



January 2016

Advising Congress on Medicaid and CHIP Policy

# **Medicaid Spending for Prescription Drugs**

Prescription drug spending was a key driver of the increase in national health spending from 2013 to 2014. After many years of low to moderate growth, CMS found that overall prescription drug spending increased 12.2 percent in 2014, compared to a 4.6 percent increase for all other health expenditures (Martin et. al. 2016).<sup>1</sup> Moreover, the CMS estimates were even higher for Medicaid—the increase in Medicaid prescription drug spending was 24.3 percent in 2014 (Martin et. al. 2016). This large increase in spending was driven in part by both coverage expansions under the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) as well as the introduction of innovative new specialty drugs to treat conditions such as hepatitis C (Keehan et. al. 2015). The large increase in drug spending in 2014 creates a challenge for policymakers; in part due to their receipt of rebates from manufacturers, states have few tools for addressing spending growth.

It is important to note this trend in its broader context. First, total Medicaid spending for outpatient prescription drugs reflects the amount paid to pharmacies as well as any rebates the program receives from drug manufacturers. In fiscal year (FY) 2014, Medicaid spent approximately \$42 billion on prescription drugs and collected about \$20 billion in rebates, for net drug spending of \$22 billion (Figure 2). Net spending for outpatient drugs accounted for about 5 percent of total Medicaid benefit spending.

This issue brief presents recent data on Medicaid prescription drug expenditures and rebates. It begins with a brief overview of Medicaid rebate policies. It then presents historical drug spending and rebate amounts in fee for service (FFS) and managed care and analyzes some of the key components contributing to recent trends in drug spending. A description of the available data sources for Medicaid drug utilization, spending, and rebate data can be found in the appendix.

# **Medicaid Drug Rebate Policy**

Under the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508), Congress created the Medicaid Drug Rebate Program to ensure that Medicaid receives a net price that is consistent with the lowest or best price for which manufacturers sold the drug. In order for states to receive federal funding for use of prescription drugs, the manufacturer must enter into a Medicaid drug rebate agreement with HHS (§1927(a)(1) of the Social Security Act (the Act)). In exchange, state Medicaid programs generally must cover a participating manufacturer's drugs although they may limit the use of some drugs through preferred drug lists (PDLs), prior authorization, or quantity limits.

The federal Medicaid rebate is based on a specific formula defined in statute. States collect rebates each quarter from manufacturers through a process that is separate from payments made by states to pharmacies (§1927(c) of the Act). This means that every state receives the same federal rebate amount for each unit of a particular drug regardless of how much it pays the pharmacy. In addition to the federally

Medicaid and CHIP Payment and Access Commission

1800 M Street NW Suite 650 South Washington, DC 20036 www.macpac.gov 202-350-2000 202-273-2452 mandated rebates, as of March 2015, 44 states and District of Columbia negotiated supplemental rebates with drug manufacturers on top of the federal rebates.<sup>2</sup>

For more detailed information on Medicaid payment to pharmacies and the Medicaid Drug Rebate Program, please refer to MACPAC's issue brief on Medicaid payment for outpatient prescription drugs.<sup>3</sup>

# **Medicaid Drug Spending Trends**

Total Medicaid spending reflects the number of people enrolled multiplied by the average spending per person. The average spending per person reflects the enrollment mix (the mix of conditions being treated and the distribution of drugs across different therapeutic classes), the volume and intensity of services (the average number of drugs taken per person and the mix of brand and generic drugs), and the prices paid for those services (both the price paid to the pharmacy to purchase the drug as well as any manufacturer rebates obtained for those drugs).

The analyses presented in this issue brief use data from the Form CMS-64 financial management report and Medicaid drug rebate utilization reports that states submit to CMS. The data are as reported by the states and may reflect differences in how states report their data. For example, some states have managed care drug spending based on their drug rebate utilization data report but claim all of their Medicaid drug rebates in the FFS category on the CMS-64 financial management report. In these states, the amount of FFS rebates would be overstated and the managed care rebates would be understated. For more detail on the data sources used in these analyses, see the appendix.

## Fee-for-service spending

Medicaid FFS prescription drug expenditures with rebate collections (net expenditures) and without rebate collections (gross expenditures) increased from FYs 2002 to 2010, with the exception of the shift in 2006 of drug spending for individuals dually eligible for Medicare and Medicaid to Medicare Part D (Figure 1). Although Medicaid is no longer directly responsible for paying for most prescription drugs used by dually eligible beneficiaries, states still pay for part of the cost of their Part D coverage through monthly phased-down state contributions—commonly referred to as clawback payments—that offset some of Medicare's spending for these individuals.<sup>4</sup> Net FFS prescription drug expenditures dropped from \$30.7 billion in FY 2005 (pre-Part D) to \$16.7 billion in FY 2006 (post-Part D). From FYs 2007 to 2010, rebates increased and slowed net FFS prescription drug expenditures significantly. Net expenditures increased 2 percent annually even though gross FFS expenditures have increased 7 percent annually.

Starting in FY 2011, gross and net FFS expenditures began to decrease due to ACA provisions extending the federal Medicaid drug rebates to drugs paid for by Medicaid managed care plans. Many states that had previously carved out drugs from their managed care contracts in order to obtain rebates began to include drugs in the managed care benefit beginning in FY 2011. Additionally, many states have either expanded managed care to new populations or implemented new risk-based managed care programs, increasing the proportion of the Medicaid population enrolled in risk-based managed care and shifting FFS pharmacy

Medicaid and CHIP Payment and Access Commission www.macpac.gov

spending to managed care. Net FFS prescription drug spending decreased even more as a result of the ACA increase in drug rebates under the federal drug rebate program.

However, net FFS expenditures began to increase again in FY 2014 due in part to the eligibility expansions under the ACA as well as new, high-cost drugs coming onto the market. Net FFS prescription drug expenditures were approximately \$8 billion for FY 2014, a 22 percent increase over the prior year. This amount includes \$21.4 billion in gross drug expenditures and an offset of \$13.3 billion in drug rebate collections.





**Notes:** FFS is fee for service. ACA is Patient Protection and Affordable Care Act. Part D refers to the Medicare Part D program. Includes federal and state funds. Gross expenditures are before the application of rebates. Net expenditures are after the application of federal and supplemental rebates. Does not include Medicare Part D clawback payments.

Source: MACPAC analysis of FYs 2002–2014 CMS-64 FMR net expenditure data as reported by states as of March 2015.

## Managed care spending

As mentioned previously, states have both carved prescription drugs into managed care and expanded the use of managed care in recent years, resulting in the steady increase of gross managed care drug spending from \$5.1 billion in FY 2011 to \$19.7 billion in FY 2014 (Figure 2). During this time period, managed care drug spending grew from 14 percent of total Medicaid drug spending to almost half (47

percent). Taking into account the rebate amounts reported on the CMS-64, net managed care drug spending increased about 19 percent in FY 2014, similar to net FFS spending.



FIGURE 2. Gross and Net Medicaid Prescription Drug Expenditures, FYs 2011-2014 (billions)

**Notes**: Includes federal and state funds. Gross expenditures are before the application of rebates. Hawaii has been excluded due to anomalous data. Managed care expenditures in FY 2011 may be underreported as states began to collect utilization data from managed care plans. Virginia data were corrected for an apparent error in fee-for-service spending in the second quarter of 2014. Does not include Medicare Part D clawback payments.

**Source**: MACPAC analysis of FYs 2011–2014 data as reported by the states. Spending amounts comes from Medicaid drug rebate utilization data, as of September 2015, and rebate amounts come from CMS-64 data, as of February 2015.

## Total spending

Both total gross and net Medicaid spending on prescription drugs remained fairly constant from FYs 2011–2013, and even decreased slightly in FY 2013 (Figure 2). However, in FY 2014, both gross and net spending increased significantly, with net spending increasing about 19 percent over the prior year.

#### •••

Overall, Medicaid rebates as a percentage of gross spending have remained fairly consistent, with rebates ranging from 44–49 percent of gross drug spending over this four-year period.

## **Components of Drug Spending**

With rebates remaining fairly consistent as a percentage of gross drug spending in FY 2014, much of the recent change in net drug spending is attributable to changes in gross drug spending. This section analyzes some of the components driving the annual changes in gross drug spending, including the Medicaid expansion, the proportion of brand and generic drugs used, and the use of high-cost drugs. These analyses are for gross drug spending and do not include any manufacturer rebates. Additionally, we use calendar years instead of fiscal years to better capture the effect of the Medicaid expansion going into effect on January 1, 2014 and to capture more of the impact of new high-priced hepatitis C drugs that were first introduced in late 2013.

## Medicaid expansion

Gross Medicaid drug spending rose between calendar years (CYs) 2013–2014, with a steeper rise in states that expanded Medicaid eligibility to adults under the ACA. Gross drug spending increased 24.6 percent in expansion states compared to 14.1 percent in non-expansion states (Table 1). This 10 percentage-point difference provides a sense of the impact of the expansion in eligibility; however, the data do not permit us to know how much of the annual increase in gross spending is due solely to the Medicaid expansion.

# **Table 1.** Gross Prescription Drug Expenditures in Medicaid Expansion vs. Non-Expansion States, CYs2013–2014 (billions)

State grouping	CY 2013 gross drug spending (billions)	CY 2014 gross drug spending (billions)	Percent change
Expansion	\$19.4	\$24.2	24.6%
Non-expansion	18.3	20.8	14.1

**Notes**: Includes federal and state funds. Gross expenditures are before the application of rebates. Expansion states include those that expanded as of January 2014; those that expanded later are not classified as expansion states. Virginia data were corrected for an apparent error in fee-for-service spending in the second quarter of 2014. Does not include Medicare Part D clawback payments. **Source**: MACPAC analysis of CYs 2011–2014 Medicaid drug rebate utilization data reported by the states as of September 2015.

## Brand and generic drug mix

A shift to generic drugs helped keep total spending relatively flat from CY 2011 to CY 2013 even as the volume of drugs dispensed increased (Tables 2 and 3). As the average generic drug is significantly cheaper than the average brand drug, an increase in the use of generic drugs can reduce total drug spending. The generic fill rate (i.e., percent of claims that are generic) has steadily increased from 74.2 percent in CY 2011 to 81.1 percent in CY 2014 (Table 2). This shift reflects both a number of brand drugs going off patent

 $\bullet \bullet \bullet$ 

in recent years and state and managed care plan efforts to encourage the use of generic drugs. The steady shift in generic fill rate over the past few years is also reflected in the distribution of spending as the share of spending on brand drugs decreased from about 80 percent in CY 2011 to 77 percent in CY 2014 (Table 3).

Calendar year	Brand drug claims (millions)	Generic drug claims (millions)	Total drug claims (millions)	Percent brand drug of total	Percent generic drug of total
2011	138.4	398.6	537.0	25.8%	74.2%
2012	125.8	433.7	559.5	22.5	77.5
2013	110.7	444.0	554.8	20.0	80.0
2014	113.5	486.4	599.9	18.9	81.1

#### Table 2. Prescription Drug Claims, by Brand vs. Generic Status, CYs 2011-2014

**Notes**: Includes federal and state funds. Gross expenditures are before the application of rebates. To assign brand and generic status, we linked the state drug utilization data to the Medicaid drug product data from CMS using the National Drug Code, the universal product identifier for drugs. Brand and generic status was assigned using the drug category indicator from the drug product file as of the end of the calendar year. Excludes drugs that could not be matched to the drug product data. Virginia data were corrected for an apparent error in feefor-service spending in the second quarter of 2014. Does not include Medicare Part D clawback payments.

Source: MACPAC analysis of CYs 2011–2014 Medicaid drug rebate utilization data as reported by states as of September 2015.

#### Table 3. Gross Prescription Drug Expenditures, by Brand vs. Generic Status, CYs 2011-2014

Calendar year	Brand drug gross spending (billions)	Generic drug gross spending (billions)	Total gross spending (billions)	Percent brand drug of total	Percent generic drug of total
2011	\$30.0	\$7.5	\$37.4	80.1%	19.9%
2012	29.6	8.2	37.8	78.2	21.8
2013	28.7	8.8	37.5	76.6	23.4
2014	34.6	10.3	44.9	77.0	23.0

**Notes**: Includes federal and state funds. Gross expenditures are before the application of rebates. To assign brand and generic status, we linked the state drug utilization data to the Medicaid drug product data from CMS using the National Drug Code, the universal product identifier for drugs. Brand and generic status was assigned using the drug category indicator from the drug product file as of the end of the calendar year. Excludes drugs that could not be matched to the drug product data. Virginia data were corrected for an apparent error in feefor-service spending in the second quarter of 2014. Does not include Medicare Part D clawback payments.

Source: MACPAC analysis of CYs 2011-2014 Medicaid drug rebate utilization data as reported by states as of September 2015.

Despite the shift to generics, total drug spending increased substantially in CY 2014 (Tables 2 and 3). This spending increase reflects both an increase in drug volume and an increase in the average spending per

claim, particularly for brand drugs. The average spending per claim for both brand and generic drugs increased more in CY 2014 than in prior years, with spending per claim for brand drugs increasing 17 percent compared to 7 percent for generic drugs (Table 4).

Year	Gross brand drug spending per claim	Gross generic drug spending per claim	Annual percent change for brand drugs	Annual percent change for generic drugs
2011	\$216.53	\$18.74	_	_
2012	234.87	18.98	8.5%	1.3%
2013	259.61	19.81	10.5	4.4
2014	304.52	21.20	17.3	7.0

#### Table 4. Gross Prescription Drug Spending per Claim, by Brand vs. Generic Status, CYs 2011-2014

**Notes**: Includes federal and state funds. Gross expenditures are before the application of rebates. To assign brand and generic status, we linked the state drug utilization data to the Medicaid drug product data from CMS using the National Drug Code, the universal product identifier for drugs. Brand and generic status was assigned using the drug category indicator from the drug product file as of the end of the calendar year. Virginia data were corrected for an apparent error in fee-for-service spending in the second quarter of 2014. Excludes drugs that could not be matched to the drug product data. Virginia data were corrected for an apparent error in fee-for-service spending in the second quarter of 2014. Does not include Medicare Part D clawback payments.

Source: MACPAC analysis of CYs 2011–2014 Medicaid drug rebate utilization data as of September 2015.

## High-cost specialty drugs

The increase in the average spending per brand drug claim is due in part to the increase in use and price of high-cost specialty drugs. One large, national pharmacy benefit manager (PBM) found that spending on a per-member-per-year (PMPY) basis in their Medicaid population increased 36 percent for specialty drugs compared to 3 percent for traditional, non-specialty drugs, leading to an overall increase in PMPY spending of 10 percent (Express Scripts 2015b).

However, analyzing trends in specialty drug use can be tricky because there is no standard definition of specialty drugs. For example, Medicare Part D defines specialty drugs as those that cost more than \$600 per month while other payers and PBMs have used a threshold of \$1,000 per month and included other criteria such as drugs that treat complex conditions or require special storage, handling, and administration. For the purposes of our analysis, we consider specialty drugs to be those that average over \$1,000 per claim at the National Drug Code (NDC) level. Because a particular drug may have several different NDC codes that reflect different dosages and forms of the drug, this means that we have included some dosages and forms of a particular drug even though the average spending across all variations of the drug may have been below \$1,000 per claim.<sup>5</sup>

In CY 2014, these high-cost drugs accounted for less than 1 percent of claims (0.9 percent) but made up almost one-third (32 percent) of total drug spending (Table 5). Additionally, as these drugs have become a

 $\bullet \bullet \bullet$ 

greater share of all prescriptions filled, the share of spending on these drugs has increased substantially, as they accounted for only 20 percent of total spending in CY 2011.

Calendar year	Drug claims (millions)	Gross spending (billions)	Spending per claim	Percent of total claims	Percent of total spend
2011	3.3	\$7.5	\$2,242	0.6%	19.9%
2012	3.8	9.0	2,359	0.7	23.7
2013	4.2	10.1	2,389	0.8	26.9
2014	5.6	14.6	2,586	0.9	32.4

#### Table 5. Prescription Drug Claims and Gross Spending for Drugs over \$1,000 per Claim, CYs 2011–2014

**Notes**: Includes federal and state funds. Gross expenditures are before the application of rebates. Includes drugs that were over \$1,000 per claim in spending at the NDC level. Excludes drugs billed under an unidentifiable National Drug Code. Virginia data were corrected for an apparent error in fee-for-service spending in the second quarter of 2014. Does not include Medicare Part D clawback payments. **Source**: MACPAC analysis of CYs 2011–2014 Medicaid drug rebate utilization data as reported by states, as of September 2015.

## Hepatitis C drugs

Hepatitis C drugs offer an example of how specialty drug prices have driven up spending in Medicaid. At the end of 2013, the Food and Drug Administration (FDA) approved Sovaldi, a highly successful treatment for hepatitis C that effectively cures 90 percent or more patients with a common form of the disease in 12 weeks and with fewer side effects than previous treatments. However, the cost of Sovaldi is substantial, with the list price of about \$1,000 per pill or \$84,000 for a 12-week course of treatment. In 2014, FDA approved additional hepatitis C drugs, Harvoni and Viekira Pak, which entered the market with list prices similar to Sovaldi's.

The introduction of these new hepatitis C treatments led to an increase in Medicaid spending for hepatitis C treatment from \$0.4-\$0.6 billion in CYs 2011-2013 to \$1.8 billion in CY 2014. In fact, Medicaid spent more for hepatitis C drugs in CY 2014 than the prior three years combined (Table 6). The \$1.4 billion spent on new hepatitis C drugs accounted for about 20 percent of the \$7.3 billion increase in gross Medicaid drug spending between CY 2013 and CY 2014.

Calendar year	Claims (millions)	Gross spending (billions)	Spending per claim
2011	0.2	\$0.4	\$2,440
2012	0.2	0.6	3,156
2013	0.1	0.4	3,301
2014	0.1	1.8	12,187

#### Table 6. Gross Prescription Drug Spending on Hepatitis C Drugs, CYs 2011-2014

**Notes**: Hepatitis C drugs were identified based on First DataBank specific therapeutic classes. Excludes drugs that could not be matched to the First Databank file. Does not include Medicare Part D clawback payments.

**Source**: MACPAC analysis of CYs 2011–2014 Medicaid drug rebate utilization data as reported by states as of September 2015, and drug classification information from the First Databank Medknowledge drug compendium.

Gross spending for these drugs is expected to be similar or higher in 2015. However, the availability of products from different manufacturers has allowed payers, including Medicaid, to negotiate significant discounts from the manufacturers. Several states report they have negotiated supplemental rebates of up to 20 to 30 percent, so we would expect these increased rebates to bring net drug spending down compared to gross spending for these drugs in 2015 (Loftus 2015).

## **Medicaid Tools for Addressing Spending Growth**

Recent drug spending trends in Medicaid are similar to those experienced by Medicare and commercial insurers. While a number of brand drugs have gone off patent, increasing the use of generic drugs, and improved benefit management has led to small increases or even decreases in spending for many traditional drugs, the introduction of new, high-cost drugs has offset these gains and lead to an overall increase in drug spending.

Hepatitis C drugs are only one example of the several hundred specialty drugs now in development (IMS Health 2014). Another is a recently approved class of drugs called PCSK9 inhibitors that have been shown to be highly effective in reducing cholesterol in cases where statins have been insufficient.<sup>6</sup> However, the list price for the PCSK9 inhibitors is over \$14,000 per year, about 50 times more than the annual price of a generic statin (Express Scripts 2015a). Because these PCSK9 drugs treat a common chronic condition, and would be prescribed for ongoing maintenance therapy, some PBMs and market analysts are projecting PCSK9 drugs to become the highest selling class of medications in history (Express Scripts 2015a, Shrank et al., 2015).

Because manufacturers typically do not release the price of the drug until it hits the market, it is a challenge for states to plan for these costs as they develop their budgets. The way many of these specialty drugs are priced—with high up-front costs for the drug leading to projected savings on medical services in the future—can be a challenge for states that must finance the program on an annual or biannual budget (NAMD 2014).

•••

Medicaid rules limit states' ability to manage prescription drug spending. Unlike other payers, statute requires drug manufacturers to pay rebates to Medicaid, which result in lower net prices. These statutory can be advantageous to states when paying for new, first-in-class products that have no true competition, However, the terms of the federal rebate agreement also mean that Medicaid cannot completely exclude coverage of any products from manufacturers participating in the rebate program. While Medicaid programs may use prior authorization, step therapy, and other tools to manage use of these drugs, they must provide coverage of almost all drugs to a certain degree, meaning states must provide some level of coverage of new, high-cost drugs when they enter the market.

Additionally, other payers have more flexibility in making coverage decisions, and can steer volume toward the most cost-effective alternatives. Other payers use beneficiary cost sharing as a tool to encourage the use of preferred alternatives. Many payers have introduced incentives through the cost sharing structure to encourage beneficiaries to use lower-cost alternatives or products that provide high clinical value. Because Medicaid allows only nominal cost sharing and few states enforce collection of copayments, incentives to change beneficiary behavior through changes in cost sharing amounts could have little impact in Medicaid.

Prior authorization is the primary tool that states have to manage the Medicaid prescription drug benefit, since they cannot exclude coverage for most drugs and have limited ability to use beneficiary cost sharing to change behavior. For the hepatitis C drugs, several states have implemented stringent prior authorization requirements including high disease severity requirements (e.g., fibrosis scores of F3 or higher) and abstinence of alcohol or drug use for several months (Center for Evidence-based Policy, 2015). However, such requirements have raised questions as to how far states may go in their prior authorization requirements and still meet the coverage requirements of the drug rebate program, with many advocacy groups considering lawsuits to improve access to these drugs (Kardish 2014, Wilkerson 2014). CMS recently issued a letter to states that expressed concern that some state restrictions on new hepatitis C drugs are contrary to the requirements in section 1927 of the Act (CMS 2015a).

The challenges of providing appropriate access to new, high-cost drugs while working within the fiscal restraints of the states' budgets are still developing and it is not clear yet where the balance will be found.

Endnotes

...

<sup>&</sup>lt;sup>1</sup> For the increase in all other health expenditures, MACPAC analyzed the Office of the Actuary, Centers for Medicare & Medicaid Services, 2015, *National health expenditures by type of service and source of funds: Calendar years 1960-2014*, as of December 2015, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE2014.zip.

<sup>2</sup> In accordance with §2501(c) of the ACA, five states—Florida, Kansas, New Hampshire, Oregon, and Texas—are expanding supplemental rebate collections to include drugs dispensed to beneficiaries who receive drugs through a managed care organization (CMS 2015b).

<sup>3</sup> https://www.macpac.gov/publication/medicaid-payment-for-outpatient-prescription-drugs/

<sup>4</sup> A state's monthly clawback payment is equal to 1/12 of the following: 1) 2003 per capital dual eligible drug expenditures trended forward to the current period, times 2) the share of costs that a state pays for most Medicaid services (100 percent minus the state's current federal medical assistance percentage, or FMAP), times 3) phased-down adjustment factor (decreasing from 90 percent in 2006 to 75 percent after 2014), times 4) the state's current number of dual eligible receiving full Medicaid benefits.

<sup>5</sup> For example, Abilify averaged less than \$1,000 per claim across all of its different dosages and forms. However, the higher dosages of 20 mg and 30 mg were more than \$1,000 per claim while the 5 mg and 10 mg versions were below \$1,000 per claim. For our analysis, we included the 20 mg and 30 mg versions but did not include the 5 mg and 10 mg versions.

<sup>6</sup> Proprotein convertase subtilisin/kexin type 9 (PCSK9)) inhibitors have been shown to be effective in reducing low-density lipoprotein cholesterol in those with familial hypercholesterolemia, patients who are not able to tolerate statins, and patients on statins or other cholesterol-lowering drugs who have not achieved sufficient reductions in cholesterol.

#### References

Center for Evidence-based Policy. 2015. *State Medicaid coverage policies for Harvoni and Viekira Pak treatment for hepatitis C*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University. http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/evidence/med/upload/02a-HCV-Medicaid-Policy-Summary-SenFin-2015.pdf.

Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services. 2015a. Letter from Alissa Mooney DeBoy to state technical contacts regarding "Assuring Medicaid beneficiaries access to hepatitis C (HCV) drugs." November 5, 2015. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.

Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services. 2015b. *Medicaid pharmacy supplemental rebate agreements—quarter ending March 2015.* Baltimore, MD: CMS. http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.

Express Scripts, 2015a. The country's first PCSK9 inhibitor. *Express Scripts Insights*, July 29. http://lab.express-scripts.com/insights/drug-options/the-countrys-first-pcsk9-inhibitor.

 $\bullet \bullet \bullet$ 

Express Scripts, 2015b. *The 2014 drug trend report*. St Louis, MO: Express Scripts. http://lab.express-scripts.com/drug-trend-report.

IMS Health white paper, 2014. *Overview of the specialty drug trend. Succeeding in the rapidly changing U.S. specialty market.* IMS Health.

https://www.imshealth.com/deployedfiles/imshealth/Global/North%20America/United%20States/Managed%20Markets/5-29-14%20Specialty\_Drug\_Trend\_Whitepaper\_Hi-Res.pdf.

Kardish, C. 2014. The risky business of limiting Medicaid access to Sovaldi. Governing, August 19.

Loftus, P. 2015. States work to strike deals for Hep C drug discounts. The Wall Street Journal, January 29.

Martin, A., M. Hartman, J. Benson, et al. 2016. National health spending in 2014: faster growth driven by coverage expansion and prescription drug spending. *Health Affairs* 35, no.1: 150-160; published ahead of print December 2, 2015.

Shrank, W., A. Lotvin, S Singh, et al. 2015. In the debate about cost and efficacy, PCSK9 inhibitors may be the biggest challenge yet. *Health Affairs Blog*, February 17. http://healthaffairs.org/blog/2015/02/17/in-the-debate-about-cost-and-efficacy-pcsk9-inhibitors-may-be-the-biggest-challenge-yet/.

Wilkerson, J. 2014. Hep C patients seriously consider suing states that restrict Sovaldi coverage. *Inside Health Policy*, August 4.

# **Appendix: Medicaid Prescription Drug Data Sources**

Medicaid drug utilization, spending, and rebate information is available from three primary federal sources of data-the Medicaid Statistical Information System (MSIS), the Form CMS-64 budget and expenditure data, and the state drug utilization data that states report to CMS as part of the Medicaid drug rebate program. All of these data have some limitations and none of these three sources can provide a complete picture of utilization, spending, and rebate amounts.

### Form CMS-64 financial management report

States report their actual expenditures for Medicaid on the Form CMS-64 on a quarterly basis for purposes of calculating their federal matching dollars. Because these data are used to claim federal matching dollars, the CMS-64 is considered to be the most accurate source of a state's actual spending on Medicaid services. The CMS-64 provides aggregate spending information by major benefit categories, including prescription drugs and corresponding drug rebate amounts. Additionally, the CMS-64 is the only available source for the amount of drug rebates that states collect. The CMS-64 has categories for states to report the rebates collected from the federal drug rebate program as well as any state supplemental rebate arrangements. It also allows states to separately identify rebates associated with FFS and managed care. Additionally, these data are generally available for most states after a couple of quarters, so it allows analysis of spending from the most recent year.

Because the CMS-64 is at the aggregate accounting of state expenditures, it does not include any eligibility, demographic, or drug-specific information that allows for analyses on specific drugs or population subgroups. Additionally, the amounts reported for managed care reflect what the state paid to the participating plans through capitation payments. The CMS-64 does not include information on what the plans paid out for specific services. As such, the CMS-64 is a good source of service-level spending in FFS but cannot provide the same level on detail on spending under managed care.

States have 60 days after the end of each quarter to invoice the drug manufacturers for rebates. Because of this invoicing period, the rebate amounts reported in a particular quarter do not directly align with the drug expenditures made in that same quarter. Rather, the rebates reported reflect the rebates obtained on purchases made in prior quarters. While the CMS-64 does provide a picture of the expenditures and rebates collected during the quarter, the difference in timing can create distortions for a particular time period should a state make changes to its program. For example, if a state puts the pharmacy benefit into managed care, the FFS drug expenditures will be reduced immediately in the following quarter but the FFS rebate amounts will not reflect this reduction for another quarter or two, potentially creating a negative amount for net FFS drug spending for a couple of quarters. Additionally, while the CMS-64 allows the state to report drug rebates separately for FFS and managed care, not all states do so, and these states may appear to have negative FFS drug spending and no managed care rebates.

Medicaid and CHIP Payment and Access Commission www.macpac.gov

## Medicaid drug rebate utilization data

As part of the Medicaid drug rebate program, each state produces drug utilization data reports on a quarterly basis that are submitted to CMS and the drug manufacturers for the purpose of invoicing for the rebates. Because individual manufacturers need to be invoiced for their own specific drugs, these reports provide information on the number of units, number of claims, and paid amount at the drug NDC level. When the ACA extended federal rebates to prescriptions paid for by Medicaid managed care organizations, states began to report managed care drug utilization and spending information as part of these reports in 2010. These data are the only federal source for calculating drug spending under managed care and can provide a comprehensive picture of drug utilization and spending in both FFS and managed care. Similar to the CMS-64, these data are generally available for most states after a couple of quarters and can provide analysis of the most recent year.

The drug rebate utilization data are aggregated at the drug NDC level and does not provide beneficiary level information such as basis of eligibility or demographics. The expenditures in the drug rebate utilization data do not match exactly to the amounts reported in MSIS or the CMS-64 reports due to differences in their purposes and timing. Because the drug rebate utilization data are used for rebate purposes, these data include utilization and spending for physician-administered drugs that are eligible for rebates. These physician-administered drugs are generally reported under physician service categories in MSIS or the CMS-64 instead of outpatient drugs. Additionally, because drugs purchased through arrangements under Section 340B of the Public Health Service Act are not eligible for rebates, these drugs should not be included in the drug rebate utilization data.