6 Part D prescription drug coverage in patients with end-stage renal disease

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The Medicare Part D prescription drug benefit went into effect in January, 2006. In December 2011, over 29 million Medicare enrollees (including elderly and disabled people, as well as individuals with end-stage renal disease) were enrolled in a Medicare Part D prescription drug plan and eligible to receive a prescription drug benefit. Prior to January 1, 2006, these patients obtained drug coverage through various insurance plans, state Medicaid programs, or pharmaceutical-assistance programs, received samples from physicians, or paid out-of-pocket. Since 2006, however, many Medicare-enrolled patients have obtained prescription drug coverage through Part D. Sixty-two percent of general Medicare patients, and 70 percent of Medicare-covered ESRD patients, were enrolled in Part D in 2011. In the ESRD population, Part D enrollment reached 75, 65 and 58 percent among Medicare-enrolled hemodialysis, peritoneal dialysis and kidney transplant patients.

Beneficiaries can obtain Part D benefits through a stand-alone prescription drug plan (PDP) or through a Medicare Advantage (MA) plan, which provides medical as well as prescription benefits. ESRD patients are precluded from entering an MA plan if they are not already enrolled in one when they reach ESRD. Most data presented in this chapter encompass both types of plans. Medicare-enrolled ESRD patients obtain outpatient medication benefits through Part B, Part D, retiree drug subsidy plans, or other creditable coverage, including employer group health plans, Veterans Administration benefits, Medicaid wrap-around programs, and state kidney programs. Some also pay out-of-pocket for plan expenses and copayments, over-the-counter medications, and low-cost generic agents at retailers. The proportion of Medicare-covered ESRD patients with no known source of drug coverage is highest in the peritoneal dialysis and transplant populations. Given that many of these patients are employed, it is likely that some have sources of prescription drug coverage not tracked by Medicare.

Prior to the start of the Medicare Part D program in 2006, patients dually-enrolled in Medicare and Medicaid received prescription benefits under state Medicaid programs. The Part D program, however, offers a substantial low-income subsidy (LIS) benefit to enrollees with limited assets and income, including those who are dually-enrolled. The LIS provides full or partial waivers for many out-of-pocket cost-sharing requirements, including premiums, deductibles, and copayments, and provides full or partial coverage during the coverage gap ("donut hole"). In 2011, 37 percent of general Medicare patients enrolled in Part D received the LIS benefit, compared to 75, 62, and 60 percent of enrolled hemodialysis, peritoneal dialysis, and transplant patients. Out-of-pocket costs are thus proportionally lower for Part D enrollees in the ESRD population than for their general Medicare counterparts. By race, white dialysis patients are the least likely and African American, Hispanics, and patients of other races are most likely to have LIS benefits.

Not surprisingly, phosphate binding agents comprise the top Part D medication class in dialysis patients (by percentage of patients with at

How then am I so different from the first men through this way?
Like them, I lived a settled life, I threw it all away.
To seek a Northwest Passage at the call of many men
To find there but the road back home again.

Stan Rogers
"Northwest Passage"

least one prescription filled), while cardiovascular agents account for three of the top five. The list of medications by cost is topped by phosphate binding agents and calcimimetics agents, as sevelamer carbonate and hydrochloride and cinacalcet are not available in generic form.

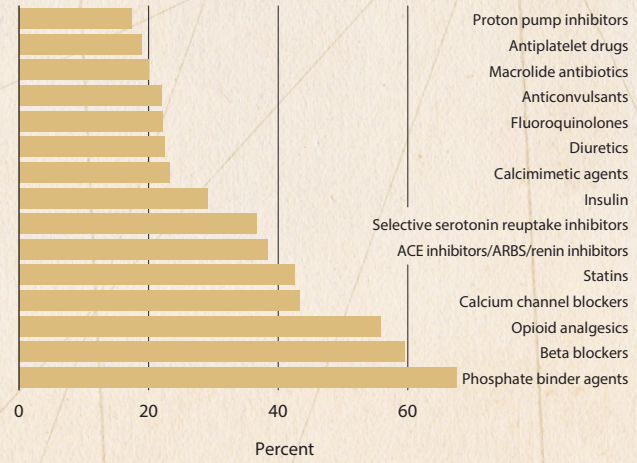
In 2011, total estimated net Medicare Part D costs for ESRD and general Medicare Part D enrollees were $2.1 billion and $63.2 billion, respectively. Between 2007 and 2011, total net costs increased by 60 and 43 percent for hemodialysis and peritoneal dialysis patients, compared to 37 percent for general Medicare patients; for transplant patients, costs rose just 20 percent. Although the percentage increase in Part D enrollment from 2007 to 2011 was similar between the general Medicare and dialysis populations, more dialysis patients receive the LIS, making each dialysis patient, on average, more expensive to Medicare. In 2011, Medicare Part D costs for hemodialysis and peritoneal dialysis patients with the LIS were $8,003 and $8,073 per person per year (PPPY), respectively, compared to $4,194 for general Medicare patients with the LIS.

Out-of-pocket Part D costs for ESRD patients are slightly higher than for general Medicare patients, at $422 versus $417 PPPY. This is not surprising, as a higher percentage of non-LIS ESRD patients reach the coverage gap (41 versus 19 percent), and the catastrophic coverage phase (11 versus 3 percent). Between 2010 and 2011, out-of-pocket Part D costs decreased in general Medicare, dialysis, and transplant patients, largely because pharmaceutical manufacturers began giving a 50 percent discount on the price of brand-name drugs, and because Part D plans now cover some of the cost sharing for generic drugs when non-LIS patients reached the coverage gap. Generic versions of several expensive brand-name drugs (including atorvastatin and olanzapine) also became available in 2011.

The Medicare Part D program works in concert with Medicare Part B, which covers medications administered in physician offices, some administered during hemodialysis (e.g. intravenous antibiotics that are not associated with dialysis-related infections), and most immunosuppressant medications required in the three-year period following a Medicare-covered kidney transplant. Medicare-covered transplant patients lose eligibility for Part B benefits after three years, but, if they become Medicare-eligible due to age or disability, they again become eligible for Part B for immunosuppressant coverage. Patients whose kidney transplant is not covered by Medicare, but who become Medicare-eligible due to age or disability, can enroll in and receive their immunosuppressant medications through Part D. Prescription drugs not covered for beneficiaries under Part B may be covered by Part D, but coverage depends on whether the drug is included on the plan formulary. Until January 2011, costs of ESAs, IV vitamin D, iron, and antibiotic agents administered during dialysis were separately reimbursable under Medicare Part B. In 2011, these products were included in the monthly bundled payment to dialysis providers. Part B costs are thus not displayed in chapter figures as they have been in previous ADRs.

In 2011, Part D costs for enrollees with LIS benefits were $8,026, $8,161 and $5,810 for a hemodialysis, peritoneal dialysis and transplant patient, respectively, and $2,299, $2,411 and $1,983 for their non-LIS counterparts. Between 2010 and 2011, and regardless of LIS status, Part D costs (PPPY) continued to increase in hemodialysis patients with and without the LIS, but declined in peritoneal dialysis and transplant patients. ⬩ **Figure p.1;** see page 440 for analytical methods. *Includes Part D claims for all adult dialysis patients. Therapeutic classification based on the Medi-Span's generic product identifier (GPI) therapeutic classification system.*

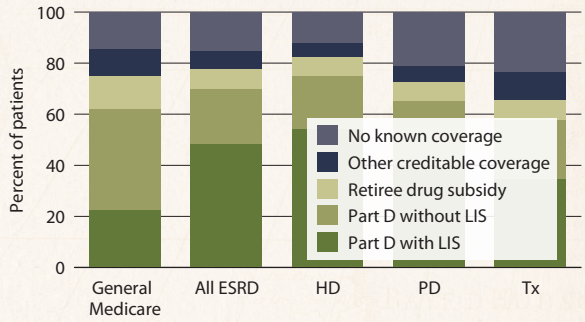
vol 2
6.1 **Top 15 drug classes used by Part D-enrolled dialysis patients, by percent of patients & drug class, 2011**



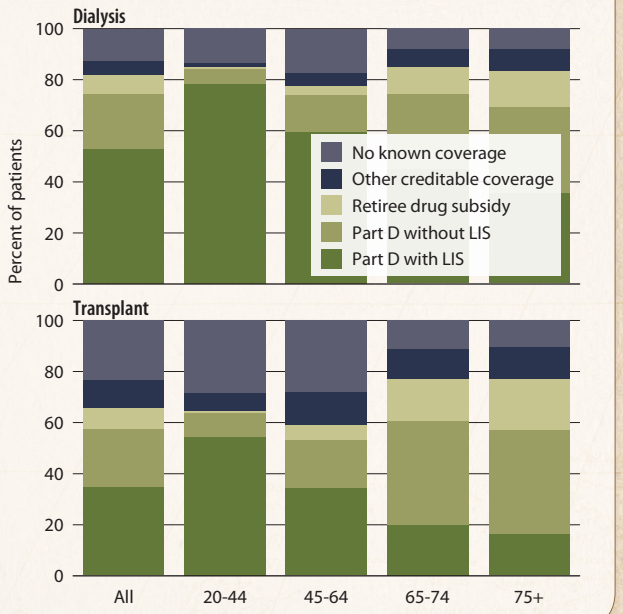
Patients with Medicare coverage can enroll in Medicare Part D for prescription drug coverage. Seventy–five and 65 percent of hemodialysis and peritoneal dialysis patients were enrolled in Part D in 2011, compared to 62 percent of general Medicare patients and 58 percent of patients with a kidney transplant.

Compared to general Medicare Part D enrollees, hemodialysis, peritoneal dialysis, and transplant patients with Part D receive the low-income subsidy (LIS) at a higher proportion (72, 62 and 60 percent, compared to 37 percent). More than 20 percent of patients on peritoneal dialysis or with a kidney transplant have no known prescription drug coverage, but many are employed and may have coverage that is not tracked by Medicare. ✦ **Figure 6.2;** see page 440 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2011.*

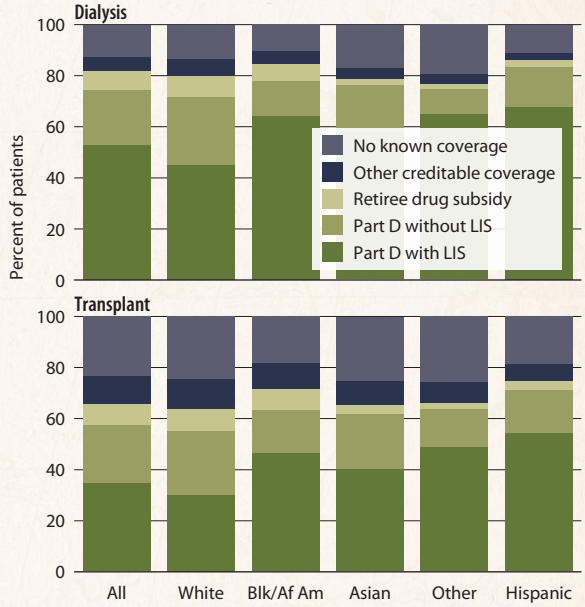
vol 2 **6.2** **Sources of prescription drug coverage in Medicare ESRD enrollees, by population, 2011**



vol 2 **6.3** **Sources of prescription drug coverage in Medicare ESRD enrollees, by age & modality, 2011**



vol 2 **6.4** **Sources of prescription drug coverage in Medicare ESRD enrollees, by race/ethnicity & modality, 2011**

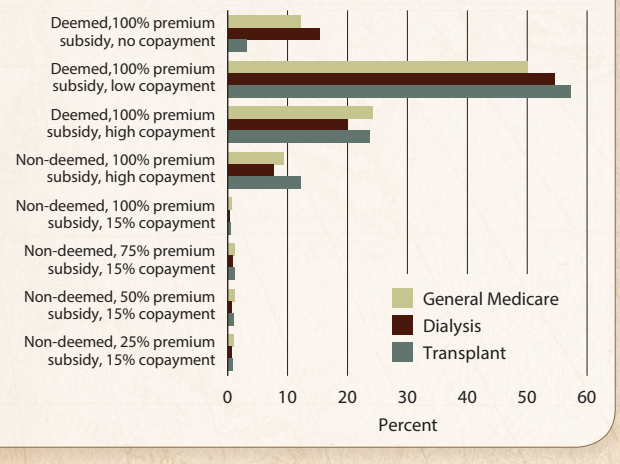


Sources of prescription drug coverage among ESRD patients vary widely by age and race. For both dialysis and transplant modalities, patients age 20–44 had the highest Part D enrollment in 2011. In addition, receipt of the low income subsidy (LIS) decrease substantially with age — from 78 and 54 percent among dialysis and transplant patients age 20–44 to just 36 and 16 percent among those age 75 and older. In each age category, transplant patients are markedly less likely than those on dialysis to have the LIS.

In the dialysis population, the percentage of dialysis patients enrolled in Part D varies by race from 72 among whites to 78 and 84 among blacks/African Americans and Hispanics, respectively. Eighty-two and 81 percent of blacks/African Americans and Hispanics with Part D coverage have the LIS, compared to 63 percent of whites. Blacks/African Americans are the least likely to have no known prescription drug coverage.

Overall and by race, Part D enrollment among transplant patients is lower than that of dialysis patients, with 56 percent of whites, and 63 and 71 percent of black/African American and Hispanic transplant patients being enrolled. Seventy-four and 77 percent of blacks/African Americans and Hispanics with Part D coverage have the LIS, compared to 54 percent of whites and 66 percent of Asians. ✦ **Figures 6.3–4;** see page 440 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2011.*

vol 2
6.5 **Distribution of low income subsidy (LIS) categories in Part D general Medicare & ESRD patients, 2011**



vol 2
6.a **Medicare Part D enrollees (%) with or without the low income subsidy (LIS), by age & race, 2011**

	General Medicare		All ESRD		Hemodialysis		Peritoneal dial.		Transplant	
	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS	Part D w/LIS	Part D w/o LIS
White										
All ages	29.9	70.1	60.7	39.3	63.5	36.5	54.5	45.5	54.3	45.7
20-44	90.3	9.7	88.6	11.4	91.8	8.2	88.4	11.6	84.4	15.6
45-64	65.2	34.8	71.8	28.2	77.3	22.7	65.2	34.8	60.2	39.8
65-74	18.2	81.8	45.9	54.1	54.5	45.5	28.4	71.6	25.7	74.3
75+	24.3	75.7	39.4	60.6	42.0	58.0	20.4	79.6	21.4	78.6
Black/Af Am										
All ages	66.2	33.8	81.0	19.0	82.4	17.6	77.4	22.6	73.7	26.3
20-44	94.5	5.5	92.8	7.2	94.4	5.6	91.8	8.2	87.3	12.7
45-64	82.1	17.9	83.6	16.4	85.6	14.4	76.4	23.6	74.6	25.4
65-74	51.2	48.8	69.7	30.3	72.7	27.3	48.9	51.1	52.1	47.9
75+	60.0	40.0	71.1	28.9	72.1	27.9	46.9	53.1	55.3	44.7
Asian										
All ages	69.8	30.2	73.9	26.1	77.4	22.6	63.5	36.5	65.5	34.5
20-44	91.3	8.7	86.0	14.0	89.5	10.5	80.3	19.7	81.3	18.7
45-64	75.1	24.9	75.6	24.4	79.1	20.9	66.0	34.0	69.6	30.4
65-74	63.6	36.4	65.9	34.1	72.0	28.0	46.6	53.4	51.9	48.1
75+	73.7	26.3	73.4	26.6	75.8	24.2	57.2	42.8	51.3	48.7
Other race										
All ages	62.4	37.6	80.6	19.4	81.8	18.2	78.8	21.2	76.5	23.5
20-44	88.1	11.9	90.6	9.4	92.9	7.1	89.4	10.6	86.3	13.7
45-64	72.5	27.5	83.9	16.1	85.8	14.2	79.7	20.3	77.9	22.1
65-74	54.0	46.0	73.3	26.7	75.7	24.3	63.4	36.6	63.8	36.2
75+	60.9	39.1	71.1	28.9	72.4	27.6	56.7	43.3	57.2	42.8

The low income subsidy (LIS) provides beneficiaries assistance with premiums, deductibles and co-payments of the Medicare Part D program. Some Medicare beneficiaries are automatically deemed eligible for LIS and do not need to file an application (deemed LIS beneficiaries). Such patients include persons eligible for both Medicaid and Medicare (dual eligible), those receiving supplemental security income and those participating in Medicare savings programs (e.g . Qualified Medicare Beneficiaries (QMB) and Qualified Individuals (QI)). Dual-eligible ESRD patients who do not choose a plan are automatically enrolled in a stand-alone Medicare Part D plan by CMS. Other Medicare beneficiaries with limited incomes and resources who do not automatically qualify for LIS (non-deemed beneficiaries) can apply for the LIS and have their eligibility determined by their state Medicaid agency or the Social Security Administration.

In 2011, 90 percent of dialysis patients with Part D LIS coverage were deemed LIS beneficiaries (with 10 percent being non-deemed), compared to 87 and 84 percent of general Medicare and transplant patients, respectively. A smaller proportion of LIS patients (10–16 percent; non-deemed) received the LIS after an application documenting low income and resources.

Within each race group, receipt of the LIS generally decreases with age. For those age 75 and older, however, an uptick is seen for general Medicare patients across all races, Asian hemodialysis and peritoneal dialysis patients, and black/African American patients with a transplant.

• **Figure 6.5 & Table 6.a;** see page 441 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2011.*

CMS provides prescription drug plans (PDPs) with guidance on structuring a "standard" Part D PDP. The upper portion of Table 6.b shows the standard benefit design for PDPs in 2007 and 2011. In 2011, for example, beneficiaries shared costs with the PDP (as co-insurance or copayments) until the combined total reached $2,840 during the initial coverage period. After reaching this level, beneficiaries went into the coverage gap, or "donut hole," where they were expected to pay 100 percent of costs.

Since 2010, the government has been providing those reaching the coverage gap with more assistance each year. In 2011, patients received a 50 percent brand discount from manufacturers, and plans paid 7 percent of generic drug costs in the gap.* Beneficiaries who paid a yearly out-of pocket drug cost of $4,550 reached the catastrophic coverage phase, in which they paid only a small copayment for their drugs until the end of the year.

PDPs have the latitude to structure their plans differently from what is presented here; companies offering non-standard plans must show that their coverage is at least actuarially equivalent to the standard plan. Many have developed plans with no deductibles or with drug copayments instead of the 25 percent co-insurance, and some plans provide generic and/or brand name drug coverage during the coverage gap. ✦ **Table 6.b.** *http://www.q1medicare.com/PartD-The-2011-Medicare-Part-D-Outlook.php. *http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8237.pdf.*

vol 2 **6.b** **Medicare Part D benefit parameters for defined standard benefit**

	2007	2011
Deductible After the deductible is met, beneficiary pays 25% of covered costs up to total prescription costs meeting the initial coverage limit.	$265	$310
Initial coverage limit Coverage gap (donut hole) begins at this point. (The beneficiary pays 100% of prescription costs up to the out-of-pocket threshold.)	$2,400	$2,840
Total covered Part D drug out-of-pocket spending including the coverage gap	$5,451.25	$6,447.50
Catastrophic coverage starts after this point.		plus a 50% brand discount
Out-of-pocket threshold This is the total out-of-pocket costs including the donut hole.	$3,850	$4,550
2011 example		
$310 (deductible)	$265	$310
+ (($2,840 – $310) * 25%) (initial coverage)	$533.75	$632.50
+ (($6,447.50 – $2,840) * 100%) (coverage gap)	$3,051.25	$3,607.50
= $4,550 (maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)	$3,850.00	$4,550.00
Catastrophic coverage benefit		
Generic/preferred multi-source drug	$2.15	*$2.50
Other drugs	$5.35	*$6.30

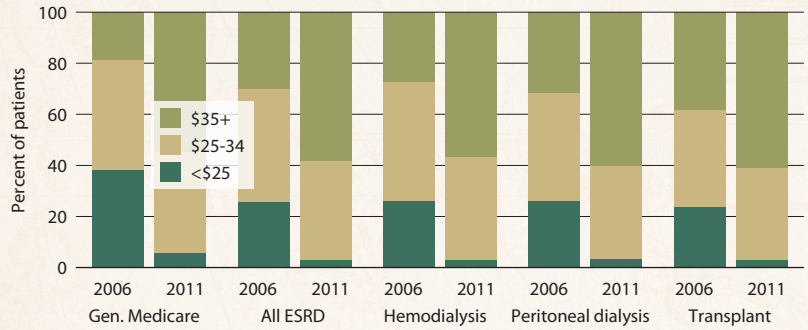
*The Catastrophic Coverage is the greater of 5% or the values shown in the chart above. In 2010, beneficiaries would be charged $2.50 for those generic or preferred multisource drugs with a retail price under $50 and 5% for those with a retail price greater than $50. As to Brand drugs, beneficiaries would pay $6.30 for those drugs with a retail price under $130 and 5% for those with a retail price over $130.

Part D enrollment increased between 2006 and 2011 in the general Medicare population and among Medicare-covered patients with ESRD. Growth was greatest in the peritoneal dialysis and transplant populations, at 9 and 10 percentage points; hemodialysis patients saw an increase of 7 percentage points. ✦ **Table 6.c.;** see page 441 for analytical methods. *Point prevalent Medicare enrollees alive on January 1 of each year.*

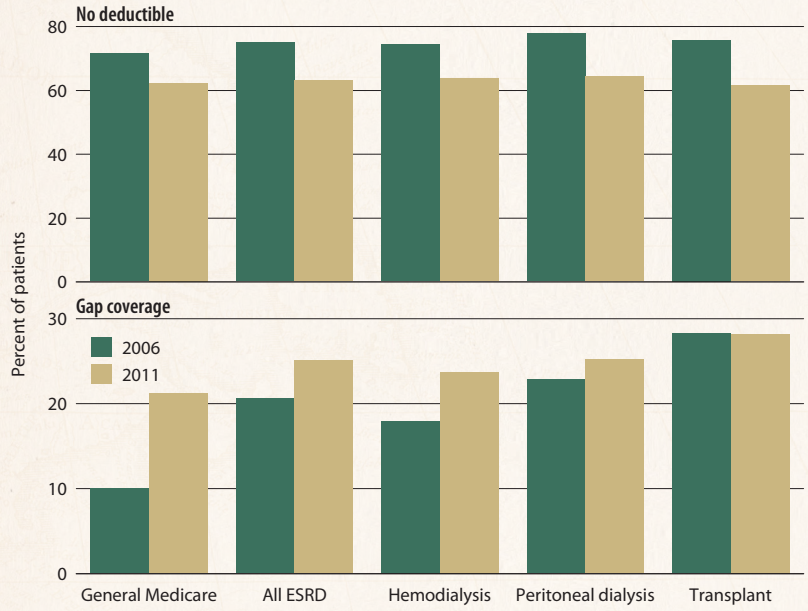
vol 2 **6.c** **General Medicare & ESRD patients enrolled in Part D (percent)**

	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
2006	54.6	62.6	68.3	56.3	48.1
2007	57.0	65.5	71.2	59.6	51.2
2008	58.6	67.0	72.4	61.3	53.3
2009	59.8	67.8	73.0	62.2	54.8
2010	60.4	68.7	73.7	63.7	55.8
2011	62.1	70.1	75.1	65.2	57.7

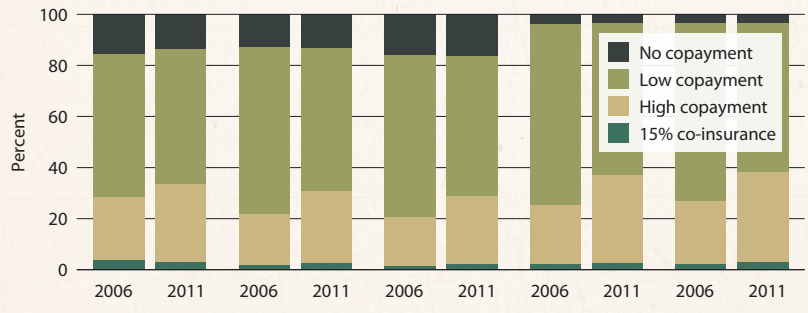
vol 2
6.6 **Part D non-LIS enrollees with specified monthly premium, 2006 & 2011**



vol 2
6.7 **Part D non-LIS enrollees with no deductible & with gap coverage, 2006 & 2011**



vol 2
6.8 **Part D LIS enrollees with specified co-insurance/copayment, 2006 & 2011**



Copayments, per generic & branded medication, respectively
High: 2006: up to $2.00 & $5.00
2011: up to $2.50 & $6.30
Low: 2006: up to $1.00 & $3.10
2011: up to $1.10 & $3.30

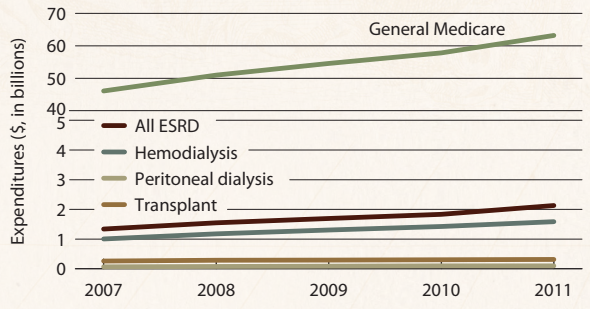
Patients without the low income subsidy (LIS) pay monthly premiums; the weighted average premium for Medicare Part D stand-alone PDPs increased from $25.93 in 2006 to $38.29 in 2011 (http://facts.kff.org/). In 2006, 38, 26, and 24 percent of general Medicare, dialysis, and transplant patients, respectively, had a monthly premium below $25. In 2011, in contrast, only 6, 3, and 3 percent had a monthly premium below $25, while 55–61 percent had a premium over $35.

The percentage of patients with no deductible declined between 2006 and 2011, and varied little by modality in 2011. Gap ("donut hole") coverage, in contrast, rose during this time frame, and is more common in the ESRD population, at 25 percent compared to 21 percent for general Medicare patients.

Most Part D enrollees with the LIS (full-benefit dual-eligible patients) do not pay monthly premiums, but non-institutionalized patients with the LIS do pay drug copayments or co-insurance based on income and assets. In 2011, 66 and 71 percent, respectively, of general Medicare and hemodialysis patients with the LIS had low or no copayments for their Part D medications, compared to 62 percent in both the peritoneal dialysis and transplant populations. The percentage of Part D LIS enrollees with low or no copayments fell between 2006 and 2011, and just 2–3 percent of LIS patients paid a 15 percent co-insurance in 2011. While 27–35 percent of patients had high copayments in 2011, these patients paid a maximum of just $2.50 per generic and $6.30 for branded medications. ✦ **Figures 6.6–8;** see page 441 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans.*

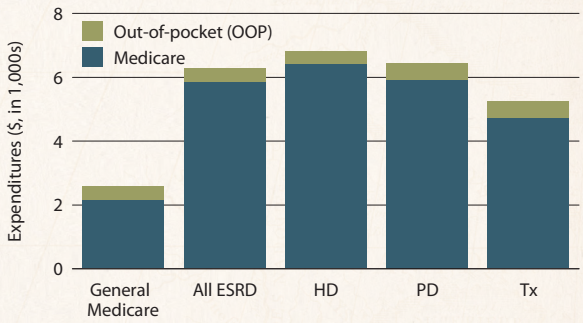
Total net Part D costs for ESRD patients increased from $1.8 billion in 2010 to $2.1 billion in 2011, accounting for about 3 percent of total Part D prescription drug costs. These costs do not include costs of drugs contained under the ESRD prospective payment system in 2011 (e.g. ESAs, IV vitamin D, iron) or billed to Medicare Part B (e.g. immunosuppressants). Between 2007 and 2011, total estimated Part D costs increased 37, 58, 43, and 20 percent for general Medicare, hemodialysis, peritoneal dialysis, and kidney transplant patients, respectively. ✦ **Figure 6.9;** see page 441 for analytical methods. *All patients enrolled in Part D.*

vol 2 **6.9** **Total estimated net Medicare Part D costs for enrollees**

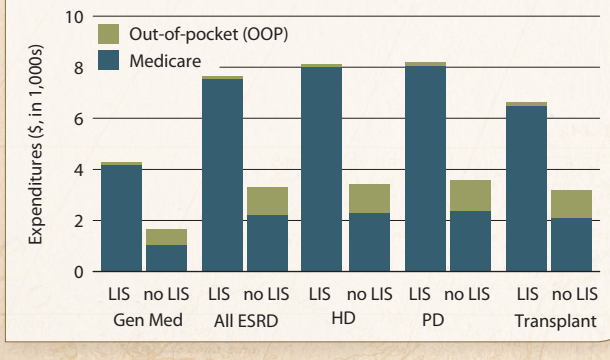


By ESRD modality, hemodialysis patients had the highest per person per year (PPPY) Medicare costs in 2011, at $6,427, compared to $5,914 and $4,730 for peritoneal dialysis and transplant patients. PPPY net Part D costs in the overall ESRD population were 2.7 times greater than those for general Medicare patients, at $5,851 compared to $2,167. As a proportion of total Part D costs, however, out-of-pocket costs were lower in ESRD patients, representing 6, 8, and 10 percent of PPPY costs for hemodialysis, peritoneal dialysis, and transplant patients, compared to 16 percent in the general Medicare population. ✦ **Figure 6.10;** see page 441 for analytical methods. *All patients enrolled in Part D.*

vol 2 **6.10** **Per person per year Medicare & out-of-pocket Part D costs for enrollees, 2011**



vol 2 **6.11** **Per person per year Medicare & out-of-pocket Part D costs for enrollees, by low income subsidy (LIS) status, 2011**



vol 2 **6.d** **Total per person per year Part D costs ($) for enrollees, by low income subsidy (LIS) status, 2011**

	Gen Medicare		Hemodialysis		Perit. Dialysis		Transplant	
	LIS	No LIS	LIS	No LIS	LIS	No LIS	LIS	No LIS
All	4,194	1,043	8,003	2,295	8,073	2,385	6,451	2,109
20-44	4,513	1,633	8,329	1,960	7,835	1,478	5,684	1,319
45-64	5,488	1,434	8,627	2,362	8,620	2,504	6,940	2,055
65-74	3,474	952	7,480	2,489	7,538	2,585	6,745	2,385
75+	3,451	1,055	6,458	2,095	6,259	2,149	5,699	1,872
Male	4,187	1,050	8,045	2,380	7,889	2,471	6,483	2,082
Female	4,199	1,038	7,961	2,238	8,287	2,324	6,427	2,127
White	4,449	1,058	8,028	2,382	8,267	2,498	6,326	2,173
Black/Af Am	3,855	938	8,034	2,064	7,643	1,947	6,660	1,891
Other race	3,567	894	7,652	2,250	8,514	2,103	6,603	1,849

Across general Medicare and ESRD populations, total Part D PPPY medication costs are 2.1–2.6 times greater in patients with LIS benefits than in those without. In the LIS population, however, out-of-pocket costs represent only 2 percent of these total expenditures, compared to 33–36 percent in each of the non-LIS populations. Regardless of LIS status, total PPPY Part D costs are 85 percent greater for patients with ESRD than for those in the general Medicare population. ✦ **Figure 6.11;** see page 441 for analytical methods. *All patients enrolled in Part D.*

Total per person per year (PPPY) Medicare Part D costs vary by age, gender, and race. By race and regardless of LIS status, PPPY costs for general Medicare and peritoneal dialysis patients are higher for whites than for blacks/African Americans. For transplant patients, however, PPPY costs for LIS patients are higher among blacks/African Americans than among whites. For ESRD patients with the LIS, younger patients have higher Part D costs than do their older counterparts. ✦ **Table 6.d;** see page 441 for analytical methods. *All patients enrolled in Part D.*

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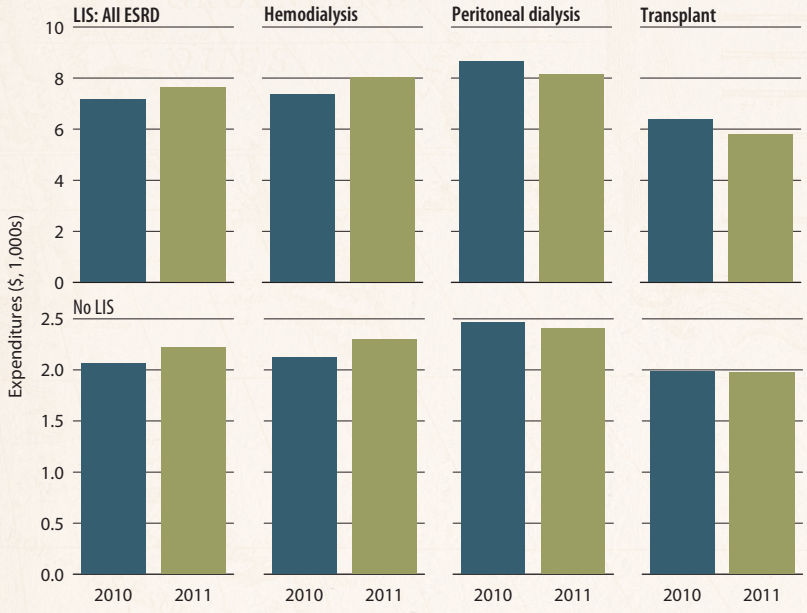
6.12 **Total per person per year Medicare costs for Part D-covered medications, by low income subsidy (LIS) status, modality, & year**



Total per person per year (PPPY) net Part D costs were slightly higher in 2011 than in 2010 among hemodialysis patients, at $8,026 and $7,366, respectively, among LIS patients; and $2,299 and $2,131 among those without the LIS. There was, however, a decrease in costs among peritoneal dialysis and transplant patients with and without the LIS during the same period. Regardless of LIS status, PPPY net Part D costs were greatest among peritoneal dialysis patients in both 2010 and 2011. ✦ **Figure 6.12;** see page 441 for analytical methods. *Period prevalent ESRD patients.*

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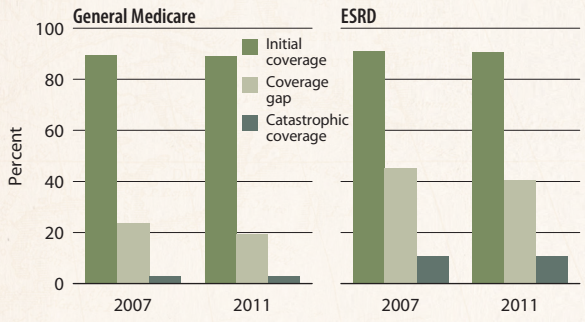
6.13 **Part D enrollees without low income subsidy (LIS) status who reach each coverage phase**



Part D enrollees who do not have the low income subsidy (LIS) may encounter three coverage phases, depending on total and out-of-pocket (OOP) costs per year. In 2011, patients with total Part D drug costs up to $2,840 were in the initial coverage phase, while those with costs over that amount entered the coverage gap ("donut hole"), in which they were responsible for 100 percent of drug costs minus the 50 percent discount on branded drugs and 7 percent discount on generics. Patients whose total OOP costs reached $4,550 then entered the catastrophic coverage phase, in which they paid only a fraction of overall drug costs. In 2011, 41 and 11 percent of ESRD patients reached the coverage gap and catastrophic coverage, respectively, compared to 19 and 3 percent of general Medicare patients. In both populations, the proportion of enrollees with LIS benefits reaching the coverage gap was lower in 2011 than in 2007. ✦ **Figure 6.13 ;** see page 441 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

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6.e **Twelve-month probability of reaching the coverage gap in Part D non-LIS enrollees (percent), by modality, 2011**

	General Medicare	Hemodialysis	Peritoneal dialysis	Transplant
All	19.2	41.3	40.6	39.0
20-44	17.4	29.7	25.7	19.7
45-64	24.2	41.2	39.4	37.5
65-74	17.0	44.7	46.3	45.9
75+	20.9	39.4	38.7	37.8
Male	19.1	38.3	38.6	38.3
Female	19.2	45.8	43.3	40.2
White	19.7	42.5	41.6	40.2
Black/Af Am	14.4	36.9	33.3	33.7
Asian	12.6	46.2	46.8	36.3
Other	15.4	41.7	35.9	41.7
Hispanic	15.2	36.9	38.5	33.3
Hypertension	27.9	41.5	41.1	40.3
CVD	32.5	42.3	42.3	45.9
Diabetes	36.7	43.7	46.0	51.7
Cancer	26.3	41.2	41.2	45.1

In 2011, the twelve-month probability of non-LIS Part D enrollees reaching the coverage gap was 39–41 percent across ESRD modalities, but varied by age, gender, race, and comorbidity. ESRD patients age 20–44, men, blacks/African Americans, and Hispanics were the least likely to reach the gap, while ESRD patients with diabetes reached it at a higher rate than did those with cardiovascular disease, hypertension, or cancer. ✦ **Table 6.e;** see page 441 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

The new dialysis Prospective Payment System, or "bundle," took effect in January, 2011. Antibiotics administered during hemodialysis for a vascular access infection or prescribed for peritonitis treatment in a peritoneal dialysis patient are considered ESRD-related, and are now covered in the bundled payment. Dialysis facilities are, however, required to document these medications on the Medicare claims form. Here we examine use of oral and intravenous (IV) antibiotics before and after implementation of the bundle. After implementation, IV antibiotics were covered under Part B (through the bundle or separate reimbursement); the proportion of patients receiving any IV antibiotics under Part D was less than 1 percent.

Overall, the proportion of patients receiving at least one IV antibiotic decreased slightly between 2010 and 2011. Vancomycin was the most used antibiotic, and daptomycin the least. Vancomycin use fell from 21.2 and 0.8 percent under Parts B and D, respectively, in 2010 to 20.7 and 0.6 percent in 2011. Cefazolin use remained constant pre- and post-dialysis bundle, and use of other antibiotics was more limited.

In 2011, DCI units had the highest percentage of patients using vancomycin, cephalosporins (including cefazolin), and aminoglycosides.

The percentage of patients receiving quinolones fell from 22.4 to 18.8 percent pre- to post-bundle, while macrolide and penicillin use increased slightly. There was a slight decrease in the percentage of patients receiving oral cephalosporins in Fresenius, DaVita and DCI units, while the numbers rose slightly in the SDOs and in independent and hospital-based units. ✦ **Figures 6.14–15;** see page 441 for analytical methods. *Point prevalent Medicare enrollees alive on January 1.*

unit affiliation

All	All units
F	Fresenius
DV	DaVita
DCI	Dialysis Clinic, Inc.
SDOs	Small dialysis organizations (defined as 20–199 dialysis units; unit classification assigned by the USRDS)
Ind	Independent units
HB	Hospital-based units

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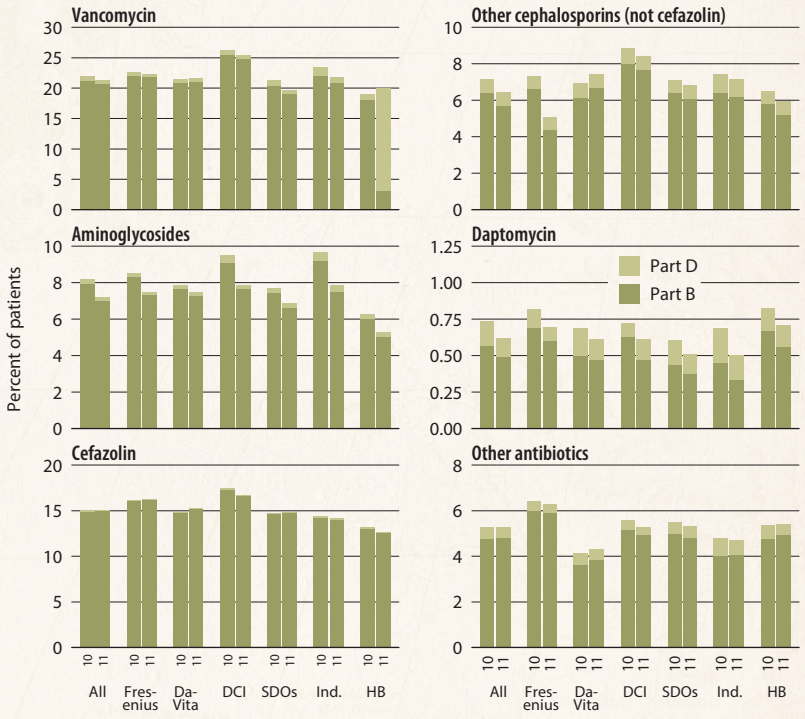
6.14 **Patients receiving intravenous antibiotics under Medicare Parts B & D pre- & post-dialysis bundle, by unit affiliation**



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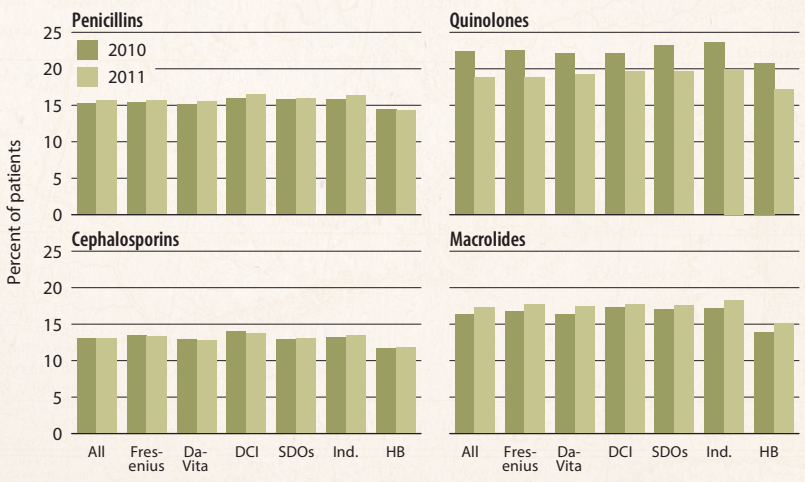
6.15 **Patients receiving oral antibiotics under Medicare Parts B & D pre- & post-dialysis bundle, by unit affiliation**



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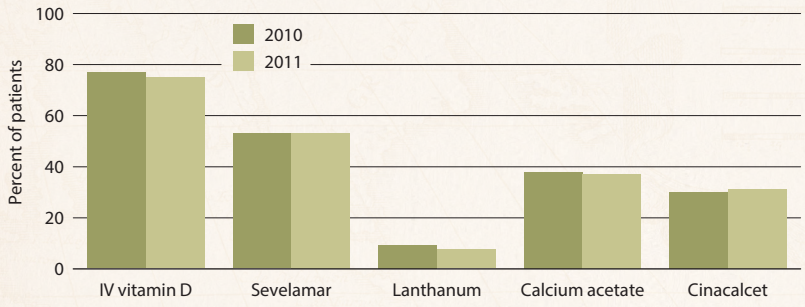
6.16 **Patients receiving bone & mineral medications pre- & post-dialysis bundle, by type of medication, 2010 & 2011**



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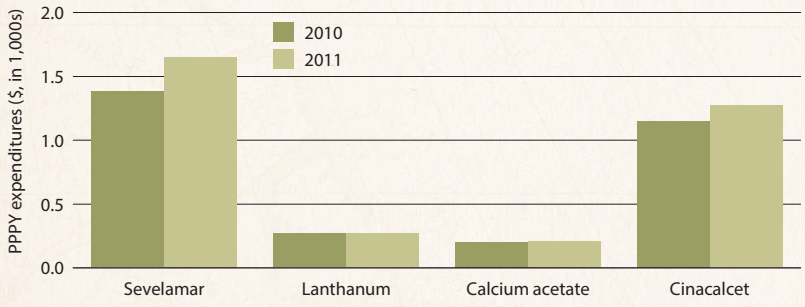
6.17 **PPPY costs of bone & mineral medications pre- & post-dialysis bundle, by type of medication, 2010 & 2011**



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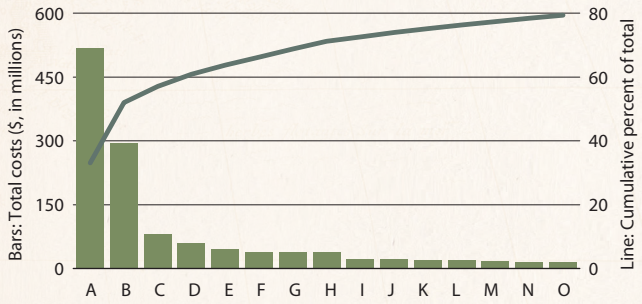
6.18 **Top 15 drug classes used by Part D-enrolled dialysis patients, by net cost, 2011**



A Phosphate binder agents
B Calcimimetic agents
C Insulin
D Antiplatelet drugs
E Antiretrovirals
F Parenteral nutrition (amino acids)
G Selective serotonin reuptake inhibitors
H Statins
I Sympathomimetics
J Opioid analgesics
K Dibenzapines
L Angiotensin II receptor blockers
M Immunomodulators
N Calcium ch. blockers
O Anticonvulsants

A substantial majority of dialysis patients enrolled in Part D (77 and 75 percent in 2010 and 2011, respectively) received intravenous (IV) vitamin D analogues, reflecting the high prevalence of bone and mineral disorders in the dialysis population. Sevelamer products (both hydrochloride and carbonate) were the most commonly used phosphate binders, and their use was relatively constant between 2010 and 2011. The use of calcium acetate was also relatively stable, at 37–38 percent, while lanthanum use fell from 9.3 to 7.7 percent. One-third of patients were prescribed cinacalcet, calcimimetics for the management of bone and mineral disorders.

Per person per year (PPPY) net Part D costs for bone and mineral medications increased between 2010 and 2011. While costs for sevelamer and cinacalcet rose 20 and 11 percent, respectively, those for lanthanum and calcium acetate rose just 0.3 and 2 percent. Among phosphate binding agents, sevelamer had the highest PPPY costs and calcium acetate the lowest. This is not surprising, as sevelamer is a branded medication while calcium acetate is available in generic form.

Phosphate binders were the most frequently prescribed Part D medication class in dialysis patients during 2011, and first as well in terms of costs. This is not surprising, as bone and mineral disorders are highly prevalent in dialysis patients and sevelamer (both hydrochloride and carbonate) is not yet available as a generic. Calcimimetic agents and insulin were the second and third most costly classes of medications. Together, phosphate binders and calcimimetics account for more than 50 percent of net Part D expenditures. ⌖ **Figures 6.16–18;** see page 441 for analytical methods. *Point prevalent Medicare enrollees alive on January 1.*

part d enrollment patterns

SOURCES OF PRESCRIPTION DRUG COVERAGE IN MEDICARE ESRD ENROLLEES, BY POPULATION, 2011 (FIGURE 6.2)

	general Medicare	all ESRD	HD	PD	TX
Part D with low income subsidy	23%	49%	54%	40%	35%
Part D without low income subsidy	39%	22%	21%	25%	23%
retiree drug subsidy	13%	8%	7%	8%	8%

MEDICARE PART D ENROLLEES WITH OR WITHOUT THE LOW INCOME SUBSIDY (LIS), BY RACE, 2011 (TABLE 6.A)

	white	black/Af Am	Asian	other
general Medicare: with LIS	30%	66%	70%	62%
general Medicare: without LIS	70%	34%	30%	38%
all ESRD: with LIS	61%	81%	74%	81%
all ESRD: without LIS	39%	19%	26%	19%

overall costs of part d enrollment

PER PERSON PER YEAR MEDICARE & OUT-OF-POCKET PART D COSTS FOR ENROLLEES, 2011 (FIGURE 6.10)

	Medicare	out-of-pocket
general Medicare	$2,167	$417
all ESRD	$5,851	$422
hemodialysis	$6,427	$388
peritoneal dialysis	$5,914	$530
transplant	$4,730	$516

PER PERSON PER YEAR PART D COSTS FOR ENROLLEES, BY LOW INCOME SUBSIDY (LIS) STATUS, 2011 (FIGURE 6.11)

	Medicare	out-of-pocket
general Medicare: with LIS	$4,194	$105
general Medicare: without LIS	$1,043	$590
all ESRD: with LIS	$7,549	$118
all ESRD: without LIS	$2,215	$1,074

terms used in the part d analyses

LOW INCOME SUBSIDY (LIS) For Medicare beneficiaries with limited income and/or assets, the costs of participation in Medicare Part D may be reduced by the LIS. Beneficiaries who are dually eligible for Medicare and Medicaid are automatically granted the LIS, while beneficiaries who are not dually eligible may apply for it. While the LIS may take eight different levels, with monthly premiums and copayments either eliminated or reduced, all dually eligible beneficiaries pay no monthly premiums.

CREDITABLE COVERAGE Prescription drug coverage that is actuarially equivalent to the standard Part D benefit, as defined annually by CMS. Beneficiaries with creditable coverage may forgo participation in Medicare Part D without having to pay increased monthly premiums upon future enrollment. Examples of creditable coverage include the Federal Employee Health Benefits Program, TRICARE, VA Health Care Benefits, State Pharmacy Assistance Programs (SPAPS), and private insurance that is eligible for the retiree drug subsidy. Private insurance for the working aged may or may not be creditable.

RETIREE DRUG SUBSIDY (RDS) A program designed to encourage employers to continue to provide prescription drug coverage to retirees eligible for Medicare Part D. Under the program, employers receive a tax-free rebate equal to 28 percent of covered prescription drug costs incurred by their retirees. The program is relatively simple to administer, but may ultimately be more costly than providing employees a type of Part D plan known as an "employer group waiver plan." Following passage of the Patient Protection and Affordable Care Act, the tax-free status of the subsidy is due to expire on December 31, 2012.

DEDUCTIBLE At the beginning of each calendar year, each non-LIS Part D enrollee is responsible for 100 percent of gross drug costs up to a set amount (i.e., the deductible), at which point cost sharing begins. In the standard benefit, the deductible was $250, $265, and $275 in 2006, 2007, and 2008, respectively.

INITIAL COVERAGE PERIOD The interval following the deductible phase, but preceding the coverage gap. During this time, the Part D enrollee without the LIS is normally responsible for 25 percent of gross drug costs (in the standard benefit).

COVERAGE GAP The interval following the initial coverage period, but preceding catastrophic coverage. During this time, non-LIS Part D enrollees are normally responsible for 100 percent of gross drug costs (in the standard benefit). In 2010, the Affordable Health Care Act made several changes to Medicare Part D to reduce the effect of the coverage gap, so that it phases out by 2020. In 2010, non-LIS enrollees received a $250 rebate from Medicare to partially cover costs during the coverage gap. In 2011, non-LIS enrollees were given a 50 percent discount on the total price of brand name drugs and a 7 percent reduction in cost of generic medications while in the gap.

CATASTROPHIC COVERAGE The interval following the coverage gap. During this time, the Part D enrollee without the LIS is normally responsible for 5 percent of gross drug costs (in the standard benefit).

MEDICARE ADVANTAGE PART D PLANS (MA-PDS) Medicare Part D plans that are offered only to participants in Medicare Part C.