Does Enrollment in Generic-Tier Zero-Copay Plans Improve Generic Use Within the Part D Program?

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Contents

Background

Since the program began in 2006, use of lower cost generic alternatives by Medicare Part D enrollees has been high and steadily increasing as single source drugs lose patent exclusivity. However, low-income subsidy (LIS) enrollees continue to have lower use of generics compared to enrollees without income subsidies. The Medicare Payment Advisory Committee (MedPAC) reported between 2009 and 2011, the generic dispensing rate (GDR) for Part D LIS enrollees increased from 68% to 74%, while the rate for Non-LIS enrollees increased from 72% to 79%[1], a consistent difference of 4 to 5 percentage points. CMS' analysis of prescription drug event (PDE) data from 2006 to 2012, using the commercially available drug information2 databases' generic status methodologies found that the GDR increased from 60.9% to 83.1% for Non-LIS Part D enrollees while the rate was slightly lower for LIS enrollees, increasing from 59.4% to 79.2% (Appendix A. Figures 1 and 2). The difference in the GDR calculated by CMS compared to MedPAC reflects an additional year of utilization data and different generic drug classification methodologies.

Although the GDR is often used to calculate generic dispensing it measures only one aspect of generic use. The GDR measures generic drug fills divided by the sum of brand and generic fills. However, a valid GDR comparison requires that both populations are similar across the number of drugs prescribed per patient, the drugs dispensed, and refill rates for these drugs. If one population receives more drugs or refills (e.g., 30 versus 90 day supply fills), the denominator would be higher and consequently, even if the number of generic prescriptions dispensed were the same, the rate would be lower. The specific drugs dispensed are also important because not all drugs have generic alternatives[3]. The generic substitution rate (GSR) addresses this issue; it calculates the fill rate between generics and their brand equivalents or multisource[4] drugs. When the GSR was calculated using 2012 PDE, we found the rate for LIS enrollees was 83.3% and Non-LIS was 84.4%, a difference of only 1.1 percentage points (Appendix A. Table 1). Although the gap is small, LIS enrollees do use brand name drugs over generic alternatives more often than Non-LIS enrollees, suggesting an opportunity to gain additional savings in Part D.

Part D plans use formulary tiers and cost-sharing differentials to encourage enrollees to use generic or preferred drugs that create strong incentives for Non-LIS enrollees. However, copays for LIS enrollees are set by Congress, while copays for Non-LIS enrollees are set by the individual Part D plan. In 2012, copays for fully-subsidized enrollees were fixed at $2.60 for generic and preferred multisource drugs, and $6.50 for 'other' drugs. This differential may not be large enough to incentivize LIS enrollees to use generic alternatives. In its 2012[5] and 2014[1] report to Congress, the MedPAC recommended that Congress give 'the Secretary broad authority and flexibility to provide stronger financial incentives to use generic drugs when clinically appropriate.' Although the Secretary can't increase the copays for LIS enrollees without Congressional authority, an alternative would be to decrease the generic-tier copay to zero dollars ($0), which does not require a change in legislation. Currently, some Part D plan benefits include a generic-tier $0 copay, therefore creating an opportunity to evaluate generic dispensing rates between generic-tier $0 and non-$0 copay plans.

[1]Report to Congress: Medicare Payment Policy, March 2014, online at the Medpac website. (http://www.medpac.gov/documents/reports/mar14_entirereport.pdf?sfvrsn=0)

[2] Drug Information Databases include Medi-Span® and FDB First Databank.

[3] To be approved by the Food and Drug Administration (FDA), a generic drug must contain the same strength(s) of the same active ingredient(s), be available in the same dosage, have the same route of administration, and have essentially the same labeling as the brand name drug. FDA gives an A rating to a generic drug that it finds to be pharmaceutically and therapeutically equivalent to the drug's brand name counterpart. Only A-rated generic drugs may be substituted by a pharmacist without permission from the prescribing physician.

[4]Multi-Source drug is a drug that is available from a brand name manufacturer and also from several generic manufacturers.

[5]Report to Congress: Medicare Payment Policy, March 2012, online at Medpac website.(http://www.medpac.gov/documents/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0)

Research Questions

The purpose of this analysis was to determine the availability of generic-tier $0 copays among plans, and the effect of generic-tier $0 copays on generic substitution rates within the LIS and Non-LIS populations. The research questions are:

- How many plans offer generic-tier $0 copays in 2012?
- Do LIS and Non-LIS enrollees within plans with and without generic-tier $0 copays have the same GSR rates?

Data Sources

Source	Information Provided
Part D Standard Analytical Files (SAF)	PDE 2012
FDA NDC Structured Product Labeling Data Elements (NSDE)	Brand/generic status (after 2010)
Common Medicare Environment (CME)	LIS status, 2012

Methods

GSR rates were calculated for each Part D plan, and separately for each plan's LIS and Non-LIS populations. GSR is the number of generic fills with brand equivalents divided by the sum of brand and generic equivalent fills. The detailed methodology for calculating GSR is described in Appendix B. A beneficiary's LIS status was determined using the CME, with a beneficiary considered LIS if he or she was ever LIS during the year. Contract type was defined using the contract-plan listed on the PDE claim. A plan's status as Basic or Enhanced was captured from the approved PBP database.

Plans with Generic-Tier $0 Copays

The generic-tier $0 copay plans were identified from the PBP MARx Tier 2012 file if the plan had a $0 one-month supply pre-initial coverage limit (ICL) copay for either Standard or Preferred Network types for tiers that included the word "Generic" in the tier label. CMS tier labels are used in the PBP to represent the overall tier offering as it relates to the drug content and assigned cost-sharing. The "Generic" tier labels included: Generic Drugs; Preferred Generic Drugs; Non-Preferred Generic Drugs; Generic and Brand Drugs; and Supplemental Brand and Generic Drugs. All E contracts and 800-series plans were considered Employer plans. Contracts beginning with S were designated as PDPs, while those beginning with H and R were classified as MA-PDs. All EGWPs, PACE plans, LI NET[6] (X0001) and plans with zero enrollments in the July 2012 enrollment data extract were excluded.

Analysis

Only plans that had at least 30 enrollees in the denominator for each population rate were included in the analyses to remove rates that may be biased due to low enrollment. The number of plans included in each analysis was dependent on if the plan had LIS-only enrollment, Non-LIS-only enrollment, or both LIS and Non-LIS enrollment that met the inclusion criteria. Therefore, the number of plans in each GSR analysis differs. The following analyses were conducted:

[6] The Limited Income Newly Eligible Transition (NET) Program covers all claims during retroactive auto-enrollment periods for full-benefit dual eligible (FBDE) beneficiaries and Supplemental Security Income (SSI)-only beneficiaries plus immediate need claims for all Low- Income Subsidy (LIS)-eligible beneficiaries. Enrollment in the LI NET is temporary and during time of transition. The LI NET plan has an open formulary with no prior authorization requirement, network pharmacy restrictions, or timely filing deadlines.

1. One-way ANOVAs to determine if the populations' (LIS, Non-LIS) GSR means differ between generic-tier $0 and greater than $0 copay plans stratified by plan type (MA-PD, PDP).
2. Two-way ANOVAs with interaction to determine if the populations' (LIS, Non-LIS) GSR means differ between generic-tier $0 and greater than $0 copay plans stratified by plan type (MA-PD, PDP) and benefit type (Basic, Enhanced).

Findings

Plans with Generic-Tier $0 Copays

In 2012, 3,253 plans were identified of which 685 (21.1%) had a generic-tier $0 copay (Table 1). The majority of generic-tier $0 copay plans were categorized as Enhanced[7] plans, n=644 (94.0%). There were almost twice as many Enhanced MA-PD plans than Enhanced PDP plans with a generic-tier $0 copay, 408 and 236 plans, respectively. The opposite was true for Basic plans, where more than twice as many PDP than MA-PD plans had a generic-tier $0 copay, although the numbers were small, 29 and 12 plans, respectively.

Table 1. Number and Percent of all Plans with Generic-Tier $0 Copays

			Basic Plans[1]			Enhanced Plans[2]		
Plans		Total	All	MAPD	PDP	All	MAPD	PDP
All	#	3,253	1,025	471	554	2,228	1,719	509
$0 Copay	#	685	41	12	29	644	408	236
	Row %		6.0%	1.8%	4.2%	94.0%	59.6%	34.5%
	Col %	21.1%	4.0%	2.5%	5.2%	28.9%	23.7%	46.4%

[1]Actuarially equivalent to the defined standard plans, but may have different deductible amounts and cost-sharing structures.

[2]The actuarial value must exceed the value of a defined standard plan.

Part D Enrollment in Plans with Generic-Tier $0 Copays

Overall, a small number of Part D beneficiaries were enrolled in generic-tier $0 copay plans, around 3.2 million beneficiaries or 11.5% of all Part D beneficiaries. About 1.2 million LIS beneficiaries or 10.9% of the LIS Part D population were enrolled in generic-tier $0 copay plans. Although the percent of LIS beneficiaries in generic-tier $0 copay plans was similar to the percent of LIS comprising the total Part D population, 36.4% and 38.7%, the percent and distribution of LIS beneficiaries in each plan type was quite different (Table 2). In general, the majority of LIS enrollees in Part D are enrolled in Basic PDP plans (73.7%). In contrast, the percent of LIS beneficiaries that were enrolled in a generic-tier $0 copay plan were split fairly evenly between Basic PDPs and Enhanced MA-PDs, 48.8% and 42.0%, respectively.

The majority of beneficiaries enrolled in Basic generic-tier $0 copay plans were LIS, 91.7% compared to 56.4% for all Part D Basic plans. Again, this shows LIS enrollees were predominantly enrolled in Basic plans and Non-LIS in Enhanced plans. However, a higher percent of Enhanced generic-tier $0 copay plan enrollment was LIS (22.1%) compared to LIS enrollment in all Part D Enhanced plans (15.6%) with the biggest difference between MA-PD plans, 31.0% within generic-tier $0 copay plans and 17.7% within all of Part D. On the other hand, Enhanced PDP plans were comprised of the smallest percent of LIS beneficiaries, 7.4% of generic-tier $0 copay and 10.2 % for all Part D plans. This difference probably reflects the higher number of available Enhanced MA-PD generic-tier $0 copay plans compared to other benefit types. We, however, did not explore enrollment choices and behaviors.

[7] An enhanced plan must exceed the value of a defined standard plan. Several techniques are used to increase the actuarial value of a plan, such as: reduced cost-sharing for generic and brand drugs; cover additional drugs that are not Part D drugs; increase the initial coverage period by delaying the point at which members enter the coverage gap; or offer gap coverage of an entire tier of covered drugs, a subset of a tier, or through a capped dollar amount of coverage within the gap.

Table 2. Comparison of LIS enrollment between All and Generic-Tier $0 Copay Plans by Plan Types, 2012

	All Plans				Generic-Tier $0 Copay Plans			
	Enrollment	LIS Enrollment			Enrollment	LIS Enrollment		
Types	#	#	Row%	Col%	#	#	Row%	Col%
Basic Plans	15,941,888	8,985,256	56.4%	82.5%	668,831	613,196	91.7%	51.9%
MAPD	1,681,905	956,831	56.9%	8.8%	43,453	36,035	82.9%	3.0%
PDP	14,259,983	8,028,425	56.3%	73.7%	625,378	577,161	92.3%	48.8%
Enhanced Plan	12,211,415	1,905,854	15.6%	17.5%	2,576,776	568,734	22.1%	48.1%
MAPD	8,821,509	1,561,279	17.7%	14.3%	1,602,805	496,842	31.0%	42.0%
PDP	3,389,906	344,575	10.2%	3.2%	973,971	71,892	7.4%	6.1%
Totals	28,153,303	10,891,110	38.7%		3,245,607	1,181,930	36.4%	

Incentivizing Generic Use through Generic-Tier $0 Copays

Table 3 reports the number of plans that met the inclusion criteria (at least 30 enrollees in the denominator) and were included in the analysis for each plan type, population, and rate[8]. For example, an LIS GSR was calculated for 1,055 PDP plans, and 264 (or 25.0%) of these plans had a generic-tier $0 copay. A similar number of plans were identified with a Non-LIS population, 1,062 PDP plans and 265 were generic-tier $0 copay plans. There were more MA-PD zero-copay plans with only a LIS population than a Non-LIS population, 415 and 338, respectively.

Table 3. Number and Percent of Generic-Tier $0 Copay Plans, by Plan Type, LIS Population and GSR meeting the Inclusion Criteria, 2012

			All Plans (#)	Generic-Tier	$0 Copay Plans
Rate	Plan Type	Population	Number	Number	Percent
GSR	PDP	LIS	1,055	264	25.0
		No-LIS	1,062	265	25.0
	MA-PD	LIS	2,074	415	20.0
		No-LIS	1,868	338	18.1

Testing for Equality

Table 4 presents the results of the one-way ANOVA tests to determine if the GSR differed for both the LIS and Non-LIS populations between plans with and without generic-tier $0 copay by plan type. Regardless of plan type, the LIS and Non-LIS GSR means were significantly different; plans with generic-tier $0 copays had higher generic substitution rates compared to plans with non-$0 generic-tier copays.

For the LIS PDP population, the absolute mean difference between generic-tier $0 and non-$0 copay for GSR was 1.8 percentage points compared 1.4 percentage points, respectively, for Non-LIS enrollees. For the LIS enrollees in MA-PD plans, the GSR absolute mean differences between generic-tier $0 and non-$0 copay plans was 1.2 percentage points compared to Non-LIS enrollees where the absolute difference was 0.8 percentage points. Although absolute differences between generic-tier $0 and non-$0 copay plans were higher for PDP compared to MA-PD plans, MA-PD

[8] The "rate" file contained 3,736 unique contract and plan combinations and the 'plan' file contained 3,253 unique contract, plan and segment records. Prior to merging, we summed the total and LIS enrollment counts across segments within the 'plan' file, 110 records were merged into 18 records for a total of 3,161 contract and plan combinations. The 'rate" file contained 575 records that did not match records in the 'plan' file. These records were excluded from the analysis and included 418 employer plans, 154 MAPDs and 3 PDPs. Only plans that had at least 30 beneficiaries in the denominator for each rate and population (LIS and Non-LIS) were included in the analysis.

plans in general had higher GSR means compared to PDP plans. This finding suggests that MA-PD plans do a better job in promoting generic use among it prescribers and beneficiaries

Table 4. Test for the Equality of GSR Means for LIS and Non-LIS Enrollees between Generic-Tier $0 and Non-$0 Copay Plans Stratified by Plan Type, 2012

		GSR					
Generic-Tier Copay		**$0**		**Non-$0**			
Plan Type	**Population**	**N**	**Mean**	**N**	**Mean**	**% Pt. Diff.**	**P Value**
PDP	LIS	264	84.8%	791	83.0%	1.8%	<.0001
	Non-LIS	265	85.0%	797	83.6%	1.4%	<.0001
MA-PD	LIS	415	85.9%	1659	84.7%	1.2%	<.0001
	Non-LIS	338	87.6%	1530	86.8%	0.8%	<.0001

The two-way ANOVA using Tukey-Kramer adjustment for multiple comparison procedures (MCP) tested the effect of plan benefit type (Basic vs. Enhanced) and generic-tier copay ($0 vs non-$0) on LIS and Non-LIS GSR means. The model also included the interaction term plan benefit type and generic-tier copay. The results are provided in Table 5.

Table 5. Test for the Equality of GSR Means for LIS and Non-LIS Enrollees between Generic-Tier $0 and Non-$0 Copay Plans Stratified by Plan Type and Benefit type (Basic, Enhanced), 2012

		Basic Benefit GSR						**Enhanced Benefit GSR**					
Generic-Tier		**$0**		**Non -$0**				**$0**		**Non -$0**			
Plan Type	**Popn.**	**N**	**Mean %**	**N**	**Mean %**	**%Pt Diff.**	**P-Value**	**N**	**Mean%**	**N**	**Mean %**	**%Pt Diff.**	**P-Value**
PDP	LIS	29	85.6	523	83.5	2.2	0.00	235	84.7	268	82.2	2.6	0.00
	Non-LIS	29	86.9	524	83.8	3.0	0.00	236	84.8	273	83.2	1.5	0.00
MA-PD	LIS	12	84.7	405	84.4	0.3	0.98	403	85.9	1,254	84.7	1.2	0.00
	Non-LIS	2	87.5	267	86.5	1.0	0.98	336	87.6	1,263	86.9	0.7	0.00

Overall, within PDP Basic and Enhanced plans, and MA-PD Enhanced plans mean GSRs were statistically different and higher for generic-tier $0 compared to non-$0 copay plans. In the LIS population these differences ranged from a low of 1.2 to a high of 2.6 percentage points. For the Non-LIS populations the difference ranged from 0.7 to 3.0 percentage points. The mean rates were not statistically different for MA-PD Basic plans for either the LIS or Non-LIS populations. However, the number of MA-PD Basic plans with $0 copays was small so detection of any difference was limited. The lack of Basic MA-PD plans may be attributed to policy that does not require MA plans to offer a basic plan if they offer an EA plan without a monthly supplemental Part D premium for drug coverage in the same service area. Overall, MA-PD plan generic rates within Enhanced plans were higher than PDP Enhanced plans regardless of the generic-tier copay or population. This finding suggests that it is the Enhanced MA-PD plans that promote generic use the best.

Discussion

In 2012, Part D plan sponsors could encourage Non-LIS beneficiaries to use lower-cost drugs by creating preferred and non-preferred tiers for both brand-name and generic drugs within their formularies. Lower copayments for drugs in the preferred tiers and higher copayments for drugs in the non-preferred tiers encourage the use of those preferred drugs.

On the other hand, copays for generic and preferred multi-source, and 'other' drugs for fully subsidized beneficiaries are fixed by Congress at $2.60 for generic and preferred multi-source drugs, and $6.50 for 'other' drugs. The low cost differential between generic and brand drug copays for LIS beneficiaries may not be sufficient to incentivize LIS beneficiaries to use generics, resulting in lower generic substitution rates compared to Non-LIS beneficiaries. Changes in copay to increase cost differential between brand and generic drugs for LIS beneficiaries requires Congressional authority, however, lowering the generic copay does not and in 2012, 685 or 21.1% of plans offered generic-tier $0-copay plans.

Our analysis found that GSR rates for generic-tier $0 copay plans were higher than in non-$0 copay plans. This finding held true for both Enhanced PDP and MA-PD plans, and PDP Basic plans for both LIS and Non-LIS populations in Part D. The GSR within MA-PD Basic plans was not statistically different for LIS or Non-LIS populations, but there were very few MA-PD Basic generic-tier $0 copay plans. Overall, MA-PD Enhanced plans had higher generic utilization suggesting that these plans do a better job in encouraging generic use compared to PDPs regardless of whether the copay is $0 or not. This is probably due to the plans' oversight responsibilities for providers that do not exist within PDPs. However, the greatest impact of generic-tier $0 copay plans on GSR was observed within PDP plans' Non-LIS populations where there is no plan direct oversight and therefore fewer mechanisms (e.g., financial incentives) for plans to encourage generic prescribing by providers. This suggests that incentives directed at the beneficiary like a generic-tier $0 copay may be more effective in increasing generic use within PDPs.

In 2012, generic-tier $0 copays appear to be an important tool to incentivize generic use for Medicare Part D beneficiaries for both LIS and Non-LIS enrollees. Hoadley et al.[9] reported the same conclusion when his team compared generic and brand-name anti-cholesterol drug use in Medicare. The authors examined the impact of several health benefit tools on generic use and found that having a generic zero-copay had the strongest effect on generic use. Overall, we found that implementing a generic-tier $0 copay could potentially increase generic substitution rates by 0.7 to 3.0 percentage points. Currently, only 11.5% of Part D beneficiaries are enrolled in generic-tier $0 copay plans and even fewer LIS enrollees (10.9%). If Part D enrollment was shifted from generic-tier non-$0 into $0 copay plans, overall generic use could potentially increase. Even small increases in generic use could mean significant savings to beneficiaries and to the Medicare Part D program.

Although our findings suggest that generic-tier $0 copay plans demonstrate higher GSRs compared to non-$0 copay plans, some limitations exist. We did not include other plan characteristics in our analysis that may affect generic use, such as, the number and actual generic entities included in the $0 copay tier. The analysis examined generic use at the plan level so plans with smaller populations may be more sensitive to the population characteristics and selection bias. We attempted to minimize this effect by limiting the analysis to plans with 30 or more beneficiaries when calculating each rate's denominator.

This quasi-experiment suggests an opportunity to use an existing policy option to improve generic utilization, especially within Basic plans where the majority of LIS beneficiaries are enrolled, which would not require Congressional authority. However, Medicare is cognizant that adding a zero-copay generic-tier may jeopardize a plan's actuarial equivalence, and therefore necessitate an increase in beneficiary cost-sharing for other tiers potentially causing Basic plans to lose LIS auto-enrollment qualification if the plan's premium rises more than the de minimus amount above the regional benchmark. Another concern is the potential waste of medications from unnecessary prescriptions and the associated costs to the Part D program due to increases in overall drug use by the removal of even minimum copays. At this time, CMS is providing these results as informational only and as an opportunity for further discussion on ways to increase generic use in Part D and in particular, the LIS population.

[9] Hoadley JH, Merrell K, Hargrave E, Summer L. In Medicare Part D Plans, Low Or Zero Copays And Other Features To Encourage The Use Of Generic Statins Work, Could Save Billions. Health Affairs, 31, no.10 (2012):2266-2275

Appendix A. Generic Dispensing Rate (GDR) Trends, Medicare Part D, 2006-2012.

Figure 1: GDR Trends, Non -LIS Medicare Part D Enrollees, 2006-2012

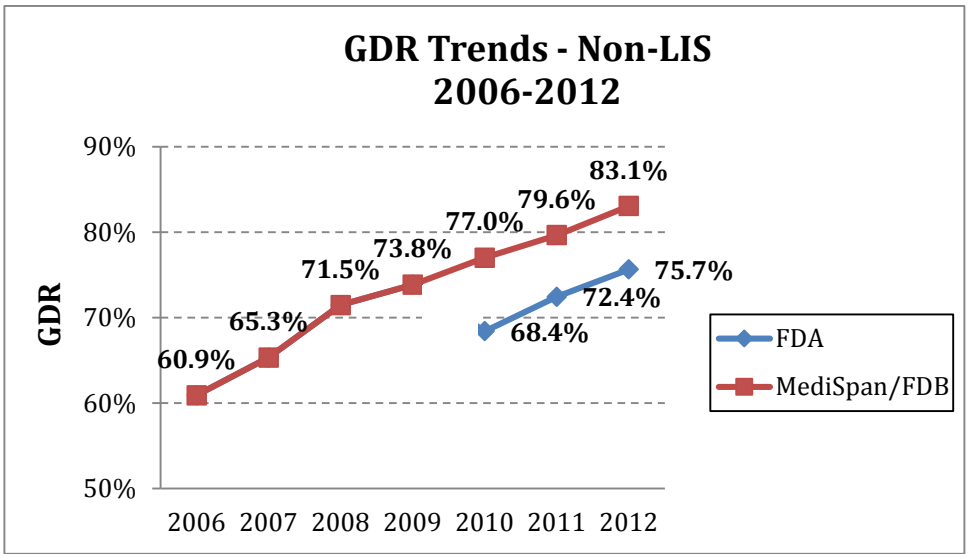
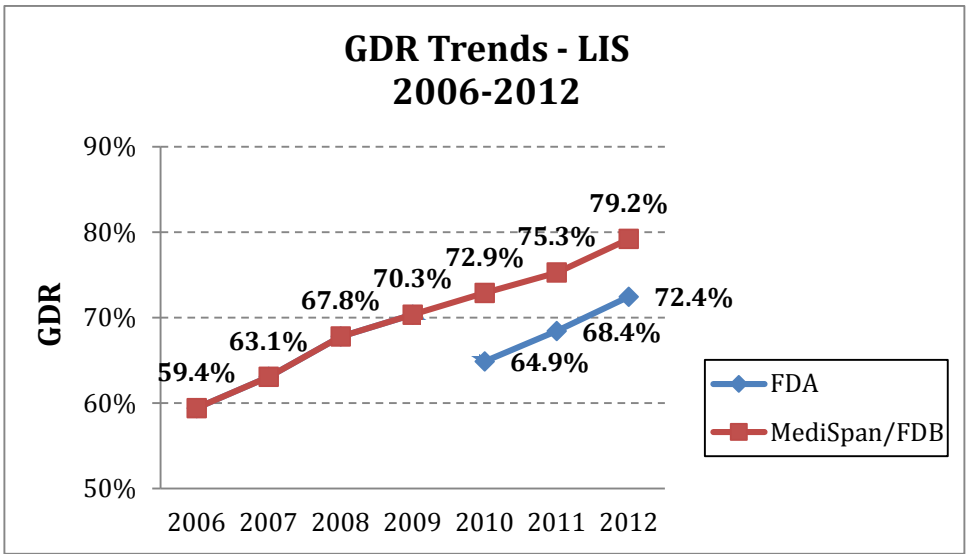


Figure 2: GDR Trends, LIS Medicare Part D Enrollees, 2006-2012



Generic Substitution Rates, Medicare Part D, by Plan Type and LIS Status, 2012

Table 1: Generic Substitution Rates (GSR), 2012

Characteristic	Total Generic Fills	Total Drug Fills	Generic (GSR)
ALL[1]	**786,344,251**	**937,024,413**	**83.9%**
MA-PD	239,569,301	279,851,181	85.6%
PDP	476,624,466	571,152,832	83.4%
LIS	372,183,982	446,542,930	83.3%
Non-LIS	414,098,657	490,408,011	84.4%

[1] The **ALL** row includes Employer PDE claims that are no included in other breakouts and LIS status not available on every PDE claim.

Appendix B. Methodology for Identification of Brand/Generic Drugs and Alternatives

Identification of Brand Drugs with Generic Alternatives

To identify generic substitutability for the calculation of the GSR, we relied on the Generic Sequence Number (GSN) concept from First DataBank (FDB) to group together NDCs for equivalent drugs (i.e., the same drug, strength and dosage form). For each combination of GSN and month in 2012, we considered the GSN to have generic alternatives if we observed at least one brand NDC and one generic NDC (using the same FDA marketing category mapping shown in Table 1) within the GSN for that month, according to FDB. The presence of a brand or generic NDC in the month was only based on its presence in FDB and irrespective of whether the NDC was actually utilized in Part D in 2012.

Then, each PDE claim was assigned a GSN according to the month of service reported on the claim. If the GSN and month combination had been determined to be one with generic alternatives, the claim was used in the calculation of the GSR, with the brand/generic status of the NDC on the claim determined, as before, according to the FDA directory.

Finally, among claims whose GSN and month of service combination was determined to have alternatives, the GSR was calculated as (total generic claims) / (total generic claims + total brand claims).

Table 1: FDA Marketing Category to Brand/Generic Mapping

FDA Marketing Category	Designation
New Drug Application (NDA)	Brand
Biologic License Application (BLA)	Brand
NDA Authorized Generic	Brand
Abbreviated New Drug Application (ANDA)	Generic