MAGELLAN RX MANAGEMENT

MEDICAID PHARMACY TREND REPORT™

2017 SECOND EDITION

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Introduction

Thank you for your support of our first-ever Medicaid Trend Report last year! We are pleased to present the second annual Magellan Rx Management Medicaid Trend Report, developed through in-depth data analysis supported by broad national experience.

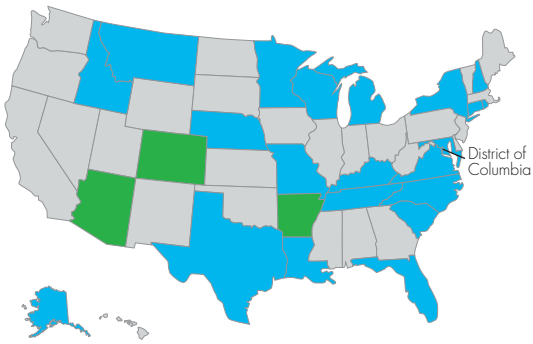
Medicaid Fee-for-Service (FFS) continues to be a costly healthcare expenditure with complex management strategies. Trends in the Medicaid FFS segment see shifts on a consistent basis. The 2017 MRx Medicaid Trend Report provides detailed insights into the pharmacy economics that drive trends in this space based on a foundational knowledge of Medicaid FFS drug rebate trends.

This report examines clinically appropriate drug use and cost-saving opportunities for Medicaid FFS drug spend, not including Medicaid managed care organization (MCO) utilization. The data in this report span two calendar years, 2015 and 2016, from 22 Medicaid FFS clients across the country (**see figure 01**). To achieve the highest level of accuracy for the Medicaid FFS space, this report incorporates the Center for Medicare & Medicaid Services (CMS) federal rebate data for both 2015 and 2016. Federal rebate data at the drug level are confidential and protected by federal law under the Social Security Act at 42 U.S. Code 1396r-8 (b)(3)(d). Therefore, this report does not disclose net cost pricing information on a per drug basis.

FIGURE 01

Medicaid State Customers

MRx customers in analysis
New MRx customers 2015/2016



For the second year of this report, we continue to examine Medicaid pharmacy economics, cost drivers, and class drug cost trends. Building on that foundation and through positive comments and feedback for last year's report, this year's report provides a breakout of traditional and specialty drug spend — our No. 1 request. In this report, we identify the top 10 traditional and specialty drugs and drug classes that drive trend and the cost of care in Medicaid FFS. We applied a standard definition across our Medicaid FFS book of business to calculate and identify trend and trend drivers for traditional classes (high-volume, low-cost orals), specialty classes (low-volume, high-cost injectables) and aggregated classes (combined) (**see definition in Report Data Methodology**).

Due to the complexity of the federal rebate calculation and the impact of the federal rebate on the net cost of drugs to state Medicaid programs, we again provide foundational background for the reader, focusing on brand and generic utilization effects on federal rebates.

The largest section of our report is dedicated to examining the drivers of trend in both the specialty and traditional drug classes. Our focus this year includes both changes in cost and utilization as the components of that trend. We continue to report Medicaid drug spend at a net cost level vs. per member per month (PMPM) because of the transitional nature of Medicaid enrollment.

Finally, we again address notable market events for state Medicaid, focusing this year on Mylan's EpiPen and other topics affecting increases in Medicaid net spend on pharmaceuticals. We also provide legislative updates focusing on the future of healthcare legislation and Medicaid rebates as well as current Medicaid drug pricing, including 340B.

We hope you find the information contained in this report relevant and educational. As always, we welcome comments and feedback that we can use to enhance the value of this report and our services in the upcoming years.

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KEY FINDINGS IN THE REPORT INCLUDE:

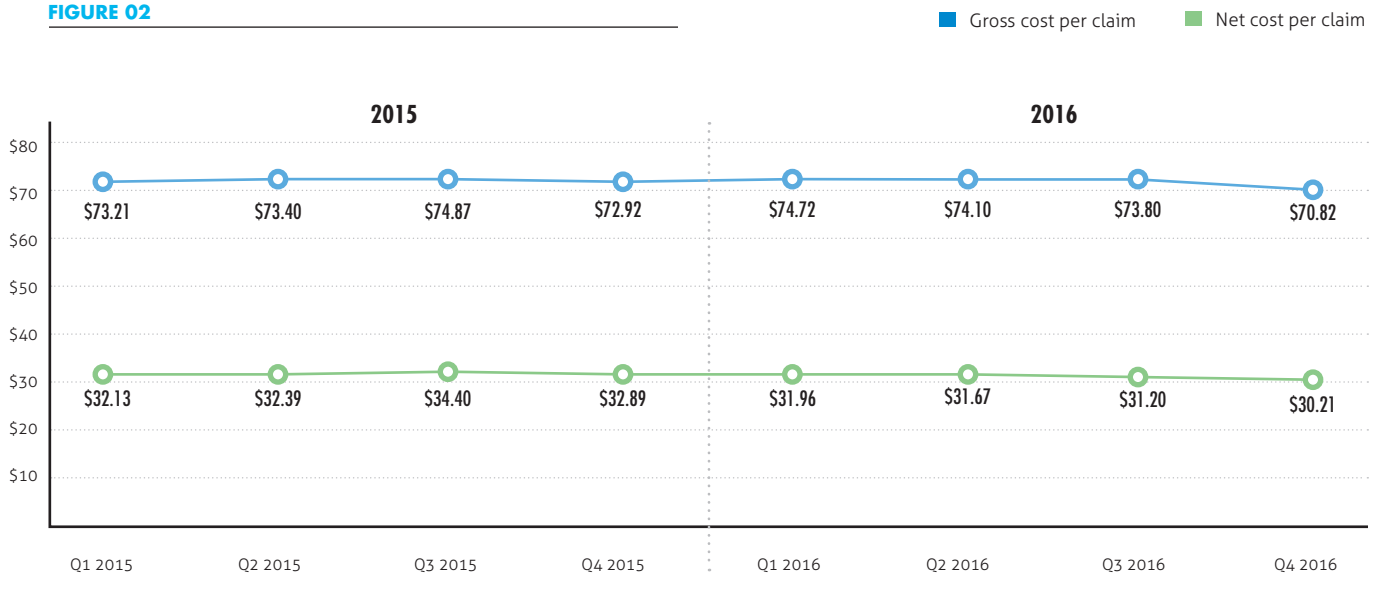
Last year's MRx Medicaid Trend Report looked at aggregate trend data and reported a 10.7 percent ($9.17) increase in gross cost per claim and a 3 percent ($1.26) increase in net cost per claim. This year, the aggregate trend was examined again, but our efforts focus on the traditional and specialty drug trends and the cost drivers behind each of these segments in response to feedback on last year's report. Similar to commercial plans, the Medicaid FFS space experienced double-digit increases in specialty net cost per claim during the reported period. Refreshingly, there was a slight decline in traditional net cost per claim over the two-year period. In the aggregate, the Medicaid FFS trend for all drugs increased 5.2 percent ($5.29) at the gross cost per claim level and 1.9 percent ($0.91) at the net cost level.

Traditional Drug Trend:

Traditional drug trend data were flat over the two-year period. State Medicaid programs can use many of the same tools that commercial plans use to manage utilization and cost, including preferred drug lists (PDLs), clinical edits, maximum allowable cost (MAC) pricing, and rebate contracting. One tool unique to Medicaid FFS is brand-over-generic programs, which will be explained in greater detail. In addition, state efforts to curb prescription volume of short-acting narcotics and reduce abuse of opioids through clinical initiatives and prior authorizations further impacted utilization. Overall, traditional drug utilization declined by 0.7% over the period.

As illustrated below (**figure 02**), the average gross cost per claim was $73.60 over the course of 2015 and $73.38 during 2016, a decline of $0.22 per claim, or 0.3 percent. The average net cost per claim was $32.95 during 2015 and $31.27 over the course of 2016, a decline of $1.68, or 5.1 percent!

FIGURE 02



Summary

Specialty Drug Trend:

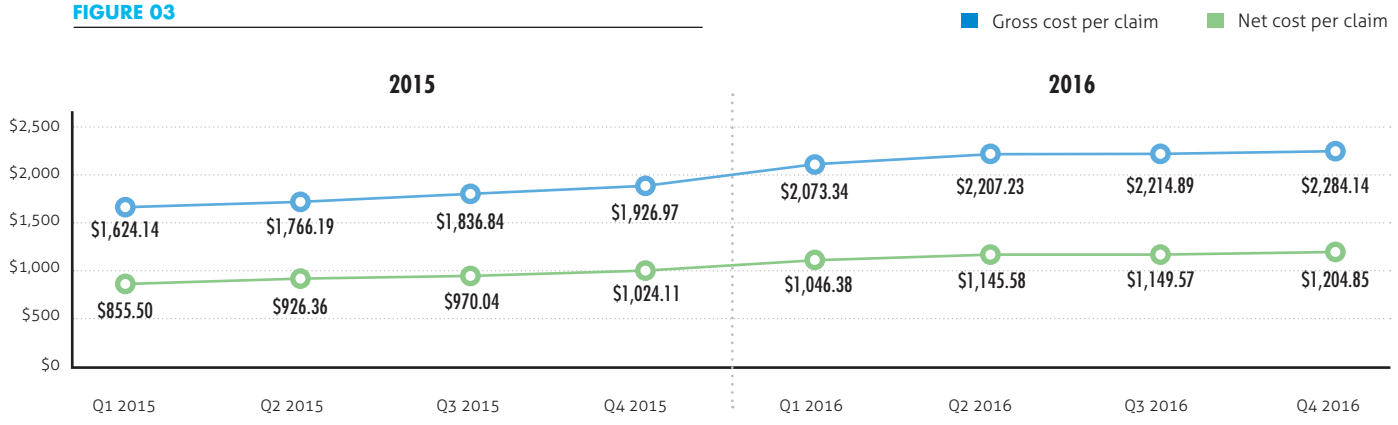
Specialty drug trend data showed double-digit growth over the course of the two-year period. State Medicaid programs struggle with utilization controls on these products for a variety of reasons, particularly with enforcing such controls at the site of service. Medical pharmacy dispensing is an area where tighter adherence to clinical pathways would be useful. As noted in this report, six of the top 10 net spend drugs fall into four specialty classes: Hepatitis C Agents, Hemophilia, HIV/AIDS, and Cystic Fibrosis, Oral. With the exception of Hepatitis C Agents, these classes often lack clinical or financial management because of legislative protections, grandfathering, or pharmacy department policy. As witnessed with Hepatitis C Agents over the past three years, the cost of specialty drugs will eventually reach the tipping point where states will need to make difficult decisions about how to best allocate available resources in order to protect this most vulnerable patient population.

In **figure 03**, the average gross cost per claim was shown to be $1,786.17 during 2015 and $2,194.27 over the course of 2016, an increase of $408.10 per claim, or 22.8 percent. The average net cost per claim was $942.72 over the course of 2015 and $1,136.60 during 2016, an increase of $193.38, or 20.5 percent. As conveyed in our 2017 Magellan Medical Pharmacy Report, specialty drug spend is expected to continue to grow at rates far exceeding that for traditional drug spend. It is expected to represent 50 percent of total pharmacy spend by the year 2020. State Medicaid FFS programs are not exempt from this trend. Interestingly, utilization of specialty products remains constant at 1.6 percent of the total claim volume in both 2015 and 2016; however, the percent of total net spend attributed to specialty drugs increased by almost 5 percent, from 31.8 percent to 36.5 percent.

Hepatitis C treatment continues to create a significant financial burden on state Medicaid programs. As it is the third-ranked specialty drug class in net spend, it is interesting to note that the decreasing cost of drugs is generally decreasing the overall cost of treatment, but that lower per-treatment cost is offset by increased utilization. Contrary to statements regarding increased spend elsewhere in this report, this increase should be viewed positively for states. Lower pharmaceutical costs in this class have led to states lowering the Metavir score requirement for treatment. Harvoni, the most commonly prescribed drug in this class, was 25 percent less expensive in 2016 than 2015 for states included in this evaluation, but its utilization increased by 42 percent. Therefore, a 5.9 percent increase in net spend was experienced overall. It is important to note that a combination of preferred status, change in Metavir score, and new competitive drugs to market impact net cost and utilization. See the Hepatitis C Agents section for additional information and changes in state Metavir criteria over time.

Finally, no discussion around Medicaid would be complete without discussing proposed legislative changes affecting the Medicaid program. Similar to last year, we include a Legislative Update section that highlights recent changes to the program including the Medicaid-Covered Outpatient Drugs Final Rule Update, Sec. 1115 Waivers, the federally mandated switch to average acquisition cost (AAC), consumer price index-urban (CPI-U) penalty on generics, Medicaid under the Affordable Care Act (ACA), the Presidential Commission on Opioid Crisis, and more.

FIGURE 03



2017 Report Data Methodology

The methodology for the second edition of the Magellan Rx Medicaid Pharmacy Trend Report focuses on the Medicaid FFS line of business and does not include Medicaid MCO utilization.

When assessing trends for this second edition, we now identify a standard set of therapeutic classes that are defined as "traditional" and "specialty." By applying this standard specialty definition across our Medicaid FFS book of business, we can calculate and identify trend and trend drivers for:

1. **Aggregate (or combined) utilization:** all therapeutic classes with prescription drug claims.
2. **Traditional:** therapeutic classes that have a lower cost per claim and a traditional route of administration, such as oral (tablets, capsules, liquids) or inhaled drugs.
3. **Specialty:** therapeutic classes with either, or any combination of, a higher cost per claim and lower claim volume or a route of administration such as infused or physician injectable drugs.

The data draw comparisons between gross cost per claim and net cost per claim. Keep in mind that we focus our analysis on net cost per claim for two primary reasons. The first is that state Medicaid FFS programs make preferred drug list (PDL) decisions using both the gross cost and net cost per claim as financial metrics. The second relates directly to fluctuations in eligibility common in this line of business, which makes a PMPM calculation ineffective.

1

Aggregate (or combined) utilization

all therapeutic classes with prescription drug claims.

2

Traditional

therapeutic classes that have a lower cost per claim and a traditional route of administration, such as oral (tablets, capsules, liquids) or inhaled drugs.

3

Specialty

therapeutic classes with either, or any combination of, a higher cost per claim and lower claim volume or a route of administration such as infused or physician injectable drugs.

Medicaid Pharmacy Economics Overview

It is essential that the reader have a basic level of understanding of Medicaid pharmacy economics to interpret the net cost data presented in this report. This knowledge is integral to understanding net cost comparisons of brand drugs to their generic equivalents, biosimilar products to their innovators, and authorized generics (AG) to non-authorized generics. All of these comparisons require the understanding of the federal rebate dynamic coupled with CMS interpretation of the law in the rule-making process.

Background

The pharmacy economics of Medicaid are different from commercial drug pricing and rebate management strategies. Medicaid is a state-run program with federal oversight. One-hundred percent of federal and supplemental rebates are paid directly to states and subsequently shared with the federal government.

In 1990, federal legislation established the foundation of the current Medicaid drug rebate program. The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) mandated, among other things, that manufacturers sign a rebate agreement with the U.S. Department of Health and Human Services, guaranteeing a minimum mandated rebate in exchange for drug coverage by state Medicaid programs. The legislation mandated that manufacturers pay:

- A minimum discount (federal rebate) for generic drugs and the larger of the minimum discount or the best price the manufacturer offered to any commercial plan for brand drugs.
- A CPI-U penalty on top of the mandatory federal rebate for brand drugs, which serves to protect the states against drug price increases should a manufacturer raise its price faster than the rate of inflation.
  - » Starting January 2017, generic drugs are now subject to an inflation penalty.

In 2016, the average federal rebate was 53 percent off of gross pharmacy reimbursement. Most new brands have a minimum rebate of 23.1 percent of average manufacturer price (AMP); conversely, established brands can approach and exceed 90 percent of AMP after years of discounting and CPI-U penalties.

In Medicaid FFS, pharmacy benefit managers (PBMs) are paid an administrative fee for clinical and financial services in support of state PDL programs and other services and are incentivized to manage to the lowest net cost on pharmaceuticals. In this model, drug pricing is completely transparent to the states. Supplemental rebates are best price-exempt and average three to six percent off of a state's gross spend, depending on state utilization management, unit cost management, and drug mix. In 2016, the average total discount ranged from 56 to 59 percent for fully implemented PDL programs.

The focus should always be on the net cost after all discounts (federal, supplemental, and rebate offset amount), not on total supplemental rebates collected. Those who look to measure the success of the PDL program by only considering the supplemental rebate dollars risk driving a higher net cost per claim in their program. Regardless of the classification of federal or supplemental rebate, these rebates are equally valuable to states. Federal and supplemental rebates are shared with the federal government according to their Federal Medical Assistance Percentage (FMAP).

The Economics

To understand Medicaid economics, one must understand the dynamics of the factors mentioned previously. **Figure 04** illustrates the financial impact on brand drugs from market entry through their patent expiration. Drug cost is represented on the y-axis by brand drug price, and the drug's life cycle is represented on the x-axis by time. For this exercise, assume pharmacy reimbursement, wholesale acquisition cost (WAC), and AMP are all the same. A new brand drug enters the market with a minimum mandatory rebate of 23.1 percent of AMP. This drug enters a competitive class with three clinically equivalent therapeutic alternatives each with higher discounts and lower net costs than the new drug. With a pharmacy reimbursement cost of $100, the net cost to the state is $76.90 ($100 reimbursement minus 23.1 percent of reimbursement, or $23.10). In order to be competitive, the manufacturer of the new brand will offer an additional discount, known in Medicaid as a "supplemental rebate," to lower the net cost from $76.90 to a competitive price of $50. The value of the supplemental rebate at time zero is thus equal to $26.90 and the total discount is 50 percent, or $50. Moving through time, manufacturer pricing actions drive the total discounts up; but due to the inverse relationship between supplemental and federal rebates, supplemental discounts decline over time as the total discount increases. As the patent expiration approaches, the manufacturer generally increases the cost of the drug and the CPI-U penalty accelerates the growth of the federal rebate in the quarters just prior to that event.

Generic Influence

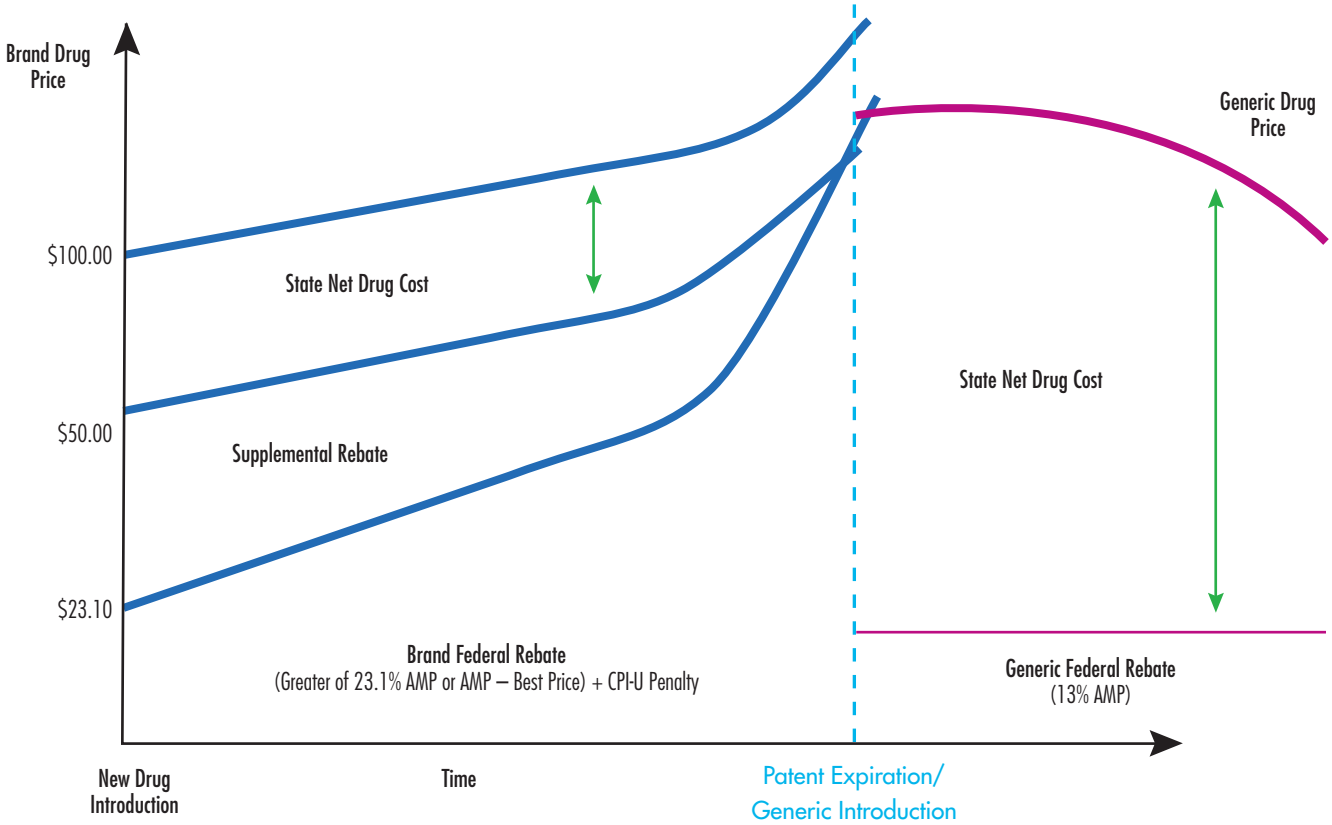
At patent expiration, the launch of a generic is a welcomed event by commercial plans as a way to lower reimbursement and overall drug cost. In Medicaid, the launch of a generic often has the exact opposite effect. When generics first enter the market, they typically launch at a price point that is discounted to the brand's gross cost and have a federal rebate fixed at 13 percent of AMP. The net cost of a brand drug can be markedly less than the generic at this time (**see figure 04**). Factors affecting the availability of this new generic can cause the net cost of the generic to remain relatively high for periods lasting from six months to multiple years. Therefore, it is imperative that states (or their PBMs) monitor these scenarios in order to take full advantage of all savings opportunities.

Brand vs. Generic

Maintaining preferred status for brands instead of their generic equivalents provides significant cost savings for states in key situations. One such example from 2016 is the management of Abilify and its generic, aripiprazole. States closely monitor

FIGURE 04

Medicaid Pharmacy Economics



the pricing of both the brand and the generic drug once brand patent expiration has occurred. In many cases, a high federal rebate (and possibly a supplemental rebate) keeps the brand at a lower net cost than its generic equivalent well beyond the initial launch of the generic. Once the savings associated with preferring the brand instead of the generic is eliminated, the states quickly switch the PDL statuses of the brand and the generic and enjoy the continued decline of the generic's price. **Figures 05 and 06** illustrate the opportunity cost of preferring brands over generics. If a state preferred the generic in Q1 2015 and continued to prefer the generic over the two-year period, the state would have spent $685,000 on the generic drug. Alternatively, if the state had instead preferred the brand over the generic, the state would have spent $400,000, a savings of $285,000 for the same two-year period. Many states employ a hybrid strategy and prefer the brand over the generic as long as the net price of the brand is less expensive than the generic. In this case, the state prefers the brand, then in Q2 2016, the generic becomes more cost-effective to the state. The state switches preferred status from the brand drug to the generic. In this model, the state spends $355,000 on a combination of brand and generic utilization over the two-year period, ultimately saving the state $330,000.

The impact of the federal rebate on brand drugs often leads to a different PDL status when considering brand drugs and their generic equivalents. As a result, Medicaid FFS programs are often reported to have lower generic utilization rates than Medicaid MCO or other commercial programs. Published reports from The Menges Group in 2016 put Medicaid MCO generic dispensing rates at 83.4 percent and Medicaid FFS rates at 78.5 percent[1], but the definition of Medicaid FFS generic dispensing rate is somewhat misleading. The CMS calculation of generic efficiency requires states to classify brand and generic drugs by their CMS drug class indicator of single-source, innovator multi-source, or non-innovator multi-source and not by their formal label name. The impact to FFS is significant because Authorized Generics (AG) that have a non-innovator multi-source (generic) label name pay an innovator multisource (brand) federal rebate and are thus counted as brand drugs by CMS.

In 2015, the states in our evaluation had a generic dispensing rate of 79.5 percent, measured using the CMS definition outlined previously. When AGs are instead counted as the generics that they are, the generic effective rate increases by 4.7 percent to 84.2 percent. This alone boosts the effective generic dispensing rate above that reported for Medicaid MCOs. Furthermore, if states were to count brand drugs that are preferred over their generic equivalents as generic utilization, the effective generic dispensing rate would increase by an additional 3.3 percent to 87.5 percent!

In 2016, we noted a one percent uptick in the CMS-reported generic dispensing rates. Using the methodology described above, we observed an 80.6 percent "CMS" rate in states included in this evaluation. This rate increases to 84.4 percent when AGs are counted as generics and 88.9 percent when including brands that are preferred over their generic equivalents.

Continuing to prefer the brand over its generic can lead to substantial cost savings for states and the federal government. In 2016, brand-over-generic programs for states in our evaluation accounted for $330 million in savings at an average cost of $135 per claim.

FIGURE 05

Example Opportunity Costs Preferring Brands Over Generics

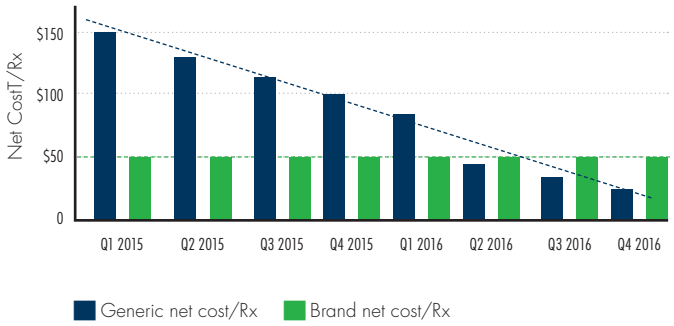


FIGURE 06

TIME PERIOD	GENERIC NET COST PER CLAIM	BRAND NET COST PER CLAIM	GENERIC TOTAL NET COST	BRAND TOTAL NET COST	BRAND OVER GENERIC PROGRAM-TOTAL NET COST	COST-EFFECTIVE DRUG
Q1 2015	$150	$50	$150,000	$50,000	$50,000	Brand
Q2 2015	$130	$50	$130,000	$50,000	$50,000	Brand
Q3 2015	$115	$50	$115,000	$50,000	$50,000	Brand
Q4 2015	$100	$50	$100,000	$50,000	$50,000	Brand
Q1 2016	$85	$50	$85,000	$50,000	$50,000	Brand
Q2 2016	$45	$50	$45,000	$50,000	$45,000	Generic
Q3 2016	$35	$50	$35,000	$50,000	$35,000	Generic
Q4 2016	$25	$50	$25,000	$50,000	$25,000	Generic
Total net spend over 2 years			$685,000	$400,000	$355,000	
Model illustrates 1,000 claims paid at generic net cost, brand net cost, or the lesser of brand or generic net cost						

1. http://www.pcmanet.org/wp-content/uploads/2016/11/medicaid-savings-report-october-2016.pdf

MEDICAID FEE-FOR-SERVICE COST DRIVERS

In 2016, the top five classes — antipsychotics, HIV/AIDS, hemophilia, stimulants and related agents, and anticonvulsants — contributed 40.1 percent of the total net spend (**see figure 07**), while they accounted for only 14.2 percent of the total claims.

The top 10 drugs by net spend were spread across four of the top five classes. Of these top drugs, the antipsychotic aripiprazole had the highest net spend across all classes constituting 23.3 percent of the antipsychotics class. Harvoni came in second constituting 43.5 percent of spend in the Hepatitis C agents class (**see figures 08 and 09**).

FIGURE 07

2016 Top Five Classes per Total Net Spend

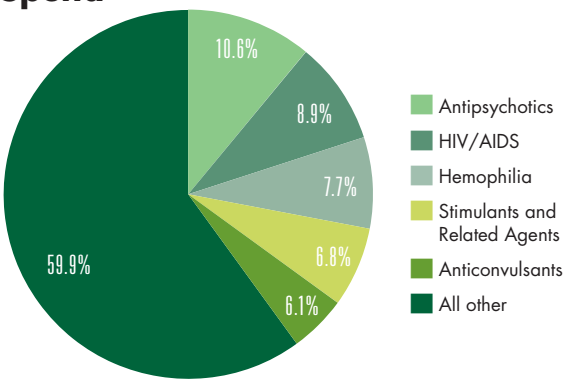


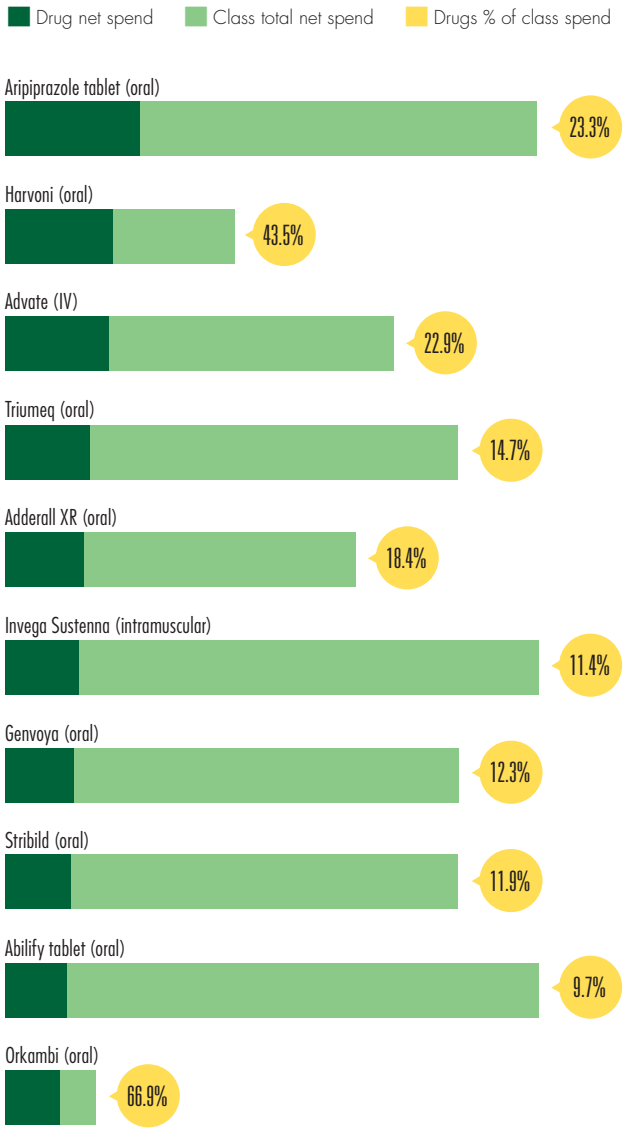
FIGURE 08

Top 10 Drugs by Class and Classification

RANK	DRUG	CLASS	CLASSIFICATION
1	Aripiprazole tablet (oral)	Antipsychotics	Traditional
2	Harvoni (oral)	Hepatitis C Agents	Specialty
3	Advate (IV)	Hemophilia	Specialty
4	Triumeq (oral)	HIV/AIDS	Specialty
5	Adderall XR (oral)	Stimulants and Related Agents	Traditional
6	Invega Sustenna (Intramuscular)	Antipsychotics	Traditional
7	Genvoya (oral)	HIV/AIDS	Specialty
8	Stribild (oral)	HIV/AIDS	Specialty
9	Abilify tablet (oral)	Antipsychotics	Traditional
10	Orkambi (oral)	Cystic Fibrosis, Oral	Specialty

FIGURE 09

2016 Top 10 Drugs Net Spend vs. Class Total Net Spend



MEDICAID FEE-FOR-SERVICE COST TREND

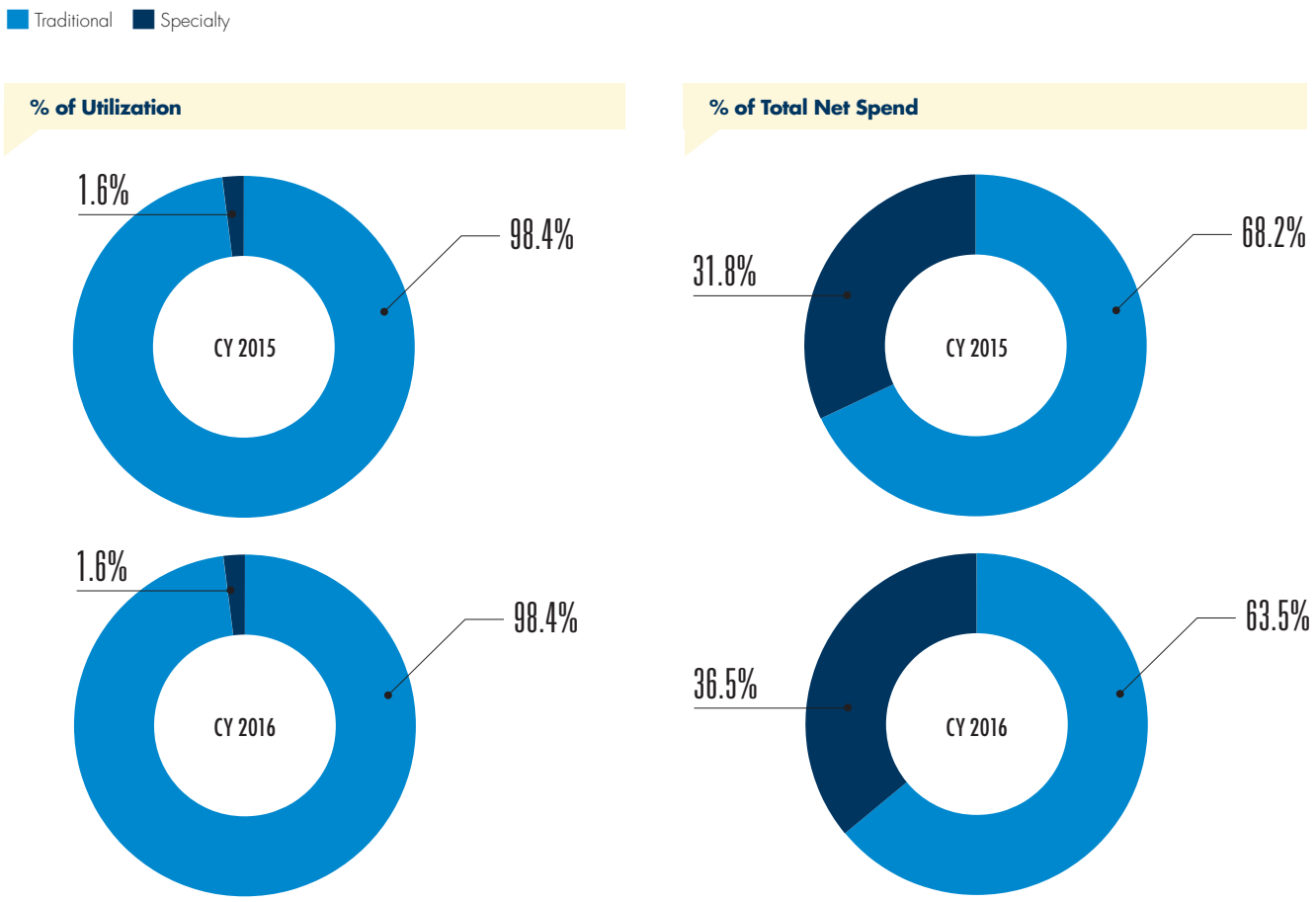
When examining utilization, specialty drug utilization contributes to only 1.6 percent of prescription drug use, but one-third of net spend. Year over year, specialty net drug spend increased almost five percentage points from 31.8 percent of net spend to 36.5 percent of net spend (**see figure 10**).

Class drivers of net spend were determined by the top 10 traditional and top 10 specialty classes. Although traditional drug net spend contributed to a decrease in aggregate net spend, specialty drugs contributed a large increase. It should be noted that change in net spend was a function of both utilization and net cost per claim.

Due to the confidential nature of the federal rebate, we cannot provide the reader with the net cost per claim at the drug level. Instead, we have provided change in claim volume, change in net cost per claim, change in net spend at the drug level, and total net spend for each drug listed. Monitoring the change in these metrics provided the opportunity to identify and illustrate the drivers of trend in each class and the impact each class has on overall net spend.

FIGURE 10

Traditional vs. Specialty Utilization and Net Spend 2015-2016



Traditional Drug Spend Class Analysis

No.1: Antipsychotics

This class continued to experience a dual shift in utilization. Market share moved predominantly toward generics among oral products except as discussed previously with the case of Abilify/aripiprazole. Increased utilization of expensive long-acting injectables combined with high volume in generic utilization to maintain a high overall net spend. The net impact was a negative class contribution to the average net cost per claim trend. Still, this was the No. 1 overall class according to net spend. Although not a top driver of average net cost per claim trend, the class contained three of the top four overall net spends for individual drugs.

Cost Drivers:

In last year's report, Abilify and aripiprazole utilization contributed a positive net impact to average net cost per claim trend. This year, aripiprazole ranked first of all products, traditional or specialty, in total net spend for the second year in a row. However, with falling generic prices over the course of 2016, these products now have a negative impact to trend. Not all states were successful in maintaining a high market share in Abilify as opposed to its generic equivalent. For those states that held utilization in the brand, the benefit was about $62 million in savings in 2016. Similar savings opportunities arose with the market introductions of generics for Seroquel XR and Invega. Net costs for these brands were far less expensive than their generic equivalents, making this a potential repeat of the Abilify/aripiprazole situation (**see figure 11**).

Rexulti provided the largest impact on average net cost per claim trend within the class at $0.14, vaulting to the No. 67 place overall on the total net cost ranking despite widespread non-preferred PDL status. Even Vraylar, a 2016 launch, entered the list at No. 172 overall under similar conditions.

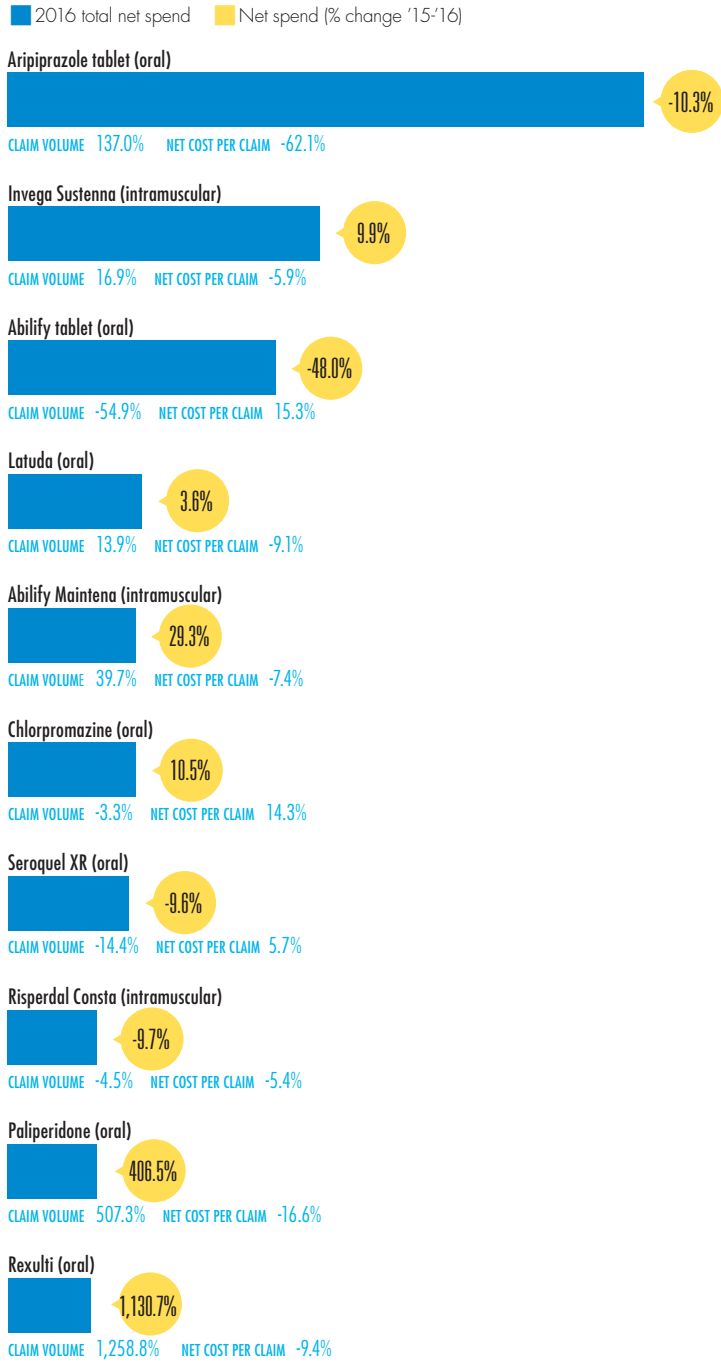
Utilization in long-acting injectable antipsychotics increased for all products except Risperdal Consta, reflecting wider acceptance of marketed brands. Collectively, these products contributed a positive average net cost per claim trend in 2016 of $0.22. This trend was led by Invega Sustenna, which moved up one place to the No. 6 overall net expenditure per drug in Medicaid FFS.

Management Strategy:

Invega and Seroquel XR generic launches should ideally be handled as was that for Abilify, with an eye on net pricing of the brand versus price erosion for the generics. Despite the low utilization, generic Invega was still an overall top 10 positive driver in average net cost per claim trend. In particular, non-authorized generic pricing needs to be monitored as it will be slower to decrease. New oral brands entering this class should provide distinct clinical advantages over existing options if preferred status is a consideration. MRx will continue to negotiate lower net costs for the long-acting injectables as they gain greater acceptance as a treatment option.

FIGURE 11

Antipsychotics Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 2: Stimulants and Related Agents

High levels of competition continued to keep both old and new preferred brands prevalent on state PDLs as low net cost options. As with antipsychotics, class utilization volume kept this group of products near the top of the list for net spend. However, this class was the top overall negative driver of average net cost per claim trend, and its overall class rank in net spend fell from 2015's No. 2 to No. 4 in 2016.

Cost Drivers:

Adderall XR and Vyvanse continued to possess the highest utilization in this class while causing a very low positive net spend to the class' overall contribution to trend. Despite their rankings as No. 5 and No. 11 overall, respectively, on the total net cost list, these two products were consistently among the lowest net costs in this class and remained unthreatened by the price of the generic for Adderall XR. Focalin XR and Adderall XR provided states with over $90 million in brand-over-generic savings in 2016. These generics have been slow to decrease in price, but generic Concerta and guanfacine ER were the leading contributors to this class' top negative average net cost per claim trend. Still, the combined net spends for Concerta AGs and non-AGs would qualify as the No. 4 net spend product overall (**see figure 12**).

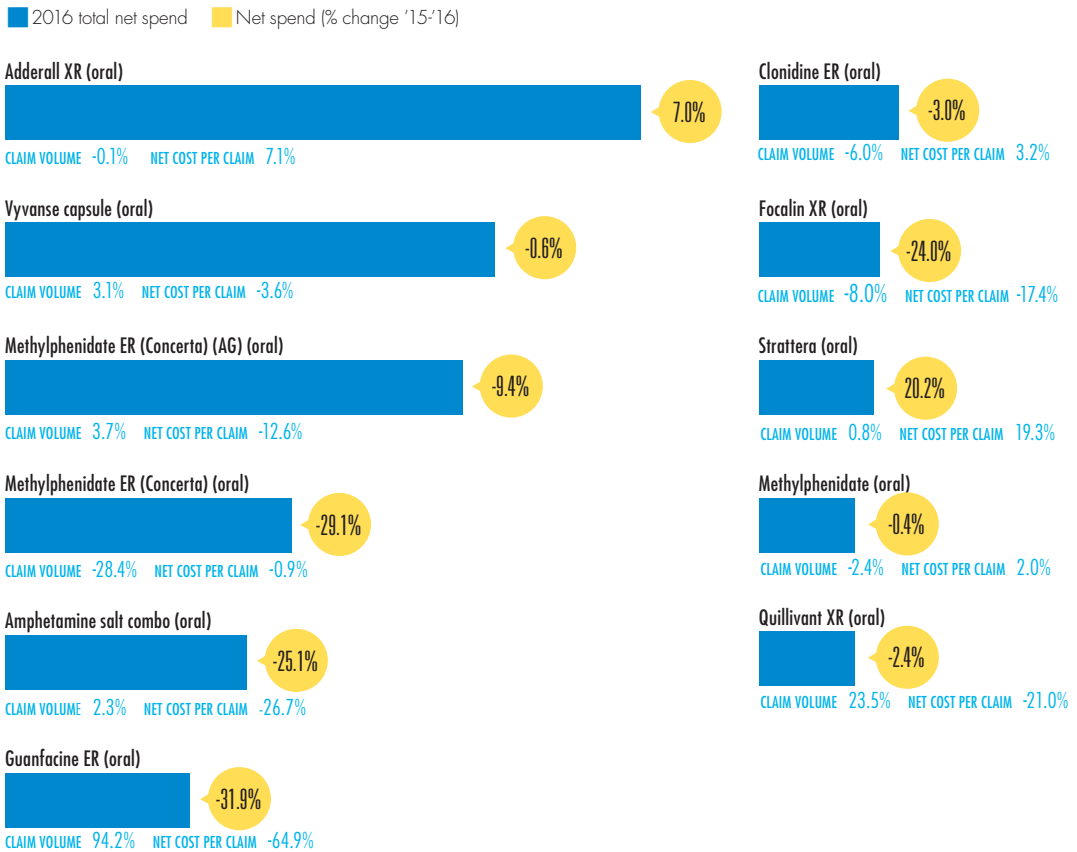
Several branded, oral, nonsolid dosage forms have been launched recently. Thanks to aggressive price reductions to states, these products collectively did not impact the class' net cost per claim. This allowed states to offer additional options to providers without impacting the bottom line.

Management Strategy:

Concerta was a difficult product to manage over the past year due to clinical equivalency issues with non-AGs. Regardless, the continued high net cost for this generic gave states reason to look elsewhere for a cost-effective extended-release methylphenidate, a trend expected to continue in 2017. New nonsolid oral formulations should be considered for preferred status in this competitive new subclass. Net costs for Adderall XR and Focalin XR keep preferred status attainable for these products compared to their generic equivalents and should continue to be monitored.

FIGURE 12

Stimulants and Related Agents Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 3: Anticonvulsants

Net costs and utilization within this class remained static over the past few years, resulting in a repeat as the third-ranked traditional drug class in terms of net spend. This class was not a driver of average net cost per claim trend.

Cost Drivers:

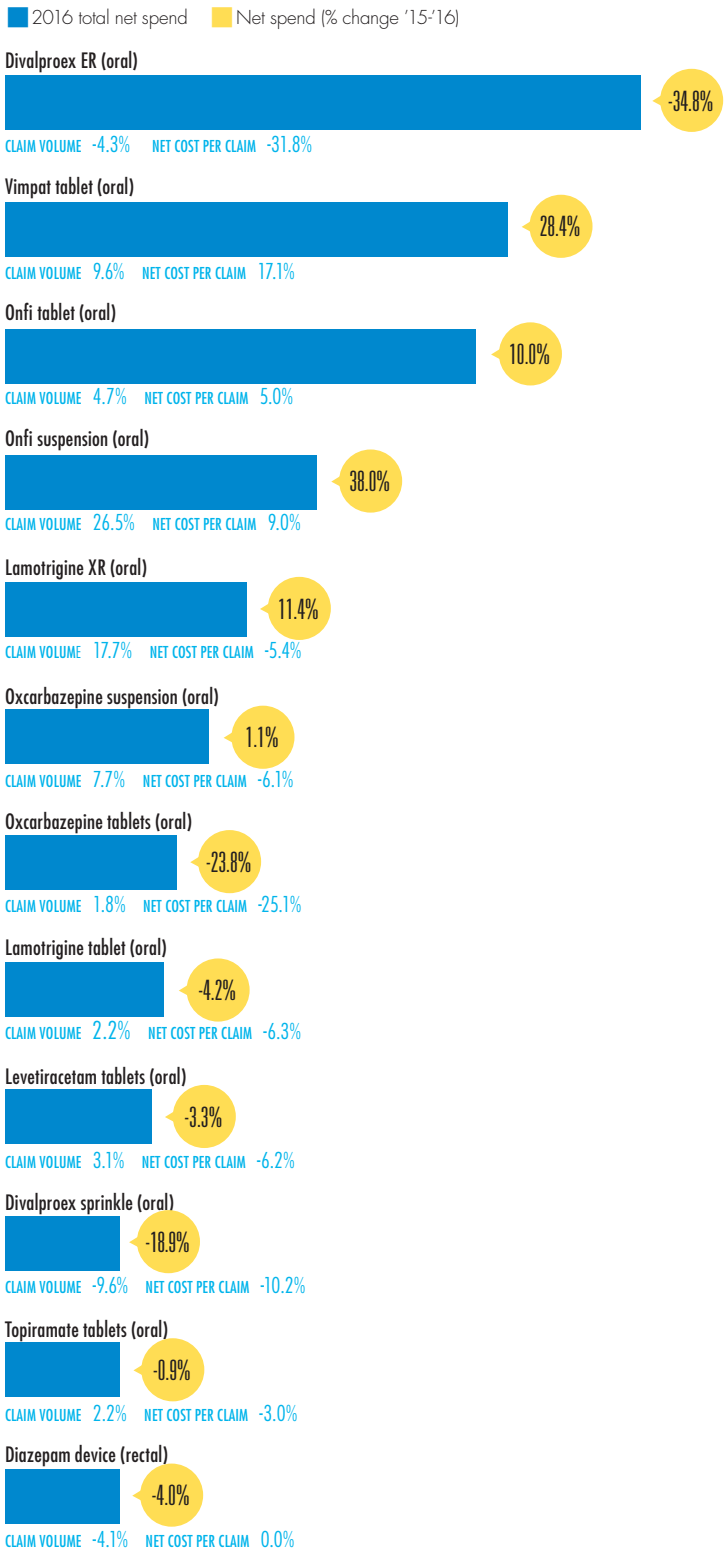
The increase in spend for this class was tied directly to the increased utilization for the few single-source brands. Products such as Aptiom, Onfi, and Vimpat experienced growth in utilization of about 12 percent in 2016 and collectively provided the counterbalance to any decreased average net cost per claim trend in the class. That decrease came largely from falling generic prices for divalproex, which experienced increased ingredient costs in recent years. That price appears to be regressing to previous levels, but divalproex ER was still the No. 8 drug on the list of top net spend for traditional products (**see figure 13**).

Management Strategy:

The key to managing the net spend in this class is to deter utilization of high-cost brands that share the same indication as multiple generics. Even incremental gains in market share by these products can produce a significant impact on the class net spend. Vimpat and Onfi are top 20 net spend products in the traditional realm.

FIGURE 13

Anticonvulsants Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 4: Neuropathic Pain

Utilization in this class grew from 2015 to 2016, perhaps as providers sought alternatives to treatment with opioids. At the same time, net spend for the class fell, indicating the effects of generic price erosion. The net result was the No. 4 overall negative driver of average net cost per claim trend.

Cost Drivers:

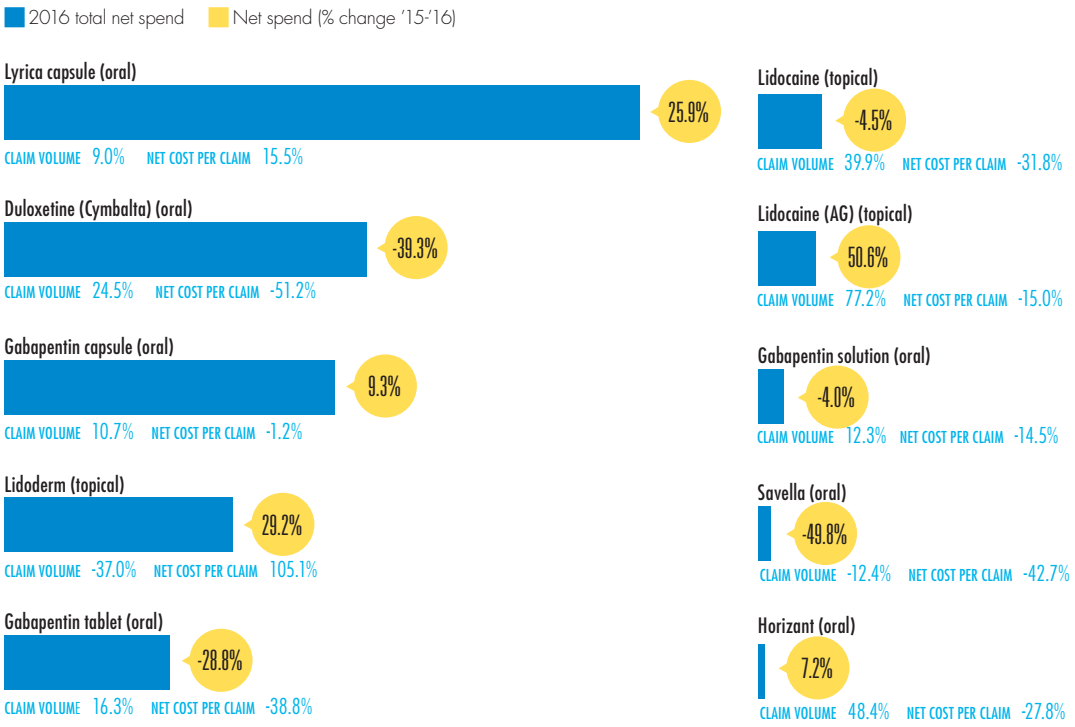
The net cost for duloxetine fell drastically in 2016. Combined with the conversion of utilization from Cymbalta, the two products contributed a negative $0.21 impact to the average net cost per claim trend for the class. The generic for Lidoderm finally surpassed the financial point of equilibrium that led to its increased use over the brand. However, a decrease in the federal rebate on the brand meant states experienced a higher net spend for Lidoderm than last year even with a significant decrease in utilization. Additional positive impact on average net cost per claim trend came from Lyrica, the No. 19 drug in overall net spend, which saw about a 10 percent increase in utilization versus 2015 (**see figure 14**).

Management Strategy:

Continued net cost monitoring leads to financial benefits in this class for those states that manage brand-over-generic expenditures closely. Even though Lidoderm and its generic are both frequently listed as non-preferred, directing utilization toward the brand for several years benefited those states able to program their systems accordingly.

FIGURE 14

Neuropathic Pain Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 5: Analgesics, Narcotic Short

None of the products in this class were ranked in the top 20 net spend; this class was in the overall top 10 net spend classes primarily due to volume. Analgesics, Narcotic Short also ranked as the No. 3 overall class in negative contribution to average net cost per claim trend.

Cost Drivers:

Another 10 percent of utilization in this class migrated away, similar to last year's market share trend. Likely explanations include increased vigilance for abuse of opioids as well as for overprescribing of acetaminophen-containing compounds. The greatest prescription volume decreases were seen in codeine, hydrocodone, and oxycodone combinations with acetaminophen. These occurrences had the highest contribution to the class' average net cost per claim trend. Still, oxycodone/acetaminophen and hydrocodone/acetaminophen ranked No. 11 and No. 13, respectively, in traditional net spend by drug (**see figure 15**).

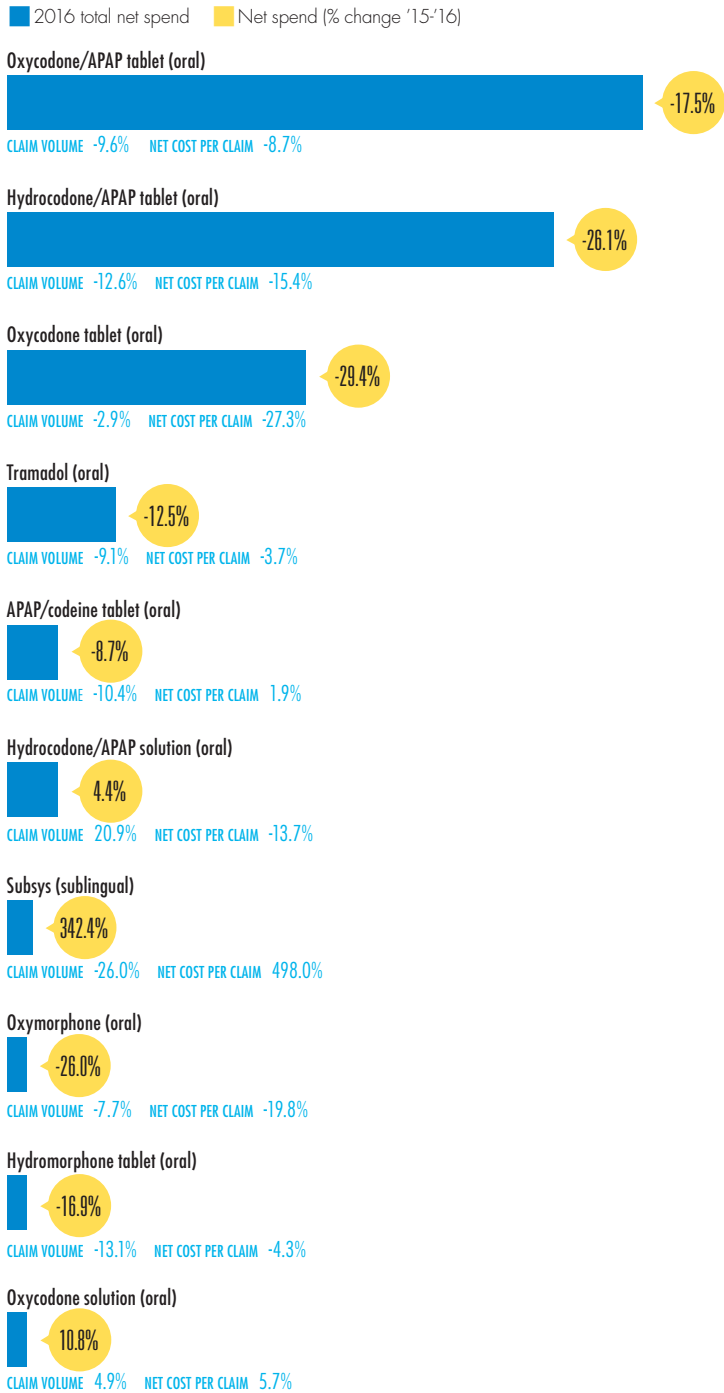
Management Strategy:

Preferred products in this class should be cost-effective generics. States will continue to address appropriate use, monitor for abuse and dependence associated with these products, and encourage movement away from acetaminophen combination products.

As it pertains to product abuse, many states are implementing a variety of criteria geared toward appropriate use of opioids. Setting morphine milligram equivalents (MME) involves clinical edits and dosing limits to guide best practices for utilization management. Further prior authorization criteria address Centers for Disease Control (CDC) guidance on maximum daily doses, if exceeded. System access is also vital for taking appropriate action, as claims and rejections can be monitored in real time to encourage resolution. With greater attention nationally to the opioid crisis, states are responding with increased efforts toward curbing opioid abuse while maintaining appropriate care for qualified patients.

FIGURE 15

Analgesics, Narcotic Short Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 6: Opioid Dependence Treatments

Expenditures in this class remained relatively high as a direct result of the opioid crisis and the increased demand for treatment. Other methods of managing opioid dependence provided greater impact to the bottom line with much lower utilization.

Cost Drivers:

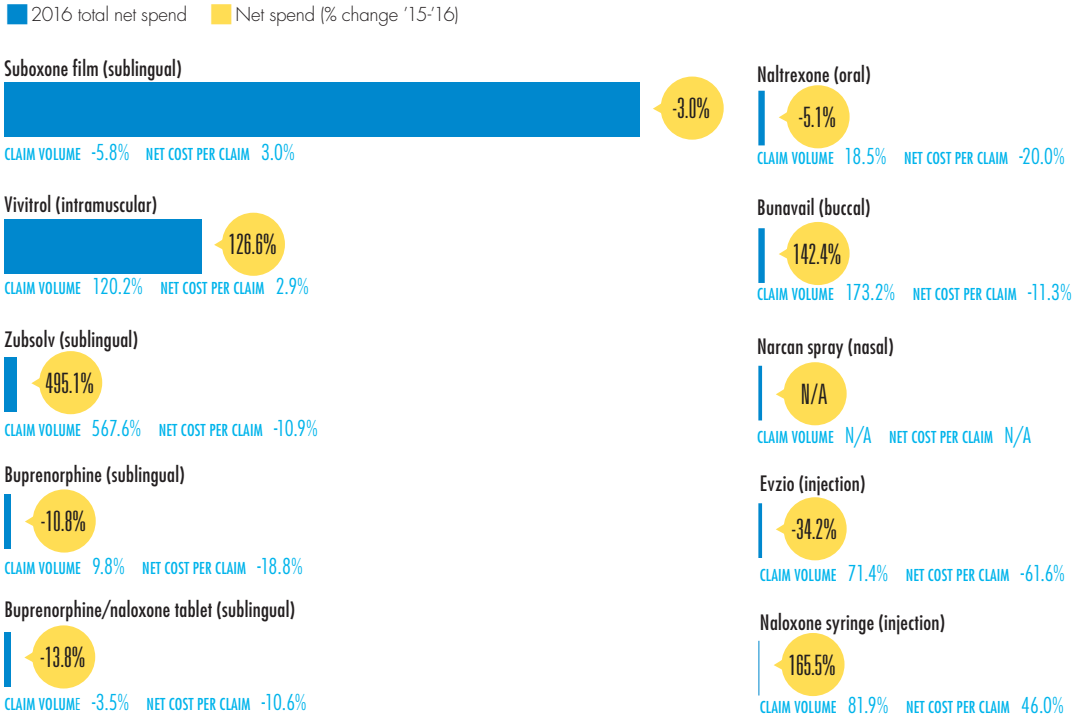
Overall utilization in this class increased about 10 percent in 2016, becoming the No. 9 overall driver of positive average net cost per claim trend. As with Neuropathic Pain, this class likely experienced an overall increase in utilization due to the effects of opioid overprescribing and abuse. The doubling of prescription volume for Vivitrol had the greatest positive contribution to average net cost per claim trend. For oral products, Suboxone film saw some of its market share move over to competing products, Zubsolv and Bunavail. Most states listed Suboxone film as the sole preferred buprenorphine combination product in this class. Suboxone film was 2016's No. 16 product in the overall net spend rankings (**see figure 16**).

Management Strategy:

Competition for a preferred buprenorphine combination product will remain high as several manufacturers vie for what is commonly an exclusive PDL product for this class. This positioning should include the generic for Suboxone tablets, which is rarely price-competitive with the branded products. The addition of new naloxone formulations may increase spend in this class as utilization migrates among the available delivery systems.

FIGURE 16

Opioid Dependence Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 7: Antidepressants, Other

As with Anticonvulsants, this class was static in terms of utilization and net spend metrics; its inclusion in the top 10 was primarily due to volume. There were no positive or negative class or drug drivers here based on net spend.

Cost Drivers:

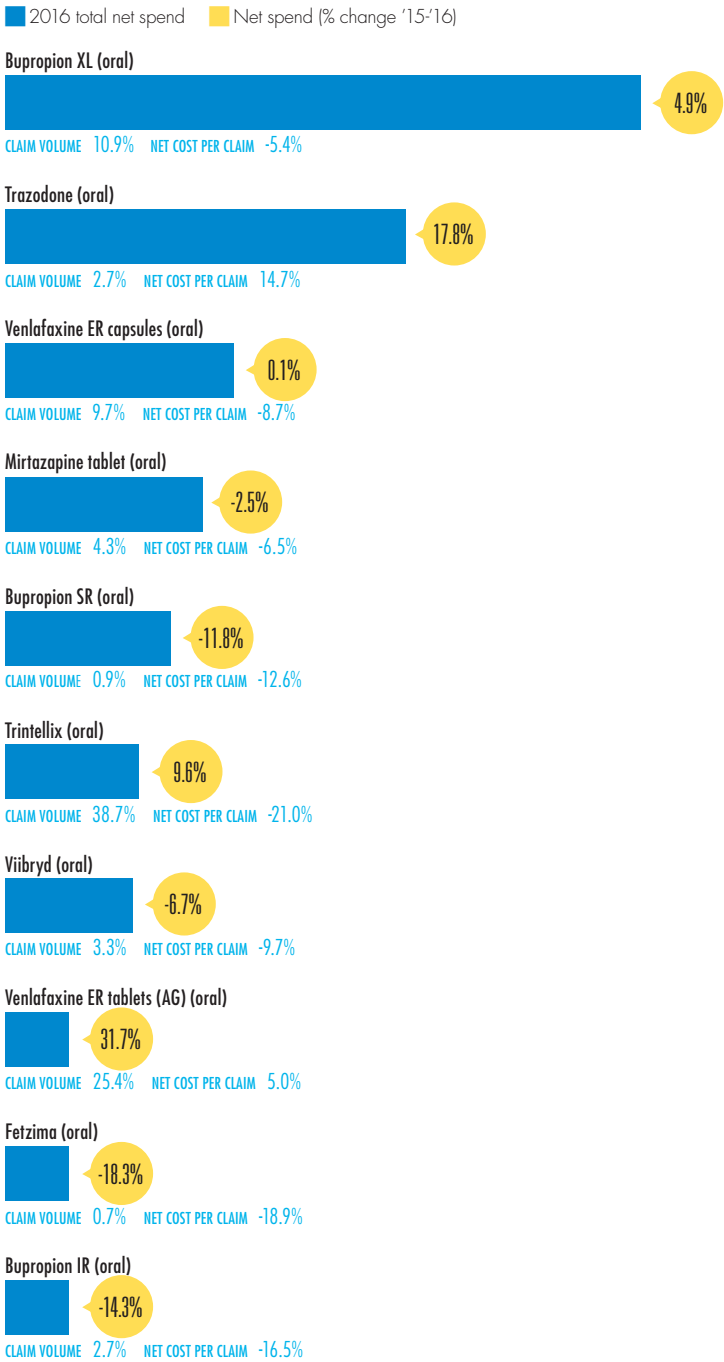
This class was so stable that only one product, trazodone, exhibited an effect on the average net cost per claim greater than $0.01 in either direction. The bulk of utilization was in generic products that have seen their pricing mature to a low net cost expected for oral generics. Nearly 97 percent of utilization in 2016 was in generics (**see figure 17**).

Management Strategy:

There is sufficient variety of products in both this class and the Antidepressants, SSRI class to step through at least one generic before dispensing a branded product. Both brand utilization and growth are at low levels, which should continue.

FIGURE 17

Antidepressants, Other Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 8: Epinephrine, Self-Injected

In 2015, this class ranked No. 29 overall in net spend. A lot has occurred since then. While utilization has remained flat, this class leaped to the No. 13 class overall, fueled by an increase in net spend of nearly 70 percent. This jump was paced by the No. 20 net spend product overall, EpiPen.

Cost Drivers:

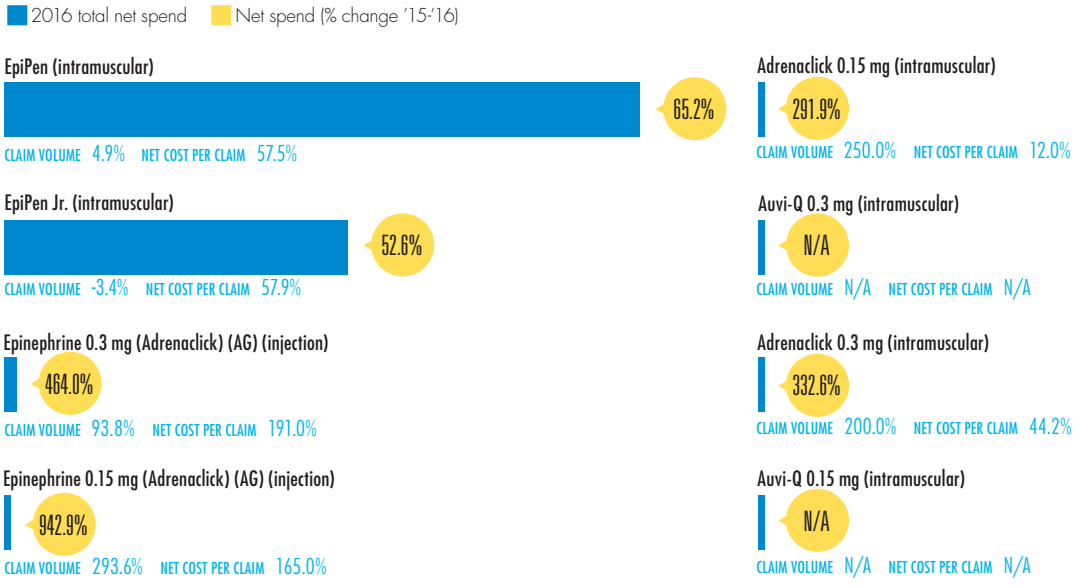
The increased net spend for this class has been an issue in Medicaid for many years, as revealed to the nation in the second half of 2016. With only Adrenaclick and its generic available, Auvi-Q's removal from the market greatly reduced the competition for EpiPen in this class. This resulted in EpiPen jumping from the No. 45 net spend product overall to No. 20, becoming the No. 11 overall positive driver of average net cost per claim, and making this class the No. 6 overall positive driver of average net cost per claim. EpiPen's market share grew to over 95 percent in 2016. Moving forward into 2017, state Medicaid programs are expected to see net spend relief in this class (**see Notable Market Events and figure 18**).

Management Strategy:

States must make epinephrine products readily available to patients, as dictated by clinical necessity as well as federal law. New product entries to the market are expected in 2017 and beyond that may provide states with a wider selection of injector attributes and net costs from which to make PDL choices.

FIGURE 18

Epinephrine, Self-Injected Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 9: Glucocorticoids, Inhaled

Utilization remained constant in this class, but a lower net spend is always welcome. This class fell from No. 9 overall for net spend last year to this year's No. 14 overall mark.

Cost Drivers:

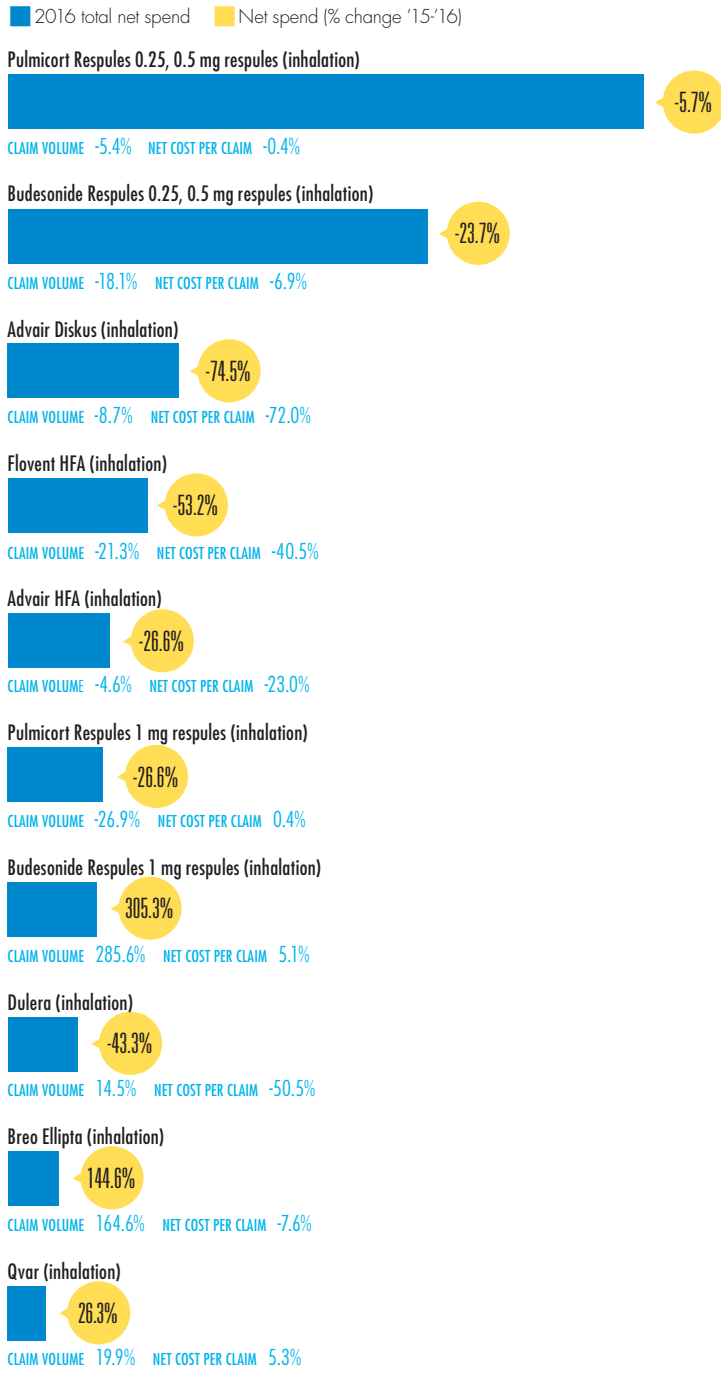
State Medicaid programs reaped a savings of nearly $20 million in 2016 from preferring Pulmicort Respules over its generic equivalent. These savings were largely from the 0.25 and 0.5 mg formulations. The 1 mg strength of Pulmicort Respules became available in 2015. It took time for state Medicaid programs to roll back utilization from the generic to the brand for the lower strengths. Judging by the utilization for the 1 mg strength, there may be a duplication of effort needed to create similar savings opportunities. Net prices for the generic are not decreasing overall. On top of that, this class was the No. 2 overall negative driver for average net cost per claim. This is largely due to continued downward pressure on net costs as competition in many books of business benefit Medicaid. Many are eagerly awaiting the first generic for Advair, but that is not expected to lead to Medicaid savings in the near future (**see figure 19**).

Management Strategy:

Brand-over-generic strategies are advantageous to states both presently and looking ahead. Both Pulmicort Respules and Advair should be evaluated continually to best manage expenditures in this class as additional generic labelers enter the market.

FIGURE 19

Inhaled Glucocorticoids Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 10: Cephalosporins and Related Antibiotics

As generic prices continued to fall in this class, so did the overall class rank in net spend. This class fell from No. 11 in 2015 to No. 16 in 2016.

Cost Drivers:

There were limited supplemental rebate opportunities in this largely generic class, but there were still brand-over-generic savings available. Suprax suspension saved states over $7 million in 2016 when preferred over its generic equivalent. As noted last year, dispensing the generic is not advisable in Medicaid (**see figure 20**).

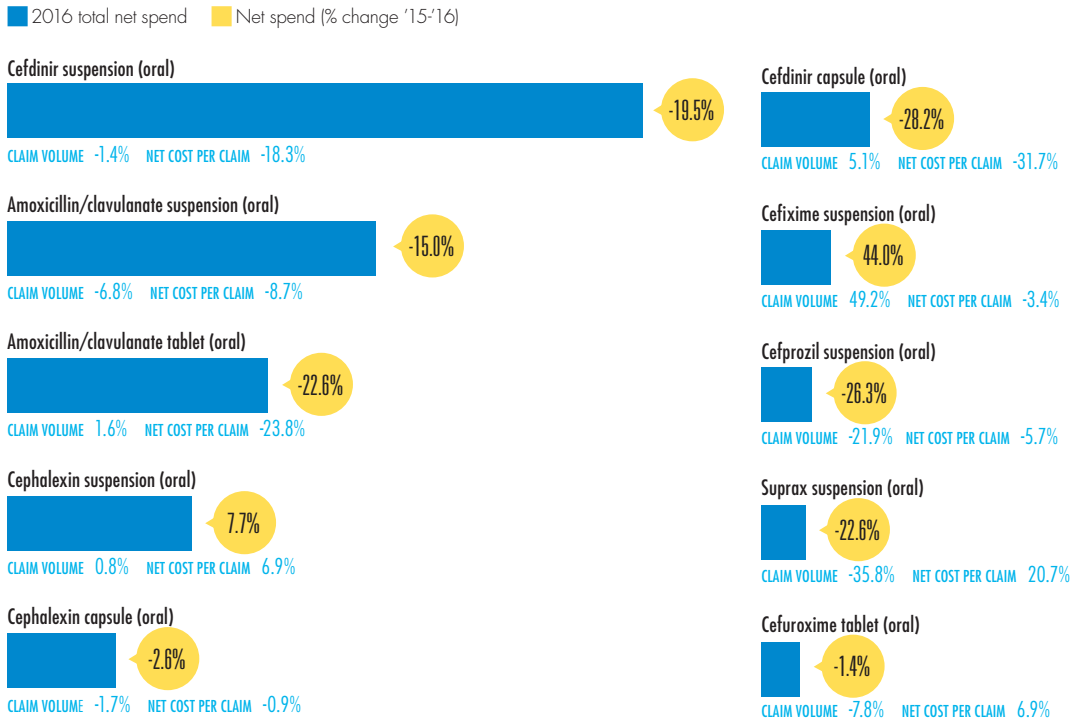
The biggest savings in this high-volume class were due to lower net prices for the generics with the highest utilization, cefdinir and amoxicillin/clavulanic acid. Together, these products contributed ($0.07) toward the average net cost per claim trend. This accounted for nearly the entire ($0.08) impact by the class overall. With continued price erosion for generics, this class was the No. 10 overall negative trend driver.

Management Strategy:

At this point, listing cost-effective generics as preferred is a simple solution for this class. State Medicaid pharmacy directors should continue to monitor for brand-over-generic savings opportunities, even in classes where utilization is already weighted toward longtime generics.

FIGURE 20

Cephalosporins and Related Antibiotics Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



Specialty Drug Spend Class Analysis

No. 1: HIV/AIDS

This class had the top net spend in the specialty division for the second consecutive year in this report despite a reduction in overall utilization for the class. The average prescription net cost soared by nearly 30 percent. Few state Medicaid programs have implemented cost-saving measures for this class. The sensitivity surrounding clinical selections for these drugs is understandable given the history of resistance and poor compliance. However, the net spend in this class was greater than that for Hepatitis C Agents, and treatment options have advanced significantly from the days of multiple pills taken several times per day.

Cost Drivers:

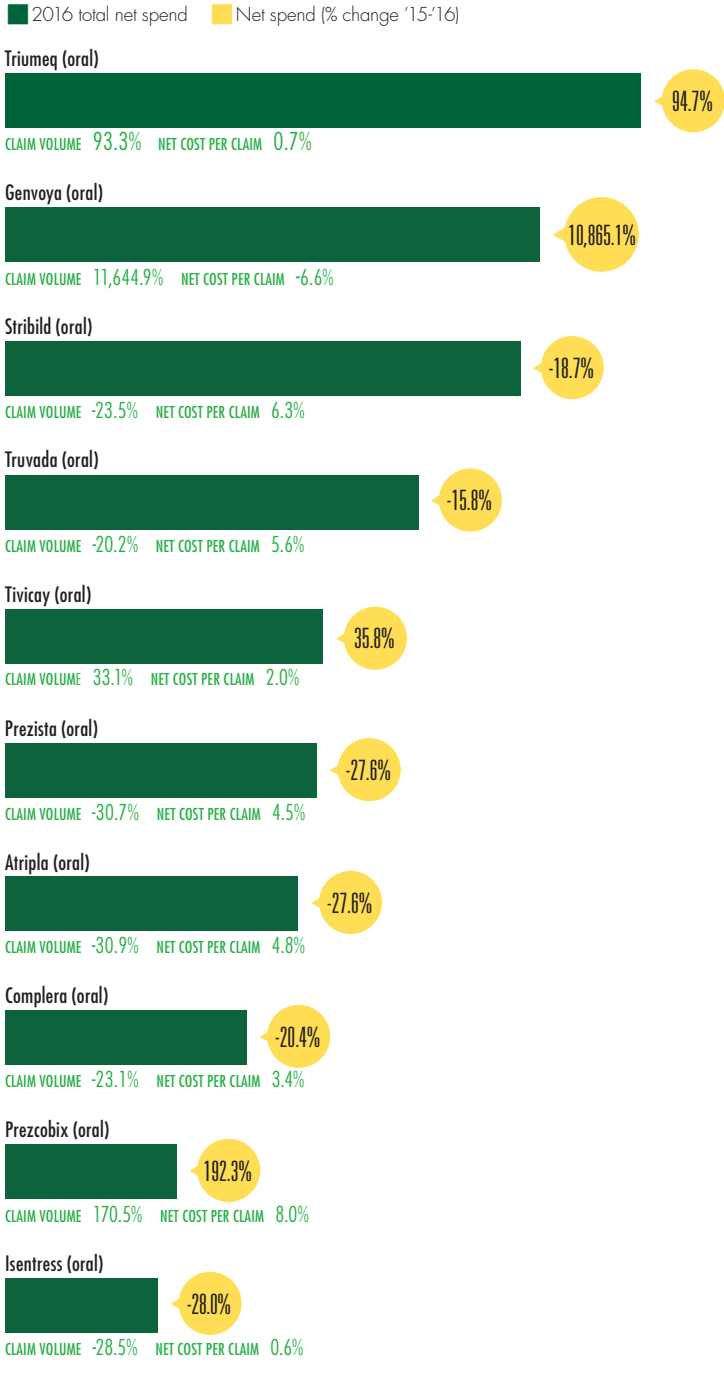
As predicted, new brands added to this class challenged states to spend their pharmacy budgets appropriately. Four of the top five contributors to the class' positive contribution to average net cost per claim were named in the 2016 report (Descovy, Genvoya, Odefsey, and Prezcobix). Those products contributed a whopping $0.85 toward the class' increase in net spend. Genvoya and Triumeq were two of the top three overall drivers of average net cost per claim trend. Meanwhile, the predecessors for those product lines experienced a corresponding decrease in utilization, but the net decrease was a collective $0.41. Less than half of the increased spend for this class was offset by decreased utilization of products that may be more cost-effective. HIV/AIDS was the top driver of positive average net cost per claim trend. This class boasted three top 10 overall net spend products, two of which are projected to continue in the top 10, Genvoya and Triumeq, and another that is on a downward path, Stribild. This pattern of increased net spend is likely to continue even as significant formulation advances become harder to develop (**see figure 21**).

Management Strategy:

States should carefully weigh the cost of new products to the clinical benefit they provide in order to prevent market share movement to products with higher net costs than existing therapies and unproven claims for improving patient care versus existing treatments.

FIGURE 21

HIV/AIDS Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 2: Hemophilia

This class contained the No. 3-ranked net spend overall in Medicaid, up from No. 4 last year.

Cost Drivers:

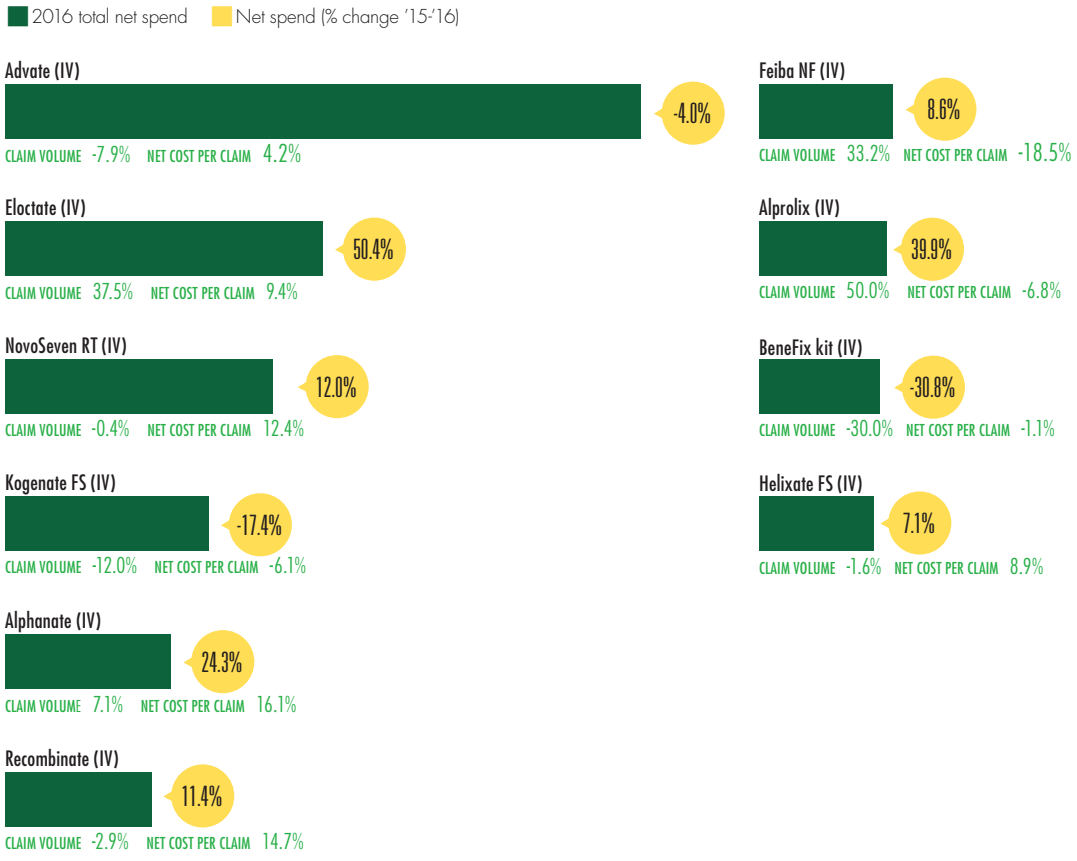
While Advate continued to possess the No. 3 ranking in products by net spend, it was newer products such as Eloctate, Adynovate, and Alprolix that threatened to take net spend in this class to new heights. This class was the No. 4 overall driver of positive average net cost per claim trend and contained five of the top 20 specialty net spend products. It contained two of the top 20 overall drivers of positive average net cost per claim trend. As mentioned last year, it is worth noting that the prescription volume did not change appreciably, yet net spend increased by 10 percent (**see figure 22**).

Management Strategy:

This class merits greater attention to management than just PDL considerations. The complexity of product distribution and optimization calls for a more complex solution. State Medicaid programs may implement PDL measures as an initial step, but the involvement of multiple steps in patient care should compel states to address each level on the way to coordinated care and cost savings.

FIGURE 22

Hemophilia Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 3: Hepatitis C Agents

Despite news that the market is flattening and even declining in commercial systems, Medicaid treatment courses continued to climb upward due to methodical gains in access to treatment for patients.

Cost Drivers:

Genotypes 2 and 3, while less prevalent in hepatitis C patients, required treatment with products that had a higher net expense than that for other genotypes. For this reason, Epclusa (No. 4 overall driver) and Daklinza (No. 2 overall driver) topped the list of products in this class contributing positive impacts to the average net cost per claim trend. Due to the additional appeal of Epclusa's pan-genotypic indication and lack of coadministered medication, Daklinza utilization (and expenditures) is expected to decline quickly. So too, however, is that for Sovaldi. The lack of need for coadministered medications with other treatment regimens will greatly reduce the need for this breakthrough product. Significant increases to utilization of Zepatier, representing the new manufacturer to the class, and Harvoni caused the other positive contributions to average cost per claim. Harvoni was the No. 2 overall net spend drug (**see figure 23**).

Management Strategy:

As net spend for individual products continues to decline based on the average treatment regimen cost, it is becoming more appetizing to state Medicaid programs to explore easing restrictions on treatable patient populations. States are gradually advancing treatment availability to patients with Metavir scores 0-2, whereas most states were in the Metavir scores 3-4 this time last year. This is illustrated by the increasing number of states allowing access at the lower fibrosis score. In February 2016, 36 percent of the states allowed treatment at F2 and F0. In December 2016, that number increased to 56 percent (**see figure 24**).

Utilization is expected to increase for Medicaid overall as this trend continues. The expected approval of additional pan-genotypic products in 2017 should continue to provide downward pressure on net pricing in this class.

FIGURE 23

Hepatitis C Agents Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016

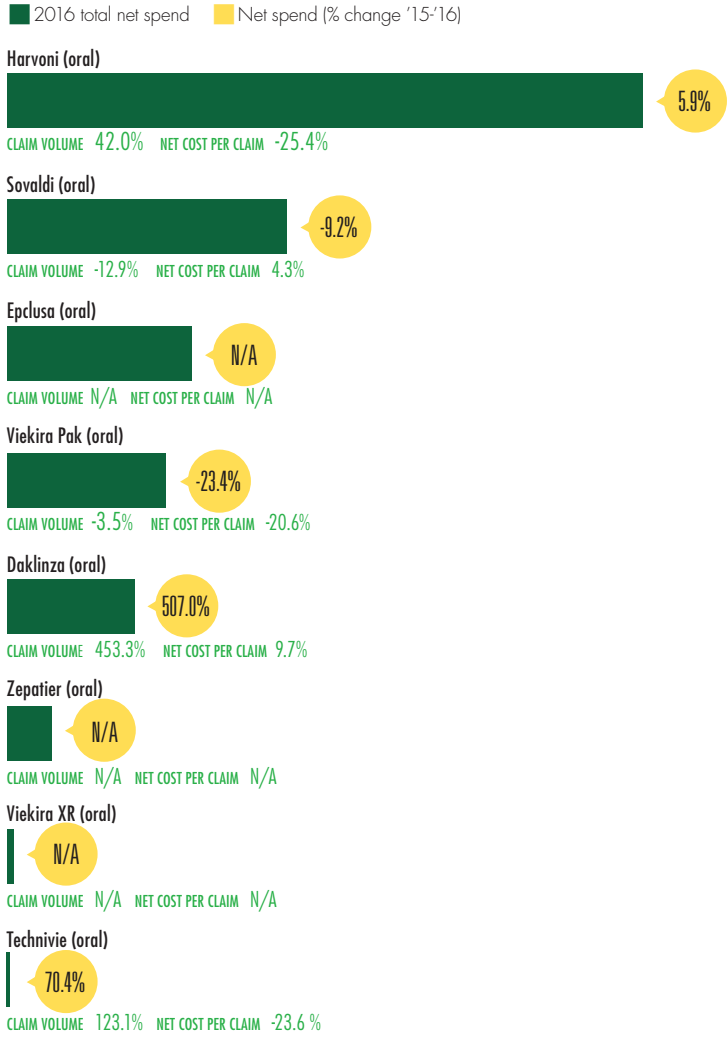
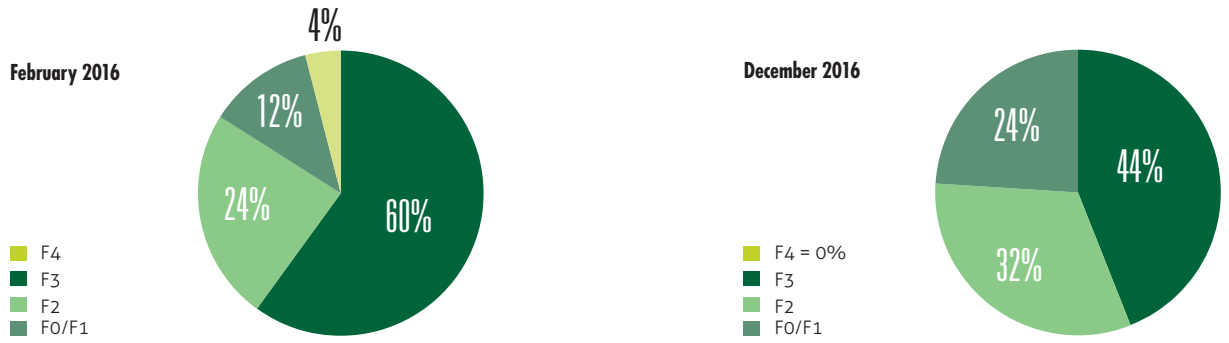


FIGURE 24

Coverage by Fibrosis Score



No. 4: Cystic Fibrosis, Oral

Utilization and net spend more than doubled in this class between 2015 and 2016, with Orkambi representing the vast majority of both metrics.

Cost Drivers:

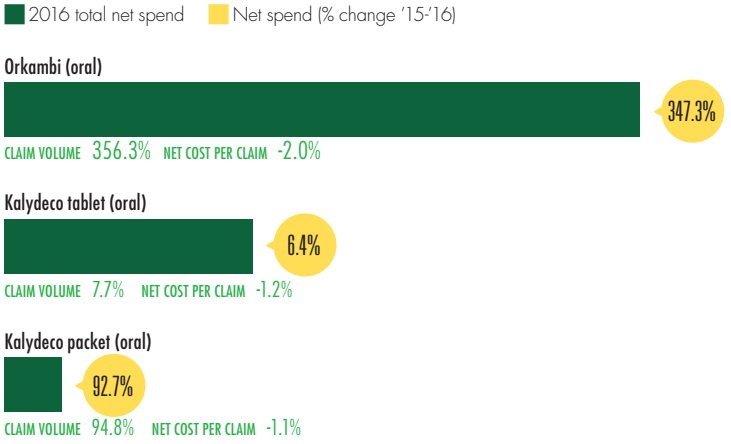
Orkambi, the No. 2 overall positive driver of average net cost per claim trend, provided the No. 10 overall net spend power, pushing this class into the forefront. It was the No. 3 overall net spend class. Kalydeco just missed the top 20 net spend for specialty products (**see figure 25**).

Management Strategy:

As discussed later in Notable Market Events, specialty products with extremely specific indications essentially write their own prior authorization criteria. Kalydeco and Orkambi are indicated for gene mutations that can be detected by genetic testing. Patients should meet the criteria for treatment advised in the products' prescribing information.

FIGURE 25

Cystic Fibrosis, Oral Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 5: Cytokine and CAM Antagonists

This class is one of the standard-bearers in terms of how specialty classes have contributed to higher gross spends in Medicaid. Utilization continued to trend upward, with an increase of 13 percent in 2016. With strong PDL management, however, the net spend actually decreased on a net cost per claim basis.

Cost Drivers:

This class could be described as the jewel of Medicaid pharmacy trend over the past several years. It has not been a class driver of trend nor has it contained a product that was a driver of trend. In fact, in this year's report, no product contributed more than $0.03 to average net cost per claim trend in either direction. It is also interesting to note that there was only one product with that $0.03 impact. In addition, the direction of that impact was actually negative. To top off this story, the product in question was Humira, the market leader! State Medicaid pharmacy departments have done a great job in leveraging net pricing in this class in a manner that produces reliable budget estimates annually (**see figure 26**).

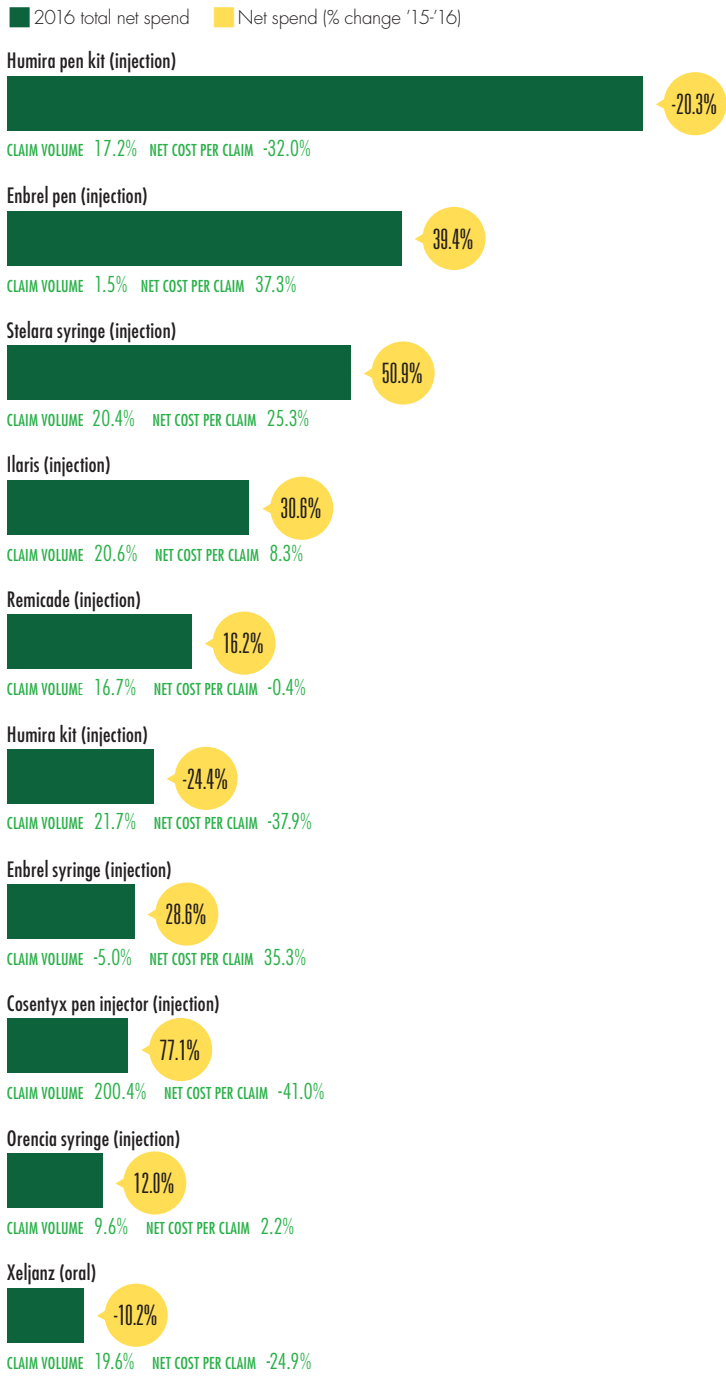
In recent years, a new wave of products to this class has made for an interesting dynamic from clinical and financial standpoints. Market leaders Enbrel and Humira have enjoyed market share domination over competing products. However, new brands touted interesting clinical data in an attempt to break through the commonly preferred products on state Medicaid PDLs as well as to recognize the net cost challenge they pose. Despite high reimbursement, market leaders' net price remained attractive based on a number of discounts and CPI-U penalty impacts in Medicaid. New brands were typically priced similarly to existing products on a WAC basis but fell well short of the net-of-all-rebates cost. In 2016, new products did not have the individual trend impacts seen in other classes like HIV/AIDS.

Management Strategy:

Novel entrants to this class will continue to struggle to meet net price challenges, but demand based on clinical data and mechanisms of action may provide opportunities for preferred PDL status. Biosimilars are not expected to make such gains in this class, despite the number expected to launch in the next few years. The relatively low WAC price set for biosimilars is unlikely to approach the net cost necessary to displace reference products and others from preferred status. This will be a strong interest of future editions of this report.

FIGURE 26

Cytokine and CAM Antagonists Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 6: Multiple Sclerosis

A bump in net spend for this class came several years ago with the launch of several oral products for the treatment of multiple sclerosis. Since then, the orals have continued to gain in market share compared to injectables but still constitute the minority formulation type.

Cost Drivers:

The focus in this class needs to be on Copaxone formulations. A generic for Copaxone 20 mg/mL became available recently, almost in conjunction with a new Copaxone 40 mg/mL strength. Brand-over-generic savings in 2016 for Copaxone 20 mg/mL exceeded $10 million. However, the larger threat to state Medicaid pharmacy budgets was the Copaxone 40 mg/mL market share, which received most of the Copaxone 20 mg/mL utilization rather than the generic. Collectively, there was an eight-digit monetary swing in increased spend based on that product line alone, even after accounting for the brand-over-generic savings (**see figure 27**).

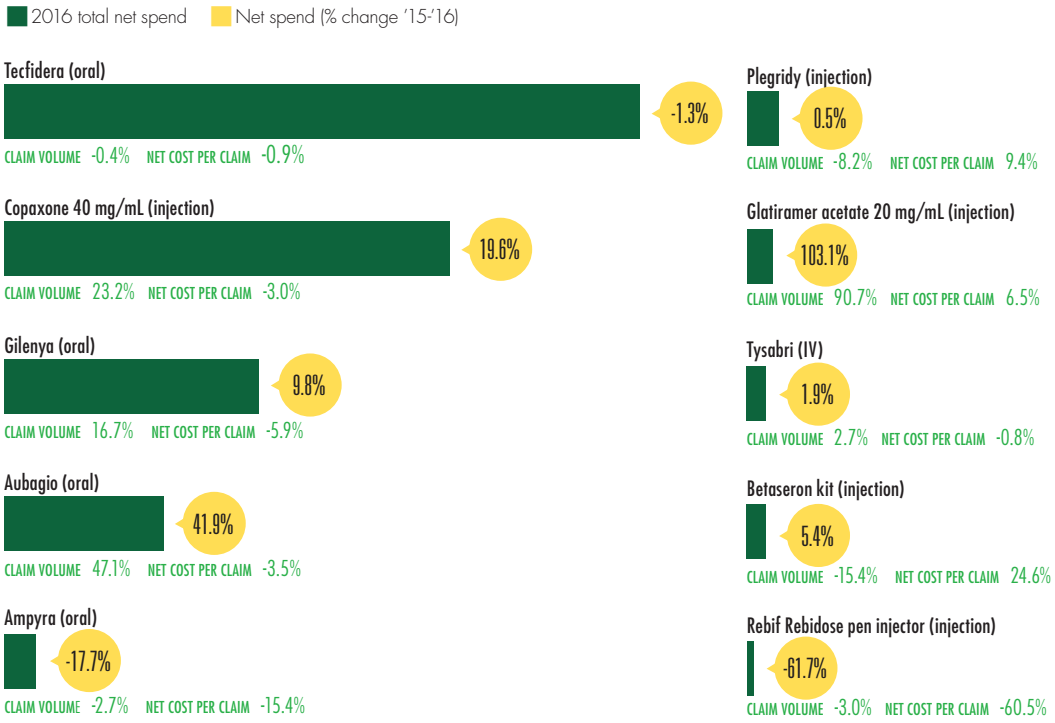
Like the previous class, the net spend trend for multiple sclerosis was probably not as expected. Utilization, net spend, and class rank for net spend were all unmoving compared to recent years. The expense of oral products has been absorbed fairly well due to the group's minority status, but that should not blind Medicaid pharmacy directors to the gradual annual increases in market share. This class possesses the potential to rise in net spend rankings if put aside.

Management Strategy:

A common practice in Medicaid for this class is a trial of an injectable product before a patient accesses an oral product. This has helped states better manage the financial impact to this class in a clinically acceptable manner. It is advisable that the injectable product be Copaxone 20 mg/mL compared to similar aforementioned products, as illustrated above.

FIGURE 27

Multiple Sclerosis Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 7: Oncology, Oral — Hematologic

It should be noted that the next two classes are only subsections of oncology treatment as a whole; this may blunt the message that this disease state represents a significant portion of Medicaid pharmacy expenditures but makes class reviews more clinically manageable.

Cost Drivers:

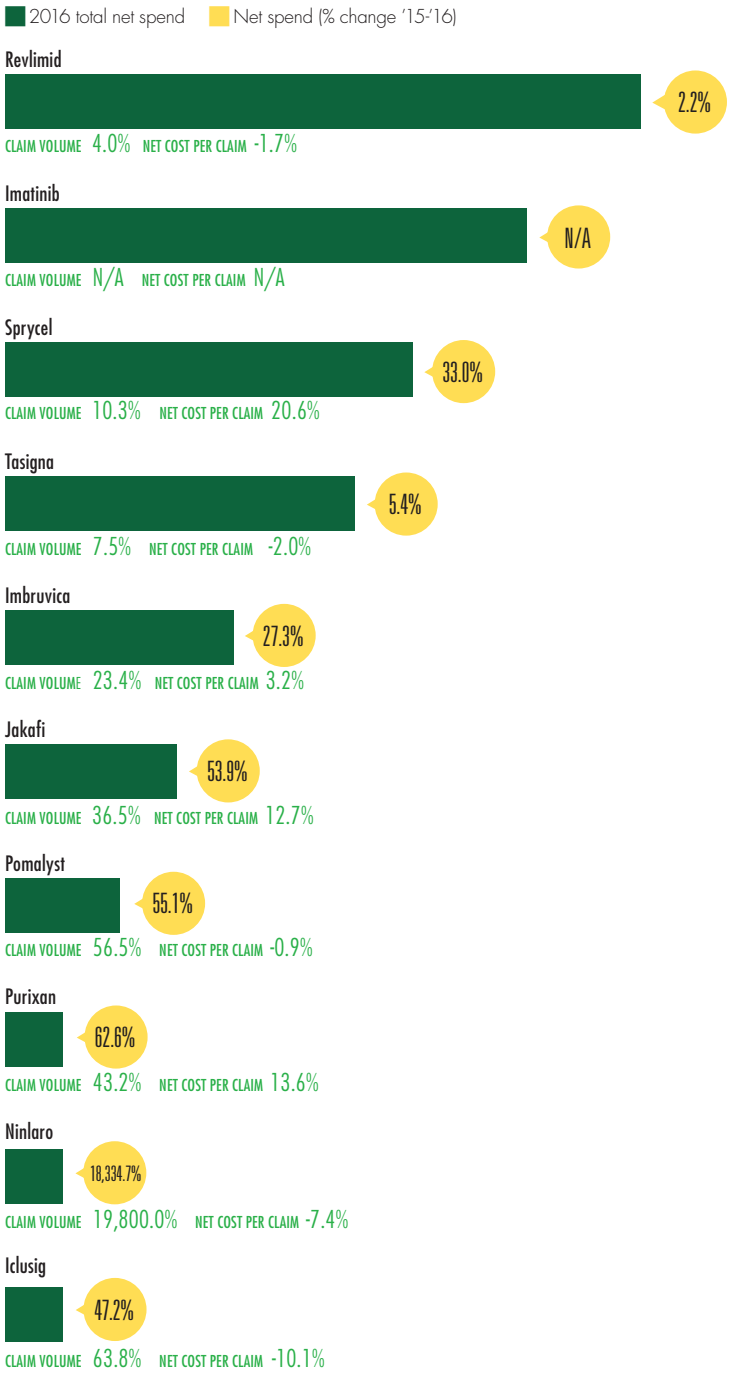
Products used in the oral treatment of oncology experience incremental gains annually, which obviously drives up the average net cost per claim trend. However, the focus for this subclass is the launch of generic Gleevec. This was a hugely anticipated event in pharmacy, the rare generic for a specialty product! Unfortunately, Medicaid pharmacy conditions largely did not permit states to stay the financial course upon its introduction to the market. Oncology is a class that states continue to restrict from PDL consideration. This is a complex issue. As discussed in the 2016 trend report, many states prevent certain drug classes from being reviewed for PDL statuses. This includes classes such as HIV/AIDS, mental health, and oncology. Such policies were enacted 10-15 years ago, as PDL management became a standard of Medicaid pharmacy management. Therefore, policies predated the influx of products dispensed at the pharmacy point of sale. This is all to say that state Medicaid pharmacy programs may have been permitted to save more than the $6.7 million experienced in 2016 by continuing to dispense brand Gleevec instead of its generic equivalent. Instead, the generic's market share was 32 percent, resulting in an increased net spend of over $10 million (**see figure 28**).

Management Strategy:

The complexity of oncology management in pharmacy, alluded to above, involves the clinical criteria component. As with hemophilia, there are several steps to the appropriate clinical management of patients afflicted with these diseases. Medicaid pharmacy departments should devise appropriate pathways for accessing products and services to combat this disease.

FIGURE 28

Oncology, Oral — Hematologic Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 8: Oncology, Oral — Breast

Cost Drivers:

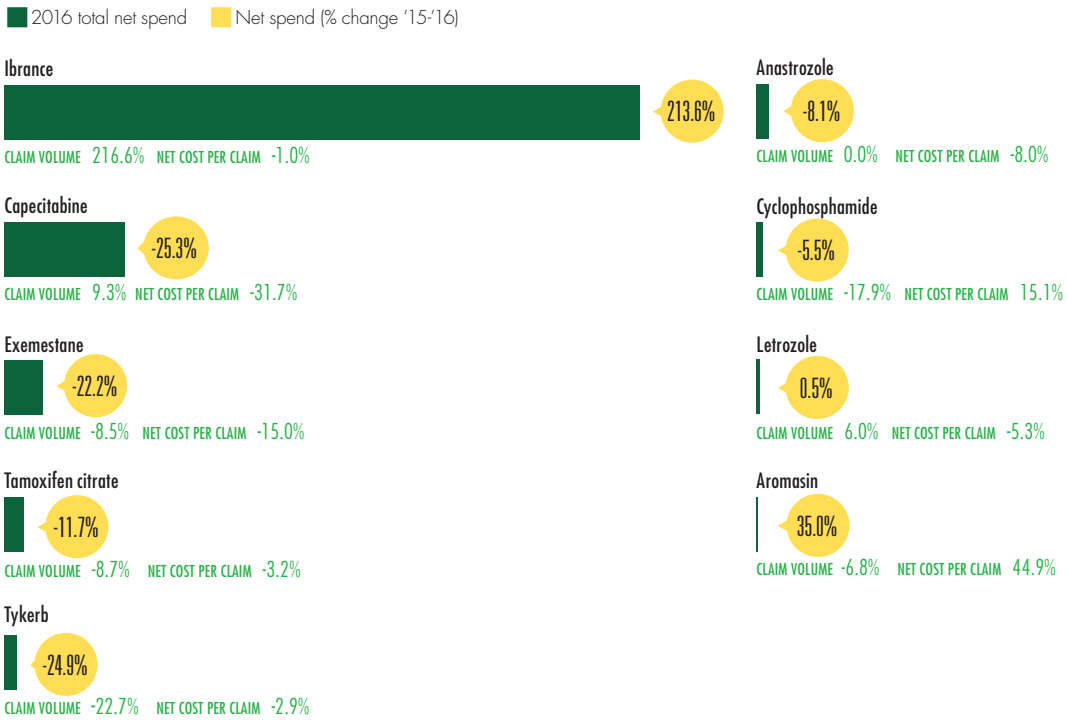
The uptake of Ibrance as a popular breast cancer treatment drove the increased spend here. Ibrance was the No. 6 overall positive driver of average net cost per claim, helping this class to the No. 8 specialty class net spend ranking and the No. 7 overall class driver of average net cost per claim. On the generic side, utilization of capecitabine instead of the brand, Xeloda, caused a similar situation to that of Gleevec above. A key brand-over-generic opportunity was largely unrealized by states, as the generic had a market share of nearly 70 percent between the two and a seven-figure net spend (**see figure 29**).

Management Strategy:

The complexity of oncology management in pharmacy, alluded to above, involved the clinical criteria component. As with hemophilia, there are several steps to the appropriate clinical management of a patient afflicted with these diseases. Medicaid pharmacy departments should devise appropriate pathways for accessing products and services to combat this disease.

FIGURE 29

Oncology, Oral — Breast Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 9: Contraceptives, Other

Alternatives to oral contraceptives are financially challenging in Medicaid due to their extended duration of action which may exceed the time a recipient is enrolled in the Medicaid program.

Medicaid pharmacy departments need to weigh the cost-effectiveness of alternative contraception verses oral contraception. Oral contraception was a sizable class itself, ranking No. 12 in net spend for traditional classes.

Cost Drivers:

A movement from oral contraceptives to non-oral alternatives was not a trend borne out by utilization data included in this report, but the average net cost per claim certainly demonstrates that orals are less expensive. Non-orals constituted about 21 percent of all contraception utilization in 2016. With all of this stability in the use of contraception, the reason for this class' inclusion in the top 10 is not obvious. By paying attention to the narrative trend in this report, though, one can derive that it is another brand-over-generic issue. This example is somewhat different, as there was no brand to rely on anymore. Ortho Evra was a contraceptive patch that was widely used for many years. However, when its first generic (Xulane) became available, the Ortho Evra manufacturer discontinued the brand product. The impact to Medicaid pharmacy was that a product that had a relatively low net cost was suddenly unavailable, with utilization shifted to a generic "equivalent" with low federal rebate responsibilities (**see figure 30**).

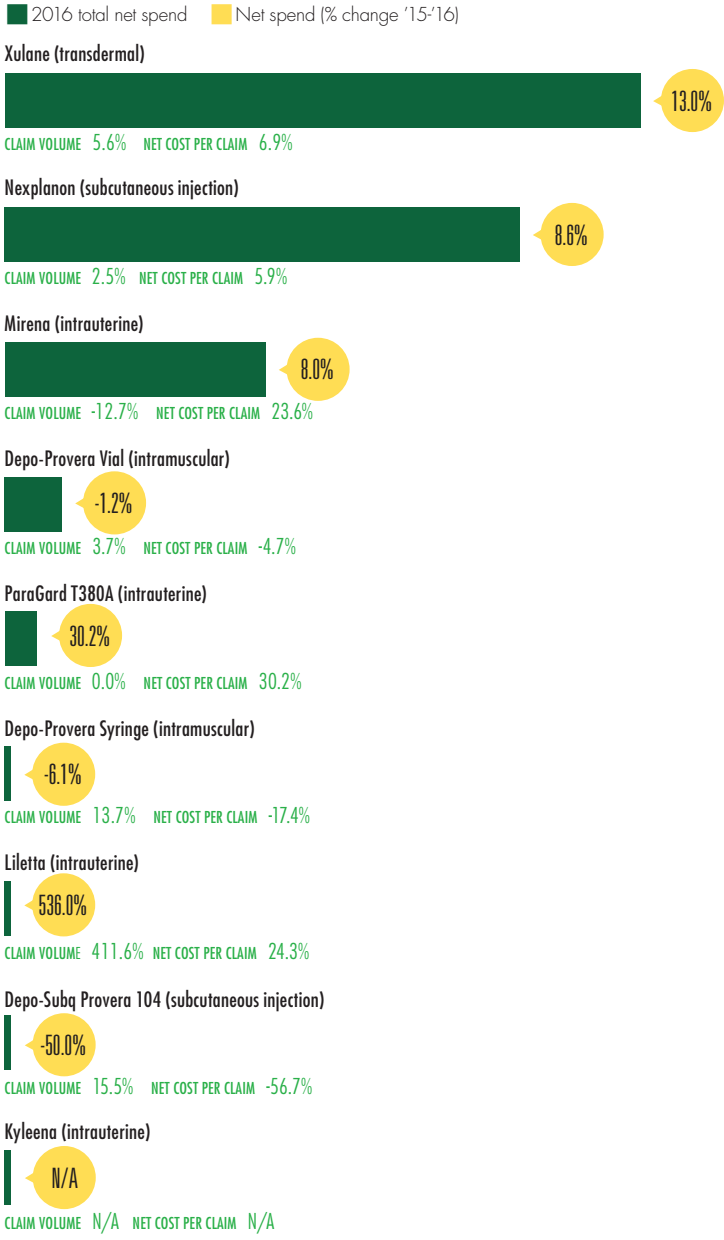
This is an example of how manufacturer decisions can impact Medicaid expenditures. There have been several notable occurrences of significant impact to Medicaid when, on the surface, the intent behind the change was well-intentioned. Manufacturers of various inhalers, gastrointestinal aids, and pain relievers have received direction from the FDA over the past 10 years to address the formulations of their respective products. The intent behind the FDA's guidance was to produce products with more reliable and/or safe outcomes in users. The adverse effect, if you will, was the financial impact on Medicaid pharmacy programs. Expenditures for the old formulations had gained a sizable rebate allocation over the years, making them relatively inexpensive. When new formulations were introduced to the market, the federal rebate calculation essentially started from scratch, inflating the net spend in classes where budgets were previously low and stable. Applied to this particular example, the market shift from Ortho Evra to Xulane was an unforeseen event that continues to impact Medicaid pharmacy budgets.

Management Strategy:

Medicaid pharmacy departments need to weigh both the cost-effectiveness of alternative contraception as well as the duration of time that expense is beneficial to Medicaid.

FIGURE 30

Contraceptives, Other Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



No. 10: Immune Globulins

Unlike the oncology classes discussed previously, the Medicaid spend represented by this class could be the tip of the iceberg. Most immune globulin utilization is dispensed through the medical pharmacy pathway. However, the utilization applicable to this report was sufficient for the class to make the top 10 specialty classes.

Cost Drivers:

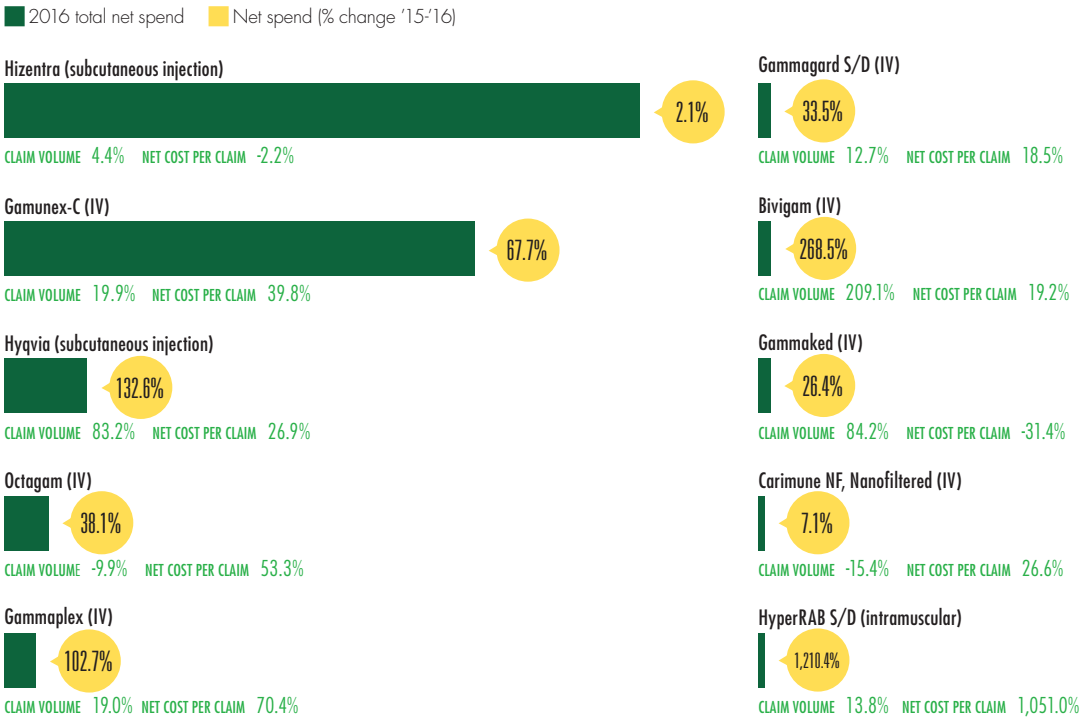
No one product in this class experienced significant fluctuations in utilization over the past year, nor did the class itself see a large increase in utilization. Still, the expense associated with this class, even in evaluating only the pharmacy spend, was substantial. Worse for state Medicaid pharmacy directors, the net spend in this class is unpredictable. This is true in both the number of patients that may require treatment as well as the volume of drug required for a given patient. Attempts to best manage drug spend here are often limited to matching up the vials according to units contained in order to minimize the amount of waste with the preparation of each prescription (**see figure 31**).

Management Strategy:

This is a complex situation that represents the next evolution of PDL management. Specialty products that are dispensed largely through the medical benefit frequently escape conventional methods of utilization management employed on the pharmacy side. Some states use a J-code/NDC-HCPCS Crosswalk to convert medical utilization to pharmacy claims in order to be able to invoice for rebates and generate some savings. However, this method does not regulate utilization proactively. As specialty drug spending continues to overtake that for traditional drugs, the need for solutions for the medical pharmacy benefit becomes urgent.

FIGURE 31

Immune Globulins Trend in Claim Volume, Net Cost per Claim, and Net Spend 2015-2016



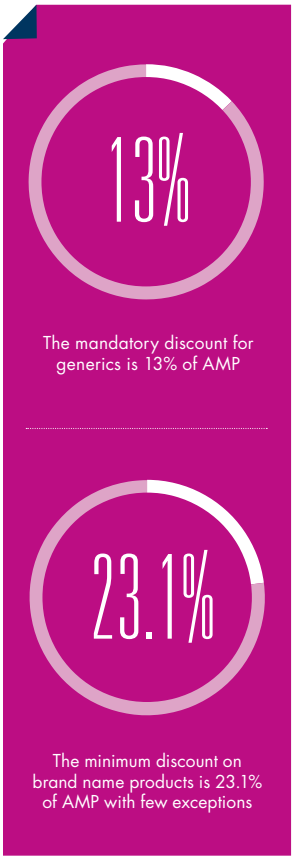
NOTABLE MARKET EVENTS

In this space last year, hepatitis C treatment issues and financial burdens were discussed from the perspective of the state Medicaid department. While the uproar for this specific disease state has subsided somewhat, the issue at hand has taken a more distinct shape. The financial management of specialty pharmacy expenditures in Medicaid is now the focus, as illustrated by the changes to the Magellan Rx Medicaid Pharmacy Trend Report™ format. It is true that this story is not significantly different from that for other pharmacy benefits. However, as reported in last year's issue, the managed care tools utilized in other markets are not so widely implemented in Medicaid. Even so, it is likely that states would not see relief through the use of such management tools. With specialized pharmaceuticals come specialized indications. Multiple products entered the market in 2016 with indications tied to the presence of a specific gene mutation in patients with the disease. This leaves no wiggle room in determining appropriate patients for treatment; the prior authorization criteria are baked into the indication! The CMS-mandated 23.1 percent rebate for Medicaid participation, in most cases, is all that state Medicaid programs have going in their favor for expensive but specific products.

As state Medicaid programs look across all of their budget classes, including drugs, physician visits, and hospitalizations, they continue to assess the best allocation of the states' funds. From a financial standpoint, the product costs can be staggering. Many medications justify their costs with positive clinical data, such as reduced hospitalizations or averted physical outcomes. Orphan drugs, for example, can have more subjective measures associated with success. Clinical trials that demonstrate these endpoints may show statistically significant differences relative to placebo (or standard of care, where applicable), but the overall success rate for the endpoint in question is low. The FDA's accelerated approval pathways also play a role. Providers, patients, and advocacy groups push for more widespread availability for investigational drugs with some indicators of success but unproven long-term benefits. As Medicaid pharmacy directors assess all of the information available to them, there are frequently hard decisions to be made on behalf of all state citizens.

One product with a high price but unquestioned drug effectiveness is EpiPen. In 2016, a number of events came together to create yet another pharmacy-related crisis for Medicaid. In particular, the combination of the market withdrawal of Auvi-Q

Affordable healthcare, particularly for Medicaid recipients, will continue to be a contentious and politically volatile topic in 2017.



and the increasing cost of EpiPen led to a congressional focus on EpiPen pricing similar to that of the previous year's investigation of hepatitis C products. The lack of brand competition to EpiPen is problem enough, financially, but this situation also brings to light the manufacturer practice of enhancing access to their products through legislation. There are many state (and federal) laws that necessitate the availability and trained delivery of various medications, not limited to epinephrine. This practice is a vital part of providing appropriate healthcare to all citizens. However, draft bills at times name a specific product in an attempt to give a competitive edge to a manufacturer. Whether intentional or just good brand-name recognition by lawmakers, Medicaid pharmacy departments need to be vigilant in order to avoid such legislative limits to PDL management. From a more general standpoint, the mandates to include epinephrine products at places of major assemblies (schools, arenas, camps, etc.) contributed to this class' inclusion in the top 10 of this trend report.

Of course, EpiPen might not be such a financial burden to states if federal rebates were calculated according to rules for a brand product in Medicaid. For years, the lower generic federal rebate percentage (13 percent of AMP) has been used in invoicing the manufacturer. The backdated federal rebates to Medicaid programs were discussed by the Department of Justice and Mylan in 2016 with an apparent settlement reported but as yet unpaid. In 2017, though, the mechanism that keeps brand federal rebate calculations in step with manufacturer price increases, the CPI-U penalty, will be applied to generics as well as brands. Over the past several years, causes for price spikes for generics have included higher raw ingredient costs, generic manufacturer consolidation, and limited generic labeler approvals via litigation settlements or FDA-assigned exclusivity periods. Although not expected to generate the level of revenue experienced for brand products in Medicaid (average federal rebate is 53 percent), this addition to the law will help states deal with the financial fallout of increases in prices for generics like chlorpromazine (as detailed in Antipsychotics of the 2016 edition) as well as address the possible continued Medicaid generic status on EpiPen.

There is somewhat of a silver lining to the EpiPen issue for Medicaid. Mylan launched an authorized generic for EpiPen in late 2016. Promoted as being half the cost of the brand, the authorized generic was expected to save money for all consumers. With a primary thanks to ACA rules, and perhaps an assist from the CPI-U penalty referenced above, we expect the authorized generic to be considerably less expensive than EpiPen in Medicaid in 2017. In brief, the ACA changed federal rebate calculations for authorized generics to include aspects of those calculations for the brand. This generally results in a much higher federal rebate commitment than the 13 percent of AMP usually seen for a generic.

Affordable healthcare, particularly for Medicaid recipients, will continue to be a contentious and politically volatile topic in 2017. The 2016 election cycle brought drug pricing to the forefront of the national political agenda, a follow-on to multiple congressional inquiries of manufacturers with questionable pricing practices. Many manufacturers are pledging to restrain themselves to single-digit price increases, which is probably the best that consumers can hope for at this point. For Medicaid, that scenario does not align with the net cost trends reflected in this report. State Medicaid agencies will continue to explore all available options in managing their drug expenditures. The cost of treatments for less common orphan diseases broke into 2016's top 10 classes; these drugs will become more prevalent in top 10 lists according to net spend.

MEDICAID LEGISLATIVE UPDATES

Future of Medicaid Under the Affordable Care Act

In May 2017, the U.S. House of Representatives narrowly passed a bill to repeal and replace the Affordable Care Act (ACA). As of this publication's deadline, the U.S. Senate was unsuccessful in several attempts to repeal and replace the ACA, including an attempt that, like the House-passed bill, would have ended the enhanced federal financial participation (FFP) for Medicaid expansion, and changed funding for the Medicaid program from an open-ended entitlement to one that would establish a federal financial cap for states. The House and Senate legislation did not address specific items within the Medicaid drug program.

Following this intense legislative activity, the Congress continues to remain gridlocked on these critical questions. The clear trend, however, is that health reform, including the Medicaid drug program, will continue to be a central part of the federal and state policy debate for the foreseeable future.

High-Priced Drugs

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 2015, Medicaid spent approximately $57 billion[1] on prescription drugs; although fiscal year (FY) 2015 data is not yet available, 2014 data suggest Medicaid collected $20 billion in rebates, of the $42 billion in FY 2014, for net drug spending of $22 billion[2]. Net spending for outpatient drugs accounted for approximately 5 percent of total Medicaid benefit spending.[3]

Despite program changes reducing state responsibility for drug costs (for example, creation of the Part D drug benefit and increase in Medicaid drug rebates under the ACA), states are struggling with the rising costs of specialty drugs. From 2013 to 2014, states saw significant increases in the annual percentage change for both brand and generic drugs: 17.3 percent and 7 percent, respectively. 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. Specialty drug spending accounted for nearly 33 percent of the total Medicaid drug spend in 2014, despite only 0.9 percent of the Medicaid population utilizing specialty medications.[4] Hepatitis C, HIV, and rheumatoid arthritis drugs continue to top the list of specialty drugs contributing to high spend amounts. Data shows competition in the hepatitis C space has driven down costs somewhat in 2015 compared to 2014.[5]

Beyond the numbers, high-priced drugs continue to remain a visible policy issue due to national and local media reporting of specific drugs and significant price increases for those drugs. The public also appears to be increasingly concerned about costs as more and more individuals have high-deductible plans that bring into sharper focus out-of-pocket costs for prescription drugs. Congressional leaders also continue to highlight this issue — though a legislative framework has yet to emerge. Prescription drug manufacturers have pressed forward with efforts to redirect national concern on price increases to pharmacy benefit managers and health plans, making this debate further politically charged. Policymakers will continue to be challenged as they attempt to slow the rising costs of these drugs within healthcare overall and Medicaid in particular.

Medicaid-Covered Outpatient Drugs Final Rule Update

CMS released a final rule[6] on Medicaid drug payment in February 2016, changing the basis of the ingredient cost payment (i.e., the estimated cost of the drug versus the dispensing fee) for brand and certain multiple-source drugs (that do not have a federal upper limit calculated) from the estimated acquisition cost to the actual acquisition cost (AAC) and requiring a state's payment methodology be in accordance with the definition of AAC. The final rule was intended to address the rise in Medicaid prescription drug costs by ensuring state Medicaid programs reform payment methodologies for prescription drugs to reflect market prices. States have some flexibility in how they establish AAC, whether using the National Average Drug Acquisition Cost survey, AMP-based pricing, or a state survey of retail pharmacy providers.[7]

1. Centers for Medicare & Medicaid Services (CMS), "Medicaid drug spending dashboard" (Nov. 14, 2016). http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-14-2.html.
2. Medicaid and Children's Health Insurance Program Payment and Access Commission (MACPAC), "Medicaid Spending for Prescription Drugs" (January 2016). http://www.macpac.gov/publication/medicaid-spending-for-prescription-drugs.
3. Ibid.
4. MACPAC, "Medicaid spending for prescription drugs — issue brief" (January 2016). MACPAC analysis of calendar years 2011-2014 Medicaid drug rebate utilization data as reported by states, as of September 2015. http://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf.
5. Express Scripts, "2015 Drug Trend Report Medicaid" (March 2016).
6. CMS, U.S. Department of Health & Human Services (HHS). "Medicaid program; covered outpatient drugs. Final rule." Federal Register, vol. 81, no. 20 (Feb. 1, 2016): 5170-5357. http://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf.
7. CMS, "RE: Implementation of the covered outpatient drug final regulation provisions regarding reimbursement for covered outpatient drugs in the Medicaid program," SHO# 16-001, Affordable Care Act #37 (Feb. 11, 2016). http://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf.

STATES MAKE THE SWITCH TO AAC

From the April 1, 2016, implementation date of the final rule, states had four quarters, or by June 30, 2017, to submit a state plan amendment to reflect the switch. All states were required to be in compliance with the reimbursement requirements of the rule by April 1, 2017. For the quarter ending March 2017, 16 states had switched to an AAC-based methodology but only two states had received CMS approval of their amended state plans.[8]

Medicaid Drug Rebate Program

States may provide coverage of outpatient drugs furnished to eligible individuals as an optional benefit under the Medicaid program. For most drugs, in order for FFP to be made available, drug manufacturers participating in states' Medicaid programs are required — under the Medicaid Drug Rebate Program (MDRP) — to offer rebates to partially offset the federal and state costs of most outpatient drugs. These rebates are paid on a quarterly basis to states and are shared between the states and the federal government.

MEDICAID DRUG REBATE AGREEMENT UPDATE

For the first time since the program's inception, CMS published a notice[9] Nov. 9, 2016, announcing proposed changes to the Medicaid National Drug Rebate Agreement (NDRA), the contractual agreement between the U.S. Department of Health & Human Services (HHS) secretary and manufacturers that governs participation in the MDRP. The notice is the first time the NDRA has been updated since February 1991 and reflects a variety of legislative, regulatory, and technical changes instituted over the past 25 years. The proposed changes include:

- Cross-referencing each defined term within the NDRA (e.g., AMP, best price, etc.) with the definition as established by statute and regulations;
- Removing definitions for "depot price" and "single award contract";
- Replacing the term "Medicaid utilization information" with "state drug utilization data" to reflect managed Medicaid utilization;
- Requiring manufacturers to ensure their drugs are listed electronically with the FDA for verification of covered outpatient drug status;
- Maintaining the allowance for manufacturers to make and maintain "reasonable assumptions" in calculating AMP and best price, but newly requiring these assumptions be made available to the HHS secretary by request;
- Requiring manufacturers to notify CMS within seven days of filing for bankruptcy;
- Extending audit authority to the HHS secretary for all manufacturer information (versus AMP and best price under the current NDRA) reported under the Medicaid statute;
- Adding new language expressly indicating the government is not limited to the remedies described in the NDRA, suggesting HHS could seek additional penalties for violations of the NDRA; and,
- Automatically assigning to the new owner — in the event of a transfer in ownership of the manufacturers — "any outstanding rebate liability."

Since the public comment period closed February 7, the proposed changes have yet to be finalized. Once and if the changes are finalized, all current manufacturers participating in the MDRP will be required to sign updated NDRAs.

CPI-U PENALTY

Pursuant to Sec. 602 of the Bipartisan Budget Act (BBA) of 2015, manufacturers of generic drugs (i.e., non-innovator multiple-source drugs [N]) are required to calculate an additional rebate, similar to the additional rebate applied to single-source and innovator multiple-source drugs. The additional rebate is an inflation-based rebate and applies when the AMP for a calendar quarter increases at a rate higher than inflation, measured using the CPI-U. Beginning with the first quarter of 2017, manufacturers of generic drugs would be responsible for both the standard rebate (calculated as 13 percent of AMP) and the additional BBA-mandated rebate.

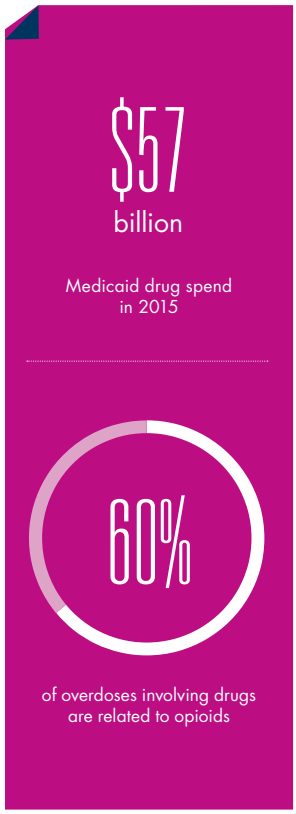
CMS provided guidance April 15, 2016[10], to manufacturers on the CPI-U penalty for generic drugs and how the additional rebate should be calculated; the federal agency provided further guidance Sept. 22, 2016.[11] Under the guidance, this inflationary rebate is calculated in a similar manner to the inflationary rebate for brand-name drugs, or by establishing a base AMP and a base CPI-U pursuant to the drug's market date. For N drugs marketed on or before April 1, 2013, the base AMP is equal to the AMP for the third quarter of 2014 and the base CPI-U is the CPI-U for September 2014. For N drugs marketed after April 1 the base AMP is equal to the AMP for the fifth full calendar quarter after which the drug is marketed and the base CPI-U is equal to the CPI-U for the last month of the base AMP quarter.

SEC. 1115 WAIVERS

In late March 2017, the commonwealth of Massachusetts submitted a letter[12] to CMS Administrator Seema Verma detailing several ways it would like to work with the federal agency on health insurance and Medicaid issues. The letter was submitted in response to an earlier March 13 joint letter[13] by HHS Secretary Tom Price, MD, and Verma inviting states to work with HHS to amend their Medicaid programs through state plan amendments and Sec. 1115 waivers.

8. CMS, HHS, "Medicaid covered outpatient prescription drug reimbursement information by state; quarter ending March 2017" (May 31, 2017). http://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxreimbursement-chart-current-qtr.pdf.
9. CMS, HHS, "Medicaid program; announcement of Medicaid Drug Rebate Program National Rebate Agreement," Federal Register, vol. 81 (Nov. 9, 2016): 78816-78835, agency/docket no. CMS-2397-PN (RIN 2016-26834), http://www.federalregister.gov/documents/2016/11/09/2016-26834/medicaid-program-announcement-of-medicaid-drug-rebate-program-national-rebate-agreement.
10. Center for Medicaid and CHIP Services (CMCS), CMS, "New additional inflation-adjusted rebate requirement for non-innovator multiple source drugs," Medicaid Drug Rebate Program Notice for Participation Drug Manufacturers, Release No. 97 (April 15, 2016), http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-097.pdf.
11. CMCS, CMS, "Clarification on the new additional inflation-adjusted rebate requirement for non-innovator multiple source drugs," Medicaid Drug Rebate Program Notice for Participation Drug Manufacturers, Release No. 101 (Sept. 22, 2016), http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-101.pdf.
12. Secretary Marylou Sudders, Executive Office of Health & Human Services, the Commonwealth of Massachusetts, "Letter to Seema Verma, administrator, U.S. Centers for Medicare and Medicaid Services" (March 22, 2017). http://www.scribd.com/document/343231298/Administrator-Verma-Letter-3-22-2017-Final#from_embed.
13. Thomas E. Price, MD, secretary of HHS, "Dear Governor" (March 13, 2017), http://www.hhs.gov/sites/default/files/sec-price-admin-verma-ltr.pdf?language=en.

Within the commonwealth's March 22 response, Massachusetts Health & Human Services Secretary Marylou Sudders requested "greater flexibility to obtain lower drug prices and enhanced rebates for Medicaid, including using the same tools for selecting preferred and covered drugs that are available to and widely used by commercial health plans." Sudders' statement refers to the MDRP's requirement that participating Medicaid programs cover all prescription drugs for which a rebate is made available, generally with limited restrictions.



Greater flexibility to manage the Medicaid prescription drug benefit has surfaced a number of times — it was proposed by Republican Governors John Kasich (OH), Asa Hutchinson (AR), Rick Snyder (MI), and Brian Sandoval (NV). It also was a focus of discussion at the April 2017 Medicaid and Children's Health Insurance Program Payment and Access Commission (MACPAC) public meeting. Short of any federal statutory changes, which would require congressional action, Sec. 1115 waivers may serve as a vehicle for CMS and states to experiment with changes to the MDRP.

Opioid Crisis and Medicaid

From 2000 to 2015, more than half a million Americans died from drug overdose; the majority (more than six out of every 10) of these deaths involving an opioid.[14] Prior to the ACA's expansion of the Medicaid program to childless adults under the age of 65, Medicaid was the largest source of coverage for behavioral health services, paying approximately $60 billion in 2014.[15] Under the ACA and Medicaid expansion, Medicaid has taken on a more significant role: in the states that have expanded Medicaid, 1.2 million individuals with substance use disorders have gained access to coverage.[16]

PRESIDENTIAL COMMISSION ON OPIOID CRISIS

On March 29, 2017, President Donald Trump (R) announced[17] the President's Commission on Combating Drug Addiction and the Opioid Crisis. New Jersey Governor Chris Christie (R) will chair the commission, which will include the attorney general; the secretaries of Education, HHS, Homeland Security, and Veterans Affairs; various HHS officials; and as many as five others whom are not federal employees. On May 10, the president announced[18] the latter would include Governors Roy Cooper (D-NC) and Charlie Baker (R-MA), former U.S. Representative Patrick Kennedy (D-RI), and former White House Office of National Drug Control Policy Deputy Director Bertha Madras. The commission, which first met June 16 and again July 17, is charged with submitting interim recommendations to the president within 90 days and submitting a final report by Oct. 1, 2017, unless more time is needed. The commission will dissolve a month later.

340B Program Update

Congress established the 340B Drug Pricing Program in 1992, which requires manufacturers to provide substantial discounts on outpatient drugs as a condition of receiving Medicaid and Medicare Part B payments. Eligible providers ("340B-covered entities," or CEs) include hospitals; community health centers; and HIV/AIDS, diabetes, cancer, dental, and primary care clinics serving the underserved and/or providing uncompensated or undercompensated care. In addition, drugs purchased by CEs at a discount can be sold to all individuals who meet the program's definition of a patient regardless of their insurance status. Since 1992, the program has largely been implemented through guidance instead of formal rule-making and regulation like most federal statutory programs.[19] In 2014, the D.C. Circuit Court held that the Health Resources & Services Administration (HRSA) does not have rule-making authority for the 340B program outside of civil monetary penalties, dispute resolution, and ceiling prices.[20] Due to this ruling, the HRSA converted its omnibus regulation — intended to establish uniform, clear, and enforceable policies — into 2015 proposed guidance[21] because it lacks explicit rule-making authority.

2016 REGULATORY LOOK-BACK

The 340B program remains an area of focus for federal policymakers, and federal-level activity and publications from 2016 indicate it should have been a year of new guidance for the program. Below is a breakdown of 2016 regulatory initiatives related to 340B.

- Through release of its May 2015 regulatory agenda, the HRSA stated it would delay the final 340B program om-

14. Rudd R.A. et al., Centers for Disease Control and Prevention, HHS, "Increases in drug and opioid-involved overdose deaths — United States, 2010-2015." Morbidity and Mortality Weekly Report ePub 65(50-51): 1445-1452 (Dec. 16, 2016), http://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.
15. CMS, "NHE Fact Sheet" (Dec. 3, 2015), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html.
16. Ali M.M., Mutter, R., and Teich, J.L., Substance Abuse and Mental Health Services Administration (SAMHSA), State Participation in the Medicaid Expansion Provision of the Affordable Care Act: Implications for Uninsured Individuals with a Behavioral Health Condition (Nov. 18, 2015), http://www.samhsa.gov/data/sites/default/files/report_2073/ShortReport-2073.pdf. This figure includes the states that had expanded Medicaid as of November 2015 per the above-cited SAMHSA report.
17. Office of the Press Secretary, The White House, "Presidential executive order establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis" (March 29, 2017), http://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission.
18. Office of the Press Secretary, The White House, "President Donald J. Trump announces key additions to his administration" (May 10, 2017), http://www.whitehouse.gov/the-press-office/2017/05/10/president-donald-j-trump-announces-key-additions-his-administration.
19. Public Health Service Act, Pub. L. 78-410, 58 Stat. 682/42 U.S.C. Sec. 256b.
20. Pharmaceutical Research and Manufacturers of America (PhRMA) v. HHS, 43 F. Supp. 3d 28 (D.D.C. 2014).
21. HRSA, HHS, "Notice: 340B drug pricing program omnibus guidance," Federal Register, vol. 80 (Aug. 28, 2015): 52300-52324, agency/docket no. 2015-21246 (RIN 0906-AB08), http://www.gpo.gov/fdsys/pkg/FR-2015-08-28/pdf/2015-21246.pdf.

nibus guidance until the end of 2016.[22] The August 2015 proposed guidance received more than 800 comments, many of which raised legal and operational concerns the agency is expected to address in the final guidance. The Office of Management and Budget (OMB) received the final guidance Sept. 1, 2016, which had been scheduled to be published in the following December.[23] It now appears unlikely the omnibus guidance will be published as sent to the OMB; the Trump administration directed heads of federal agencies to conduct a full review of items unpublished, pending publication, and recently published (i.e., on or around the inauguration date of January 20) in the Federal Register, which includes the OMB-pending omnibus final guidance.[24]

- Originally scheduled to be issued in 2015, the agency published a notice of proposed rulemaking on the 340B program's administrative dispute resolution process in August 2016.[25] The proposed rule reflects an ACA requirement to implement enhancements to the 340B program by establishing a binding administrative dispute resolution process to resolve certain disputes between CEs and manufacturers arising under the program.
- Also required by the ACA, a final rule imposing monetary sanctions (not to exceed $5,000 per instance) on drug manufacturers "who intentionally charge a CE a price above the ceiling price established under the" program, plus standards and methodology for the calculation of ceiling prices, was published in the Federal Register Jan. 5, 2017, following a delay from the May 2016 release estimate.[26] On May 18, the final rule's effective date — intended to be May 22, 2017 — was delayed to October 1.[27]

340B AND MEDICAID MANAGED CARE

In June 2016, the HHS Office of the Inspector General (OIG) released a report[28] on Medicaid managed care rebates and 340B drugs, concluding that many states use methods (i.e., often at the provider level or using the HRSA Medicaid Exclusion File) that may inaccurately identify 340B drug claims when calculating manufacturer rebates for drugs paid through Medicaid health plans. While fewer states use claim-level methods, this level of methodology was found to be more accurate because it permits CEs to differentiate among specific claims. Consistent with its position in the Medicaid managed care final rule, CMS disagreed with the OIG's claim-level recommendation. Separately and relevant to the long-delayed 340B program omnibus final guidance, HRSA agreed with OIG's recommendation that, for Medicaid health plan drugs, the agency-specified CEs must follow state instructions to facilitate claim-level identification of drugs purchased through the program. In further comment, HRSA stated this issue would be incorporated in the forthcoming final guidance and married with public comments received. With the delay of the final guidance and new administration, it is unclear how the OIG's findings will be incorporated into future parameters for the program.

A draft executive order on drug costs was leaked in June 2017. The Trump administration continues to suggest it is interested in taking regulatory steps to address high drug costs, including greater scrutiny of the 340B program. Such an executive order could be released soon. The clear trend is that drug spending within the Medicaid program will continue to be part of the national policy debate for the foreseeable future.

22. Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Executive Office of the President, "Agency rule list — spring 2016: Department of Health and Human Services," http://www.reginfo.gov/public/do/ eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900.
23. Inside Health Policy, "OMB Reviews Wide-Ranging 340B 'Mega-Guidance'" (Sept. 2, 2016), http://insidehealthpolicy.com/daily-news/omb-reviews-wide-ranging-340b-mega-guidance.
24. Office of the Press Secretary, the White House, Assistant to the President and Chief of Staff Reince Priebus, "Memorandum for the heads of executive departments and agencies; subject: regulatory freeze pending review" (Jan. 20, 2017), http://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.
25. HRSA, HHS, "Notice of proposed rulemaking: 340B Drug Pricing Program; administrative dispute resolution," Federal Register, vol. 81 (Aug. 12, 2016): 53381-53388 (RIN 0906-AA90), http://www.gpo.gov/fdsys/pkg/FR-2016-08-12/pdf/2016-18969.pdf.
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