State Opportunities To Save With Generic Drugs

Generic Drugs and Illinois
August 2010

Opportunities to Reduce State Prescription Drug Expenditures
"Practical, Implementable Strategies to Increase Access to Prescription Medicines While Preserving Funds for Vital State Programs"
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Overspending on Multi-Source Drugs in Medicaid
July 21, 2010 Alex Brill, American Enterprise Institute

State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid
July 2010, William H. Shrank, Niteesh K. Choudhry, Jessica Agnew-Blais, Alex D. Federman, Joshua N. Liberman, Jun Liu, Aaron S. Kesselheim, M. Alan Brookhart, and Michael A. Fischer Health Affairs

Generic Drugs and Illinois

IN ILLINOIS…

The generic utilization in Illinois Medicaid was 72% in 2009. 19 states had 70% or greater generic utilization.[1]

In 2009, generic drugs saved the US health care system $139.6 billion, adjusted for population, that's approximately $5.9 billion in savings for the state of Illinois. [2]

What If Illinois Increased Medicaid Generic Utilization in 2009 from 72%-80%			
Increase in Generic Usage	**Total Savings**	**Federal Government Share**	**State Share**
1% to 73%	$35,365,272	$17,753,367	$17,611,906
5% to 77%	$176,826,362	$88,766,834	$88,059,528
8% to 80%	$282,922,179	$142,026,934	$140,895,245

STATE BY STATE: THE BEST AND THE WORST

Highest Generic Utilization Rates Top 5 States [3]		Lowest Generic Utilization Rates Bottom 5 States [4]	
State	**% of Total Scripts**	**State**	**% of Total Scripts**
Hawaii	77%	New Jersey	61%
Massachusetts	76%	Maryland	61%
Washington	76%	New York	62%
Nebraska	73%	California	62.5%
Utah	73%	AK, CT, LA, VT	63%

DID YOU KNOW?

- ✓ In 2009, more than 2.9 billion generic prescriptions were dispensed.[5]
- ✓ Seven of the ten largest drug manufacturers are generic drug companies.[6]
- ✓ Generic drugs have the same active ingredient as brand name drugs. [7]
- ✓ Generic drugs are required by the Food and Drug Administration (FDA) to have the same quality, strength, purity, and stability as brand name drugs.[8]

GENERIC UTILIZATION

- ✓ A 3% increase in generic use nationally would generate approximately $9 billion in additional savings to the US healthcare System. [9]

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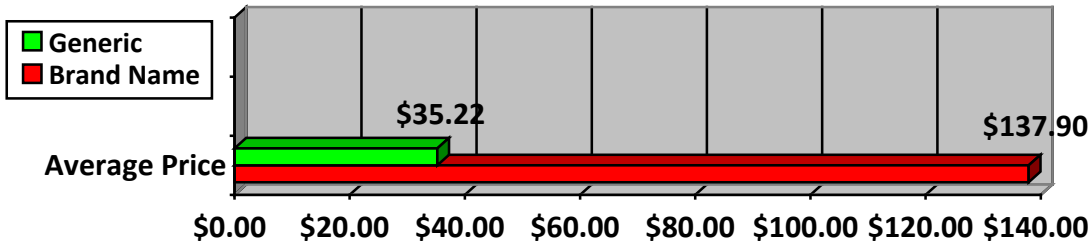
[1] 2009 National Brand and Generic Prescription Medicaid Drug Utilization and Expenditures by State, Excludes Rebates, Generic Pharmaceutical Association
[2] July 2010 Economic Analysis of Generic Pharmaceuticals 2000-2009 Generic Pharmaceutical Association; Population Division, U.S. Census Bureau December 22, 2008
[3] 2009 National Brand and Generic Prescription Medicaid Drug Utilization and Expenditures by State Generic Pharmaceutical Association
[4] 2009 National Brand and Generic Prescription Medicaid Drug Utilization and Expenditures by State Generic Pharmaceutical Association
[5] IMS Health, National Prescription Audit, Dec 2009
[6] ibid.
[7] FDA website (http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134444.htm) [Accessed April 15, 2010]
[8] Ibid
[9] May 2009 *Economic Analysis of Generic Pharmaceuticals 1999-2008* Generic Pharmaceutical Association

Year	Total Rx Sales	% of Generic Rx Dispensed	% of Generic RX Sales
2003	$217 billion	54%	17%
2004	$235 billion	57%	18%
2005	$252 billion	60%	19%
2006	$275 billion	63%	20%
2007	$286 billion	67%	21%
2008	$291 billion	72%	22%
2009	$300 billion	74%	23%

GENERICS OFFER SAVINGS TO CONSUMERS

- ✓ Competition from generic drugs helps keep the cost of drugs down and encourages research-based drug companies to keep finding better medicines.[10]
- ✓ Generic drugs have saved the US healthcare system around $734 billion dollars in the last decade and $121 billion in 2008 alone.[11]

Generic pharmaceuticals on average are 75% cheaper than brand name pharmaceuticals.[12]



MEDICARE AND MEDICAID GENERIC DRUG SPENDING

- ✓ The national average for Medicaid Generic Drug Utilization in the states is approximately 64%.[13]
- ✓ Nationally, the average cost to Medicaid for a generic prescription is $21, compared to $191 for the average brand version of the same drug.[14]
- ✓ A 1% increase in the generic utilization rate in the Medicaid program could yield approximately $490 million in added annual savings.[15]
- ✓ The Centers for Medicare and Medicaid Services (CMS) report for the FY 2008 showed total prescription drug spending for the year at $22.8 billion. Only 17% of this, or $3.9 billion, was spent for prescriptions filled with generics.[16]

TOP 10 GENERICS BY PRESCRIPTION[17]

	Product	Therapeutic Area
1	Hydrocodone/APAP	Pain Management
2	Simvastatin	Cardiovascular
3	Lisinopril	Cardiovascular
4	Levothyroxine SOD	Thyroid Hormone
5	Azithromycin	Antibiotic
6	Metformin HCL	Diabetes
7	Amlodipine Besy	Cardiovascular
8	Amoxicillin	Antibiotic
9	Hydrochlorothiazid	Cardiovascular
10	Omeprazole	Gastrointestinal

[10] FDA website op.cit.
[11] Generic Pharmaceutical Association op. cit.
[12] Nation Association of Chain Drug Stores (http://www.nacds.org/wmspage.cfm?parm1=6536) [Accessed: April 15, 2010]
[13] Generic Pharmaceutical Association op. cit.
[14] Ibid.
[15] Ibid.
[16] Ibid
[17] IMS Health

Opportunities to Reduce State Prescription Drug Expenditures

Practical, Implementable Strategies to Increase Access to Prescription Medicines While Preserving Funds for Vital State Programs

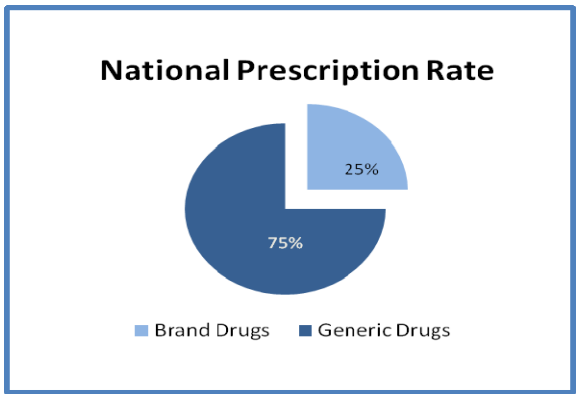
The budget challenges facing state governments have become acute, and governors and state legislatures are searching for solutions. The current recession has resulted in the steepest decline in state tax receipts since the Great Depression, with 46 states reporting fiscal year 2011 gaps totaling $121 billion, or 19% of budgets.[1] Within state budgets, health care is one of the biggest cost drivers and, thus, one of the most important areas in which to identify savings.

According to the National Association of State Budget Officers, Medicaid spending alone was estimated to reach 21% of state spending in fiscal year 2009.[2] To put this in context, states' Medicaid spending was estimated to be only 0.1 percentage point less than states' spending on K–12 public education. Health care spending is only going to increase as many states will be required to assume greater financial obligations under health care reform once it is fully enacted.

Faced with fiscal crises and rising health care costs, policymakers can look to generic drug utilization as a way to cut spending without reducing services, given that generic pharmaceuticals are usually significantly less expensive than brands. There are a number of practical, proven policy solutions, discussed below, for lowering health care costs through use of affordable generic drugs while maintaining high quality care, and the resulting savings can be allocated to other important state programs.

Generic Sameness and Safety

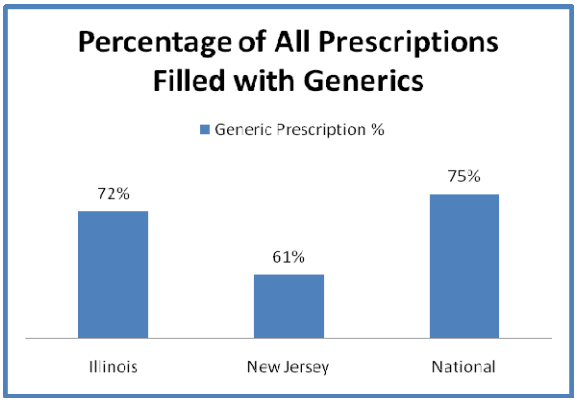
Cost is the only difference between brand pharmaceuticals and their Food and Drug Administration (FDA) approved generic equivalents. For nearly two and a half decades, America's generic pharmaceutical industry has been developing, manufacturing, and marketing generic versions of brand prescription drugs. These products have been used by hundreds of millions of consumers and offer the same safety and effectiveness as their brand counterparts. Generics now make up 75% of prescriptions that pass over pharmacy counters each day.[3]



To receive FDA approval, a generic pharmaceutical must contain the same amount of the active ingredient, in the same dosage form, strength, and route of administration as the brand drug. The generic must also meet the same standards for strength, purity, and quality as the brand. Thus, consumers can have the same level of confidence in approved, therapeutically equivalent generics that they do in brand drugs.

Current State Generic Utilization and Opportunities for Savings

While all states can generate some savings, the opportunities for savings are clearly greater for those with lower generic drug use. A few simple questions to the appropriate budget authority can reveal a state's level of generic use and, thus, the size of the opportunities to save. For example, one should ask, ***what is the generic substitution rate?*** This is the generic utilization success rate. This figure describes how successful a state is at using generics when they are available. Brand drugs that do not have expired patents and no available generics are not included. States should aim for a generic substitution rate of 100% for maximum cost-effectiveness. If a state's rate is lower than 90%, then huge opportunities exist for savings.



The second question is more commonly known, ***what is the generic prescription rate or generic dispensing rate?*** This number indicates the percentage of all prescriptions that are filled with generic products. According to 2009 Medicaid data, Illinois has one of the highest rates at 72%, and New Jersey has the lowest at 61 percent.[4] For the entire U.S. population, the generic prescription rate is 75% and the brand prescription rate is 25%, according to IMS Health.[5]

Five Strategies to Increase Medicaid/State Program Generic Utilization

The generic substitution rate drives the generic utilization rate, so many of the strategies outlined below focus on encouraging substitution when a generic is available.

1. Mandatory Generic Dispensing. By far, the most effective method to increase generic utilization is mandatory generic dispensing (see case study on the following page), which means that, if a generic is available for a brand drug, the generic must be given to a patient by the pharmacist. The higher cost brand version of the drug remains available to beneficiaries if the prescribing physician receives "prior authorization" via an explanation by state form, letter or fax. Common methods some states currently employ to aim for a high generic dispensing rate include:

- Requiring "prior approval" for all "dispensed as written" prescriptions
- Requiring physicians to submit a completed FDA MedWatch form prior to any brand drug override
- Requiring physicians to submit a written explanation why a brand is medically necessary
- Instituting a pharmacy reimbursement policy that only pays at the generic rates even if a brand drug is dispensed.

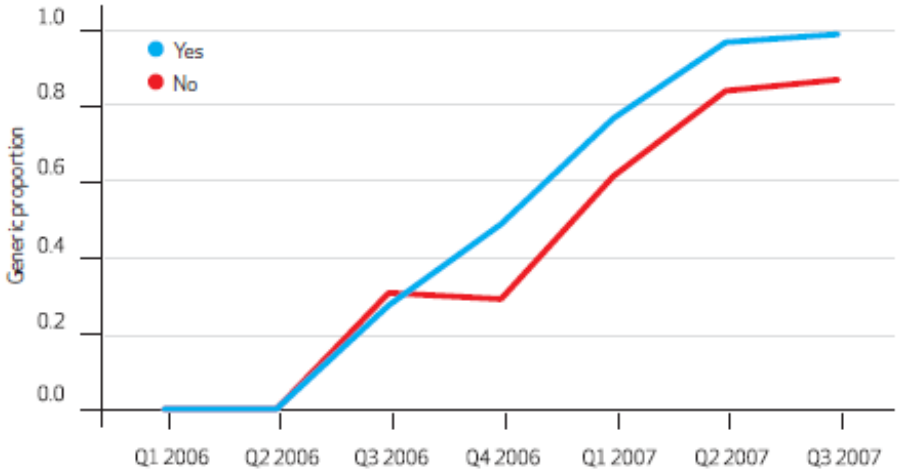
Sixteen states currently require mandatory generic dispensing, unless the physician indicates that the brand prescription must be dispensed as written or that the brand is medically necessary. In 2002, Massachusetts's Medicaid program went from spending between $10 million to $11

million per month for brand drugs with FDA-approved generic equivalents to between $200,000 and $300,000 after implementing a generic substitution policy.[6]

Case Study: Zocor Medicaid

The exclusivity for Zocor® (simvastatin) expired on June 23, 2006. A recent study in *Health Affairs* found that, in the first six months that generics were available, states with limited policies encouraging generic substitution filled 30% of statin prescriptions with the generic, while states with mandatory generic substitution filled 48% of prescriptions with generics. Illinois, Oregon, Massachusetts, and similar states that do not require patient permission to substitute a generic, reached 98% substitution in six months. According to the study, increasing the ability of pharmacists to substitute brand drugs for newly available generics before the upcoming expirations of three drugs (Lipitor®, Zyprexa®, and Plavis®) would result in a one-year savings of $100 million.

Relationships Between Legislation Requiring Mandatory Generic Substitution At The Pharmacy And Generic Fill Rates For Simvastatin, 2006 And 2007



SOURCE Centers for Medicare and Medicaid Services, aggregate Medicaid prescription medication use data. **NOTE** Yes/no indicates whether or not generic substitution is mandatory.

Source: William H. Shrank et al., "State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid," *Health Affairs*, July 2010.

2. Preferred Drug List. A preferred drug list (PDL) is intended to ensure that the lowest-cost drugs are dispensed within state programs. Brand manufacturers offer supplemental rebates for inclusion on the PDL. But given that in 2009 generic drugs averaged $39 per prescription while brand drugs averaged $155 per prescription,[7] if generic drugs are available in a class, they are

most often the lowest-cost option. North Carolina's Medicaid program is expected to save over $90 million after implementing a PDL in March 2010.[8]

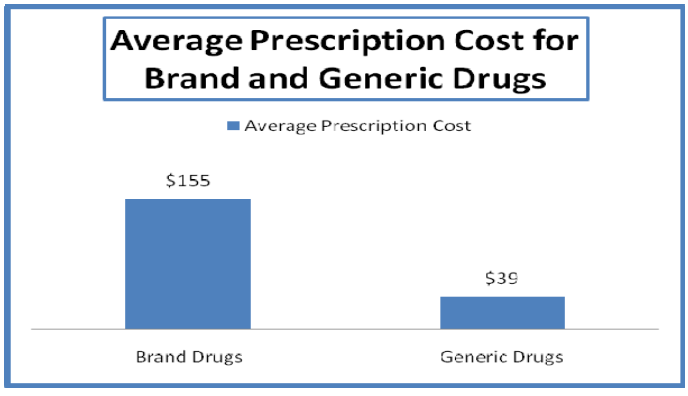
PDLs are now widely used by most state Medicaid plans. While they require time and effort on the part of state officials, they are one of the most effective ways to lower taxpayer costs and increase generic drug use. The effectiveness of state PDLs varies because specific drugs or entire classes of drugs are excluded from consideration. For example, drugs to treat cancer and HIV are generally excluded from a PDL. Until the last few years, atypical antipsychotics were a rare PDL drug class, but given that these drugs are usually at the top of the drug expenditures list, states are reconsidering this class's exclusion. Even if a state already has a PDL, it could still potentially be made a more effective vehicle for savings.

The enforcement of the PDL is accomplished through the prior approval process. This ensures that the state Medicaid plan only pays for drugs on the PDL, unless the patient or provider seeks prior approval to use a non-PDL drug. For instance, if physicians wish to prescribe a drug that is not on the PDL, they must seek approval by telephone or fax from the state Medicaid program, with appropriate clinical justification for the use of a non-PDL drug. This prior approval process requires that the use of a more expensive product be backed up with a scientific explanation. Thanks to this policy, it is not uncommon in some states to have PDL compliance in the 90% range.

3. Patient Copayment Differential. Patient copayment differentials are plan design features with financial incentives for lower-cost prescription drugs. Out-of-pocket expense can be one of the most powerful economic motivators for a patient, making a copayment differential a powerful tool to shape purchasing behavior. Because an FDA-approved generic drug is interchangeable with its brand version, assuming the patient and physician have no documentable medical reason not to use a generic drug, patients with copayment differentials will almost always request the drug with the lowest out-of-pocket cost.

Understanding this behavioral component has prompted several states to increase generic utilization by lowering or eliminating copayments for generic drugs. While this may seem counterintuitive, because copayments are commonly only $1 for generics (and $3 for brand drugs), the state Medicaid revenue lost from generic copayments is actually more than made up by the lower total cost of the generic drugs. For many state beneficiaries, copayment cost is the major motivating factor in the selection of a drug.

4. Brand Limits. Several states have adopted limits on the number of brand drugs each patient can fill each month without prior approval. (These programs typically will exclude entire classes of drugs, such as cancer and HIV drugs, from such limits.) Current brand limits implemented in some states range from three to six brand name drugs per patient, per month, without prior approval.



Because patients are often being treated by more than one physician at a time, without physician coordination, a hypothetical limit of three brand drugs is often met quite easily. Enforcement of brand limit programs typically occurs at the point-of-sale. When a patient goes to fill the fourth brand prescription, the pharmacy will get a notification and either the pharmacist or the prescribing physician will have to seek prior approval on behalf of the patient, with clinical justification for this choice. In 2004 and 2005, the brand limit plan in the Alabama Medicaid program resulted in savings of $4.6 million and $7.3 million, respectively.[9]

It is critically important to note that *the only difference between brand pharmaceuticals and their generic equivalents is cost*.

5. Appropriate Pharmacy Payments. Appropriately motivated pharmacies and pharmacists can drive generic dispensing rates. Conversely, if the pharmacy is financially advantaged to dispense brand drugs, it will most certainly be neutral, at best, with respect to generic dispensing rates and, at worst, fill prescriptions more often with the higher-cost brand name drug.

Recently, the state of North Carolina and the Association of Community Pharmacists, Inc. (a North Carolina–based pharmacists' trade association) faced this issue and negotiated a reimbursement arrangement with the retail pharmacies that encouraged generic dispensing. The result was that North Carolina increased its generic dispensing rate from 66 percent to over 73 percent in a matter of six months.[10]

State Employee/Retiree Plan Recommendations

Unlike Medicaid plans, which must comply with numerous federal rules and regulations, state employee/retiree plans generally are free to design a benefits package more in line with the private sector. However, state employee/retiree benefits are often governed by state statutes and can be subject to state insurance laws, and employee benefits plans can be subject to union collective-bargaining agreements.

Many states will have unique applications to employee/retiree plans of the five strategies listed above, but others may have plans somewhat identical to Medicaid programs and could thus implement these strategies. For instance, a patient copayment differential, the third strategy above, is an effective policy in employee/retiree health plans. Two other recommendations, outlined below, for states to increase generic drug utilization among employees and retirees are "hard" generic dispensing and a 90-day maintenance drug supply.

1. "Hard" Generic Dispensing. "Hard" generic dispensing requires a patient to pay the difference between the cost of an available generic drug and the cost of the patient-requested brand drug. In some plan designs, the patient must pay the cost difference plus the copayment. For example, the patient may request the brand drug Zocor® instead of simvastatin (generic for

Zocor®). The plan design provides for a generic copayment of $11 and a non-formulary copayment of $48. The patient cost will be the difference between the brand drug ingredient cost and the generic ingredient cost, plus the brand name copayment. Assuming for the sake of the example that the brand ingredient cost is $90 and the generic ingredient cost is $20, the patient would pay the difference of $70 plus the brand name copayment of $48 for a total patient cost of $118. As this example illustrates, the plan is held harmless for the patient's choice.

In some states, the "hard" generic rules can be overridden if a physician can provide clinical evidence that the patient is unable to take the generic drug. For example, if a patient has shown severe allergic reaction to one of the known ingredients in the generic drug (binding agent, dye, etc.), then the patient would not be required to pay the cost difference. These types of appeals are often handled by the state's pharmacy benefits manager (PBM) or some other outside clinical vendor.

2. Ninety-Day Maintenance Drug Supply. A 90-day maintenance drug supply policy allows patients with chronic and complex conditions to obtain a three-month supply of drugs for which they have established a stable regimen (dosage, frequency, etc.) and which they will likely take for at least one year. Maintenance drugs typically are obtained from a mail-order pharmacy or a retail pharmacy that has contracted with a PBM to participate in a 90-day retail maintenance network.

The major advantages to maintenance medication being dispensed in ninety-day increments are payer (and patient) cost savings, better patient compliance due to the lower frequency of refill need and home delivery, and the pharmacy's ability to work with the patient and physician to optimize generic dispensing. Mail-order pharmacies and properly contracted retail pharmacies have the highest generic utilization and the lowest payer cost.

Conclusion

Many of these tools can be taken in whole or in part and it is possible to make improvements to each with some innovative thinking. The first five policy strategies—mandatory generic dispensing, preferred drug lists, patient copayment differentials, brand limits, and appropriate pharmacy payments—are all options for Medicaid and other state programs. Variations on these strategies could also be used for state employee/retiree plans, in addition to "hard" generic dispensing and ninety-day maintenance drug supply policies. All options lead to the same result: more generic dispensing, lower drug expenditures, and the same high quality care.

Generic drugs have been a winner for policymakers for over twenty-five years, and in the current budgetary climate, a renewed focus on the cost savings generics offer will be beneficial for policymakers and their constituents.

Strategies to Increase Medicaid/ State Program Generic Utilization

- Mandatory Generic Dispensing
- Preferred Drug List
- Patient Copayment Differential
- Brand Limits
- Appropriate Pharmacy Payments

Strategies Applicable to State Employee/Retiree Benefits

- "Hard" Generic Dispensing
- 90-Day Maintenance Drug Supply

Notes

[1] "Recession Continues to Batter State Budgets; State Responses Could Slow Recovery," Center on Budget and Policy Priorities, July 15, 2010. http://www.cbpp.org/cms/index.cfm?fa=view&id=711 [Accessed: July25, 2010]
[2] "Fiscal Year 2008 State Expenditure Report," National Association of State Budget Officers, Fall 2009, http://nasbo.org/Publications/StateExpenditureReport/tabid/79/Default.aspx [Accessed: July 10, 2010]
[3] "IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion," IMS press release, April 6, 2010.
[4] Generic Pharmaceutical Association, "National Brand & Prescription (Rx) Medicaid Drug Utilization and Expenditures by State 2009Q1 – Q4."
[5] IMS, 2010.
[6] "Strategies to Increase Generic Drug Utilization and Associated Savings," AARP. http://assets.aarp.org/rgcenter/health/i16_generics.pdf [Accessed: July 10, 2010]
[7] "Industry Facts-at-a-Glance," National Association of Chain Drug Stores. http://www.nacds.net/wmspage.cfm?parm1=6536 [Accessed: July 27, 2010]
[8] "NC Medicaid Starts Preferred Drug List Program," Associated Press, March 15, 2010. http://www.businessweek.com/ap/financialnews/D9EFBL7G0.htm [Accessed: July 10, 2010]
[9] "Legislative Council Approves State Medicaid Drug Plan," Associated Press, May 18, 2004.
[10] Phone interview with Bill Rustin, President, and Mike James, RPh, Vice President, Director of Government Affairs, Association of Community Pharmacists, Inc., conducted February 23, 2010.

Special Thanks: Many of the tools described were sourced from the Generic Pharmaceutical Association's (GPhA) "Toolkit: Strategies to Increase Dispense Rates of Generic Prescription Drugs in the United States" by Scott McKibbin.

Overspending on Multi-Source Drugs in Medicaid

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Summary

Brand drugs are generally significantly more expensive than therapeutically equivalent generic products. This report analyzes a large subset of 2009 Medicaid drug data from the Medicaid Drug Rebate Program and identifies multi-source drugs (i.e., products for which there are brand and generic versions) for which there are significant sales of more costly brand products. The results show that states' Medicaid programs engage in a large amount of unnecessary and wasteful drug spending by reimbursing pharmacies for relatively costly brand products when identical generic products are available.

Generic substitution refers to the percentage of total prescriptions for a particular chemical compound, strength, and dosage form filled by a generic. Because there is usually a large price differential between brand and generic drugs, a high generic substitution rate ensures cost-effectiveness in the Medicaid drug program without engaging in policies that affect clinical decisions.

This report assesses wasteful spending in Medicaid by examining specific brand drugs and quantifying the potential savings that could have been achieved had these drugs been replaced with lower-cost, therapeutically equivalent generics that were available but not used. The report bases its conclusions on an analysis of Medicaid drug spending from data made available by the Centers for Medicare & Medicaid Services.

The analysis, which examines a subset of approximately two-thirds of total Medicaid drug spending in 2009, identifies an estimated $271 million of wasteful spending as a result of underutilization of available generics. Had generics been fully substituted for the brands identified, Medicaid's total spending on the identified drugs could have been $1.49 billion instead of $1.76 billion.

Given rising pressures on states' fiscal budgets, these findings, considered in conjunction with the conclusions of previous studies, indicate that continued wasteful spending in Medicaid is a problem requiring the prompt attention of policymakers.

Key Findings

- In total, Medicaid spent $21.8 billion on drugs in 2009. Following a review of approximately two-thirds ($14 billion) of 2009 Medicaid drug spending, which included single-source and multi-source products, this report identified twenty brand drugs for which a therapeutically equivalent generic was available, but on which Medicaid overspent in 2009 by not fully utilizing the available generics.
- Within this subsample, Medicaid's overspending on prescription drugs is estimated to be $271 million. This waste is based on only twenty drug compounds, but there are 139 unique NDCs within those compounds. While the analysis examined two-thirds of total Medicaid drug spending ($14 billion of the total $21.8 billion), total spending on the twenty multi-source drugs was approximately $1.76 billion. Thus, for the identified products, Medicaid spent 15 percent more than it would have had generics been fully utilized ($1.76 billion versus $1.49 billion).
- Among the twenty drugs studied, Medicaid wasted an average of $96 per prescription. For half of the drugs, Medicaid averaged over $100 in waste per prescription.
- Most of the waste (94 percent) was concentrated in twelve of the twenty identified chemical compounds. Total waste for these drugs was roughly $256 million.

- The majority of the waste identified relates to drugs that recently experienced a generic launch. Nearly three-quarters of the waste (73 percent) was tied to generic products that launched in 2008 or 2009.
- The top underutilized generics in terms of wasteful spending were lamotrigine (brand Lamictal®) and risperidone (brand Risperdal®), with overspending on the corresponding brand drugs totaling approximately $51 million and $45 million, respectively.
- The average rate of generic substitution for the twenty products was 87 percent over the four quarters of 2009, but nine of the twenty drugs had substitution rates lower than 80 percent.

Objective

This report is intended to identify and quantify excessive and wasteful Medicaid spending on brand drugs when less expensive, therapeutically equivalent generic versions are available.

Introduction

The Medicaid prescription drug program carries a very high price tag. In 2009 alone, Medicaid spent $21.8 billion on prescription medicines. And total Medicaid spending—the federal share in particular—is certain to grow in the future. The 2009 stimulus bill included an additional $87 billion of federal funding for the program above and beyond ordinary cost sharing.[1] President Barack Obama's budget for fiscal year 2011 proposes increasing federal spending on Medicaid by $25.5 billion through the first six months of 2011.[2]

Most significantly, the recently enacted health care reform stipulates the expansion of Medicaid eligibility to all nonelderly individuals with incomes below 133 percent of the federal poverty line beginning in 2014, which will add 16 million individuals to the program by 2019, according to the Congressional Budget Office.[3] Initially, the federal government will pay the entire cost of these new Medicaid beneficiaries; after 2019 it will pay 90 percent of their costs. Considering the size, significance, and projected growth of the program, policymakers have a responsibility to ensure that it operates in the most fiscally responsible manner possible, devoid of waste, fraud, and abuse.

An important and relatively simple approach to reducing wasteful spending is to maximize the use of available generic drugs in the Medicaid Drug Rebate Program. According to the National Association of Chain Drug Stores, the average generic prescription price in 2008 was $35.22, while brand drugs averaged $137.90, a difference of 392 percent.[4] Clearly, potential savings from using generic versions of brand drugs is significant in a program that spent nearly $22 billion on prescription medications in 2009.

Research has shown that when generics enter the market after the Food and Drug Administration (FDA) declares them therapeutically equivalent with a brand drug, the generic price falls drastically below the original brand price. Brand prices do not fall in parallel to the generic price and have been found to increase an average of 1 percent after generic market entry.[5] This market price bifurcation is due to brand-loyal or price-insensitive customers who are willing to continue to pay high prices for the brand drug despite the availability of a lower-price equivalent.

In examining efficiency in Medicaid drug spending, one metric to consider is the generic prescribing rate—the percentage of all prescriptions filled by a generic product. A higher prescribing rate (that is, more generics dispensed relative to brands) will result in lower total drug spending. However, many drugs are single-source (no generic is available), and therefore the optimal generic prescribing rate is unknowable (but far less than 100 percent).

An alternative means of analyzing Medicaid prescription drug spending is to determine a state Medicaid program's generic substitution rate—that is, for a given chemical drug in a specific dosage form and strength, the percentage of total prescriptions filled by a generic *when a generic is available*. To ensure the highest possible cost-effectiveness, it is important that Medicaid programs not reimburse for more expensive brand drugs when a less expensive, therapeutically equivalent generic is available.

Background

Only a few studies have assessed brand overspending in Medicaid and none using recent data. In 2006, the Department of Health and Human Services Office of Inspector General (HHS OIG) released a report measuring generic drug utilization and substitution rates in Medicaid state programs.[6] The report found that in 2004 the average generic substitution rate for Medicaid patients' prescriptions was 89 percent, which means that brand drugs were dispensed 11 percent of the time when a therapeutically equivalent generic was available. Considering that generic drugs are generally less expensive than brand drugs, this 11 percent gap means that significant wasteful spending is occurring in the program. According to the report, the state with the poorest record for substitution was California, at 83 percent. Florida and Hawaii, each with a rate of 92 percent, were the most effective at substitution. However, the HHS OIG report did not produce any cost estimate of overspending related to generic substitution rates.

A 2003 *Health Services Research* study by Michael A. Fischer and Jerry Avorn examined 2000 data from the Medicaid drug program and identified $229 million of overspending in that period on brand drugs that could have been substituted with generics.[7] Fischer and Avorn, physicians specializing in pharmacoepidemiology and pharmacoeconomics, found much of the waste in a relatively small number of drugs. Over $109 million—nearly 50 percent of the identified overspending—was associated with ten medications. Because the analysis was limited to drugs in tablet and capsule form (excluding inhalants, topical medications, and transdermal patches, among others), the study acknowledges that the total amount of waste in 2000 was likely much higher than $229 million.

Fischer, Avorn, and Aaron S. Kesselheim also published a study in *Health Affairs* in 2006 examining the deleterious effects of delayed adoption of generic drugs in the Medicaid drug program and how the extension of intellectual property rights for brand drugs beyond the original patent expiration affects Medicaid drug spending.[8]

A 2005 *Annals of Internal Medicine* study by Jennifer S. Haas, Kathryn A. Phillips, Eric P. Gerstenberger, and Andrew C. Seger examined data from the Medical Expenditures Panel Survey Household Component (MEPS) and identified potential savings from generic substitution across all payer types.[9] They estimate overspending in 2000 in Medicaid *and other public programs* to be $388 million. This estimate relies on patient-reported estimates of drug prices through the MEPS survey. Overall, the authors analyzed 7,056 national drug codes (NDCs) and found broad failures to maximize generics across all payer types.

Data and Methodology

The analysis in this report is based on Medicaid drug program data from 2009, the latest data available from the Centers for Medicare & Medicaid Services.[10] The dataset presents quarterly reimbursements to pharmacies for each NDC and includes the product name, the number of units reimbursed, the number of prescriptions filled, the total amount reimbursed, and the total amount reimbursed by Medicaid.

This dataset contains over 120,000 data points, many for products for which few prescriptions were filled or the total amount reimbursed was small. In my initial review, I looked within the top two-thirds (by NDC, by quarterly reimbursement amount) of Medicaid drugs for brand products for which there are generics that the FDA deems therapeutically equivalent. Using the FDA Orange Book,[11] I cross-referenced the Medicaid dataset and found twenty multi-source products with overspending caused by the reimbursement of more costly brand drugs.[12] The NDC numbers from the dataset allowed me to

identify exact generic/brand matches by (1) dosage form (capsule, tablet, and so forth), (2) drug strength, (3) package type (such as a bottle or blister pack), and (4) package size (for example, the number of tablets in the pharmacist's bottle).[13]

It should be noted that in the comparison I took a conservative approach on two levels. First, I considered a chemical eligible for quarterly analysis only if a generic had entered the market *before* a quarter began—thereby excluding waste from the quarter in which the generic launched.[14] Second, I matched only generics and brands that were identical for all four of the above-mentioned criteria. For example, if a generic matched a brand by dosage form, strength, and package type but was not supplied in the exact package size in which the brand was available, I eliminated it as a nonmatch. Similarly, if spending could be reduced if a pharmacist provided a patient with, for example, two five milligram generic pills instead of one ten milligram brand dose, I did not include that savings in this analysis.

For the brand-to-generic matches in the dataset that did meet these strict criteria, I calculated average unit prices and the price difference between the generic and brand.[15]

An additional step necessary in the analysis was to account for state Medicaid rebates from drug companies. When a pharmacist fills a prescription for a Medicaid patient, Medicaid reimburses the pharmacy for the drugs dispensed and pays a dispensing fee. By law, pharmaceutical companies that provide drugs for Medicaid patients are required to give Medicaid a rebate. The rebate for brand drugs in 2009 was 15.1 percent of the average manufacturer price (AMP) per unit or the difference between the AMP and an inflation-adjusted best price per unit, whichever is larger. The rebate for generic drugs in 2009 was 11 percent of the AMP per unit.[16]

Because AMPs are proprietary, I estimated the brand drug rebate as 15.1 percent of the average reimbursed cost per unit and the generic rebate as 11 percent of the average reimbursed cost per unit. As noted below, a report by the Government Accountability Office (GAO) found that average Medicaid reimbursement per unit was, on average, 12 percent higher than AMP. Thus, the true rebate is likely calculated as a share of a smaller price than that reimbursed by Medicaid and therefore would be less than assumed in this analysis.

Using the postrebate estimate of the unit-price difference, I calculated waste for each product by multiplying the postrebate unit-price difference between brand and generic by the number of brand units reimbursed, thus determining the amount that would have been saved if generics had been prescribed exclusively.

Findings

This research indicates that underutilization of available generics resulted in $271 million of unnecessary spending in 2009. I identified twenty chemical compounds and, more precisely, 139 NDCs for which a generic substitute was available in the identical dosage form, strength, package type, and package size. (In addition, there were eighty-three NDCs among the twenty drugs for which there was no generic.)

Twelve chemicals constituted nearly $256 million (94 percent) of the unrealized savings. Leading these were the brand drugs Lamictal® (generic lamotrigine) and Risperdal® (generic risperidone). Waste for these drugs equaled approximately $51 million and $45 million, respectively, over the four quarters of 2009 (see table 1). Total spending for these products (brand and generic combined) was $1.76 billion and was 15 percent higher than it would have been had generics been fully substituted.

The average generic substitution rate—that is, the percentage of total prescriptions filled by a generic—for the identified drugs was 87 percent. This is slightly lower than the 89 percent rate reported by the 2006 HHS OIG study of 2004 Medicaid drug program data. Nine of the twenty drugs identified had rates lower than 80 percent, including five of the top six drugs identified.

Among the twenty drugs studied, Medicaid wasted an average of $96 per prescription. In other words, for these twenty chemicals, every time a Medicaid beneficiary received a brand prescription instead of a generic, Medicaid wasted nearly $100. By this metric, Clozaril® and Percocet® are the most wasteful, with average overspending exceeding $200 per prescription. Fully half of the drugs had average waste of over $100 per prescription. Toprol-XL® and Zithromax® waste averaged only $8 and $12 per prescription, respectively. They were found to be significant causes of overspending only because the total volume of prescriptions filled for these drugs was very high.

Table 1. Summary of Findings, Medicaid Overspending on Twenty Drugs, 2009

Brand name	Therapeutic category	Estimated waste	Brand prescriptions	Avg. waste per prescription	Generic substitution rate
Lamictal®	Anticonvulsant	$50,731,285	308,178	$165	75%
Risperdal®	Antipsychotic	$44,608,823	350,713	$127	86%
Topamax®	Anticonvulsant	$34,270,551	201,929	$170	73%
Keppra®	Anticonvulsant	$30,663,575	198,578	$154	67%
Depakote®	Anticonvulsant	$29,603,564	511,902	$58	71%
Duragesic®	Analgesic	$19,163,511	97,836	$196	78%
Wellbutrin®	Antidepressant	$16,150,861	164,355	$98	83%
Trileptal®	Anticonvulsant	$9,746,004	80,289	$121	87%
Zofran®	Antiemetic	$7,021,222	153,785	$46	85%
Imitrex	Antimigraine	$4,690,224	75,779	$62	61%
CellCept®	Immunosuppressant	$4,632,612	30,160	$154	44%
Flonase®	Respiratory Inhalant	$4,621,733	95,392	$48	92%
Clozaril	Antipsychotic	$3,625,241	14,734	$246	96%
Depo-Provera	Contraceptive	$2,547,977	212,572	$12	75%
Protonix®	Gastrointestinal Agent	$2,349,390	83,707	$28	66%
Percocet®	Analgesic	$2,100,600	9,335	$225	98%
DDAVP®	Antidiuretic	$1,876,058	14,528	$129	95%
Toprol-XL®	Antihypertensive	$1,002,691	123,609	$8	94%
Omnicef®	Antibiotic	$963,970	34,927	$28	98%
Zithromax®	Antibiotic	$851,145	68,645	$12	99%
Total		**$271,221,034**	**2,830,953**	**$96**	**87%**

Note: Waste is calculated for an NDC only if a generic was available before a quarter started. Waste calculations for CellCept®, Imitrex®, Keppra®, and Topamax®, as well as five Depakote® NDCs and one Risperdal® NDC, do not include all of 2009.
Source: Author's calculations.

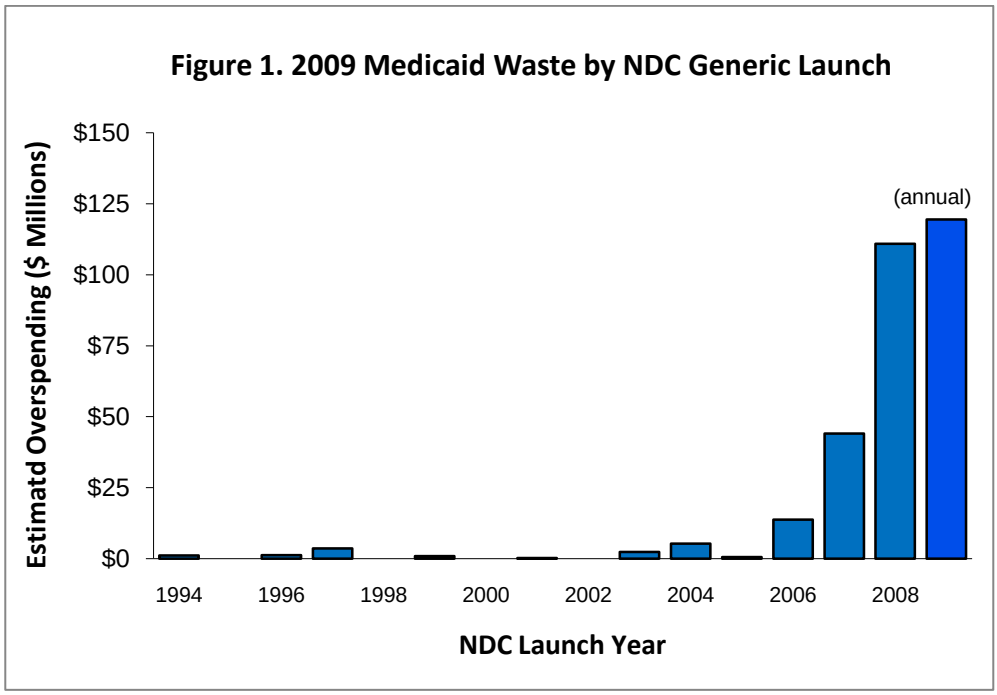
Table 2 provides details about generic entry into brand markets and the range of dates during which entry occurred. For most drugs, certain strengths, dosage forms, or package types or sizes do not have a generic equivalent. For example, four NDCs for sumatriptan succinate (brand Imitrex®) entered the market in February 2009 (with overspending on the brand totaling $4.7 million in just the last three quarters of 2009), but Imitrex® has six NDCs for which it still has no generic competitor.

Table 2. Generic Equivalents			
Brand name/generic name	**NDCs with generic equiv.**	**NDCs without generic equiv.**	**Generic market entry**
Lamictal®/lamotrigine			
Tablet	4	0	July 2008
Starter Kit	0	3	n/a
Tablet, Chewable	2	0	June 2006, Aug. 2006
Tablet, Extended Release	0	7	n/a
Tablet, Orally Disintegrating	0	7	n/a
Risperdal®/risperidone			
Tablet	17	0	Jan. 1994–June 2008
Oral Solution	1	0	July 1996
M-TAB	6	1	May 2003–Feb. 2009
Consta® Kit	0	4	n/a
Topamax®/topiramate			
Tablet	4	0	Mar. 2009
Capsule	2	0	Apr. 2009
Keppra®/levetiracetam			
Tablet	4	3	Jan. 2009
Tablet, Extended Release	0	2	n/a
Oral Solution	1	0	Jan. 2009
Injection	0	1	n/a
Depakote®/divalproex sodium			
Capsule	1	1	Jan. 2009
Tablet, Delayed Release	8	0	July 2008
Tablet, Extended Release	4	0	Jan.–May 2009
Duragesic®/fentanyl			
Patch, Extended Release	4	6	Aug. 2007
Patch	0	5	n/a
Wellbutrin®/bupropion HCl			
Tablet	2	0	Dec. 1999
Tablet, Extended Release	3	0	June 2007, Nov. 2008
Tablet, Sustained Release	3	0	Jan.–July 2005
Trileptal®/oxcarbazepine			
Tablet	6	4	Oct.–Nov. 2007
Oral Suspension	0	1	n/a
Zofran®/ondansetron HCl			
Tablet	4	2	Oct. 2007
Tablet, Orally Disintegrating	3	0	Oct. 2007

Table 2, continued			
Brand name/generic name	**NDCs with generic equiv.**	**NDCs without generic equiv.**	**Generic market entry**
Zofran®/ondansetron HCl, continued			
Oral Solution	1	0	Dec. 2006
Injection	3	0	Nov. 2006, Feb. 2007
Imitrex®/sumatriptan succinate			
Tablet	3	0	Feb. 2009
Injection	1	4	Feb. 2009
Nasal Spray	0	2	n/a
CellCept®/mycophenolate mofetil			
Tablet	2	0	May 2009
Capsule	3	0	May 2009
Oral Suspension	0	1	n/a
Injection	0	1	n/a
Flonase®/fluticasone propionate			
Nasal Spray	1	0	Feb. 2006
Clozaril®/clozapine			
Tablet	4	0	Dec. 1997
Depo-Provera®/medroxyprogesterone acetate			
Injection, Suspension	4	7	Apr. 1996–Sept. 2005
Protonix®/pantoprazole sodium			
Tablet, Delayed Release	2	1	Dec. 2007
Injection	0	4	n/a
Oral Suspension	0	2	n/a
Percocet®/oxycodone HCl			
Tablet	7	6	June 1994–Dec. 2008
DDAVP®/desmopressin acetate			
Tablet	2	0	Jan. 2006
Nasal Spray	2	0	Sept. 1990, Jan. 1999
Injection	1	2	Oct. 1997
Toprol-XL®/metoprolol succinate			
Tablet, Extended Release	7	1	July 2007–Mar. 2008
Omnicef®/cefdinir			
Capsule	1	1	May 2007
Oral Suspension	4	0	May 2007
Zithromax®/azithromycin			
Tablet	7	1	Nov. 2005, Sept. 2006
Injection	1	1	Mar. 2006
Oral Suspension	4	2	Sept. 2008

Note: Generic equivalents were not necessarily available in all four quarters of 2009. There can be multiple market entry dates for one generic because NDCs for a given chemical compound do not always enter the market at the same time. Furthermore, in many instances, brand products are available within a chemical compound in a certain strength, dosage form, or package type or size for which there is no generic.
Source: Author's calculations.

Much of the wasteful spending is related to products for which generic entry has occurred recently (see figure 1). The 2009 waste attributable to generic NDCs launched in 2008 totaled $111 million. Waste from products that launched during 2009 totaled $87 million ($119 million on an annualized basis). Thus, nearly three-fourths of total identified waste is for brand spending for which the generic launched during or after 2008. However, there are important exceptions to this observation.



Note: Waste calculation for products launched during 2009 was annualized for it to be comparable to data on products launched prior to 2009.
Source: Author's calculations.

For example, despite facing generic competition since February 2006—one of the earliest generic entry points in the analysis—and a substitution rate of 92 percent, Flonase® (generic fluticasone propionate) was responsible for nearly $5 million in waste. Duragesic® has faced generic competition since August 2007, yet it has an average substitution rate of only 78 percent. In 2009, Medicaid overspent by more than $19 million on this drug.

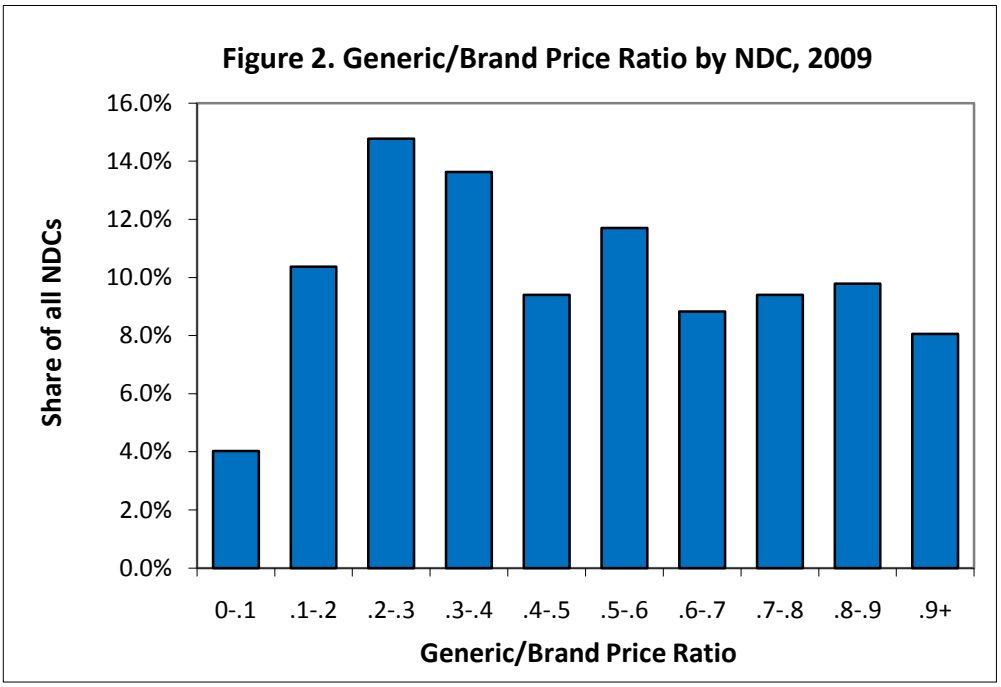
Sensitivity Analysis

It should be noted that this analysis is based on only a subset of total Medicaid drug spending; overspending by Medicaid potentially could be calculated for hundreds, if not thousands, of additional brand NDCs. A straight linear extrapolation of the waste estimate—assuming a constant ratio of waste to spending for the one-third of Medicaid drug spending not analyzed in this study—suggests that total waste across all drugs in the Medicaid program would approximate $411 million.

Furthermore, there are two reasons to believe that my calculations included a modest overestimate of the rebate manufacturers pay to state Medicaid programs. (Overestimating the rebate implies a conservative approach that would lead to an underestimate of wasteful spending.) First, the average reimbursement cost per unit used to estimate the rebate includes a dispensing fee as well as the cost of the drug, while the actual rebate is based on only the average price per unit of the drug that wholesalers pay the manufacturer (the aforementioned AMP). Second, evidence reported by GAO indicates that, on

average, Medicaid reimbursement (in a five-state sample) exceeded the AMP by 12 percent.[17] A similar study by HHS OIG confirms that the metrics used to calculate Medicaid reimbursement are substantially larger than the AMP.[18]

Conversely, I have not accounted for potential brand manufacturers' discounts to states, or for the possibility that rebates may in some circumstances exceed 15.1 percent.[19] To explore the possibility that additional brand discounts could affect my waste estimate, I analyzed the distribution per quarter of generic-to-brand price ratios per NDC (see figure 2), estimating the basic rebate as 15.1 percent and 11 percent of the average reimbursed cost per brand and generic unit, respectively. The weighted average generic-to-brand price ratio is 0.34. In other words, the generic price is, on average, 66 percent lower than the brand price among the 20 products analyzed, far lower than any estimates of additional rebates brand manufacturers might pay.



Source: Author's calculations.

On net, these offsetting factors seem to be of comparable magnitude: discounts not included in this estimate would be offset by the overestimated rebate and the fact that the analysis excluded one-third of total Medicaid reimbursements, where additional waste certainly also exists.

Policy Options

Recognizing the cost-effectiveness of using generic pharmaceuticals in the Medicaid program, forty-one states encourage that a generic version of a drug, if available, be dispensed to Medicaid beneficiaries.[20] However, California, Illinois, Iowa, Louisiana, Michigan, Nebraska, New Mexico, Ohio, and Washington do not have generic substitution laws for Medicaid,[21] and even among states that do have such laws, many states have exceptions and carve outs. "Dispense as written" exceptions that allow physicians to override generic substitution in many states are one example.

The inadequacy of current laws to ensure maximum cost savings is also recognized in a recent *Health Affairs* study on the Medicaid drug program that finds that mandating generic substitution at the pharmacy level does not significantly influence substitution rates. Instead, Dr. William Shrank and his co-authors identify patient consent to generic substitution as a critical policy affecting Medicaid substitution rates.[22] In fact, states requiring that a Medicaid beneficiary consent to a generic had substitution rates 25 percent lower than states without patient-consent requirements.

Another policy tool states have used to lower Medicaid drug spending is a preferred drug list, which states issue to guide the cost-effective use of drugs within certain classes. A second option is a copayment differential, which lowers or eliminates a patient's copayment for a generic drug. Some states have also established limits on the number of prescriptions per month a Medicaid beneficiary can have filled by a brand product. To reduce or eliminate waste in Medicaid drug programs, policymakers will need to consider wider implementation of these policies or others like them.

In addition to policies that distinguish between generic and brand drugs to encourage cost savings, policymakers should implement policies that promote lowest-cost products among multi-source drugs. Currently, only sixteen states require pharmacists to dispense the lowest-cost multi-source drugs to Medicaid patients.

Conclusion

These results are similar to the findings of the 2003 *Health Services Research* study, which identified much of the Medicaid waste in 2000 in just a handful of drugs. However, except for one instance (Clozaril® and its generic, clozapine), the drugs identified in 2009 differ from those identified in 2003 (using 2000 data).[23] Overspending is occurring on new drugs and not those of nine years ago, which points to the need for constant watchfulness in state Medicaid programs as new generic drugs become available.

The health care reform bills signed into law in March expand Medicaid eligibility beginning in 2014 to those under the age of sixty-five with incomes below 133 percent of the federal poverty line.[24] Under the new law, total enrollment in Medicaid and the smaller Children's Health Insurance Program will increase by an additional 16 million by 2019.[25] Expanded Medicaid coverage will increase the size of the drug program, thereby increasing the amount of waste if new policies are not implemented. Given that policy options to address this overspending likely rely on both federal and state decisions and that such reforms will likely take time to design and implement, future research is needed to identify how to move more quickly to generics in the Medicaid program.

Future research should seek to analyze Medicaid waste on a state-by-state basis and test the effectiveness of various policy tools for minimizing wasteful spending in the program on brand products when equivalent, lower-cost generic products are available.

Notes

[1] See *American Recovery and Reinvestment Act*, 111th Cong., 1st sess., February 13, 2009, available through www.recovery.gov.
[2] Office of Management and Budget, FY 2011 budget fact sheet for Department of Health and Human Services, available at www.whitehouse.gov/omb/factsheet_department_health.
[3] Congressional Budget Office (CBO) director Douglas Elmendorf, letter to Speaker of the House Nancy Pelosi, March 20, 2010, available at www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf.
[4] National Association of Chain Drug Stores, "Industry Facts-at-a-Glance," available at www.nacds.org/wmspage.cfm?parm1=6536. Brand averages include products for which there is no generic alternative.
[5] Tracy L. Regan, "Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market," *International journal of Industrial Organization* 26 (2008), available at http://moya.bus.miami.edu/~tregan/Pharmacy.pdf.
[6] Health and Human Services Office of Inspector General (HHS OIG), *Generic Drug Utilization in State Medicaid Programs*, July 2006, available at www.oig.hhs.gov/oei/reports/oei-05-05-00360.pdf.
[7] Michael A. Fischer and Jerry Avorn, "Economic Consequences of Underuse of Generic Drugs: Evidence from Medicaid and Implications for Prescription Drug Benefit Plans," *Health Services Research* 38, no. 4 (August 2003): 1,051–64, available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1360932.
[8] Aaron S. Kesselheim, Michael A. Fischer, and Jerry Avorn, "Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending," *Health Affairs* 25, no. 6 (2006), available at http://content.healthaffairs.org/cgi/content/full/25/6/1637.
[9] Jennifer S. Haas, Kathryn A. Phillips, Eric P. Gerstenberger, and Andrew C. Seger, "Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997–2000," *Annals of Internal Medicine* 142, no. 11 (June 7, 2005), available at www.annals.org/content/142/11/891.full.pdf.
[10] For national and state drug utilization data, see Centers for Medicare & Medicaid Services (CMS), "Medicaid Drug Rebate Program: Overview," available at www.cms.hhs.gov/MedicaidDrugRebateProgram.
[11] FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 30th ed., 2010, available at www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.
[12] Oral contraceptives were not included in the analysis.
[13] This information is available through the U.S. National Library of Medicine's DailyMed website, available at http://dailymed.nlm.nih.gov/dailymed.
[14] For drug product data, including market entry dates, for drugs reimbursed through Medicaid, see CMS, "Medicaid Drug Rebate Program: Drug Product Data," available at www.cms.hhs.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp.
[15] Although there is often more than one generic NDC that matches a brand NDC, I matched only one generic per brand, assuming that generic prices would be comparable.
[16] CMS, "Medicaid Drug Rebate Program: Overview."
[17] See Government Accountability Office, letter to Congressman Edward Whitfield, "Medicaid: States' Payments for Outpatient Prescription Drugs," October 31, 2005, available at www.gao.gov/new.items/d0669r.pdf.
[18] HHS OIG, *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices*, June 2005, available at http://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf.
[19] CBO, "The Rebate Medicaid Receives on Brand-Name Prescription Drugs," June 21, 2005, available at www.cbo.gov/ftpdocs/64xx/doc6493/06-21-MedicaidRebate.pdf. Also, according to the HHS OIG, "While generic substitution generally achieves savings, it may not save money in all circumstances... In some cases, it is possible that the higher Medicaid rebate could lead to a lower net payment for a brand name drug than for its generic equivalent." See HHS OIG (2006), 11.
[20] National Pharmaceutical Council (NPC), *Pharmaceutical Benefits under State Medical Assistance Programs* (Reston, VA: NPC, 2007), available at www.npcnow.org/App_Themes/Public/pdf/Issues/pub_related_research/pub_medicaid/2007%20Pharmaceutical-Benefits-Under-State-Medical-Assistance-Programs.pdf. Arizona is excluded because it does not participate in the

Medicaid drug program, but the District of Columbia is included. Four states (Arkansas, New York, North Carolina, and Texas) offer a generic substitution incentive fee, ranging from $0.50 to $2.00.

[21] It should be noted that the waste this report identifies is not limited to these nine states. Despite measures adopted to encourage substitution, there is evidence of overspending in other states.

[22] William H. Shrank, Niteesh K. Choudhry, Jessica Agnew-Blais, Alex D. Federman, Joshua N. Liberman, Jun Liu, Aaron S. Kesselheim, M. Alan Brookhart, and Michael A. Fischer, "State Generic Substitution Laws Can Lower Drug Outlays under Medicaid," *Health Affairs* 29, no. 7 (2010).

[23] In 2004, Wisconsin announced that it would require prior authorization for any prescription to be filled with a brand drug when a generic equivalent is available. Simultaneously, the state issued specific guidelines on substituting generic clozapine for the brand drug Clozaril®. While commendable, the guidelines were issued more than a year after the study and four years after the data the study analyzed. Clozaril® continues to be a source of overspending for Medicaid nationally. See Wisconsin Department of Health Services, "Clozapine and Clozaril®," available at http://dhs.wi.gov/medicaid/recpubs/pde_3192.htm.

[24] Kaiser Family Foundation, "Financing New Medicaid Coverage under Health Reform: The Role of the Federal Government and States," *Focus on Health Reform* (May 2010), available at www.kff.org/healthreform/upload/8072.pdf.

[25] CBO director Douglas Elmendorf, letter to Speaker of the House Nancy Pelosi, March 20, 2010.

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State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid

ABSTRACT To stem the rising costs of medications provided to patients enrolled in Medicaid, states have implemented varying policies about generic substitution. These policies differ in the extent to which pharmacists or patients can influence which medications they choose. Using national Medicaid data, we evaluated the relationship between different generic substitution policies and the use of generic simvastatin, a cholesterol-lowering drug, after the patent for the brand-name equivalent, Zocor, expired. States that implemented policies requiring patients' consent prior to generic substitution experienced rates of substitution that were 25 percent lower than those of states that did not require patient consent. By eliminating patient consent requirements, state Medicaid programs could expect to save more than $100 million in coverage for three top-selling medications that are nearing patent expiration. Although these consent requirements are probably intended to increase patient autonomy, policy makers should consider the sizable opportunity costs.

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In a time of shrinking budgets, state governments seek strategies to reduce unnecessary costs of health care without compromising quality. The expiration of patents on many best-selling drugs represents one particularly appealing opportunity to encourage patients to switch to generic products, and thus to reduce costs without major disruptions in established medication regimens.

Generic drugs are clinically equivalent, less costly versions of the identical molecule used in brand-name drugs[1] but are typically sold at a fraction of the cost. In 2011, patents will expire for Lipitor, a cholesterol-lowering drug; Plavix, an antiplatelet medication; and Zyprexa, a so-called atypical antipsychotic frequently used in the treatment of schizophrenia. Together, these drugs accounted for almost $17 billion in U.S. sales in 2007. Patents for numerous other blockbuster medications are also scheduled to expire in the next four years.[2]

By and large, state governments have relatively few tools available to influence Medicaid enrollees' prescription drug use. But by adopting policies that encourage the substitution of generic drugs after patents expire, states may greatly reduce costs without compromising quality. All states have adopted generic substitution laws. Many require so-called step therapy—starting patients on one relatively low-cost drug, and moving to a more costly medication if the first doesn't work. Other states require prior authorization from a health plan or pharmacy benefits manager to certify that a patient needs a more expensive brand-name medication before it can be prescribed.

Affecting The Use Of Generics

Although step therapy and prior authorization have a substantial effect on the use of medications, little is known about what levers are most

effective for encouraging the use of generics.[3] Studies in the late 1970s and 1980s indicated that generic substitution laws increase these drugs' use.[4,5] However, generic drugs represented only a tiny proportion of filled prescriptions at that time, and the marketplace for medications has changed markedly since then.[6]

A more recent study of generic substitution laws in Sweden also found that such laws increase generic use,[7] although Sweden has a very different health care delivery system than the United States has.

STATE LAWS U.S. generic substitution laws are determined by individual states and can differ among states in several important ways. Some state boards of pharmacy have adopted mandatory generic substitution laws. These require pharmacists to substitute a generic for a brand-name medication if the prescriber did not specify that the latter drug should be dispensed. More-permissive generic substitution laws enacted in other states give pharmacists more discretion by allowing, but not requiring, pharmacists to substitute generics. In addition, some states require patients to provide consent prior to the substitution of a generic, while other states do not. States that require patient consent provide patients with a greater opportunity to influence the use of medications.

The mandatory substitution and patient consent laws are separate statutes, and states could adopt one, both, or neither of them. No recent studies have assessed the relationship between these variations in generic substitution laws and the resulting rates of generic substitution. Similarly, no studies have explored whether or not these regulations affect rates of generic substitution at all.

THE CASE OF ZOCOR The end of market exclusivity for Zocor (simvastatin) on 23 June 2006 offered an opportunity to study the effect of varying generic substitution laws on the rate of generic drug substitution. Annual spending on Zocor in the United States exceeded $4.6 billion before the patent expired, and Zocor was one of the top-selling medications in the world for several years.[2] We selected Medicaid as the source population to use in evaluating the effects of different substitution practices because cost containment is a topic of particular importance to state governments, especially in the current economic climate.

Study Data And Methods

DATA SOURCES The Centers for Medicare and Medicaid Services (CMS) produces quarterly data on drug use by Medicaid programs.[8] These state-level data include the total number of prescriptions filled, the total number of units (tablets, capsules, and so on) dispensed, and the total Medicaid reimbursement for each product, aggregated by calendar quarter. No data at the level of individual patients are available. We obtained data for forty-nine states and the District of Columbia. Because Arizona has a decentralized Medicaid program, its data were not included.

States' generic substitution laws were obtained from an annual survey of state boards of pharmacy, published by the National Association of Boards of Pharmacy.[9] This survey characterizes states' generic substitution laws in two broadly different ways. First, it asks whether the state requires or permits the pharmacist to decide whether or not to substitute a generic product for a brand-name drug in filling a prescription. Second, it asks whether or not the state requires the patient's consent to fill a prescription with a brand-name rather than a generic drug. Data regarding legislation in Oklahoma were not available in the survey from the National Association of Boards of Pharmacy; data from that state were excluded from this analysis.

We contacted all state Medicaid agencies in our sample between September and December 2008 to determine whether Medicaid programs had specified and implemented any prior authorization policy regarding brand-name Zocor or brand-name Lipitor during the study period. Lipitor is another molecule in the same class as Zocor, but Lipitor did not have a generic alternative.

STATISTICAL ANALYSIS We evaluated quarterly frequencies of filled prescriptions for all statins, generic simvastatin, brand-name Lipitor, and brand-name Zocor between the first quarter of 2006—approximately six months before simvastatin became available—and the third quarter of 2007—the most recent calendar quarter posted on the CMS Web site at the time of these analyses.

Our primary result was the generic drug use ratio: the number of simvastatin prescriptions divided by the total number of prescriptions of both simvastatin and Zocor. Secondary results included the proportion of all statin prescriptions that were filled for Lipitor; the total Medicaid reimbursement for the sum of simvastatin and Zocor use; and the cost per prescription for simvastatin or Zocor.

Because generic simvastatin became available on 23 June 2006, there were data for only one week of minimal simvastatin use in the second calendar quarter of 2006.

There is a limit on potential confounding in this analysis stemming from the timing of a change in Medicaid enrollment. Specifically, our study period began after the implementation of Medicare Part D. Patients enrolled in both

Laws providing patients with greater discretion in determining generic drug substitution were most influential.

Medicare and Medicaid were automatically enrolled in a Part D drug plan on 1 January 2006. Thus, any changes to the size of the population enrolled in Medicaid as a result of Part D should have occurred before simvastatin arrived on the market.

We used data describing actual Medicaid reimbursement to assess the relation between patient consent laws and costs to states. To calculate the average cost per prescription per calendar quarter, we divided total reimbursement per quarter for simvastatin and Zocor prescriptions by the total number of prescriptions filled per quarter for these medications. In the five calendar quarters after Zocor's patent expired, we compared the savings per prescription between states that did not require patient consent and those that did.

We evaluated bivariate relations independently between the three policies of interest—mandatory generic substitution, patient consent, and prior authorization—and the primary result, the generic use ratio of simvastatin. To assess the comparative effects of different laws on generic drug use, we used a generalized linear regression model with repeated measures, in which each calendar quarter by state was an observation.

The models included time as a categorical variable, to capture the nonlinear time trend in generic prescribing. The effects of the different laws were modeled through the use of time-varying indicator variables, as some states changed policies during the study period. We used an identity link function, so the parameter estimates are appropriately interpreted as the average monthly change in generic prescribing across the study period, attributable to the different policies. Standard errors were estimated robustly to account for repeated observations within states.[10]

To assess the relationship between generic substitution laws and rates of substituting generic simvastatin for brand-name Lipitor, another statin, we conducted a time-series analysis in which the outcome was Lipitor's proportion of all prescriptions filled for statins. Effects on Lipitor use were estimated in a multivariable adjusted linear regression model, with time treated as a class variable. Because prior authorization policies affecting Lipitor may be correlated with similar policies for other drugs and are likely to affect the use of medications, we included an indicator for Lipitor prior authorization as well as for the other policies in the model. All analyses were conducted with SAS statistical software.

Study Results

Mandatory generic substitution regulations, patient consent regulations, and prior authorization requirements for brand-name Zocor for 2006 and 2007 are listed in Exhibit 1.

In 2006, 1.6 million prescriptions were filled for either generic simvastatin or brand-name Zocor in Medicaid programs in forty-eight states and the District of Columbia. In the states that used mandatory generic substitution, 492,443 simvastatin and Zocor prescriptions were filled in 2006; in the states that did not require patient consent, 146,654 simvastatin and Zocor prescriptions were filled in 2006.

The aggregate of simvastatin and Zocor use constituted 25.8 percent of all statin use in 2006 in Medicaid programs nationally. In the first two calendar quarters after Zocor's patent expired, approximately half of all simvastatin prescriptions were filled with the generic form (Exhibit 2). This proportion increased to more than 90 percent in the fourth calendar quarter after patent expiration.

EFFECTS AFTER PATENT EXPIRATION In the six months following patent expiration, the states with laws requiring mandatory generic substitution at the pharmacy filled 48.7 percent of simvastatin prescriptions with the generic version. States with permissive substitution laws filled 30.0 percent of statin prescriptions with the generic (Exhibit 3). In the states that did not require patient consent for generic substitution, 98.1 percent of simvastatin prescriptions were for the generic version six months after patent expiration. Less than one-third of simvastatin prescriptions were filled with the generic in states that did require patient consent (Exhibit 4).

In states that required prior authorization for the use of Zocor after its patent expired, we found inconsistent and small changes in generic substitution rates when compared to states without prior authorization requirements (Appendix Exhibit 1).[11]

EXHIBIT 1

State Regulations Regarding The Use Of Prescription Drugs In Medicaid Programs, 2006 And 2007

State	Patient consent required	Mandatory generic substitution	Prior authorization for Zocor
AL	N	N	N
AK	Y	N	N
AZ[a]	Y	N	N
AR	Y	N	Y
CA	Y	N	Y
CO	Y	N	N
CT	Y	N	Y
DE	Y	N	Y
DC	Y	N	N
FL	Y	Y	N
GA	Y	N	N
HI	Y	O	N
ID	Y	N	Y
IL	Y	N	N
IN	Y	N	Y
IA	Y	N	Y
KS	Y	N	N
KY	Y	Y	N
LA	Y	N	N
ME	Y	N	Y
MD	Y	N	Y
MA	N	Y	N
MI	Y	N	N
MN	Y	N	Y
MS	Y	N	N
MO	Y	N	N
MT	Y	N	N
NE	Y	N	N
NV	X	O	N
NH	Y	N	Y
NJ	N	Y	Y
NM	N	Y	N
NY	Y	N	Y
NC	O	N	Y
ND	Y	N	N
OH	Y	N	Y
OR	N	Y	N
PA	Y	N	Y
RI	N	Y	N
SC	Y	N	Y
SD	Y	N	N
TN	N	Y	N
TX	Y	N	Y
UT	Y	N	Y
VT	Y	N	N
VA	Y	N	N
WA	N	Y	Y
WV	Y	N	Y
WI	Y	N	Y
WY	N	Y	N

SOURCES Survey of state boards of pharmacy, published by the National Association of Boards of Pharmacy; and contact with individual state Medicaid programs. **NOTES** Y is required in 2006 and 2007. N is not required in 2006 and 2007. O is requirement added in 2007. X is requirement dropped in 2007. [a]Not used in this analysis because of a lack of Medicaid data.

In multivariable models controlling for generic substitution policies, prior authorization policies for Zocor, and repeated observations within states, mandatory generic substitution laws had no statistically significant effect on the use of generic simvastatin (95 percent confidence interval: −0.12, 0.35, $p = 0.33$; see Appendix Exhibit 2).[11] Laws requiring patients

EXHIBIT 2

Trends In Simvastatin, Zocor, And Total Statin Use, By Calendar Quarter, 2006 And 2007

Year	Calendar quarter	Total number of simvastatin Rx filled in Medicaid programs	Sum of simvastatin and Zocor Rx filled in Medicaid programs	Total number of statin Rx filled	Average state-level proportion (standard deviation) of filled simvastatin Rx that were generic
2006	2	9	394,616	1,536,213	–
2006	3	106,755	360,118	1,397,266	0.47 (0.35)
2006	4	135,196	370,805	1,431,234	0.50 (0.45)
2007	1	259,843	386,496	1,450,384	0.77 (0.29)
2007	2	360,976	404,923	1,405,863	0.92 (0.21)
2007	3	411,012	447,647	1,465,682	0.94 (0.20)

SOURCE Centers for Medicare and Medicaid Services, aggregate Medicaid prescription medication use data. **NOTE** Simvastatin is the generic form of Zocor.

to provide consent prior to generic substitution reduced the use of generics by an average of 24.8 percent per calendar quarter in the five quarters after Zocor's patent expired (95 percent confidence interval: −0.43, −0.05; $p = 0.01$). We found no significant relationship between a prior authorization requirement for Zocor and the generic substitution rate ($p = 0.63$).

LIPITOR BY COMPARISON Lipitor use declined from 43 percent of total statin use in the first quarter of 2006 to 36 percent in the fourth quarter of 2007. Adjusting for other policy effects, Lipitor prior authorization requirements were associated with 30.6 percentage points lower use of Lipitor, compared to states without prior authorization requirements for Lipitor. Mandatory generic substitution, patient consent requirements, and prior authorization requirements for Zocor did not affect either overall levels of Lipitor use or changes in rates of Lipitor use following the entrance of generic simvastatin into the market.

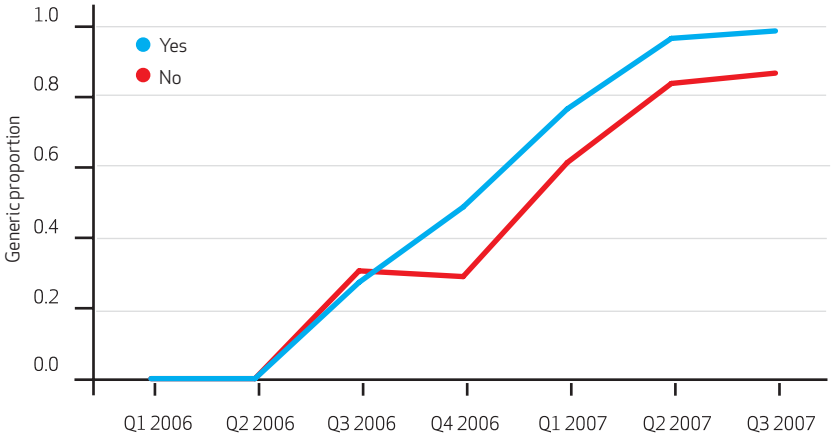
COST PER PRESCRIPTION We used actual Medicaid reimbursement levels to assess the cost per prescription of all prescriptions of brand-name Zocor and generic simvastatin filled by calendar quarter after patent expiration (Exhibit 5). In the first calendar quarter, states that did not require patient consent for generic substitution paid, on average, $15.35 less per prescription for the sum of Zocor and simvastatin than states that did require patient consent. In the second and third calendar quarters, states that did not require consent paid $16.10 and $18.19 less per prescription, respectively. These differences declined to $5.70 and $2.68 per prescription, respectively, in the fourth and fifth calendar quarters after Zocor's patent expiration (as generic substitution rates increased in all states), with costs per prescription remaining lower in states that did not require consent.

POTENTIAL SAVINGS TO MEDICAID We estimated the potential savings of adopting generic substitution laws that do not require patient consent in all of those states that did require patient consent during the study period. We multiplied the number of prescriptions for Zocor and simvastatin filled after patent expiration in states that required patient consent by the difference in cost of prescriptions in states that did and did not require consent in that calendar quarter.

We found that Medicaid programs nationally could have saved approximately $19.8 million—almost 12 percent of all expenditures for simvastatin—in the five calendar quarters after patent expiration if all states had adopted generic substitution policies that did not require patient consent.

EXHIBIT 3

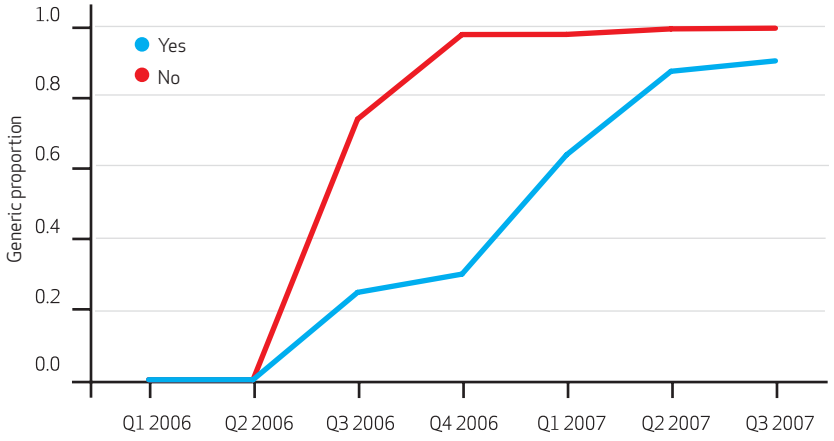
Relationships Between Legislation Requiring Mandatory Generic Substitution At The Pharmacy And Generic Fill Rates For Simvastatin, 2006 And 2007



SOURCE Centers for Medicare and Medicaid Services, aggregate Medicaid prescription medication use data. **NOTE** Yes/no indicates whether or not generic substitution is mandatory.

EXHIBIT 4

Relationships Between Legislation Requiring Patient Consent For Generic Substitution And Generic Fill Rates For Simvastatin, 2006 And 2007



SOURCE Centers for Medicare and Medicaid Services, aggregate Medicaid prescription medication use data. **NOTE** Yes/no indicates whether or not patient consent is required for generic substitution.

Discussion

In this study, we evaluated the relation between three state-level policies and generic substitution rates after the expiration of the patent for Zocor, one of the world's top-selling medications. We adjusted for two generic substitution policies that affect either the pharmacist's or the patient's ability to influence whether a generic medication is used to fill a prescription, and for prior authorization policies limiting the use of brand-name Zocor.

After doing so, we found that laws providing patients with greater discretion in determining generic drug substitution were most influential. Requiring patients to provide consent prior to generic substitution led to an approximately 25 percent reduction in rates of generic substitution, while the other policies we studied had no statistically significant effect in our adjusted model.

EFFECT OF PATIENT CONSENT It is not surprising that requiring patients to provide consent would limit generic substitution. Recent surveys indicate that most patients believe that generics are safe and effective, that generics offer greater value than brand-name medications, and that more Americans should use generics.[12] However, a majority of patients do not agree when asked if they, personally, prefer to use generics. Poor patients and less-educated patients—groups more likely to be covered by Medicaid—are least likely to express positive views of generics.[12,13]

It may be the most vulnerable patients, for whom cost is the greatest barrier, who refuse generic substitution when offered. This may explain why patients who live in poorer neighborhoods are less likely to use generic medications.[14] Such an attitude toward generics may adversely affect patients' adherence to essential medications.[15] Pharmacists probably are more comfortable with generics than patients are, which may explain why we found little effect of laws requiring mandatory generic substitution on the rate of filling generic prescriptions.[16] The minimal effect of prior authorization requirements on generic substitution was surprising; it suggests that generic substitution regulations are more potent stimulifor generic use upon patent expiration.

Although patient consent requirements were strongly associated with generic substitution of simvastatin, we found no relationship between any of the regulations studied here and rates of switching from Lipitor, which did not have a generic alternative, to other statins, such as simvastatin. Policy makers should be aware that these regulations may have the greatest effect on substitution for the same generic molecule, with little effect on switching among other molecules in the class.

Costs per prescription were much lower in states with generic substitution laws that did not require patient consent than in other states. However, the differences we observed may be attenuated by a number of factors.

VARIATIONS IN STATE MEDICAID PROGRAMS The spending reported in the aggregate Medicaid files reflect direct payments to pharmacies, set by each state Medicaid program as a portion of the average wholesale price plus a dispensing fee for that pharmacy. States vary in the level of

EXHIBIT 5

Average Cost Per Prescription Of All Zocor And Simvastatin Prescriptions Filled Per Calendar Quarter, 2006 And 2007

	Q2 2006	Q3 2006	Q4 2006	Q1 2007	Q2 2007	Q3 2007
In states requiring patient consent	$142.19	$138.80	$137.21	$88.92	$45.95	$35.72
In states not requiring patient consent	142.43	123.45	121.11	70.73	40.25	33.04
Difference	−0.24	15.35	16.10	18.19	5.70	2.68

SOURCE Authors' analysis of aggregate Medicaid prescription medication use data, Centers for Medicare and Medicaid Services. **NOTE** Simvastatin is the generic form of Zocor.

Prices per prescription are much lower in states that do not require patient consent for generic substitution than in other states.

the dispensing fee and the proportion of average wholesale price that is included in the retail price. States with more-lenient generic substitution laws may be more aggressive about setting lower prescription drug prices for brand-name medications than is the case in other states. They may also be more aggressive in negotiating rebates from manufacturers, which could reduce the potential savings we estimate from eliminating patient consent policies.

MARKET DYNAMICS In addition, for the first six months after generics came on the market, the simvastatin market was characterized by an oligopoly. Teva Pharmaceuticals and Ranbaxy Laboratories shared a period of generic market exclusivity, while Merck (which held the original patent) also introduced an "authorized" generic made through a contract with Dr. Reddy's Laboratories.[17] As a result, during this time, simvastatin prices fell only slightly. The first substantial simvastatin price reductions did not occur until the first quarter of 2007, when the oligopoly period ended and additional competitors entered the market.[18]

Nonetheless, prices per prescription are much lower in states that do not require patient consent for generic substitution than in other states. Laws requiring patient consent probably reflect an attempt to preserve patients' autonomy in making decisions about their medical care. Although this is an important priority, it is likely that such policy decisions are made in the abstract, without a sense of their opportunity costs.

POLICY IMPLICATIONS Our findings provide policy makers with insights into the anticipated costs of these regulations. If we simply multiply the proportion of drug costs for simvastatin saved in the year after the expiration of Zocor's patent in states that did not require consent by the annual spending for medications nearing patent expiration, we can roughly estimate the potential savings of implementing laws that eliminate patient consent requirements.

If the savings experienced by states that do not require patient consent were extended to states that currently do require it, we would expect savings of more than $100 million for state Medicaid programs for only three medications—Lipitor, Zyprexa, and Plavix—in the year after their respective patents expire. These projected savings would be just for Medicaid, which accounts for about 10 percent of total drug purchasing nationwide. Additional savings could be expected for private payers and for Medicare Part D plans. Policy makers will need to decide if they can justify not realizing these savings in order to provide patients with greater choice, in the context of current economic strains on the health care system.

STUDY LIMITATIONS Our study has a number of limitations. One is the Medicaid population we examined. Generic substitution rates in this population were lower than those seen in patients with private insurance.[6] Similar studies in a population with private insurance are needed before broader generalization is possible.

In addition, we evaluated generic substitution after the expiration of only a single medication's patent. Results should be confirmed for other medications. We also did not control for different copayment requirements in the states we studied. We could not fully control for all formulary coverage policies within states, or for the precise levels of prices and rebates worked out by each state.

We could not measure the intensity with which each state enforces its coverage preferences. We hoped to capture a proxy for formulary management by assessing prior authorization rules, which have been shown to influence drug use,[3] but additional policies may have been influential as well. However, it is unlikely that copayment requirements or other formulary procedures closely track with consent laws and not also with the other two laws studied here, mandatory substitution and prior authorization. We think it unlikely that our findings could be entirely attributable to unmeasured confounding.

CONCLUSION As states and other payers continue to experience the strain of reduced revenue to support health care expenses, those that require patient consent for generic substitution might consider changing their laws. Although it is generally appealing to give patients more choice in their medical care, a more restrictive approach to generic substitution may lead to cost savings without compromising quality. It may also provide opportunities to invest health care dollars more cost-effectively. ■

$100 million

Projected Savings

If states with patient consent policies would remove the need for patient consent for generic substitutions, Medicaid could save $100 million from just three drugs Lipitor, Zyprexa, and Plavix in the year after their patents expire.

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NOTES

1 Kesselheim AS, Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, et al. The clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta analysis. JAMA. 2008;300(21): 2514 26.

2 IMS Health. Top line industry data: 2007 U.S. sales and prescription in formation [Internet]. Norwalk (CT): IMS Health; 2009 [cited 2009 May 21]. Available from: http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=936d9df4609e9110VgnVCM10000071812ca2RCRD&vgnextfmt=default

3 Fischer MA, Schneeweiss S, Avorn J, Solomon DH. Medicaid prior authorization programs and the use of cyclooxygenase 2 inhibitors. N Engl J Med. 2004; 351(21):2187 94.

4 Goldberg T, DeVito CA, Smith D, Stano M, Vidis JS, Moore WE, et al. Evaluation of economic effects of drug product selection legislation. Med Care. 1979;17(4):411 9.

5 Carroll NV, Fincham JE, Cox FM. The effects of differences in state drug product selection laws on pharmacists' substitution behavior. Med Care. 1987;25(11):1069 77.

6 Aitken M, Berndt ER, Cutler DM. Prescription drug spending trends in the United States: looking beyond the turning point. Health Aff (Millwood). 2009;28(1):w151 60.

7 Andersson K, Bergström G, Petzold MG, Carlsten A. Impact of a generic substitution reform on patients' and society's expenditure for pharma ceuticals. Health Policy. 2007; 81(2 3):376 84.

8 Centers for Medicare and Medicaid Services. State drug utilization data [Internet]. Baltimore (MD): CMS; c2000 [cited 2009 May 22]. Avail able from: http://www.cms.hhs.gov/medicaid/drugs/drug5.asp

9 National Association of Boards of Pharmacy. Survey of pharmacy law [CD ROM]. Mount Prospect (IL): The Association; 2008.

10 Zeger SL, Liang KY. Longitudinal data analysis for discrete and con tinuous outcomes. Biometrics. 1986;42:121 30.

11 The Appendix can be accessed by clicking on the Appendix link in the box to the right of the article online.

12 Shrank WH, Cox E, Fischer MA, Mehta J, Choudhry NK. Patient perceptions of generic medications. Health Aff (Millwood). 2009;28(2): 546 56.

13 Iosifescu A, Halm EA, McGinn T, Siu AL, Federman AD. Beliefs about generic drugs among elderly adults in hospital based primary care practices. Patient Educ Couns. 2008;73(2):377 83.

14 Shrank WH, Stedman M, Ettner SL, DeLapp D, Dirstine J, Brookhart MA, et al.Patient, physician, phar macy, and pharmacy benefit design factors related to generic medication use. J Gen Intern Med. 2007;22(9): 1298 304.

15 Shrank WH, Hoang T, Ettner SL, Glassman PA, Nair K, DeLapp D, et al. The implications of choice: prescribing generic or preferred pharmaceuticals improves medica tion adherence for chronic condi tions. Arch Intern Med. 2006;166: 332 7.

16 Kirking DM, Gaither CA, Ascione FJ, Welage LS. Pharmacists' individual and organizational views on generic medications. J Am Pharm Assoc. 2001;41:723 8.

17 Glass G. Authorized generics. Nat Rev Drug Discov. 2005;4:952 4.

18 Bloomberg News. Regulators clear 6 more companies to sell generic Zo cor. New York Times. 2006 Dec 28.