



# *ASPE*

## *ISSUE BRIEF*

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### **HEALTH CARE SPENDING GROWTH AND FEDERAL POLICY** **March 22, 2016**

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Six years after enactment of the Affordable Care Act, the pace of health care spending growth remains a topic of keen policy interest, with recent trends subject to competing interpretations. Specifically, following a recent period of historically low growth, many expected that the sizable increase in the number of insured Americans resulting from the Affordable Care Act's coverage expansions would temporarily increase national healthcare spending growth, while others have posited that such increases are the beginning of a return to historical patterns of higher spending growth. Similarly, analysts have questioned whether sharp increases in prescription drug spending that occurred in 2014 were a unique phenomenon tied to a breakthrough cure for a prevalent illness or something more fundamental.

In this Issue Brief, we examine spending growth through 2014, the first year the Affordable Care Act's coverage provisions were in effect, and 2015, where possible. We provide detailed cost growth trends for Medicare and the private insurance market. We also estimate the effect of recently introduced specialty drugs on current and future spending growth.

### Key Findings

- *National health care spending increased moderately in 2014 by 4.3 percent per person.*
- *Federal programs, such as Medicare, have benefitted from a sustained period of slow growth.*
  - Medicare spent \$473.1 billion less on personal health care expenditures between 2009 and 2014 than would have been spent if the 2000-2008 average growth rate had continued through 2014.
  - Medicare could spend approximately \$648.6 billion less on personal health spending between 2009 and 2015 than would have been spent if the 2000-2008 average growth rate had continued if per enrollee spending growth continues to be low as current data suggest, at approximately 1.1 percent. To put this in context, this reduction in spending is greater than all of Medicare's spending for personal health care expenditures in 2015.
- *Medicare spending for inpatient and post-acute care remained flat in 2014.*
  - Hospital inpatient spending growth was lower than outpatient/ambulatory service growth in traditional Medicare, likely due to the ongoing transition from inpatient to outpatient settings of care, and may have also been driven, in part, by various payment policies such as the Hospital Readmissions Reduction program.
- *As expected, the ACA's major insurance coverage expansion provisions accounted for most of the faster growth in national health expenditures in 2014.*
  - In 2014 national health care spending per person was 4.3 percent compared to the lower per enrollee spending growth for Medicare (2.4 percent), private insurance (2.9 percent), and especially Medicaid (-3.6 percent). This shows that cost growth in 2014 is being driven in large part by people shifting from being under- or uninsured to having quality health coverage, while the underlying cost growth trend experienced by payers has remained low.
- *Specialty drugs were an important secondary contributor to spending growth in 2014.*
  - Expenditures on new specialty drugs, especially those used to treat Hepatitis C, accounted for the large increases observed across payers in prescription drug spending.
    - The prescription drug spending growth rate for traditional Medicare would have remained the same in 2014 and 2013 in the absence of new Hepatitis C drugs, but instead increased by 4.5 percentage points.
    - Prescription drug spending accounted for 56 percent of per enrollee spending growth in Medicare and 47 percent of per enrollee spending growth in private insurance in 2014. However, the increase in per enrollee drug spending from 2013 to 2014 constituted only around 2 percent of total spending per enrollee for Medicare and private insurance in 2014. Since spending on other spending categories experienced moderate to no growth, overall spending growth remained moderate.

## Health Care Spending Growth, 2000-2013

In earlier work, we found that the rate of national health care spending growth per person was on a downward trajectory between 2002 and 2012, and this trend was especially significant for Medicare starting in 2009.<sup>1</sup> For instance, the average growth rate in per enrollee spending for the Medicare program for 2009-2012 (2.3 percent) was 4.0 percentage points lower than the average growth rate for the years 2000-2008 (6.3 percent).<sup>2</sup>

The slowdown in spending growth was widespread across service categories. Several factors have likely contributed to the underlying slowdown in spending. These factors include the slow recovery from the great recession; expiring prescription drug patents and concurrent uptake of generic drugs; ongoing shifts in the site of care from inpatient to outpatient settings and to prescription drugs; and state and federal policies. Examples of state and federal policies affecting spending growth include reductions in provider payment updates and Medicare Advantage payment rates; new value-based purchasing reforms; increased program integrity efforts; state Medicaid cost containment efforts; shifts in coverage to public programs; and changes in private insurance benefit design that place a greater emphasis on enrollee cost sharing.<sup>3</sup> Below, we present data on current trends in national health care spending through 2015 (where possible) and provide more detailed data on trends in Medicare and the private insurance market.

## Current Trends in Health Care Spending Growth

Subsequent to 2013, the United States experienced substantial gains in health insurance coverage due to implementation of the major coverage provisions of the ACA.<sup>4</sup> During the initial year of operations of the Health Insurance Marketplaces in 2014, growth in national health care expenditures per person remained modest by historical standards at 4.3 percent (see Figure 1).<sup>5</sup>

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<sup>1</sup> Andre Chappel, Arpit Misra and Steven Sheingold, *Medicare's Bending Cost Curve* (Washington, D.C.: Office of the Assistant Secretary for Planning & Evaluation, U.S. Dept. of Health & Human Services, 28 July 2014) <<http://tinyurl.com/on86pro>>.

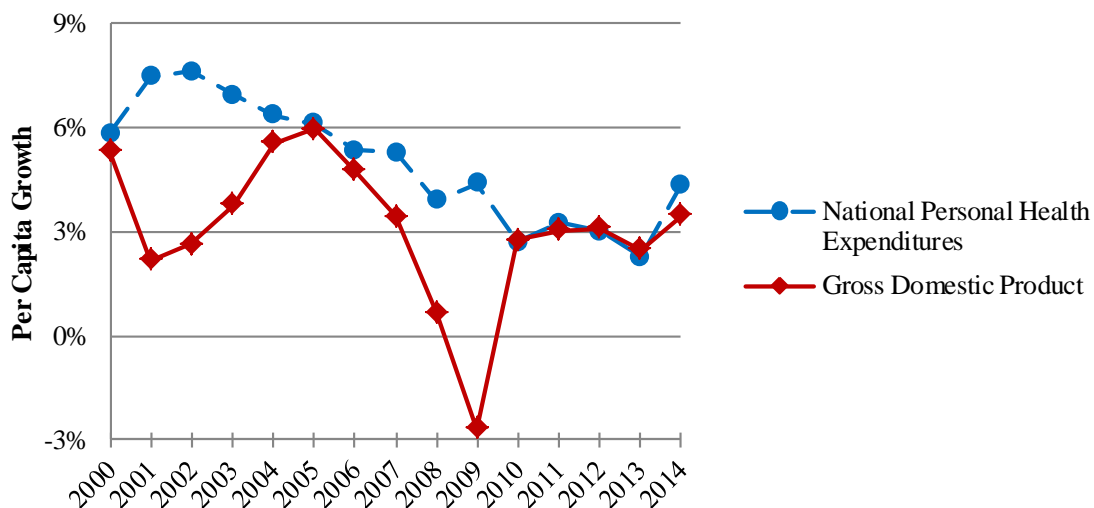
<sup>2</sup> Although the total spending growth rate was 3.1 percent in 2013, we focus most of our analyses on per enrollee growth, since total spending is affected by growth in enrollment. For instance, although total Medicaid spending on personal health care expenditures in 2014 grew by 9.1 percent reflecting expansions in coverage stemming from the Affordable Care Act's (ACA's) coverage expansions, spending on a per enrollee basis declined by 3.6 percent.<sup>2</sup>

<sup>3</sup> John Holahan and Stacey McMorro, *Has Faster Health Care Spending Growth Returned?* (Washington, DC: Robert Wood Johnson Foundation and the Urban Institute, August 2015) <<http://tinyurl.com/nqbxld>>; Alice Chen and Dana Goldman, 'Health Care Spending: Historical Trends and New Directions', *NBER Working Paper Series*, Working Paper 21501 (2015) <<http://www.nber.org/papers/w21501>>; Mary K. Catlin, John A. Poisal and Cathy A. Cowan, 'Out-Of-Pocket Health Care Expenditures, By Insurance Status, 2007-10', *Health Affairs*, 34.1 (2015), 111-16; Chapin White, *Medicare's Role in the Recent Health Care Spending Slowdown* (Washington, DC: RAND Corporation, January 2015) <<http://tinyurl.com/ko6vprh>>; David Dranove, Craig Garthwaite and Christopher Ody, 'Health Spending Slowdown Is Mostly Due To Economic Factors, Not Structural Change In The Health Care Sector', *Health Affairs*, 33.8 (2014), 1399-1406; Chappel, Misra and Sheingold.

<sup>4</sup> *Health Insurance Coverage and the Affordable Care Act* (Washington, DC: Office of the Assistant Secretary for Planning & Evaluation, U.S. Dept. of Health & Human Services, 22 September 2015) <<http://tinyurl.com/zp7dnwf>>.

<sup>5</sup> Growth rates calculations are not adjusted for changes in the age distribution of the US population over time. As described on page 161 of the 2014 Economic Report of the President (<http://tinyurl.com/ho6ptmz>), the Council of Economic Advisors estimates that aging of the US population added only 0.8 percent to annual growth in health care spending between 2010 and 2013.

**Figure 1.**  
**Per Capita Annual Spending Growth Rates,**  
**National Personal Health Care Expenditures, 2000-2014**



**Data Sources:** 2000-2014 data from CMS National Health Expenditure Accounts.

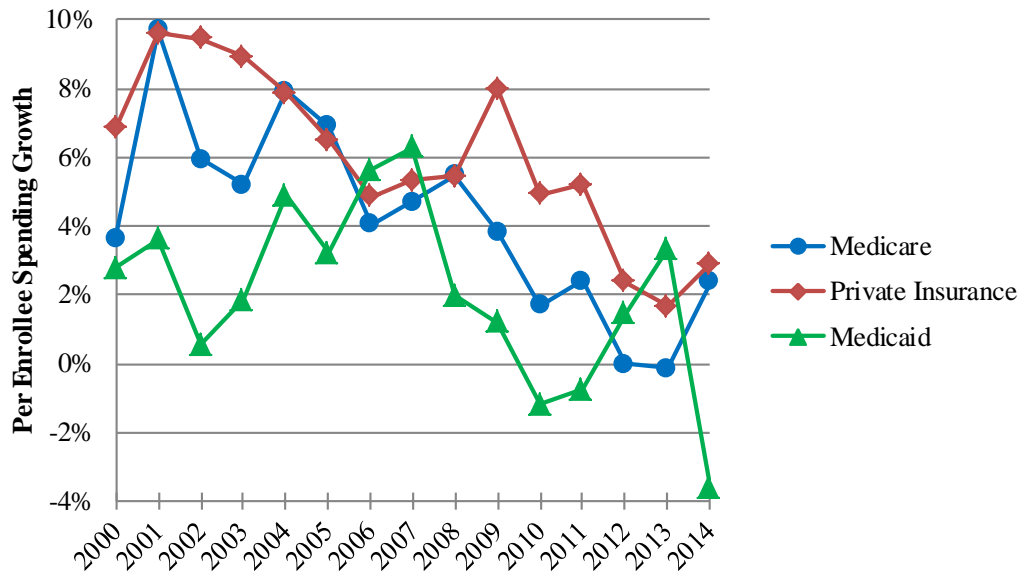
Figure 2 compares per enrollee spending growth for Medicare, private insurance, and Medicaid. Spending per enrollee increased modestly for both Medicare (2.4 percent) and the private insurance market (2.9 percent) in 2014, and declined 3.6 percent for Medicaid. The difference between national spending growth per person in 2014 (4.3 percent) and these payer-specific spending growth rates indicates that the recent insurance expansions made a meaningful contribution to growth in national health care spending by moving people from being uninsured to gaining insurance coverage. As the uninsured and previously underinsured gained quality health insurance coverage and therefore greater access to care, their health expenditures increased as expected. These expenditures may reflect, in part, pent-up demand that will moderate over time.<sup>6</sup> An important secondary contributor to spending growth has been the introduction of new specialty drugs, especially those used to treat Hepatitis C, as discussed in detail below.<sup>7</sup> Setting aside these factors, the underlying growth in national health care would have likely remained close to the historical lows seen in prior years.<sup>8</sup>

<sup>6</sup> Nigel Lo and others, 'Increased Service Use Following Medicaid Expansion Is Mostly Temporary: Evidence from California's Low Income Health Program', *Policy Brief (UCLA Center for Health Policy Research)*, 2014, 1-8; Rachel Gold and others, 'Estimating Demand for Care After a Medicaid Expansion: Lessons From Oregon', *The Journal of Ambulatory Care Management*, 37.4 (2014), 282-92.

<sup>7</sup> IMS Institute for Health care Informatics, 'Medicine Use and Shifting Costs of Health care: A Review of the Use of Medicines in the U.S. in 2013' (presented at the Briefing to ASPE and CMS, Washington, D.C., 2014).

<sup>8</sup> Holahan and McMorrow.

**Figure 2**  
**Per Enrollee Annual Spending Growth Rates,**  
**Medicare, Private Insurance, and Medicaid Personal Health care Expenditures**



**Data sources:** 2000-2014 data from CMS National Health Expenditure Accounts.

### ***Trends in Medicare Spending:***

Reduced rates of spending growth in recent years have translated into substantial reductions in expenditures for Medicare.<sup>9</sup> Updating prior estimates through 2014, Medicare spent \$473.1 billion less on personal health care expenditures between 2009 and 2014 than what would have been spent if the 2000-2008 average growth rate had continued through 2014 (see Table 1). Using data from the Treasury Department on Medicare benefit outlays in 2015, we estimate that per enrollee spending growth will continue to be low at around 1 percent<sup>10</sup>, leading to a cumulative reduction in spending of approximately \$648.6 billion between 2009 and 2015. To put this in context, this reduction in spending represents an amount that is greater than total Medicare spending on personal health expenditures in 2015 (see Table 2).

Figure 3 displays per enrollee spending growth for the Traditional Medicare fee-for-service program and the Medicare program as a whole (including both Traditional Medicare and Medicare Advantage). Both trend lines exhibit general declines in spending growth between 2009 and 2012 with per enrollee spending growth remaining below 3 percent since 2010.

<sup>9</sup> *Medicare Spending Growth Since 2009* (Washington, DC: Office of the Assistant Secretary for Planning & Evaluation, U.S. Dept. of Health & Human Services, 15 April 2015) <<http://tinyurl.com/ozao9mu>>.

<sup>10</sup> This estimate assumes that reconciliation payments made in 2016 to Part D plans for calendar year 2015 plan spending will be the same as those made in 2015 for calendar year 2014 plan spending. This assumption is based on projections from the CMS Office of the Actuary that prescription drug spending growth will slow in 2015.

**Table 1.**  
**Accumulated Difference in Medicare Spending between 2009 and 2014**

<b>Year</b>	<b>Total Medicare Spending (2009-2014)</b>	<b>Total Medicare Spending for 2009-2014 Based on 2000-2008</b>	<b>Difference for Total Medicare</b>	<b>Difference for Traditional Medicare</b>	<b>Difference for Medicare Advantage</b>
2009	\$470.3 B	\$479.9 B	-\$9.6 B	-\$3.5 B	-\$6.1 B
2010	\$489.8 B	\$520.7 B	-\$30.9 B	-\$16.5 B	-\$14.4 B
2011	\$513.4 B	\$564.6 B	-\$51.3 B	-\$34.7 B	-\$16.6 B
2012	\$534.8 B	\$623.3 B	-\$88.5 B	-\$61.8 B	-\$26.7 B
2013	\$551.2 B	\$681.6 B	-\$130.4 B	-\$89.3 B	-\$41.1 B
2014	\$580.7 B	\$743.2 B	-\$162.5 B	-\$97.4 B	-\$65.1 B
<b>Total</b>	<b>\$3,140.1 B</b>	<b>\$3,613.2 B</b>	<b>-\$473.1 B</b>	<b>-\$303.1 B</b>	<b>-\$170.0 B</b>

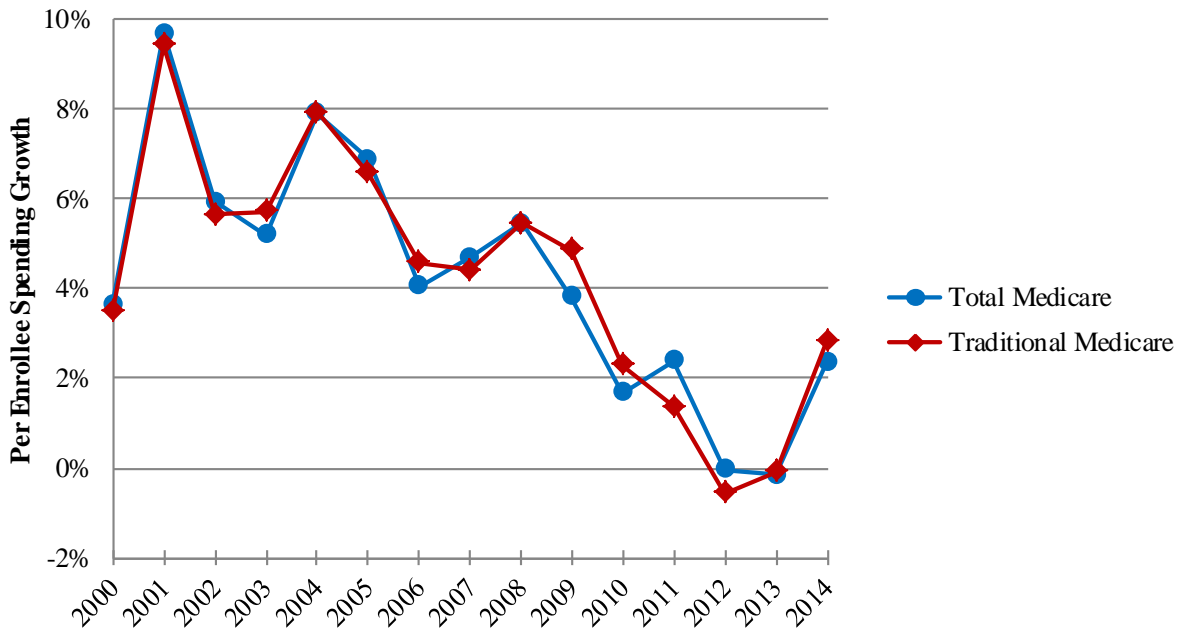
**Data Sources:** 2000-2014 Total Medicare personal health expenditure data from National Health Expenditure Accounts; 2000-2013 Traditional Medicare personal health expenditure data from Master Beneficiary Summary File; 2014 Traditional Medicare personal health expenditure data based on growth rate used to produce 2015 Medicare Trustees Report; Growth for 2006 excludes growth due to introduction of Part D.

**Table 2.**  
**Accumulated Difference in Medicare Spending between 2009 and 2015**

<b>Year</b>	<b>Total Medicare Spending (2009-2014)</b>	<b>Total Medicare Spending for 2009-2014 Based on 2000-2008</b>	<b>Difference for Total Medicare</b>
2009-2014	\$3,140.1 B	\$3,613.2 B	-\$473.1 B
2015	\$637.2 B	\$812.7 B	-\$175.5 B
<b>Total</b>	<b>\$3,777.3 B</b>	<b>\$4,425.9 B</b>	<b>-\$648.6 B</b>

**Data Sources:** See Table 1 for 2009-2014 data; 2015 Total Medicare personal health expenditure growth rate based on Medicare benefit outlays reported in Treasury Monthly Statements for CY 2015.

**Figure 3**  
**Per Enrollee Annual Spending Growth Rates,**  
**Medicare Personal Health care Expenditures, 2000-2014**

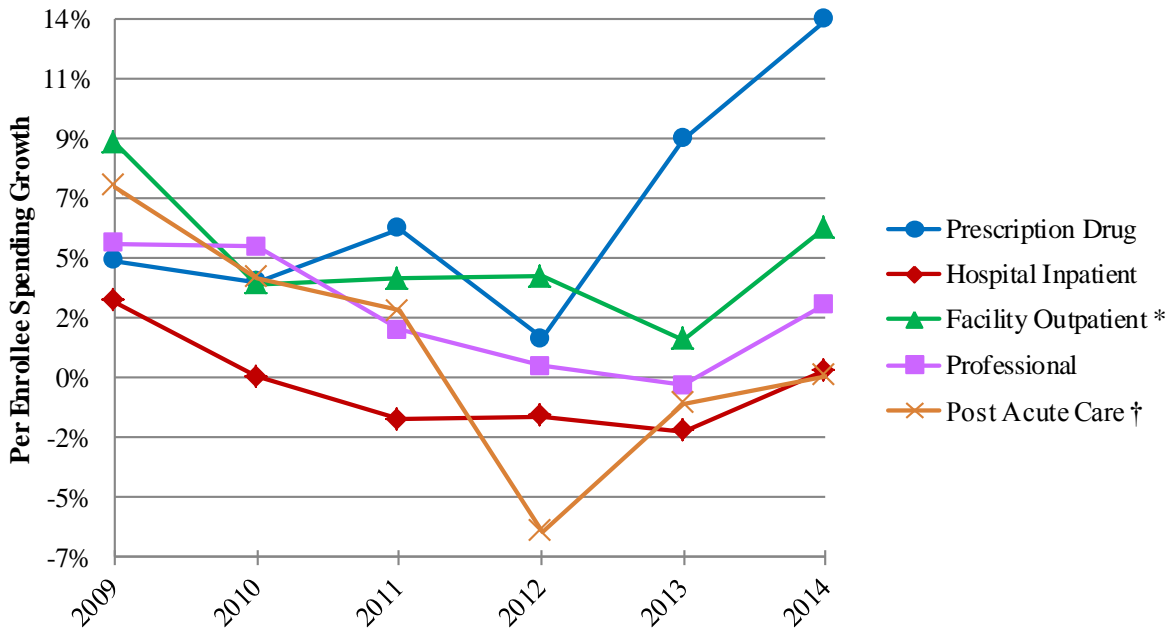


**Data Sources:** 2000-2014 Total Medicare growth rates from CMS National Health Expenditure Accounts; 2000-2013 Traditional Medicare growth rates from CMS Medicare Beneficiary Summary File; 2014 Traditional Medicare growth rate from data used to produce 2015 Medicare Trustees Report.

Figure 4 displays per enrollee spending growth rates for the Traditional Medicare fee-for-service program by service category between 2009 and 2014. All service categories had higher growth rates in 2014 than in prior years. Spending growth on prescription drugs increased substantially in both 2013 (9.1 percent) and 2014 (13.7 percent). Prescription drug spending grew because of the introduction of new specialty drugs, discussed in detail below. Both hospital inpatient and post-acute care spending remained flat in 2014. Higher growth rates observed for outpatient facilities and professional services may be reflective of an ongoing shift in the site of care for various conditions from inpatient to outpatient settings. This trend may also have been driven in part by various payment policies such as the Hospital Readmissions Reduction program.



**Figure 4**  
**Per Enrollee Annual Spending Growth Rates by Service Category,**  
**Medicare Personal Health care Expenditures, 2009-2014**



**Data Sources:** 2009-2013 data from CMS Medicare Beneficiary Summary File;  
 2014 data from ASPE analysis of Medicare claims data.

\* Includes hospital outpatient, ambulatory surgical center, imaging, and end-stage renal disease spending.  
 † Includes skilled nursing facility, hospice, and home health spending.

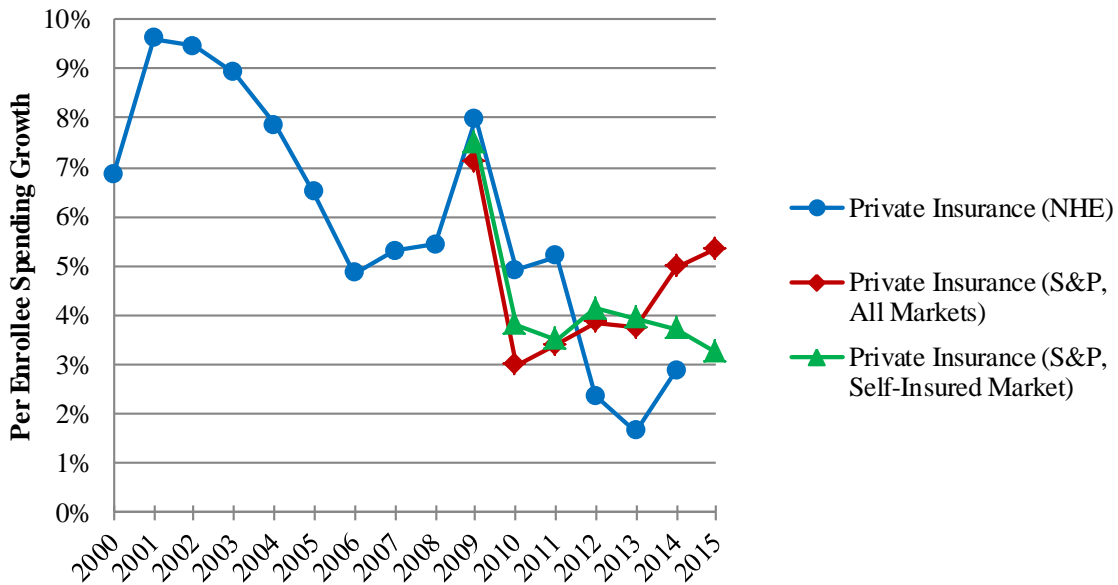
**Private Insurance:**

In Figure 5, we display per enrollee spending growth for private insurance using the Centers for Medicare and Medicaid Services’ (CMS) National Health Expenditure (NHE) data; we also display trends from Standard and Poor’s (S&P) Health Care Claims Indices, which include data on approximately 57 million privately insured individuals in 2015. The NHE and S&P All Markets data series show that per-enrollee spending in private insurance ticked up modestly in 2014, although growth remained low in historical terms. As with Medicare, rapid growth in prescription drug spending was an important contributor, as shown in Figure 6.

It is important to note that this modest uptick in per enrollee spending growth in 2014 likely does not reflect an increase in the underlying rate of growth of private-sector health care costs. Notably, the 2014 coverage year was the first year in which the Affordable Care Act’s most important reforms to the individual (and small group) markets were in place. These reforms increased the comprehensiveness of benefit packages available to consumers and eliminated barriers to coverage, such as pre-existing condition exclusions. By increasing the quality of the coverage held by many individuals with private insurance, these reforms increased access to care and likely created temporary upward pressure on per enrollee spending growth. Indeed, Figure 5 shows that when using the S&P data to focus solely on self-insured employer plans, which were not significantly affected by these reforms, per enrollee spending growth actually fell in 2014 and appears to have fallen further through September 2015.

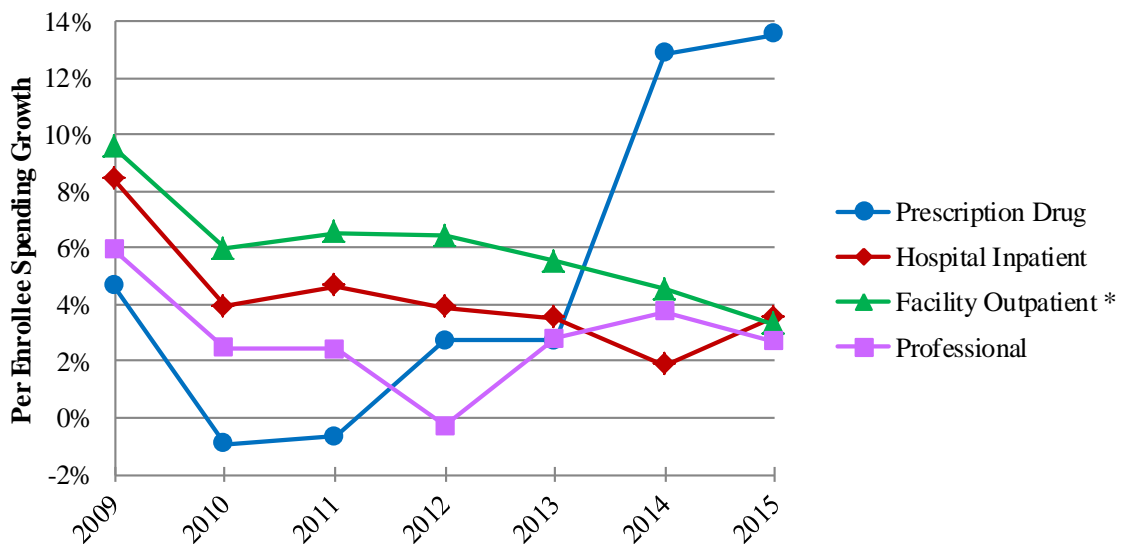


**Figure 5**  
**Total per Enrollee Annual Spending Growth Rates,**  
**Private Insurance Personal Health care Expenditures, 2000-2015**



**Data Sources:** 2000-2014 Private Insurance (NHE) data from CMS National Health Expenditure Accounts; 2015 Private Insurance (NHE) estimate from CMS National Health Expenditures Projections; Standard and Poor’s Health Care Claims Indices annualized through September 2015.

**Figure 6**  
**Per Enrollee Annual Spending Growth Rates by Service Category,**  
**Private Insurance Personal Health care Expenditures, 2009-2015**



**Data source:** Standard and Poor’s Health care Claims Indices, annualized through September 2015.

\* Includes hospital-owned outpatient facilities and independently operated outpatient facilities (e.g., ambulatory surgical centers, imaging facilities, urgent care facilities).

### ***Contribution of Specialty Drugs to Health Care Spending Growth:***

A primary contributor to spending growth in 2014 was specialty drugs, particularly drugs used to treat Hepatitis C. For Medicare Part D, CMS limits specialty tier medications to those costing at least \$600 per month. However, there is no universally accepted definition of specialty drugs. Such drugs frequently include biologicals and are typically high cost products.<sup>11</sup> Below, we analyze the contribution of two specific classes of drugs used to treat Hepatitis C and hypercholesterolemia.

Four new Hepatitis C drugs entered the market in 2014 that demonstrated extraordinary improvements in outcomes and side effects in clinical trials over previously existing treatment options, showing cure rates exceeding 90 percent.<sup>12</sup> Although subsequent competition among these drugs has resulted in some negotiated discounts off their base price, the first of the new generation of drugs to enter the market carried a price of approximately \$1,000 per pill, or \$84,000 for a full course of treatment.<sup>13</sup> Other specialty drugs, such as those used to treat cancer, can be substantially more costly, but apply to small patient populations. In comparison, approximately 3 million people in the United States were infected with Hepatitis C prior to the introduction of new specialty drugs used to treat this disease.<sup>14</sup> For many of these individuals, these drugs represented the first opportunity to obtain a cure.

Figure 7 displays the impact of these newly introduced Hepatitis C drugs on prescription drug spending in the traditional Medicare fee-for-service program in 2014, estimated to have been \$2.5 billion.<sup>15</sup> The broken line shows that spending growth for Part D of Medicare (the drug benefit) in 2014 would have been 9.2 percent in the absence of these drugs, or 4.5 percentage points lower than actual growth (13.7 percent). It should be noted that even a 9.2 percent growth rate (that is, the growth rate excluding Hepatitis C specialty drugs) in prescription drug spending is considerably higher than the average in recent years.

<sup>11</sup> *Medicare Part D Specialty Tier* (Baltimore, MD: Centers for Medicare & Medicaid Services, U.S. Dept. of Health & Human Services, 7 April 2015) <<http://tinyurl.com/ju9rw6a>>; *Specialty Drugs and Health Care Costs* (Philadelphia, PA: The Pew Charitable Trusts, 16 November 2015) <<http://pew.org/1MRtwwM>>; Ian Spatz and others, 'Specialty Pharmaceuticals', *Health Affairs - Health Policy Briefs*, 2013 <<http://tinyurl.com/z8agr2k>>.

<sup>12</sup> T. Jake Liang and Marc G. Ghany, 'Therapy of Hepatitis C — Back to the Future', *New England Journal of Medicine*, 370.21 (2014), 2043–47.

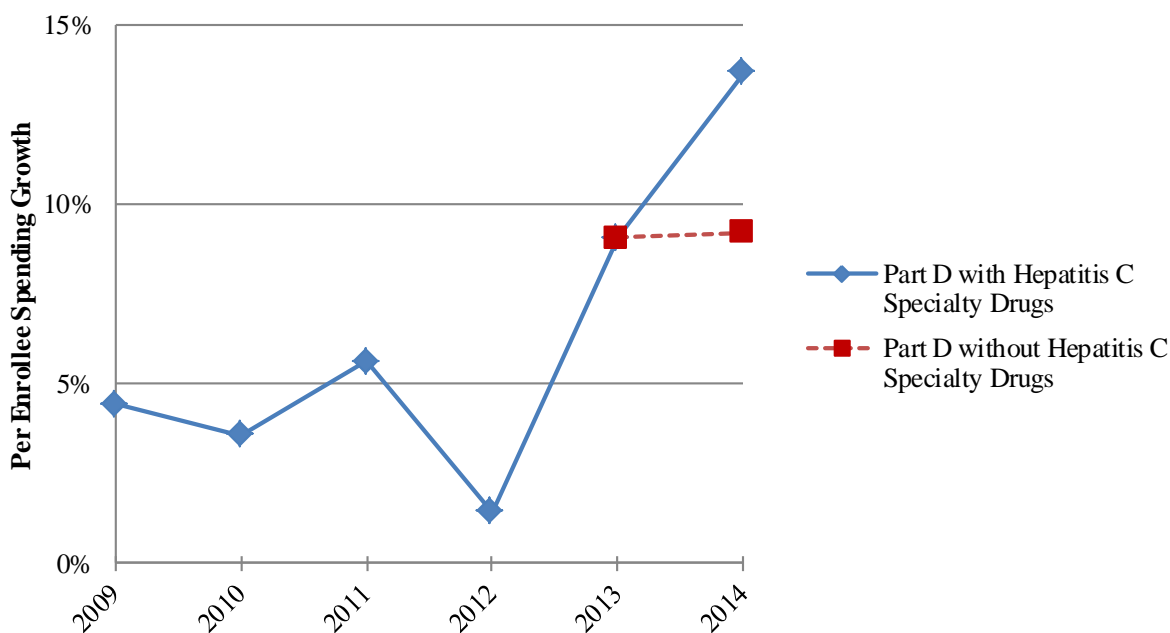
<sup>13</sup> After the Dec 2013 FDA approval of Sovaldi (originally costing \$84,000 for a standard 12-week course of treatment), Gilead Sciences obtained FDA approval in Oct 2014 for Harvoni, another Hepatitis C drug that is even more expensive, with a list price of about \$95,000 for a 12-week course of treatment without a discount. In 2015, Gilead announced that it would give an average discount of 46 percent off the list prices of its two drugs. The benefits of these drugs are undeniable as they can treat the infection in eight to 24 weeks, depending on the patient population.

<http://tinyurl.com/oh8rd2m>

<sup>14</sup> *Hepatitis C: The Facts* (Washington, DC: Office of Population Affairs, U.S. Dept. of Health & Human Services, 19 October 2012) <<http://tinyurl.com/hcmhuhz>>; *Hepatitis C FAQs for the Public* (Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept. of Health & Human Services, 15 October 2015) <<http://tinyurl.com/qd7xog3>>.

<sup>15</sup> ASPE analysis of Medicare Part D claims data for calendar year 2014. The hepatitis agents used in the estimate include: Harvoni, Incivek, Olysio, Sovaldi, Victrelis, and Viekira Pak. Incivek and Victrelis were introduced into the market in 2011. Olysio and Sovaldi arrived in 2013. Harvoni and Viekira Pak arrived in 2014.

**Figure 7**  
**Per Enrollee Annual Spending Growth Rates for Part D with and without Hepatitis C Specialty Drugs\* Included in 2014**



**Data Sources:** 2009-2013 data from CMS Medicare Beneficiary Summary File; 2014 data from ASPE analysis of Medicare claims data.

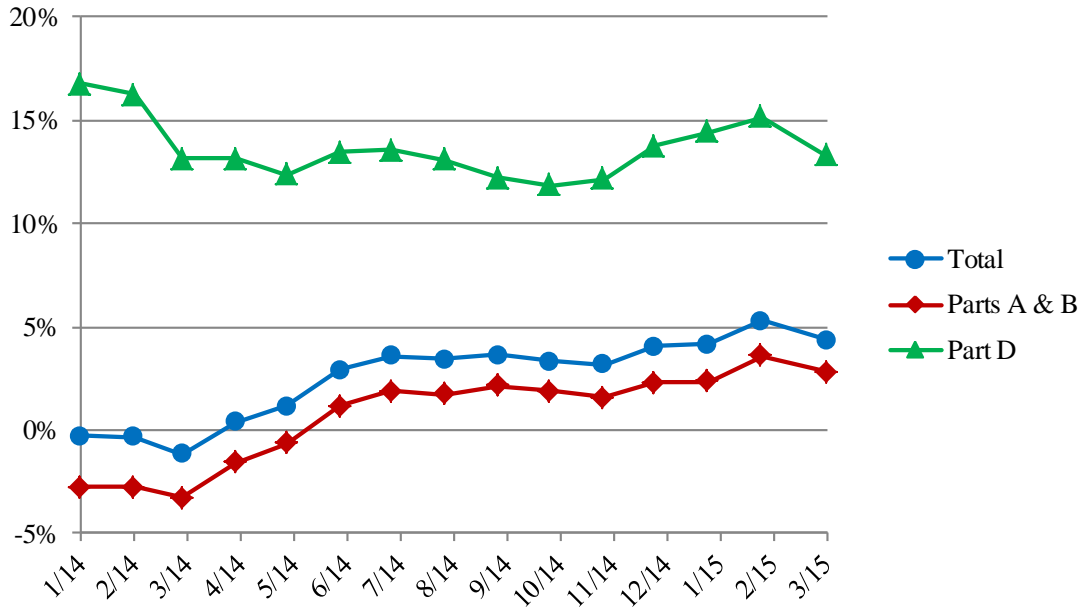
\* Includes drugs with brand names Harvoni, Incivek, Olysio, Sovaldi, Victrelis, and Viekira Pak

The long run budgetary impacts of these new drugs relative to pre-existing treatment options are hard to ascertain. The benefits of these new drugs are undeniable as they can treat an infection in eight to twenty-four weeks, depending on the patient population. Studies indicate that curing patients decreases the risk of liver cancer, liver failure, or the need for a liver transplant by about 80 percent.<sup>16</sup>

Figure 8 displays 3-month moving average year-over-year growth rates in monthly aggregate incurred expenditures for beneficiaries in the traditional Medicare fee-for-service program on Parts A, B, and D in 2014 and the first three months of 2015. This chart shows that while year-over-year spending growth on prescription drugs was relatively high throughout this time period, this only had a modest effect on growth in total expenditures. While prescription drug spending accounted for the majority of per capita spending growth (56 percent) in 2014, the increase in per enrollee drug spending in 2014 relative to 2013 constituted only around 2 percent of total Medicare spending in 2014. Similar to Medicare, prescription drug spending growth accounted for a substantial portion (47 percent) of total per capita spending growth in private insurance in 2014, but the increase in per enrollee drug spending in 2014 relative to 2013 constituted around 2 percent of spending per enrollee.

<sup>16</sup> T. Jake Liang and Marc G. Ghany, 'Current and Future Therapies for Hepatitis C Virus Infection', *New England Journal of Medicine*, 368.20 (2013), 1907–17.

**Figure 8**  
**3-Month Moving Average of Year-over-Year Growth in Monthly Aggregate Expenditures**  
**by Medicare Fee-for-Service Beneficiaries for Parts A, B, and D,**  
**January 2014 to March 2015**



**Data Source:** ASPE analysis of Medicare claims data.

A more recent example highlighting concerns regarding the price of specialty drugs is the new anti-cholesterol drugs called PCSK-9 inhibitors. Until the introduction of these drugs, the primary drug treatment option for high cholesterol has been a class of products known as statins that are now available as generics. According to the Centers for Disease Control, 28 percent of adults over the age of 40 (equating to approximately 42 million adults in 2014) report using cholesterol-lowering medications.<sup>17</sup> Although the annual cost of the first PCSK-9 inhibitor to come onto the market was \$14,600 per year, these drugs are not curative and are therefore used to help manage a chronic condition over a period of time. For instance, even assuming a highly discounted price of \$8,000, 20 years of treatment would cost \$160,000.<sup>18</sup> Although approved to treat patients with certain conditions who have very high levels of low-density lipoprotein cholesterol in concert with the maximum tolerated dosage of statins, many patients experience a side effect on statins that leads them to stop taking these medications. Hence, it is possible that a number of patients will end up solely on PCSK-9 treatment, if these drugs prove to be better

<sup>17</sup> Qiuping Gu and others, *Prescription Cholesterol-Lowering Medication Use in Adults Aged 40 and over: United States, 2003-2012* (Washington, DC: Centers for Disease Control and Prevention, US Dept. of Health & Human Services, December 2014) <<http://www.cdc.gov/nchs/data/databriefs/db177.htm>>; Population estimate generated using United States Census Bureau American FactFinder.

<sup>18</sup> We use 20 years as the average life of a drug patent posted by the FDA for illustrative purposes. The net present value over 20-years assuming a 4 percent inflation and a similar discount rate yields the same result.

tolerated by patients.<sup>19</sup> While it difficult to estimate precisely how many patients would ultimately be treated with PCSK-9 and information is not yet available regarding the size of discounts that may be negotiated as multiple alternatives come onto the market, using assumptions we believe to be reasonable, we estimate that spending on PCSK-9 inhibitors could exceed \$100 billion per year.<sup>20</sup> To put this dollar amount in perspective, spending on statins was approximately \$24.2 billion in 2014,<sup>21</sup> while total spending on prescription drugs was \$297.7 billion<sup>22</sup> in 2014.

<sup>19</sup> Patrick M. Moriarty and others, 'Efficacy and Safety of Alirocumab, a Monoclonal Antibody to PCSK9, in Statin-Intolerant Patients: Design and Rationale of ODYSSEY ALTERNATIVE, a Randomized Phase 3 Trial', *Journal of Clinical Lipidology*, 8.6 (2014), 554–61.

<sup>20</sup> ASPE estimates total annual spending as the product of annual cost per user times the number potential users.

#### Annual Cost per User:

By September 2015, FDA had approved two PCSK-9 drugs for patients with hard-to-treat levels of low-density lipoprotein cholesterol. Sanofi and Regeneron's Praluent costs about \$14,600 a year, and Amgen's Repatha costs about \$14,100 a year. We also assume that manufacturers will offer a discount for three reasons: (1) to respond to political and payers' pressure for favorable pricing, (2) to maintain market power from potential entrants, and (3) to follow a precedent by manufacturers of Hepatitis C drugs when Gilead announced in 2015 that it would give an average discount of 46 percent off the list prices of its two drugs, Sovaldi and Harvoni (<http://tinyurl.com/ppjnu2d>). Since market competition is more intense in the Hepatitis C market (Gilead's Sovaldi and Harvoni are facing competition from AbbVie's Viekira Pak and Bristol-Myers Squibb's Daklinza), ASPE assumes a lower discount of 35 percent to reflect lower competition in the PCSK-9 market. The average annual price of a PCSK-9 treatment after discount is therefore about \$9,500 [(\$14,600 + \$14,100) x (1 - 0.35) = \$9,490]

#### Number Of Potential Users and their Costs:

The target population includes 4 groups following the outline by William Shrank, Alan Lotvin, Surya Singh, and Troyen Brennan in their February 17, 2015 Health Affairs Blog: <http://tinyurl.com/oz5doq8>.

First, the number of people with familial hypercholesterolemia is estimated to be 620 thousand. Hence, their annual cost is about \$5.9 billion [\$9,500 x 620,000 = \$5.89 billion].

Second, the number of people with LDL > 190 (generally not helped by statins) is about one million. Hence, their annual cost is \$9.5 billion [\$9,500 x 1,000,000 = \$9.5 billion].

Third, the number of hypercholesterolemia and statin intolerant who would potentially switch out of statins to PCSK-9 is estimated to be about 2.7 million people. We estimated that there are about 27 million regular statin users including the added 13 million potentially eligible based on the new Guidelines (Pencina M.J., et al; April 10, 2014; Application of New Cholesterol Guidelines; NEJM 370:15). Since statin intolerance is approximately 5 percent to 15 percent, applying an average of 10 percent to the 27 million statin users gives us the 2.7 million. For this group, the added cost (PCSK-9 net of their current statins cost – estimated to be \$657 per person per year averaging branded and generic statins) is \$23.9 billion.

Adding the cost of the 3 target groups above gives us a lower-bound estimate of \$40 billion a year.

Fourth, the target population may also include certain people with a history of coronary disease. Assuming that 50 percent of 15 million having previous cardiac event will switch to the new drugs, the added cost net of their current statin cost would be \$66 billion.

Based on these assumptions, the total cost of PCSK-9 drugs is estimated to be \$106 billion. ASPE also estimated that Medicare would spend about \$27 billion a year on these new drugs based on the Medicare share of dispensed drugs of 26 percent estimated by IMS (IMS, 2015 April, Medicines Use and Spending Shifts in the U.S. in 2014).

<sup>21</sup> 2014 statin spending estimate based on 2011 statin spending estimate (\$21.6 billion) in AHRQ Statistical Brief #458: *Trends in Statin Therapy among Adults (Age ≥ 18), United States, 2000 to 2011*, multiplied by the Medicare Part D per beneficiary spending growth factor between 2011 and 2014 equal to 1.12, as reported in the 2015 Medicare Trustees Report.

<sup>22</sup> Total prescription drug spending estimate from CMS National Health Expenditure Accounts.

**Conclusion**

During the initial two years of implementing the ACA's major insurance coverage expansion provisions, growth in national health expenditures has remained modest, especially when considered on a per person basis within payer categories. The ACA's coverage expansions were posited to increase national health care expenditures as previously uninsured Americans gained access to quality health coverage. The coverage expansions did drive up spending growth moderately. However, current trends suggest that the increase in spending growth from these changes may well be transitory. An important secondary contributor to spending growth has been the introduction of new specialty drugs, some demonstrating significant improvements in treatment outcomes. It will likely take several more years to fully understand how changes in the prescription drug market will affect spending growth in that sector and more broadly.