

GENERIC DRUG SAVINGS IN THE U.S.

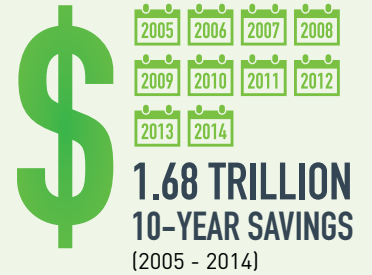
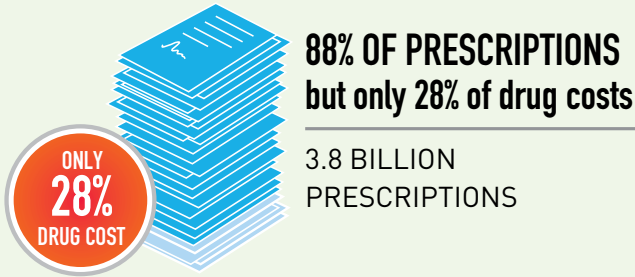
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Rising health care costs continue to be a major concern for everyone from patients to policymakers. But there is some good news. Savings from generic drugs reached an all-time high in 2014, according to the seventh annual Generic Drug Savings in the United States report, compiled on behalf of the Generic Pharmaceutical Association (GPhA) by the IMS Institute for Healthcare Informatics.

The 2015 report shows that generic drugs are an essential part of any solution to sustaining our health system and are central to efforts that increase patient access and generate savings for patients, taxpayers, employers, payers, providers and others.

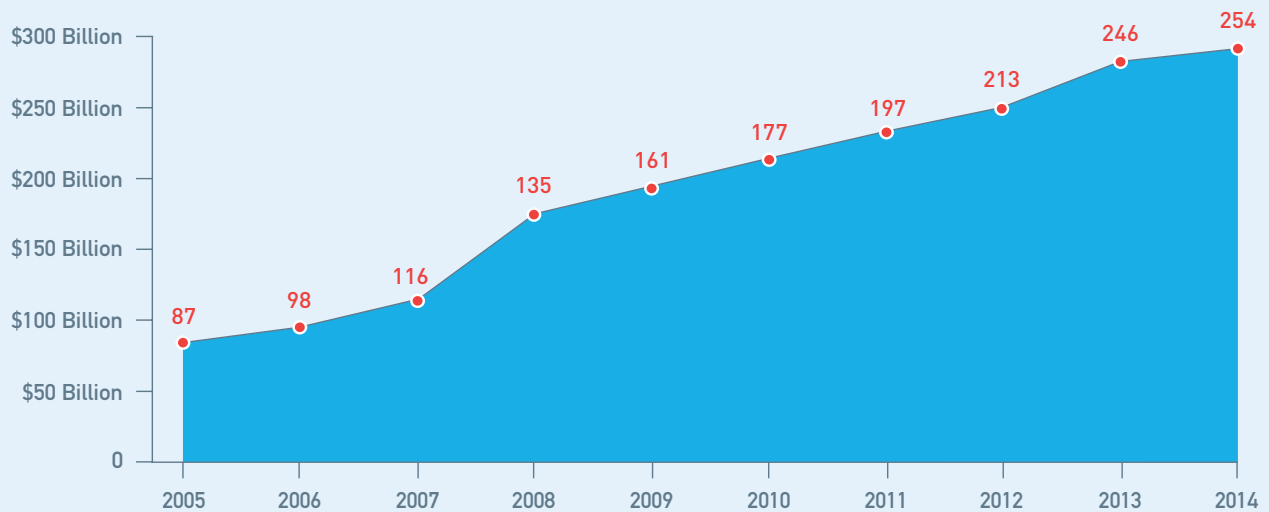
GENERIC DRUGS IN THE UNITED STATES



Nearly 3.8 billion of the total 4.3 billion prescriptions dispensed in the U.S. in 2014 were filled using generic drugs. This means that generic drugs now account for nearly nine out of every 10 (88%) prescriptions dispensed in the United States. Yet generic prescriptions account for only 28% of total drug spending.

Generic drugs were responsible for \$254 billion in health system savings in 2014, bringing the total savings over the last 10 years to \$1.68 trillion. Generic drug manufacturers can proudly point to a legacy of savings and access that brings expensive treatments within reach for millions of people. It is important to note that savings are growing and are expected to continue to grow.

ANNUAL GENERIC DRUG SAVINGS IN THE UNITED STATES



Historic savings have been revised to include standard data restatements.

Newer generic drugs (introduced within the last 10 years) are making significant impacts on patient and health system savings. Newer generics make up more than half (57%) or \$145 billion of the \$254 billion saved in 2014. These newer generic drugs also saved the health system \$638 billion of the most recent decade's \$1.68 trillion. Older generics generated upwards of \$100 billion in health system savings in 2014 and \$1.05 trillion in savings in the last ten years.

EXPERTS AGREE: GENERIC DRUG SAVINGS ARE WIDELY RECOGNIZED AS A LONG-TERM SOLUTION TO RISING HEALTH COSTS

- The 2014 Express Scripts Drug Trend Report shows that **SINCE 2008, THE PRICE OF BRAND DRUGS HAS ALMOST DOUBLED** but the **PRICE OF GENERIC DRUGS HAS BEEN CUT ROUGHLY IN HALF**.
- A May 2015 report from AARP notes that **RETAIL PRICES FOR GENERIC DRUGS FELL AN AVERAGE OF 4% IN 2013**, marking nearly a decade of consecutive years of decreasing generic drug costs. That report also notes that **73% OF GENERIC DRUGS** in the study **EXPERIENCED PRICE DECREASES**.
- An August 2015 Drug Channels blog noted that in the **SECOND QUARTER OF 2015 ALMOST HALF (44%) OF GENERIC DRUGS EXPERIENCED A DECLINE IN COST**.

The most effective way to keep costs low is to increase competition. GPhA believes that there are several ways policymakers can help increase generic competition.

First, in partnership with the industry, Congress should encourage timely FDA review of the more than 3,800 generic drug applications that have been filed with the Agency and await regulatory action. Once those products are approved and enter the market, consumers will have more options and that helps prices drop.

“Patients, taxpayers and others will find no better partner than the generic industry in efforts to reduce health expenses and promote savings and access. The best way to accomplish this is to increase competition from generic drugs.”

- Chip Davis, President and CEO, Generic Pharmaceutical Association

Second, Congress should review the abuse by some brand drug companies of FDA programs designed to protect patient safety. Misuse of these programs, such as Risk Evaluation and Mitigation Strategies (REMS), prevents generic drugs from entering the market and reaching patients, which dampens competition and can keep drug prices high. This misuse comes at a cost of \$5.4 billion annually to our health system, according to a separate analysis conducted in 2014 by Matrix Global Advisors.

Congress can also encourage the FDA to increase competition for biologics by implementing regulations and policies for approving biosimilar products. This includes supporting a biosimilar naming system and interchangeability policy that encourages competition from safe, more affordable biosimilar medicines. These policies would provide American consumers with more choices, greater access to medicines, and billions of dollars in increased savings.

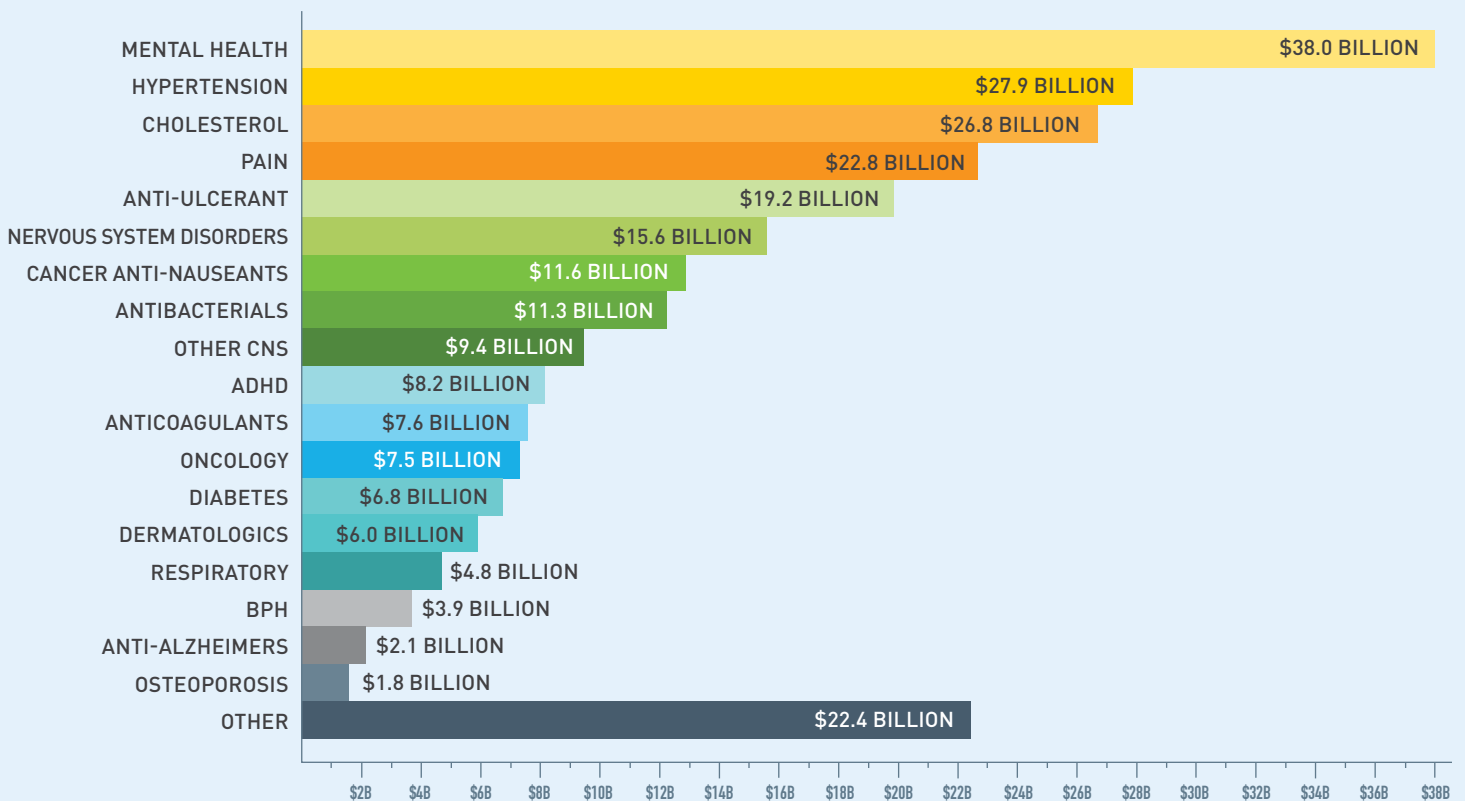
GENERIC DRUG SAVINGS BY THERAPY AREA

Generic drug manufacturers continue to invest in innovation. America's generic drug industry is constantly introducing new generic therapies and finding faster, smarter, safer ways to manufacture medicines that translate into savings and access for millions of people.

In 2014, the majority of generic drug savings are accrued in therapy areas that address mental health conditions (\$38.0 billion), treat hypertension (\$27.9 billion), or help manage or lower cholesterol levels (\$26.8 billion). Rounding out the top 10, therapy area savings are accrued in pain medicines (\$22.8 billion), anti-ulcerants (\$19.2 billion), nervous system disorders (\$15.6 billion), anti-nauseants for cancer (\$11.6 billion), anti-bacterials (\$11.3 billion), other central nervous system disorders (\$9.4 billion), and attention deficit hyperactivity therapies (\$8.2 billion).

With respect to oncology treatments, the National Cancer Institute reports that breast cancer affects nearly 3 million people annually, making it the second most common cancer. Generic drugs for breast cancer and other cancers saved \$4.1 billion in 2014. Prostate cancer is second only to skin cancer as the most common cancer in men. Savings from prostate cancer generic drugs totaled \$765 million in 2014. Savings from generics used to treat depression, a disease that affects 19 million Americans, totaled \$23.3 billion in 2014. About one in 26 Americans will develop a seizure disorder such as epilepsy. Generic anti-seizure drugs saved the health system \$13.8 billion in 2014.

GENERIC DRUG SAVINGS BY THERAPY (2014)



It is evident that annual spending on many medication classes would soar in the absence of generic competition. This underscores the need to sustain the generic drug industry and actively pursue policies that support or grow, rather than undermine, patient and health system savings from generic drugs.

ANNUAL THERAPY AREA SPENDING SOARS WITHOUT GENERICS



SAVINGS FROM GENERIC DRUGS FOR SENIORS AND PUBLIC PROGRAMS

The need for prescription medicines typically increases with age and the savings made possible by generic drug use among older adults and seniors is critical to sustaining affordable health care. More than one-third (36%) of the total savings in 2014, or \$92 billion, came from generic drugs used by seniors age 65 and up. The healthcare system saved \$111 billion because of generic use by older adults.

Nearly 20 percent of the \$254 billion in total savings in 2014 stemmed from the use of generic drugs by children and young adults. Generic drug use by children and teens generated \$16 billion (6%) in savings while young adults (age 20-39) generated an additional \$34 billion (13%) of the total savings.

GENERIC SAVINGS BY PATIENT AGE



Seniors (65+):
**\$92 BILLION
IN SAVINGS**



Older Adults (40-64):
**\$111 BILLION
IN SAVINGS**



Young Adults (20-39):
**\$34 BILLION
IN SAVINGS**

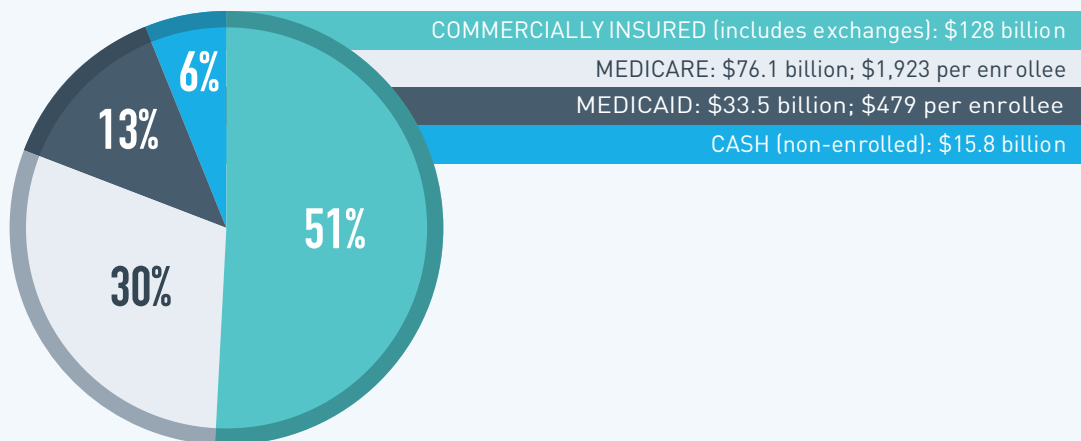


Children (0-19):
**\$16 BILLION
IN SAVINGS**

While the majority of savings are attributed to the commercially insured, the federal government is the single largest purchaser of generic drugs in the United States, primarily through Medicaid and Medicare. According to the Centers for Medicare and Medicaid Services (CMS), there are 72 million Medicaid beneficiaries and another 54 million enrolled in Medicare.

Spending on medicines in each of these programs would nearly double without the availability of generic drugs. In Medicare, for instance, spending for medicines would have reached approximately \$160 billion without the \$76.1 billion in savings achieved by using generics in 2014. Nationally, Medicare enrollee savings per capita was \$1,923 last year.

GENERIC SAVINGS BY PAYOR



In the Medicaid program, estimated spending reached \$26.1 billion in 2014, with savings from generics totaling \$33.5 billion. Without generic savings, the Medicaid drug tab would have reached nearly \$60 billion. That translates to Medicaid savings of \$479 per enrollee attributed to generic drugs. These savings are essential for the vital government programs that protect our lower-income and older citizens.

MEDICAID AND MEDICARE SAVINGS PER ENROLLEE



State savings, particularly for public programs, continue to help taxpayers and strained program budgets. Medicaid is operated differently across states and it is important to note that this report is not ranking or evaluating the merits of any particular state programs in this analysis. Evaluation or comparison beyond the savings data highlighted here requires a separate and more thorough analysis that accounts for variables such as generic efficiency, distribution method, population and other demographic factors.

Savings from the use of generics by Medicare, Medicaid, the commercially insured, and non-insured patients resulted in an average of \$5 billion per state. The highest per capita Medicaid savings were accrued by Kentucky, West Virginia, Maine, Rhode Island and Massachusetts.

New York saved \$3.9 billion, California saved \$2.9 billion and Texas, a state with 4.7 million Medicaid enrollees, saved \$1.7 billion. For detailed state-by-state findings, please see the report appendix.

There has never been a more important time to sustain and grow savings from generic drugs. GPhA and its member companies look forward to working with Congress, the FDA and stakeholders from all corners of the supply chain to ensure that measures that encourage pharmaceutical competition and expand access without compromising patient safety are given thoughtful consideration.

GPhA and its membership are committed to delivering savings and enhancing access to affordable medicines for all Americans. The generic drug industry's 30-year track record of savings is unequalled in healthcare. Still, the potential for growth and expansion is great. Increasing health savings and expanding access to medicine will continue to be a priority for this industry and all who strive to promote the sustainability of our nation's health care system.

APPENDIX

I. GENERIC SAVINGS: STATE-BY-STATE (\$)

	MEDICAID	MEDICARE	CASH	COMMERCIAL	TOTAL
ALABAMA	444,851,779	1,802,393,720	387,795,708	2,771,621,529	5,406,662,736
ALASKA	39,678,170	54,903,180	25,689,539	195,233,167	315,504,056
ARIZONA	651,848,266	1,277,759,282	280,085,049	2,282,206,206	4,491,898,803
ARKANSAS	356,121,682	1,028,723,148	270,810,691	1,582,775,188	3,238,430,709
CALIFORNIA	2,896,471,432	6,964,739,108	1,302,777,776	10,332,598,166	21,496,586,482
COLORADO	399,054,698	698,640,258	220,741,342	1,623,080,190	2,941,516,488
CONNECTICUT	487,198,605	814,457,553	142,188,288	1,497,180,219	2,941,024,665
DELAWARE	155,910,372	186,896,196	35,827,082	337,820,890	716,454,540
DISTRICT OF COLUMBIA	161,539,568	161,716,513	32,105,892	394,496,255	749,858,228
FLORIDA	1,684,543,656	5,404,597,240	1,122,243,980	6,835,958,584	15,047,343,460
GEORGIA	931,489,983	2,458,908,926	723,672,992	4,244,424,056	8,358,495,957
HAWAII	137,797,928	255,346,611	48,718,237	382,103,556	823,966,332
IDAHO	127,702,619	304,849,301	94,462,313	574,293,261	1,101,307,494
ILLINOIS	1,285,130,830	2,720,922,627	640,058,619	5,125,514,696	9,771,626,772
INDIANA	605,553,217	1,645,604,054	382,449,067	2,963,300,806	5,596,907,144
IOWA	358,377,591	907,585,619	162,079,085	1,430,541,569	2,858,583,864
KANSAS	230,436,775	719,773,896	230,547,468	1,474,954,932	2,655,713,071
KENTUCKY	1,098,648,233	1,634,353,302	341,225,103	2,246,046,266	5,320,272,904
LOUISIANA	556,884,346	1,501,092,152	385,962,582	2,602,068,503	5,046,007,583
MAINE	228,201,849	305,872,924	38,236,119	571,010,047	1,143,320,939
MARYLAND	778,326,627	921,962,289	237,944,247	2,338,411,956	4,276,645,119
MASSACHUSETTS	1,116,765,783	1,669,762,815	195,928,917	3,088,530,695	6,070,988,210
MICHIGAN	1,140,867,964	2,581,234,679	598,371,985	4,300,916,599	8,621,391,227
MINNESOTA	473,365,226	1,163,989,095	236,510,463	1,992,074,023	3,865,938,807
MISSISSIPPI	241,175,220	1,119,694,512	308,418,363	1,541,800,025	3,211,088,120
MISSOURI	579,786,676	1,668,473,366	378,498,506	2,798,437,872	5,425,196,420
MONTANA	67,756,531	193,748,347	64,434,941	355,851,516	681,791,335
NEBRASKA	159,389,664	540,019,433	122,841,651	923,415,374	1,745,666,122
NEVADA	262,779,539	501,906,214	119,046,929	1,001,786,421	1,885,519,103
NEW HAMPSHIRE	68,343,246	261,388,896	44,738,213	587,495,486	961,965,841
NEW JERSEY	887,990,448	1,843,530,433	320,150,714	3,224,123,408	6,275,795,003
NEW MEXICO	147,374,037	361,065,998	100,158,340	740,058,272	1,348,656,647
NEW YORK	3,916,879,368	6,512,990,393	702,219,894	8,867,475,384	19,999,565,039
NORTH CAROLINA	921,047,904	2,780,321,465	574,871,170	4,402,999,023	8,679,239,562
NORTH DAKOTA	55,923,995	195,739,194	57,489,065	344,152,806	653,305,060
OHIO	1,723,663,137	3,075,465,603	606,676,053	5,217,740,415	10,623,545,208
OKLAHOMA	372,437,674	862,722,757	262,164,002	1,740,192,443	3,237,516,876
OREGON	417,931,739	802,402,711	146,378,892	1,314,892,129	2,681,605,471
PENNSYLVANIA	1,641,835,713	3,803,198,250	478,488,768	6,053,663,255	11,977,185,986
RHODE ISLAND	192,058,518	383,580,682	32,673,629	584,286,498	1,192,599,327
SOUTH CAROLINA	407,836,736	1,399,159,991	292,421,289	2,232,625,274	4,332,043,290
SOUTH DAKOTA	56,861,026	210,260,694	55,436,578	344,308,340	666,866,638

	MEDICAID	MEDICARE	CASH	COMMERCIAL	TOTAL
TENNESSEE	754,657,833	2,357,962,208	489,837,541	3,513,613,089	7,116,070,671
TEXAS	1,692,398,872	4,922,319,889	1,410,237,858	9,950,792,330	17,975,748,949
UTAH	138,199,190	392,810,316	201,257,810	1,285,690,748	2,017,958,064
VERMONT	89,998,513	131,927,191	11,724,094	209,543,405	443,193,203
VIRGINIA	414,657,032	1,581,925,297	339,366,733	3,901,376,278	6,237,325,340
WASHINGTON	692,416,756	1,038,784,866	253,278,727	2,411,355,581	4,395,835,930
WEST VIRGINIA	524,707,512	738,949,139	96,946,022	1,031,041,848	2,391,644,521
WISCONSIN	680,614,308	1,167,781,230	232,726,109	2,293,231,553	4,374,353,200
WYOMING	30,971,617	84,671,899	27,693,272	204,946,028	348,282,816
TOTAL	33,486,460,003	76,118,885,462	15,866,607,707	128,264,056,160	253,736,009,332

II. METHODOLOGY

The IMS Institute for Healthcare Informatics provides key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information. It is a research-driven entity with a worldwide reach that collaborates with external healthcare experts from across academia and the public and private sectors to objectively apply IMS Health's proprietary global information and analytical assets. More information about the IMS Institute can be found at <http://www.theimsinstitute.org>.

The seventh edition of the generic drug savings report was created using ten years of sales and volume data from the IMS MIDAS database. An examination of all brand and generic medicines sold in the United States between 2004 and 2014 resulted in the identification of 235 molecules that became available as generics between 2005 and 2014 and 441 molecules that were available as generics prior to 2005.

The value of generics currently on the market was estimated using the pre-expiry invoice prices of the brands they replaced. The current dataset includes pre-expiry brand prices for the 235 newly generic molecules. Pre-expiry brand prices for the 441 older generics were pulled forward from previous editions of the study. The value of each generic molecule was determined by multiplying its pre-expiry brand price by the generic volume sold in each of the last ten years. This value represents what would have been spent on brand name medicines in the absence of generic competition.

The savings attributed to each of the 622 generic molecules was determined by subtracting historic generic spending from the estimated brand spending in the absence of generic competition.

State level generic savings was estimated by apportioning total savings for each molecule by each state's share of the national retail prescription volume. This method embeds two simplifying assumptions; first, that prices are uniform across the country, and second, that retail prescription activity mirrors prescription activity in other channels, notably mail order.

Savings by pay type was estimated using the share of each molecule dispensed via retail pharmacies to patients paying with cash and those covered by Medicare, Medicaid, and commercial insurance. After calculating savings at the molecule, state, and payer level, results were summed to the state-payer level. This method does not analyze the cost to the patient who may have a co-pay or discount card; rather it divides generic savings equally amongst patients based on prescription use, regardless of insurance plan.

NOTES & LIMITATIONS

This analysis was refreshed with annual sales and volume data for all medicines sold in the United States between 2004 and 2014. Savings from newer generics launched in the 2005 to 2014 study period is based on the most current knowledge of their pre-expiry prices. Savings from generics launched prior to 2005 were calculated using prices calculated in previous editions of the study.

Generic savings were calculated at the molecule-class level using a single average price for each molecule across all formulations (oral solid, liquid, injectable). Molecules that are available in multiple formulations are assumed to have the same pre- and post-expiry utilization patterns.

State level savings were estimated using retail prescription volumes. The state level analysis assumes prescriptions dispensed via mail order pharmacies and institutional settings follow the same patterns as the retail market.

Savings generated by children, young adults, older adults, and seniors were estimated based on national generic prescription trends captured in the IMS National Prescription Audit™. These figures represent the portion of the national savings, not the personal savings amassed by patients of a certain age.

Patients with Medicaid, Medicare, and commercial insurance pay different prices for their medications based on their insurance benefit design. This analysis did not attempt to estimate savings to individual patients based on their method of payment. Instead, total generic savings for each molecule was divided evenly based on the number of prescriptions filled by patients of each pay type.



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