proper format.	13.8%	7.8%–19.7%
The material ID on the comprehensive formulary did not follow the proper format.	32.4%	22.8%–42.0%
The material ID on the enrollment form did not follow the proper format.	18.4%	10.6%–26.2%
The material ID on the pharmacy directory did not follow the proper format.	39.7%	29.5%–50.1%
The material ID on the summary of benefits did not follow the proper format.	18.8%	11.0%–26.6%
Estimates Discussed in Finding 2: CMS's Model Documents Are Not Consistent With Its Guidelines		
The summary of benefits did not direct the beneficiary to either the State Medicaid agency or Social Security Administration.	94.9%	88.1%–97.9%*
The enrollment form did not include a statement that if the beneficiary enrolls in more than one plan, the last choice will be the one to take effect.	100%	Unable to quantify sampling error because review outcomes for all sample materials were the same
The enrollment form did not explain that enrollment in a PDP automatically disenrolls the beneficiary from any other PDP, MA plan, or Program of All Inclusive Care for the Elderly (PACE) plan.	88.3%	81.5%–95.0%
The enrollment form does not explain the expected date of enrollment in the PDP.	88.0%	81.2%–94.7%
The enrollment form does not state that the PDP contracts with the Federal Government.	69.3%	59.9%–78.7%
The enrollment form did not include the statement that it is available in alternative formats.	84.7%	77.2%–92.3%
The summary of benefits included the statement that it is available in alternative formats.	99.6%	98.9%–99.8%*

* Confidence interval calculated using the logit transformation because of poor coverage properties of the standard approximation method when a small or large number of sample elements possess the characteristic of interest.

Source: Office of Inspector General (OIG) analysis of marketing material reviews, 2007.

Estimates Discussed in Finding 2: CMS's Model Documents Are Not Consistent With Its Guidelines (continued)		
Estimate Description	**Point Estimates**	**95-Percent Confidence Intervals**
The enrollment form did not include hours of operation with 1-800-MEDICARE in all places.	84.6%	77.0%–92.1%
The summary of benefits did not include hours of operation with 1-800-MEDICARE in all places.	86.4%	79.3%–93.4%
The enrollment form did not include a TTY/TDD number in conjunction with all 1-800-MEDICARE appearances.	37.5%**	27.7%–47.3%
The comprehensive formulary did not include a TTY/TDD number in conjunction with all customer service number appearances.	0.1%	0.03%–0.7%*
The comprehensive formulary did not include hours of operation with 1-800-MEDICARE in all places.	0%	Unable to quantify sampling error because review outcomes for all sample materials were the same
"You may be able to get extra help to pay for your prescription drug premiums and costs" was not included in the summary of benefits.	98.4%	93.5%–99.6%*
Estimates Discussed in Finding 3: PDP Marketing Materials Did Not Consistently Meet CMS Guidelines		
Materials had at least one element that did not meet the guidelines.	85.1%	82.0%–88.2%
The enrollment form had at least one element that did not meet the guidelines.	100%	Unable to quantify sampling error because review outcomes for all sample materials were the same
The summary of benefits had at least one element that did not meet the guidelines.	100%	Unable to quantify sampling error because review outcomes for all sample materials were the same
The comprehensive formulary had at least one element that did not meet the guidelines.	96.5%**	89.8%–98.9%*
The pharmacy directory had at least one element that did not meet the guidelines.	86.2%	79.2%–93.2%
The advertisements had at least one element that did not meet the guidelines.	72.9%	66.9%–78.9%
The mean number of elements that did not meet the guidelines for the enrollment form.	10.2	9.7–10.8
The mean number of elements that did not meet the guidelines for summary of benefits.	9.0	8.7–9.3
The mean number of elements that did not meet the guidelines for the comprehensive formulary.	2.0	1.9–2.2
The mean number of elements that did not meet the guidelines for the pharmacy directory.	2.2	1.8–2.5

* Confidence interval calculated using the logit transformation because of poor coverage properties of the standard approximation method when a small or large number of sample elements possess the characteristic of interest.

**Number is not the same as in the text because of rounding.

Source: OIG analysis of PDP marketing material reviews, 2007.

Estimates Discussed in Finding 3: PDP Marketing Materials Did Not Consistently Meet CMS Guidelines (continued)

Estimate Description	Point Estimates	95-Percent Confidence Intervals
The mean number of elements that did not meet the guidelines for advertisements.	1.1	1.0–1.3
The average percent of elements not meeting the guidelines for enrollment forms.	17.0%	16.1%–17.9%
The average percent of elements not meeting the guidelines for summaries of benefits.	17.7%	17.1%–18.3%
The average percent of elements not meeting the guidelines for comprehensive formularies.	5.2%	4.8%–5.7%
The average percent of elements not meeting the guidelines for pharmacy directories.	8.1%	6.8%–9.3%
The average percent of elements not meeting the guidelines for advertisements.	4.9%	4.3%–5.5%
Where cobranding was present on the advertisement, the advertisement did not include the statement "<Other Pharmacies/Physicians/Providers> are available in our network."	79.2%	72.5%–85.9%
The pharmacy directory did not include the process for beneficiaries to follow if their mail order prescription was delayed.	41.6%	31.0%–52.2%
Where the pharmacy directory did not include the process for beneficiaries to follow if their prescription was delayed, it stated that the sponsor will call the beneficiary.	85.2%	74.3%–96.2%
The mail order section in the pharmacy directory did not include a toll-free number and a TTY/TDD number.	31.3%	21.6%–41.0%
The comprehensive formulary did not contain an index.	16.6%	8.8%–24.3%

Source: OIG analysis of PDP marketing material reviews, 2007.

APPENDIX ~ C

Number of Elements Not Meeting the Centers for Medicare & Medicaid Services' Guidelines in Each Type of Marketing Material

TABLE 10
Number of Elements That Did Not Meet Guidelines for Enrollment Form

Number of Elements Not Met	Percentage of Enrollment Forms	95-Percent Confidence Intervals
0-4	0%	Unable to quantify sampling error because review outcomes for all sample materials were the same
5	11.7%	5.0%–18.5%
6-7	0%	Unable to quantify sampling error because review outcomes for all sample materials were the same
8	0.9%	0.3%–2.6%*
9	21.9%	13.3%–30.4%
10	30.7%	21.2%–40.2%
11	1.9%	0.6%–6.3%*
12	12.0%	5.6%–18.5%
13	5.0%	0.5%–9.5%
14	15.9%	8.3%–23.4%

* Confidence interval calculated using the logit transformation because of poor coverage properties of the standard approximation method when a small number of sample elements possess the characteristic of interest.
Source: Office of Inspector General (OIG) analysis of Prescription Drug Plan (PDP) marketing materials, 2007. Based on 60 elements.

TABLE 11
Number of Elements That Did Not Meet Guidelines for Summary of Benefits

Number of Elements Not Met	Percentage of Summaries of Benefits	95-Percent Confidence Intervals
0-3	0%	Unable to quantify sampling error because review outcomes for all sample materials were the same
4	1.2%	0.2%–7.7%*
5	0.3%	0.1%–0.9%*
6	1.2%	0.2%–7.7%*
7	12.6%	5.8%–19.4%
8	15.0%	7.6%–22.2%
9	39.1%	29.1%–49.1%
10	15.5%	8.2%–22.9%
11	7.2%	1.8%–12.6%
12	7.2%	1.8%–12.6%
13	0.6%	0.3%–1.2%*
14-17	0%	Unable to quantify sampling error because review outcomes for all sample materials were the same
18	0.2%	0.03%–0.7%*

* Confidence interval calculated using the logit transformation because of poor coverage properties of the standard approximation method when a small number of sample elements possess the characteristic of interest.
Source: OIG analysis of PDP marketing materials, 2007. Based on 51 elements.

TABLE 12
Number of Elements That Did Not Meet Guidelines for Comprehensive Formulary

Number of Elements Not Met	Percentage of Comprehensive Formularies	95-Percent Confidence Intervals
0	3.5%	1.2%–10.3%*
1	25.2%	16.4%–34.1%
2	37.8%	28.0%–47.8%
3	32.4%	22.7%–42.1%
4	0.9%	0.5%–1.6%*
5-13	0%	Unable to quantify sampling error because review outcomes for all sample materials were the same
14	0.2%	0.03%–0.7%*

* Confidence interval calculated using the logit transformation because of poor coverage properties of the standard approximation method when a small number of sample elements posses the characteristic of interest.
Source: OIG analysis of PDP marketing materials, 2007. Based on 39 elements.

TABLE 13
Number of Elements That Did Not Meet Guidelines for Pharmacy Directory

Number of Elements Not Met	Percentage of Pharmacy Directories	95-Percent Confidence Intervals
0	13.8%	6.8%–20.8%
1	30.1%	20.4%–39.8%
2	11.5%	5.5%–17.5%
3	18.3%	10.7%–25.9%
4	24.5%	14.7%–34.4%
5	0.1%	0.03%–0.7%*
6	0.6%	0.2%–1.4%*
7	1.1%	0.2%–7.3%*

* Confidence interval calculated using the logit transformation because of poor coverage properties of the standard approximation method when a small number of sample elements posses the characteristic of interest.
Source: OIG analysis of PDP marketing materials, 2007. Based on 27 elements.

TABLE 14
Number of Elements That Did Not Meet Guidelines for Advertisements

Number of Elements Not Met	Percentage of Advertisements	95-Percent Confidence Intervals
0	27.1%	21.1%–33.0%
1	37.2%	33.5%–40.9%
2	32.8%	24.9%–40.8%
3	2.0%	1.0 % –4.3%*
4	0.4%	0.2 %–0.8%*
5	0.3%	0.1 %–2.5% *

* Confidence interval calculated using the logit transformation because of poor coverage properties of the standard approximation method when a small number of sample elements posses the characteristic of interest.
Source: OIG analysis of PDP marketing materials, 2007. Based on 23 elements.

APPENDIX ~ D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 23 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Marketing Materials for Medicare Prescription Drug Plans" (OEI-01-06-00050)

Thank you for the opportunity to review and comment on this OIG draft report to (1) assess the Centers for Medicare & Medicaid Services (CMS) oversight of marketing materials for stand-alone Medicare Prescription Drug Plans (PDPs) and (2) determine the extent to which marketing materials for PDPs meet CMS guidelines.

The CMS is committed to ensuring that Medicare beneficiaries are provided timely and accurate information about the Medicare Prescription Drug Benefit program. However, this study only examined the marketing material review process that was underway in 2007. Even before 2007, CMS was examining its own processes and systems to determine how to improve the consistency and quality of its reviews and monitoring. CMS continues to refine the review and approval processes of marketing and beneficiary material developed and distributed by plan sponsors as well as continuing to improve its oversight of plan marketing.

The CMS has implemented a number of additional steps to improve its oversight of marketing materials. These steps include identifying required elements in the Medicare Marketing Guidelines that must be contained in plan-developed materials to improve the operational efficiency of plan oversight in addition to other elements that are critical to ensuring that beneficiaries understand the plan benefits and operations. While CMS considers all of these requirements important, oversight and review is focused on the requirements that are most critical to beneficiary understanding (i.e., if incorrect they could lead to a misunderstanding by the beneficiary).

The CMS has also examined its marketing processes and products to identify areas for improvement that would result in a more effective and efficient marketing review process. These improvements include:

1. Developing standardized review protocols for reviewers,
2. Piloting a process for national retrospective review of file & use materials,

3. Updating current model documents to include all marketing requirements contained in the Medicare Marketing Guidelines,
4. Focusing marketing reviews on those marketing materials that are most critical in ensuring beneficiaries understand the information provided to them,
5. Developing checklists for plans to use when developing specific marketing material to improve compliance,
6. Developing an electronic attestation of the accuracy of marketing material in the submission system and
7. Making improvements and updates to the Health Plan Management System (HPMS) to accommodate specific needs for tracking and monitoring marketing materials.

The CMS continues to refine and improve its oversight efforts as part of its ongoing goal to ensure that beneficiaries receive reliable information from their health and drug plans.

Finally, CMS concurs with many of the report's recommendations. CMS believes that many of the issues reported in the OIG study are not atypical during the initial start-up of a new program and have begun to put in place necessary safeguards to ensure that marketing materials are reviewed consistently and in compliance with CMS guidance. CMS' comments on this report follow.

OIG Recommendation

The OIG recommends that CMS revise model documents to ensure consistency between model documents and guidelines.

CMS Response

The CMS concurs with this recommendation. In early 2008, CMS completed a study of the consistency of marketing reviews among reviewers. One of the study findings revealed that some of the model marketing materials developed by CMS were not consistent with requirements in the marketing guidelines. Based on this finding, CMS identified models that were inconsistent with the guidelines and updated them to make them consistent.

OIG Recommendation

The OIG recommends that CMS develop protocols for the review of marketing materials.

CMS Response

The CMS concurs with this recommendation. Based on the findings of CMS' consistency study, it has developed review protocols to assist reviewers in ensuring the consistency of marketing reviews among them. While these protocols do not include all of the elements contained in the guidelines, they do capture the elements that CMS considers most critical to beneficiary understanding of plan benefits and operations. In addition, CMS is developing checklists for organizations to use to ensure that they have developed materials that include the required elements.

OIG Recommendation

The OIG recommends that CMS conduct and complete more frequent retrospective reviews of file & use materials to monitor these materials.

CMS Response

The CMS concurs with this recommendation. Due to increasing demand on review staff and limited staff resources, CMS is reexamining its monitoring process of the file & use certification process. Prior to 2006, the Regional Offices conducted their own file & use retrospective reviews which they continue to do today. In 2006, the dramatic increase in marketing materials received by CMS signaled a new program management challenge for CMS; the number of materials received exceeds the capacity of the CMS staff to review them. This was the motivation for CMS to implement a national file & use retrospective review. CMS has completed its first national retrospective review and is conducting its second. Additionally, CMS is developing its standard operating procedure for future reviews.

OIG Recommendation

The OIG recommends that CMS enforce the use of the current tracking system and enhance it to include an identifier for marketing materials written in non-English languages and alternative formats.

CMS Response

The CMS concurs with this recommendation. CMS believes that the current tracking system is used by sponsors as intended and does not require any additional enforcement. There are a number of required elements listed in the Medicare Marketing Guidelines that must be contained in a marketing material. Some of these required elements are purely for our internal, operational efficiency, while others are critical to beneficiary understanding of plan benefits and operations. While we consider all of these requirements important, we focus our reviews on the requirements that are most critical to beneficiary understanding (i.e., if incorrect they could lead to a misunderstanding by the beneficiary). The Material ID is a requirement that has no meaning to a beneficiary. It is a mechanism by which CMS may access materials in our system quickly.

It is our understanding that the OIG could not locate some documents in the Health Plan Management System (HPMS) when they entered the Material ID into the search criteria. We have had similar experiences while conducting our own reviews. However, with the assistance of the staff that manages HPMS, we were able to find all of the materials in question. These materials had the correct Material IDs, but the system did not pull them into the search. We will continue to enhance HPMS to improve its usability and efficiency.

We share the OIG's concerns about the identification in HPMS of non-English materials and materials in alternative formats. We have enhanced HPMS for 2009 to include a flag for materials in alternative formats including non-English materials. We have also conducted industry training on how to use this new indicator.

Other Comments

Page ii Findings, and page 9, paragraph 2 -- The first finding states that CMS "has yet to complete a retrospective review…." The Regional Offices have conducted (and continue to conduct) retrospective reviews of file & use materials since file & use came into existence under Medicare+Choice. At the time this OIG study was conducted, CMS was implementing a national file & use retrospective review in which a national sample of materials would be reviewed by a smaller number of reviewers. The intent was to pilot a process that achieved efficiencies without compromising integrity. The results of CMS' 2006 File & Use Retrospective Review were released to OIG in May 2008.

Page ii Findings, and page 11, paragraph 4 -- Also, there is a discrepancy about the matching of ID numbers in the system with hardcopies of materials in the marketplace. CMS is aware that there are cases in which it is difficult to retrieve materials from the system using ID numbers. However, CMS believes that all documents submitted in the system can be found with some assistance from the HPMS staff.

Page ii Findings, and page 12, paragraph 3-- The second finding incorrectly identifies the summary of benefits (SB) as a model. It is a standardized document. A standardized document is mandatory and cannot be modified in any way that is not allowed within the document (i.e., variable or plan specific information). While CMS will consider the comments regarding the consistency between the guidelines and the SB, the guidelines were developed for materials that sponsors create. Since standardized documents are created by CMS, they are related differently to the guidelines.

Page ii Findings, and page 17, paragraph 2 -- The third finding relates to the correspondence of the marketing guidelines elements to the elements in the actual marketing materials reviewed. CMS focuses its reviews on the most critical elements contained in the guidelines. CMS defines its critical elements as those that could have a negative impact on beneficiary understanding if they are missing, incorrect, or inaccurate.

Page 15, paragraph 2 -- The report states that the model enrollment form failed to include the hours of operation and TTY/TDD phone numbers for 1-800-MEDICARE. However, the report should note that CMS corrected this error in the model enrollment form included in revised guidance published in June 2007.

Page 14, paragraph 2 -- The report states that the model enrollment form does not include all of the elements listed in the enrollment guidelines. More specifically, the report states that: "Further, 88 percent of enrollment forms did not explain that enrollment in a PDP automatically disenrolls the beneficiary from any other PDP, Medicare Advantage (MA) plan, or PACE plan in which the beneficiary is enrolled." CMS revised its model enrollment form in June 2007 to include the following statement in the acknowledgement section of the form:

> I can only be in one Medicare prescription drug plan at a time – if I am currently in a Medicare prescription drug plan, my enrollment in <PDP Name> will end that enrollment.

In addition, elsewhere in the current model form, beneficiaries are advised of the consequences of enrolling in PDP, if they are currently in a Medicare Advantage plan, as shown below:

> If you are a member of a Medicare Advantage Plan (like an HMO or PPO), you may already have a prescription drug benefit from your Medicare Advantage plan that will meet your needs. By joining <PDP name>, your membership in your Medicare Advantage plan may end. This will affect both your doctor and hospital coverage as well as your prescription drug benefits. Read the information that your Medicare Advantage plan sends you and if you have questions, contact your Medicare Advantage plan.

This language is specifically highlighted for beneficiaries in a separate, bordered box with a "Stop Sign" icon and the bolded heading, "Please Read This Important Information." While this language does not use the exact terminology cited in the report above, it provides a more thorough explanation of the possibility of disenrollment from the MA plan, and the consequences of such an action, and has been prominently placed on the form. Therefore, we ask that the Report acknowledge that the current model form does address, at least in part, one of the discrepancies cited by the OIG.

Page 17, Table 6: Percentage of PDP Marketing Materials that Fail to Meet CMS Guidelines for One or More Elements – Table 7: Average Number and Percentage of Elements of CMS Guidelines That PDP Marketing Materials Fail to Meet, provides more detail and context and much more accurately coveys the key point the OIG is attempting to make. We recommend removing Table 6 from the report.

Page 20, Recommendations – The recommendations section makes several references that the OIG identified "problems" with the reviewed materials. We recommend OIG use "deficiencies" rather than "problems" since it is difficult to measure if the cited deficiencies have actually led to problems for Medicare beneficiaries.

Page 20, Paragraph 1 - The OIG indicates they "found problems with language created by sponsors," however; we were unable to identify any findings in the report that support this statement. Therefore, we recommend removing this reference.

Again, we appreciate the opportunity to review and comment on this draft correspondence.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce M. Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Russell W. Hereford, Deputy Regional Inspector General.

Maria Maddaloni served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Boston regional office who contributed to the report include Bailey G. Orshan and Robyn Sterling; central office staff who contributed include Linda B. Abbott, Kevin Farber, Sandy Khoury, and Megan Ruhnke.