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Report to the Chairman, Committee on Energy and Commerce, House of Representatives

December 2008

MEDICARE PART D

Opportunities Exist for Improving Information Sent to Enrollees and Scheduling the Annual Election Period

GAO-09-4

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Highlights

Highlights of GAO-09-4, a report to the Chairman, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In Medicare Part D, enrollees in stand-alone prescription drug plans (PDPs) are allowed to switch plans during an annual coordinated election period (AEP) set under law from November 15 to December 31, with new coverage effective January 1. The Centers for Medicare & Medicaid Services (CMS) required that plan sponsors send an Annual Notice of Change (ANOC)—using either its model or a nonmodel format—before the 2008 AEP. Among other things, GAO examined: (1) stakeholders' views of the model ANOC and CMS's efforts to assure its effectiveness, and (2) how the scheduling of the AEP affects the enrollment process for beneficiaries switching PDPs. Among the largest PDP sponsors, we selected eight to interview along with other stakeholders involved in the AEP. We also obtained and analyzed data from CMS.

What GAO Recommends

To improve the AEP, GAO recommends that CMS strengthen its evaluation of its model materials by reviewing alternative formats to communicate plan changes. Additionally, Congress should consider authorizing the Secretary of Health and Human Services to amend the AEP schedule to include a processing interval between the end of the AEP and the effective date of new coverage. In commenting on our draft, CMS stated that it concurs with our recommendation and will consider reviewing other ANOC formats.

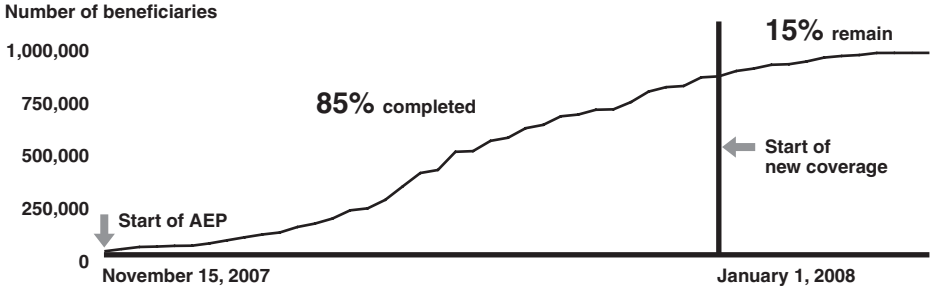
To view the full product, including the scope and methodology, click on GAO-09-4.
For more information, contact Kathleen King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

Sponsors, pharmacists, beneficiary advocates, and counselors GAO interviewed expressed concern that CMS's model ANOC for the 2008 AEP did not effectively communicate drug plan changes to enrollees. They noted that it contained language at a reading level too high for some beneficiaries as well as too much, often irrelevant, information. To help ensure their enrollees understood how plan changes would affect them personally, two study sponsors mailed additional information detailing specific changes in coverage and costs for drugs the beneficiary took in the past year. Despite GAO's previous recommendation that CMS ensure that its Part D materials meet communications guidelines, CMS's process for developing its model ANOC did not include a systematic evaluation of its effectiveness. However, CMS officials reported that they recently initiated an evaluation of their annual Medicare beneficiary materials for the 2010 AEP that will examine reading levels, effectiveness, and length, among other factors. Such an evaluation is important in light of changes CMS has made for the 2009 AEP, which have raised further concerns among stakeholders. It is unclear whether alternative formats for communicating plan changes to beneficiaries will be considered.

Although CMS and plan sponsors made improvements to the enrollment process, CMS data showed that about 15 percent of beneficiaries who chose to switch plans in the 2008 AEP were not fully enrolled in their new plan by January 1. Modifications to the enrollment process for the 2008 AEP reduced the time needed to enroll beneficiaries in a new plan to a median of 5 days. However, the volume of applications submitted late in the AEP contributed to beneficiaries being at risk of not having access to their new coverage by January 1. In fact, among the beneficiaries who submitted applications after December 15, 40 percent were not completely processed until after the effective date of their new coverage. As a result, stakeholders reported that beneficiaries, pharmacies, and sponsors faced various operational challenges, including the risk of inaccurate charges and additional administrative burden. Some stakeholders we interviewed for our study said that creating an interval for enrollment processing between the end of the AEP and the effective date of coverage would help ensure that beneficiaries switching plans would have their coverage in place on January 1.

Enrollments Completed during and after the 2008 AEP



Source: GAO analysis of CMS data.

Contents

Abbreviations

AEP	annual coordinated election period
ANOC	Annual Notice of Change
CMS	Centers for Medicare & Medicaid Services
EOB	Explanation of Benefits
EOC	Evidence of Coverage
FEHBP	Federal Employees Health Benefits Program
MA	Medicare Advantage
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
PDP	prescription drug plans
SB	Summary of Benefits
SHIP	State Health Insurance Assistance Program
SSA	Social Security Administration
TRR	Transaction Reply Reports

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United States Government Accountability Office
Washington, DC 20548

December 12, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established an outpatient drug benefit, known as Medicare Part D, that provides prescription drug coverage for beneficiaries who opt to enroll in the program.[1] Congress designed Medicare Part D to be a market-driven program which promotes competition among private health plans. Of the roughly 25 million beneficiaries enrolled in Part D as of January 2008, about 17 million beneficiaries—those in traditional Medicare—received coverage through stand-alone prescription drug plans (PDPs).[2] PDPs are offered by private entities, known as drug plan sponsors, that contract with the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program within the Department of Health and Human Services (HHS). In its administration of Part D, CMS is responsible for implementing program requirements and overseeing plan sponsors' compliance with these requirements.

[1]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (2003) (codified, as amended, at 42 U.S.C. §§ 1395w-101—1395w-152).

[2]Part D drug coverage also may be provided through Medicare Advantage (MA) plans. MA plans are Medicare's private health plan option, providing coverage of benefits beyond prescription drugs. As of January 2008, about 8 million beneficiaries were enrolled in MA plans that provide drug coverage.

Generally, beneficiaries enrolled in PDPs are only allowed to change their drug plan during the Part D annual coordinated election period (AEP).[3] As required under federal law, the AEP runs from November 15 to December 31, with drug coverage under the elected new plan effective on January 1 of the next year.[4] In considering their options, beneficiaries may have a choice of more than 50 PDPs in the state where they live. Plans differ, for example, in the particular drugs covered, monthly premiums, or copayments beneficiaries are responsible for paying.

Beneficiaries may consider changing their PDP plan for a variety of reasons, including changes in their health and prescription drug needs or modifications by their plan. Generally, sponsors make changes to benefits offered by their plans effective at the beginning of each benefit year.[5] After the opportunity to change plans during the AEP, most beneficiaries enrolled in PDPs are locked into their plan for the benefit year. Thus, beneficiaries should determine whether drugs they previously used will continue to be covered, have increased copayments, or have any new access requirements in the next benefit year. In light of these types of changes, and without the opportunity to switch plans until the next AEP, it is important that enrollees evaluate whether their drug plans will continue to meet their needs. To this end, it is essential that CMS ensure that information sent to enrollees by plan sponsors prior to the AEP clearly and effectively communicates plan changes.

To inform enrollees about their benefits for the coming year, CMS requires that sponsors mail enrollees an Annual Notice of Change (ANOC) for receipt by October 31. This document describes modifications to the plan's

[3]Some beneficiaries may change PDPs at other times throughout the year during special enrollment periods approved by CMS. For example, beneficiaries may enroll in a new plan if they move to areas not served by their plan. Beneficiaries who are eligible for both Medicare and Medicaid—a joint federal-state program that covers certain low-income individuals—known as full-benefit dual-eligibles may change drug plans throughout the year. Dual-eligible beneficiaries generally qualify for low-income subsidies that cover premiums and most of their out-of-pocket costs for Part D drugs. If CMS assigned a dual-eligible beneficiary to a PDP and that PDP, based on its bid for the ensuing year, would impose a premium on the beneficiary, CMS will reassign the beneficiary during the AEP to a different PDP in which the beneficiary will have no premium liability. In 2008, CMS reassigned about 2 million dual-eligible beneficiaries.

[4]42 U.S.C. §§ 1395w-21(e)(3), (f)(3), 1395w-101(b).

[5]Each year, plan sponsors must submit bids, including any changes to formularies and plan benefit designs, to CMS. Sponsors must receive approval from CMS prior to implementing these changes for the next benefit year.

premium, drug coverage, cost sharing, and other features for the next benefit year. For the 2008 AEP that began November 15, 2007, sponsors could either adopt the model ANOC provided by CMS or create a nonmodel ANOC that included elements required by CMS that describe plan modifications.[6] Nonmodel ANOCs were subject to a longer review period by CMS. The agency also required that sponsors mail enrollees an Evidence of Coverage (EOC) document, which details enrollees' benefits, rights, and responsibilities under a plan, for receipt by January 31, 2008. For the 2009 AEP starting November 15, 2008, sponsors must use CMS's standardized ANOC and EOC, mailed together, so that enrollees receive them by October 31, 2008. Sponsors no longer have the option to use non-model materials.

CMS's schedule provides beneficiaries with at least 2 weeks to review the ANOC prior to November 15—the first day plans can accept AEP enrollments. In addition, for the 2008 AEP CMS advised beneficiaries opting to change plans to do so by December 7—3 weeks prior to the official December 31 end date for the AEP. CMS recommended that beneficiaries apply to switch plans by early December to avoid potential problems in January, such as late or missing membership cards or inaccurate copayment charges that may result if their applications were not fully processed prior to January 1, 2008, the effective date of coverage.

Despite the potential for cost increases or changes in drug coverage from year to year, the vast majority of enrollees do not switch their drug plans. In the 2008 AEP, about 1 million beneficiaries initiated a change from one PDP to another. You expressed concern about how beneficiaries are notified of plan benefit changes for the AEP. In this report, we reviewed the notices sent to enrollees as well as the enrollment process for those opting to switch between drug plans. Specifically, we examined: (1) sponsors' timeliness in mailing the ANOC for the 2008 AEP and the use of CMS's model, (2) stakeholders' views of CMS's model ANOCs and the extent to which the agency assures that they effectively communicate plan changes to beneficiaries, and (3) how the scheduling of the AEP affects the enrollment process for beneficiaries choosing to switch plans.

[6]Required elements include how the monthly premium will change, how drug coverage and cost sharing will change, what to do if a drug the beneficiary uses will no longer be on the formulary or will have higher cost sharing, and how to change plans.

To address these issues, we obtained information on the practices and experiences of sponsors, pharmacies, beneficiary advocates, and Medicare counselors during the 2008 AEP. We interviewed representatives from eight sponsors, each with 100,000 or more non-dual-eligible PDP enrollees as of November 2007, which together accounted for about 70 percent of all non-dual-eligible PDP beneficiaries.[7] Additionally, we spoke to associations representing pharmacists, pharmacy benefit management companies, and health plans. We also interviewed counselors who assist Medicare beneficiaries through the State Health Insurance Assistance Programs (SHIPs) in California, Texas, Florida, and New York, which were among the states with the largest number of PDP enrollees. Because we used selective samples of sponsors and SHIPs, our conclusions cannot be generalized to all PDP sponsors or SHIPs.

We reviewed CMS's 2008 AEP "Readiness Checklist", which contains sponsor-reported information on compliance with ANOC mailing requirements, to determine PDP sponsors' timeliness. We also obtained sample ANOCs from our study sponsors along with templates of any supplementary documents addressing plan benefit changes that our study sponsors disseminated between September and December 2007. In addition, we asked sponsors and other stakeholders about their perspectives on CMS's 2008 and proposed 2009 AEP requirements, and reviewed their formal comments submitted to CMS. To learn about CMS's process for developing and evaluating ANOCs, we interviewed CMS officials responsible for beneficiary materials related to the AEP. We also reviewed previous GAO work on CMS's Part D communications and relevant literature on principles of effective communication with Medicare beneficiaries. To examine the effect of the AEP schedule on the enrollment process, we obtained CMS data on PDP beneficiaries who initiated a switch to another PDP during the 2008 AEP, including beneficiary application dates, as reported by PDP sponsors, and the CMS processing dates for enrollees changing plans. To assess the reliability of these data, we interviewed CMS officials responsible for the collection and analysis of the data, and we determined that the data were sufficiently reliable for purposes of this report.

[7]We excluded dual-eligible beneficiaries from our analysis because full-benefit dual-eligibles have the opportunity to change their Part D plans throughout the year. We also excluded beneficiaries enrolled in MA drug plans because, in addition to changes made during the AEP, these beneficiaries may change their plans once between January 1 and March 31 each year. In addition, we excluded beneficiaries enrolled in PDPs that are sponsored by employer or union groups.

We conducted this performance audit from October 2007 through October 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

For the 2008 AEP, PDP sponsors were timely in providing ANOCs to nearly all enrollees by October 31, 2007. CMS data indicate that 99.8 percent of the ANOCs for the 2008 AEP were on time. Of the eight sponsors in our study, six chose to use CMS's model ANOC largely for the convenience of undergoing a shorter CMS review period. The two remaining sponsors developed their own, nonmodel notices to beneficiaries. They found that the flexibility to produce nonmodel ANOCs allowed them to highlight particular features of their plans while presenting the required information on plan changes.

Stakeholders expressed concerns regarding the readability of the ANOC and we found that CMS's process in developing the model ANOC did not include a systematic evaluation of its effectiveness, which we have previously demonstrated is needed for Part D materials. GAO's 2006 study recommended that CMS ensure that its written materials follow commonly recognized communications guidelines. According to our study sponsors and other stakeholders, CMS's 2008 model ANOC was not sufficiently concise or beneficiary friendly and contained language at a reading level too high for some beneficiaries. Additionally, stakeholders noted that the model ANOC contained too much, often irrelevant, information that made it difficult for beneficiaries to determine how changes would affect them personally. To help ensure that enrollees understood how plan changes would affect their drug coverage and costs, two sponsors in our study supplemented the 2008 ANOC with personalized mailings that showed changes in coverage for specific drugs that the enrollees took in the past year. We found that CMS did not take steps to formally evaluate the ANOC used for the 2008 or 2009 AEPs for effectiveness in communicating plan changes, citing inadequate resources and a lack of trained staff. CMS officials recently reported that on October 1, 2008, they initiated an evaluation of their annual Medicare beneficiary materials for the 2010 AEP to assess their reading levels, effectiveness, and length, among other factors. Such an evaluation is particularly important in light of changes CMS made for the 2009 AEP, which raised further concerns among stakeholders. However, it is unclear whether the evaluation will consider

potential benefits of alternative formats for communicating plan changes to beneficiaries.

Although CMS and plan sponsors made improvements to the enrollment process, about one in seven of the roughly 1 million beneficiaries who chose to switch PDPs during the 2008 AEP were not fully enrolled in their new plan by January 1, 2008, the effective date of coverage. CMS officials and sponsors reported modifications to the enrollment process for the 2008 AEP that reduced the time needed to enroll beneficiaries in a new plan compared to 2007. However, the volume of applications submitted late in the AEP combined with the processing time required contributed to about 15 percent of beneficiaries who switched plans being at risk of not having access to their new coverage on January 1. Compared to beneficiaries submitting applications earlier in the AEP, 40 percent of the beneficiaries who submitted applications during the last 2 weeks of December were not completely processed until after the new benefit year began. Despite a median processing time of 5 days, the statutorily mandated AEP schedule—November 15 to December 31 with coverage effective January 1—provided insufficient time in which to fully process all enrollment applications. As a result, stakeholders reported inaccurate charges to beneficiaries, pharmacies, and sponsors as well as additional administrative burden. CMS officials and sponsors in our study agreed that creating an interval for enrollment processing between the end of the AEP and the effective date of new coverage would reduce the risk of these challenges.

To improve the Part D AEP, Congress should consider authorizing the Secretary of HHS to amend the current AEP schedule to include a sufficient processing interval to fully enroll beneficiaries prior to the effective date of their new coverage. We also recommend that the Acting Administrator of CMS strengthen the agency's evaluation of its model materials by reviewing alternative formats that include personalized drug coverage and cost information. We provided a draft of this report to CMS for its review and comment. In its written comments, CMS stated that it concurred with our recommendation and will consider reviewing other ANOC formats.

Background

The Medicare Part D Program

In the Medicare Part D program, drug plan sponsors compete to deliver prescription drug benefits and attract enrollees. Sponsors offer, through their PDPs, one or more benefit packages that differ in their levels of premiums, deductibles, cost sharing, and coverage in "the gap"—the period when beneficiaries would otherwise pay all of the costs of their drugs. Sponsors must offer plans with standard prescription drug coverage established under the MMA or actuarially equivalent prescription drug coverage as approved by CMS, or may opt to offer plans with supplemental prescription drug coverage.[8] In 2008, only about 10 percent of PDPs—5 of 47—offered the defined standard coverage.

Each plan must cover a set of drugs—generally known as a formulary—that meets certain criteria.[9] Beyond the minimum formulary requirements, sponsors have discretion in designing their formularies and may exclude particular drugs from coverage, thus contributing to variation in formularies across PDPs. For drugs included on a plan formulary, sponsors may assign drugs to tiers that correspond to different levels of cost sharing.[10] In general, sponsors encourage the use of generic

[8]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2075-2081 (2003) (codified, as amended, at 42 U.S.C. § 1395w-102). Sponsors may only offer plans with a supplemental prescription drug benefit, defined as when the total value of the coverage exceeds the standard prescription drug benefit, in areas where sponsors also offer plans with the standard prescription drug benefit. In 2008, the defined standard prescription drug benefit includes a $275 deductible, 25 percent coinsurance—the percentage of the costs that a beneficiary is responsible for—up to an initial benefit limit of $2,510 when the gap in coverage begins, and catastrophic coverage after $5,726.25 in total Part D drug costs.

[9]Under federal law, formularies must include drugs within each therapeutic category and class of covered Part D drugs. CMS generally requires sponsors to cover at least two Part D drugs in each category and class, subject to approved exceptions or when there is only one drug in the particular category or class. According to CMS guidelines, for six designated drug categories, plan formularies must include "all or substantially all" drugs within these categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and HIV/AIDS drugs.

[10]Formulary tiers are groups of drugs with different pricing levels. For example, a plan may have a tier for generic drugs that have the same active-ingredient formula as brand-name drugs, but usually cost less, and other tiers for higher-cost drugs. Tiers with higher cost-sharing include preferred brand-name drugs, which are deemed by the sponsor to be the first choice of drug provided; and nonpreferred drugs, which are covered by the plan but will cost the enrollee more than a preferred drug. Additionally, under CMS guidance, sponsors are permitted to set apart relatively expensive drugs on a specialty tier and charge more for these drugs than they typically do for preferred and nonpreferred drugs.

medications by putting them on a cost-sharing tier that imposes the lowest out-of-pocket costs on beneficiaries.

PDP sponsors are required to implement drug utilization management programs to reduce cost when medically appropriate. As part of these programs, sponsors may apply various utilization management restrictions to specific drugs on their formularies. Utilization management restrictions may include (1) prior authorization, which requires the beneficiary to obtain the sponsor's approval before a drug is covered for that individual; (2) quantity limits, which restrict the dosage or number of units of a drug provided within a certain period of time; and (3) step therapy, which requires that a beneficiary try lower-cost drugs before a sponsor will cover a more costly drug.

2008 Plan Benefit Changes

From year to year, sponsors can make changes in their plans' benefit structure including premiums, cost-sharing levels, formularies, and utilization management restrictions. Prior to the AEP, plan sponsors must submit to CMS bids for approval in order to implement significant changes to benefit structures that will go into effect the next benefit year. As part of this bid negotiation process, CMS reviews formularies and the design of the plan and benefits offered, including removals of drugs from formularies, use of utilization management restrictions, and the application of copayments for drugs.[11] Sponsors have limited opportunities to change benefit structures that may adversely impact enrollees,

[11]CMS approves Part D plans based on certain criteria including the offering of qualified prescription drug coverage and the sufficiency of actuarial determinations. CMS will not approve a bid if the agency determines that benefits offered—including the formulary and tiered formulary structure or utilization management restrictions—would be likely to substantially discourage enrollment by certain Part D beneficiaries.

including removing particular drugs from formularies or moving drugs to higher cost-sharing tiers.[12]

Changes to plan benefit structures can have significant effects on a beneficiary's out-of-pocket costs and access to particular drugs. For example, a 2008 analysis conducted by Avalere Health—a health care research and consulting firm—showed that average monthly premiums in the 10 most popular Medicare PDPs increased by 16 percent from 2007 to 2008.[13] The analysis also noted that some of the most popular plans raised their premiums by more than 50 percent.

In addition to changes in premiums, PDPs made significant changes from 2007 to 2008 in cost sharing and utilization management of formulary drugs, according to a study sponsored by the Kaiser Family Foundation.[14] For example, the study found that the average copayment for a 30-day supply of nonpreferred name-brand drugs increased 13 percent from $63.31 in 2007 to $71.31 in 2008. Additionally, it reported that PDPs increased their use of utilization management restrictions, such as step therapy and quantity limits, from 25 percent of a sample of the most commonly prescribed drugs in 2007 to 30 percent in 2008.[15]

[12]For example, sponsors may only change the therapeutic categories and classes in a formulary at the beginning of each benefit year, except to account for new uses and drugs newly approved for coverage under the Part D program. In addition, sponsors may not remove Part D drugs from their formularies or change their cost-sharing tiers between November 15 and March 1 of each benefit year, unless the drug has been determined unsafe or has been removed from the market by the manufacturer. After March 1, sponsors may replace a brand-name drug with a generic drug, remove a drug from a formulary, or increase cost sharing for particular drugs only if the sponsor provides 60 days notice to all affected parties, including CMS, enrollees, physicians, and pharmacies and CMS approves the change. In these circumstances, the sponsor may not alter coverage of the drug for affected enrollees for the remainder of the plan year.

[13]See *Avalere Analysis Shows 16 Percent Increase for Enrollees in Top 10 Medicare Drug Plans*, June 4, 2008, for weighted enrollment analysis of CMS enrollment data, available on Avalere Health Web site, http://www.avalerehealth.org/wm/show.php?c=1&id=781 accessed on August 28, 2008.

[14]J. Hoadley, E. Hargrave, et al, *Medicare Prescription Drug Plans in 2008 and Key Changes Since 2006: Summary of Findings*, The Henry J. Kaiser Family Foundation (Washington, D.C.: April 2008).

[15]The Kaiser study analyzed data from CMS on a sample of 169 drugs selected to include the most commonly prescribed drugs and all alternative medications in some of the drug classes most commonly used by Medicare beneficiaries. The use of step therapy tripled from 4 percent of the sample drugs in 2007 to 12 percent in 2008.

Written Communications for Medicare Beneficiaries

The design of written materials for Medicare beneficiaries is particularly important in light of evidence that some older individuals have challenges reading and retaining written information. For example, studies have found that individuals ages 65 and older were less proficient than younger adults in locating information in documents and making health decisions based on what they read.[16] Further, a 2003 national survey of adult literacy showed that 27 percent of Medicare beneficiaries were unable to understand information in short, simple texts.[17]

Previous GAO work highlights the importance of assuring that Part D materials, in particular, communicate clearly to this population.[18] Our 2006 study noted that the reading levels of a sample of Part D materials exceeded the capacity of 40 percent of the seniors surveyed. Additionally, the Part D materials reviewed in this study did not include about half of 60 common elements of effective communication, such as language that is free of jargon and consists of familiar words in short sentences, sometimes referred to as "plain language."[19] As a result of these findings, we recommended that CMS ensure that its written materials describe the Part D benefit in a manner that is consistent with commonly recognized communications guidelines and is responsive to the reader's needs.

Since the mid-1990s, a group of federal employees from different agencies and specialties has promoted the use of plain language in government communications, particularly those that describe federal benefits and

[16]See C. A. Paulsen and C. Bransfield, *Readability, Heuristic and Usability Evaluation of the Medicare Prescription Drug Plan Materials*, American Institutes for Research (Concord, Mass: March 2006) and J. Hibbard, J. Greene, and M. Tusler, *An Assessment of Beneficiary Knowledge of Medicare Coverage Options and the Prescription Drug Benefit* (Washington, D.C.:May 2006).

[17]M. Kutner, E. Greenberg, et al, *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy* (September 2006).

[18]GAO, *Medicare: Communications to Beneficiaries on the Prescription Drug Benefit Could Be Improved*, GAO-06-654 (Washington, D.C.: May 3, 2006).

[19]Plain language (also called Plain English) is defined as communication the audience can understand the first time they read it. Material is considered to be written in plain language if the audience can find what they need, understand what they find, and use the information to meet their needs.

services for the public.[20] Documents that conform to principles of plain language are organized with the reader in mind and:

- include only the information the reader needs;
- omit unnecessary words and use short sentences of 15 to 20 words;
- avoid technical terms and use simple words and active voice;
- facilitate comprehension using headings, tables, lists, and white space; and
- incorporate customer feedback using surveys, focus groups, or protocol testing.[21]

Currently, no formal plain language initiative is in place for federal executive agencies; however, some agencies have chosen to incorporate plain language principles in their documents. For example, officials from CMS's Office of External Affairs indicated that they will conduct a plain language review of CMS documents if requested by agency staff.

Other consumer research supported the use of information customized to individuals' preferences and circumstances to reduce the risk that consumers dismiss the information as irrelevant.[22] Under this approach, consumers are provided with only data that are most relevant to them, thus making it less likely they will be overwhelmed by the information communicated. One study noted the importance of providing streamlined information that helps individuals understand the consequences of their choices.[23]

[20]The Plain Language Action and Information Network is a group of federal employees that promotes the principles of plain language in government materials as a strategy for saving money and improving government efficiency. See www.plainlanguage.gov.

[21]Federal Plain Language Guidelines: *Improving Communications from the Federal Government to the Public*, accessed from www.plainlanguage.gov/howto/guidelines/reader-friendly.cfm on October 22, 2008.

[22]D. Shaller, *Consumers in Health Care: The Burden of Choice*, California HealthCare Foundation (Oakland, Calif: October 2005).

[23]J. Hibbard, J. Greene, et al, *An Assessment of Beneficiary Knowledge of Medicare Coverage Options and the Prescription Drug Benefit* (Washington, D.C.: May 2006).

AEP Materials for Beneficiaries

CMS requires sponsors to mail all enrollees an ANOC that shows how various features of their drug plan—such as the premium, coverage, cost sharing, and formulary—will change for the next benefit year.[24] In addition to the ANOC, sponsors are required to send beneficiaries other enrollment-related documents, such as the EOC, a Summary of Benefits (SB), and a comprehensive or abridged formulary.[25] Table 1 describes selected information included in each of these documents, as prepared by sponsors in our study.

Table 1: 2008 AEP Materials for Plan Enrollees

Document	Selection of key information conveyed[a]
Annual Notice of Change (ANOC)	• How plan's monthly premium, prescription drug coverage, and cost sharing will change • What enrollees should do if their drugs are no longer on the formulary or are in a more expensive cost-sharing tier • Information on changes in costs for beneficiaries receiving financial assistance directly from Medicare to pay for drugs
Evidence of Coverage (EOC)	• Plan's service area, initial coverage limit, cost sharing under initial coverage limit, and cost sharing under the coverage gap • General exclusions and restrictions (i.e., utilization management restrictions) • Description of the right to request coverage determination, and procedures for requesting a grievance, coverage determination, or appeal
Summary of Benefits (SB)	• An introduction and beneficiary information section, which provides information on who is eligible to join the plan, where enrollees can go to obtain their prescriptions, and enrollees' protections in the plan • A benefit comparison matrix, which summarizes the benefit packages and premiums across the different plans offered by the sponsor
Formulary (Abridged or Comprehensive)[b]	• Definition of a formulary and explanation of how to use the document • Description of the plan's general utilization management policies and procedures • Chart of covered drugs organized by therapeutic category that includes drug name, tier placement, and any utilization management restrictions

Source: GAO analysis of sample 2008 AEP materials provided by study sponsors.

[24]In its call letter to plan sponsors for benefit year 2008, CMS required sponsors to send an ANOC to enrollees by October 31, 2007. For AEP enrollment requests received prior to November 15 plan sponsors must submit all transactions to CMS on November 15 with an "application date" of November 15 of the current year, according to CMS guidance.

[25]Under federal law, plan sponsors are required to disclose to Medicare beneficiaries certain information about the PDPs when they enroll and on at least an annual basis. This information must include a description of the plan's service area, benefits (including premiums and cost sharing), access, out-of-network coverage, formulary (including tiers and utilization management restrictions), plan grievance and appeals procedures, and quality assurance programs. Under regulations effective September 18, 2008, CMS is requiring plan sponsors to provide this information to enrollees at least 15 days prior to each year's AEP. 73 *Fed. Reg.* 54208, 54222 (Sept. 18, 2008).

Notes: In this report we refer to the ANOC, the EOC, the SB, and an abridged or comprehensive formulary as AEP materials. However, for the 2008 AEP, plan sponsors had the option to send the EOC to their enrollees by January 31.

[a]The information selected does not include all of the elements of the listed documents.

[b]In accordance with CMS guidelines, sponsors may provide comprehensive or abridged formularies to enrollees and indicate how enrollees may access a complete formulary.

For the 2008 AEP, sponsors could opt to mail the EOC along with the ANOC to beneficiaries for receipt by October 31, 2007, or separately mail the EOC to enrollees for receipt by January 31, 2008. If sponsors chose to mail EOCs separately, sponsors were required to mail a SB along with the ANOC. For the 2009 AEP, CMS required plan sponsors to mail the ANOC, a formulary, and the EOC together for receipt by enrollees by October 31, 2008.[26]

In developing these materials for the 2008 AEP, sponsors could choose to adopt CMS's model documents or create nonmodel documents that contained CMS's required elements. Sponsors are required to submit all AEP materials to CMS for review prior to mailing to enrollees. As a result, use of model versus nonmodel documents had implications for the amount of time for CMS review and the time frame for plan sponsors to mail materials. When sponsors used CMS model documents without modification, CMS reviewed the materials within 10 days; for documents considered nonmodel, CMS required a 45-day review period. For the 2009 AEP, CMS required plan sponsors to use a standardized ANOC-EOC with no modifications to the text permitted.

Sponsors Were Timely in Mailing 2008 ANOCS to Nearly All Beneficiaries and Most Sponsors Used CMS's Model ANOC

PDP sponsors reported to CMS that nearly all enrollees received their ANOCs on time for the 2008 AEP and most of our study sponsors used CMS's model ANOC. Our analysis of CMS's Readiness Checklist and information reported from certain sponsors indicated that 99.8 percent of the approximately 17.2 million PDP beneficiaries enrolled as of November 1, 2007, received ANOCs from their plan sponsors by the required October 31 deadline. Of the 35,630 beneficiaries who received ANOCs late, the majority (21,902) received them by November 15, 2007—the start of the AEP—and the remainder received them by December 10,

[26]In its call letter to plan sponsors for benefit year 2009, CMS requires plan sponsors to combine the ANOC and EOC in one mailing to enrollees for receipt by October 31, 2008.

2007.[27] Given the limited delays in distributing ANOCs, CMS did not take enforcement action against any of the sponsors reporting late mailings for the 2008 AEP.

Six sponsors in our study adopted CMS's model ANOC to inform beneficiaries of upcoming plan changes rather than develop their own ANOCs. Five of these six sponsors using the model reported doing so to qualify for a shorter CMS review period—10 days versus 45 days—and in some instances to help ensure that they could produce and send their ANOCs by the October 31 deadline. The remaining two study sponsors chose to develop nonmodel ANOCs for the 2008 AEP. Although their ANOCs contained all of CMS's required information elements, we found that they were substantially different in format from the CMS template and from each other. For example, these ANOCs contained sponsor-developed text rather than CMS's model language. Also, information was presented in a different order and with different section headings than CMS's model ANOC. These two sponsors told us that in electing to create nonmodel materials, such as the ANOC, they were able to highlight unique aspects of their plans. For example, one of the sponsors included information that one of its plans would begin covering the cost of administering Part D vaccines for the 2008 benefit year.

Stakeholders Raised Concerns about the ANOC's Readability; CMS Did Not Assess the Effectiveness of Its Model ANOCs

Stakeholders have expressed various concerns regarding the readability of the ANOC and we found that prior to the 2008 and 2009 AEPs CMS did not systematically evaluate its effectiveness in conveying plan changes to beneficiaries. Stakeholders in our study noted that, because CMS's model ANOC was not beneficiary friendly, it was difficult for individuals to determine how changes would affect them personally. To help ensure that their enrollees understood the significance of plan changes, two sponsors in our study mailed supplemental information that showed changes in coverage and costs for the specific drugs the enrollee took in the past year. Although CMS used in-house experts when developing its model ANOC, the agency did not formally assess whether its 2008 model materials incorporated commonly recognized communication guidelines to effectively inform beneficiaries about plan changes. CMS officials recently reported that on October 1, 2008, they initiated an evaluation of their

[27]An additional 57,000 ANOCs were received after the October 31 deadline by beneficiaries in one employer-sponsored PDP. However, according to a CMS official, the agency does not consider these ANOCs late because the timeliness of ANOC delivery was out of the control of these sponsors and was dependent on negotiations with employer groups.

annual Medicare beneficiary materials—particularly the combined ANOC-EOC for the 2010 AEP—to assess their reading level, effectiveness, and length, among other factors. Such an evaluation is particularly important in light of changes that CMS made for the 2009 AEP, which raised further concerns among stakeholders. However, it is unclear whether the evaluation will consider potential benefits of alternative formats for communicating plan changes to beneficiaries.

Stakeholders Expressed Concern about the Readability of CMS Model ANOC

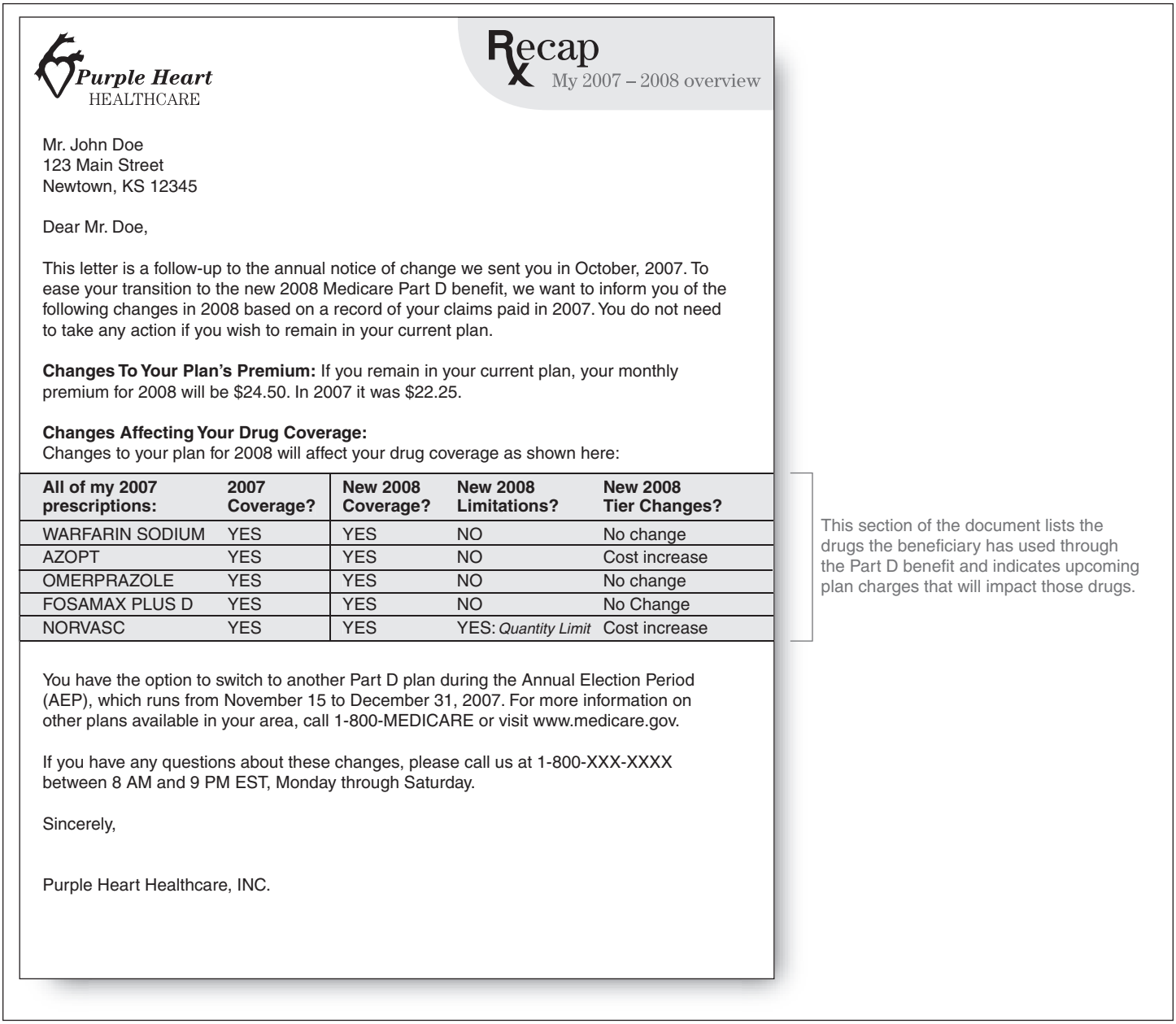
Five sponsors and other stakeholders in our study noted that CMS's model materials for the 2008 AEP were not sufficiently concise or beneficiary friendly and felt that the language in the model ANOC was at a reading level too high for some beneficiaries. One sponsor—concerned about the reading level of the documents and the complexity of the language used—noted that the model ANOC contained some sentences with more than 40 words.[28] According to another sponsor, the inclusion of excess information that did not contribute to understanding the benefit made it more likely that beneficiaries would become overwhelmed and less likely to find the information they need. Another sponsor stated that beneficiaries generally do not read the ANOC because it is a confusing document that lacks more basic information on plan changes and simpler language. Additionally, one study sponsor pointed out that the CMS model materials were not reader friendly or concise; it preferred to create its own simplified materials that use plain language and easy-to-read graphics and layouts. Similarly, stakeholders that assisted individuals during the AEP told us that some beneficiaries found the ANOC overwhelming and had difficulty processing the large amounts of information provided. Health care researchers, advocates, and SHIP counselors we spoke with concluded that much of the information contained in the model ANOC was too general in nature or irrelevant to the reader, making it hard for beneficiaries to determine how changes would affect them personally.

To help ensure that enrollees understood their plan changes, two sponsors in our study provided additional information to beneficiaries that showed how coverage of their specific drugs would change in the next benefit year. For the 2008 AEP, these sponsors reported supplementing their use of the CMS model ANOC with additional personalized mailings distributed

[28]Such sentence lengths are inconsistent with established elements of effective communication such as clear language and short sentences ranging from 15 to 20 words. See *Federal Plain Language Guidelines: Improving Communications from the Federal Government to the Public*, accessed from www.plainlanguage.gov on August 13, 2008.

prior to and during the AEP. Using their pharmacy claims database, these sponsors reported producing documents that indicated whether the particular medications each beneficiary used in 2007 would continue to be covered in 2008. The documents also showed any changes in cost sharing and utilization management restrictions to be applied to these drugs in the new benefit year. These personalized mailings went to approximately 3.6 million of the 7.3 million PDP enrollees served by our study sponsors. Figure 1 shows a hypothetical example that we created of a sponsor's mailing containing personalized information on changes for the next benefit year.

Figure 1: Hypothetical Example of a Personalized Mailing on Annual Plan Changes



Purple Heart
HEALTHCARE

Recap
My 2007 – 2008 overview

Mr. John Doe
123 Main Street
Newtown, KS 12345

Dear Mr. Doe,

This letter is a follow-up to the annual notice of change we sent you in October, 2007. To ease your transition to the new 2008 Medicare Part D benefit, we want to inform you of the following changes in 2008 based on a record of your claims paid in 2007. You do not need to take any action if you wish to remain in your current plan.

Changes To Your Plan's Premium: If you remain in your current plan, your monthly premium for 2008 will be $24.50. In 2007 it was $22.25.

Changes Affecting Your Drug Coverage:
Changes to your plan for 2008 will affect your drug coverage as shown here:

All of my 2007 prescriptions:	2007 Coverage?	New 2008 Coverage?	New 2008 Limitations?	New 2008 Tier Changes?
WARFARIN SODIUM	YES	YES	NO	No change
AZOPT	YES	YES	NO	Cost increase
OMERPRAZOLE	YES	YES	NO	No change
FOSAMAX PLUS D	YES	YES	NO	No Change
NORVASC	YES	YES	YES: *Quantity Limit*	Cost increase

You have the option to switch to another Part D plan during the Annual Election Period (AEP), which runs from November 15 to December 31, 2007. For more information on other plans available in your area, call 1-800-MEDICARE or visit www.medicare.gov.

If you have any questions about these changes, please call us at 1-800-XXX-XXXX between 8 AM and 9 PM EST, Monday through Saturday.

Sincerely,

Purple Heart Healthcare, INC.

This section of the document lists the drugs the beneficiary has used through the Part D benefit and indicates upcoming plan charges that will impact those drugs.

Source: GAO analysis of literature from two plan sponsors.

Note: This hypothetical notice contains features from both sponsors' mailings to their enrollees.

One of the two sponsors reported including personalized drug information as a separate communication to beneficiaries shortly after the ANOC was sent. This sponsor sent these personalized mailings only to those beneficiaries whose drugs would undergo coverage changes for the upcoming year. Sponsor staff told us they created personalized mailings because they made substantial modifications to their formularies for 2008 and they wanted to make certain that beneficiaries were aware of these changes.

Similarly, the other sponsor reported that it wanted to ensure that beneficiaries would not be surprised by drug benefit changes effective in January and thus felt that it was important to provide more information than required by CMS. This sponsor inserted personalized information on upcoming plan changes in its monthly Explanation of Benefits (EOB) sent to beneficiaries in October, November, and December 2007.[29] The sponsor reported that it sought to communicate information in a succinct format to enable beneficiaries to focus only on the plan changes relevant to them, individually, without having to examine the longer plan formulary document. Additionally, this sponsor had conducted focus groups to identify the specific information elements, such as individual drug coverage and cost changes, beneficiaries look for when reviewing their plan notices. Sponsor staff noted that they chose to supplement the EOB with this information because industry research indicated that readership of the EOB is high—90 to 95 percent.

CMS Has Not Assessed Effectiveness of ANOCs, Which May Be More Critical in Light of Changes to 2009 AEP Materials

Agency officials told us that they had not systematically evaluated the effectiveness of the agency's ANOCs or incorporated beneficiary feedback or the principles of plain language. Instead, in developing the 2008 model, CMS officials said the agency relied on in-house expertise gained through the development of other Medicare materials. They reported making slight wording modifications to the draft 2008 ANOC based on comments from the agency's Office of External Affairs, but said that plain language review was not part of the document clearance process. CMS officials said they recognize the need to incorporate feedback from beneficiaries and increase the use of commonly recognized elements of plain language in their documents. However, they cited a lack of adequate in-house

[29]The EOB mailing is a required monthly statement that shows a beneficiary's use of Part D drugs since the beginning of that benefit year. Sponsors are required to mail these statements to beneficiaries every month in which beneficiaries access their drug benefits.

resources to conduct consumer testing. Additionally, a CMS official cited an insufficient number of staff to meet additional requests for plain language review.

After the release of standardized materials for the 2009 AEP, a CMS official reported that the agency had awarded a contract for an evaluation of its annual Medicare beneficiary materials—particularly the combined ANOC-EOC—which CMS required sponsors to send to beneficiaries in a single mailing for the 2009 AEP.[30] The official also noted that this assessment began on October 1, 2008, and is to be completed by February 2009. According to the contract and CMS officials, this evaluation will redesign and standardize beneficiary materials including the ANOC-EOC to provide more understandable information to beneficiaries.[31] CMS officials indicated that the redesigned ANOC-EOC should be completed for the 2010 AEP.

This effort by CMS is particularly important in light of changes that CMS has made for the 2009 AEP, which raised further concerns among stakeholders. One such change requires that sponsors use only a standardized ANOC, rather than giving sponsors the option of creating their own. In adopting this standardized document, sponsors may insert plan-specific information where appropriate, but cannot otherwise modify the language. According to CMS, this standardization is consistent with the materials for the Federal Employees Health Benefits Program (FEHBP). Additionally, the agency expects the required use of a standardized ANOC to reduce misinformation on plan changes because this document was more likely to contain errors than other documents submitted to CMS for review. CMS also expects this change to speed its review of materials by eliminating the 45-day review of nonmodel materials. When sponsors use CMS standardized documents without modification they are available for use 5 days after submission to CMS.

[30]For the 2008 AEP, sponsors had the option to mail a short Summary of Benefits (SB) with the ANOC for receipt by October 31, with the more detailed EOC to follow. For the 2009 AEP, CMS requires all sponsors to mail the ANOC and EOC together for receipt by October 31; the SB will be available to beneficiaries only upon request.

[31]In addition to reviewing annual beneficiary notification materials, the contractor's responsibilities include an enrollment/disenrollment analysis among Medicare Advantage (MA) plans, an analysis of how MA plans and benefit packages have changed over time from 2006-2012, and an analysis of enrollees with certain chronic diseases to evaluate cost-sharing scenarios and impacts for those in MA and fee-for-service arrangements. For the initial year of this contract, the agency estimates that the contractor will be reimbursed $894,088.

While one sponsor and two beneficiary advocates supported greater standardization, six of the eight sponsors expressed concerns that the 2009 ANOC requirements will render notices to beneficiaries less effective in communicating plan changes. In formal written comments to CMS and in interviews on the proposed changes for the 2009 AEP, some study sponsors noted that the mandatory use of CMS's standardized documents requires the use of language already considered to be at a reading level that is too high for some beneficiaries. Additionally, two sponsors told us that, in the past, they have conducted focus groups with their enrollees on the clarity of their materials. They pointed out that the requirement to use only standardized materials prevents them from developing an ANOC that incorporates enrollees' feedback and provides information in a way that they believe would enhance beneficiaries' comprehension of plan changes.

Some of these concerns may be addressed in CMS's forthcoming evaluation of the combined ANOC-EOC. The contract includes the development of beneficiary materials at an appropriate reading level and that incorporates plain language principles. Additionally, a CMS official said that the evaluation will involve in depth interviews with consumers in an effort to develop more effective beneficiary materials for PDP enrollees. The interviews will include special populations such as dual eligibles.

Another change CMS implemented for the 2009 AEP was a requirement that the EOC be sent to beneficiaries with the ANOC in a single mailing. For the 2008 AEP, sponsors had the option to mail a short Summary of Benefits (SB) with the ANOC in October and follow this with the more detailed EOC in January. For the 2009 AEP, CMS requires all sponsors to mail to beneficiaries the ANOC and EOC together for receipt by October 31; the SB will be available to beneficiaries only upon request. According to CMS, this change gives beneficiaries comprehensive information on their current plan in advance of the AEP. Furthermore, CMS considers the EOC a resource document that beneficiaries will keep and refer to as appropriate.

Sponsors, advocates, and SHIPs expressed concern that sending the ANOC and EOC as one mailing results in a lengthy document that could confuse some beneficiaries and deter others from reading the materials. Because CMS's new set of required materials replaces the abbreviated SB (approximately 4 pages in length) with the more detailed EOC (that could

be more than 100 pages in length), the size of sponsors' mailings for the AEP could grow from about 51 pages in 2008 to about 86 pages in the 2009 AEP.[32] One sponsor noted that beneficiaries want information about changes that affect them significantly, such as changes to their formulary or cost-sharing responsibility. Another sponsor cited the importance of highlighting changes to step therapy and prior authorization for beneficiaries. These sponsors expressed concern that the long combined ANOC-EOC may not be useful for beneficiaries in understanding such changes.

According to the contract and CMS officials, the evaluation of beneficiary materials including the ANOC-EOC requires the development of shorter documents. However, it is unclear whether the evaluation will include an examination of alternatives such as the use of specific information tailored to the individual—an approach favored by communications researchers. It is also unclear whether the evaluation will include an assessment of the decision to combine the ANOC and EOC mailings despite concerns expressed in comments to CMS on the draft 2009 call letter.

Despite Improved Procedures, the AEP Schedule Does Not Allow Sufficient Time to Process All Enrollments

Despite improved AEP enrollment procedures, one in seven of the approximately 1 million beneficiaries choosing to switch PDPs were not fully enrolled in their new plan by January 1. CMS and sponsors made modifications to the enrollment process that resulted in a median processing time of 5 days for applications submitted throughout the 2008 AEP. However, the statutorily mandated AEP schedule—November 15 to December 31 with coverage effective January 1—lacks sufficient time in which to fully process enrollment applications. As a result, stakeholders reported inaccurate charges, additional administrative burden, and inconveniences for the beneficiary following the 2008 AEP. CMS officials and sponsors in our study agreed that creating an interval for enrollment processing between the end of the AEP and the effective date of new coverage would reduce the risk of these challenges.

[32]This estimation of the increased number of pages that must be sent to beneficiaries for the 2009 AEP is based on a comparison of the number of pages that one sponsor sent for the 2008 AEP (the ANOC, a formulary, and a SB) versus the documents that could be sent, as required for the 2009 AEP (the ANOC, a formulary, and the EOC).

CMS and Sponsors Improved Procedures to Reduce Enrollment Processing Time

For the 2008 AEP, CMS and sponsors implemented changes to expedite enrollment processing in order to avoid difficulties encountered the previous year.[33] To be fully enrolled in a new plan a beneficiary must submit a complete application, eligibility must be verified by sponsors and CMS, billing codes must be assigned and disseminated, adjustments must be made to premium amounts and any relevant subsidies, and the beneficiary must receive documentation of new coverage, in the form of either a confirmation letter or a new membership card. The complete processing of an enrollment application requires data exchanges among not only CMS, sponsors, and pharmacies, but also the Social Security Administration (SSA), state Medicaid programs for certain beneficiaries, and various CMS contractors.[34] The multiple data exchanges among partners that are necessary for processing a beneficiary's change in plans occur sequentially over a period of time.[35]

A previous study by GAO on Part D complaints and grievances found that 63 percent of the complaints received by CMS over an 18-month period cited problems related to processing beneficiary enrollments and disenrollments.[36] We noted that CMS received numerous complaints about late or missing membership cards, incorrect enrollments and disenrollments, inaccurate premiums, involuntary switching, and problems regarding cost-sharing amounts. To address concerns, CMS continually works with its partners through work groups, task forces, and coalitions to improve program quality and improve Part D processes.

The changes CMS implemented for the 2008 AEP reduced the time needed for processing enrollments by at least 14 days, compared to the previous year. CMS achieved this reduction by requiring sponsors to:

[33]Of 630,000 complaints filed over an 18-month period, most related to problems processing beneficiaries' enrollments and disenrollment requests. See GAO, *Medicare Part D: Complaint Rates Are Declining, but Operational and Oversight Challenges Remain*, GAO-08-719 (Washington, D.C.: June 27, 2008).

[34]SSA is responsible for withholding Part D premiums from beneficiaries' monthly Social Security payments if they selected that payment method. State Medicaid offices determine which individuals are dually eligible for Medicare and Medicaid and eligible for help with paying for their premium and copayments. CMS also partners with various companies to manage different aspects of Part D.

[35]CMS's April 2008 Transmission Overview lists 73 different data exchanges between CMS and MA and PDPs.

[36]See GAO, *Complaint Rates are Declining, but Operational and Oversight Challenges Remain*, GAO-08-719 (Washington, D.C.: June 27, 2008).

- transmit new enrollment information to CMS "as early as possible" or, at most, within 7 days instead of the 14 days permitted during the 2007 AEP;
- contact beneficiaries regarding missing information within 10 days of receipt versus 21 days as previously required; and
- provide beneficiaries with information on their enrollment in a new plan from CMS's earliest notification, which is likely to be the weekly report, rather than waiting for CMS's monthly report as previously permitted.

In addition, CMS improved the process by requiring sponsors to assign billing codes to new enrollments earlier in the process.[37] Pharmacies need these codes in order to identify and charge the appropriate plan and collect the correct copayment amounts from beneficiaries. Previously, sponsors assigned this information at various times and in separate transactions that sometimes followed CMS's confirmation of a beneficiary's Part D eligibility by as much as 14 days, delaying availability of billing codes at the pharmacy. In contrast, for the 2008 AEP, the agency required sponsors to submit the billing codes for each beneficiary simultaneously with the initial enrollment transaction. Since 2006, CMS has required sponsors to include this information on the acknowledgement and confirmation letters sent to beneficiaries informing them of the effective date of their new coverage. These letters could be used by pharmacists to verify coverage prior to the beneficiaries' receipt of their new plan membership cards. Streamlining the assignment of the billing codes significantly decreased the time to complete enrollment processing and increased overall program efficiency.

Four sponsors in our study also took steps to complete AEP enrollments and transmit the billing codes to their claims systems prior to receiving the weekly report from CMS confirming eligibility.[38] Two sponsors went further to expedite enrollments by establishing processes to independently

[37]Part D billing codes are used by pharmacies in order to identify a beneficiary's correct plan and benefit package and include four primary payer data elements known collectively as the 4RX data.

[38]CMS sends weekly Transaction Reply Reports (TRR) to plan sponsors listing the status of all the transactions CMS processed for the plan that week. The TRR includes a final disposition code for each transaction. Once a sponsor receives an affirmative enrollment on the TRR report, it sends a confirmation letter to beneficiaries notifying them that their enrollment is complete. The monthly TRR aggregates the disposition of all transactions processed for a plan in the preceding month.

obtain information needed to complete an application or verify enrollees' eligibility for Part D. Because these sponsors did not wait for CMS to confirm eligibility via their weekly or monthly reports, they were able to provide pharmacies with information regarding a beneficiary's new coverage more quickly.

Additional time-saving modifications to the enrollment process identified by CMS officials and sponsors in our study included:

- use of customer service representatives to complete telephone enrollments, conduct the preliminary eligibility check required by CMS, and ask the caller pertinent questions;
- more detailed beneficiary information provided by CMS to sponsors in the initial eligibility query;[39]
- more detailed information provided to pharmacies by CMS and sponsors during the query used to obtain billing information for beneficiaries without membership cards or other documentation of coverage;[40]
- increased staffing during December to manage the volume of late-month enrollments; and
- automation of certain tasks to reduce processing time.

Not All Beneficiaries Switching Plans Were Fully Enrolled Before Their New Coverage Began

Despite these improvements, we found that 15 percent of the approximately 1 million beneficiaries choosing to switch plans during the 2008 AEP were at risk of not having access to their new coverage on January 1, 2008. Reasons for these delayed enrollments included the volume of late-December applications combined with the processing time required to fully enroll a beneficiary in a new plan, and the AEP schedule that accepts enrollments through December 31 with coverage effective the next day.[41] To prevent problems in January resulting from these delays, in

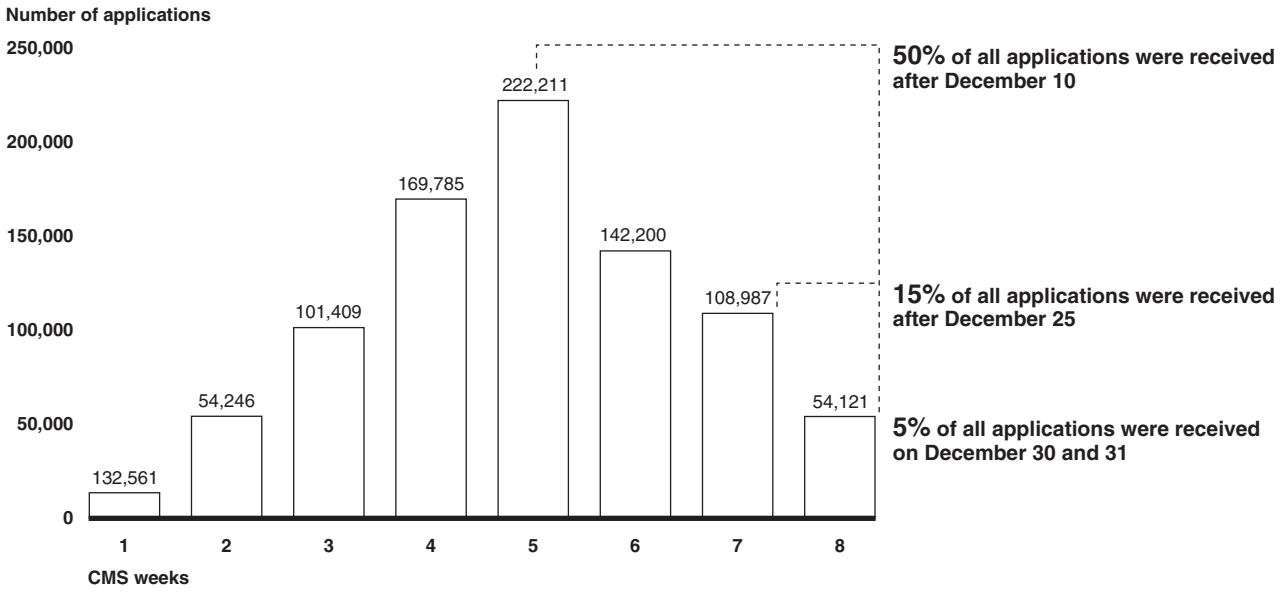
[39]Sponsors submit an electronic file called a Batch Eligibility Query to CMS to verify members' Medicare eligibility prior to accepting an application for Part D.

[40]If a beneficiary does not have documentation of his or her Part D enrollment, the beneficiary's pharmacist can submit an electronic request known as an E1 Query to CMS to verify the beneficiary's coverage and billing codes.

[41]Of those beneficiaries whose AEP enrollments were completed after January 1, 2008, 85 percent had submitted their enrollment applications after December 15, 2007.

2007 CMS sponsored a media campaign and distributed guidance to its partners to encourage beneficiaries to submit their 2008 AEP applications by December 7, 2007. Despite this effort, CMS weekly report data revealed that 50 percent of the applications to change PDPs were received after December 10. Furthermore, sponsors received 5 percent of enrollment applications for beneficiaries during the last 2 days of the AEP. Figure 2 shows the distribution of enrollment applications received during the 2008 AEP.

Figure 2: Enrollment Applications Received by PDP Sponsors during 2008 AEP, by Week



Source: GAO analysis of CMS data.

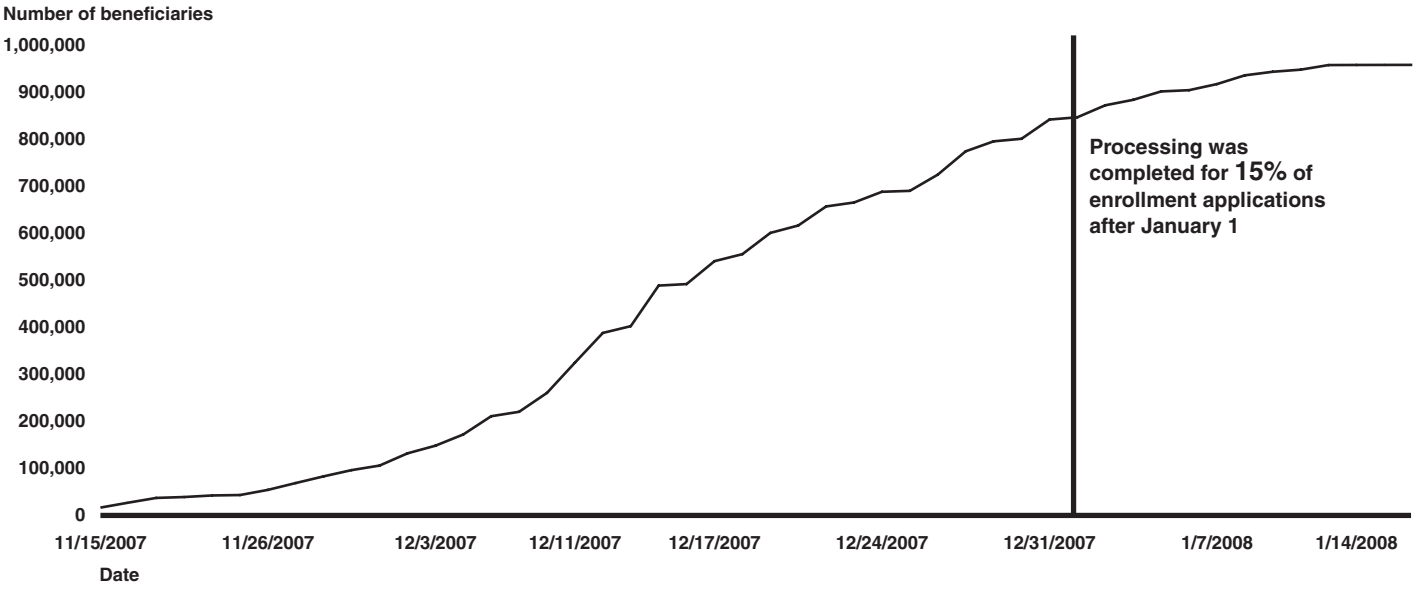
Note: The weeks shown reflect enrollment application dates by week reported by sponsors to CMS throughout the AEP. The first and last weeks of the 2008 AEP covered less than 7 days; week 1 includes data from November 15 through November 17 and week 8 includes data from December 30 to December 31.

CMS data also show that the time needed to fully process an enrollment application varied over the course of the AEP. Overall, the median processing time was 5 days. However, in week 1 of the AEP the median processing time was 20 days and in week 5 the median was 3 days.

Of the applications received after December 15—which accounted for nearly one third of all 2008 AEP applications—40 percent were not processed until after January 1. On average, applications received in late December took 3 days longer to process than applications received earlier

in the month. Not until January 11—2 weeks into the new coverage year, did CMS and its partners complete the processing of 97 percent of the applications of beneficiaries choosing to switch PDPs during the 2008 AEP.[42] Figure 3 shows when enrollment processing for the 2008 AEP was completed.

Figure 3: Enrollments Completed During and After the 2008 AEP



Source: GAO analysis of CMS data.

The capacity to process late December enrollments also varied across sponsors. We found that larger sponsors were quicker in processing enrollments received after December 15. Thus, sponsors with more than 3 million PDP beneficiaries were able to process 81 percent of late December applications prior to the effective date of new coverage. In contrast, sponsors with less than 100,000 PDP enrollees were able to process 48 percent of applications before the new year. Regardless of sponsor size, the AEP schedule provided insufficient time in which to fully process all enrollment applications.

[42]The remaining 3 percent of AEP enrollments were completed by June 2008. GAO did not examine the specific reasons why these applications were delayed.

The inability of CMS and sponsors to complete all the steps in the enrollment process prior to the effective date of new coverage for beneficiaries choosing to switch plans created a number of challenges. One consequence is the heightened risk of inaccurate charges or payment amounts for beneficiaries, pharmacies, and sponsors. Following the 2008 AEP, beneficiary advocates, SHIPS, and pharmacists reported that some individuals were charged the wrong copayment or deductible, especially those who had applied for a low-income subsidy—which must be authorized by SSA—to reduce their cost-sharing levels. Two pharmacy associations reported that if new coverage could not be verified, their members risked filling a prescription for which they would not get reimbursed or the beneficiary would need to pay for a temporary supply of the medication while coverage issues were resolved. Pharmacy association representatives also reported delayed receipt of payment from sponsors related to prescriptions filled when a beneficiary's enrollment status changed. In addition, stakeholders told us about significant payment inaccuracies that took time to resolve.[43]

Additional administrative burden was another consequence of the incomplete processing of all AEP enrollments prior to January 1, according to several stakeholders we interviewed. Until beneficiaries switching plans received documentation of their new coverage from the sponsor on a membership card or letter, pharmacies had to use alternative means to locate the updated enrollment and billing information in order to fill a prescription and submit a claim correctly. CMS guidance requires pharmacists to complete electronic inquiries and, if necessary, phone calls to try to identify the beneficiary's correct enrollment status and billing codes if that information is not in the claims system. Pharmacy associations reported that this procedure was overly complex and required extensive staff time. Sponsors and pharmacy associations said that claims filed under a beneficiary's old plan had to be reversed retroactively and charged to the correct plan, requiring additional time and resources. Stakeholders we interviewed noted that beneficiaries lack a single point of contact to resolve enrollment issues promptly and might need to follow up with multiple sources including their plan, CMS, SSA, and the prescribing physician.

[43]At the time of this study, CMS officials reported that the plan-to-plan reconciliation process in place during the 2008 AEP was not timely and that the agency was testing automated reconciliation software for use in 2009.

Stakeholders Favor Changes to the AEP Schedule to Better Manage Plan Switching

CMS, sponsors, pharmacy associations, SHIPS, and beneficiary advocates recognize that the current AEP schedule—November 15 through December 31—is problematic. Some stakeholders we interviewed in our study said that creating an interval for enrollment processing between the end of the AEP and the effective date of coverage would help ensure that coverage for a beneficiary switching plans would be in place on January 1. Additional time for enrollment processing would also help beneficiaries receive their new membership information prior to the effective date of coverage. In addition, we recently reported that such an interval may address some challenges that result from premium withholdings from Medicare beneficiaries' Social Security checks.[44] Requiring a "quiet period" is standard practice in private health insurance and other federal health programs, allowing sponsors time to process applications and provide enrollees appropriate information about their new coverage prior to its effective date. For example, in Medicare Part B,[45] open enrollment is followed by a 3-month processing interval that extends from March 31 to July 1. Similarly, in the FEHBP, enrollment is followed by approximately a 3-week processing interval that extends from the second Monday in December to January 1.

More than half the sponsors interviewed supported the creation of an enrollment processing interval. CMS officials and two sponsors recommended ending enrollment in mid December, while two other sponsors suggested ending the AEP on November 30. Stakeholders also noted that some of the difficulties associated with an AEP schedule that includes the end-of-the-year holidays could be avoided with an earlier end date.

[44]GAO has previously reported that in 2006 slightly more than a half million Medicare beneficiaries who chose to have their Medicare Part C & D premium deducted from their Social Security benefit experienced problems due, in part, to the limited processing window established by SSA and driven by Treasury's timetable. GAO also reported that the AEP does not end in time for all enrollment changes affecting premium withholding to be processed, resulting in a delay of several months before the correct premiums are withheld from a beneficiary's Social Security payment. See GAO, *Schedule and Timing Issues Complicate Withholding Premiums for Medicare Parts C and D from Social Security Payments*, GAO-08-816R (Washington, D.C.: July 15, 2008).

[45]Medicare Part B typically covers outpatient health care expenses including physicians' fees.

Several sponsors recommended an earlier start date to address concerns they have regarding CMS's guidance prohibiting sponsors from processing applications submitted between the receipt of the ANOC (October 31) and the beginning of the AEP (November 15). Although CMS officials told us they expected beneficiaries to use this time to become informed about their choices, sponsors reported that this waiting period was inconvenient for those beneficiaries who were prepared to make an enrollment change. Similarly, SHIP counselors pointed out that they too must wait until November 15 to forward beneficiaries' completed applications. SHIP counselors in one state reported that the need to double check enrollment applications completed prior to November 15 limited the number of Part D beneficiaries they were able to assist during the AEP. However, stakeholders noted that starting the AEP earlier would have implications for the preceding AEP deadlines.

Conclusions

Effective written communication about plan changes helps beneficiaries determine whether their current PDP will continue to meet their needs and may reduce the risk of surprises at the pharmacy when beneficiaries fill their prescriptions in the new benefit year. From a program perspective, beneficiaries must be sufficiently aware of plan changes in order to fully use their ability to switch plans to foster the competition that Congress intended in designing the Part D program. To this end, CMS designed a model ANOC to provide a consistent format for the information sent to beneficiaries about upcoming plan changes. Sponsors as well as advocates have voiced concerns that the model lacked the attributes—particularly simplicity and personalization—that researchers say are needed for beneficiaries to understand and act on the information provided. Although CMS told us that they recently initiated an evaluation of its annual notification materials, it is unclear whether alternative formats for the ANOC-EOC will be considered. Based on our findings as well as research on the need to make information relevant to the reader, CMS's evaluation should consider alternative models that incorporate a beneficiary's personal drug information. Such an alternative may be more effective in highlighting key changes in drug costs and coverage for plan enrollees. Two sponsors in our study supplemented the 2008 ANOC by mailing additional information on specific drug coverage and cost changes to nearly 3.6 million enrollees, thus demonstrating the feasibility of providing such personalized information to their members.

Although CMS and sponsors implemented improvements to better manage the 2008 AEP enrollment process, their efforts are hampered by a schedule that lacks a sufficient interval in which to complete processing beneficiary enrollment changes prior to the effective date of new coverage. Under the current mandated schedule, it is not possible to guarantee that beneficiaries choosing to switch plans late in December are fully enrolled in their new plans with pharmacists having sufficient evidence of the new coverage by January 1. In addition, sponsors and pharmacies reported excessive administrative complexity and diminished program efficiency as a result of the nearly 15 percent of enrollments still in process in January. Stakeholders agree that modifying the schedule and creating an interval between the end of the AEP and the effective date of coverage would minimize these challenges as well as mitigate issues related to low-income subsidies and premium withholding from beneficiaries' Social Security checks. Establishing a processing interval would be consistent with the open enrollment periods in Medicare Part B, the FEHBP, and commercial insurance and create a more streamlined program to better serve beneficiaries.

Matter for Congressional Consideration

To improve the Part D enrollment process, Congress should consider authorizing the Secretary of HHS to amend the current AEP schedule to include a sufficient processing interval to fully enroll beneficiaries prior to the effective date of their new coverage.

Recommendation for Executive Action

To ensure that beneficiaries are informed effectively of plan changes, we recommend that the Acting Administrator of CMS strengthen the agency's evaluation of the ANOC-EOC by reviewing alternative formats that include personalized drug coverage and cost information.

Agency Comments and Our Evaluation

We provided CMS with a draft of this report for their review and comment. The agency provided written comments, which have been reprinted in appendix I. It also provided technical comments that we incorporated as appropriate.

CMS concurred with our recommendation and agreed that beneficiaries need plan benefit information that is easy to read and understand. The agency noted that its process for developing the model ANOC and the EOC included a review of other programs' model materials such as those used in the FEHBP, as well as restructuring the model to eliminate duplication and increase readability. CMS pointed out that, in preparation for the 2010 AEP, it has engaged a contractor to evaluate and improve the required notification materials sent to beneficiaries. CMS expects this evaluation to further address issues of length and readability. The contractor will obtain input from beneficiaries as part of its effort to redesign the ANOC for the 2010 AEP.

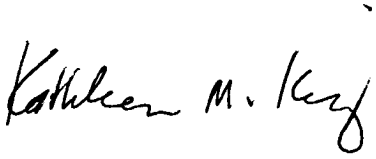
Citing the near perfect timeliness rate for plans' 2008 AEP ANOC mailing, CMS asserted that beneficiaries had the information they needed to make informed decisions about their plan options. However, we remain concerned that despite this timeliness, the volume and complexity of documents exceeding 100 pages continue to pose challenges for some beneficiaries. While CMS's effort to evaluate the ANOC-EOC is an important, worthwhile step, such a review would benefit by a focus on streamlining as opposed to maximizing the amount of information that beneficiaries receive. Beyond the current evaluation, CMS should continue its efforts to improve the understandability of its AEP materials by testing more concise formats with beneficiaries. As we note in this report, a single-page, customized model that shows each beneficiary's drug use and any upcoming changes in coverage and costs may more clearly communicate the essential information Part D beneficiaries need to be adequately informed.

CMS acknowledged the challenges inherent in the current AEP schedule. The agency reiterated its strategies for ensuring that beneficiaries are able to access their new plan benefits while their enrollment is still being processed. For example, CMS highlighted its consistent efforts to encourage beneficiaries to submit their enrollment applications by early December. However, as we discuss in this report, one consequence of this approach is a reduction in the amount of time beneficiaries have to consider and enroll in an alternative plan that could better meet their needs.

We are sending copies of this report to the Administrator of CMS, committees, and others. The report also is available at no charge on the GAO Web site at http://www.gao.gov/.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.

Sincerely,



Kathleen M. King
Director, Health Care

Appendix I: Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

DEC 02 2008

Kathleen M. King
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. King:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "Medicare part D: Opportunities Exist for Improving Information Sent to Enrollees and Scheduling the Annual Election Period" (GAO 09-04).

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Jennifer R. Lucas
for Vincent J. Ventimiglia, Jr.
Assistant Secretary for Legislation

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: DEC 0 1 2008

TO: Vincent J. Ventimiglia, Jr.
Assistant Secretary for Legislation
Department of Health and Human Services

FROM: Kerry Weems
Acting Administrator

SUBJECT: Government Accountability Office (GAO) Draft Report: "Medicare Part D: Opportunities Exist for Improving Information Sent to Enrollees and Scheduling the Annual Election Period" (GAO-09-4)

Thank you for the opportunity to review and comment on the GAO Draft Report, "Medicare Part D: Opportunities Exist for Improving Information Sent to Enrollees and Scheduling the Annual Election Period" (GAO-09-4). The Centers for Medicare & Medicaid Services (CMS) reiterates its commitment to ensuring that Medicare beneficiaries are provided timely and accurate information about the Medicare Prescription Drug Benefit Program and appreciates the GAO's interest in assessing the model Annual Notice of Change (ANOC) for the 2008 Annual Election Period (AEP) that is provided to enrollees in stand-alone Medicare Prescription Drug Plans (PDPs).

We concur with GAO's recommendation and agree that beneficiaries need information that is easy to read and understand. While, the ANOC is a standardized document, the standardization relates to the structure of the document and is not intended to prevent plans from providing useful information to beneficiaries. In fact, plans are provided with the opportunity to provide plan-specific information within designated areas of the ANOC. We would also like to clarify that although consumer research and testing of model documents was limited, there was a careful and thoughtful process in developing the model ANOC and the Evidence of Coverage (EOC). This development process included the review of other existing models such as those used in the Federal Employees Health Benefits Program, as well as restructuring several models to eliminate duplication and increase readability to better ensure understanding of the benefits and services offered.

While we acknowledge that additional communications research could assist in modifying model documents, we do believe these documents clearly convey key information needed to help beneficiaries understand their health care benefits and future changes. Given the complex nature of the Medicare Program, the ultimate goal is to ensure that beneficiaries are provided with all of the information they need to fully understand their health care options in an easy-to-read and understandable way.

To this end, we have already taken steps to ensure that beneficiary notification materials for 2010 will be easier to understand and include the information necessary for beneficiaries to make an informed decision. CMS has procured a contractor to evaluate the effectiveness of the ANOC and to assist in redesigning the document. This process will include conducting intensive beneficiary interviews to help ensure content is understandable and plan-specific benefit information is adequately disclosed.

The draft GAO report indicates that stakeholders suggested the model ANOC contains too much, and sometimes irrelevant, information. We would emphasize that CMS does have a formal process through which health plans, beneficiary advocacy groups, and trade organizations may comment on the draft ANOC prior to the document's final release. CMS carefully considers those comments, and many are incorporated into the final model ANOC.

The draft GAO report also implies that as a consequence of problems with the ANOC/EOC beneficiaries did not have the information needed to review their coverage during the open enrollment period. Given that 99.8 percent of the ANOCs were mailed timely, we believe that beneficiaries had the information in time to make an informed decision about their health care options. In addition, it was stated that the new rules for the combined ANOC/EOC do not provide for beneficiary protection. We disagree since the new requirement provides additional protection for beneficiaries to receive comprehensive information prior to the annual election period.

The report highlights the need to reduce enrollment delays and the impact on beneficiaries when a new coverage year begins. As noted in the report, the statute requires that enrollments received as late as December 31 be effective the following January 1. CMS recognizes that this presents challenges for plans and beneficiaries. Therefore, in the 2006 AEP we took steps to ensure that our model acknowledgement and confirmation letters included the necessary billing information so that beneficiaries could access services even while their enrollment was still being processed by the plan. To help mitigate this issue, we have consistently encouraged beneficiaries to submit their enrollment applications by early December instead of waiting until later in the month. In addition, in a November 13, 2008 HPMS memorandum, we reminded plans that we expect them to frequently submit batch files for enrollment and disenrollment, rather than waiting until the end of the month.

The CMS will continue to work closely with Congress, GAO, beneficiary advocacy groups, and other interested parties to ensure that beneficiaries have complete and accurate information.

Below is CMS' response on the draft report's recommendation as well as technical comments.

GAO Recommendation:

To ensure that beneficiaries are informed effectively of plan changes, GAO recommends CMS strengthen the agency's evaluation of the model ANOC-EOC by reviewing alternative formats that include personalized drug coverage and cost information.

CMS Response:

We concur with the GAO's recommendation of the model ANOC-EOC and will consider reviewing alternative formats that include personalized drug coverage and cost information. We have undertaken several efforts to address some of the concerns, such as readability, effectiveness, and the length of documents. Over the past year, we have conducted a comprehensive examination of our informational materials, which included the ANOC and the EOC. As a result, we have incorporated plain language to assist in readability. In addition, the ANOC/EOC was restructured to ensure that important information was included at the beginning of the document to make is easier to use. Finally, by combining and standardizing the ANOC/EOC, the length of the documents was reduced and unnecessary information was eliminated. Recognizing that these documents communicate the most crucial and comprehensive benefit and plan information to beneficiaries, we have efforts underway to make additional changes for the 2010 plan year.

For calendar year 2010, CMS has procured a contractor to ensure that annual beneficiary notification materials are being redesigned and standardized to provide better and more comprehensive information to beneficiaries. Specifically, this redesign has an overarching goal to provide information so that Medicare beneficiaries are confident and informed with regard to their health care options. In considering alternative formats that would include personalized drug coverage and cost information, we will do the following:

- Develop and target the content of beneficiary notification materials at appropriate language and reading levels, and reduce the length of the existing models;
- Conduct intensive beneficiary interviews to ensure these materials meet beneficiaries' information needs;
- Ensure that materials include information for special populations such as dual-eligible beneficiaries;
- Ensure that the materials conform to CMS' regulations and guidance; and
- Ensure that benefit information (for example, drug changes) are adequately explained.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen King, (202) 512-7114 or kingk@gao.gov

Acknowledgments

In addition to the contact named above, Rosamond Katz, Assistant Director; Jennie Apter; Ramsey Asaly; Anne Hopewell; JoAnn Martinez-Shriver; Jessica Smith; and Hemi Tewarson made major contributions to this report.

Related GAO Products

Medicare Part D: Complaint Rates Are Declining, but Operational and Oversight Challenges Remain. GAO-08-719. Washington, D.C.: June 27, 2008.

Medicare Part D Low-Income Subsidy: SSA Continues to Approve Applicants, but Millions of Individuals Have Not Yet Applied. GAO-08-812T. Washington, D.C.: May 22, 2008.

Medicare Part D: Plan Sponsors' Processing and CMS Monitoring of Drug Coverage Requests Could Be Improved. GAO-08-47. Washington, D.C.: January 22, 2008.

Medicare Part D Low-Income Subsidy: Additional Efforts Would Help Social Security Improve Outreach and Measure Program Effects. GAO-07-555. Washington, D.C.: May 31, 2007.

Retiree Health Benefits: Majority of Sponsors Continued to Offer Prescription Drug Coverage and Chose the Retiree Drug Subsidy. GAO-07-572. Washington, D.C.: May 31, 2007.

Medicare Part D: Challenges in Enrolling New Dual-Eligible Beneficiaries. GAO-07-272. Washington, D.C.: May 4, 2007.

Medicare Part D: Prescription Drug Plan Sponsor Call Center Responses Were Prompt, but Not Consistently Accurate and Complete. GAO-06-710. Washington, D.C.: June 30, 2006.

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