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United States Government Accountability Office
Washington, DC 20548

December 16, 2005

The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

Subject: *Medicare: Contingency Plans to Address Potential Problems with the Transition of Dual-Eligible Beneficiaries from Medicaid to Medicare Drug Coverage*

Dear Senator Baucus:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a voluntary outpatient prescription drug benefit, known as Medicare Part D.[1] The Centers for Medicare & Medicaid Services (CMS) is responsible for implementing this benefit. This new drug coverage will be provided through competing private Part D plans sponsored by health care organizations, which may charge premiums, deductibles, or copayments for drugs.[2] As a result of MMA, on January 1, 2006, drug coverage for dual-eligible beneficiaries will transition from Medicaid to Medicare Part D. This transition will occur for approximately 6 million full-benefit dual-eligible beneficiaries—Medicare beneficiaries who receive full Medicaid benefits for services not covered by Medicare.[3]

CMS is in the process of implementing this transition. During May and June 2005, CMS mailed notices to these beneficiaries informing them of the transition in coverage and that they will receive a subsidy to cover their entire deductible and help cover any prescription drug plan (PDP) premiums. During October and November 2005, CMS automatically assigned dual-eligible beneficiaries to PDPs and mailed

[1]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152.

[2]MMA and CMS regulations require that each Part D plan meet standards as to the categories of drugs it must cover, or include on its formulary, and the extent of its pharmacy networks. Within these standards, the specific formulary and pharmacy network of each plan may vary. However, CMS required all plans to cover all or substantially all drugs in six categories, including antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and human immunodeficiency virus and acquired immunodeficiency syndrome drugs.

[3]Of these 6 million beneficiaries, approximately 0.6 million are enrolled in managed care organizations and other plans and will not be addressed in this report. There are also approximately 1 million other dual-eligible beneficiaries, known as partial-benefit dual-eligible beneficiaries, who do not receive Medicaid drug coverage, and thus, are not involved in this transition.

notices to these beneficiaries informing them of the assignment and also that they may select a different PDP if they wish.[4] If they do not switch from their assigned PDP by December 31, 2005, CMS will automatically enroll them in that drug plan with coverage effective January 1, 2006. MMA provides that, after that date, dual-eligible beneficiaries may switch PDPs at any time.[5]

Dual-eligible beneficiaries are poorer and tend to have far more extensive health care needs than other Medicare beneficiaries.[6] They are also more likely to be disabled, at least 85 years old, or to have cognitive impairments.[7] You raised concerns that the single-day transition from one type of drug coverage to another could create difficulties in ensuring that prescriptions for this vulnerable population are filled. You asked us to review (1) the potential problems that may arise during the transition and (2) the contingency plans that CMS, PDPs, and states have developed to respond to potential problems with the transition. Enclosure I contains information we provided during our November 14, 2005 briefing to your staff. You also expressed concerns that dual-eligible beneficiaries in the areas affected by Hurricane Katrina may not be able to obtain necessary drugs on and after January 1, 2006.[8] Enclosure II contains information we provided during our briefing to your staff on contingency plans related to this concern.

To address these objectives, we interviewed officials from CMS and from Medicaid agencies in California, Montana, and Texas—states with large urban or rural populations. We interviewed representatives from three organizations offering Medicare PDPs, eleven drug-store chains, and the CMS contractor responsible for implementing the Eligibility Transaction—a contingency plan designed to identify the PDP in which a beneficiary is enrolled. In addition, we reviewed CMS's plan for managing the transition and the transition plans of three organizations offering PDPs, which outline their plans to assist beneficiaries who are transitioning to Medicare drug coverage. We spoke with officials from the American Association of Homes and Services for the Aging, the Center for Medicare Advocacy, the Commonwealth Fund, the Kaiser Family Foundation, the Long Term Care Pharmacy Alliance, the Medicare Rights Center, the National Association of Chain Drug Stores, and the National Community Pharmacists Association. We also spoke with two independent

[4]According to CMS, as of November 2005, the agency had identified approximately 6.1 million dual-eligible beneficiaries. Of these, approximately 5.5 million individuals have been automatically assigned to a PDP. Most of the remaining 0.6 million beneficiaries are enrolled in and will receive drug coverage through managed care organizations or other plans.

[5]According to CMS, beneficiaries' choices will only be effective the first day of the month following the month in which their new PDP receives their completed application.

[6]Medicare Payment Advisory Commission, *Report to the Congress: New Approaches in Medicare* (Washington, D.C.: June 2004). Includes all dual-eligible beneficiaries, both full- and partial-benefit.

[7]Medicare Payment Advisory Commission, *Report to the Congress*. Includes all dual-eligible beneficiaries, both full- and partial-benefit.

[8]On August 29, 2005, Hurricane Katrina made landfall on the U.S. Gulf Coast, causing widespread devastation, particularly in Alabama, Louisiana, and Mississippi.

researchers. We conducted our work from September 2005 through December 2005 in accordance with generally accepted government auditing standards.

Results in Brief

We identified three potential problems that may leave some dual-eligible beneficiaries facing difficulties immediately obtaining necessary drugs beginning January 1, 2006. The likelihood and magnitude of these potential problems is not known. First, some individuals may not be identified for automatic enrollment in a PDP due to potential inaccuracies in state or federal data. Second, not all beneficiaries who become dually eligible in late 2005 and beyond may be identified and automatically enrolled by the date they become dually eligible. Third, given that MMA and implementing regulations require that dual-eligible beneficiaries be randomly enrolled in PDPs using two criteria—the region in which the beneficiary resides and the amount of the PDP premium—beneficiaries' prescription drugs may not be on their PDP formulary or their customary pharmacy may not be in their PDP pharmacy network.

CMS, PDP, and state contingency plans address potential problems with the transition. Although each of these contingency plans is useful in mitigating risks for dual-eligible beneficiaries, their effectiveness is uncertain.

- For dual-eligible beneficiaries who do not have Medicare drug coverage because they were either not identified and enrolled on January 1, 2006 or are newly qualified dual-eligible beneficiaries, CMS has developed a point-of-sale enrollment mechanism designed to enable pharmacies to assist these beneficiaries in obtaining immediate Part D coverage. The agency signed a contract with a designated PDP on November 22, 2005 to implement this mechanism. Because these arrangements were completed less than 6 weeks before the transition is to occur, limited time remains to educate all pharmacies about its availability and details of its operation.

- For beneficiaries who were enrolled in a PDP but do not have their PDP information, CMS has facilitated a new information-technology process, known as the Eligibility Transaction, that will allow pharmacies to identify a beneficiary's PDP and provide the beneficiary with the PDP's contact information. As with the point-of-sale enrollment mechanism, it is unclear to what extent pharmacies are informed about the Eligibility Transaction and will use it. Despite CMS efforts to publicize this tool to industry organizations, a pharmacy industry association representative stated that it is unclear how many independent drug stores, which dispense the majority of the nation's retail prescription drugs, plan to use the Eligibility Transaction.

- To assist dual-eligible beneficiaries with prescriptions for drugs not on their PDP's formulary, according to CMS, all PDPs will offer dual-eligible beneficiaries at network pharmacies first fills of prescriptions for drugs not covered by formularies. First fills will give beneficiaries time to work with a physician to switch to a formulary drug, file an appeal for a formulary exception with their PDP, or switch PDPs. However, in order to obtain a first

fill without paying out-of-pocket, beneficiaries must be at a network pharmacy.[9] CMS officials stated that PDP formularies are robust and access to PDP pharmacy networks is broad. However, they noted that PDP formularies typically include upwards of 80 percent of the 100 most commonly used drugs. We did not evaluate the extensiveness of PDP formularies or pharmacy networks.

- To provide beneficiaries with time to resolve problems they may encounter and thereby minimize disruptions in treatment, state Medicaid agencies have the option to offer early or extended drug refills to dual-eligible beneficiaries prior to January 1, 2006. However, because of financial disincentives associated with the transition, state officials indicated that not all states are expected to provide such refills.

Agency Comments and Our Response

CMS reviewed a draft of this report and provided written comments, which appear in enclosure III.

In its comments, CMS objected to any implication that it has not taken all steps to keep potential problems to a minimum. Furthermore, the agency asserted that its contingency plans fully address the problems we describe and that they will ensure that dual-eligible beneficiaries will have immediate access to needed drugs. While we credit CMS for taking steps to mitigate potential risk for dual-eligible beneficiaries, we believe that the agency's complete confidence in contingency plans that have yet to be fully tested, publicized, or implemented may be premature. Our report provides valid reasons why the effectiveness of these plans is uncertain at this time.

CMS also suggested that we restructure the report. It proposed that (1) the discussion of potential problems be provided as set-up or background information, (2) the finding on potential problems focus on the efforts CMS has taken that ensure continuity of coverage for dual-eligible beneficiaries, and (3) the "Results in Brief" section be expanded to more fully describe CMS contingency plans. We organized this report to address the two objectives set forth by our requester—to review potential problems associated with the transition and to review contingency plans developed to address them. In this way, the reader is first given information on anticipated problems that may arise from MMA transition provisions as context for understanding the strengths and weaknesses of various contingency plans. Our "Results in Brief" provides a balanced description of what each contingency plan is designed to do and its potential effectiveness.

In addition, CMS contended that we did not adequately take into account new information provided to us on November 18, 2005. The agency referred specifically to our discussion of its point-of-sale enrollment mechanism to guarantee immediate access to needed drugs for any dual-eligible beneficiary not already enrolled in a

[9]At out-of-network pharmacies, beneficiaries may pay the retail price out-of-pocket for their drugs and submit a claim for reimbursement to their PDP. However, CMS acknowledged that it is unlikely that dual-eligible beneficiaries will be able to pay the retail price out-of-pocket.

PDP. At our meeting on November 18, agency officials reported that negotiations for the point-of-sale enrollment mechanism had not been finalized and details about the prospective contract could not be discussed. Our draft described the design and prospective nature of this contingency plan. While the draft report was at CMS for review, the agency signed and publicly announced the contract with its designated point-of-sale PDP. We have revised our report to reflect this new information.

CMS provided technical comments which we incorporated as appropriate. Also, the agency asked us to publish several informational documents attached to its comments. We reviewed these documents and determined that they did not address our findings and conclusions.

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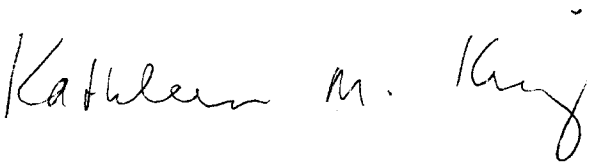
We are sending a copy of this report to the Administrator of CMS and appropriate congressional committees. We will also make copies available to others on request. In addition, the report is available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions, please contact me at (202) 512-7119 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of the report. GAO staff who made major contributions to this report are listed in enclosure IV.

Sincerely yours,



Kathleen M. King
Director, Health Care

Enclosures—4

Enclosure I

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Contingency Plans to Address Potential Problems with the Transition of Dual-Eligible Beneficiaries from Medicaid to Medicare Drug Coverage

Briefing to the Staff of Senator Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

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Enclosure I

Introduction

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created a voluntary outpatient prescription drug benefit, known as Medicare Part D, to begin on January 1, 2006.
- The Centers for Medicare & Medicaid Services (CMS) is responsible for implementing this benefit.
- Drug coverage will be provided through competing private Part D plans sponsored by health care organizations, which may charge premiums, deductibles, or copayments for drugs.
- As a result of MMA, on January 1, 2006, drug coverage for dual-eligible beneficiaries will transition from Medicaid to Medicare Part D.[1]

[1]This transition will occur for the approximately 6 million full-benefit dual-eligible beneficiaries—Medicare beneficiaries that receive full Medicaid benefits for services not covered by Medicare. Of these 6 million beneficiaries, approximately 0.6 million are enrolled in managed care organizations and other plans and will not be addressed in this report. There are also approximately 1 million other dual-eligible beneficiaries, known as partial-benefit dual-eligible beneficiaries, who do not receive Medicaid drug coverage and are not involved in the transition.

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Introduction (continued)

- CMS is currently working to help dual-eligible beneficiaries transition from Medicaid to Medicare drug coverage.
  - During May and June 2005, CMS mailed notices to these beneficiaries informing them of the transition in coverage and that they will receive a subsidy to cover prescription drug plan (PDP) premiums and deductibles.
  - During October and November 2005, CMS automatically assigned dual-eligible beneficiaries to a PDP and mailed notices to these beneficiaries informing them of the assignment.
  - Beginning November 15, 2005, beneficiaries can switch to a PDP other than their assigned PDP. If they do not switch by December 31, 2005, CMS will automatically enroll them in their assigned plan, effective January 1, 2006.

Enclosure I

Introduction (continued)

- Dual-eligible beneficiaries are poorer and tend to have far more extensive health care needs than other Medicare beneficiaries.[2]
- They are also more likely to be disabled, at least 85 years old, or to have cognitive impairments.[3]

[2]Medicare Payment Advisory Commission, *Report to the Congress: New Approaches in Medicare* (Washington, D.C.: June 2004). Includes all dual-eligible beneficiaries, both full-benefit and partial-benefit.
[3]Medicare Payment Advisory Commission, *Report to the Congress*. Includes all dual-eligible beneficiaries, both full-benefit and partial-benefit.

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Enclosure I

Purpose and Key Questions

- The Ranking Minority Member of the Senate Finance Committee raised concerns about potential problems associated with a complex transition process that shifts approximately 6 million beneficiaries from one type of drug coverage to another with no overlap in coverage between the two.

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Purpose and Key Questions (continued)

- The Ranking Minority Member requested that we respond to the following key questions:

  (1) What potential problems may arise during the transition?

  (2) What contingency plans have CMS, states, and PDPs developed to respond to potential problems with the transition?

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Enclosure I

Methodology

- In conducting this study, we interviewed officials from CMS and from Medicaid agencies in California, Montana, and Texas—states with large urban or rural populations.
- We interviewed representatives of three organizations offering Medicare PDPs, two beneficiary advocacy groups, two research organizations, three pharmacy industry organizations, eleven drug store chains, and a long-term care facility industry organization. We also spoke with two independent researchers.
- We reviewed CMS's plan for managing the transition and the transition plans of three PDPs, which outline their plans to manage beneficiaries transitioning to Medicare drug coverage.
- We conducted our work in accordance with generally accepted government auditing standards from September 2005 through December 2005.

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Results In Brief

- Some dual-eligible beneficiaries may face difficulties in immediately obtaining necessary drugs beginning January 1, 2006, (1) if they are not identified and automatically enrolled in a PDP, (2) if they are newly qualified dual-eligible beneficiaries, or (3) if their drugs are not on their PDP's formulary or if their customary pharmacy is not in their PDP's network. The likelihood and magnitude of these potential problems is not known.

- CMS's, PDPs', and states' contingency plans address potential problems with the transition, but the effectiveness of these plans is uncertain.

  - For dual-eligible beneficiaries who do not have Medicare drug coverage because they were either not identified and enrolled on January 1, 2006 or are newly qualified, CMS recently developed a point-of-sale enrollment mechanism designed to enable pharmacies to assist these beneficiaries in obtaining immediate Part D coverage.
  - Given the limited time remaining before the transition occurs, educating pharmacies about the availability and details of this mechanism could present implementation challenges.

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Enclosure I

Results In Brief (continued)

- For enrolled beneficiaries who do not have their PDP information, CMS has facilitated a new information-technology process, known as the Eligibility Transaction, that will allow pharmacies to identify a beneficiary's PDP.
  - The extent to which independent pharmacies are aware of the Eligibility Transaction is unclear.
- To assist dual-eligible beneficiaries with prescriptions for drugs not on their PDP's formulary, CMS stated that all PDPs will offer a first fill of drugs not covered by formularies to beneficiaries. To obtain a first fill, beneficiaries must be at a network pharmacy.
- To provide beneficiaries with time to resolve problems they encounter and thereby minimize disruptions in treatment, state Medicaid agencies may choose to offer early or extended drug refills to dual-eligible beneficiaries prior to January 1, 2006. Not all states are expected to provide these refills.

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Enclosure I

Background

Dual-Eligible Beneficiaries

- In 2005, there are approximately 6 million dual-eligible beneficiaries.
- About 77 percent of dual-eligible beneficiaries live in the community and about 23 percent live in long-term care facilities.[4]
- A community-based dual-eligible beneficiary filled, on average, at least 10 more prescriptions than other Medicare beneficiaries with supplemental drug coverage.[5]
- Dual-eligible beneficiaries are much poorer and tend to have far more extensive health care needs than other Medicare beneficiaries. In addition, in 2001, over 33 percent were disabled, about 14 percent were age 85 or older, and about 38 percent had a cognitive or mental impairment.[6]

[4]Medicare Payment Advisory Commission, *Report to the Congress*. Includes all dual-eligible beneficiaries, both full- and partial-benefit.
[5]The Henry J. Kaiser Family Foundation, *Medicare Chartbook* (Third Edition, Summer 2005).
[6]Medicare Payment Advisory Commission, *Report to the Congress*. Includes all dual-eligible beneficiaries, both full- and partial-benefit.

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Background

Dual-Eligible Beneficiaries (continued)

- Dual-eligible beneficiaries who reside in the community typically obtain drugs through retail pharmacies, although a limited number use mail-order pharmacies. Dual-eligible beneficiaries who reside in long-term care facilities generally obtain drugs through pharmacies that specifically serve such facilities.

- Beneficiaries typically obtain 30-day supplies of drugs, although some state Medicaid programs currently allow for extended prescriptions of 90 to 100 days for certain drugs.

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Enclosure I

Background
Medicare Part D

- Currently, state Medicaid programs pay for drugs provided to dual-eligible beneficiaries using a combination of state Medicaid funds and federal matching funds.

- As of January 1, 2006, Medicaid will no longer provide coverage for Part D covered drugs for these beneficiaries. Instead, Medicare will provide coverage.

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Enclosure I

Background

Medicare Part D (continued)

- MMA and CMS regulations require that each PDP meet standards as to the categories of drugs it covers, or includes on its formulary,[7] and the extent of its pharmacy networks.
- Within these standards, however, the specific formulary and pharmacy network of each PDP may vary.

[7]All PDPs are required to cover all or substantially all drugs in six categories, including antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and human immunodeficiency virus and acquired immunodeficiency syndrome drugs .

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Background

Medicare Part D (continued)

- Under Part D, dual-eligible beneficiaries will pay reduced copayments[8] and receive a low-income subsidy to cover their entire deductible and help cover any PDP premiums.
- In addition, according to law and regulations, dual-eligible beneficiaries will be able to switch PDPs at any time. However, according to CMS, beneficiaries' choices will only be effective the first day of the month following the month in which their new PDP receives their completed application.

[8]Dual-eligible beneficiaries who reside in an institution are not required to make copayments.

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Finding 1: Potential Problems May Leave Some Dual-Eligible Beneficiaries Facing Difficulties in Immediately Obtaining Necessary Drugs Beginning January 1, 2006

- The transition of dual-eligible beneficiaries from Medicaid to Medicare drug coverage requires two major steps: identifying these beneficiaries, and assigning them to PDPs.
- We identified three potential problems with these steps that may leave some dual-eligible beneficiaries facing difficulties in immediately obtaining necessary drugs beginning January 1, 2006.
- The likelihood and magnitude of these potential problems is not known.

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Finding 1: Potential Problems

Identification of Dual-Eligible Beneficiaries

- First, dual-eligible beneficiaries may be at risk of not obtaining necessary drugs because they may not be identified by CMS for automatic enrollment into a PDP.
- To identify dual-eligible beneficiaries, CMS is obtaining monthly lists of these beneficiaries from states; however, any beneficiary who is not identified will not be automatically enrolled into a PDP.

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Finding 1: Potential Problems

Identification of Dual-Eligible Beneficiaries (continued)

- Research organizations and advocacy groups are concerned about the accuracy of state enrollment data, noting, for example, that discrepancies exist between state and CMS lists of dual-eligible beneficiaries.
- CMS has asserted that it is confident the state data are reliable.
  - A CMS contractor performed validation tests on state data identifying dual-eligible beneficiaries. CMS specified that the contractor would follow up with states to determine the reason for any anomalies or unexpected results.
  - CMS reported that state lists have varied little from month to month and have been statistically consistent with data states have historically reported to CMS.
- We did not assess the accuracy of the state lists.

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Finding 1: Potential Problems
Coverage Gaps

- Second, newly qualified dual-eligible beneficiaries may experience coverage gaps.
  - State Medicaid agency officials expressed concerns that beneficiaries who become dually eligible in late 2005 and beyond may face a 1- to 2-month gap before Medicare drug coverage takes effect.
  - These coverage gaps would result from time lags with the process of a state submitting its monthly eligibility file and the dual-eligible beneficiary's coverage becoming effective.

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Finding 1: Potential Problems
Coverage Gaps (continued)

- For Medicaid beneficiaries who states anticipate will become Medicare-eligible, CMS is developing a process to assign prospective dual-eligible beneficiaries to PDPs prior to the end of their Medicaid coverage.
- For Medicare beneficiaries not already enrolled in Part D who subsequently qualify for Medicaid, CMS is developing a process to automatically enroll them in a PDP.
- However, until this process is implemented, CMS will not be able to identify, automatically enroll, and notify all newly qualified dual-eligible beneficiaries by the time their dual-eligible status begins.

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Finding 1: Potential Problems
PDP Formularies and Networks

- Third, beneficiaries may not be in the PDP that best meets their needs because their drugs may not be on their PDP formulary and their customary pharmacy may not be in their PDP pharmacy network.

- MMA and its implementing regulations require that dual-eligible beneficiaries be randomly enrolled in PDPs using two criteria: the region in which the beneficiary resides and the amount of the PDP premium.

- PDPs must meet formulary and network standards, but within these standards the specific formulary and pharmacy network of each PDP may vary. PDP formularies may be more restrictive than state Medicaid formularies and PDP pharmacy networks may differ from the pharmacies currently used by Medicaid beneficiaries.

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Finding 1: Potential Problems

PDP Formularies and Networks (continued)

- Advocacy groups noted that this method of assignment may disrupt beneficiaries' drug regimens or customary pharmacy usage. Specifically, beneficiaries' drugs may be not be on their PDP's formulary or their customary pharmacy may not be in their PDP's pharmacy network.
- If a beneficiary's drugs are not on their PDP's formulary, they may work with their physician to switch to a formulary drug or file an appeal for a formulary exception with their PDPs.[9]
  - Advocacy groups also noted that these processes will take time.
- If a beneficiary's customary pharmacy is not in their PDP's network, they may pay the retail price out-of-pocket and submit a claim for reimbursement to their PDP or they may switch to a network pharmacy.
  - However, CMS acknowledged that it is unlikely that dual-eligible beneficiaries will be able to pay the retail price out-of-pocket.

[9]Appeals for a formulary exception must be completed within 72 hours, or 24 hours for expedited cases.

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Finding 2: Contingency Plans Address Potential Problems, But Effectiveness Is Uncertain

- CMS, PDP, and state contingency plans address potential problems with the transition of dual-eligible beneficiaries from Medicaid to Medicare drug coverage.
- However, the effectiveness of the these plans is uncertain.

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Finding 2: CMS Contingency Plan
Point-of-Sale Enrollment Mechanism

- First, to assist dual-eligible beneficiaries who do not have Medicare drug coverage—because they were either not appropriately identified and enrolled on January 1, 2006 or are newly qualified dual-eligible beneficiaries—CMS recently developed and contracted for a point-of-sale enrollment mechanism designed to enable pharmacies to assist these beneficiaries in obtaining immediate Part D coverage.

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Finding 2: CMS Contingency Plan
Point-of-Sale Enrollment Mechanism (continued)

- Under this mechanism, after a pharmacy determines a beneficiary is not enrolled in a PDP, it will ask the beneficiary for evidence of dual eligibility.
- If the beneficiary has evidence of dual eligibility, the pharmacy will submit a bill to a designated PDP, which will provide interim coverage to allow the beneficiary to immediately obtain drugs while a CMS contractor officially verifies their eligibility.

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Finding 2: CMS Contingency Plan
Point-of-Sale Enrollment Mechanism (continued)

- CMS finalized its contract with the point-of-sale PDP on November 22, 2005—less than 6 weeks before the transition is to occur.
- In December 2005, the agency reported that it is producing a CD-ROM containing information on this mechanism for distribution to pharmacies.
- Given the time remaining before the transition takes place, educating pharmacies about the availability and details of this mechanism could present implementation challenges.

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Finding 2: CMS Contingency Plan
Eligibility Transaction

- Second, to assist beneficiaries who were enrolled in a PDP, but do not have their PDP information, CMS has facilitated a new information-technology process, known as the Eligibility Transaction, that will allow pharmacies to identify a beneficiary's PDP.
  - If that pharmacy is in the beneficiary's PDP network, the prescription will be filled. If the pharmacy is not in their PDP network, the pharmacy will provide the beneficiary with their PDP's contact information.
- The Eligibility Transaction operates in "real time" and is designed to determine in which PDP a dual-eligible beneficiary has been enrolled.
- It requires pharmacies to modify a computerized billing transaction system that all pharmacies routinely use to bill insurance companies and other payers.

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Finding 2: CMS Contingency Plan
Eligibility Transaction (continued)

- Interviewees all stated that the Eligibility Transaction will be useful.
- However, the effectiveness of this process is uncertain.
- For example, the Eligibility Transaction does not alleviate beneficiaries' responsibility to locate a network pharmacy.
    - If the pharmacy is not in the network the beneficiary will be responsible for contacting their PDP to determine the location of a network pharmacy.

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Finding 2: CMS Contingency Plan

Eligibility Transaction (continued)

- In addition, it is unclear to what extent pharmacies will use the Eligibility Transaction.
  - Officials from CMS and drug store chains stated that large chain pharmacies are aware of and will use the Eligibility Transaction.
  - CMS officials stated that, to help publicize this system, the agency has contacted the largest pharmacy industry organization representing independent drug stores.
  - A pharmacy industry representative told us that independent drug stores—which dispense the majority of the nation's retail prescription drugs—are becoming increasingly aware of the Eligibility Transaction, but it is unclear how many independent pharmacies plan to use the system.

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Finding 2: PDP Contingency Plan
First Fills

- Third, CMS officials stated that all PDPs will offer a one-time first fill of a prescription for drugs not covered by formularies to dual-eligible beneficiaries at network pharmacies.
- PDPs are offering first fills in response to a CMS requirement that they address situations where a beneficiary at a network pharmacy has a prescription for a drug that is not on the formulary.
- First fills will give beneficiaries time to work with a physician to switch to a formulary drug, file an appeal for a formulary exception with their PDP, or switch PDPs.

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Finding 2: PDP Contingency Plan
First Fills (continued)

- According to the transition plans of two PDPs, they will provide 30-day one-time first fills for beneficiaries who have prescriptions for drugs excluded from their formulary, if the beneficiaries fill their prescriptions at network pharmacies. A third PDP will provide 60-day one-time first fills.
  - Two PDPs also specified that beneficiaries in long-term care facilities will receive 30-day first fills; the third specified that they will receive 60-day first fills.
  - All three PDPs reported that they will extend first-fill supplies as needed to allow beneficiaries time to switch drugs or file an appeal for a formulary exception.

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Finding 2: PDP Contingency Plan
First Fills (continued)

- Officials from three state Medicaid agencies, two pharmacy industry organizations, two advocacy groups, and the long-term care facility industry organization all stated that the first-fill policy was a useful contingency plan.
- However, in order to obtain a first fill without paying out-of-pocket, beneficiaries must be at a network pharmacy.
  - The beneficiary will have to contact their PDP to determine the location of a network pharmacy.
- CMS officials stated that PDP formularies are robust and access to PDP pharmacy networks is broad. However, they also noted that PDP formularies typically include upwards of 80 percent of the 100 most commonly used drugs.
- We did not evaluate the extensiveness of PDP formularies or pharmacy networks.

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Finding 2: State Contingency Plan
Early or Extended Drug Refills

- CMS clarified that, to provide beneficiaries with time to resolve problems they encounter and thereby minimize disruptions in treatment, state Medicaid agencies, in accordance with their transition plans, may choose to offer early or extended drug refills to dual-eligible beneficiaries before January 1, 2006.

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Finding 2: State Contingency Plan
Early or Extended Drug Refills (continued)

- State officials indicated that not all states are expected to provide for early or extended refills.
  - Medicaid agencies in Texas and California currently offer extended refills of 90 and 100 days on certain drugs.
    - One state official, however, anticipated that few dual-eligible beneficiaries will plan ahead and obtain extended refills.
  - The Medicaid agency in Montana does not plan to offer extended refills, but currently offers 34-day early refills—refills when beneficiaries have used 75 percent, or 90 percent for narcotic drugs, of their previous supply.

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Finding 2: State Contingency Plan
Early or Extended Drug Refills (continued)

- Officials from two state Medicaid agencies, advocacy groups, and two pharmacy industry organizations asserted that if a state offers extended refills that are filled in late 2005 and used by the beneficiary in 2006, it would essentially pay twice for these drugs, once for the extended refill, and again under the state phased-down contribution.
    - This contribution is a monthly payment that states must make to the federal government beginning January 2006; it equals a percentage of the estimated amount the state would have paid had it continued to provide Medicaid drug coverage for dual-eligible beneficiaries.
- Therefore, it is unlikely that all states will offer early or extended refills.

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Concluding Observations

- The complex process for transitioning dual-eligible beneficiaries on a single day with no overlap could create difficulties ensuring that prescriptions for some members of this vulnerable population are filled.

- The success of the transition will largely depend on the extent to which dual-eligible beneficiaries (1) are properly identified and enrolled in PDPs, (2) do not have to change their customary pharmacy, and (3) are enrolled in PDPs that cover their medications.

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Concluding Observations (continued)

- Contingency plans developed by CMS, PDPs, and states address potential problems with the transition of dual-eligible beneficiaries from Medicaid to Medicare drug coverage.

- Although these contingency plans are considered appropriate and may be beneficial, it is too soon to know the extent to which they will mitigate potential risks for dual-eligible beneficiaries.

  - CMS's contract for the point-of-sale enrollment mechanism was signed on November 22, 2005, leaving limited time to provided information to pharmacies concerning its availability and the details of its operation.
  - The CMS point-of-sale enrollment mechanism and the Eligibility Transaction rely heavily on the ability and willingness of pharmacies to assist beneficiaries.
  - PDP first fills and state early or extended refills are also useful contingency plans. However, they only "buy time" and rely on the beneficiary, who may be unable to resolve complex problems.
  - The use of early or extended refills will likely be limited, due to financial disincentives for state Medicaid agencies and the need for dual-eligible beneficiaries to plan ahead to obtain the refills.

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Potential Problems and Contingency Plans Related to the Transition of Dual-Eligible Beneficiaries Affected By Hurricane Katrina

On August 29, 2005, Hurricane Katrina made landfall on the U.S. Gulf Coast, causing widespread devastation, particularly in Alabama, Louisiana, and Mississippi. Concerns have been raised related to dual-eligible beneficiaries in the areas affected by the hurricane and whether they will be able to obtain necessary drugs through Medicare Part D on or after January 1, 2006.[1] Specifically, these beneficiaries may have evacuated and may no longer live in the region in which they were assigned to a prescription drug plan (PDP). Alternatively, certain dual-eligible beneficiaries may still reside in the region in which they were assigned to a PDP, but the extent to which pharmacies in the hurricane-affected areas will be available to fill prescriptions is not known.

To address problems dual-eligible beneficiaries affected by Hurricane Katrina may have in obtaining drugs, the Centers for Medicare & Medicaid Services (CMS) has created a system that allows beneficiaries assigned to PDPs in Alabama, Louisiana, or Mississippi to immediately obtain drugs from any pharmacy they visit. Under this plan, pharmacies will electronically submit a bill for the drugs to the beneficiary's PDP.[2] If the PDP's network does not include that pharmacy, the PDP will reject the bill. In addition, if the PDP serves the hurricane-affected areas of Alabama, Louisiana, or Mississippi, it will notify the pharmacy that the beneficiary may be a hurricane evacuee and advise the pharmacy to contact the PDP.

The pharmacy will contact the beneficiary's PDP and work with it to submit an out-of-network bill. Submitting an out-of-network bill may take up to 24 hours, but the pharmacy will immediately collect the beneficiary's copayment and immediately dispense their drugs. To compensate the out-of-network pharmacies for the additional effort they must make in these cases, PDPs will reimburse them the retail price for the drug, with Medicare contributing the difference between the retail price and the PDP's negotiated price for network pharmacies.

CMS has directed PDPs to follow up with beneficiaries it identifies through this process. The agency reported that if the original PDP determines that the beneficiary has permanently relocated, that PDP will assist them in switching to another PDP that serves their region. If the original PDP determines that the beneficiary may return to their home in Alabama, Louisiana, or Mississippi, or never left but cannot access a network pharmacy, it will attempt to incorporate the pharmacy that the beneficiary accessed into its network.

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[1]Major hurricanes also made landfall in other areas of the United States in 2005. However, contingency plans related to the transition are in place only with respect to Alabama, Louisiana, and Mississippi.

[2]If necessary, pharmacies will first use the Eligibility Transaction to determine the PDP to which the beneficiary belongs.

One PDP representative we spoke with stated that this plan was quite feasible. Another stated that it was cumbersome, but useful. Two pharmacy industry organizations we spoke with did not express concern about this plan, and one stated that it was useful and workable.

Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

DEC 1 2005

Administrator
Washington, DC 20201

TO: Kathleen M. King
Director, Health Care
Government Accountability Office

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: GAO Draft Correspondence: *MEDICARE: Contingency Plans to Address Potential Problems with the Transition of Dual-Eligible Beneficiaries from Medicaid to Medicare Drug Coverage* (GAO-06-278R)

Thank you for the opportunity to review and comment on the GAO draft correspondence entitled, *MEDICARE: Contingency Plans to Address Potential Problems with the Transition of Dual-Eligible Beneficiaries from Medicaid to Medicare Drug Coverage*.

The Centers for Medicare & Medicaid Services (CMS) has significant concerns about the GAO findings. CMS has been working diligently on the transition from Medicaid to Medicare drug coverage for full-benefit dual eligible beneficiaries, and as a result, these individuals will get effective, comprehensive prescription drug coverage when the new Medicare prescription drug benefit begins on January 1, 2006. Establishing a standard of absolute perfection for this transition, when dealing with over 6 million dual eligible individuals, is clearly untenable—and certainly State Medicaid programs do not meet such a standard with access to drugs today. Yet even in GAO's own analysis, GAO notes in slide 24 that CMS contingency plans will allow a dual eligible beneficiary to "immediately" obtain needed drugs. Consequently, we object to any implication that we have not taken all steps to keep potential problems to a minimum, including establishing a point-of-sale safety net for any dual eligible individual that somehow are not identified and assigned to a plan in advance of January 1, 2006. Thus, we believe that the CMS contingency plans have fully addressed the problems that GAO was asked to investigate, and that they will produce prescription drug coverage for the dual eligible population that is at least as accessible and comprehensive as the coverage they have had in the past.

As discussed in detail below, CMS has provided a great deal of information to answer the two key questions raised by the Senate Finance Committee's Ranking Minority Member. Thus, we believe that both the letter to Senator Baucus and the report's major findings should be revised to reflect the fact that CMS has developed appropriate contingency plans to address potential problems, and that these contingency plans will ensure that dual eligible beneficiaries will have immediate access to needed drugs.

Moreover, CMS remains concerned with the inappropriate and premature distribution of the preliminary GAO findings, which prompted inaccurate press coverage of the correspondence in the November 18, 2005 *Washington Post* concerning the GAO's alleged findings.

Page 2 – Kathleen M. King

General Comments

CMS has made an intensive effort to identify and auto-enroll dual eligible individuals prior to the effective date of their Medicare Part D eligibility. However, it is possible that some individuals may go to pharmacies before they have been auto-enrolled in a Part D plan. For this reason CMS has developed a process for a point-of-sale interaction to ensure full-benefit dual eligible beneficiaries experience no coverage gap. Beneficiaries who present at a pharmacy with evidence of both Medicaid and Medicare eligibility, but without current enrollment in a Part D plan, can have the claim for their medication submitted to a single account for payment. The beneficiary can leave the pharmacy with a filled prescription, and a CMS contractor will immediately follow up to validate eligibility and facilitate enrollment of the full-benefit dual eligible into a Part D plan. We described this process to the GAO at our exit conference on November 18, 2005 (a detailed description of this process is attached). **Therefore, as we stated at the time, CMS believes the first formal finding of the report should reflect the fact that CMS has established effective contingency plans to ensure that dual-eligible beneficiaries will be able to obtain comprehensive coverage and obtain necessary drugs beginning January 1, 2006.**

Similarly, we recommend that the second finding of the report should be revised substantially. Currently, the "Results in Brief" section of the cover letter to the report includes only one sentence noting that CMS contingency plans "address potential problems with the transition but have limitations." This statement is preceded by a full paragraph laying out the potential problems under investigation and then another paragraph describing the alleged limitations. **Instead, we believe that this key section of the letter should (1) clarify that the potential problems identified in the first paragraph were the intended subject of the report—not the findings; and (2) prominently describe the CMS contingency plans.**

Thus, despite extensive discussions at the November 18, 2005, GAO exit conference, we do not believe GAO has adequately taken into account the new information provided by CMS. Most notably, although additional technical information was incorporated into both the GAO letter to Senator Baucus and the GAO report itself, these documents continue to assert that (1) some dual-eligible beneficiaries will encounter difficulties immediately obtaining necessary drugs, and (2) some dual-eligible beneficiaries will face 1-2 month coverage gaps. Neither of these assertions is accurate and the GAO's own slide presentation recognizes this. For example, slide 24 of the report states that, "The pharmacy will submit a bill to a designated PDP, which will provide interim coverage to allow the beneficiary to immediately obtain drugs while a CMS contractor officially verifies their eligibility." (Emphasis added.) CMS' point of sale enrollment system guarantees immediate access to needed drugs for any dual eligible beneficiary not already enrolled in a prescription drug plan.

Enclosure IV

GAO Contact and Staff Acknowledgments

GAO Contact

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Acknowledgments

In addition to the contact named above, Rosamond Katz, Assistant Director; Joanna L. Hiatt; and Grace A. Materon made key contributions to this report.

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