Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

DUAL ELIGIBLES' TRANSITION: PART D FORMULARIES' INCLUSION OF COMMONLY USED DRUGS

Daniel R. Levinson
Inspector General

January 2006
OEI-05-06-00090

Office of Inspector General

http://oig.hhs.gov

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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

EXECUTIVE SUMMARY

OBJECTIVE

To determine the extent to which Medicare prescription drug plan formularies include drugs commonly used by dual eligibles under Medicaid.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) makes comprehensive prescription drug coverage under Medicare Part D available to all Medicare beneficiaries through prescription drug plans (PDP) or Medicare Advantage plans.

More than 6 million Medicare beneficiaries are full benefit dual eligibles, i.e., beneficiaries enrolled in both Medicare and Medicaid (for brevity, herein referred to as "dual eligibles"). Until December 31, 2005, dual eligibles received outpatient prescription drug benefits through Medicaid. On January 1, 2006, drug coverage for dual eligibles switched from Medicaid to Medicare.

States, Congress, and beneficiary advocates have expressed concern that the movement of dual eligibles to Medicare drug coverage presents unique challenges given the low income and poor health status that characterize this population. In addition, this population is historically hard to reach through outreach and education efforts.

In light of these concerns and to avoid disruptions in coverage, the Centers for Medicare & Medicaid Services (CMS) has randomly assigned each dual eligible (except those already enrolled in a Medicare Advantage plan) to a PDP, as required by the MMA. Dual eligibles who did not select a drug plan by December 31, 2005, have been automatically enrolled in their preassigned plans.

Medicaid and Medicare drug coverage differ in certain respects. Drug plans under Medicare have more flexibility than State Medicaid programs to set their own formularies and limit coverage of drugs within broad parameters. Also, Medicare drug plans are prohibited from covering certain categories of drugs ("excluded drugs") that Medicaid programs may opt to cover.

We assessed the extent to which PDP formularies include the drugs that dual eligibles commonly used under Medicaid, as differences in coverage may present challenges during dual eligibles' transition to Medicare.

We did not assess or compare the overall benefits provided to dual eligibles under Medicaid versus Medicare.

We identified 200 of the drugs most highly utilized by the dual eligible population in 2005. These drugs account for approximately 78 percent of prescriptions dispensed to dual eligibles. Of these 200 drugs, 178 are eligible for PDP coverage and 22 are excluded. We reviewed the formularies of PDPs to which dual eligibles are assigned to determine how many of the 178 eligible drugs each formulary includes. Dual eligibles are being assigned to 409 PDPs that use 37 unique formularies. We also interviewed 47 State Medicaid representatives regarding their Medicaid coverage policies for the 22 excluded drugs.

FINDINGS

Prescription drug plan formularies include between 76 and 100 percent of the commonly used drugs we reviewed. The PDP formularies vary in their inclusion of the 178 common drugs in our review that are eligible for PDP coverage. Therefore, random assignment to PDPs may affect the number of dual eligibles who take a specific drug that is not included on their PDP's formulary. Formulary inclusion of the 178 commonly used drugs ranges from a low of 135 drugs (76 percent) to a high of 178 drugs (100 percent).

Nineteen percent of formularies include all 178 of the Part D eligible drugs we reviewed; an equal proportion include 151 or fewer (less than 85 percent). By formulary, the average rate of inclusion is 92 percent of these commonly used drugs. It is important to note that dual eligibles who take drugs not included by their PDP's formulary may obtain a prescription for a different drug that treats the same condition, apply for an exception if the nonformulary drug is medically necessary, or switch to a PDP that includes their drug. CMS has urged PDPs to cover a one-time supply of the nonformulary drug to aid in this transition.

Nationally, almost one-fifth of dual eligibles (18 percent) are assigned to PDPs that include all 178 drugs in our review. On the other hand, almost one-third of dual eligibles (30 percent) are assigned to plans that include less than 85 percent (151 or fewer) of the 178 commonly used drugs. In every PDP region, at least one plan uses a formulary that includes all 178 of the high utilization drugs in our review. This means that every dual eligible has the opportunity to enroll in a plan that includes all of these commonly used drugs.

Approximately half of the 178 commonly used drugs that we reviewed were included by all formularies. Most of the drugs reviewed are included by the majority of formularies, and in fact, about half of the 178 commonly used drugs (51 percent) are included by all 37 formularies. By drug, formulary inclusion ranges from 43 percent (16 formularies) to 100 percent (37 formularies). The average rate of inclusion is 34 out of 37 formularies (92 percent).

Certain drugs are omitted from formularies more frequently than others. Of the 178 drugs, 21 drugs (12 percent) were omitted from at least one-fourth of the formularies. CMS staff report that they have reviewed each formulary to verify compliance with minimum requirements and ensure overall adequacy of each formulary. Dual eligibles who are taking a nonformulary drug are therefore able to obtain a different drug that treats their condition and is included on their PDP's formulary, but they would need to obtain a prescription for the new drug from their physician.

Dual eligibles' access under Medicaid will not change in 45 of 47 States for the 22 drugs we reviewed that are statutorily excluded from Medicare Part D coverage. Of the 200 drugs commonly used by dual eligibles, 22 drugs fall into categories that are statutorily excluded from Medicare Part D coverage. States may cover drugs in these categories for dual eligibles under Medicaid. All 47 States interviewed currently provide coverage of at least some excluded drugs. In 45 of these 47 States, dual eligibles will continue to have access to the same drugs currently covered by their Medicaid program after they make the transition to Medicare. One State is eliminating Medicaid coverage of one category of excluded drugs (for all beneficiaries), and another State is eliminating Medicaid coverage of two categories of excluded drugs.

CONCLUSION

Our review focused on differences between drugs that dual eligibles most commonly used under Medicaid and drugs included in Part D formularies, as these differences may affect the ease of dual eligibles' transition from Medicaid to Medicare.

We reviewed 200 drugs commonly used by the dual eligible population in aggregate. Of the 200 drugs, 22 drugs fall into categories excluded by law from PDP coverage, and 178 drugs are eligible for PDP coverage. We compared the 178 Part D eligible drugs to PDP formularies and found that inclusion of these drugs varies.

Because PDP formularies vary, random assignment to PDPs may affect the number of dual eligibles who take a specific drug that is not included on their PDP's formulary. Dual eligibles have several options to ensure appropriate drug coverage if this occurs. They can apply for an exception for the nonformulary drug. They can get a new prescription from their doctor for a different drug that treats their condition and is included on their PDP's formulary. They may also choose to switch plans, with new coverage effective the following month. Because each PDP region has at least one plan that includes all 178 commonly used drugs we reviewed, every dual eligible has the opportunity to enroll in a plan that includes all of these drugs. Finally, CMS has urged PDPs to cover a one-time supply of the nonformulary drug to aid in this transition.

Navigating these options requires a dual eligible to have a certain level of understanding of the Medicare Part D benefit and take specific action. Given the medical and resource challenges faced by this population, dual eligibles may need targeted assistance, in addition to the efforts CMS and State Medicaid agencies have already undertaken, to successfully navigate the transition from Medicaid to Medicare coverage. Reported experiences of some dual eligibles highlight the need for further targeted assistance to this population to ease this transition.

OIG will continue to study issues associated with dual eligibles as they make the transition from Medicaid to Medicare Part D.

Agency Comments

CMS provided comments on the draft report in which it highlighted its concerns with this report. These concerns fall into two general categories: methodology and scope. CMS also provided its own analysis comparing individuals' drug histories to PDP formularies for a sample of dual eligibles. Despite the differences in our methodologies, CMS's results were remarkably similar to ours and we believe further support our conclusions. Discussion of CMS's comments and OIG's response are included in the conclusion, beginning on page 17. CMS's comments and analysis are included in Appendix E. CMS also provided technical comments, which we incorporated into the report where appropriate.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

To determine the extent to which Medicare prescription drug plan formularies include drugs commonly used by dual eligibles under Medicaid.

BACKGROUND

The Medicare Prescription Drug Benefit

Effective January 1, 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) made comprehensive prescription drug coverage under Medicare Part D available to all 43 million Medicare beneficiaries.[1] Beneficiaries generally have the option to enroll either in a stand-alone prescription drug plan (PDP) and receive all other Medicare benefits through fee-for-service or to enroll in a Medicare Advantage plan (MA plan) and receive all Medicare benefits (including drug coverage) through managed care.[2]

Private sponsors contract with Medicare to offer PDPs and MA plans in one or more of the PDP or MA regions. The Centers for Medicare & Medicaid Services (CMS) has designated 34 PDP regions and 26 MA regions.[3] Each region covers at a minimum one State, and some regions cover multiple States. Plans must cover the entire region in which they are offered. Many sponsors offer more than one PDP or MA plan.

Transferring Dual Eligibles from Medicaid to Medicare Drug Coverage

Over 6 million Medicare beneficiaries are full benefit dual eligibles, i.e., beneficiaries enrolled in both Medicare and Medicaid (for brevity, herein referred to as "dual eligibles"). Until December 31, 2005, dual eligibles received outpatient prescription drug benefits through Medicaid. However, pursuant to section 1935(c) of the Social Security Act (the Act), as amended by the MMA, Federal financial participation ended for Medicaid drug coverage for dual eligibles on January 1, 2006.[4] Instead, dual eligibles now receive drug coverage through either a PDP or an MA plan.

Medicare subsizes Part D coverage for dual eligibles and other beneficiaries who meet minimum resource and income requirements. A regional low-income premium subsidy amount is calculated for each PDP region. A person with limited resources and means who qualifies for extra assistance and who enrolls in a Part D plan will have his or her basic Part D premium subsidized up to the regional low-income subsidy amount for the region in which he or she resides. Thus, for dual

eligibles enrolled in PDPs that offer standard benefits (or equivalent) with premiums at or below the benchmark, Medicare will pay for drug plan premiums, deductibles, and other cost sharing. Dual eligibles' cost sharing responsibilities will be limited to copayments of up to $5 per prescription.

States are required to make payments, based on a per-capita methodology, to contribute toward dual eligibles' drug costs under Medicare Part D. These payments are referred to as the phase-down State contribution payments.[5]

States, Congress, and beneficiary advocates have expressed concern that the movement of dual eligibles to Medicare drug coverage will present unique challenges given the fact that dual eligibles have greater health and resource challenges than other Medicare beneficiaries.[6] Nearly three-quarters of dual eligibles have an annual income of $10,000 or less. Thirty-eight percent have a cognitive or mental impairment. Over a third are disabled. Less than half have graduated from high school. On average, dual eligibles use at least 10 more prescription drugs than nondual eligible beneficiaries. In addition, this population is historically hard to reach through outreach and education efforts.

In light of these concerns and to avoid interruptions in coverage, in November 2005, CMS randomly assigned most dual eligibles to PDPs eligible for the full low-income subsidy. Random assignment of these dual eligibles to PDPs was required by the MMA.[7] Dual eligibles who were already members of an MA plan (approximately 10 percent of dual eligibles) were passively enrolled in that MA's drug plan. Dual eligibles who were assigned to PDPs and did not select a different PDP or MA plan prior to December 31, 2005, were automatically enrolled in the PDP to which they were randomly assigned.

Unlike the general Medicare population, dual eligibles are permitted to switch plans at any time, with their new plan's coverage effective at the beginning of the following month.[8] This allowance increases dual eligibles' opportunities to identify and enroll in the plan that best meets their prescription drug needs.

Differences in Medicaid and Medicare Drug Coverage Requirements

Dual eligibles will encounter some important differences between their current Medicaid drug coverage and their new coverage under Medicare. Generally, Medicaid is required to cover all drugs except for those that fall into a specific list of excludable drug categories. However,

utilization for Medicaid covered drugs may be controlled by various cost containment measures. For example, States may establish preferred drug lists and may require prior authorization for nonpreferred drugs or step therapy (i.e., requiring a beneficiary to try a less expensive therapeutic alternative before covering the more expensive drug). Twelve States also limit the number of prescriptions per beneficiary per month.[9]

In contrast, Medicare drug plans can establish their own formularies, excluding drugs from formulary inclusion within broad parameters. These parameters are intended to balance beneficiaries' needs for adequate drug coverage with plans' needs to contain costs. The minimum statutory requirement is that a formulary must include at least two drugs in each approved therapeutic category and class (unless only one drug is available for a particular category or class), regardless of the drug classification system used.[10] CMS may require formulary inclusion of more than two drugs per category or class in cases in which additional drugs present unique and important therapeutic advantages in safety and efficacy, and in which their absence from the plan formulary may substantially discourage enrollment in the plan by beneficiaries with certain diseases.[11] In addition, CMS has designated six drug categories for which plans must cover "all or substantially all" of the drugs.[12] These six categories are antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant, and HIV/AIDS drugs.

Similar to Medicaid, Medicare drug plans may also control access to drugs on their formularies by requiring prior authorization and/or step therapy to obtain drugs. Drug plans may change their formularies but must provide beneficiaries with written notice of such changes and must obtain approval from CMS before deleting a drug from their approved formulary.[13]

CMS Efforts to Ensure an Effective Transition and Comprehensive Coverage for Dual Eligibles

Formulary Review. In the Fall of 2005, CMS completed its review of all Medicare drug plan formularies for 2006 to verify that they met minimum requirements. CMS also used narrower drug classifications designated by U.S. Pharmacopeia as "key drug types" to ensure overall adequacy of each formulary.[14] CMS also reviewed whether each formulary is consistent with widely used industry best practices and whether benefit management tools (such as step therapy) are applied in a clinically appropriate fashion.[15]

Formulary Exceptions. All beneficiaries have the right to request Part D coverage of a nonformulary drug (that is otherwise eligible for Part D coverage) and to appeal denials. A drug plan must provide access to a nonformulary drug if the prescribing physician provides a statement (and supporting documentation upon request) that the nonformulary drug is medically necessary because all drugs on the formulary would not be as effective for the enrollee and/or would have adverse effects.[16] CMS has developed procedures intended to ensure that beneficiaries receive prompt decisions regarding formulary exceptions.[17]

Transition Process. Drug plan sponsors are required to establish a transition process for new enrollees (including dual eligibles) who are in transition from other drug coverage to Part D and whose current drug therapies may not be included on their drug plan's formulary. CMS recommends but does not require that sponsors allow a temporary, one-time transition supply for new enrollees who are taking a drug that is not included by their drug plan's formulary.[18] This would accommodate the beneficiary's immediate drug needs the first time that he or she attempts to fill a prescription for a nonformulary drug and allow the beneficiary time to work with the prescribing physician to either switch drug therapies or request a formulary exception.

Drugs Excluded From Medicare Part D

The MMA excludes certain categories of drugs from Medicare Part D coverage. These are the same categories of drugs that States have had the option to exclude from their Medicaid program. In 2006, this list includes:

- Agents when used for anorexia, weight loss, or weight gain;
- Agents when used to promote fertility;
- Agents when used for cosmetic purposes or hair growth;
- Agents when used for the symptomatic relief of cough and colds;
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations;
- Nonprescription drugs;
- Barbiturates; and
- Benzodiazepines. [19]

Beginning in 2007, this list will also include "agents when used for the treatment of sexual or erectile dysfunction, unless such agents are

used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration."[20]

Drugs that are covered under Medicare Part A or Part B are also excluded from coverage under Medicare Part D.

State Wraparound Coverage Options

State Medicaid programs can claim Federal matching funds for coverage of Part D excluded drugs for dual eligibles. If a State provides coverage of any excluded drugs to its nondual eligible Medicaid population, it must provide that same coverage to its dual eligibles.

In addition, States may use State-only funds to offer wraparound coverage to dual eligibles for additional (i.e., nonexcluded) drugs not included by Medicare drug plan formularies. States may provide this supplemental coverage through their Medicaid program or through a State Pharmaceutical Assistance Program (SPAP). SPAPs are voluntary, State-funded programs and do not receive a Federal match. Typically, SPAPs have provided drug coverage assistance to low-income seniors and others who did not qualify for Medicaid coverage. Twenty-seven States have SPAPs that have either received a transitional grant from CMS for MMA or have been recognized by CMS as "qualified" SPAPs.[21]

Drug Coverage Notification Process for Dual Eligibles

In addition to general outreach efforts, CMS has developed a three-pronged approach to directly notify all dual eligibles of their impending transition from Medicaid to Medicare drug coverage. This involves mailing directly to dual eligibles notification letters and other materials from CMS, State Medicaid agencies, and the drug plans to which they were assigned.

Many States have sent beneficiaries additional information and materials, either with their required official notice of drug coverage change or in separate mailings throughout the Fall of 2005. For example, many States have included information about specific features of the Medicare Part D benefit and transition (e.g., that the dual eligible has a choice of plans) and contact information for sources of assistance (e.g., 1-800-MEDICARE). Some States have taken more proactive steps to assist dual eligibles. For example, a few States planned to send dual eligibles personalized drug profiles that compare their individual drug history to each PDP formulary to help dual eligibles select the plan that best meets their drug needs.

CMS has developed special protocols and is making available specially trained operators and casework coordinators to provide targeted assistance to dual eligibles. These efforts are intended to address questions or concerns that arise during the transition and respond to issues quickly.[22]

SCOPE AND METHODOLOGY

Scope

Our assessment of drug coverage for dual eligibles under Medicare Part D included two components: determination of PDP formulary inclusion of commonly used drugs and review of State wraparound coverage policies. We did not assess or compare the overall benefits provided to dual eligibles under Medicaid versus Medicare. Rather, we more narrowly focused our review on dual eligibles' transition from Medicaid to Medicare.

See Appendix A for detailed scope and methodology.

Formulary Inclusion. We used aggregate drug utilization data to identify drugs commonly used by the dually eligible population as a whole. We did not assess individual dual eligibles' prescription drug use or whether individual dual eligibles are assigned to formularies that include the specific drugs that each uses.

Our analysis assessed only whether PDP formularies include the specific drugs in our review. We did not assess the overall adequacy of formularies or whether these formularies comply with mandated minimum coverage requirements.

Our review included 200 of the most commonly used drugs based on the estimated number of prescriptions dispensed to dual eligibles under Medicaid fee-for-service in the first two quarters of 2005. These drugs account for approximately 78 percent of prescriptions to dual eligibles during this period. Of these 200 drugs, 22 fall into categories excluded from Medicare Part D coverage, and 178 are eligible for Part D coverage.

We included these 200 drugs in our review because they are highly utilized by the dual eligible population under Medicaid, and therefore, their inclusion or noninclusion by PDP formularies may have an impact on the ease of the dual eligibles' transition from Medicaid to Medicare Part D. We did not assess the clinical value of any of these drugs or of

any therapeutically equivalent drugs that formularies may include instead of the particular drugs on this list.

We included the formularies of all 409 PDPs to which dual eligibles have been randomly assigned by CMS for autoenrollment. Many plans use the same formulary; these 409 plans use a total of 37 unique formularies. We excluded the formularies of MA plans. CMS did not assign dual eligibles to an MA drug plan unless they were already enrolled in that MA plan for their health care. Approximately 10 percent of dual eligibles were assigned to MA drug plans.

State Wraparound Coverage. We interviewed Medicaid representatives from 47 (out of 51) States and SPAP representatives from 23 (out of 27) States. We inquired about States' provision of Medicaid coverage for the 22 excluded drugs in our review and asked about States' plans to use State-only funds to provide wraparound coverage to dual eligibles for nonformulary drugs.

This information represents a snapshot at the time of our data collection (November and December 2005) and is self-reported data from State Medicaid and SPAP representatives. State coverage plans are subject to change.

Methodology

Commonly Used Drugs. We used aggregated 2005 drug utilization data from the Medicaid drug rebate program and 2003 dual eligible-specific data from the Medicaid Statistical Information System to estimate Medicaid prescriptions dispensed to dual eligibles in the first two quarters of 2005. Based on this estimate, we identified 200 highly utilized drugs. This list includes 22 drugs that are excluded by law from Part D coverage and 178 drugs eligible for PDP coverage. For a detailed explanation of how we identified the 200 highly utilized drugs, see Appendix A.

We defined a drug by its active ingredient(s) regardless of specific strengths, dosages, manufacturers, or package sizes. For example, a multiple-source drug (i.e., a drug with generic equivalents) such as fluoxetine HCl (the active ingredient for the multiple-source brand name drug Prozac) has only one entry on our list, covering all strengths of the brand name drug Prozac, as well as the generic versions of fluoxetine HCl available. We also considered similar routes of administration (e.g., tablets, pills, and other oral versions) to be the same drug, while substantially different routes of administration (e.g., oral vs. injection) were treated as different drugs.

Because we had to rely on estimates to develop this list, we cannot state with confidence that our list of 200 drugs precisely mirrors the actual top 200 drugs used by dual eligibles. Additionally, because the list was drawn from national aggregate data, it may not exactly reflect the top 200 drugs used by dual eligibles in a given State due to different patient mix and different State policies meant to control utilization and costs. However, these drugs account for approximately 78 percent of prescriptions dispensed to dual eligibles, and therefore represent the actual utilization of a significant number of dual eligibles. The 200 drugs reviewed are listed in Appendix B.

Formulary Inclusion. Our assessments of formulary inclusion considered the 178 commonly used drugs that are eligible for PDP coverage. We counted a drug as included if the formulary included the active ingredient(s) in any strength, dosage, manufacturer (either brand name or generic), or package size of the same general route of administration. For consistency with CMS policy regarding minimum formulary coverage requirements, we also considered a drug to be included if either the standard form or the extended release version of the same active ingredient(s) was included in the formulary. Our determination of formulary inclusion was based solely on whether each drug was included in the formulary. We did not consider tier level, prior authorization, or step therapy requirements.

State Wraparound Coverage. For the 22 drugs in categories excluded from PDP coverage, we used information from our State interviews to determine how many States currently provide coverage for these drug categories under Medicaid and whether this coverage will change in any State Medicaid programs. We also determined how many States plan to offer State-funded wraparound coverage for any nonexcluded drugs that a dual eligible's PDP formulary does not include.

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

Prescription drug plan formularies include between 76 and 100 percent of the commonly used drugs we reviewed

Of 200 drugs with high utilization by the dual eligible population, 178 drugs are eligible for coverage by PDPs and the other 22 drugs fall into categories excluded by law from Part D coverage. Dual eligibles are assigned to 409 PDPs that use a total of 37 unique formularies. Because these PDP formularies vary in the number of commonly used drugs they include, random assignment to PDPs may affect prescription drug coverage. Formulary inclusion of the 178 commonly used drugs ranges from a low of 135 drugs (76 percent) to a high of 178 drugs (100 percent).

Nineteen percent of formularies include all 178 of the Part D eligible drugs we reviewed; an equal proportion include 151 or fewer (less than 85 percent). By formulary, the average rate of inclusion is 92 percent of these commonly used drugs.

To meet minimum coverage requirements, all formularies must include therapeutic alternatives (i.e., drugs that treat the same medical condition) for drugs that are not included on the formulary. Additionally, CMS staff reported that they had ensured in their formulary review that formularies include at least one of each key drug type, unless the plan presented reasonable clinical justification for not including a key drug type. Dual eligibles who are taking a drug that is not included on their PDP formulary should therefore have coverage for a different drug that treats their condition. However, a dual eligible in this situation will need to obtain a new prescription from his or her doctor before the alternative drug can be dispensed.

Eighteen percent of dual eligibles were assigned to plans that include of all of the 178 commonly used drugs we reviewed

As of November 2005, almost one-fifth of dual eligibles (18 percent) nationally have been assigned to PDPs that use formularies that include all 178 drugs in our review. If these dual eligibles took no action, they were automatically enrolled in these plans on January 1, 2006, and maintained formulary inclusion of all of these 178 commonly used drugs. While we reviewed 178 of the most common drugs, any individual dual eligible may be taking drugs not included in our review that may or may not be included on these formularies.

Almost one-third of dual eligibles (30 percent) were assigned to plans that include less than 85 percent (151 or fewer) of the 178 commonly

used drugs. If these dual eligibles took no action to switch plans, they were automatically enrolled in plans with a formulary that omits 15 percent or more of these common drugs. An individual dual eligible assigned to one of these plans may not take any of the omitted drugs, and lack of formulary inclusion of these drugs may not affect that individual. However, because our review included drugs with high utilization by this population, it is likely that at least some dual eligibles assigned to these plans use drugs that are omitted from the formulary. If dual eligibles were assigned to a plan that does not include a drug they take, they may obtain a new prescription for an alternative drug that is included, apply for a formulary exception if the nonformulary drug is the only drug that meets their needs, or switch to a plan that includes their drug.

Table 1 breaks out dual eligibles' autoassignment by formulary inclusion nationally. Appendix C provides this breakout by PDP region.

TABLE 1: Random Assignment of Dual Eligibles and Formulary Inclusion of Commonly Used Drugs

Random Assignment to Plans That Include:	Number of Dual Eligibles*	Percentage of Dual Eligibles
100% of Common Drugs Reviewed (178 Drugs)	979,000	18%
85% to 99% of Common Drugs Reviewed (152 to 177 drugs)	2,892,000	52%
Less than 85% of Common Drugs Reviewed (151 or fewer drugs)	1,628,000	30%
Totals	**5,499,000**	**100%**

* Rounded to the nearest 1,000.

Source: Office of Inspector General (OIG) Analysis of Formulary Inclusion of Drugs Commonly Used by Dual Eligibles, 2005.

Every PDP region has at least one plan using a formulary that includes all 178 commonly used drugs. This means that all dual eligibles have the opportunity to switch to a plan including all of these 178 drugs. To change PDPs, dual eligibles need to identify which PDP formulary best meets their needs and take action to enroll in that plan.

Four States planned to offer wraparound coverage for at least some drugs omitted from plan formularies

At the time of our interviews (November to December 2005), 4 of the 47 States planned to use State-only Medicaid funds to provide wraparound coverage to dual eligibles for drugs that are eligible for PDP coverage but are omitted from a plan's formulary. Two of these States, Connecticut and New York, planned to cover any drugs that are not included on a PDP's formulary and that the State covers for its nondual eligible Medicaid population. The other two States, New Jersey and Vermont, planned to cover a limited group of nonformulary drugs. All four States planned to require dual eligibles to exhaust the exceptions and appeals process with their PDP before the State will provide Medicaid coverage.

Since the transition of dual eligibles on January 1, 2006, several additional States have announced plans to offer temporary safety net coverage to dual eligibles in response to problems with the transition. States' supplemental coverage may apply in a variety of circumstances in which dual eligibles are having difficulty obtaining drugs under Part D, including but not limited to formulary issues. For example, Maine reinstituted State-funded drug coverage for its dual eligible population on January 3, 2006.[23] In California, the State passed emergency legislation to guarantee medication coverage for dual eligibles who have been unable to get their prescriptions filled under the new Medicare drug benefit. The bill provides up to $150 million for 1 month to pay for medications for dual eligibles.[24] Numerous other States have reported similar actions.[25]

Approximately half of the 178 commonly used drugs we reviewed were included by all formularies

Most of the 178 commonly used drugs are included by a large percentage of formularies and, in fact, half of these drugs (51 percent) are included by all 37 formularies. Therefore, dual eligibles will be assured formulary inclusion of many of the highly utilized drugs regardless of the plan to which they were assigned. An additional 27 of these highly utilized drugs (15 percent) are included by all but 1 or 2 formularies.

By drug, formulary inclusion ranges from 43 percent (i.e., included by 16 formularies) to 100 percent (37 formularies). However, because most of the drugs are included by the vast majority of formularies, the

average rate of inclusion is relatively high at 34 out of 37 formularies (92 percent). Table 2 provides a summary of formulary inclusion by drug, and Appendix B provides the number and percentage of formularies that include each of the 178 drugs.

TABLE 2: Formulary Inclusion by Drug

Drugs Included by…	Percentage of 178 Drugs
100% of the 37 Formularies (37 formularies)	51% (91 drugs)
85% to 99% of the 37 Formularies (32 to 36 formularies)	29% (52 drugs)
75% to 84% of the 37 Formularies (28 to 31 formularies)	8% (14 drugs)
43% to 75% of the 37 Formularies (27 or fewer formularies)	12% (21 drugs)
Total	**100% (178 drugs)**

Source: OIG Analysis of Formulary Inclusion of Drugs Commonly Used by Dual Eligibles, 2005.

Among formularies that do not include all 178 drugs, certain drugs are omitted more frequently than others

Of the 178 common drugs we reviewed, 21 drugs (12 percent) were omitted from at least one-fourth of the formularies. Table 3 lists these 21 drugs and the percentage of formularies covering each. All are single source drugs, i.e., brand name drugs with no generic equivalents. Six of these twenty-one drugs are used to treat high blood pressure. Three of these drugs are used to lower cholesterol and three are used for pain relief.

Minimum formulary coverage guidelines and CMS review should ensure that all formularies include a therapeutic alternative for any of these omitted drugs. If a dual eligible takes a specific drug that is omitted from his or her PDP formulary, obtaining an alternative drug requires the dual eligible to get a new prescription from his or her doctor. Dual eligibles may also apply for a formulary exception to obtain coverage for a nonformulary drug (by submitting a written statement of medical necessity from their physician). Finally, dual eligibles may switch to a PDP that includes their drug (with new coverage effective the following

month). In the meantime, CMS has urged PDPs to cover a one-time transition supply of the nonformulary drug.[26]

TABLE 3: Drugs Omitted From at Least 25 Percent of Formularies

Drug Brand Name (Generic Name)	Primary Indication(s)[27]	Percentage of Formularies Omitting
Mobic (Meloxicam)	Osteoarthritis (pain relief, anti-inflammatory)	57%
Aciphex (Rabeprazole sodium)	Ulcers, gastroesophageal reflux disease, and Zollinger-Ellison syndrome	51%
Lidoderm (Lidocaine patch)	Postherpetic neuralgia (relief of pain following shingles infection)	46%
Ultracet (Tramadol HCl/acetaminophen)	Pain relief	43%
Lescol (Fluvastatin sodium)	Hyperlipidemia (high cholesterol)	43%
Lexapro (Escitalopram oxalate)[28]	Depression, generalized anxiety disorder	41%
Clarinex (Desloratadine)	Antihistamine (hay fever, hives)	41%
Pravachol (Pravastatin sodium)	Hyperlipidemia (high cholesterol)	41%
Cozaar (Losartan potassium)	Hypertension (high blood pressure)	38%
Hyzaar (Losartan potassium/HCTZ)	Hypertension (high blood pressure)	38%
Crestor (Rosuvastatin)	Hyperlipidemia (high cholesterol)	38%
Avalide (Irbesartan/HCTZ)	Hypertension (high blood pressure)	38%
Avapro (Irbesartan)	Hypertension (high blood pressure)	35%
Benicar (Olmesartan medoxomil)	Hypertension (high blood pressure)	35%
Razadyne (Galantamine HBr)	Alzheimer's disease	32%
Travatan (Travoprost eye drop)	Glaucoma, ocular hypertension	32%
Nexium (Esomeprazole magnesium)	Gastroesophageal reflux disease	30%
Levaquin (Levofloxacin)	Antibiotic	27%
Catapres patch (Clonidine HCl)	Hypertension (high blood pressure)	27%
Zyrtec (Cetirizine HCl)	Antihistamine (hay fever, allergies, hives)	27%
Aggrenox	Antiplatelet (to prevent excessive clotting and reduce the risk of stroke)	27%

Source: OIG Analysis of Formulary Inclusion of Drugs Commonly Used by Dual Eligibles, 2005.

Dual eligibles' access under Medicaid will not change in 45 of 47 States for the 22 drugs we reviewed that are statutorily excluded from Medicare Part D coverage

Of the 200 commonly used drugs we reviewed, 178 are eligible for Part D coverage and 22 (11 percent) fall into categories that are statutorily excluded from Part D coverage. Under Medicaid, States have the option to cover or exclude these categories of drugs. If States opt to cover these drugs for their nondual eligible population, they must also cover them for dual eligibles. States will continue to receive Federal matching funds to provide coverage of drugs in these excluded categories to dual eligibles. These 22 high utilization drugs fall into 5 excluded drug categories:

- Nonprescription (i.e., over the counter) drugs (12 drugs),
- Benzodiazepines (5 drugs),
- Prescription vitamin and mineral products (3 drugs),[29]
- Barbiturates (1 drug), and
- Drugs used for symptomatic relief of cough and colds (1 drug).

All 47 States that we interviewed provided coverage for at least some excluded drugs in 2005. Coverage ranged by category. All 47 States covered benzodiazepines in 2005, but only 33 of these States covered drugs used for symptomatic relief of cough and colds.[30]

In 45 of these 47 States, dual eligibles continue to have access to the same drugs covered by their Medicaid program in 2005. One State (Tennessee) planned to end Medicaid coverage of benzodiazepines and barbiturates, accounting for 6 of the 200 highly utilized drugs in our review, for all beneficiaries (including dual eligibles). Another State (North Dakota) planned to discontinue Medicaid coverage of drugs used for symptomatic relief of cough and colds (1 of the 200 drugs reviewed). No States we interviewed planned to expand their current coverage of excluded drugs. Appendix D summarizes State coverage by category for these 22 excluded drugs.

CONCLUSION

Our assessment of drug coverage for dual eligibles under Medicare Part D included two components: determination of PDP formulary inclusion of commonly used drugs and review of State wraparound coverage policies. We did not assess or compare the overall benefits provided to dual eligibles under Medicaid versus Medicare. Rather, our review focused on differences between the drugs that the dual eligible population used under Medicaid and the drugs included in PDP formularies, as these differences may affect the ease of dual eligibles' transition from Medicaid to Medicare.

We reviewed 200 drugs commonly used by the dual eligible population in aggregate. We did not assess individual dual eligibles' prescription drug use or whether individual dual eligibles are assigned to formularies that include the specific drugs they use. Of the 200 commonly used drugs, 22 drugs fall into categories excluded by law from PDP coverage and 178 drugs are eligible for PDP coverage.

We determined whether these 178 Part D eligible drugs were included on each PDP formulary and found that formulary inclusion varies. Some plans use formularies that include all 178 of these highly utilized drugs; other plans use formularies that include as few as 135 (76 percent) of these drugs.

Because PDP formularies vary, random assignment to PDPs may affect the number of dual eligibles who take a specific drug that is not included on their PDP's formulary. Dual eligibles have several options to ensure appropriate drug coverage if this occurs. They may apply for an exception for the nonformulary drug. They may get a new prescription from their doctor for a different drug that treats their condition. They may also choose to switch plans on a monthly basis. Because each PDP region has at least one plan that includes all 178 commonly used drugs we reviewed, every dual eligible has the opportunity to enroll in a plan covering all of these drugs. Finally, CMS has urged plans to provide a one-time supply of the nonformulary drug to aid in this transition.

However, navigating these options requires a dual eligible to have a certain level of understanding of the Medicare Part D benefit and take specific action. At a basic level, the dual eligible must be aware that formularies vary by plan and that CMS and State agencies have created options to ease the transition. Next, the dual eligible must make proactive efforts to ensure his or her drug needs are met as outlined above. These actions may present a minor administrative obstacle to

some and a major barrier to others given the fact that dual eligibles face greater health and resource challenges than other Medicare beneficiaries.[31] Thirty-eight percent of dual eligibles have cognitive or mental impairments. Over a third are disabled. On average, dual eligibles use at least ten more prescription drugs than nondual eligible beneficiaries.

Given the variation we found in PDP formularies' inclusion of 178 commonly used drugs, as well as the medical and resource challenges faced by this population, dual eligibles may need targeted assistance to navigate the transition from Medicaid to Medicare coverage. CMS has undertaken efforts to educate and assist dual eligibles and to incorporate safeguards into the program to ensure access to needed drugs. Some State Medicaid agencies have also taken the initiative to educate dual eligibles and a few are directly assisting dual eligibles to identify which PDP formulary offers optimal coverage for their needs to make the transition as seamless as possible. However, reported experiences of some dual eligibles highlight the need for further targeted assistance to this population to ease this transition.[32]

OIG will continue to study issues associated with dual eligibles as they make the transition from Medicaid to Medicare Part D.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS provided comments on the draft report in which it highlighted its concerns with this report. These concerns fall into two general categories: methodology and scope. CMS's comments are included in Appendix E. CMS also provided technical comments, which we incorporated into the report where appropriate.

Methodology Concerns and Response

CMS contended that this study has significant methodological flaws, primarily because we used a national list of 178 drugs commonly used by the dual eligible population. CMS favors a methodology that analyzes drug histories and formulary assignment for individual beneficiaries.

We disagree that our study has significant flaws. We are confident that our analysis provides an appropriate measure of potential vulnerabilities that dual eligibles face while making the transition from

Medicaid to Medicare. Our national list of drugs represents the top drugs that the dual eligible population actually used under Medicaid, accounting for approximately 78 percent of all Medicaid prescriptions dispensed to dual eligibles. For the Part D eligible drugs in our review, we determined whether each drug was included on each formulary of the PDPs in which dual eligibles were automatically enrolled. Differences between the list of drugs that dual eligibles commonly use and the drugs on PDP formularies signal potential challenges for dual eligibles during the transition.

While we used one methodological approach, CMS advocated another approach that measures formulary coverage at the beneficiary level. CMS provided its own analysis comparing individuals' drug histories to PDP formularies for a sample of dual eligibles. This analysis is included in Appendix E.

In fact, CMS's results were remarkably similar to ours and we believe further support our conclusions. In our study, we found that, on average, PDP formularies include 92 percent of the 178 Part D eligible drugs we reviewed. In its analysis, CMS found that, on average, PDP formularies include 92.8 percent of the prescriptions of the individual dual eligibles it sampled. Our report concluded that, given the variation in PDP formularies, random assignment to PDPs may affect the number of dual eligibles who take specific drugs that are not included on their PDP formulary. CMS's analysis found that 31.8 percent of the dual eligibles in its sample took at least one drug that is not covered by their randomly assigned PDP formulary. The fact that CMS and OIG conducted independent analyses, using different methodologies, and found very similar results further strengthens our confidence in our findings and conclusions.

Scope Concerns and Response

CMS's other concerns generally relate to the scope of our review and, specifically, to issues we do not address in this study. Our review determined the extent to which PDP formularies include drugs commonly used by dual eligibles under Medicaid, as differences in coverage may present challenges during dual eligibles' transition to Part D. We did not assess or compare the overall benefits provided to dual eligibles under Medicaid versus Medicare. While CMS's concerns about Medicaid drug restrictions and whether beneficiaries have better coverage under Part D are important issues, they are outside the scope

of this review, which focused on assessing challenges during the transition.

Consistent with our goal to assess dual eligibles' transition to the Part D benefit, we assessed only whether PDP formularies include the specific highly utilized drugs in our review. We did not assess the clinical quality of PDP formularies, the clinical value of the drugs in our review, or their therapeutic alternatives. For the purposes of this study, we presumed that CMS ensures that PDP formularies meet minimum statutory requirements and provide adequate coverage from a clinical perspective.

However, as CMS explains in its comments, a formulary can meet minimum coverage requirements without covering all drugs. CMS provided the example of Crestor and Lipitor (two drugs used to lower cholesterol) and explained that the plans would generally choose to include only one of these two drugs on their formularies for cost containment purposes.

While we make no assessment of the relative clinical values of Crestor and Lipitor, we point out that a dual eligible who is taking Crestor may be autoenrolled in a plan that covers only Lipitor and vice versa. In this situation, the dual eligible must take action to maintain access to any drug to treat his or her condition. The dual eligible must contact a physician to switch the prescription to the formulary drug, apply for an exception to continue taking the nonformulary drug, or switch to a plan that covers the specific drug. Dual eligibles may need assistance navigating these options. Ideally, CMS and other stakeholders could assist dual eligibles to understand their PDP formularies and encourage them to take proactive steps (e.g., contacting their physician to change prescriptions), if needed, before the beneficiary arrives at the pharmacy counter.

We hope that the information in this report, in conjunction with CMS's own analysis, helps CMS and other stakeholders to assist dual eligibles who may be experiencing challenges in the transition to their Part D formularies. OIG will also continue to study issues associated with dual eligibles as they make the transition from Medicaid to Medicare Part D.

ENDNOTES

[1] Public Law 108-173.

[2] In addition to these two primary options, there can be beneficiaries who enrolled in PDPs who receive their benefits through cost plans or private fee-for-service plans, as well as other beneficiaries who receive Part D through PACE organizations.

[3] CMS. "MA & PDP Regions: State by State Summary Table." Available online at http://www.cms.hhs.gov/medicarereform/mmaregions/pdpmaosum.asp, accessed October 20, 2005.

[4] Federal financial participation is available for Medicaid coverage of any of the Medicaid "excludable" drugs, which are excluded by law from Medicare Part D coverage.

[5] Section 1935(c) of the Social Security Act, as amended by Public Law 108-173.

[6] GAO. "Contingency Plans to Address Potential Problems With the Transition of Dual-Eligible Beneficiaries From Medicaid to Medicare Drug Coverage." 2005. Available online at http://www.gao.gov/new.items/d06278r.pdf, accessed December 29, 2005.

Elliot, Rachel, et al. "Benefits and Consequences for the Poor and the Disabled." New England Journal of Medicine. 353:26, pp. 2793-2741. December 29, 2005.

Kaiser Commission on Medicaid and the Uninsured. "Resources on Dual Eligibles and Issues Related to Their Transition to the New Medicare Drug Benefit." Available online at http://www.kff.org/medicaid/dualsrx.cfm, accessed December 29, 2005.

Nemore, Patricia. "Medicare Part D: Issues for Dual Eligibles on the Eve of Implementation." Kaiser Family Foundation. November 2005. Available online at https://www.kff.org/medicare/upload/Medicare-Part-D-Issues-for-Dual-Eligibles-on-the-Eve-of-Implementation-Issue-Brief.pdf, accessed December 29, 2005.

[7] Section 1860D-1(b)(1)(C) of the Social Security Act, as amended by Public Law 108-173.

[8] 42 CFR § 423.38(c)(4) and 423.40(c). Nondual eligibles may only change their plan selections during the open enrollment period, unless they meet specific criteria for a Special Election Period. For 2006, the open enrollment period began on November 15, 2005, and continues through May 15, 2006. In future years, the open enrollment period will begin on November 15 and end on December 31.

[9] National Pharmaceutical Council. "Pharmaceutical Benefits Under Medicaid 2004." 2005. Available online at http://www.npcnow.org/resources/PharmBenefitsMedicaid.asp, accessed December 30, 2005.

[10] Section 1860D-4(b)(3)(C)(ii) of the Social Security Act, as amended by Public Law 108-73, required that CMS request the U.S. Pharmacopeia (USP) to develop model guidelines that PDP sponsors could use to develop their formularies. The USP guidelines include 41 therapeutic categories. Of these, 32 categories also have associated pharmacologic classes (total of 137 classes). For example, the USP guidelines include the therapeutic category of "Blood Glucose Regulators" and three pharmacologic classes ("Antihypoglycemics;" "Hypoglycemics, Oral;" and "Insulins") associated with that category. USP, "Medicare Prescription Drug Benefit Model Guidelines," December 31, 2004. Available online at http://www.usp.org/pdf/EN/mmg/finalModelGuidelines2004-12-31.pdf, accessed October 27, 2005.

[11] CMS, "A Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Prescription Drug Coverage," May 2, 2005, page 5. Available online at http://www.cms.hhs.gov/medicarereform/strategyforduals.pdf, accessed October 21, 2005.

[12] "Substantially all" means that all drugs in these categories are expected to be included in plan formularies with a few specified exceptions. CMS Special Guidance Materials, "Clarification: Formulary Review," updated June 16, 2005. Available online at http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf, accessed October 19, 2005.

[13] Section 1860D-4(b)(3)(E) of the Social Security Act, as amended by Public Law 108-173.

[14] USP created "key drug types" to aid CMS review of formularies for overall adequacy of coverage. Key drug types are more specific than categories or classes. For the review of PDP formularies for 2006, USP's list identified 118 key drug types. For 2007, USP's proposed list has expanded to include 170 key drug types. USP, "Preamble to the Proposed Revisions to the USP Model Guidelines." Available online at http://www.usp.org/healthcareInfo/mmg/phase2/preamble.html, accessed December 19, 2005; USP, Draft Drug Listing, available online at http://www.usp.org/pdf/EN/mmg/draftDrugListingV2.0-2005-12-09.pdf, accessed December 19, 2005.

[15] CMS. "Fact Sheet: Ensuring an Effective Transition of Dual Eligibles from Medicaid to Medicare Part D." December 1, 2005.

[16] CMS, Prescription Drug Benefit Manual, Chapter 18: "Enrollee Grievance, Coverage Determinations, and Appeals." Available online at http://www.cms.hhs.gov/pdps/part_d_manualappeals20051130.pdf, accessed December 2, 2005.

[17] CMS, "Fact Sheet: Ensuring an Effective Transition of Dual Eligibles from Medicaid to Medicare Part D." December 1, 2005.

[18] CMS, "Information for Part D Sponsors on Requirements for a Transition Process," March 16, 2005. Available online at www.cms.hhs.gov/pdps/specguidncmaterials.asp, accessed December 2, 2005.

[19] 42 U.S.C. § 1396r-8(d)(2).

[20] Public Law 109-91 § 104(a) added the category of drugs used for sexual or erectile dysfunction, applicable to drugs dispensed on or after January 1, 2007.

[21] The 21 States that received grants are CT, DE, IL, IN, KS, MA, MD, ME, MI, MN, MO, NC, NJ, NV, NY, PA, RI, TX, VT, WI, and WY. CMS, "State Pharmaceutical Assistance Program Transitional Grant

Distribution Awards," October 2004. Available online at http://www.cms.hhs.gov/medicarereform/spap_state_awards.pdf, accessed November 17, 2005.

"Qualified" SPAPs are eligible for certain benefits in coordinating coverage with Medicare Part D. These 25 States are AK, CA, CT, DE, FL, IL, IN, MA, MD, ME, MI, MO, MN, MT, NC, NJ, NV, NY, RI, SC, TX, VT, WA, WI, and WY. CMS, "Qualified SPAP List," November 8, 2005. Available online at http://www.cms.hhs.gov/medicarereform/states/qual_spap_list.pdf, accessed November 17, 2005.

[22] CMS, "Fact Sheet: Ensuring an Effective Transition of Dual Eligibles from Medicaid to Medicare Part D." December 1, 2005.

[23] BNA. "Dual Eligibles: Low Income Seniors Denied Benefits in Transition to Medicare Part D, Groups Say." January 13, 2005.

[24] San Francisco Chronicle. "Move to Cover Drug Benefits: Legislature Steps in on Prescriptions for Medicare Patients." January 20, 2006.

[25] Kaisernetwork. "Kaiser Daily Health Policy Report Highlights News of State Actions Related to Launch of Medicare Drug Benefit," January 11, 2006; and "More States Take Emergency Measures To Provide Rx Drugs to Medicare Beneficiaries," January 13, 2006. Available online at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=34786, accessed January 20, 2005.

[26] CMS, Memorandums to Medicare Part D Sponsors, issued January 13 and January 18, 2006.

[27] Information on indications from MedlinePlus, a service of the U.S. National Library of Medicine and the National Institutes of Health. Available online at http://www.nlm.nih.gov/medlineplus/druginformation.html, accessed November 30, 2005.

[28] Although Lexapro (escitalopram oxalate) is in one of CMS's protected categories, i.e., antidepressants, it falls under one of the "substantially all" exceptions. This exception is that formularies must cover either

escitalopram oxalate or citalopram. Therefore, those formularies that omit escitalopram oxylate must cover citalopram.

[29] Prenatal vitamins and fluoride preparations are exceptions to this exclusion.

[30] These States may restrict their coverage within these categories (e.g., requiring prior authorization, only covering certain drugs in a category), but all States provide at least some coverage of drugs in the category.

[31] GAO. "Contingency Plans to Address Potential Problems with the Transition of Dual-Eligible Beneficiaries from Medicaid to Medicare Drug Coverage." 2005. Available online at http://www.gao.gov/new.items/d06278r.pdf, accessed December 29, 2005.

Elliot, Rachel, et al. "Benefits and Consequences for the Poor and the Disabled." New England Journal of Medicine. 353:26, pp. 2793-2741. December 29, 2005.

Kaiser Commission on Medicaid and the Uninsured. "Resources on Dual Eligibles and Issues Related to Their Transition to the New Medicare Drug Benefit." Available online at http://www.kff.org/medicaid/dualsrx.cfm, accessed December 29, 2005.

Nemore, Patricia. "Medicare Part D: Issues for Dual Eligibles on the Eve of Implementation." Kaiser Family Foundation. November 2005. Available online at https://www.kff.org/medicare/upload/Medicare-Part-D-Issues-for-Dual-Eligibles-on-the-Eve-of-Implementation-Issue-Brief.pdf, accessed December 29, 2005.

[32] CBS News. "Medicare Reality Check." Available online at http://www.cbsnews.com/stories/2006/01/06/eveningnews/main1185180.shtml, accessed January 13, 2006.

Detroit Free Press. "Seniors' Drugs Held Up in Drug Plan Switch." Available online at www.freep.com, accessed January 10, 2005.

USA Today. "Medicare Drug Benefit Costly for Some Poor." Available online at http://www.usatoday.com/news/health/2006-01-12-medicare-poor_x.htm, accessed January 13, 2006.

USA Today. "Seniors Denied Rx Drug Benefits." Available online at http://www.usatoday.com/news/health/2006-01-12-seniors-medicare_x.htm, accessed January 13, 2006.

DETAILED SCOPE AND METHODOLOGY

Scope of Inspection

Our assessment of drug coverage for dual eligibles under Medicare Part D included two components. Primarily, we determined whether PDP formularies include (nonexcluded) drugs that were highly utilized by dual eligibles under Medicaid. Secondarily, we identified how many States plan to offer wraparound drug coverage for excluded drugs and/or nonformulary drugs for dual eligibles.

Our study focused on the transition of dual eligibles from Medicaid to Medicare Part D drug coverage. We assessed the extent to which PDP formularies include the drugs that dual eligibles commonly used under Medicaid, as differences in coverage may affect the ease of dual eligibles' transition to Medicare. We did not assess or compare the overall benefits provided to dual eligibles under Medicaid versus Medicare.

Our review included 200 of the most commonly used drugs based on the number of prescriptions dispensed to dual eligibles under Medicaid fee-for-service in the first two quarters of 2005. These drugs account for approximately 78 percent of prescriptions to dual eligibles during this period. Of these 200 drugs, 22 fall into categories excluded from Medicare Part D coverage, and 178 are eligible for Part D coverage.

We included these 200 drugs in our review because they are highly utilized by the dual eligible population under Medicaid and, therefore, their inclusion or noninclusion by PDP formularies may have an impact on the ease of the dual eligibles' transition from Medicaid to Medicare Part D. We did not assess the clinical value of any of these drugs or of any therapeutically equivalent drugs that formularies may include instead of particular drugs on this list.

We used aggregate drug utilization data to identify drugs commonly used by the dual eligible population as a whole. We did not assess individual dual eligibles' prescription drug use or whether individual dual eligibles are assigned to formularies that include the specific drugs that each uses.

Our review included 200 of the most commonly used drugs based on estimated utilization among dual eligibles under Medicaid fee-for-service in the first two quarters of 2005. Of these 200 drugs, 22 are excluded from Medicare Part D coverage.

Formulary Inclusion. Our determinations of formulary inclusion considered the 178 nonexcluded drugs from our list of 200 drugs with high dual eligible utilization.

We included the formularies of all PDPs to which dual eligibles have been randomly assigned by CMS for autoenrollment, i.e., PDPs offering standard benefits (or equivalent) with premiums at or below the regional benchmark cost. In total, 409 PDPs (offered by 60 PDP sponsors) met these criteria. Many plans use the same drug formularies; these 409 plans use a total of 37 unique formularies.

We excluded the formularies of PDP plans with enhanced benefits and/or with premiums above the regional benchmark because dual eligibles will face additional cost-sharing requirements if they enroll in such plans. We also excluded the formularies of MA plans. While dual eligibles may opt to enroll in an MA plan, this decision affects their entire health care delivery system by enrolling them in managed care, and therefore includes many important considerations beyond drug coverage. CMS did not assign dual eligibles to an MA drug plan unless they were already enrolled in that MA plan for their health care. Approximately 10 percent of dual eligibles were assigned to MA drug plans.

Our analysis of PDP formularies assessed only whether they include the specific drugs in our review. We did not assess the overall adequacy of the PDP formularies or whether these formularies comply with mandated minimum coverage requirements.

State Wraparound Coverage. Our inquiry into State wraparound coverage considered two issues. The first was States' provision of Medicaid coverage (with Federal matching funds) for the 22 excluded drugs on our list of 200 drugs commonly utilized by dual eligibles. The second was States' plans to use State-only funds to provide wraparound coverage to dual eligibles for nonformulary drugs.

We contacted the Medicaid programs of all States and the District of Columbia. Forty-six States responded. We inquired about current Medicaid coverage of excludable drugs, as well as wraparound policies States planned to have in place in January 2006 to cover excluded drugs and/or nonformulary drugs. We also contacted the 27 States with SPAPs that were either recognized as "qualified" SPAPs by CMS or received transitional grants from CMS to inquire about wraparound coverage for dual eligibles. Twenty-three States with SPAPs responded.

This information represents a snapshot at the time of our data collection (November and December 2005) and is self-reported data from States; we did not independently verify States' responses. We did not assess sources outside of the State Medicaid programs or SPAPs that could potentially offer dual eligibles access to excluded drugs or nonformulary drugs.

Methodology

Data Sources for Formulary Comparisons

Data sources for the comparison of formularies to dual eligibles' commonly used drugs included:

- Medicaid Drug Rebate (MDR) program drug utilization data from the first two quarters of 2005,
- Medicaid Statistical Information System (MSIS) data from 2003 (the most recent year available),
- First Databank drug product data,
- Medispan drug product data,
- Redbook drug product data, and
- PDP formulary information.

Identifying 200 Drugs With High Utilization by Dual Eligibles

We identified 200 highly utilized drugs using the estimated number of prescriptions dispensed to dual eligibles in the first two quarters of 2005. To do so, we used MSIS data to calculate the proportion of prescriptions for each drug that was dispensed to dual eligibles in 2003. We applied these proportions to MDR drug utilization data from 2005. When MSIS data were not available for a specific drug, we applied the average proportion of prescriptions written to dual eligibles for drugs in the same therapeutic class in that State. Our list of 200 drugs highly utilized by dual eligibles is based on the compilation of dual eligibles' drug utilization in the 2003 MSIS data (32 States) and 2005 MDR utilization data (43 States, January through June 2005). This list includes 22 drugs that are excluded by law from Part D coverage that most Medicaid programs had opted to cover in 2005.

Because we had to rely on estimates to develop this list, we cannot state with confidence that our list of 200 drugs precisely mirrors the actual top 200 drugs used by dual eligibles. Additionally, because this list was developed from aggregate national data, it may not exactly reflect the top 200 drugs used by dual eligibles in a given State. However, we

conducted a preliminary comparison of the top National Drug Codes (NDCs) by dual eligibles' utilization nationally and the top NDCs by dual eligibles' utilization in 10 States of varying regions, population densities, and Medicaid policies. We found only minimal differences between the national and State lists of highly utilized drugs.

The 200 drugs on our list account for approximately 78 percent of prescriptions dispensed to dual eligibles. Consequently, the inclusion or noninclusion of these drugs on Part D formularies is likely to affect significant numbers of dual eligibles. We are therefore confident that our national list of 200 highly utilized drugs is a good proxy by which to assess potential disruptions in dual eligibles' prescription drug access during the transition process. These 200 drugs are listed in Appendix B.

Determining Formulary Inclusion

We defined each drug by its active ingredient(s) regardless of specific strengths, dosages, manufacturers, or package sizes. For example, a single source drug (i.e., a drug with no generic equivalents), such as Lipitor, appears only once on our list of 200 drugs; we did not include separate entries for Lipitor 10-mg strength and Lipitor 20-mg strength. A multiple-source drug such as fluoxetine HCl (the active ingredient for the multiple-source brand name drug Prozac) has only one entry on our list, covering all strengths of the brand name drug Prozac, as well as the generic versions of fluoxetine HCl available. We considered the standard form and extended release version of the same active ingredient(s) to be the same drug. We also considered similar routes of administration (e.g., oral) to be the same drug, while substantially different routes of administration were treated as different drugs. For example, if the same active ingredient was available in caplets, tablets, and oral liquids, we considered these versions to be the same drug. However, the same active ingredient in a nonoral form, such as an injection, would be considered a different drug.

A drug was considered to be included by the formulary if the active ingredient was included in any strength, dosage, manufacturer, or package size of the same general route of administration. When a drug included multiple ingredients that could be dispensed separately and combined by the patient to the same effect as the combined drug, then the drug was treated as included when the ingredients were included in the formulary either separately or in combination. For example, one drug on our list is Vytorin (ezetimibe/simvastatin), a combination of

Zetia (ezetimibe) and Zocor (simvastatin). If the formulary included both Zetia and Zocor, then we considered Vytorin to be included.

Once we made formulary inclusion determinations for each of the nonexcluded drugs, we analyzed these results. For each formulary, we calculated the percentage of the 178 drugs (i.e., the 200 drugs minus the 22 drugs excluded by law from coverage) that are included in the plan formulary. For each of the 178 nonexcluded drugs, we calculated the percentage of formularies that include that drug.

Identifying State Medicaid and SPAP Wraparound Coverage

We called all State Medicaid directors and the directors of 26 of the 27 CMS-recognized and/or grantee SPAPs to identify whether these programs are planning to offer wraparound coverage of excluded and/or nonformulary drugs. Forty-six State Medicaid programs and 23 SPAPs responded.

For the 22 drugs that fell into categories excluded from Medicare Part D coverage, we used our information from State interviews to determine how many States currently provide coverage for these drug categories under Medicaid and whether this coverage will change in any State Medicaid programs.

We also determined how many States will offer State-funded wraparound coverage for any nonexcluded drugs that a dual eligible's PDP formulary does not include.

APPENDIX ~ B

THE 200 DRUGS INCLUDED IN OUR REVIEW

Our review included 200 of the most commonly used drugs based on the number of prescriptions dispensed to dual eligibles under Medicaid fee-for-service in the first two quarters of 2005. We included these particular drugs in our review because they are highly utilized by the dual eligible population under Medicaid and, therefore, their inclusion or noninclusion by formularies may have an impact on the ease of the dual eligibles' transition from Medicaid to Medicare Part D. We did not assess the clinical value of any of these drugs or of any therapeutically alternative drugs that formularies may include instead of particular drugs on this list. CMS has reviewed all PDP formularies to verify that they meet minimum requirements and to ensure overall adequacy of each formulary.

We used aggregated 2005 MDR drug utilization data and 2003 dual eligible-specific data from the MSIS to estimate Medicaid prescriptions dispensed to dual eligibles in the first two quarters of 2005. Based on these estimates, we identified 200 highly utilized drugs. Because we had to rely on estimates to develop this list, we cannot state with confidence that our list of 200 drugs exactly mirrors the actual top 200 drugs used by dual eligibles. However, these drugs account for approximately 78 percent of prescriptions to dual eligibles, and therefore represent the actual utilization patterns of a significant number of dual eligibles.

TABLE 4: 200 Commonly Utilized Drugs by Dual Eligibles

Rank	Generic Name	Brand Name	Formulary Inclusion (of 37)	Percentage Included
1	Furosemide	Lasix	37	100%
2	Atorvastatin	Lipitor	35	95%
3	Potassium chloride oral	Klotrix	37	100%
4	Metoprolol	Lopressor	37	100%
5	Lansoprazole SR	Prevacid	29	78%
6	Amlodipine Besylate	Norvasc	35	95%
7	Levothyroxine sodium	Levoxyl	37	100 %
8	Lisinopril	Prinivil	37	100%
9	Hydrocodone/APAP	Vicodin	36	97%
10	Clopidogrel bisulfate	Plavix	37	100%
11	Warfarin sodium	Coumadin	37	100%
12	Atenolol	Tenormin	37	100%
13	Olanzapine	Zyprexa	37	100%
14	Risperidone	Risperdal	37	100%
15	Hydrochlorothiazide	Microzide	37	100%
16	Sertraline	Zoloft	37	100%
17	Quetiapine	Seroquel	37	100%
18	Simvastatin	Zocor	31	84%
19	Aspirin	Bayer	Excluded	
20	Lorazepam	Ativan	Excluded	
21	Ranitidine	Zantac	37	100%
22	Metformin HCL	Glucophage	37	100%
23	Digoxin	Digitek	37	100%
24	Divalproex sodium	Depakote	37	100%
25	Donepezil	Aricept	37	100%
26	Esomeprazole magnesium	Nexium	26	70%
27	Zolpidem tartrate	Ambien	36	97%
28	Escitalopram oxalate	Lexapro	22	59%
29	Phenytoin sodium	Dilantin	37	100%
30	Alendronate sodium	Fosamax	35	95%
31	Alprazolam	Xanax	Excluded	
32	Albuterol inhaler	Ventolin	37	100%
33	Pantoprazole	Protonix	30	81%
34	Celecoxib	Celebrex	33	89%
35	Glipizide	Glucotrol	37	100%
36	Isosorbide mononitrate	Ismo	37	100%
37	Propoxyphene Nap/ Acetaminophen	Darvocet	31	84%
38	Gabapentin	Neurontin	37	100%
39	Trazodone	Desyrel	37	100%
40	Clonazepam	Klonopin	Excluded	

200 Commonly Utilized Drugs by Dual Eligibles, *Continued*				
Rank	**Generic Name**	**Brand Name**	**Formulary Inclusion (of 37)**	**Percentage Included**
41	Valsartan	Diovan	34	92%
42	Risedronate sodium	Actonel	36	97%
43	Rosiglitazone maleate	Avandia	37	100%
44	Azithromycin oral	Zithromax	36	97%
45	Salmeterol xinafoate/ Fluticasone propionate xinafoate/Fluticasone propionate	Advair Diskus	36	97%
46	Pioglitazone	Actos	35	95%
47	Montelukast sodium	Singulair	37	100%
48	Paroxitine HCL	Paxil	37	100%
49	Omeprazole SA	Prilosec	Excluded	
50	Levofloxacin	Levaquin	27	73%
51	Tramadol	Ultram	35	95%
52	Carvedilol	Coreg	36	97%
53	Tolterodine tartrate	Detrol	34	92%
54	Venlafaxine HCL	Effexor	37	100%
55	Loratadine	Claritin	Excluded	
56	Triamterene/HCTZ	Dyazide	37	100%
57	Folic acid	Folic acid	Excluded	
58	Docusate sodium	Colace	Excluded	
59	Clonidine HCL	Catapres	37	100%
60	Insulin 70/30	Humulin	34	92%
61	Tamsulosin HCl	Flomax	32	86%
62	Losartan potassium	Cozaar	23	62%
63	Albuterol/Ipratropium	Combivent	35	95%
64	Fluoxetine HCL	Prozac	37	100%
65	Amlodipine/Benazepril	Lotrel	31	84%
66	Prednisone	Deltasone	37	100%
67	Pravastatin sodium	Pravachol	22	59%
68	Glyburide	Micronase	37	100%
69	Nifedipine	Adalat	37	100%
70	Latanoprost	Xalatan	32	86%
71	Clozapine	Clozaril	37	100%
72	Famotidine	Pepcid	36	97%
73	Fluticasone propionate nasal spray	Flonase	34	92%
74	Metoclopramide	Reglan	37	100%
75	Diltiazem	Cartia XT	37	100%
76	Valsartan/HCT	Diovan HCT	35	95%
77	Temazepam	Restoril	Excluded	
78	Oxybutynin chloride	Ditropan	37	100%
79	Oxycodone/Acetaminophen	Endocet	37	100%
80	Acetaminophen/Codeine	Tylenol #3	37	100%

200 Commonly Utilized Drugs by Dual Eligibles, *Continued*				
Rank	**Generic Name**	**Brand Name**	**Formulary Inclusion**	**Percentage Included**
81	Ibuprofen	Advil	37	100%
82	Insulin N, Insulin NPH	Humulin N	37	100%
83	Amoxicillin oral	Amoxil	37	100%
84	Polyethylene glycol 3350	Miralax	34	92%
85	Meloxicam	Mobic	16	43%
86	Aripiprazole	Abilify	37	100%
87	Insulin R, Insulin Regular	Humulin R	37	100%
88	Benztropine mesylate	Cogentin	37	100%
89	Estrogens conjugated oral	Premarin	36	97%
90	Amitriptyline HCL	Elavil	37	100%
91	Cephalexin	Keflex	37	100%
92	Ramipril	Altace	28	76%
93	Oxycodone	OxyContin	36	97%
94	Bupropion	Wellbutrin	37	100%
95	Fentanyl transdermal	Duragesic	32	86%
96	Ezetimibe	Zetia	35	95%
97	Spironolactone	Aldactone	37	100%
98	Meclizine	Antivert	33	89%
99	Cyclobenzaprine	Flexeril	33	89%
100	Mirtazapine	Remeron	37	100%
101	Sulfamethoxazole/TMP	Bactrim	37	100%
102	Glimepiride	Amaryl	31	84%
103	Nitrofurantoin MCR	Macrobid	37	100%
104	Lovastatin	Mevacor	37	100%
105	Fenofibrate	Tricor	33	89%
106	Topiramate	Topamax	37	100%
107	Carbidopa/Levodopa	Sinemet	37	100%
108	Diazepam	Valium	Excluded	
109	Enalapril maleate	Vasotec	36	97%
110	Quinine	Quinine SO4	32	86%
111	Raloxifene	Evista	37	100%
112	Nitroglycerin patch	Nitrodur	37	100%
113	Multivitamin	Thera-vite	Excluded	
114	Promethazine	Phenergan	37	100%
115	Acetaminophen	Tylenol	Excluded	
116	Losartan potassium/HCTZ	Hyzaar	23	62%
117	Nitroglycerin tablet	Nitroquick	37	100%
118	Verapamil	Verelan	37	100%
119	Diphenhydramine	Benadryl	Excluded	

200 Commonly Utilized Drugs by Dual Eligibles, *Continued*

Rank	Generic Name	Brand Name	Formulary Inclusion	Percentage Included
120	Allopurinol	Zyloprim	37	100%
121	Lamotrigine	Lamictal	37	100%
122	Brimonidine tartrate	Alphagan	37	100%
123	Ferrous sulfate	Feosol	Excluded	
124	Gemfibrozil	Lopid	37	100%
125	Lidocaine patch	Lidoderm	20	54%
126	Carbamazepine	Carbatrol	37	100%
127	Olopatadine HCl eye drops	Patanol	30	81%
128	Naproxen	Naprosyn	37	100%
129	Irbesartan	Avapro	24	65%
130	Clonidine HCL patch	Catapres patch	27	73%
131	Cetirizine HCL	Zyrtec	27	73%
132	Dorzolamide/Timolol maleate	Cosopt	32	86%
133	Oyster shell/vitamin D	Oscal-D	Excluded	
134	Galantamine HBr	Razadyne	25	68%
135	Ziprasidone	Geodon	37	100%
136	Hydroxyzine HCL	Atarax	35	95%
137	Fexofenadine	Allegra	29	78%
138	Mupirocin	Bactroban	37	100%
139	Mometasone furoate nasal	Nasonex	36	97 %
140	Oxcarbazepine	Trileptal	37	100%
141	Balsam peru/Castor oil USP-NF/Trypsin USL	TBC Aero	31	84%
142	Rivastigmine tartrate	Exelon	37	100%
143	Amox TR-K CLV oral	Augmentin	37	100%
144	Glyburide/Metformin	Glucovance	37	100%
145	Metolazone	Zaroxolyn	37	100%
146	Nabumetone	Relafen	34	92%
147	Timolol optic	Timoptic	37	100%
148	Enulose	Lactulose	37	100%
149	Tramadol HCl/ Acetaminophen	Ultracet	21	57%
150	Duloxetine hydrochloride*	Cymbalta	31	84%
151	Rosuvastatin	Crestor	23	62%
152	Theophylline	Theo-dur	37	100%
153	Ipratropium bromide inhaled	Atrovent inhaler	36	97%
154	Baclofen	Lioresal	36	97%
155	Pentoxifylline	Trental	34	92%
156	Rabeprazole sodium	Aciphex	18	49%
157	Diphenoxylate/Atropine	Lomotil	34	92%
158	Fosinopril sodium	Monopril	32	86%
159	Memantine hydrochloride	Namenda	37	100%

* This drug falls into a protected category that should be included by all formularies. CMS is working to ensure that all plans include this drug as required.

200 Commonly Utilized Drugs by Dual Eligibles, *Continued*

Rank	Generic Name	Brand Name	Formulary Inclusion	Percentage Included
160	Fluvastatin sodium	Lescol	21	57%
161	Megestrol acetate oral*	Megace	36	97%
162	Calcium carbonate	Oyst-cal	Excluded	
163	Sevelamer HCL	Renagel	31	84%
164	Promethazine/Codeine	Phenergan w/ codeine	Excluded	
165	Senna	Senokot	Excluded	
166	Cyanocobalamin (synthetic vitamin B12) injectable	Nascobal	Excluded	
167	Fluticasone propionate inhaled	Flovent	34	92%
168	Travoprost eye drop	Travatan	25	68%
169	Ezetimibe/Simvastatin	Vytorin	31	84%
170	Citalopram HBR	Celexa	37	100%
171	Propranolol	Inderal	37	100%
172	Clotrimazole/Betamethasone	Lotrisone	32	86%
173	Triamcinolone cream	Aristo	37	100%
174	Olmesartan medoxomil	Benicar	24	65%
175	Felodipine	Plendile	35	95%
176	Carisoprodol	Soma	32	86%
177	Phenobarbital	Luminal	Excluded	
178	Lithium carbonate	Eskalith	37	100%
179	Prednisolone solution	Prelone	37	100%
180	Terazosin	Hytrin	37	100%
181	Bimatoprost eye drops	Lumigan	34	92%
182	Moxifloxacin HCl	Avelox ABC	32	86%
183	Desloratadine	Clarinex	22	59 %
184	Torsemide	Demadex	35	95%
185	Haloperidol	Haldol	37	100%
186	Irbesartan/HCTZ	Avalide	23	62%
187	Loperamide	Immodium	Excluded	
188	Buspirone	Buspar	37	100%
189	Finasteride	Proscar	35	95%
190	Hydralazine	Apresoline	37	100%
191	Cefdinir	Omnicef	28	76%
192	Amiodarone HCL	Cordarone	37	100%
193	Cilostazol	Pletal	32	86%
194	Levetiracetam	Keppra	37	100%
195	Calcitonin salmon	Miacalcin	35	95%
196	Tiotropium	Spiriva	37	100%
197	Prednisolone AC eye drop	Pred-Forte	37	100%
198	Dipyridamole/Aspirin	Aggrenox	27	73%
199	Methadone	Methadose	34	92%
200	Clotrimazole cream	Lotrimin	Excluded	

* This drug falls into a protected category that should be included by all formularies. CMS is working to ensure that all plans include this drug as required.

Source: OIG Analysis of Formulary Inclusion of Drugs Commonly Used by Dual Eligibles, 2005.

DISTRIBUTION OF DUAL ELIGIBLES AMONG FORMULARIES

Dual eligibles were randomly assigned to PDPs for autoenrollment (unless they were among the approximately 10 percent of dual eligibles who were members of an MA plan). Individuals were allocated equally among plan sponsors in a PDP region. If a sponsor offered more than one eligible plan, dual eligibles assigned to that sponsor were allocated equally to each plan. The same formulary is often used by many plans, even those with different sponsors.

For each PDP region, we determined the percentage of dual eligibles that will be covered by each formulary based on random assignment. Table 5 shows the percentage of dual eligibles whose formulary inclusion of commonly used drugs will be most broad (covering all 178 of the most commonly used nonexcluded drugs) or more restricted (covering less than 85 percent of these drugs).

TABLE 5: Random Assignment of Dual Eligibles and Formulary Inclusion of Commonly Used Drugs

PDP Region	State(s)	Dual Eligibles Autoassigned	Percentage of Dual Eligibles Randomly Assigned to PDPs That Include: 100% of Commonly Used Drugs	Percentage of Dual Eligibles Randomly Assigned to PDPs That Include: Less Than 85% of Commonly Used Drugs
1	Maine, New Hampshire	63,290	18%	18%
2	Connecticut, Massachusetts, Rhode Island, Vermont	289,849	17%	39%
3	New York	499,708	23%	32%
4	New Jersey	135,498	25%	25%
5	Delaware, Maryland, Washington, D.C.	81,176	14%	21%
6	Pennsylvania, West Virginia	175,674	14%	29%
7	Virginia	101,352	15%	23%
8	North Carolina	216,703	9%	18%
9	South Carolina	110, 530	15%	15%
10	Georgia	135,599	8%	25%
11	Florida	326,139	17%	33%
12	Alabama, Tennessee	295,262	25%	25%
13	Michigan	185,486	15%	15%

Random Assignment of Dual Eligibles and Formulary Inclusion of Commonly Used Drugs, *Continued*

PDP Region	State(s)	Dual Eligibles Autoassigned	Percentage of Dual Eligibles Randomly Assigned to PDPs That Include: 100% of Commonly Used Drugs	Percentage of Dual Eligibles Randomly Assigned to PDPs That Include: Less Than 85% of Commonly Used Drugs
14	Ohio	169,704	25%	25%
15	Indiana, Kentucky	169,660	18%	18%
16	Wisconsin	109,024	17%	17%
17	Illinois	247,254	17%	25%
18	Missouri	144,243	25%	25%
19	Arkansas	60,770	8%	17%
20	Mississippi	129,988	9%	18%
21	Louisiana	89,493	10%	20%
22	Texas	294,295	14%	29%
23	Oklahoma	72,880	20%	20%
24	Kansas	38,828	10%	30%
25	Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming	185,129	9%	18%
26	New Mexico	31,082	13%	38%
27	Colorado	37,342	11%	33%
28	Arizona	44,413	30%	50%
29	Nevada	16,895	17%	50%
30	Oregon, Washington	125,190	21%	29%
31	Idaho, Utah	37,018	17%	25%
32	California	847,996	21%	50%
33	Hawaii	22,460	14%	29%
34	Alaska	10,674	14%	29%

Source: OIG Analysis of Formulary Inclusion of Drugs Commonly Used by Dual Eligibles, 2005.

MEDICAID COVERAGE OF DRUGS EXCLUDED FROM PART D

Of the 200 drugs commonly used by dual eligibles, 22 fall into categories that are statutorily excluded from Medicare Part D coverage. State Medicaid programs have the option to cover drugs in these categories. Table 6 summarizes these 22 drugs, including their categories and the number of State Medicaid programs (of 47 States interviewed) that currently cover and/or plan to cover drugs in these categories.

TABLE 6: State Medicaid Coverage of Excluded Drugs

Category of Excluded Drugs	# of Drugs (of 200 Commonly Used)	States Currently Covering (of 47)	States Planning to Cover in 2006 (of 47)
Nonprescription drugs	12	45	45
Benzodiazepines	5	47	46
Prescription vitamins and mineral products	3	35	35
Barbiturates	1	46	45
Drugs for symptomatic relief of cough and colds	1	33	32

Source: OIG Interviews With States and Analysis of Formulary Inclusion of Common Drugs for Dual Eligibles, 2005.

AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: JAN 23 2006

TO: Daniel R. Levinson
Inspector General
Office of Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: "Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs" (OEI-05-06-00090)

Thank you for the opportunity to review and comment on the revised OIG draft report. The report focused on the extent to which Medicare prescription drug plan (PDP) formularies include the drugs that dual eligibles commonly used under Medicaid. We highlight our initial concerns with the report and further explain them in more detailed comments below. The Centers for Medicare & Medicaid Services (CMS) believes this report has significant flaws. Our fundamental concern is that it is based on a list of 178 drugs rather than an examination of actual use of drugs at the individual beneficiary level. Because of that, it does not provide direct evidence on the extent to which full benefit dual eligibles are assigned to plans that cover their drugs. In contrast, as we describe below, a CMS analysis of *actual drug use* by full benefit dual eligibles shows that, in the vast majority of cases, all of the drugs used by the beneficiaries in our sample are covered. On average, 93 percent of all their drugs are covered. In addition, because all formularies cover multiple drugs in each therapeutic class, and essentially all drugs in key classes of medicines, *all* beneficiaries have formularies where they can get drugs that are very similar to their medications (i.e., antihistamines and stomach acid medicines that have the same mechanism of action). Finally, through these broad formulary requirements and other beneficiary protections, like a prompt appeals process, all plans are required to cover all medically necessary treatments.

Key OIG Report Issues/CMS Findings:

- The OIG's approach of comparing the top 178 drugs most commonly used by dual eligible enrollees nationally to those covered by plan formularies does not take into account the drugs actually used by *individual beneficiaries*. In comparison, the CMS beneficiary-level analysis provides direct evidence on whether Medicare's drug plan formularies cover dual eligible beneficiaries' actual medications. The OIG approach is also flawed because it does not take into

account state Medicaid plans' limitations on drug coverage and number of prescriptions.

- To conduct a clinically relevant analysis, CMS worked with our clinicians and pharmacists and found that, on average, 93 percent of the medications dual eligibles actually used before their transition to Part D are covered by the PDP formularies available to them. There was minimal variation in these findings across the states and regions that were studied.

- In our study, more than two-thirds of beneficiaries, randomly assigned for study purposes, were found to be in plans that covered all of their drugs (68.2 percent). On average, less than one drug per beneficiary was not covered.

- Because Medicare drug plans must cover at least two drugs in each therapeutic category, 100 percent of dual eligible beneficiaries are in plans that cover therapeutic alternatives that are often used interchangeably with any particular drug that is not on the formulary. For example, antihistamines, stomach acid medicines, and cholesterol medicines – drugs that are generally covered selectively on Medicaid preferred drug lists as well – often have many therapeutic alternatives.

- Finally, we would note that dual eligibles may actually receive more generous coverage under the Part D Medicare program because of Medicaid's various restrictions on drug coverage and variability by state. For example, about one-fourth of states limit the number of prescriptions that dual eligibles can fill each month.

We appreciate the revisions you incorporated in the draft OIG report; however, the CMS is still concerned with some of its findings. As we have noted, the report's analysis of a national drug list does not directly support its own conclusions at the beneficiary level. Even with the revised wording, we continue to believe that many of our previous comments were not fully addressed. For example:

1. While it is true that not all drug plan formularies cover all of the 178 most commonly utilized Part D drugs in the dual eligible population, we do not believe that this fact alone would support the conclusion that random assignment impacts prescription drug coverage. An individual dual eligible beneficiary would not take all of the drugs analyzed by the OIG. Therefore, determining whether the drug use of a full-benefit dual eligible (FBDE) individual is affected depends on whether the beneficiary is actually assigned to a plan that does not include one or more of that beneficiary's drugs on its formulary. We believe that the analysis should make this clear.

2. The national list of 178 commonly used drugs by dual eligible beneficiaries is based on a national sample, while the formularies used by Medicaid beneficiaries are based on State prescription drug lists (PDLs). Any change a

dual eligible beneficiary may have to make is not based on the 178 commonly used drugs, but rather on the Medicaid PDL relevant to that particular beneficiary. Many Medicaid PDLs omit some of the 178 drugs as well.

3. We believe it is confusing for the report to compare aggregate utilization data with individual formularies. For example, there are 21 "sole source" (generally brand-name) drugs that are commonly omitted from formularies because plans negotiate with manufacturers or wholesalers for competitive rebates in exchange for selective formulary placement in order to lower overall costs. Competitive, cost-effective plans cannot cover all of those drugs without forfeiting significant price concessions. For instance, both Crestor and Lipitor are on the list of most commonly used drugs, as are Nexium and Prilosec, but both will generally not appear on the same formulary. Thus, just because a formulary does not include all or nearly all drugs does not imply that it will not cover all drugs used by a beneficiary. Moreover, because all drug plans cover multiple drugs in each of these classes, beneficiaries will always have access to drugs that generally work in similar ways to any particular drug that is not on the formulary.

4. We believe the report should take into account how State Medicaid programs' PDLs compare to the prescription drug plan formularies available in each State. The correlation between these on a PDP regional (generally State) basis may be higher than at a national level and, in many categories, Medicare drug plans may cover more drugs.

5. The OIG's report also does not recognize the statutory mandate that CMS randomly enroll dual eligible beneficiaries. The statute is clear that the Secretary "shall enroll [full-benefit dual eligibles] on a random basis" among plans in the PDP region that meet specified requirements. Therefore, it is not correct to imply that CMS has discretion to enroll beneficiaries into PDPs based on their current drug usage. Rather, CMS imposed substantial formulary requirements and many other steps (described in the next section) to help assure that beneficiaries have access to all needed drugs regardless of the drug plan in which they are enrolled.

CMS has undertaken its own analysis to examine individual dual eligibles' access to their prescription drugs. While this analysis, given time limitations, is based on a limited sample of beneficiaries, our findings demonstrate that most beneficiaries are in plans that cover all their drugs and that, on average, 93 percent of beneficiaries' actual drugs are covered.

The CMS study examined individual dual eligibles' access to their prescription drugs using the most up-to-date source of drug information, self-reported Medicare Current Beneficiary Survey (MCBS) data. Using 2003 MCBS data, 200 dual eligible beneficiaries who have reported prescription drug use were randomly identified. The beneficiaries were chosen from 5 different PDP regions so as to include states with both generous and restrictive Medicaid coverage. For purposes of the study, these

beneficiaries were then randomly "assigned" to a Part D plan certified to serve dual eligibles in their region. Finally, the percentage of each beneficiary's drugs that were covered by the formulary of the plan to which they were "assigned" was determined.

Our findings were that, on average, the weighted average coverage rate was 93 percent. There was minimal variation in this coverage rate across the 5 regions examined. The majority of beneficiaries (68.2 percent) were assigned to plans that covered all of their drugs. Very few beneficiaries (8.2 percent) were assigned to plans that covered less than 70 percent of all of their drugs. Qualitative review of the drugs not covered under the beneficiaries' assigned plans' formularies showed that several of these drugs were those that have multiple therapeutic alternatives (e.g. ACE-Inhibitors, Angiotensin II Receptor Blockers (ARBs), Proton Pump Inhibitors (PPIs), and antihistamines). By law, PDP formularies must include at least two drugs in every therapeutic class.

Thus, using a methodology based on the experiences of actual beneficiaries rather than simply comparing drug lists, the data suggest that FBDE beneficiaries have access to robust formularies that cover, on average, more than 90 percent of the medications they utilized before their transition to Part D coverage. The coverage rate for the plans in our study would be 100 percent if therapeutic alternatives are included. CMS' person-level analysis provides direct evidence regarding the extent to which Medicare's drug benefit provides coverage of the actual drugs used by dual eligibles. I have included the report as an attachment to our comments.

Overview of CMS Activities to Assure Access to Medically Necessary Drugs

CMS continues to work diligently on the transition from Medicaid to Medicare drug coverage to ensure that every FBDE beneficiary gets the coverage they need. CMS is committed to providing an appropriate set of checks and oversight activities to ensure that prescription drug plans offer a comprehensive benefit that reflects best practices in the pharmacy industry, as well as current treatment standards. CMS clinicians and pharmacists have reviewed all prescription drug plan formularies and benefit structures to verify that plans are in compliance with the following requirements:

- Multiple drugs in each class: The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the drug classification system that is utilized.

- Pharmacy and Therapeutics Committees (P&T): A Medicare prescription drug plan's formulary must be developed and reviewed by a P&T committee. Our oversight will ensure that plan formularies are designed to provide appropriate, up-to-date access for beneficiaries and give plans the flexibility to offer benefit designs that provide affordable access to medically necessary drugs. A majority of the P&T committee members must be physicians, pharmacists, or both.

- Review of Drug Classification System and Drug Lists: CMS has evaluated formulary classification systems, as well as the actual lists of drugs included in the formulary, using existing widely used classification systems and drug plans as checks.

- Benefit Management Tools: CMS has compared the prescription drug plans' use of benefit management tools (such as prior authorization) to the way these tools are used in existing drug plans to ensure that they are being applied in a clinically appropriate fashion.

These safeguards contributed to the OIG's primary finding that the average formulary covers 92 percent of the most commonly used drugs. Thus, the vast majority of the drugs most frequently used by Medicaid beneficiaries have been specifically included in the plans' formularies.

Review of Drug Coverage for Auto-Enrolled Full-Benefit Dual-Eligible Beneficiaries Based on Drug Use at the Individual Beneficiary Level
Centers for Medicare & Medicaid Services
Medicare Drug Benefit Group
January 20, 2006

Background:

In January 2006, the Centers for Medicare and Medicaid Services (CMS) conducted a study to assess drug coverage for full benefit dual eligible (FBDE) beneficiaries auto-assigned to a Part D Prescription Drug Plan (PDP). In brief, Medicare Part D drug plans must meet formulary standards that include, at a minimum, two drugs in each therapeutic class (i.e., drugs with very similar mechanisms of action), as well as essentially all drugs for treating serious conditions such as mental illnesses, HIV/AIDS, and cancer, where the specific medications may not be therapeutically similar. Thus, all FBDE beneficiaries are assigned to plans that cover multiple therapeutically equivalent medicines (e.g., equivalent antihistamines or stomach acid medicines, and other types of drugs where multiple drugs are available that work in a very similar way and are generally viewed as therapeutically equivalent). Although some plans have essentially "open formularies," and all plans must have broad coverage of all types of drugs, some FBDE beneficiaries may be auto-assigned to plans that do not cover all of their individual medications.

To provide evidence on actual beneficiaries' drug coverage, CMS examined the medications used by a sample of FBDE beneficiaries and compared each beneficiary's drugs to those in actual PDP formularies. The findings detailed below demonstrate that measures of coverage depend on whether the study design reflects actual drug use among the FBDE population. When the methodology is based on the experiences of actual beneficiaries, the data suggest that this population does have access to robust formularies that cover, on average, more than 90% of the medications they used before their transition to Part D coverage. Through this approach, medications are accounted for in a weighted manner such that they are not all counted equally. Thus, medications that are used more commonly are appropriately given more weight in the analysis. This approach also accounts for whether an actual individual's list of drugs will be included on a given PDP's formulary, which is the most relevant measure of beneficiary access.

In November 2005, the Office of the Inspector General (OIG) initiated a study that compared the formularies of PDPs eligible to receive auto-assigned FBDE beneficiaries to a list of the top 178 drugs most commonly used by dual-eligible enrollees, as identified by OIG based on state Medicaid files. The purpose of the OIG study was to determine whether the formularies of plans receiving auto-enrollees were sufficient to meet the needs of the FBDE beneficiaries. The OIG compared the list of 178 drugs—many of which were therapeutic substitutes for one another—to PDP formularies. They counted each of these drugs equally in their analysis, even though drugs much further down on the list are used much less frequently by the FBDE population. Using such data that was not reflective of actual FBDE experience, they concluded that a significant proportion of beneficiaries were assigned to plans that cover less than 85% of these 178 drugs used by FBDE beneficiaries. By design, the OIG study did not account for whether a beneficiary's actual list of drugs was included on a given PDP's formulary. Consequently, the OIG study does not provide evidence on coverage of drugs that is relevant at the beneficiary level.

Objective:

The objective of this study is to evaluate individual drug coverage for FBDE beneficiaries auto-enrolled into stand-alone PDPs.

Methods:

We examined individual FBDE beneficiaries' access to their prescription drugs using the most up-to-date source of drug information, self-reported Medicare Current Beneficiary Survey (MCBS) data. Using the

most recent MCBS data (2003), we randomly identified 200 fee-for-service, FBDE beneficiaries within 5 different PDP regions. We chose regions which include states with both generous and restrictive Medicaid coverage, based on Medicaid data used to determine the "phase-down provision" in the Medicare Modernization Act. The PDP regions included regions: 08 (North Carolina), 12 (Tennessee and Alabama), 14 (Ohio), 22 (Texas), and 30 (Washington and Oregon).

The FBDE beneficiaries in our sample are known to have been Medicare-eligible throughout 2003 and Medicaid-eligible at some point during that year. They also reported prescription drug use during the year. Institutionalized beneficiaries are not included in our sample because prescription drug use is not reported for these beneficiaries in MCBS data.

For the purposes of this study, beneficiaries in the sample were hypothetically assigned randomly to a plan in their region that was eligible to receive auto-assigned beneficiaries; that is, beneficiaries were assigned to Part D plans with premiums below the regional low-income premium subsidy amount. The assignment process used in the study, which is briefly described below, mirrored that which was used in the actual 2006 Medicare Part D auto-assignment process. Within a region, beneficiaries were first randomly distributed among all Part D contracts eligible to receive auto-assigned beneficiaries (in the instance where multiple contracts were owned by a single parent organization, beneficiaries were distributed among the parent organization, not the individual contracts). Next, if a contract offered multiple plans eligible to receive auto-assigned beneficiaries, beneficiaries were then randomly distributed among all such plans.

A distinct drug list (by molecular entity name) was derived based on the 200 beneficiaries' prescription medication regimens and was reviewed by clinical pharmacists. Any medications that were non-Part D-covered drugs, available exclusively over-the-counter, withdrawn from the market, or indicated for acute conditions were excluded from the study. All remaining medications utilized by study beneficiaries were then compared to formulary medications offered by the plans to which they were assigned within this study. For each beneficiary, a binary indicator was generated for each medication to specify whether that medication was covered under the assigned plan's formulary. A list of the medications included in the study is shown in Appendix A.

The number of drugs utilized by a beneficiary that were covered under the assigned plan's formulary along with the total number of drugs utilized were determined for each beneficiary. The percent coverage rate (([number of covered utilized drugs] / [total number of utilized drugs]) x 100) was also calculated for individual beneficiaries. Univariate statistics, including the mean, standard deviation, median, minimum and maximum were then calculated for the number of covered utilized drugs, the total number of utilized drugs, and the percent coverage rate. The percent coverage rate was also calculated as a weighted average based on the number of medications utilized. The frequency distribution of percent coverage rates was examined based on the following categories: less than 70%, 70-79%, 80-89%, 90-99% and 100%. The above calculations were repeated, stratified by region.

Results:

Out of the 200 sample beneficiaries, 195 were included in the analysis, and 5 beneficiaries were not included in the analysis since they utilized only medications that were excluded from the study.

Table 1 shows results from the univariate statistical analyses and the weighted average calculation. In general, beneficiaries utilized an average of 6.9 medications, 6.4 of which were covered under the assigned plan's formulary. On average, the percent coverage rate was found to be 92.8%; accounting for the number medications utilized, the weighted average was 93.0%.

Examining the average coverage rate by region showed little variation, as Table 2 shows. The unweighted percent coverage rate ranged from 90.2% in region 14 (Ohio) to 94.9% in region 12 (Tennessee and Alabama). Even less variation was found in the weighted percent coverage rate, which ranged from 91.8% in region 14 (Ohio) to 94.7% in region 12 (Tennessee and Alabama).

The frequency distribution for the percent coverage rates is shown in Table 3. The majority of beneficiaries (68.2%) were assigned to plans that covered all of their drugs. Very few beneficiaries (8.2%) were assigned to plans that covered less than 70% of all of their drugs.

Review of the drugs not covered under the beneficiaries' assigned plans' formularies showed that, as expected given the Medicare formulary requirements, these drugs included those that have multiple therapeutic alternatives (e.g. ACE-Inhibitors, Angiotensin II Receptor Blockers (ARBs), Proton Pump Inhibitors (PPIs), and antihistamines). By law, PDP formularies must include at least two drugs in every therapeutic class.

Conclusions:

Consistent with CMS' comprehensive formulary requirements, which ensured a minimum of 2 drugs per therapeutic class or category, we found most FBDE beneficiaries had all of their medications covered by the formulary of the plan to which they were assigned within this study. Not only does a typical dual-eligible beneficiary have all of their medications covered; on average, 93 percent of a beneficiary's medications are covered. Furthermore, in instances when a medication is not covered, multiple therapeutic alternatives are covered on the formulary within the same therapeutic class or category. Appeals processes provide yet another means of access to specific medications prescribed by physicians. Furthermore, dual-eligible enrollees are not constrained by open-enrollment periods and may switch plans throughout the year.

Although this study examined drug utilization for a sample and not the entire FBDE population, little variation was found in the average coverage rate between regions, which include FBDE beneficiaries from states with high, low, and intermediate per-capita spending. In conclusion, this study demonstrates that plans are generally offering robust formularies to FDBEs in terms of their actual use of medications, and these beneficiaries will have access to the medications they need and, in the vast majority of cases, medications they have used in the past. Unlike the approach taken in studies that do not examine actual patterns of use, this study's findings are based on the drug regimens of individual beneficiaries. By simulating their actual experiences under Medicare Part D, these findings suggest that dual-eligible enrollees will have broad access to the medications they need and demonstrate the importance of tracking this issue at the beneficiary level, in contrast with the approach of looking at a list of medications rather than actual use.

Table 1.
Univariate Statistics for Drug Coverage for Auto-Enrolled Dual-Eligible Beneficiaries

	Mean	Standard Deviation	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	Weighted Average
Number of Covered Utilized Drugs	6.4	4.6	0.0	2.0	6.0	9.0	28.0	-
Total Number of Utilized Drugs	6.9	4.8	1.0	3.0	6.0	10.0	28.0	-
Percent Coverage Rate	92.8%	14.1%	0.0	88.2%	100.0%	100.0%	100.0%	93.0%

Table 2.
Univariate Statistics by PDP Region for Drug Coverage for Auto-Enrolled Dual-Eligible Beneficiaries

PDP Region		Mean	Standard Deviation	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	Weighted Average
08 North Carolina	Number of Covered Utilized Drugs	6.8	4.6	1	3	6	11	19	-
	Total Number of Utilized Drugs	7.4	4.7	1	4	7	11	19	-
	Percent Coverage Rate	92.2%	15.3%	33.3%	85.7%	100.0%	100.0%	100.0%	93.0%
12 Tennessee and Alabama	Number of Covered Utilized Drugs	6.6	4.4	1	3	6	9	19	-
	Total Number of Utilized Drugs	6.9	4.5	1	3	6.5	9	20	-
	Percent Coverage Rate	94.9%	10.5%	55.6%	95.0%	100.0%	100.0%	100.0%	94.7%
14 Ohio	Number of Covered Utilized Drugs	7.9	5.7	1	3.5	6.5	11	28	-
	Total Number of Utilized Drugs	8.6	5.8	1	4.5	7	13	28	-
	Percent Coverage Rate	90.2%	14.0%	50.0%	84.6%	100.0%	100.0%	100.0%	91.8%
22 Texas	Number of Covered Utilized Drugs	5.3	4	1	2	4	8	17	-
	Total Number of Utilized Drugs	5.7	4.2	1	2.5	5	8	17	-
	Percent Coverage Rate	93.9%	12.0%	50.0%	93.3%	100.0%	100.0%	100.0%	93.4%
30 Washington and Oregon	Number of Covered Utilized Drugs	5.2	4.1	0	1	4.5	8	14	-
	Total Number of Utilized Drugs	5.7	4.4	1	1	4.5	9	15	-
	Percent Coverage Rate	93.0%	18.0%	0.0%	93.3%	100.0%	100.0%	100.0%	92.1%

Table 3.
Frequency Distribution of Percent Coverage Rates (N = 195)

Coverage Rate	Percent of Full-Benefit Dual-Eligible Beneficiaries
<70%	8.2%
70-79%	3.1%
80-89%	14.9%
90-99%	5.6%
100%	68.2%

Appendix A:
List of Medications Used by Full-Benefit Dual-Eligible Beneficiaries Included in the CMS Dual Study

Generic Name
ALBUTEROL
ALBUTEROL SULFATE
ALBUTEROL SULFATE/IPRATROPIUM
ALENDRONATE SODIUM
ALLOPURINOL
AMIODARONE HCL
AMITRIPTYLINE HCL
AMLODIPINE BESYLATE
AMLODIPINE BESYLATE/BENAZEPRIL
AMPHET ASP/AMPHET/D-AMPHET
AMYLASE/LIPASE/PROTEASE
ASPIRIN/DIPYRIDAMOLE
ATENOLOL
ATENOLOL/CHLORTHALIDONE
ATORVASTATIN CALCIUM
AZATHIOPRINE
AZELASTINE HCL
BACLOFEN
BECLOMETHASONE DIPROPIONATE
BENAZEPRIL HCL
BENZOCAINE
BENZTROPINE MESYLATE
BUDESONIDE
BUMETANIDE
BUPROPION HCL
BUSPIRONE HCL
CALCITONIN,SALMON,SYNTHETIC
CALCITRIOL
CALCIUM ACETATE
CAPECITABINE
CAPTOPRIL
CARBAMAZEPINE
CARBIDOPA/LEVODOPA
CARISOPRODOL
CARVEDILOL
CELECOXIB
CEPHALEXIN MONOHYDRATE
CETIRIZINE HCL
CEVIMELINE HCL
CHLORHEXIDINE GLUCONATE
CHLORPROMAZINE HCL
CHOLESTYRAMINE/SUCROSE
CICLOPIROX
CILOSTAZOL
CIMETIDINE
CITALOPRAM HYDROBROMIDE
CLOBETASOL PROPIONATE
CLONIDINE HCL
CLOPIDOGREL BISULFATE
CLOTRIMAZOLE
CLOTRIMAZOLE/BETAMET DIPROP

Generic Name
CLOZAPINE
CODEINE PHOS/ACETAMINOPHEN
COLCHICINE
CYCLOBENZAPRINE HCL
CYCLOPENTOLATE HCL
DALTEPARIN SODIUM,PORCINE
DESIPRAMINE HCL
DESLORATADINE
DHCODEINE BT/ACETAMINOPHN/CAFF
DICYCLOMINE HCL
DIGOXIN
DILTIAZEM HCL
DIPHENHYDRAMINE HCL
DIPHENOXYLATE HCL/ATROP SULF
DIPYRIDAMOLE
DIVALPROEX SODIUM
DONEPEZIL HCL
DOXAZOSIN MESYLATE
DOXEPIN HCL
ENALAPRIL MALEATE
ENALAPRIL/HYDROCHLOROTHIAZIDE
ESCITALOPRAM OXALATE
ESOMEPRAZOLE MAG TRIHYDRATE
ESTRADIOL
ESTROGEN,CON/M-PROGEST ACET
ESTROGENS,CONJUGATED
ETANERCEPT
ETHINYL ESTRADIOL/NORELGEST
ETHINYL ESTRADIOL/NORETH AC
ETODOLAC
EZETIMIBE
FAMOTIDINE
FELODIPINE
FENOFIBRATE,MICRONIZED
FENTANYL
FEXOFENADINE HCL
FINASTERIDE
FLUOCINONIDE
FLUORIDE ION/MULTIVITAMINS
FLUOROURACIL
FLUOXETINE HCL
FLUPHENAZINE HCL
FLUTICASONE PROPIONATE
FLUTICASONE/SALMETEROL
FLUVASTATIN SODIUM
FOSINOPRIL SODIUM
FUROSEMIDE
GABAPENTIN
GEMFIBROZIL
GLIMEPIRIDE
GLIPIZIDE
GLYBURIDE
GLYBURIDE/METFORMIN HCL

Generic Name
GUAIFENESIN/P-EPHED HCL
HC ACETATE/PRAMOXINE HCL
HYDRALAZINE HCL
HYDROCHLOROTHIAZIDE
HYDROCODONE BIT/ACETAMINOPHEN
HYDROCORTISONE
HYDROCORTISONE ACETATE
HYDROXYCHLOROQUINE SULFATE
HYDROXYZINE HCL
HYDROXYZINE PAMOATE
IBUPROFEN
INDOMETHACIN
INSULIN GLARGINE,HUM.REC.ANLOG
INSULIN LISPRO,HUMAN REC.ANLOG
INSULIN NPL/INSULIN LISPRO
IPRATROPIUM BROMIDE
IRBESARTAN
ISOSORBIDE DINITRATE
ISOSORBIDE MONONITRATE
ISRADIPINE
KETOCONAZOLE
KETOTIFEN FUMARATE
LABETALOL HCL
LACTULOSE
LAMIVUDINE
LAMOTRIGINE
LANSOPRAZOLE
LATANOPROST
LEVOTHYROXINE SODIUM
LIDOCAINE
LIDOCAINE HCL
LISINOPRIL
LISINOPRIL/HYDROCHLOROTHIAZIDE
LITHIUM CARBONATE
LOPERAMIDE HCL
LOSARTAN POTASSIUM
LOSARTAN/HYDROCHLOROTHIAZIDE
MAPROTILINE HCL
ME-TESTOSTERONE/ESTROGEN,ESTER
MECLIZINE HCL
MEDROXYPROGESTERONE ACET
MELOXICAM
METAXALONE
METFORMIN HCL
METHOCARBAMOL
METHOTREXATE SODIUM
METHYLDOPA
METHYLPREDNISOLONE
METOCLOPRAMIDE HCL
METOLAZONE
METOPROLOL SUCCINATE
METOPROLOL TARTRATE
METRONIDAZOLE

8

Generic Name
MIRTAZAPINE
MOEXIPRIL/HYDROCHLOROTHIAZIDE
MOMETASONE FUROATE
MONTELUKAST SODIUM
MORPHINE SULFATE
MUPIROCIN
NABUMETONE
NADOLOL
NADOLOL/BENDROFLUMETHIAZIDE
NAPHAZOLINE HCL
NAPROXEN
NAPROXEN SODIUM
NEFAZODONE HCL
NELFINAVIR MESYLATE
NIFEDIPINE
NITROGLYCERIN
NORTRIPTYLINE HCL
NYSTATIN
OLANZAPINE
OLMESARTAN MEDOXOMIL
OMEPRAZOLE
OPIUM
ORLISTAT
ORPHENADRINE CITRATE
OXAPROZIN
OXCARBAZEPINE
OXYBUTYNIN CHLORIDE
OXYCODONE HCL
OXYCODONE HCL/ACETAMINOPHEN
P-EPHED HCL/FEXOFENADINE HCL
PANTOPRAZOLE SODIUM
PAROXETINE HCL
PENTOXIFYLLINE
PHENTERMINE HCL
PHENYTOIN
PHENYTOIN SODIUM EXTENDED
PIMECROLIMUS
PIOGLITAZONE HCL
PIROXICAM
POLYETHYLENE GLYCOL 3350
POTASSIUM BICARBONATE/CIT AC
POTASSIUM CHLORIDE
PRAVASTATIN SODIUM
PRAZOSIN HCL
PREDNISONE
PRIMIDONE
PROCHLORPERAZINE MALEATE
PROGESTERONE,MICRONIZED
PROPAFENONE HCL
PROPOXYPHENE HCL
PROPOXYPHENE HCL/ACETAMINOPHEN
PROPOXYPHENE/ACETAMINOPHEN
PROPRANOLOL HCL

Generic Name
PROTRIPTYLINE HCL
QUETIAPINE FUMARATE
QUINAPRIL HCL
QUINIDINE SULFATE
QUININE SULFATE
RABEPRAZOLE SODIUM
RALOXIFENE HCL
RAMIPRIL
RANITIDINE HCL
RESERPINE
RISEDRONATE SODIUM
RISPERIDONE
RITONAVIR
RIVASTIGMINE TARTRATE
ROSIGLITAZONE MALEATE
ROSIGLITAZONE/METFORMIN HCL
ROSUVASTATIN CALCIUM
SALMETEROL XINAFOATE
SAQUINAVIR MESYLATE
SERTRALINE HCL
SEVELAMER HCL
SIMVASTATIN
SIROLIMUS
SOD SULF/SOD/NAHCO3/KCL/PEG'S
SODIUM BICARBONATE
SPIRONOLACT/HYDROCHLOROTHIAZIDE
SPIRONOLACTONE
STAVUDINE
SULINDAC
TACROLIMUS ANHYDROUS
TAMSULOSIN HCL
TERAZOSIN HCL
TERBUTALINE SULFATE
TERCONAZOLE
TERIPARATIDE
THEOPHYLLINE ANHYDROUS
THIORIDAZINE HCL
THIOTHIXENE
THYROID
TIAGABINE HCL
TICLOPIDINE HCL
TIMOLOL MALEATE
TIZANIDINE HCL
TOLTERODINE TARTRATE
TOPIRAMATE
TORSEMIDE
TRAMADOL HCL
TRAMADOL HCL/ACETAMINOPHEN
TRANDOLAPRIL
TRAVOPROST
TRAZODONE HCL
TRIAMCINOLONE
TRIAMCINOLONE ACETONIDE

Generic Name
TRIAMTERENE/HYDROCHLOROTHIAZIDE
TRIHEXYPHENIDYL HCL
VALSARTAN
VALSARTAN/HYDROCHLOROTHIAZIDE
VENLAFAXINE HCL
VERAPAMIL HCL
WARFARIN SODIUM
ZAFIRLUKAST
ZALEPLON
ZIPRASIDONE HCL
ZOLPIDEM TARTRATE

ACKNOWLEDGMENTS

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

Erin Lemire, *Project Leader*

Louise Schoggen, *Program Analyst*

Mark Stiglitz, *Program Analyst*

Janet Kilian, *Intern*

Linda Boone Abbott, *Program Specialist*

Tricia Davis, *Director, Medicare and Medicaid Branch*