

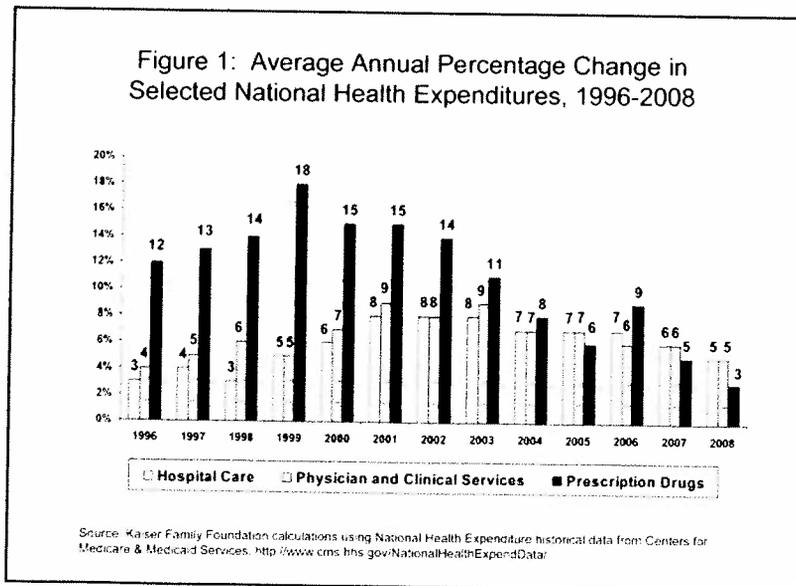
## Prescription Drug Trends

### Overview

Prescription drugs are vital to preventing and treating illness and in helping to avoid more costly medical problems. Rising drug costs, implementation of the Medicare Part D drug benefit in 2006, and expansion of both the number of people covered by health insurance and the breadth of their benefits from the passage of health reform legislation in March 2010 have highlighted the need for a better understanding of the pharmaceutical market and for new approaches to address increasing prescription costs.

### Rising Expenditures for Prescription Drugs

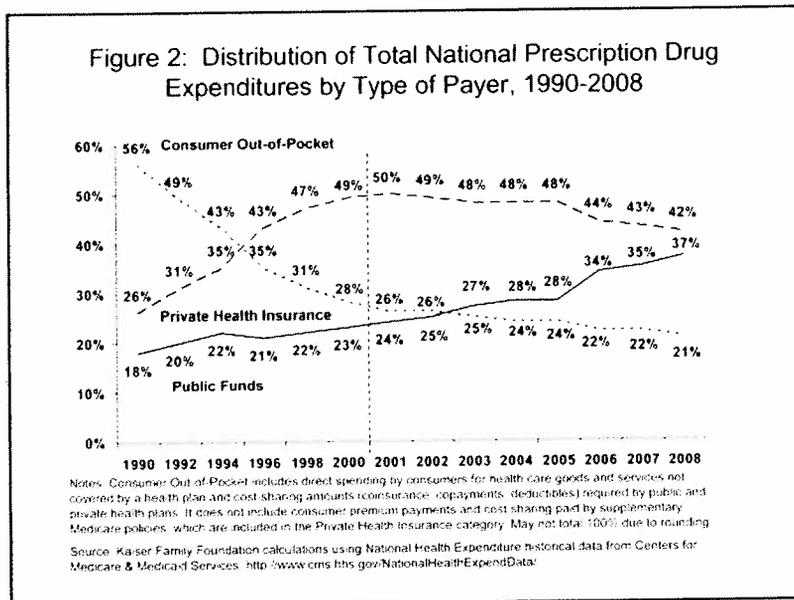
Spending in the US for prescription drugs was \$234.1 billion in 2008, nearly 6 times the \$40.3 billion spent in 1990.<sup>1</sup> Although prescription drug spending has been a relatively small proportion of national health care spending (10% in 2008, compared to 31% for hospitals and 21% for physician services), it has been one of the fastest growing components, until the early 2000's growing at double-digit rates compared to single-digit rates for hospital and physician services. Since 2000, the rate of increase in drug spending has declined each year except for 2006, which was the year Medicare Part D was implemented. By 2008, the annual rate of increase in prescription spending was 3%, compared to 5% for hospital care and 5% for physician services (Figure 1). From 1998 to 2008, prescription drugs contributed 13% of the total growth in national health expenditures, compared to 30% for hospital care and 21% for physician and clinical services.<sup>2</sup>



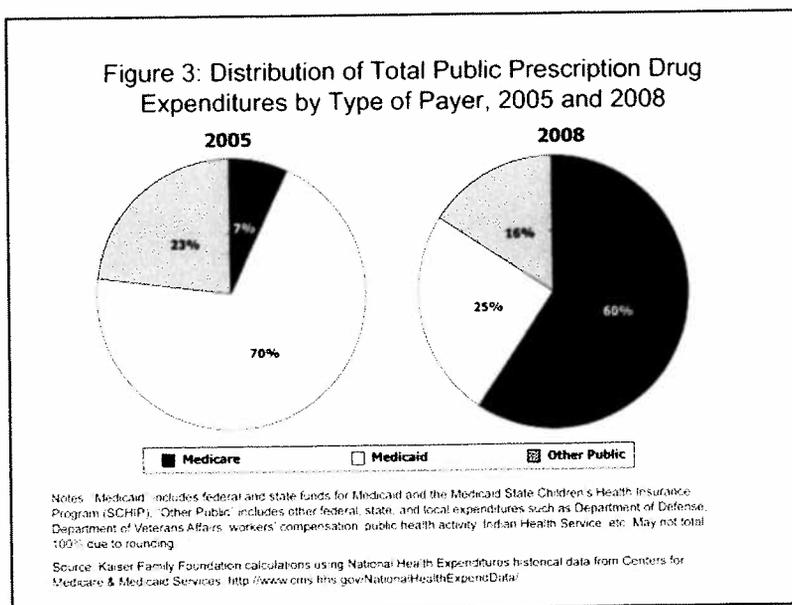
Annual prescription spending growth slowed from 1999 (18%) to 2005 (6%) because of the increased use of generic drugs, the increase in tiered copayment benefit plans, changes in the types of drugs used, and a decrease in the number of new drugs introduced.<sup>3</sup> The annual change in drug spending in 2006 (9%) increased as a result of 1) increased use of prescription drugs which was attributable to a number of factors including the implementation of Medicare Part D, new indications for existing drugs, strong growth in several therapeutic classes, and increased use of specialty drugs; 2) lower rebates from drug manufacturers; and 3) changes in the mix of drugs (both brand versus generic, and changes in the therapeutic mix).<sup>4</sup>

The 2007 change in drug spending (5%) decelerated because of an increase in the generic dispensing rate (which was affected in part by the loss of patent exclusivity for some blockbuster drugs), slower growth in prescription drug prices, and growing consumer safety concerns about certain drugs.<sup>5</sup> The 2008 drug spending change (3%) declined (as did the spending growth for most health care goods and services) because of a slight decline in per capita use of prescription drugs due to the impact of the recession, a low number of new drug products, and safety and efficacy concerns.<sup>6</sup>

The share of prescription drug spending paid by private health insurance increased substantially from 1990 to 2005 (from 26% to 48%), contributing to a decline in the share that people paid out-of-pocket (from 56% to 24%); the public funds (government) share of expenditures increased from 18% in 1990 to 28% in 2005. However, the implementation of the Medicare Part D drug benefit in 2006 substantially changed the mix of funding sources, as the government's share rose from 28% to 37% between 2005 and 2008, while the private insurance portion fell from 48% to 42%, and the consumer out-of-pocket share declined from 24% to 21% (Figure 2).



Medicare's and Medicaid's shares of public funding changed when the Medicare drug benefit took effect in 2006: between 2005 and 2008, Medicare's share grew from 7% to 60%, and Medicaid's share fell from 70% to 24% (Figure 3) because Medicare replaced Medicaid as the primary source of drug coverage for beneficiaries with coverage under both programs (known as "dual eligibles").



## Factors Driving Changes in Prescription Spending

Three main factors drive changes in prescription drug spending: changes in the number of prescriptions dispensed (utilization), price changes, and changes in the types of drugs used.

*Utilization.* The number of prescriptions dispensed in the US in 2009 increased 2.1% (from 3.8 billion to 3.9 billion), a larger growth rate than the 1.0% increase in 2008 over 2007. From 1999 to 2009, the number of prescriptions increased 39% (from 2.8 billion to 3.9 billion), compared to a US population growth of 9%. The average number of retail prescriptions per capita increased from 10.1 in 1999 to 12.6 in 2009.<sup>7</sup> The percent of the population with a prescription drug expense in 2007 was 62%, the same as in 1997. The proportion of those with an expense varied by age -- 58% for those under age 65 and 90% for those 65 and older, with little change since 1997 when the proportions were 59% and 86%, respectively.<sup>8</sup>

A recent study found that the rate of unfilled prescriptions has increased, from both denials and abandonment. Health plan denials of commercial prescription claims in 2009 were 8.1% for new prescriptions and 4.2% for refills; denials of new brand name drug prescriptions (10.3% in 2009) were down 1.4% from 2008, but were up 22.5% since 2006 (denials are prescriptions that have been submitted to a pharmacy but rejected by a patient's health plan). Abandoned prescriptions (those that are submitted to a pharmacy but are never picked up) as a percent of commercial prescription drug claims were 6.3% for new prescriptions and 2.6% for refills in 2009; for new brand name prescriptions, the abandonment rate was up 23% from 2008 and up 68% from 2006. Together, health plan denials and patient abandonment resulted in 14.4% of all new, commercial plan prescriptions going unfilled in 2009, up 5.5% from 2008.<sup>9</sup>

A 2009 study found that the cost of drug-related morbidity, including poor adherence (not taking medication as prescribed by doctors) and suboptimal prescribing, drug administration, and diagnosis, is estimated to be as much as \$289 billion annually, about 13% of total health care expenditures. The barriers to medication adherence are many: cost, side effects, the difficulty of managing multiple prescriptions, patients' understanding of their disease, forgetfulness, cultural and belief systems, imperfect drug regimens, patients' ability to navigate the health care system, cognitive impairments, and a reduced sense of urgency due to asymptomatic conditions.<sup>10</sup>

*Price.* Prescription drug prices as measured by the Consumer Price Index increased 3.4% in 2009, 2.5% in 2008, 1.4% in 2007, and 4.3% in 2006. The average annual growth in prescription drug prices from 2000 to 2009 was 3.6 percent, compared to 4.1% for all medical care and 2.5% for all items.<sup>11</sup> Industry data show that retail prescription prices<sup>12</sup> (which reflect both manufacturer price changes for existing drugs and changes in use to newer, higher-priced drugs) rose from an average price of \$38.43 in 1998 to \$71.69 in 2008; the average brand name prescription price in 2008 was almost 4 times the average generic price (\$137.90 vs. \$35.22).<sup>13</sup> Of the average retail prescription price of \$71.69, manufacturers received 78%, retailers received 17%, and wholesalers received 4% in 2008.<sup>14</sup>

*Changes in Types of Drugs Used.* Prescription drug spending is affected when new drugs enter the market and when existing medications lose patent protection. New drugs can increase overall drug spending if they are used in place of older, less expensive medications; if they supplement rather than replace existing drugs treatments; or if they treat a condition not previously treated with drug therapy. New drugs can reduce drug spending if they come into the market at a lower price than existing drug therapies; this can occur when a new drug enters a therapeutic category with one or two dominant brand competitors. New drug use is affected by the number of new drugs (new molecular entities) approved by the US Food and Drug Administration; approvals have fluctuated over the past decade, with 35 approvals in 1999, 20 in 2005, and 25 in 2009.<sup>15</sup> U.S. pharmaceutical research and biotechnology companies spent about \$65 billion on research and development of new medicines and vaccines in 2009, an increase of about \$1.5 billion over 2008.<sup>16</sup>

Drug spending is also typically reduced when brand name drugs lose patent protection and face competition from new, lower cost generic substitutes. FDA analysis of 1999-2004 data shows that generic competition is associated with lower drug prices: on average, the first generic competitor prices its product only slightly lower than the brand name manufacturer; the second generic manufacturer reduces the average generic price to nearly half the brand name price; prices continue to fall but more slowly as additional generic manufacturers market the product. For products with a large number of generics, the average generic price falls to 20% of the branded price and lower.<sup>17</sup>

Almost 80% of FDA-approved drugs have generic counterparts. In 2008, 22% of total prescription drug sales and 72% of total prescriptions dispensed were generic medicines. Generic sales grew 8% from 2005 to 2006.<sup>18</sup>

Several high-sales brand name drugs are expected to go off-patent in the next 5 years, peaking in 2011 and 2012 when 6 of today's 10 largest products in the U.S. are expected to face generic competition. While total drug sales may decline as a result, the competition from generic drugs may bring down costs for patients.<sup>19</sup>

An issue receiving Congressional and Federal Trade Commission attention is the payments that brand name drug companies make to generic drug manufacturers to not release their products for a certain period of time, which the FTC says costs American consumers \$3.5 billion per year.<sup>20</sup>

*Advertising.* Both prescription use and shifts to higher-priced drugs can be influenced by advertising, which is usually conducted for brand name rather than generic drugs. Manufacturer spending on advertising was over 1.5 times as much in 2009 (\$10.9 billion) as in 1999 (\$6.6 billion). After increasing every year since 1996, the total amount manufacturers spent on advertising declined from 2004 to 2005 (from \$12.1 billion to \$11.7 billion), rose to \$12.4 billion in 2006, and fell to \$11.8 billion in 2007, \$11.3 billion in 2008, and \$10.9 billion in 2009. The share directed toward consumers in 2009 (through advertising on television, radio, magazines, newspapers, and outdoor advertising), was over twice the amount spent in 1999 (\$4.3 billion compared to \$1.8 billion), though spending decreased 2% from 2008 (\$4.4) to 2009 (\$4.3 billion). The share directed toward physicians (through the sales activities of pharmaceutical representatives and through professional journals) in 2009 (\$6.6 billion) was almost 1.5 times the amount in 1999 (\$4.8 billion); such spending decreased 3% from 2008 (\$6.8 billion) to 2009 (\$6.6 billion).<sup>21</sup> The FDA held hearings in November 2009 and bills have been introduced in the 111<sup>th</sup> Congress addressing changes to prescription advertising rules, particularly as they relate to on-line advertising.

*Sales and Profitability.* Prescription drug sales were \$300.3 billion in 2009, an increase of 5.1% over 2008. This increase was more than 2½ times the 1.9% increase from 2007 to 2008, but lower than the double-digit increases in the early 2000's. IMS Health attributes the 2009 growth to a stronger demand for prescription drugs despite economic conditions; sustained pricing practices by pharmaceutical manufacturers; inventory management actions by retail pharmacies to bring stocking levels in line with market demand; greater use of specialty pharmaceuticals, which comprise 21% of U.S. market value; lower impact of patent expirations; and no significant product safety issues during the year.<sup>22</sup> IMS Health forecasts a 3%-6% annual growth in the U.S. pharmaceutical market in the next 5 years, reaching \$360-\$390 billion in 2014.<sup>23</sup>

From 1995 to 2002, pharmaceutical manufacturers were the nation's most profitable industry (profits as a percent of revenues). They ranked 3<sup>rd</sup> in profitability in 2003 and 2004, 5<sup>th</sup> in 2005, 2<sup>nd</sup> in 2006, and 3<sup>rd</sup> in 2007 and 2008, with profits of 19.3% in 2008.<sup>24</sup>

*Selected PPACA Changes Affecting the Pharmaceutical Industry.* The Patient Protection and Affordable Care Act (PPACA, P.L.11148, enacted March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA, P.L.111-152, enacted March 30, 2010), includes several provisions that affect the pharmaceutical industry:

- Imposes an annual fee on certain manufacturers and importers of brand name drugs (including biological products but excluding orphan drugs) whose branded sales exceed \$5 million: an annual fee of \$2.5 billion beginning in 2011, rising to \$4.1 billion in 2018 and dropping to \$2.8 billion in 2019 and thereafter, allocated across the industry according to the proportion of sales for government programs.
- Establishes a process for FDA licensure of biosimilar (i.e., interchangeable) versions of brand name biological products; biological products are granted 12 years of exclusive use before biosimilar versions of a biological product can be approved, with certain drugs receiving additional years of exclusivity; FDA is authorized to collect associated user fees for the review of applications for approval.
- Changes certain drug labeling requirements and requires the HHS Secretary to determine whether adding certain information to a prescription drug's labeling and advertising would improve health care decision-making.

## Insurance Coverage for Prescription Drugs

Lack of insurance coverage for prescription drugs can have adverse effects. An April 2009 survey found that uninsured nonelderly adults (ages 18-64) are more than twice as likely as insured nonelderly adults to say that they or a family member did not fill a prescription (45% vs. 22%) or cut pills or skipped doses of medicine (38% vs. 18%) in the past year because of the cost.<sup>25</sup> Among nonelderly adults in 2008, 27% of the uninsured could not afford a prescription drug in the past 12 months, compared to 13% of those with Medicaid or other public coverage, and 5% of those with employer or other private coverage.<sup>26</sup> A September 2009 survey found that during the past 12 months, 26% of American adults did not fill a prescription, and 21% cut pills in half or skipped doses of medicine, because of cost.<sup>27</sup>

Prescription drug coverage comes from a variety of private and public sources:

**Employer Coverage.** Employers are the principal source of health insurance in the United States, providing coverage for 176 million (58%) of Americans in 2008.<sup>28</sup> Sixty percent of employers offered health insurance to their employees in 2009, and 65% of employees in those firms are covered by their employer's health plan.<sup>29</sup> Other employees may have obtained coverage through a spouse. Nearly all (98%) of covered workers in employer-sponsored plans had a prescription drug benefit in 2009.<sup>30</sup>

**Individually Purchased Policies.** About 9% of Americans purchased individual coverage in 2008.<sup>31</sup> According to a summer 2009 survey by America's Health Insurance Plans, the vast majority of policies purchased by individuals (rather than employer or other group coverage) had drug benefits.<sup>32</sup>

**Medicare.** Prior to January 1, 2006, the traditional Medicare program (the federal health program for the elderly and disabled) did not provide coverage for outpatient prescription drugs. As a result, about one-quarter (27%) of seniors age 65 and older, and one-third of poor (34%) and near-poor (33%) seniors, had no drug coverage in 2003.<sup>33</sup> The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a voluntary Medicare outpatient prescription drug benefit (known as Part D), effective January 1, 2006, under which the 47 million eligible Medicare beneficiaries can enroll in private drug plans. These plans vary in benefit design, covered drugs, and utilization management strategies.

Department of Health and Human Services data show that as of February 16, 2010, approximately 41.8 million (90%) of the 46.5 eligible Medicare beneficiaries had drug coverage. The total number of beneficiaries in a Medicare Part D plans was 27.7 million (60%), including 17.7 million beneficiaries (38%) in stand-alone prescription drug plans and 9.9 million (21%) in Medicare Advantage drug plans. Another 14.2 million beneficiaries (31%) had coverage from either employer or union retiree plans including FEHB and TRICARE (8.3 million, or 18%) and drug coverage from the VA and other sources (5.9 million, or 13%). About 4.7 million Medicare beneficiaries (10%) had no drug coverage.<sup>34</sup>

**Medicaid.** Medicaid is the joint federal-state program that pays for medical assistance to 60 million low-income individuals and is the major source of outpatient pharmacy services to the nonelderly low-income population. Although prescription drugs is an optional service, all state Medicaid programs cover prescription drugs for most beneficiary groups, although there are important differences in state policies with regard to copayments, preferred drugs, and the number of prescriptions that can be filled. Since January 1, 2006, states have been required to make payments to Medicare (known as the "clawback") to help finance Medicare drug coverage for those who are dually eligible for both Medicare and Medicaid.

**Selected PPACA Changes Affecting Prescription Drug Coverage.** The PPACA provisions affecting prescription drug coverage include:

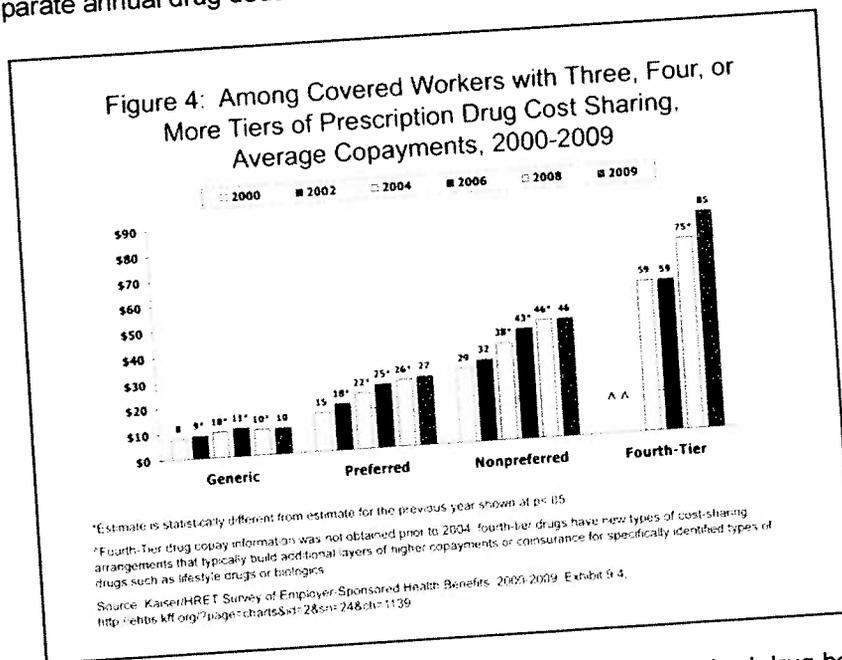
- **Coverage expansion:** Provides for a significant expansion of coverage to the uninsured through a Medicaid expansion, an individual requirement to obtain health insurance, and subsidies to help low and middle income individuals buy coverage through newly established Health Benefit Exchanges. PPACA provides that prescription drugs is one of the "essential health benefits" that must be included in health plans in the Exchanges and in the benchmark benefit package or benchmark-equivalent for newly eligible adults under Medicaid.

- Medicare changes: Provides for a \$250 rebate to Medicare Part D beneficiaries with out-of-pocket spending in the Medicare Part D coverage gap in 2010, a 50% discount for brand name drugs for beneficiaries in the coverage gap starting in 2011, a phasing-in of coverage in the gap for generic and brand name drugs which will reduce the beneficiary coinsurance rate from 100% in 2010 to 25% in 2020, a reduction between 2014 and 2019 in the threshold that qualifies enrollees for catastrophic coverage, and elimination of the tax deduction for employers who receive Medicare Part D retiree drug subsidy payments, starting in 2013.

### Responses to Increasing Prescription Drug Costs

A variety of public and private strategies have been implemented to attempt to contain rising costs for prescription drugs, as described below.<sup>35</sup>

**Utilization Management Strategies.** Health plans have responded to rising prescription drug costs by increasing enrollee cost-sharing amounts, using formularies to exclude certain drugs from coverage, applying quantity dispensing limits, requiring prior authorization, and using step therapy (starting with the most cost-effective drug and progressing to more costly therapy only if necessary). In 2009, over three-quarters (78%) of workers with employer-sponsored coverage were in plans with 3 or more tiers of cost sharing for prescription drugs, almost 3 times the proportion in 2000 (27%).<sup>36</sup> Worker copayments have increased from 2000-2009: 25% for generic drugs, 80% for preferred drugs, 59% for nonpreferred drugs, and 44% for fourth-tier drugs (data from 2004-2009) (Figure 4). The average copayment amounts in 2009 were \$10 for generics, \$27 for preferred drugs, \$46 for nonpreferred drugs, and \$85 for fourth-tier drugs. Twelve percent of covered workers had a separate annual drug deductible which averaged \$108.



A 2009 survey of individually purchased health policies found that the vast majority had drug benefits, with copayments being the predominant form of cost sharing. All HMOs and the majority of PPO/POS policies charged copayments which averaged, respectively, about \$10/\$13 for generic drugs, \$26/\$28 for preferred brand name drugs, and \$44/\$48 for non-formulary drugs. Fewer than half of the PPO/POS policies had a prescription drug deductible (averaging \$481 for single coverage and \$833 for family coverage); over half of the HMOs had a drug deductible (averaging \$320 for single coverage and \$1,002 for family coverage).<sup>37</sup>

**Discounts and Rebates.** Private and public drug programs negotiate with pharmaceutical manufacturers (often using contracted organizations known as pharmacy benefit managers) to receive discounts and rebates which are applied based on volume, prompt payment, and market share. Manufacturers who want their drugs covered by Medicaid must provide rebates to state Medicaid programs for the drugs they purchase; many states have also negotiated additional rebates, known as supplemental rebates.

Several federal government agencies, including the Department of Veterans Affairs, the Defense Department, the Public Health Service, and the Coast Guard, participate in a program known as the Federal Supply Schedule through which they purchase drugs from manufacturers at prices equal to or lower than those charged to their "most-favored" nonfederal purchasers.<sup>38</sup> In order to participate in Medicaid, another program, the Section 340B Program, requires manufacturers to provide drugs to certain nonfederal entities (such as community health centers and disproportionate share hospitals) at discounted prices. PPACA expands the entities that qualify for the program to include non-PPS children's and free-standing cancer hospitals, critical access hospitals and sole community hospitals, and rural referral centers; establishes new auditing, reporting, and other compliance requirements; and provides for an alternative dispute resolution process and penalties for violations.<sup>39</sup>

*Medicaid.* Historically, prescription drugs have been one of the fastest-growing Medicaid services. The Deficit Reduction Act of 2005 gave states more authority to control Medicaid drug spending through increased cost sharing for non-preferred drugs, changes in the way Medicaid pays pharmacists, allowing pharmacists to refuse prescriptions for beneficiaries who don't pay their cost sharing, and inclusion of authorized generic drugs in the calculation of "best price" for drugs. By 2007, most states had already implemented many of these approaches, so new action to control drug spending slowed.<sup>40</sup> A 2009 survey of 50 states+DC found that more than half had Medicaid pharmacy cost containment measures in place by FY2009, including preferred drug lists and prior authorization programs (about 45% of states), supplemental rebates from manufacturers and state Maximum Allowable Cost programs for generic and multi-source brand drugs (44%); smaller proportions of states were members of multi-state purchasing coalitions (26%) or had limits on quantities dispensed per prescription (16%).<sup>41</sup> Medicaid spent \$19.4 billion for prescription drugs in 2008, an increase of 3.5% over 2007; Medicaid drug spending decreased 1.7% between 2006 and 2007.<sup>42</sup>

Medicaid requires drug manufacturers who want to sell their products to Medicaid patients to agree to pay rebates to states for outpatient drugs purchased on behalf of Medicaid beneficiaries. PPACA increases the Medicaid drug rebate percentages for several types of outpatient drugs and requires that the resulting savings be remitted to the federal government. The law also extends the drug rebate to Medicare Managed Care Organizations and allows states to retain a portion of the savings generated from these rebates.

*Medicare.* The Medicare Part D drug benefit shifted spending from the private sector and Medicaid to Medicare, making Medicare the nation's largest public payer of prescription drugs (from 7% in 2005 to 60% in 2008). Medicare prescription drug spending as a share of total US prescription spending rose from 2% in 2005 to 22% in 2008. Medicare prescription drug spending totaled \$52.1 billion in 2008, an increase of 13% over 2007.<sup>43</sup>

Part D plans use various cost containment approaches including tiered cost sharing, formulary coverage that varies considerably across plans, and utilization management (UM) restrictions such as prior authorization, step therapy, or quantity limits; UM use among stand-alone drug plans has increased from 18% in 2007 to 28% in 2009.<sup>44</sup> Medicare is prohibited by law from directly negotiating drug prices or rebates with manufacturers to control costs. In the 110<sup>th</sup> Congress, the 2008 presidential campaign, and the 111<sup>th</sup> Congress, proposals to allow or require Medicare to negotiate drug prices with drug makers have been considered but not enacted.

*Purchasing Pools.* Some public and private organizations have banded together to form prescription drug purchasing pools to increase their purchasing power through higher volume and shared expertise. Examples include joint purchasing by the Department of Defense and VA; multi-state bulk buying pools through which states purchase drugs for their Medicaid, state employees, senior/low-income/uninsured pharmacy assistance programs, or other public programs; and individual state purchasing pools.<sup>45</sup>

*Consumers.* Consumers are turning to a variety of methods to reduce their prescription costs,<sup>46</sup> including requesting cheaper drugs or generic drugs from their physicians and pharmacies, using the Internet and other sources to make price comparisons, using the Internet to purchase drugs, buying at discount stores, buying over-the-counter instead of prescribed drugs, buying drugs in bulk and pill-splitting, using mail-order pharmacies,<sup>47</sup> and using pharmaceutical company or state drug assistance programs. Over half of physicians say they frequently talk with patients about the out-of-pocket costs of medicines they prescribe, 62% say they switch patients to less expensive drugs, and 58% say they give patients office samples.<sup>48</sup>

*Importation.* The high cost of prescriptions has led some to suggest that individuals be permitted to purchase prescription products from distributors in Canada or other countries (called "importation," or "reimportation" if the drug is manufactured in the US). Although it is generally not lawful for individuals or commercial entities such as pharmacies or wholesalers to purchase prescription drugs from other countries, the government does not always act to stop individuals from purchasing drug products abroad. Importation of pharmaceutical products from Canada through Internet sales and travel to Canada totaled about \$700 million in sales in 2003, or 0.3% of total US prescription sales. An equivalent amount of prescription drugs was estimated to have entered the US from the rest of the world, mostly through the mail and courier services.<sup>49</sup> P.L. 109-295 (enacted in 2006) allows US residents to transport up to a 90-day supply of qualified drugs from Canada to the US. Importation issues such as actual savings amounts, drug safety, and marketplace competition and pricing continue to be debated.

### **Outlook for the Future**

HHS projects US prescription drug spending to increase from \$234.1 billion in 2008 to \$457.8 billion in 2019, almost doubling over the 11-year period. The average annual increase in drug spending from the previous year is projected to increase from 3.2% in 2008 to 5.2% in 2009 (reflecting growth in the use of prescription drugs per person, driven by an increase in the use of anti-viral drugs related to the H1N1 virus), and then rise to 7.3% in 2019 (reflecting increases in drugs prices, the number of new drug approvals, and the share of expensive specialty drugs). Drug spending as a percent of overall national health spending is projected to increase somewhat from 10.0% in 2008 to 10.2% in 2019.<sup>50</sup>

In the coming years, implementation of various provisions of PPACA will affect prescription drug coverage, utilization, prices, and regulation. Coverage and utilization of prescription drugs will be expanded by PPACA's health insurance mandate and premium and cost-sharing subsidies; the designation of prescription drugs as an essential health benefit to be covered by private health plans through the new health benefit Exchanges and by Medicaid for newly eligible adults; and Medicare's prescription drug rebate, cost-sharing, and catastrophic threshold changes. Prices charged to government programs will be affected by changes to Medicaid rebate requirements and expansions to the Section 340B program. Prescription drug regulation will be affected by the new process for licensure of biosimilar versions of brand name biological products and by drug labeling requirements. These and other PPACA changes will ultimately impact national spending for prescription drugs in ways yet to be seen.

- <sup>1</sup> All spending amounts in this report are in current dollars (i.e., not adjusted for inflation.)
- <sup>2</sup> Centers for Medicare & Medicaid Services, National Health Expenditure Accounts, Historical, <http://www.cms.gov/NationalHealthExpendData/>, accessed October 6, 2009.
- <sup>3</sup> Aaron Catlin et al., "National Health Spending In 2005: The Slowdown Continues," *Health Affairs* 26, no. 1 (January/February 2007)142-153.
- <sup>4</sup> Aaron Catlin et al., "National Health Spending In 2006: A Year Of Change For Prescription Drugs," *Health Affairs* 27, no. 1 (January/February 2008), 14-29.
- <sup>5</sup> Micah Hartman et al., "National Health Spending In 2007: Slower Drug Spending Contributes To Lowest Rate Of Overall Growth Since 1998," *Health Affairs* 28, no. 1 (January/February 2009) 246-261.
- <sup>6</sup> Micah Hartman et al., "Health Spending Growth At A Historic Low In 2008," *Health Affairs* 29, no. 1 (January 2010)147-155.
- <sup>7</sup> Kaiser Family Foundation calculations using data from IMS Health, <http://www.imshealth.com> (Press Room, US Top-Line Industry Data 2008), and Census Bureau, <http://www.census.gov>. The per capita number may differ from the number reported at KFF's website [www.statehealthfacts.org](http://www.statehealthfacts.org) because of differing data sources which use different retail pharmacy definitions (e.g., IMS Health includes mail order, Verispan does not).
- <sup>8</sup> Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey Component Data, "Prescription Medicines – Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment," table 2, 1997 and 2007, <http://www.meps.ahrq.gov/mepsweb/>, accessed March 5, 2010.
- <sup>9</sup> Wolters Kluwer Pharma Solutions, Inc., *Pharma Insight 2009: Patients take More Power Over Prescription Decisions (March 2010)*, <http://www.wolterskluwerpharma.com/Press/Pharma%20Insight%202009%20-%20Media.pdf>.
- <sup>10</sup> New England Healthcare Institute, *Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease (August 2009)*, [http://www.nehi.net/publications/44/thinking\\_outside\\_the\\_pillbox\\_a\\_systemwide\\_approach\\_to\\_improving\\_patient\\_medication\\_adherence\\_for\\_chronic\\_disease](http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease).
- <sup>11</sup> Kaiser Family Foundation analysis of Consumer Price Index, All Urban Consumers, U.S. City Average, not seasonally adjusted, <http://www.bls.gov/cpi/home.htm>, accessed April 28, 2010.
- <sup>12</sup> Retail prescription prices reflect the prices paid by insured and uninsured patients, and do not reflect rebates, discounts, and other payments that in effect lower the cost of prescriptions.
- <sup>13</sup> National Association of Chain Drug Stores, "Industry Facts-at-a-Glance," <http://www.nacds.org> (based on data from IMS Health), accessed March 8, 2010.
- <sup>14</sup> Ibid.
- <sup>15</sup> US Food and Drug Administration, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ucm121136.htm> ; 2004-2009 data include new BLAs (biologic license applications) for therapeutic biologic products transferred from FDA's Center for Biologics Evaluation and Research to its Center for Drug Evaluation and Research.
- <sup>16</sup> PhRMA, "R&D Investment by U.S. Biopharmaceutical Companies Remains Strong Despite Ongoing Economic Challenges," March 16, 2010, [http://www.phrma.org/news/news/rd\\_investment\\_us\\_biopharmaceutical\\_companies\\_remains\\_strong\\_despite\\_ongoing\\_economic\\_chall](http://www.phrma.org/news/news/rd_investment_us_biopharmaceutical_companies_remains_strong_despite_ongoing_economic_chall)
- <sup>17</sup> US Food and Drug Administration, Center for Drug Evaluation and Research, "Generic Competition and Drug Prices," <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm>, accessed March 12, 2010.
- <sup>18</sup> Generic Pharmaceutical Association, <http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm>.
- <sup>19</sup> IMS Health, "IMS Forecasts Global Pharmaceutical Market Growth of 5-8% Annually Through 2014; Maintains Expectations of 4-6% Growth in 2010," April 20, 2010, <http://www.imshealth.com> (Press Room, Press Releases).
- <sup>20</sup> Federal Trade Commission, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," January 2010, <http://www.ftc.gov/lo/2010/01/100112payfordelayrpt.pdf>.
- <sup>21</sup> IMS Health, <http://www.imshealth.com> (Press Room, US Top-Line Industry Data 2009); Kaiser Family Foundation, *Prescription Drug Trends, a chartbook*, (July 2000), ex. 3.13, <http://www.kff.org/rxdrugs/3019-index.cfm>. The data on spending for advertising directed towards physicians excludes the retail value of drug samples left at sales visits to physicians' offices, which totaled about \$16 billion in 2004, the last year such data were available online from IMS Health.
- <sup>22</sup> IMS Health, "IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to \$300.3 Billion" (April 1, 2010), online at <http://www.imshealth.com> (Press Room, Press Releases).
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**For More Information:**

In addition to the Kaiser Family Foundation reports found in the Endnotes above, this Fact Sheet (#3057-08) and the following reports are available on the Foundation's website at <http://www.kff.org>: *Trends and Indicators in the Changing Health Care Marketplace* (#7031), *Prescription Drug Trends—A Chartbook Update* (#3112), *Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature* (#7295), *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* (#7296), *Medicare Prescription Drug Benefit Fact Sheet* (#7044-10), *Medicare Payments and Beneficiary Costs for Prescription Drug Coverage* (#7620), several Data Spotlights on the Medicare Part D drug benefit, *Explaining Health Care Reform: Key Changes to the Medicare Part D Drug Benefit Coverage Gap* (#8059), *Federal Policies Affecting the Cost and Availability of New Pharmaceuticals* (#3254), *Views on Prescription Drugs & the Pharmaceutical Industry, Public and Physician Views of Direct-to-Consumer Prescription Drug Advertising*. See also <http://www.statehealthfacts.org> for state-specific prescription drug utilization and sales (under Health Costs & Budgets); <http://www.kaiserEDU.org> (Prescription Drugs) for a Tutorial, Issue Modules, and SmartLinks on prescription drugs; and <http://facts.kff.org/> (search for Prescription Drugs) for Fast Facts about prescription drugs.

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