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The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Frank Pallone
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable John D. Dingell
House of Representatives

Subject: *Medicare Part D: Changes in Utilization Similar for Randomly Reassigned and Other Low-Income Subsidy Beneficiaries*

To help defray out-of-pocket prescription drug costs for limited or low-income Medicare beneficiaries, the Medicare Part D outpatient prescription drug program offers a low-income subsidy (LIS) for eligible beneficiaries.[1] In 2010, about 9.4 million beneficiaries received the LIS—about 40 percent of the approximately 23 million Medicare Part D beneficiaries in that year.[2,3] Most of the LIS beneficiaries received the full LIS, thus paying no premiums or deductibles as long as they enrolled in so-called "benchmark" stand-alone prescription drug

[1]Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071 (adding a new Part D to title XVIII of the Social Security Act (SSA) which establishes a voluntary Medicare prescription drug benefit program (codified at 42 U.S.C. §§ 1395 w-101 et seq.)) (SSA § 1860D-14 establishes premium and cost-sharing subsidies for low-income individuals (codified at 42 U.S.C. § 1395w-14)). Under the Part D drug program, coverage for all Medicare beneficiaries is subsidized; however, LIS beneficiaries receive additional subsidy support.

[2]The Part D population eligible for LIS may be substantially greater. For example, according to a September 2010 report by the Henry J. Kaiser Family Foundation, more than 2 million Medicare beneficiaries were eligible for the LIS in 2009 but did not receive it.

[3]The number of total Medicare Part D enrollees excludes individuals enrolled in plans with restricted enrollment, i.e., employer-sponsored, Demonstration, Cost, PACE, religious fraternal benefits plans, and plans with zero enrollment as of January 1 of each year.

plans (PDP).[4] Benchmark PDPs are those plans with premiums at or below a specified benchmark for a given geographic region, calculated by the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that administers the Medicare program. Full LIS beneficiaries may also enroll in other Part D plans—either nonbenchmark PDPs or Medicare Advantage prescription drug plans (MA-PD)—but must pay any difference between the premium of the plan in which they choose to enroll and the benchmark for their region.[5]

Because plan premiums can change from year to year and because CMS recalculates the premium benchmarks annually, some PDPs may be benchmark PDPs in one year and not in the following year. In these instances, CMS is required to randomly reassign those LIS beneficiaries who are in plans whose premiums will no longer be at or below the new benchmark the following year into PDPs with premiums that will be at or below the benchmark.[6] Beneficiaries subject to random reassignment can choose to either stay in their current plan or enroll in a new plan prior to being randomly reassigned by CMS, but if they choose either option, and that plan's premium is higher than the new benchmark, they are responsible for paying any premiums above the new benchmark.[7] From 2007—the first year LIS beneficiaries could be randomly reassigned—through 2010, an average of almost 1.3 million LIS beneficiaries has been randomly reassigned into new PDPs each year.

Questions have been raised by Medicare beneficiary advisors and others about the benefits of available benchmark PDPs, and some suggest that the random reassignment process may create challenges for affected LIS beneficiaries. For example, according to some advisors, random reassignment may impact LIS beneficiaries' drug coverage. Specifically, beneficiaries may be randomly reassigned by CMS into benchmark PDPs that do not cover the drugs they are taking, requiring them to consult with a medical provider to prescribe a therapeutically equivalent alternate drug. Similarly, they may be randomly reassigned by CMS into benchmark PDPs that impose more or different utilization management (UM) requirements—such as prior authorization requirements, quantity limits, or step therapy[8]—on certain drugs they are currently taking, thus also requiring the intervention of a medical provider. In addition, there are concerns that random reassignment may lead to changes in pharmacies impacted LIS beneficiaries have access to, which may further impact drug utilization.

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[4]The full LIS covers 100 percent of the premium up to the benchmark amount and all of the deductibles. To be eligible for the full LIS in 2011, a beneficiary needs to have an income at or below 135 percent of the Federal Poverty Level (FPL) and resources of no more than $8,180, if single, or $13,020, if married. Beneficiaries with greater income and resources, but no more than 149 percent of the FPL and resources no more than $12,640, if single, or $25,260, if married, are eligible to receive the partial LIS, which covers 25 to 75 percent of the premium and a portion of the deductible. According to CMS, in 2010, about 97 percent of LIS beneficiaries received the full LIS. Regardless of the type of subsidy, LIS beneficiaries may have to pay some portion of their copayments.

[5]MA-PDs provide drug coverage to beneficiaries enrolled in Medicare Advantage, Medicare's managed care program. Medicare Advantage plans provide all Part A and Part B coverage and may offer extra coverage, such as vision, hearing, dental, and/or health and wellness programs. Most Medicare Advantage plans include Part D prescription drug coverage.

[6]MMA, Pub. L. No. 108-173, § 101, 117 Stat. 2073 (adding SSA, § 1860D-1(b)(1)(C) (codified at 42 U.S.C. § 1395w-101(b)(1)(C)). Only LIS beneficiaries eligible for the full LIS are subject to random reassignment unless a plan terminates (in which case all affected beneficiaries may be randomly reassigned). According to CMS officials, the vast majority of reassignments—from almost 100 percent in 2007 to about 73 percent in 2010—occur as a result of premium increases.

[7]The LIS beneficiaries we refer to in this report as "randomly reassigned" are those who actually underwent random reassignment to new benchmark PDPs by CMS.

[8]Step therapy requires that a beneficiary try lower-cost drugs before a plan will cover a more costly drug.

Moreover, according to Medicare beneficiary advisors and others, LIS beneficiaries are generally more likely than other Medicare beneficiaries to have physical or cognitive impairments in addition to lower incomes, potentially confounding their ability to navigate the various processes associated with changing prescription drug plans. Thus, some Medicare beneficiary advisors and others have expressed concerns that randomly reassigned beneficiaries may experience greater changes in their drug and pharmacy utilization compared to other LIS beneficiaries, such as a delay or a discontinuation in filling a prescription.

You asked us to examine the features of benchmark PDPs and explore how the random reassignment process may affect beneficiaries' drug utilization. In this report, we describe:

1. how drug coverage and access to pharmacies compared between benchmark and nonbenchmark PDPs from 2007 through 2010;[9] and

2. how changes in drug and pharmacy utilization compared between randomly reassigned and other LIS beneficiaries who were not randomly reassigned from 2007 to 2008.[10]

To determine how drug coverage and access to pharmacies compared between benchmark and nonbenchmark PDPs from 2007 through 2010, we obtained CMS's Health Plan Management System (HPMS) files for these years.[11] We analyzed the data to determine the drugs covered, the percentage of drugs subject to UM requirements, and the number of retail and mail order pharmacies available per plan by year and by state. We reviewed the HPMS data for soundness and consistency and determined that they were sufficiently reliable for our purposes. We also interviewed representatives of nine different State Health Insurance Assistance Programs (SHIP).[12] We asked the SHIP representatives about issues related to the LIS, such as drug formularies, UM requirements, and pharmacy access among plans available to LIS beneficiaries.

To determine whether a group of randomly reassigned LIS beneficiaries experienced changes in their drug utilization following reassignment between 2007 and 2008, we analyzed CMS's Prescription Drug Event (PDE) claims data to compare beneficiaries' utilization of selected drugs taken continuously in 2007 before their random reassignment to their utilization of

[9]While LIS beneficiaries may enroll in MA-PDs, they may be randomly reassigned only into benchmark PDPs. Also, because MA-PDs are part of Medicare Advantage plans, which cover all Medicare benefits, the decision to enroll in an MA-PD is likely to take into account factors in addition to drug benefits, such as the plan medical benefits and network access to doctors and hospitals. For these reasons, we focus the comparative analysis of drug plans on benchmark and nonbenchmark PDPs. However, where applicable, we do provide some comparable information for MA-PDs.

[10]The most recent data available at the time of our review was for 2008.

[11]The Health Plan Management System (HPMS) is the electronic information and communication system between CMS and sponsors participating in Medicare parts C and D. HPMS collects data for and manages a number of plan enrollment processes, such as: application process, bid/benefit package submissions, and formulary submissions.

[12]The State Health Insurance and Assistance Program (SHIP) is a state-based program, funded through CMS grants, that offers free counseling and assistance to people with Medicare and their families. For example, according to SHIP representatives, SHIP counselors often help LIS beneficiaries in selecting plans or understanding and dealing with the random reassignment process. The program is administered by the states. For our interviews, we selected SHIPs based on geographical diversity and the size of states' LIS population. We interviewed SHIP representatives from Alabama, Arizona, California, Colorado, Illinois, Louisiana, Maine, New York, and West Virginia.

those same drugs in 2008.[13] In so doing, we estimated the prevalence of any drug utilization changes in 2008. Specifically, we estimated the number of LIS beneficiaries who experienced a reduction in fills, a substitution with a therapeutic equivalent,[14] or a complete discontinuation in 2008 of one or more selected drugs taken continuously in 2007. We then compared reassigned beneficiaries' drug utilization changes to those of two other groups—LIS beneficiaries who chose new plans, and LIS beneficiaries who did not change plans.[15] We also compared changes in pharmacies used among the three groups between 2007 and 2008.[16] While we cannot attribute all drug utilization and pharmacy changes to the random reassignment process, we believe any differences in the rate of utilization changes between the randomly reassigned study group and the two comparison groups may suggest the potential influence of random reassignment on utilization. We reviewed the PDE data for soundness and consistency and determined that they were sufficiently reliable for our purposes. During interviews with SHIP representatives, we discussed the implications of the random reassignment process on LIS beneficiaries. For more details on the methodology used to estimate drug utilization and pharmacy changes following reassignment, see enclosure I.

We conducted our work from June 2009 to May 2011 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

Results in Brief

Drug coverage was somewhat more limited for benchmark compared to nonbenchmark PDPs and became gradually more restrictive for all PDPs from 2007 through 2010, while pharmacy access was comparable. The average number of drugs covered by benchmark PDP formularies was slightly smaller than the average covered by nonbenchmark PDP formularies—about 5 percent smaller in 2010, for example. Benchmark PDPs also imposed UM requirements on a similar to slightly greater share of drugs than other PDPs. For example, benchmark PDPs imposed at least one UM requirement on 28 percent of covered drugs compared with about 26 percent among nonbenchmark PDPs, on average, in 2010. Both benchmark and nonbenchmark PDPs experienced a gradual reduction in the number of drugs covered and a gradual increase in the number of drugs subject to at least one UM requirement from 2007 through 2010. Access to retail and mail order pharmacies was

[13]CMS's Prescription Drug Event (PDE) claims data contain a record of each claim reimbursed under Part D, including, among other things, the plan in which the beneficiary was enrolled, whether the drug was covered by the plan, the quantity of drug supplied, and LIS status of the beneficiary. PDE claims data for 2008 were the most recent available at the time of our review.

[14]Drugs that possess a similar chemical structure and similar therapeutic effects are grouped into therapeutic classes. There are five therapeutic class levels, ranging from therapeutic class level 1 (the broadest possible classification) to therapeutic class level 5 (the narrowest possible classification). We used Thomson Reuters' *RED BOOK*™ data on therapeutic class, specifically therapeutic class level 2 (TC2). Examples of TC2s include Antidepressant, Antidiabetic, Antiasthma, and Calcium Channel Blocker. In our analysis, we consider drugs to be therapeutically equivalent if they are in the same therapeutic class level 2.

[15]LIS beneficiaries who were originally subject to random reassignment but instead decided to either self-select a new plan or stay in their original plan were also included in these two comparison groups.

[16]Our analysis of pharmacy changes did not include changes from one pharmacy to another within the same pharmacy chain.

comparable among benchmark and nonbenchmark PDPs, with the average number of pharmacies per plan per state generally increasing during the period for both types of plans.

The extent to which randomly reassigned LIS beneficiaries experienced changes in their drug and pharmacy utilization after reassignment was comparable to the extent of such changes among other LIS beneficiaries. Specifically, for drugs they had taken continuously for the full year of 2007, randomly reassigned and other LIS beneficiaries experienced comparable rates of reductions in drug fills, substitutions to therapeutically equivalent drugs, and discontinuations of the drugs in 2008. For example, 32 percent of randomly reassigned LIS beneficiaries experienced a reduction in fills in 2008, compared with 32 percent of LIS beneficiaries who chose new plans and 31 percent of LIS beneficiaries who did not change plans. Additionally, the share of LIS beneficiaries who experienced a change in pharmacies used in 2008 compared to 2007 was comparable across randomly reassigned and other LIS beneficiaries. While we did not identify measurable differences in the rates of utilization changes experienced by randomly reassigned beneficiaries compared to other LIS beneficiaries, beneficiary advisors said that the uniquely vulnerable LIS population may nevertheless experience hardships or inconvenience when changing prescription drug plans.

HHS generally agreed with our findings. In particular, HHS stated that it concurred with our principal finding that the extent to which randomly reassigned LIS beneficiaries experienced changes in their drug and pharmacy utilization after reassignment was comparable to the extent of such changes among other LIS beneficiaries. However, HHS noted that our finding concerning the uniquely vulnerable LIS beneficiary population potentially facing particular hardships or inconveniences when changing drug plans was not supported by data in the report. Our report did not associate this finding to our data analyses, but instead noted that based on our discussions with beneficiary advisors, the particular hardships or inconveniences may exist despite our data analysis findings.

Background

Medicare Part D offers prescription drug coverage for individuals age 65 or older, certain disabled individuals under age 65, and people of all ages with End-Stage Renal Disease. The program offers additional subsidies for certain low income beneficiaries to help cover their out-of-pocket prescription drug costs.

Medicare Part D Benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) expanded Medicare coverage to include a voluntary benefit program covering outpatient prescription drugs. Coverage under the program, known as Medicare Part D, went into effect on January 1, 2006,[17] and in 2010, enrolled about 23 million beneficiaries. Beneficiaries may purchase drug coverage through stand-alone PDPs or through MA-PD plans; the latter are part of Medicare Advantage plans, which provide all Medicare benefits. In each of these types of plans, both the beneficiary and the plan pay a portion of the cost of covered prescription drugs, with the beneficiary typically paying a monthly premium, an annual deductible, and copayments.

[17]See SSA § 1860D-1(a)(2), as added by MMA 117 Stat. 2072.

Part D plans must offer a standard Part D benefit, set each year by CMS, or offer coverage that is actuarially equivalent to the standard Part D benefit.[18] Part D plans must also meet certain requirements as to which drugs they cover. Specifically, CMS generally requires that plan formularies—lists of covered drugs—must include at least two drugs from each therapeutic class.[19] Formularies must also include all or substantially all drugs within six designated drug categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and HIV/AIDS.[20] In addition, plans must offer pharmacy networks that are robust enough to ensure access to covered Part D drugs for their beneficiaries—specifically the plans must include a retail pharmacy in their network that is within 2 miles of 90 percent of urban beneficiaries, 5 miles of 90 percent of suburban beneficiaries, and 15 miles of 70 percent of rural beneficiaries.[21]

Part D plans have discretion in designing their formularies. As long as they meet the minimum formulary requirements, they may exclude particular drugs from their formularies. Additionally, plans may attempt to lower their drug costs by applying various UM requirements to specific drugs on their formularies.[22] UM requirements may include (1) prior authorization, which requires the beneficiary, with help from their prescribing physician, to obtain the plan's approval before it will cover a particular drug; (2) quantity limits, which restrict the supply of a drug to the dosage or quantity provided within a certain period of time; and (3) step therapy, which requires the beneficiary to first try lower-cost drugs before a plan will cover a more costly drug.

Medicare Part D Low-Income Subsidy

Part D offers a low-income subsidy program to eligible beneficiaries. To qualify for the LIS, Medicare beneficiaries must be enrolled in a Part D plan and have income and resources less than a threshold established by the MMA.[23] In 2011, beneficiaries were eligible if their income was at or below 149 percent of the Federal Poverty Level (FPL) and their resources were equal to or below $12,640, if single, or $25,260, if married. Beneficiaries may receive a full or partial LIS, depending on their household income and resources. The majority of the LIS beneficiaries—almost 97 percent in 2010—received the full LIS. In 2011, full LIS beneficiaries would pay no premium if enrolled in a benchmark PDP, no deductible, and a zero or nominal copayment for all out-of-pocket spending up to $4,550. Partial LIS beneficiaries would pay a share of a plan's premium based on a sliding scale, a $63 deductible, and a 15 percent

[18]See SSA § 1860D-2(c), as added by MMA 117 Stat. 2079.

[19]See 42 C.F.R. § 423.120(b)(2) (2010). This requirement to cover at least two drugs per therapeutic class does not apply when there is only one drug in the class or category or when CMS has given approval to a plan to cover fewer than two drugs.

[20]See SSA § 1860D-4(b)(3)(G), as added by Pub. L. No. 110-275, 122 Stat. 2581.

[21]MMA, Pub. L. No. 108-173, § 101, 117 Stat. 2083 (adding SSA, § 1860D-4(b)(1)(C) (codified at 42 U.S.C. § 1395w-114(a)); 42 C.F.R. §423.120(a)(1)(2010).

[22]See SSA § 1860D-4(c)(1)(A), as added by MMA 117 Stat 2086.

[23]See MMA, Pub. L. No. 108-173, § 101, 117 Stat. 2107 (adding SSA, § 1860D-14(a)) (codified at 42 U.S.C. § 1395w-114(a)). This provision directs CMS to update the resource limits for the LIS each year based on the annual percentage increase in the Consumer Price Index, All Urban Consumers, as of September of the previous year.

copayment up to $4,550; beyond that, copayments were $2.50 for generic and $6.30 for brand name drugs.[24]

Each year, CMS establishes an LIS premium benchmark for each of the 34 PDP regions[25,26] by determining the average of the premiums charged by all Part D plans in the region and weighting that average by the number of LIS beneficiaries enrolled in each plan.[27] Benchmark PDPs are those PDPs that offer standard Part D coverage and have premiums at or below the benchmark for their PDP region in a given year. Full LIS beneficiaries are entitled to a premium subsidy equal to 100 percent of the LIS premium subsidy amount if they are enrolled in a benchmark PDP. Full LIS beneficiaries may enroll in plans with premiums above the benchmark, but are responsible for paying the difference between their plan's premium and the benchmark. In 2010, there were 307 benchmark PDPs, constituting 8 percent of the 3,849 total Part D plans; in which over 6 million LIS beneficiaries, or about 65 percent of the total, were enrolled.[28] (See table 1.)

Table 1: Number of Plans Available, Average Premium, and LIS Enrollment by Type of Part D Plan, 2010

	Plans available[a]			LIS enrollment	
Type of plan	Number of plans	Percent of all Part D plans	Average premium[b] (national)	Number of enrollees	Percent of total enrollment
Benchmark PDP	307	8	$28.83	6,115,221	65.15
Nonbenchmark PDP	1,269	33	$44.27	1,566,651	16.69
MA-PD	2,273	59	$14.46[c]	1,704,744	18.16
Total Part D plans	**3,849**			**9,386,616**	

Source: GAO analysis of CMS data.

[a]The number of available Part D plans excludes plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, religious fraternal benefits plans, and plans with zero enrollment as of January 1 of each year.

[b]Enrollment-weighted average.

[c]This represents only the Part D portion of MA-PD premiums. In 2010, MA-PD premiums ranged from $0 to $157. Overall, the drug portion of MA-PD premiums tends to be relatively lower than stand-alone PDP premiums in part because Medicare Advantage plans can use savings from other health services (rebates) to reduce their drug benefit premiums.

CMS's recalculation of the premium benchmark every year coupled with plan's yearly adjustment of premiums means some plans lose their status as benchmark PDPs from one year to the next. Additionally, some plans choose to leave the Part D program. To protect those LIS beneficiaries who were enrolled in a benchmark PDP in one year but whose plans

[24]The MMA requires the copayments for LIS beneficiaries under the standard benefit to be indexed annually to the increase in average total drug expenses of Medicare beneficiaries. MMA, Pub. L. No. 108-173, § 101, 117 Stat. 2077 (adding SSA, §§ 1860D-2(b)(4)(A) (codified at 42 U.S.C. § 1395w-102(b)(4)(A)).

[25]CMS established 34 geographic regions for the administration of PDPs and 26 regions for the administration of MA-PDs. *See* MMA, Pub. L. No. 108-173, §§ 101, 221(c), 117 Stat. 2092, 2181 (adding SSA, §§ 1860D-11(a), 1858(a)) (codified at 42 U.S.C. § 1395w-111(a)). Plan costs and coverage vary by region.

[26]This benchmark is set at the regional level but applies to each state within the region.

[27]The MMA directed CMS to use a weighted average to calculate the benchmark amount. Since then, according to CMS officials, CMS has adjusted its weighting method for calculating the benchmark, mostly in an effort to increase the benchmark, and consequently, to increase the number of benchmark PDPs.

[28]Using numbers reported in a September 2010 report by the Henry J. Kaiser Family Foundation, we calculated that, in 2010, only about 11 percent of LIS beneficiaries enrolled in MA-PD plans paid any drug-related premiums.

lost benchmark status or departed the program the following year, the MMA requires CMS to randomly reassign such beneficiaries to other PDPs whose premiums are at or below the benchmark. From 2007 through 2010, about 3.5 million LIS beneficiaries were randomly reassigned at least once; about 36 percent of them were reassigned two or more times.[29]

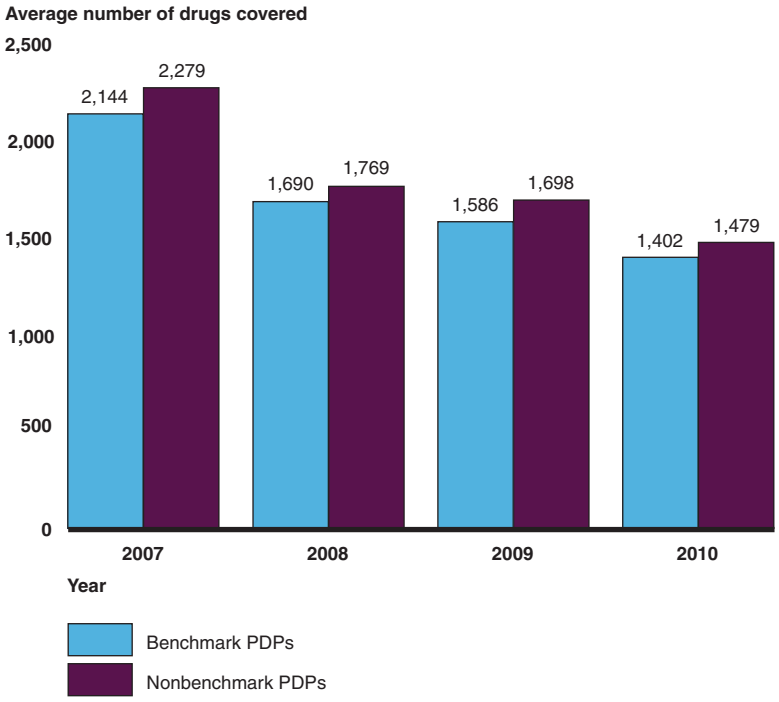
Drug Coverage Was Somewhat More Limited for Benchmark Compared to Nonbenchmark PDPs and Became Gradually More Restrictive among All PDPs from 2007 through 2010, While Pharmacy Access Was Comparable

Benchmark PDPs generally covered a somewhat smaller number of drugs compared with nonbenchmark PDPs, and the number of drugs covered declined among all PDPs from 2007 through 2010. In 2010, for example, benchmark PDPs covered an average of 1,402 drugs, about 5 percent fewer than the average of 1,479 drugs covered by nonbenchmark PDPs. (See figure 1.) Between 2007 and 2010, the average number of drugs covered by benchmark and nonbenchmark PDPs declined by about 35 percent.[30]

[29]LIS beneficiaries who would otherwise be randomly reassigned because they are enrolled in PDPs losing their benchmark status the following year may decide instead to choose their own plan. They may either stay in their original plan or enroll in a plan of their own choosing. In 2010, of the 922,272 LIS beneficiaries who would have been subject to random reassignment, almost 92 percent were randomly reassigned. The other 8 percent chose their own plan—roughly half chose to stay in their current plan and half chose a new plan.

[30]Benchmark PDPs also covered fewer drugs than MA-PDs during this period. For example, in 2010, benchmark PDPs covered, on average, about 13 percent fewer drugs than MA-PDs. In addition, as among benchmark and nonbenchmark PDPs, the number of drugs covered by MA-PDs declined from 2007 to 2010.

Figure 1: Average Number of Drugs Covered among Benchmark and Nonbenchmark PDPs, 2007 through 2010



Source: GAO analysis of CMS data.

Notes: The number of available Part D plans used in this analysis excludes plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, religious fraternal benefit plans, and plans with zero enrollment as of January 1 of each year.

In 2007 and 2008, CMS established a "de minimis" policy allowing full LIS beneficiaries in plans with premiums rising above the benchmark by no more than $2 in 2007 and no more than $1 in 2008 to remain in their plans without having to pay the difference between the plan's premium and the benchmark. In our analysis, we included de minimis plans in our count of 2007 and 2008 benchmark PDPs—de minimis plans accounted for almost 24 percent of our total count of benchmark PDPs in 2007 and almost 11 percent in 2008.

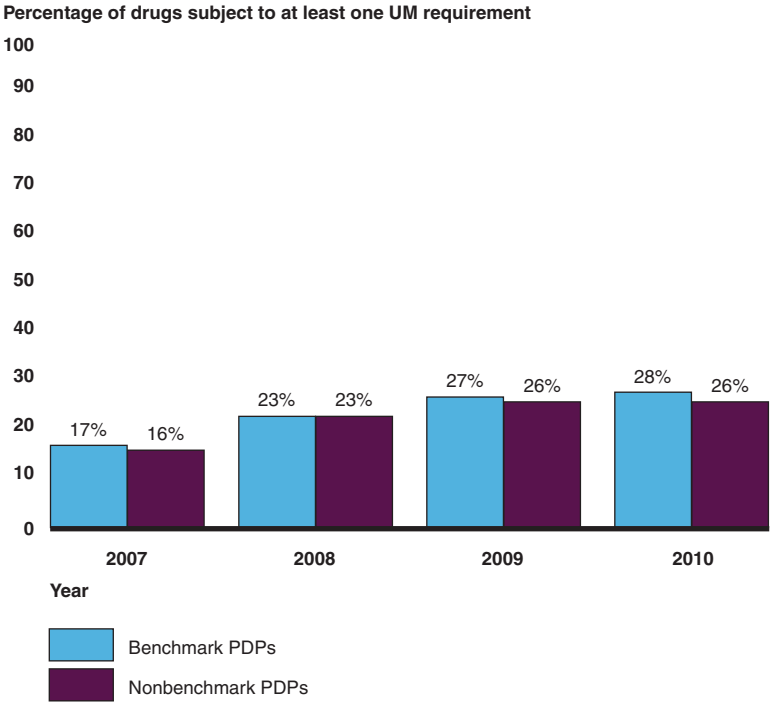
Though benchmark PDPs covered somewhat fewer drugs overall from 2007 through 2010, coverage at the therapeutic class level was comparable between benchmark and nonbenchmark PDPs, on average, for about 75 percent of about 170 therapeutic classes covered throughout this time period. Within these classes, benchmark PDPs covered at least as many drugs as did nonbenchmark PDPs. In the remaining 25 percent of therapeutic classes, nonbenchmark PDPs generally covered, on average, from 1 to 5 more drugs within those classes than did benchmark PDPs.[31]

All PDPs imposed at least one type of UM requirement—prior authorization, quantity limits, or step therapy—to control utilization of certain drugs that are expensive, potentially risky, or subject to abuse, misuse, or experimental use. In 2010, benchmark PDPs generally imposed UM requirements on a similar to slightly greater share of drugs than nonbenchmark PDPs, and the use of such controls has increased among all PDPs since 2007. Specifically, in 2010, benchmark PDPs imposed at least one of the three UM requirements on an average of 28 percent of drugs, compared with an average of about 26 percent among nonbenchmark PDPs. The percentage of covered drugs subject to at least one UM requirement has generally

[31]In 2010, analgesics was the only therapeutic class where the difference was more than 5 drugs—nonbenchmark PDPs covered an average of 76 drugs, 9 drugs more than the average of 67 drugs covered by benchmark PDPs.

increased among all PDPs over time—among benchmark PDPs, it increased from 17 percent in 2007 to 28 percent in 2010; for nonbenchmark PDPs, it increased from 16 percent to 26 percent.[32] (See figure 2.)

Figure 2: Average Percentage of Drugs Subject to at Least One Utilization Management (UM) Requirement among Benchmark and Nonbenchmark PDPs, 2007 through 2010



Source: GAO analysis of CMS data.

Notes: The number of available Part D plans used in this analysis excludes plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, religious fraternal benefit plans, and plans with zero enrollment as of January 1 of each year.

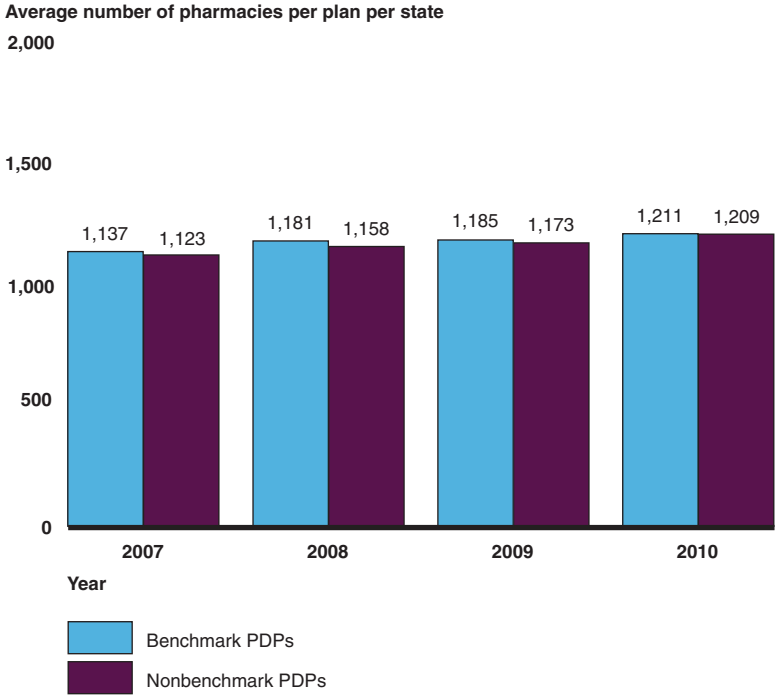
In 2007 and 2008, CMS established a "de minimis" policy allowing full LIS beneficiaries in plans with premiums rising above the benchmark by no more than $2 in 2007 and no more than $1 in 2008 to remain in their plans without having to pay the difference between the plan's premium and the benchmark. In our analysis, we included de minimis plans in our count of 2007 and 2008 benchmark PDPs—de minimis plans accounted for almost 24 percent of our total count of benchmark PDPs in 2007 and almost 11 percent in 2008.

Benchmark PDPs provided generally comparable access to retail and mail order pharmacies compared with other plans since 2007. During this period, the average number of pharmacies per plan per state was about the same between benchmark and nonbenchmark PDPs—1,179 and 1,166, respectively. (See figure 3.) Over time, the average number of pharmacies per plan per state increased slightly among both types of PDPs—reaching 1,211 and 1,209 for benchmark and nonbenchmark PDPs in 2010, up from 1,137 and 1,123 in 2007. In addition, the percentage of benchmark and nonbenchmark PDPs offering a mail order pharmacy was relatively comparable during this period, ranging between 83 and 92 percent among

[32]Benchmark PDPs also imposed at least one UM requirement on a slightly greater number of drugs than MA-PDs. For example, in 2010, benchmark PDPs, imposed on average, at least one UM requirement on 28 percent of drugs compared to 24 percent among MA-PDs. As among benchmark and nonbenchmark PDPs, use of UM requirements among MA-PDs increased from 2007 to 2010.

benchmark PDPs, and between 87 and 94 percent among nonbenchmark PDPs from 2007 through 2010.[33]

Figure 3: Average Number of Pharmacies, per Plan, per State, for Benchmark and Nonbenchmark PDPs, 2007 through 2010



Source: GAO analysis of CMS data.

Notes: The number of available Part D plans used in this analysis excludes plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, religious fraternal benefit plans, and plans with zero enrollment as of January 1 of each year.

In 2007 and 2008, CMS established a "de minimis" policy allowing full LIS beneficiaries in plans with premiums rising above the benchmark by no more than $2 in 2007 and no more than $1 in 2008 to remain in their plans without having to pay the difference between the plan's premium and the benchmark. In our analysis, we included de minimis plans in our count of 2007 and 2008 benchmark PDPs—de minimis plans accounted for almost 24 percent of our total count of benchmark PDPs in 2007 and almost 11 percent in 2008.

Changes in Drug and Pharmacy Utilization Were Comparable among Randomly Reassigned and Other LIS Beneficiaries from 2007 to 2008

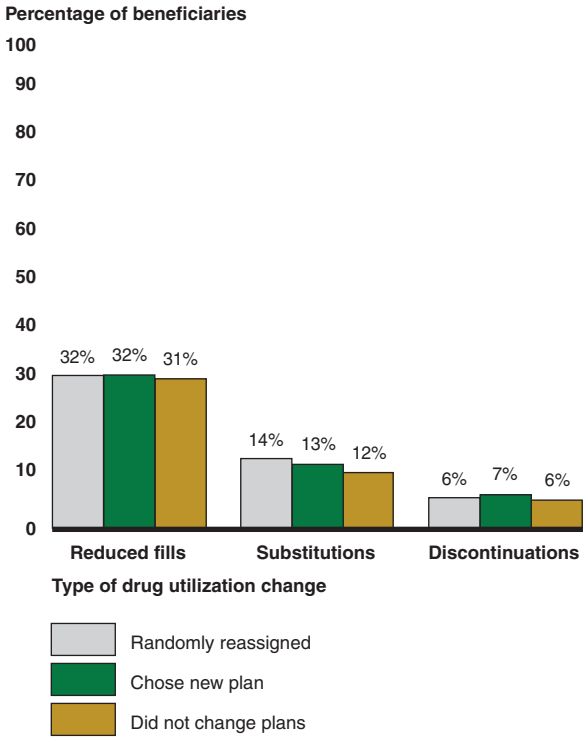
Randomly reassigned LIS beneficiaries experienced similar rates of changes in their drug and pharmacy utilization compared with other LIS beneficiaries in 2008.[34] Reductions in fills were the most common drug utilization change, and the share of beneficiaries who experienced a reduction in fills was similar across randomly reassigned and other LIS beneficiaries.

[33]Benchmark PDPs offered better access to retail pharmacies compared to MA-PDs. From 2007 through 2010, the average number of pharmacies per plan per state was significantly higher among benchmark PDPs than among MA-PDs at 1,179 and 323 respectively. Access to mail order pharmacies among MA-PDs was relatively comparable to benchmark PDPs.

[34]For our analysis, we compared drug and pharmacy utilization changes among three groups: beneficiaries who were randomly reassigned in 2008; beneficiaries who chose new plans in 2008; and beneficiaries who did not change plans in 2008. The three groups included: 540,723 randomly reassigned LIS beneficiaries; 1,712,495 LIS beneficiaries who did not change plans; and 197,653 LIS beneficiaries who chose a new plan for 2008. All beneficiaries included in the groups took one or more drugs used to treat chronic conditions continuously in 2007.

Specifically, about 32 percent of randomly reassigned beneficiaries, 32 percent of beneficiaries who chose a new plan, and 31 percent of beneficiaries who did not change plans experienced a reduction in fills in 2008 for at least one of the drugs they took continuously in 2007. A smaller, but comparable, share of randomly reassigned and other LIS beneficiaries substituted at least one of their drugs taken continuously in 2007 with a therapeutic equivalent (including generics) in 2008. Specifically, about 14 percent of randomly reassigned beneficiaries, 13 percent of those beneficiaries who chose a new plan, and 12 percent of beneficiaries who did not change plans substituted at least one of their 2007 drugs for a therapeutic equivalent in 2008. Similarly, a small but comparable share of randomly reassigned and other LIS beneficiaries discontinued taking at least one drug in 2008 that they had taken continuously in 2007. Specifically, about 6 percent of randomly reassigned beneficiaries, 7 percent of beneficiaries who chose a new plan, and 6 percent of beneficiaries who did not change plans experienced a drug discontinuation in 2008. (See figure 4.)

Figure 4: Drug Utilization Changes in 2008 among Randomly Reassigned and Other LIS Beneficiaries



Source: GAO analysis of CMS data.

We also compared changes in pharmacy utilization from 2007 to 2008 between randomly reassigned and other LIS beneficiaries and found that the share who experienced a change was comparable among randomly reassigned and other LIS beneficiaries. Specifically, about 33 percent of randomly reassigned beneficiaries, 29 percent of those who chose a new plan, and 32 percent of those who did not change plans had a change in pharmacy in 2008.

While randomly reassigned LIS beneficiaries experienced comparable changes in drug and pharmacy utilization compared to other LIS beneficiaries, the LIS population may nevertheless experience particular hardships or inconvenience when changing prescription drug plans relative to other, non-LIS beneficiaries. According to representatives from several SHIPs we spoke with, LIS beneficiaries are generally more likely than other Medicare beneficiaries to have physical or cognitive impairments in addition to lower incomes. These limitations may affect their ability to navigate changes associated with their new prescription

drug plans. For example, according to SHIP representatives, accounting for changing or increased UM requirements may present challenges to LIS beneficiaries, who may need to seek reauthorization from their new plan for prescriptions they are currently taking. According to CMS officials, the agency has policies in place to help beneficiaries transition between Part D drug plans. For example, plans are required to provide newly enrolled beneficiaries with access to at least a 30 day transition supply of any drug covered by a prior plan within the first 90 days of their enrollment, even if the new plan does not include the drug on its formulary.

Agency Comments and Our Evaluation

We received written comments from HHS on a draft of this report (see encl. II). HHS generally agreed with our findings. In particular, HHS stated that it concurred with our principal finding that the extent to which randomly reassigned LIS beneficiaries experienced changes in their drug and pharmacy utilization after reassignment was comparable to the extent of such changes among other LIS beneficiaries. However, the agency also stated that our finding concerning the LIS beneficiary population potentially facing particular hardships or inconveniences when changing drug plans was not supported by data in the report. Our report did not associate this finding with our data analyses, but instead noted that particular hardships or inconveniences may exist despite our data analysis findings. Beneficiary advisors from several SHIP organizations we contacted discussed how the LIS beneficiaries are more likely than other Medicare beneficiaries to have physical or cognitive impairments in addition to lower incomes, which could affect their ability to navigate changes associated with new prescription drug plans.

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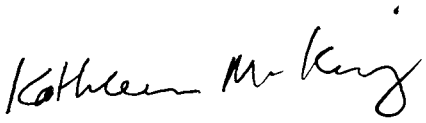
As arranged with your offices, unless you publicly announce the contents of this correspondence earlier, we plan no further distribution until 30 days from the date of this report. At that time, we will send copies of this correspondence to the Secretary of HHS. In addition, the correspondence will be available at no charge on GAO's Web site at http://www.gao.gov. If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this correspondence. GAO staff who made major contributions to this correspondence are listed in enclosure III.



Kathleen M. King
Director, Health Care

Enclosures – 3

Enclosure I

Methodology for Determining Use Changes Following Reassignment

This enclosure provides additional details regarding our scope and methodology for reporting changes in drug and pharmacy utilization between 2007 and 2008 for randomly reassigned and other low-income subsidy (LIS) beneficiaries.

To determine whether a study group of randomly reassigned LIS beneficiaries experienced changes in their drug utilization following reassignment between 2007 and 2008, we obtained and analyzed Prescription Drug Event (PDE) claims data[1] to compare beneficiaries' use of selected drugs taken continuously in 2007 before their random reassignment to their use of those same drugs in 2008. To control for expected changes from year to year, we compared experiences among our study group of those randomly reassigned in 2008 to the experiences among two comparison groups: LIS beneficiaries who chose new plans in 2008 and LIS beneficiaries who did not change plans in 2008. We also compared changes in pharmacies used among the three groups between 2007 and 2008.

Step 1: Identify Selected Drugs for Analysis

We compiled a list of the most utilized chronic condition drugs by LIS beneficiaries in 2007 to form the basis of our analysis of drug utilization changes in 2008 among randomly reassigned and other LIS beneficiaries. To develop this list, we analyzed PDE claims data from 2007 to determine the frequency of drugs utilized by LIS beneficiaries in that year. Drugs were identified at their drug name level.[2] We then limited this list of drugs utilized by LIS beneficiaries to the top 100 drugs taken primarily for the long-term treatment of chronic conditions.[3,4] Selecting only drugs used to treat chronic conditions was done to ensure no changes could be attributed to a routine discontinuation of a short-term medication.

Step 2: Creating Study Groups

To determine how utilization changes for selected drugs compared among randomly reassigned and other LIS beneficiaries, we created a study group—beneficiaries who were

[1]CMS's Prescription Drug Event (PDE) claims data contain a record of each claim reimbursed under Part D, including, among other things, the plan in which the beneficiary was enrolled, whether the drug was covered by the plan, the quantity of drug supplied, and LIS status of the beneficiary. PDE claims data for 2008 were the most recent available at the time of our review.

[2]We identified these drugs using their National Drug Code. This code identifies a drug's manufacturer, product name, strength, and dosage form, among other information. We then condensed this information to capture all drugs with the same product name, regardless of strength and dosage form.

[3]We used the maintenance drug code data field from Thomson Reuters' *RED BOOK*™—a database containing drug pricing and other drug-related information—to determine which drugs were used primarily for the long-term treatment of chronic conditions.

[4]We also identified these drugs' therapeutic classes. Drugs that possess a similar chemical structure and similar therapeutic effects are grouped into therapeutic classes. There are five therapeutic class levels, ranging from therapeutic class level 1 (the broadest possible classification) to therapeutic class level 5 (the narrowest possible classification). We used Thomson Reuters' *RED BOOK*™ data on therapeutic class in our analysis, specifically therapeutic class level 2 (TC2). Examples of TC2s include Antidepressant, Antidiabetic, Antiasthma, and Calcium Channel Blocker. Our analysis excluded drugs that were not associated with a TC2 code.

randomly reassigned in 2008, and two comparison groups—beneficiaries who chose new plans in 2008, and beneficiaries who did not change plans in 2008.[5]

To create these groups, we first established our study population. To be included in our analysis, LIS beneficiaries had to meet the following criteria:

- they received the LIS throughout 2007 and 2008;
- they were enrolled continuously in a plan throughout 2007 and 2008;[6] and
- they filled prescriptions for one or more of the 100 most utilized drugs for chronic conditions continuously through 2007.[7]

Step 3: Determining Drug Utilization Changes

To determine if beneficiaries in the three study groups experienced any changes in their drug utilization in 2008 for at least one of the drugs they took continuously in 2007, we identified instances of discontinuations, substitutions, and reduced fills in 2008. We used the following rules to define what constituted a discontinuation, substitution, or reduced fill:

- Discontinuations
  - The beneficiary had zero fills in 2008 for a drug taken continuously in 2007; or
  - The beneficiary had only one fill for a drug taken continuously in 2007 during the first quarter of 2008[8] and zero fills during the rest of 2008; and
  - The beneficiary had zero fills for a therapeutically equivalent (substitute)[9] drug in 2008.
- Substitutions
  - The beneficiary had at least one fill for a therapeutically equivalent drug in 2008; and
  - The beneficiary had fewer than 11 fills of the original drug in 2008.

[5]LIS beneficiaries who were subject to random reassignment but instead decided to either self-select a new plan or stay in their original plan were also included in these two comparison groups.

[6]Beneficiaries did not need to be enrolled in the same plan for both 2007 and 2008; they only needed to be enrolled continuously within a plan during each of these two years.

[7]Each Part D claim for these 100 drugs had to have been for a minimum of a 28-day supply of the drug, which was then adjusted to a 30-day equivalent. For our analysis, we consider each 30-day equivalent to be one "fill." To have taken a drug continuously, the beneficiary must have had between 11 and 13 "fills" for that drug in 2007.

[8]Permitting one fill accounts for likely instances where a randomly reassigned beneficiary uses the one transition fill required under Medicare Part D while pursuing a change to a therapeutically equivalent drug. *See* 42 C.F.R. § 423.120(b)(3) (2010).

[9]In our analysis, we consider a drug to be therapeutically equivalent if it has the same TC2 classification as the original drug.

- Reduced fills[10,11]

  - A beneficiary filled a drug taken continuously in 2007 at least one time in 2008, but had fewer than the 11 fills that constitute continuous coverage; or

  - A beneficiary filled a substituted therapeutically equivalent drug at least one time in 2008, but had fewer than 11 fills; or

  - A beneficiary's combined fills for the original drug and a substituted drug in 2008 are greater than zero but less than 11 fills.

Using these rules, we estimated the percentage of beneficiaries in each study group who experienced a discontinuation, substitution, or reduced fill in 2008 for at least one of the drugs they took continuously in 2007.

Step 4: Determining Changes in Pharmacy Utilization

To determine the extent to which beneficiaries in our study groups used a different pharmacy in 2008 from those used in 2007, we analyzed PDE claims data to identify instances where a beneficiary filled a prescription at a specific pharmacy in 2007 but not at that pharmacy in 2008, or where a beneficiary filled a prescription at a specific pharmacy in 2008, but not at that pharmacy in 2007. We controlled for instances where a beneficiary filled a prescription at different pharmacies within the same chain.

Data Reliability and Limitations

This analysis does not take into account the specific clinical circumstances of each change in utilization, and not all changes can be accurately identified by our measures of discontinuations, reduced fills, or substitutions. For example, a beneficiary may have had one 2007 drug replaced with two substitute drugs in 2008. Our approach would count just one substitution. Our analysis thus provides estimates of discontinuations, substitutions, and reduced fills—not actual counts. However, because the extent of any inaccurately identified utilization changes is not likely to differ systematically among the study groups, we believe our estimates of the rates of differences in utilization changes among the groups are reasonable.

To ensure the claims and enrollment data we used were sufficiently reliable for our purposes, we reviewed related documentation and tested the data to identify outliers, missing data, and other potential sources of errors. We concluded that the data were sufficiently reliable for the purposes of this report.

[10]To adjust for any fills that may span between 2007 and 2008, if a beneficiary's last prescription in 2007 occurred in October, November, or December, and if the days supply was for greater than 45 days, we adjusted the prescription to its 30-day equivalent and added that number to a beneficiary's 2008 fill count.

[11]This measure also captured delays in prescription fills.

Enclosure II

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 10 2011

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

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft correspondence entitled, "Medicare Part D: Changes in Utilization Similar for Randomly Reassigned and Other Low Income Subsidy Beneficiaries" (GAO 11-546R).

The Department appreciates the opportunity to review this draft correspondence prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT CORRESPONDENCE ENTITLED, "MEDICARE PART D: CHANGES IN UTILIZATION SIMILAR FOR RANDOMLY REASSIGNED AND OTHER LOW INCOME SUBSIDY BENEFICIARIES" (GAO-11-546R)

The Department appreciates the opportunity to review and comment on this draft correspondence.

Access to medication for Low Income Subsidy (LIS) beneficiaries, a vulnerable population, is critical for their continuity of care. The findings of this report are positive and do not show any negative effect of the reassignment of LIS beneficiaries to a different plan.

The Centers for Medicare and Medicaid Services (CMS) does note that on Page 6, where GAO writes, "While we did not identify measurable differences in the rates of utilization changes experienced by randomly reassigned beneficiaries compared to other LIS beneficiaries, beneficiary advisors said that the uniquely vulnerable population may nevertheless experience hardships or inconvenience when changing prescription drug plans," that this statement is not supported by data represented in the report.

We concur with GAO's principal conclusion that the extent to which reassigned LIS beneficiaries experienced changes in their drug and pharmacy utilization after reassignment was comparable to the extent of such changes among other LIS beneficiaries.

Enclosure III

GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, Randy DiRosa, Assistant Director; Nick Bartine; George Bogart; Zhi Boon; Shirin Hormozi; Megan M. Moore; Laurie Pachter; and Pauline Seretakis made key contributions to this report.

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