

Glacier National Park, Montana

PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

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Of all the questions which can come before this nation, short of the actual preservation of its existence in a great war, there is none which compares in importance with the great central task of leaving this land even a better land for our descendants than it is for us, and training them into a better race to inhabit the land and pass it on. Conservation is a great moral issue, for it involves the patriotic duty of insuring the safety and continuance of the nation.

THEODORE ROOSEVELT,
“The New Nationalism” speech

In December 2010, over 28 million Medicare-enrolled elderly and disabled people, as well as individuals with ESRD, were enrolled in a Medicare Part D prescription drug plan (PDP). Before 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. After 2006, however, the majority obtained Part D coverage. Sixty percent of general Medicare patients, and 58 and 69 percent of CKD and ESRD patients, were enrolled in Part D in 2010.

Part D benefits can be managed through a stand-alone PDP or through a Medicare Advantage (MA) plan, which provides medical as well as prescription benefits. CKD patients can choose to enroll in an MA plan; ESRD patients, in contrast, 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 CKD patients obtain outpatient medication benefits through Part B, Part D, retiree drug subsidy plans, or other creditable coverage (equivalent to or better than Part D), 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 percentage of CKD patients with creditable coverage increased from 12.5 to 13.2 percent between 2008 and 2010. The proportion of patients with other creditable coverage is slightly higher among CKD than general Medicare patients (at 13.2 versus 12.6 percent), but a higher proportion of CKD patients have retiree drug subsidy coverage, at 21 compared to 14 percent. The percentage of CKD patients with no known coverage fell from 8.8 to 7.8 between 2008 and 2010, reaching a level lower than the 12.6 percent seen in the general Medicare population.

Part D does not cover every medication prescribed to Medicare enrollees. Several drug categories — including over-the-counter medications, barbiturates, benzodiazepines, anorexia and weight loss or gain medications, prescription vitamins (except for prenatal vitamins), and cough and cold medications — are excluded from the Part D program by law. This means that some drugs commonly used in CKD patients (oral iron, ergocalciferol, cholecalciferol) are not currently covered through Medicare Part D. Oral calcitriol, doxercalciferol, and paricalcitol, however, are not considered prescription vitamins, and are thus covered.

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”). Fifty percent of CKD patients enrolled in Part D have LIS, compared with only 37 percent of general Medicare patients and 70 percent of ESRD patients. Eighty-six percent of Asian patients with CKD have LIS, compared to

Terms used in the Part D analyses can be found at the end of this chapter, on page 96.

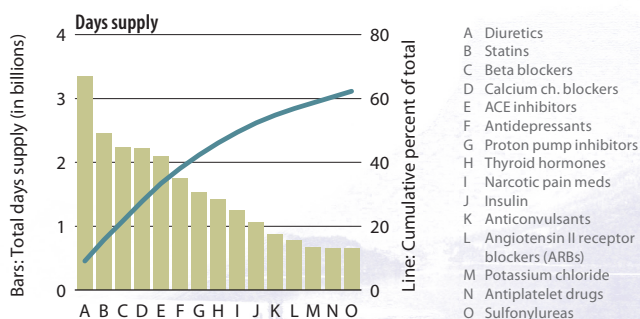
79 percent of blacks/African Americans and 41 percent of whites. In general, CKD patients thus pay proportionally lower out-of-pocket costs than general Medicare patients for their Part D prescriptions. CKD patients enrolled in Part D and without LIS, however, pay higher premiums for their plans than do general Medicare or ESRD patients.

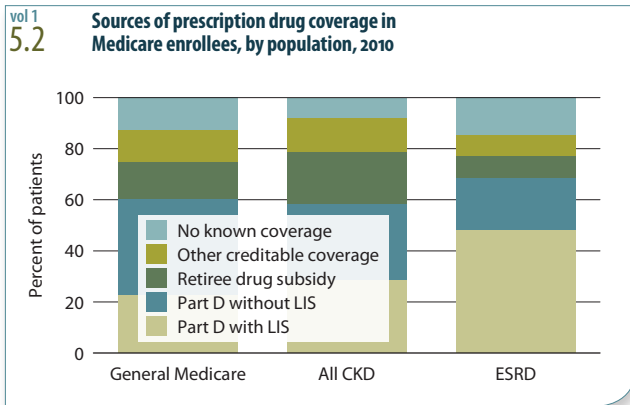
The net Part D payment for identified CKD patients rose from \$2.9 billion in 2007 to \$4.5 billion in 2010 — a 56 percent growth, as compared to a 25 percent increase for general Medicare patients. This can be at least partially explained by increased identification of CKD; recognized CKD prevalence has increased 37 percent since 2007.

Out-of-pocket (OOP) Part D costs for CKD patients are higher than for general Medicare patients, at \$738 versus \$478 per person per year (PPPY). This reflects a greater mean number of Part D prescriptions for CKD patients. CKD patient OOP costs relative to total Part D costs, however, are proportionally lower than those in the general Medicare population; a higher percentage of CKD patients enrolled in Part D have the LIS, which lessens their OOP costs. Non-LIS CKD patients pay over \$700 more per year for Part D prescriptions than do their non-LIS counterparts in the general Medicare population. Accordingly, a higher percentage of non-LIS CKD patients reach the coverage gap (37 versus 19 percent) and the catastrophic coverage phase (7 versus 2 percent).

As measured by total days supply, statins represented 7.3% of Part D drug use among CKD patients but 4.9% of their Part D costs— the same relative proportion seen in general Medicare patients, where represented 9.1% of Part D drug use and 5.7% of the costs. Of the top 15 drug classes used by CKD patients, cardiovascular therapies (statins, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, diuretics, calcium channel blockers and beta blockers) are the most common both by frequency of use. » **Figure 5.1;** see page 145 for analytical methods. *Part D claims for all patients in the Medicare 5 percent sample; claims & costs scaled up by a factor of 20 to estimate totals. Costs are the sum of Medicare payment & low income subsidy. Therapeutic classifications based on Medi-span's generic product identifier (GPI) therapeutic classification system.*

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5.1 Top 15 drug classes used by general Medicare Part D enrollees with CKD, by days supply, 2010



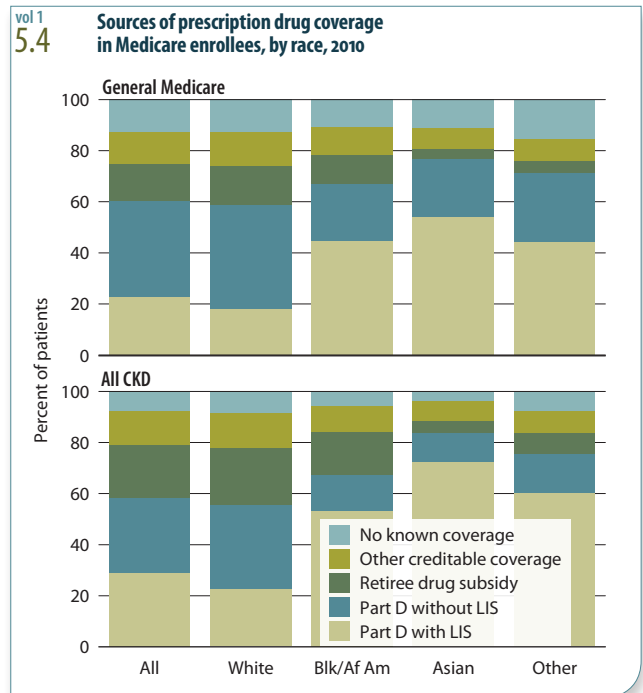
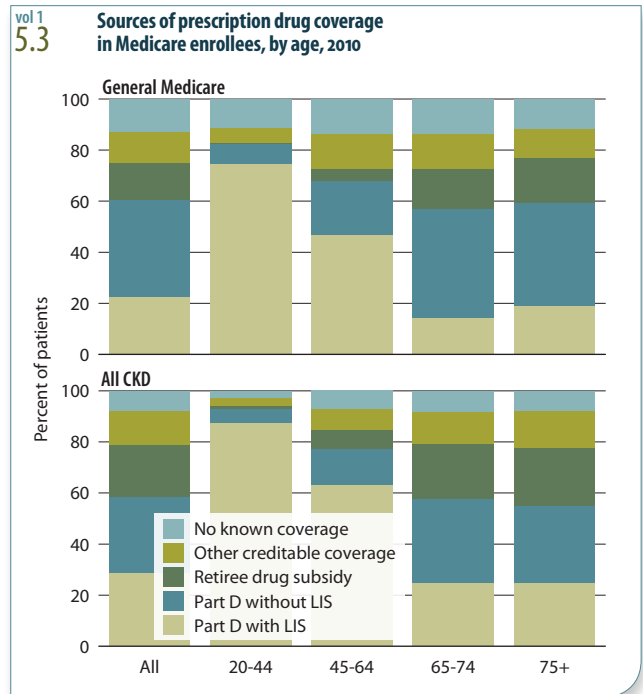


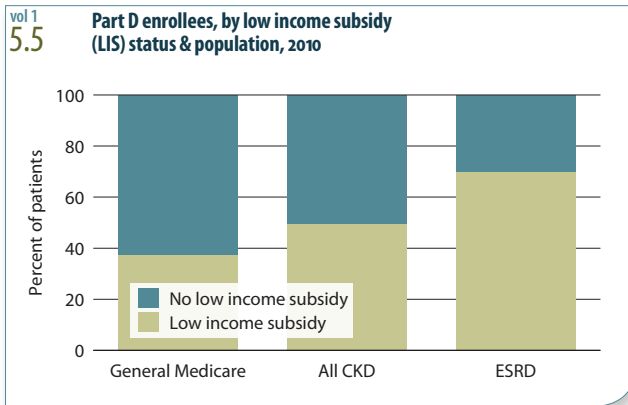
Sixty percent of general Medicare patients, and 58 percent of patients with CKD, were enrolled in Part D in 2010, as were 69 percent of patients with ESRD. The proportion of patients with other creditable coverage is similar among CKD and Medicare patients, at about 13 percent, but a higher proportion of CKD patients have retiree drug subsidy coverage, at 21 compared to 14 percent. Eight percent of CKD patients have no known source of drug coverage—a level lower than the 13 percent seen in the general Medicare population.

Among both general Medicare beneficiaries and those with CKD, the percentage enrolled in Part D generally declines with age, although, in the general Medicare population, it is higher among those age 75 and older than for those age 65–74.

Nearly 75 percent of general Medicare patients age 20–44 receive the low income subsidy (LIS). It is important to note that most patients in the younger two age groups are disabled. In the two older age groups, similar proportions of general Medicare and CKD patients are enrolled in Part D, at 55–60 percent. The proportion of patients with LIS declines with age in both populations (with the exception of those age 75 and older in the general Medicare population), but CKD patients in each age category are more likely to receive this subsidy.

Patterns of coverage by race are similar in the general Medicare and CKD populations, with both Part D enrollment overall and Part D coverage with LIS highest in Asian patients, and lowest in whites. LIS coverage is higher across races for CKD patients than among their general Medicare counterparts » **Figures 5.2–4**; see page 145 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2010.*





Fifty percent of CKD patients with Part D coverage had LIS benefits in 2010, compared to 70 percent of dialysis patients. A higher proportion of CKD patients are thus at risk to experience the coverage gap and to have higher premiums, deductibles, and drug copayments, on average, than dialysis patients. » **Figure 5.5;** see page 145 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2010.*

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5.a **Percent of Part D enrollees with low income subsidy (LIS), by age & race, 2010**

	General Medicare		All CKD	
	Part D w/LIS	Part D wo/LIS	Part D w/LIS	Part D wo/LIS
White				
All ages	30.6	69.4	41.2	58.8
20-44	90.0	10.0	93.5	6.5
45-64	65.3	34.7	78.4	21.7
65-74	18.8	81.3	34.7	65.3
75+	25.4	74.6	36.8	63.2
Black/Af Am				
All ages	66.6	33.4	78.9	21.1
20-44	93.7	6.4	95.5	4.5
45-64	81.6	18.4	87.7	12.3
65-74	51.8	48.2	72.7	27.4
75+	61.4	38.6	77.5	22.5
Asian				
All ages	70.5	29.6	86.5	13.5
20-44	91.6	8.4	93.8	6.3
45-64	74.9	25.1	85.7	14.3
65-74	65.3	34.8	86.7	13.3
75+	73.4	26.6	86.3	13.7
Other				
All ages	62.4	37.6	79.9	20.1
20-44	87.3	12.7	93.2	6.8
45-64	71.4	28.6	86.0	14.0
65-74	54.7	45.3	75.3	24.7
75+	61.0	39.0	80.0	20.0

Among both general Medicare beneficiaries and those with CKD, and in each race category, the proportion of patients with LIS generally declines with age, though it is greater for patients age 75 and older than for those age 65–74. In each age group within each race category, patients with known CKD are more likely to have LIS than their general Medicare counterparts. And in both the general Medicare and CKD populations, Asians are the most likely by race to have LIS, and whites the least. » **Table 5.a;** see page 145 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, 2010.*

CMS provides prescription drug plans (PDPs) with guidance on structuring a “standard” Part D PDP. The upper portion of Table 5.b shows the standard benefit design for PDPs in the years 2006 through 2010. In 2010, for example, beneficiaries shared costs with the PDP (as co-insurance or copayments) until the combined total reached \$2,830 during the initial coverage period. After reaching this level, beneficiaries went into the coverage gap, or “donut hole,” where they paid 100 percent of costs. Since 2010, the government has been providing those reaching the coverage gap with more assistance each year; they received a \$250 rebate in 2010 and a 50 percent brand discount in both 2011 and 2012.

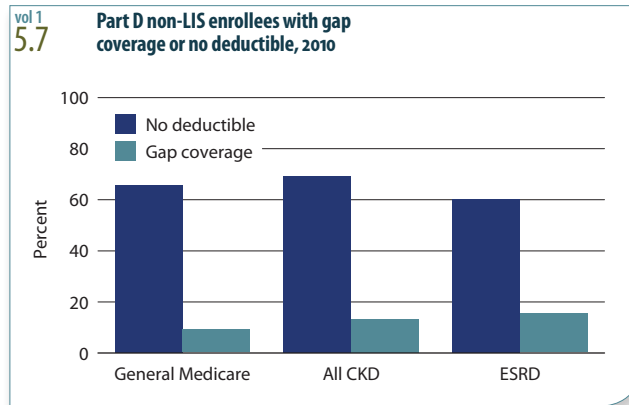
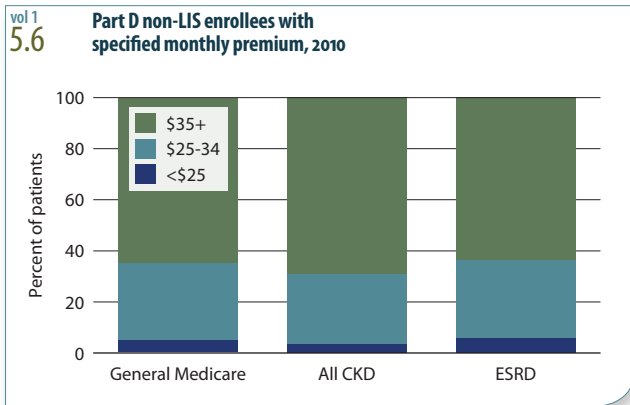
In 2010, beneficiaries who obtained a yearly out-of-pocket drug cost of \$4,550 reached the catastrophic coverage phase, in which they paid only a small copayment for their drugs until the end of the year.

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 5.b.** <http://www.q1medicare.com/PartD-The-2010-Medicare-Part-D-Outlook.php>.

vol 1 5.b Medicare Part D benefit parameters for defined standard benefit, 2006–2010		2006	2007	2008	2009	2010
Deductible	After the deductible is met, beneficiary pays 25% of covered costs up to total prescription costs meeting the initial coverage limit.	\$250	\$265	\$275	\$295	\$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.)	\$2,250	\$2,400	\$2,510	\$2,700	\$2,830
Total covered Part D drug out-of-pocket spending including the coverage gap	Catastrophic coverage starts after this point.	\$5,100.00	\$5,451.25	\$5,726.25	\$6,153.75	\$6,440.00 plus a \$250 rebate
Out-of-pocket threshold	This is the total out-of-pocket costs including the donut hole.	\$3,600	\$3,850	\$4,050	\$4,350	\$4,550
2010 example						
	\$310 (deductible)	\$250.00	\$265.00	\$275.00	\$295.00	\$310.00
	+ ((\$2,830 – \$310) * 25%) (initial coverage)	\$500.00	\$533.75	\$558.75	\$601.25	\$630.00
	+ ((\$6,440 – \$2,830) * 100%) (coverage gap)	\$2,850.00	\$3,051.25	\$3,216.25	\$3,453.75	\$3,610.00
	= \$4,500 (maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)	\$3,600.00	\$3,850.00	\$4,050.00	\$4,350.00	\$4,550.00
Catastrophic coverage benefit						
	Generic/preferred multi-source drug	\$2.00	\$2.15	\$2.25	\$2.40	\$2.50
	Other drugs	\$5.00	\$5.35	\$5.60	\$6.00	\$6.30

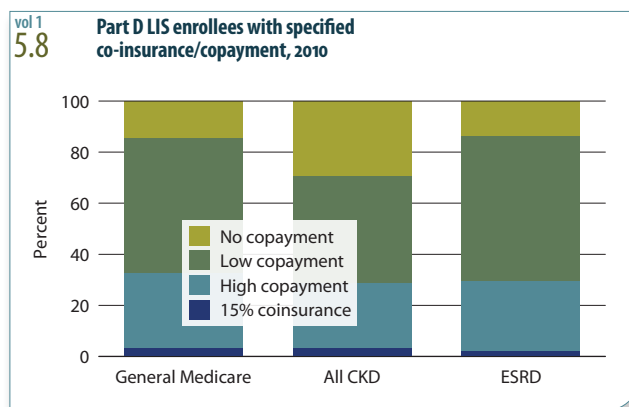
Among general Medicare beneficiaries, those with CKD, and those with ESRD, enrollment in Medicare Part D rose between 2006 and 2010. In each of the first two years of Part D, enrollment was slightly higher for those with CKD than in the general Medicare population. In 2008–2010, however, the reverse was true. And in each year since the inception of Part D, enrollment has been greatest for patients with ESRD. » **Table 5.c;** see page 145 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans.*

vol 2 5.C Prevalent general Medicare, CKD, & ESRD patients enrolled in Part D (%)		General Medicare	All CKD	ESRD
2006		54.6	55.1	62.6
2007		57.0	57.2	65.5
2008		58.6	57.7	67.0
2009		59.8	58.2	68.0
2010		60.4	58.4	68.9

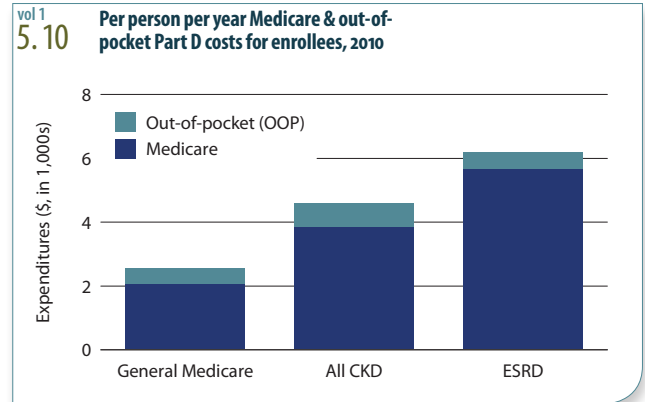
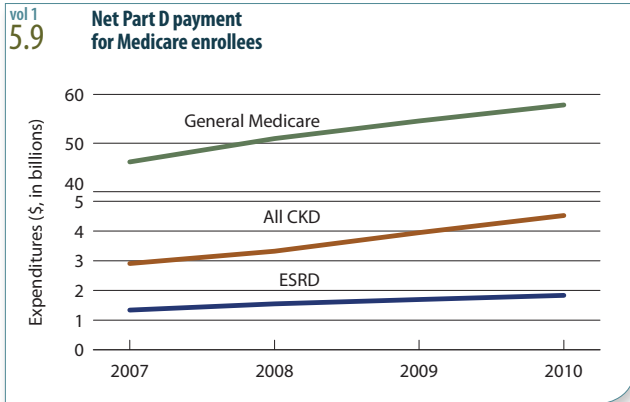


Patients without the low income subsidy (LIS) pay full monthly premiums. Between 2006 and 2010, the weighted average premium for Medicare Part D stand-alone prescription drug plans (PDPs) increased from \$25.93 to \$37.25 (facts.kff.org). In 2010, 69 percent of CKD patients were enrolled in plans with premiums greater than \$35 per month, compared to 65 percent of Medicare patients.

The percentage of Part D non-LIS enrollees with no deductible is similar in the general Medicare and CKD populations, at 66–69, and has declined since 2008 (2011 USRDS ADR). Gap (“donut hole”) coverage, in contrast, is more common in CKD patients, at 13 compared to 9 percent. Sixteen percent of ESRD patients in 2010 were enrolled in plans with gap coverage. In 2010, most PDPs (80 percent) did not offer gap coverage (<http://www.kff.org/medicare/8008.cfm>).

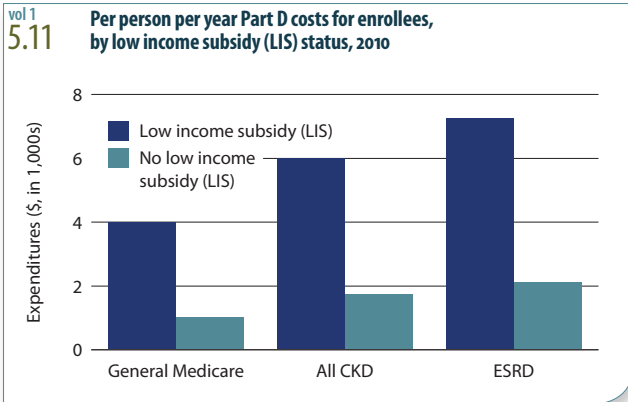


Most Part D LIS enrollees (full-benefit dual-eligible patients) pay no monthly premium, but non-institutionalized LIS patients do pay drug copayments or co-insurance based on income and assets. Seventy one percent of CKD patients with LIS have low or no copayments for their Part D medications, compared to 67 percent of general Medicare patients. Only 3–4 percent pay 15 percent co-insurance for their medications. And even CKD patients with high copayments (25 percent, on average, in 2010) paid a maximum of just \$2.50 per generic and \$6.30 for branded medications. » **Figures 5.6–8**; see page 145 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans.*



In 2010, total net Part D payment for patients with identified kidney disease (CKD patients not on dialysis, and ESRD patients) was \$6.4 billion — about 10 percent of total Part D prescription drug costs. These costs do not include costs of drugs billed to Part B, including intradialytic medications (ESAs, IV vitamin D, iron) and immunosuppressants. » [Figure 5.9](#); see page 145 for analytical methods. General Medicare totals include Part D claims for all patients in the Medicare 5 percent sample enrolled in Part D. CKD total includes Medicare CKD patients, as determined from claims. ESRD totals include all Part D claims for Medicare ESRD patients enrolled in Part D.

At \$4,580, the per person per year (PPPY) total cost of medications covered by Medicare Part D in 2010 was 1.8 times higher in CKD patients than in the general Medicare population. Proportional to total Part D costs, however, out-of-pocket costs were lower in CKD patients, representing 16 percent of their PPPY costs compared to 19 percent for the general Medicare population. » [Figure 5.10](#); see page 145 for analytical methods. General Medicare totals include Part D claims for all patients in the Medicare 5 percent sample enrolled in Part D. CKD totals includes Medicare CKD patients, as determined from claims. ESRD totals include all Part D claims for Medicare ESRD patients enrolled in Part D. Medicare total is the sum of Medicare net payment plus LIS amount.



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5.d Total per person per year (PPPY) costs (\$) for Part D enrollees, by LIS status, 2010

	General Medicare		All CKD		ESRD	
	LIS	No LIS	LIS	No LIS	LIS	No LIS
All	3,985	1,010	5,997	1,733	7,243	2,114
20-44	4,296	1,284	8,182	1,324	7,153	1,634
45-64	5,148	1,292	8,069	2,652	7,782	2,148
65-74	3,301	924	6,033	1,830	6,909	2,267
75+	3,392	1,046	4,990	1,620	6,019	1,978
Male	3,956	1,001	6,146	1,757	7,277	2,210
Female	4,003	1,016	5,912	1,711	7,211	2,050
White	3,375	864	6,234	1,746	7,248	2,203
Black/Af Am	4,236	1,026	5,395	1,514	7,270	1,853
Other race	3,625	879	5,884	1,753	7,057	2,001

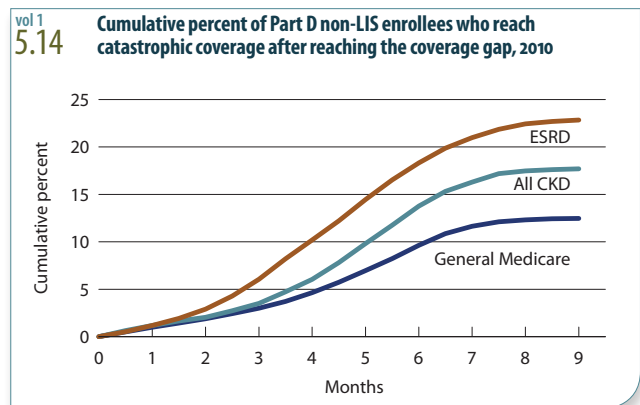
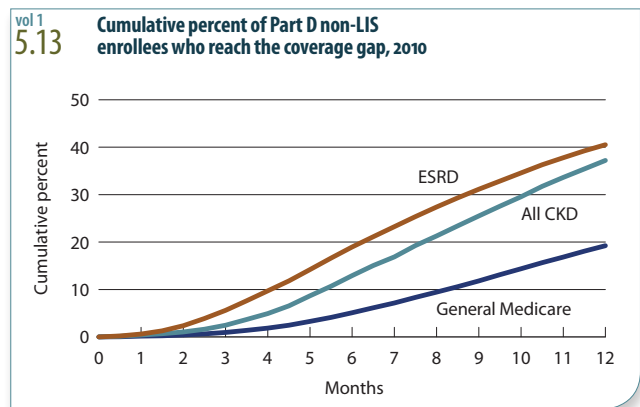
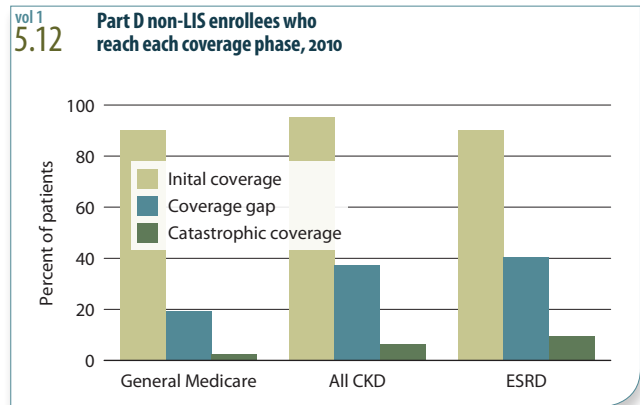
Per person per year (PPPY) total costs for Part D-covered medications in 2010 were 3.3–3.9 times greater for patients with the LIS than for those without. Costs in LIS and non-LIS patients vary from \$3,985 and \$1,010 PPPY, respectively, in the general Medicare population to \$5,997 and \$1,733 among patients with CKD, and to \$7,243 and \$2,114 among those with ESRD. » **Figure 5.11**; see page 145 for analytical methods. Medicare patients surviving 2010. General Medicare totals include Part D claims for all patients in the Medicare 5 percent sample enrolled in Part D. CKD total includes Medicare CKD patients, as determined from claims. ESRD totals include all Part D claims for Medicare ESRD patients enrolled in Part D.

Total per person per year (PPPY) Medicare Part D costs vary widely between those with and without the LIS. Overall, ESRD patients have the highest costs in both categories, at \$7,243 and \$2,114, respectively, followed by CKD (\$5,997 and \$1,733) and general Medicare (\$3,985 and \$1,010) patients. By race, and regardless of LIS status, PPPY costs in the general Medicare population are highest for blacks/African Americans, and in the CKD population are highest for whites. » **Table 5.d**; see page 145 for analytical methods. All Medicare patients enrolled in Part D in 2010. CKD determined from claims. ESRD patients are period prevalent ESRD in 2010.

Part D enrollees without the low income subsidy (LIS) may encounter three coverage phases, depending on total and out-of-pocket costs per year. In 2010, patients with total Part D drug costs up to \$2,830 fell into 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 \$250 rebate given in 2010. Patients whose out-of-pocket total reached \$4,550 then entered the catastrophic coverage phase, in which they paid only a fraction of overall drug costs.

In 2010, 37 percent of all CKD patients (those not on dialysis) reached the coverage gap, compared to 19 percent in the general Medicare population and 41 percent of ESRD patients. Seven percent of CKD patients reached catastrophic coverage, compared to 2 percent of general Medicare and 9.3 percent of ESRD patients.

Patients with ESRD generally reach the coverage gap slightly sooner than those with CKD, while general Medicare patients on average take much longer. And 18 percent of CKD patients who reach the coverage gap subsequently attain catastrophic coverage, compared to 13 percent of general Medicare and 23 percent of ESRD patients. Patients with ESRD reach catastrophic coverage faster than do patients with CKD, and patients with CKD reach this coverage faster than general Medicare patients. » **Figures 5.12–14**; see page 145 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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5.e

Twelve-month probability (percent) of reaching the coverage gap in Part D non-LIS enrollees, 2010

	General Medicare	All CKD	ESRD
All	19.2	37.2	40.5
45-64	23.7	41.0	39.3
65-74	16.7	38.4	45.7
75+	21.6	36.4	39.7
Male	18.6	36.2	38.2
Female	19.7	38.1	44.1
White	19.8	38.0	42.3
Black/African American	14.2	26.4	34.8
Asian	12.9	31.9	40.3
Other	15.1	33.9	34.2
Hypertension	27.9	38.3	41.0
CVD	32.1	40.2	42.2
Diabetes	36.3	46.3	44.9
Cancer	28.1	35.1	42.7

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5.f

Rate of Part D-covered prescription fills (PPPM) in Part D non-LIS enrollees, 2010

	Gen Med.	All CKD	ESRD
Patients who do not reach the coverage gap	2.0	3.1	2.7
Patients who reach coverage gap, but not catastrophic coverage			
During initial coverage period	4.5	5.3	5.0
During coverage gap	4.4	5.1	4.6
Patients who reach catastrophic coverage			
During initial coverage period	6.6	7.5	6.4
During coverage gap	7.1	7.9	6.7
During catastrophic coverage	7.1	8.5	7.2

Thirty-seven percent of non-LIS Part D enrollees with CKD reach the coverage gap within 12 months; this varies little by age or gender. Among all three populations — general Medicare, CKD, and ESRD — white patients are most likely, by race, to reach the gap. By diagnosis, patients with diabetes reach the gap at the highest rate. » [Table 5.e](#); see page 145 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

Number, fill rate, and prescription cost influence whether patients stay in the initial coverage phase or progress to the coverage gap and then to catastrophic coverage. Among patients who reach either the coverage gap or catastrophic coverage, CKD patients have a higher fill rate than patients in the general Medicare population.

Among patients who reach the coverage gap but do not get to catastrophic coverage, the fill rate consistently declines from that of the initial coverage period. This could be due either to a reduction in medication adherence or to a decision to obtain medications outside the Part D plan, and it is a pattern not seen in patients who reach catastrophic coverage. In these patients, the fill rate generally rises as patients move from initial coverage to the gap, and then again as they reach catastrophic coverage. Patients with a higher number of Part D medications could be incentivized to fill prescriptions in order to reach this phase more quickly, as their out-of-pocket expenses then decrease dramatically. » [Table 5.f](#); see page 145 for analytical methods. *Point prevalent Medicare enrollees alive on January 1, excluding those in employer-sponsored & national PACE Part D plans.*

In terms of frequency of use, the top 15 drugs covered by Medicare Part D are similar in the general Medicare and CKD populations. Simvastatin, for example, is the most frequently used drug in the general Medicare population, and second on the list for CKD patients. Three drugs — atenolol, metformin and hydrochlorothiazide — appear in the top 15 for general Medicare patients, but not for CKD patients, in whom furosemide (a loop diuretic) has a more potent diuretic effect, and metformin is contraindicated secondary to the increased risk of lactic acidosis. Carvedilol, allopurinol, and hydrocodone, in contrast, make the list only for CKD patients. Interestingly, potassium chloride is one of the most frequently used medications in the CKD population, which may indicate a more aggressive use of diuretics in these patients.

When ranked by net cost, the list of medications used in the general Medicare population contains more psychiatric and Alzheimer-related drugs than do the lists for CKD patients. Sitagliptin, in contrast, appear only in the CKD lists. The highest net costs in the CKD population are for insulin, reflecting both the high prevalence of diabetes in these patients and the fact that many new insulin therapies are still under patent and not available as generics. » **Tables 5.g–i**; see page 145 for analytical methods. *Part D claims for all patients in the Medicare 5 percent sample (5.g & 5.h); claims & costs scaled up by a factor of 20 to estimate totals. Costs are the sum of Medicare payment & low income subsidy. All patients in the Medicare 5 percent sample. CKD Medicare patients (5.h), with Medicare as primary payor for calendar year 2009; all Part D claims for calendar year 2010 are included. ESRD patients (5.i); all Part D claims regardless of payor status.*

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5.g Top 15 drugs used by general Medicare Part D enrollees, by days supply & net cost, 2010

By days supply Generic name	Total days supply	By net cost Generic name	Total days supply	Total cost (dollars)
Simvastatin	1,702,375,780	Insulin	511,312,380	2,204,924,900
Levothyroxine	1,408,144,720	Clopidogrel bisulfate	560,273,580	2,202,262,860
Lisinopril	1,310,638,440	Quetiapine	193,120,900	1,819,768,660
Metoprolol	1,248,935,160	Atorvastatin	589,820,100	1,578,663,040
Amlodipine	1,050,487,820	Esomeprazole	298,881,780	1,486,140,140
Omeprazole	954,590,700	Olanzapine	82,157,060	1,464,146,720
Furosemide	880,613,700	Donepezil	231,598,180	1,311,955,200
Metformin	790,663,320	Fluticasone/salmeterol	212,550,980	1,189,165,040
Hydrochlorothiazide	741,156,420	Aripiprazole	66,393,740	960,720,360
Atenolol	682,587,600	Pioglitazone	188,729,080	960,720,360
Potassium chloride	648,922,600	Rosuvastatin	273,186,300	770,944,720
Atorvastatin	589,820,100	Tiotropium	151,008,040	738,255,540
Warfarin	570,131,360	Oxycodone	100,246,640	711,985,100
Clopidogrel bisulfate	560,273,580	Memantine	160,681,280	659,503,080
Insulin	511,312,380	Duloxetine	136,667,420	617,850,360

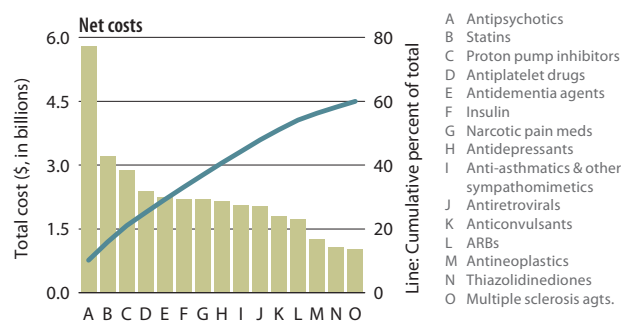
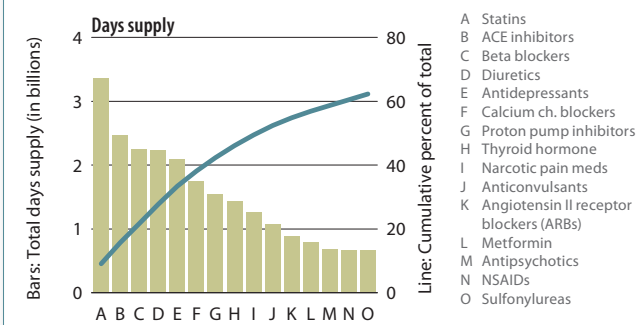
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5.h Top 15 drugs used by general Medicare Part D enrollees with CKD, by days supply & net cost, 2010

By days supply Generic name	Total days supply	By net cost Generic name	Total days supply	Total cost (dollars)
Furosemide	116,549,920	Insulin	74,735,540	359,843,460
Simvastatin	96,025,260	Clopidogrel bisulfate	53,989,880	227,155,480
Metoprolol	95,041,300	Donepezil	19,567,440	122,565,260
Levothyroxine	88,402,280	Esomeprazole	21,754,600	114,521,000
Amlodipine	84,617,740	Atorvastatin	38,651,260	113,114,980
Lisinopril	76,513,600	Quetiapine	13,461,420	108,079,420
Insulin	74,735,540	Pioglitazone	17,299,760	93,359,820
Omeprazole	64,962,340	Fluticasone/salmeterol	14,054,300	86,148,580
Potassium chloride	58,766,760	Olanzapine	4,762,140	78,968,440
Clopidogrel bisulfate	53,989,880	Memantine	13,856,500	63,059,380
Warfarin	50,785,740	Epoetin alfa	1,938,100	61,496,720
Carvedilol	47,520,840	Tiotropium	11,196,580	58,903,920
Atorvastatin	38,651,260	Sitagliptin	11,133,600	56,650,900
Allopurinol	37,697,680	Valsartan	24,878,640	55,643,200
Hydrocodone/acetaminophen	31,742,560	Rosuvastatin	18,313,300	54,392,300

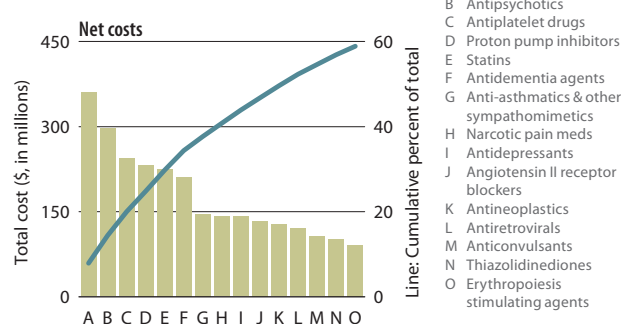
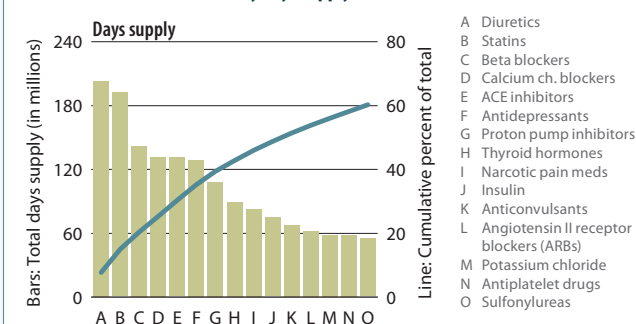
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5.i Top 15 drugs used by Part D enrollees with ESRD, by days supply & net cost, 2010

By days supply Generic name	Total days supply	By net cost Generic name	Total days supply	Total cost (dollars)
Insulin	25,682,414	Cinacalcet	13,811,538	275,814,134
Metoprolol	25,587,800	Sevelamer carbonate	15,808,229	236,471,065
Amlodipine	24,678,440	Insulin	25,682,414	104,947,191
Simvastatin	19,554,349	Sevelamer HCL	5,621,239	97,133,405
Lisinopril	17,370,355	Lanthanum carbonate	2,802,068	64,195,302
Omeprazole	16,345,094	Clopidogrel bisulfate	11,906,189	54,664,026
Sevelamer carbonate	15,808,229	Calcium acetate	14,909,212	52,169,404
Calcium acetate	14,909,212	Valganciclovir	1,004,129	46,174,583
Furosemide	14,073,278	Esomeprazole	6,582,989	37,187,989
Cinacalcet	13,811,538	Atorvastatin	8,932,963	29,344,213
Clonidine	13,755,734	Pantoprazole	5,183,660	18,592,221
Carvedilol	13,572,585	Tacrolimus	1,323,415	17,419,846
Levothyroxine	12,879,923	Doxercalciferol	1,021,253	15,982,039
Clopidogrel bisulfate	11,906,189	Pioglitazone	2,706,705	15,654,163
Prednisone	9,887,450	Valsartan	5,502,069	15,163,109

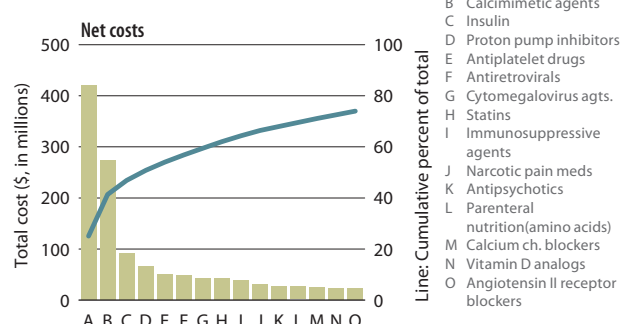
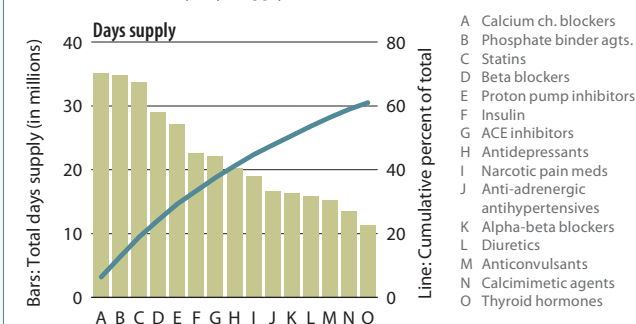
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5.15 Top 15 drug classes used by general Medicare Part D enrollees, by days supply & net cost, 2010



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5.16 Top 15 drug classes used by general Medicare Part D enrollees with CKD, by days supply & net cost, 2010



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5.17 Top 15 drug classes used by Part D-enrollees with ESRD, by days supply & net cost, 2010



Statins and beta-blockers are two of the top three most frequently used drug classes in both the CKD and the general Medicare populations. Three drug classes,—metformin, antipsychotics, and non-steroidal anti-inflammatory agents—appear in the top 15 for general Medicare patients, but not for CKD patients. Potassium chloride, insulin and antiplatelet drugs in contrast, make the list only for patients with CKD.

When ranked by net cost, the lists of medication classes used in the general Medicare population are similar in the general Medicare and CKD populations. Multiple sclerosis agents appears only in the general Medicare list while erythropoiesis stimulating agents appears only in the CKD list. The highest net costs in the CKD population are for insulin, reflecting both

the high prevalence of diabetes in these patients and the fact that many new insulin therapies are still under patent and not available as generics. For CKD patients, eight drug classes are among the top 15 based both on frequency of use and net costs. » Figures 5.15–17; see page 145 for analytical methods. Part D claims for all patients in the Medicare 5 percent sample (5.15 & 5.16); claims & costs scaled up by a factor of 20 to estimate totals. Costs are the sum of Medicare payment & low income subsidy. All patients in the Medicare 5 percent sample. CKD Medicare patients (5.16), with Medicare as primary payor for calendar year 2009; all Part D claims for calendar year 2010 are included. ESRD patients (5.17); all Part D claims regardless of payor status. Therapeutic classification based on Medi-Span's generic product identifier (GPI) therapeutic classification system.

PART D ENROLLMENT PATTERNS

sources of prescription drug coverage among Medicare enrollees, 2010 (Figure 5.2)

Part D with low income subsidy	» general Medicare · 23%	» CKD · 29%	» ESRD · 48%
Part D without low income subsidy	· 38%	· 29%	· 21%
retiree drug subsidy	· 14%	· 21%	· 8%

Medicare Part D enrollees with low income subsidy, 2010 (Figure 5.5)

» general Medicare · 38% » CKD · 50% » ESRD · 70%

OVERALL COSTS OF PART D ENROLLMENT

per person per year Medicare & out-of-pocket Part D costs for enrollees, 2010 (Figure 5.10)

general Medicare	» Medicare · \$2,089	» out-of-pocket · \$478
all CKD	· \$3,843	· \$738
ESRD	· \$5,684	· \$506

per person per year Part D costs for enrollees, 2010 (Figure 5.11)

patients with low income subsidy	» general Medicare · \$3,985	» CKD · \$5,997	» ESRD · \$7,243
patients with no low income subsidy	· \$1,010	· \$1,733	· \$2,114

COVERAGE PHASE ANALYSES FOR PART D ENROLLEES

Part D non-LIS enrollees who reach the coverage gap, 2010 (Figure 5.13)

at 12 months » general Medicare 19% » all CKD 37% » ESRD 41%

Part D non-LIS enrollees who reach catastrophic coverage after reaching the coverage gap, 2010 (Figure 5.14)

at 9 months » general Medicare 12% » all CKD 18% » ESRD 23%

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.

Fills per person Each prescription drug purchase constitutes a fill. Fills per person are calculated from the quotient of cumulative fills in a population and the number of people in that population.

Total days supply Each prescription drug is disbursed with sufficient quantity to administer for a set number of days, so long as instructions are followed

(i.e., so long as adherence is perfect). Total days supplied equals the cumulative number of days supplied through all fills of a particular medication in a population.

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.