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OFFICE OF INSPECTOR GENERAL

GENERIC DRUG UTILIZATION IN STATE MEDICAID PROGRAMS

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EXECUTIVE SUMMARY

OBJECTIVE

To determine the extent of generic drug utilization in State Medicaid programs during 2004.

BACKGROUND

Medicaid is a jointly funded Federal and State health insurance program for certain low income and medically needy persons. Prescription drug costs are one of the largest and fastest growing Medicaid expenditures, totaling more than $34 billion in fiscal year 2003.

Rising Medicaid costs have bolstered Federal support for using generic drugs to contain Medicaid prescription drug expenditures. A generic drug is chemically identical to its brand name counterpart, with the same therapeutic effect and the same risk-benefit profile. Generic drugs are, on average, 63 percent less expensive than brand name drugs.

The Centers for Medicare & Medicaid Services (CMS) has encouraged generic drug substitution (i.e., substituting a generic drug for its brand name equivalent) as a safe and effective way for States to increase generic drug utilization and reduce costs. Many States have implemented policies to encourage generic substitution in their State Medicaid programs.

Generic substitution is not possible when a provider prescribes a single source drug (i.e., a drug that has no generic equivalent). While single source drugs are the only available treatment for some conditions, other conditions are treatable with a number of drugs, some of which have generic equivalents and some of which do not. Some States and private insurers encourage health care providers to prescribe drugs with generic equivalents rather than single source drugs, which tend to be newer and more expensive.

The overall level of generic drug utilization is determined both by the frequency of generic substitution at the pharmacy counter and by physician prescribing patterns. Therefore, in addition to assessing overall generic drug utilization (i.e., the percentage of all prescriptions that were generics), this study calculated the following indicators that contributed to overall generic utilization:

1. Generic substitution rate: the percentage of all prescriptions for multisource drugs (i.e., drugs that have a generic substitute) that were dispensed as generics.
2. Single source prescribing rate: the percentage of all prescriptions that were written for single source drugs (i.e., drugs that have no generic version).

FINDINGS

On average, generics were dispensed 89 percent of the time when generic substitutes were available. The "generic substitution rate" measures how often generics are dispensed when generic substitutes are available. Across all States, both the median and the average generic substitution rates were 89 percent. Twenty-three States had generic substitution rates at or above 90 percent. This compares favorably with a 90 percent private sector benchmark.

Overall, generic substitution rates were similar across States. However, States showed substantial variation in their generic substitution rates within certain therapeutic classes (i.e., groups of drugs that treat the same medical condition). For example, the generic substitution rate for anticoagulant drugs (blood thinners) ranged from 27 percent in one State to 100 percent in another.

On average, 41 percent of prescriptions were written for drugs that have no generic substitutes. Single source drugs have no generic substitutes. Therefore, the proportion of prescriptions that are written for them (i.e., the single source prescribing rate) limits States' opportunities for generic drug utilization.

On average, single source drugs comprised 41 percent of all prescriptions filled. Thus, for this 41 percent of prescriptions, there was no opportunity to dispense a generic drug. Across State Medicaid programs, the single source prescribing rate ranged from 34 percent to 50 percent.

On average, 54 percent of all drugs dispensed were generics. The "generic utilization rate" is the percentage of all prescriptions dispensed that were generics. Across all States, both the median and the average generic utilization rates were 54 percent. By State, generic utilization rates varied from 44 percent to 61 percent. To place these rates in context, trade publications report 2004 generic utilization rates of approximately 48 percent to 52 percent for many private pharmacy benefit organizations and health plans.

Variation in generic utilization was primarily explained by variation in single source prescribing. Generic drug utilization is affected both by generic drug substitution and by physician prescribing patterns. However, because generic substitution was both high and consistent across States, single source prescribing was the primary explanation for differences in generic drug utilization overall. Generic utilization was highest in States where single source prescribing was lowest.

CONCLUSION

We found that overall, State Medicaid programs demonstrated high generic drug utilization in 2004. On average, 54 percent of all prescriptions dispensed were generics, a figure that compares favorably to rates reported in the private sector.

On average, generics were dispensed 89 percent of the time when generic substitutes were available. The high levels of generic substitution that we found for many Medicaid programs suggest that many States may have already achieved most of the growth in generic utilization possible through increasing generic substitution. However, certain therapeutic classes show substantial variation in States' generic substitution rates, and thus, greater potential for gains in States with lower rates in these classes.

To achieve significant increases in generic drug utilization, it is important to recognize that single source drug prescribing caps the level of generic drug utilization that a State Medicaid program can attain. States may realize greater gains by encouraging the prescribing of multisource drugs, which have generic equivalents, through counter-detailing, step therapy requirements, or other means. However, such efforts must be undertaken with caution to ensure that patients maintain access to appropriate treatment.

In light of these findings, we suggest that CMS consider the following:

- For States seeking to further increase generic substitution, CMS could assist States in identifying and targeting their efforts to promote generics in therapeutic classes wherein their State rate is substantially lower than other States and opportunities for gains are greatest.
- For States seeking more substantial gains in generic utilization, CMS could offer information and technical assistance in shifting utilization from single source to multisource drugs in a clinically

responsible manner. In particular, CMS has developed expertise in the therapeutic interchangeability of drugs through Medicare's oversight of Part D formularies. Such expertise would be a valuable resource for States that desire assistance in developing policies to influence prescribing patterns while ensuring that beneficiaries maintain access to appropriate treatment.

AGENCY COMMENTS

In its comments, CMS indicated that it strongly encourages the dispensing of generic drugs. As OIG noted in our report, drug manufacturer rebates may occasionally provide States with better prices on some brand name drugs than on generics. CMS suggested that this could account for lower generic utilization rates for certain therapeutic classes in some States. In response to our suggestions, CMS stated that it will share this report with States and encourage State Medicaid agencies to review their generic drug use by therapeutic class. Finally, CMS indicated its willingness to share its expertise on therapeutic interchangeability with States but noted that States also have other qualified sources of this information.

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INTRODUCTION

OBJECTIVE

To determine the extent of generic drug utilization in State Medicaid programs during 2004.

BACKGROUND

Medicaid Prescription Drug Coverage

Medicaid is a jointly funded Federal and State health insurance program for certain low-income and medically needy persons. Individual States establish eligibility requirements, benefit packages, and payment rates for their Medicaid programs under broad Federal standards administered by the Centers for Medicare & Medicaid Services (CMS). Medicaid requires that States provide basic services to beneficiaries to receive Federal matching funds. States may also receive Federal funding if they provide other optional services.

All State Medicaid programs have elected to include prescription drug coverage. States are constrained by Federal law and regulation from implementing certain drug cost containment tools that are available to private health plans. Most significantly, Medicaid must cover all drugs, brand and generic, whose manufacturers have entered into Medicaid Rebate Agreements (with a few specific exceptions).[1]

Medicaid Prescription Drug Expenditures

Prescription drug coverage is one of the largest and fastest growing Medicaid expenditures. In fiscal year 2003, Medicaid spent more than $34 billion on prescription drugs.[2] Medicaid prescription drug costs doubled between 1998 and 2002, rising from less than 8 percent to over 11 percent of the total Medicaid budget.[3] From 2000 to 2002 alone, prescription drug expenditures in fee-for-service Medicaid programs grew faster than expenditures in any other Medicaid service category, averaging an 18.8 percent increase per year.[4] As a result of rising costs, States currently devote over one-fifth of their budgets to Medicaid spending.[5]

Approximately 6 million beneficiaries are eligible for both Medicaid and Medicare (dual eligibles).[6] This population represents about 15 percent of all Medicaid beneficiaries.[7] On January 1, 2006, prescription drug coverage for these beneficiaries transferred from Medicaid to Medicare.[8] This shift may affect Medicaid drug utilization patterns and

expenditures, given dual eligibles' extensive utilization of prescription drugs. However, Medicaid will continue to be responsible for 45 million nondually eligible beneficiaries.

Generic Drugs

A generic drug is chemically identical to its brand name counterpart, with the same therapeutic effect and the same risk-benefit profile. To be approved by the Food and Drug Administration (FDA), a generic drug must contain the same amount(s) of the same active ingredient(s) as the brand name product.[9] (For a detailed definition of this and other key terms, please see Appendix A.) The generic drug must also be the same strength, be available in the same dosage, have the same route of administration, and have essentially the same labeling as the brand name drug. Generic drug manufacturing and packaging facilities are held to the same safety and quality standards as those of brand name drugs.

Potential Savings from Increasing Generic Drug Utilization

Generic drugs are much less expensive than brand name drugs. In 2003, the average brand name prescription cost $83.66, while the average generic prescription cost $30.58, a 63 percent difference.[10]

Rising Medicaid costs have bolstered Federal support for using generic drugs to contain Medicaid prescription drug expenditures.[11] During congressional hearings on Medicaid prescription drug reimbursement held in December 2004, the Chairman of the Committee on Energy and Commerce stated that ". . . generic drugs have a critical role to play in containing soaring drug costs."[12] Congress has also indicated its interest in using generic drugs to control costs; the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 includes provisions to promote generics in the new Medicare prescription drug benefit.

Pursuant to Federal law and regulation, States retain some flexibility in containing Medicaid drug costs through encouraging a shift from brand name to generic drug utilization. States can achieve this shift by encouraging pharmacies to dispense generics when possible and by encouraging doctors to prescribe multisource drugs (i.e., drugs with generic equivalents) when clinically indicated.

Forty-one State Medicaid programs have "mandatory generic substitution" policies, which require that generic drugs be dispensed whenever a generic version of the drug is available.[13] However, many States allow physicians to override mandatory generic substitution by

indicating "Dispense as Written" and/or "Brand Medically Necessary" on the prescription. A few States require physicians or pharmacists to take additional steps to override the substitution, such as obtaining prior authorization from the Medicaid program and/or citing a specific medical necessity for the brand (such as allergy to an inactive ingredient in the generic) before the brand name drug can be dispensed.

Some State Medicaid programs have taken other measures to encourage generic drug utilization. These include placing generics on the preferred drug list, setting higher copayments for brand name drugs, paying higher pharmacy dispensing fees for generic drugs, requiring beneficiaries to try a generic drug for their condition before covering a brand name drug ("step therapy"), and educating health care providers about use of generic drugs ("counter-detailing").[14]

Generic Drug Substitution

"Generic substitution" means dispensing a generic drug instead of its brand name equivalent. Generic substitution is only possible when a health care provider prescribes a multisource drug (i.e., a drug with a generic equivalent). Generic substitution occurs when a physician prescribes the generic version of a multisource drug rather than its brand name equivalent, or when a pharmacist is presented with a prescription for a multisource brand name drug and dispenses the generic version instead.[15]

Theoretically, States should be able to achieve high generic substitution rates, because generic drugs are chemically and therapeutically equivalent to their brand name counterparts. There are situations in which generic substitution is not possible, but these circumstances are rare. For example, a small percentage of patients may medically require the brand name version of a drug if they are allergic to an inactive ingredient such as a dye or binder found in the generic version. Additionally, disruptions in the supply chain may mean that a pharmacy occasionally does not have the generic version of a drug in stock and must dispense the brand name.[16] Despite these potential barriers, generic substitution rates above 90 percent have been reported by private health plans.[17]

Generic substitution is an attractive option for cost containment, because it can save money without adversely affecting beneficiaries' health. CMS encourages generic substitution as a safe and effective strategy by which States may lower Medicaid drug costs, noting the 90 percent substitution rates achieved in some private health plans.[18]

While generic substitution generally achieves savings, it may not save money in all circumstances. Medicaid's net drug payments are based on reimbursement to pharmacies, minus rebates from drug manufacturers. Shifting from brand name to generic drugs will almost always lower Medicaid reimbursements because generic drugs are generally much less expensive than brand name drugs. However, States usually receive higher Medicaid rebates for brand name drugs than for generic drugs. 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.

Single Source Drug Prescribing

The rate at which single source drugs (i.e., drugs with no generic equivalents) are prescribed in a State depends on a number of factors. These include prescriber habits, patient demand for newer or highly advertised drugs, and therapeutic advances associated with newer drugs. For some conditions, single source drugs are the only available treatment. However, other conditions are treatable with a number of different drugs, some of which have generic equivalents and some of which do not. For some patients, only one prescription drug option is appropriate, but for other patients, a variety of drugs may work equally well. In those instances, some States and private insurers encourage health care providers to prescribe drugs with generic equivalents rather than single source drugs, which tend to be newer and more expensive.

SCOPE AND METHODOLOGY

Scope

This study focused on analyzing States' patterns of generic drug utilization rather than describing States' policies. Detailed information on State Medicaid policies, including policies that encourage generic utilization, is available from multiple sources. Further, we did not test for evidence of causal links between State policies and patterns of generic drug utilization. Generic drug utilization is influenced by numerous factors in addition to State Medicaid policies, and we had no means of controlling for those factors to identify the effects of the policies themselves.

Instead, by calculating indicators of generic utilization and benchmarking States against one another, this study explored the potential avenues for increasing generic drug utilization. We did not make any clinical assessments as to what rates of generic substitution,

single source drug prescribing, or overall generic utilization are desirable or appropriate.

Methodology

In this study, we analyzed the population of national drug codes (NDC) for drugs purchased by State Medicaid programs through fee-for-service in 2004. To do so, we used utilization data from the Medicaid Drug Rebate (MDR) program and drug product data from First DataBank. The MDR data do not include utilization for drugs purchased by managed care organizations or pharmacy benefit managers under contract with State Medicaid agencies. The data also do not include utilization for drugs purchased from entities that receive the 340B discount.[19] Drug utilization data were not available for the State of Arizona because it did not participate in the MDR program.

Because the populations that use prescription drugs most heavily, as well as pharmacy benefits as a whole, are frequently excluded from Medicaid managed care, the fee-for-service population accounts for the majority of Medicaid prescriptions.[20]

Measuring Generic Utilization

For each State (including the District of Columbia, herein referred to as a State), we calculated the overall rate of generic drug utilization by dividing the total number of generic drug prescriptions by the total of all prescriptions. We also calculated the following two indicators that contribute to overall utilization:

1. Generic substitution rate: we divided the number of generic drug prescriptions by the total of all multisource prescriptions (both generic and multisource brand). We considered a drug substitutable if it has an FDA A-rated generic equivalent available.[21]
2. Single source prescribing rate: we divided the total of all single source prescriptions by the total of all prescriptions.

To determine whether the shift of dual eligibles from Medicaid to Medicare drug coverage will likely affect Medicaid generic utilization patterns, we repeated our calculation of the generic substitution rate, single source prescribing rate, and generic utilization rate with dual eligibles excluded from the analysis. We estimated the proportion of prescriptions for each NDC that were dispensed to dual eligibles using 2003 Medicaid Statistical Information System data (the most recent available). See Appendix C for our analysis of the impact on Medicaid

generic drug utilization of the dually eligible population's shift to Medicare.

Comparing Patterns of Generic Utilization

To compare generic drug utilization among State Medicaid programs, we calculated the mean, median, standard deviation, and range for each indicator.

Standards

This study was conducted in accordance with "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

FINDINGS

On average, generics were dispensed 89 percent of the time when generic substitutes were available

The "generic substitution rate" measures how often generics are dispensed when generic substitutes are available. CMS has encouraged State Medicaid programs to increase generic substitution, noting that some private health plans have achieved rates of over 90 percent.[22]

Overall, Medicaid was close to achieving this private sector benchmark in 2004. Across all States, both the median and the average generic substitution rates were 89 percent. Twenty-three States had generic substitution rates at or above 90 percent. Appendix B displays the generic substitution rate for each State Medicaid program.

We found no evidence that generic substitution will change substantially due to the 2006 transfer of dual eligibles from Medicaid to Medicare drug coverage. Excluding dual eligibles from the analysis produced an average generic substitution rate of 88 percent for nondual eligibles, just 1 percentage point lower than the overall average. Appendix C provides additional analysis of the impact on Medicaid generic drug utilization of the dually eligible population's shift to Medicare.

Generally, generic substitution rates were similar across States

Across States, Medicaid programs did not demonstrate substantial variation in their levels of generic substitution. The lowest State rate was 83 percent, 9 percentage points below the highest State rate of 92 percent. However, the majority of States were clustered tightly around the median substitution rate of 89 percent. For example, substitution rates for the middle 80 percent of States all fell within a 4 point range, from 87 percent to 91 percent.

However, States' generic substitution rates varied within certain therapeutic classes of drugs

Within certain therapeutic classes (i.e., groups of drugs that treat the same medical condition), some State Medicaid programs achieved substantially higher generic substitution rates than others. For example, the generic substitution rate for anticoagulant drugs (blood thinners) ranged from 27 percent in one State to 100 percent in another. For other therapeutic classes, States demonstrated greater consistency in their generic substitution rates. For example, generic substitution rates for narcotic analgesics (pain relievers) ranged from 95 percent to 100 percent across the States. Table 1 presents the minimum and maximum generic substitution rates across States for selected

therapeutic classes, as well as the total 2004 Medicaid reimbursement for multisource drugs in each class to provide an overview of fiscal significance.

Table 1: Substitution Rates and Reimbursement Across State Medicaid Programs for Selected Therapeutic Classes in 2004

Therapeutic Class	Minimum	Maximum	Percentage Point Difference	Medicaid Reimbursement*
Narcotic analgesics	95%	100%	5	$712,000,000
Psychostimulants-Antidepressants	61%	89%	28	$616,000,000
Anticonvulsants	80%	99%	19	$570,000,000
Diabetic therapy	63%	91%	28	$396,000,000
Antiulcer/gastrointestinal preparations	69%	99%	30	$302,000,000
Antiarthritics	86%	100%	14	$264,000,000
Anticoagulants	27%	100%	73	$187,000,000
Bronchial dilators	31%	78%	47	$154,000,000
Antinauseants	93%	100%	7	$130,000,000
Systemic contraceptives	4%	79%	75	$98,000,000

*Rounded to the nearest million. Includes reimbursement only for multisource drugs in each therapeutic class.

Source: Office of Inspector General analysis of 2004 State Medicaid drug utilization data, 2006.

On average, 41 percent of prescriptions were written for drugs that have no generic substitutes

Single source drugs have no generic substitutes. When a single source drug is prescribed, a generic drug cannot be dispensed. Therefore, the proportion of prescriptions that are written for single source drugs (i.e., the single source prescribing rate) limits States' opportunities to utilize generic drugs.

On average, single source drugs comprised 41 percent of all prescriptions filled. Thus, for this 41 percent of prescriptions, there was no opportunity to dispense a generic drug.

Levels of single source drug prescribing varied across States

Across State Medicaid programs, the single source prescribing rate ranged from a high of 50 percent (New Jersey) to a low of 34 percent (Washington and Hawaii). Consequently, there were substantially fewer opportunities to dispense generic drugs in some States than in others. Many factors may affect single source drug prescribing, including patient mix, prescriber habits, advances in certain drug treatments, and patient demand for newer or highly advertised drugs. Appendix B provides the single source prescribing rate for each State.

On average, 54 percent of all drugs dispensed were generics

The "generic utilization rate" is the percentage of all prescriptions dispensed that were generics. Across all States, both the median and the average generic utilization rates were 54 percent. To place these numbers in context, trade publications report 2004 generic utilization rates of approximately 48 percent to 52 percent for many private pharmacy benefit organizations and health plans.[23]

State Medicaid programs varied in their generic utilization. The highest State rate (61 percent) was 17 percentage points higher than the lowest State rate (44 percent). In four States, 60 percent or more of all drugs dispensed were generics. By comparison, in eight States less than half of all drugs dispensed were generics. Appendix B provides the generic utilization rate for each State.

Variation in generic utilization was primarily explained by variation in single source drug prescribing

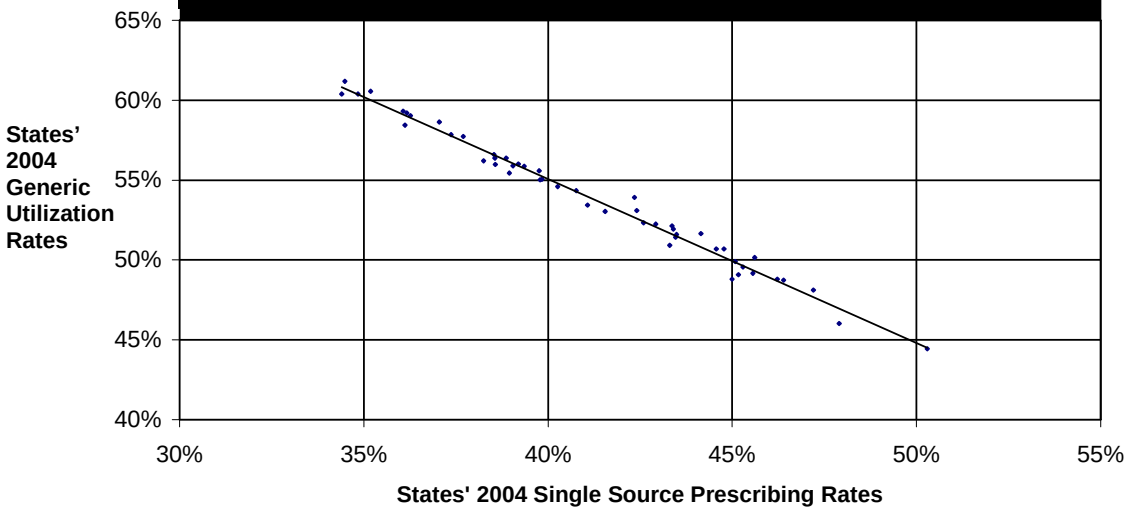
Generic drug utilization is affected both by generic drug substitution and by physician prescribing patterns. However, because there was little variation in generic substitution, it did not play a major role in explaining differences between States in overall utilization. For example, 17 States had generic substitution rates of 90 percent. However, generic utilization in those States ranged from 48 percent to 61 percent.

In contrast, the relationship between generic utilization and single source prescribing was strong. Generic utilization was highest in States where single source prescribing was lowest. For example, of all 50 States reviewed, Washington had the highest generic utilization (State rate was 61 percent) and the lowest single source prescribing (34 percent). Conversely, New Jersey had both the lowest generic

utilization (State rate was 44 percent) and the highest single source prescribing (50 percent).

Chart 1 displays 2004 generic utilization and single source prescribing data from the 50 States.

Chart 1: State Medicaid Programs' Generic Utilization Rates vs. Single Source Drug Prescribing Rates in 2004



CONCLUSION

We found that, overall, State Medicaid programs demonstrated high generic drug utilization in 2004. On average, 54 percent of all prescriptions filled were generics. To place this rate in context, trade publications report 2004 generic utilization rates of 48 percent to 52 percent for many private pharmacy benefit organizations and health plans.[24]

On average, generics were dispensed 89 percent of the time when generic substitutes were available. Twenty-three States had generic substitution rates at or above 90 percent, comparing favorably with the 90 percent private sector benchmark noted by CMS. The high levels of generic substitution that we found for many Medicaid programs suggest that many States may have already achieved most of the growth in generic utilization possible through increasing generic substitution. Still, some States, particularly those with substitution rates below the median, may wish to consider taking additional measures to increase generic substitution. Certain therapeutic classes show substantial variation in States' generic substitution rates, and thus, greater potential for gains in States with lower rates in those classes.

To achieve significant increases in generic drug utilization, it is important to recognize that single source drug prescribing caps the level of generic drug utilization a State Medicaid program can attain. States may realize greater gains by encouraging the prescribing of multisource drugs, which have generic equivalents, through counter-detailing, step therapy requirements, or other means. However, such efforts must be undertaken with caution to ensure that patients maintain access to appropriate treatment.

In light of these findings, we suggest that CMS consider the following:

- For States seeking to further increase generic substitution, CMS could assist States in identifying and targeting their efforts to promote generics in therapeutic classes wherein their State rate is substantially lower than other States and opportunities for gains are greatest.
- For States seeking more substantial gains in generic utilization, CMS could offer information and technical assistance in shifting utilization from single source to multisource drugs in a clinically responsible manner. In particular, CMS has developed expertise in the therapeutic interchangeability of drugs through Medicare's oversight of Part D formularies. Such expertise would be a valuable resource for States that desire assistance in developing policies to influence prescribing patterns.

AGENCY COMMENTS

In its comments, CMS indicated that it strongly encourages the dispensing of generic drugs. As OIG noted in our report, drug manufacturer rebates may occasionally provide States with better prices on some brand name drugs than on generics. CMS suggested that this could account for lower generic utilization rates for certain therapeutic classes in some States. In response to our suggestions, CMS stated that it will share this report with States and encourage State Medicaid agencies to review their generic drug use by therapeutic class. Finally, CMS indicated its willingness to share its expertise on therapeutic interchangeability with States but noted that States also have other qualified sources of this information.

The full text of CMS's comments is included in Appendix D.

ENDNOTES

[1] These exceptions include: agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs; barbiturates; and benzodiazepines. 42 U.S.C. § 1396r-8(d)(2).

[2] Testimony of Dennis Smith, Director, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, before the House Energy and Commerce Subcommittee on Oversight and Investigations, December 7, 2004. Available online at new.cms.hhs.gov/apps/media/press/testimony.asp?Counter=1278. Accessed January 18, 2006.

[3] Bruen, Brian and Ghosh, Arunabh. Kaiser Commission on Medicaid and the Uninsured. "Medicaid Prescription Drug Spending and Use," page 3. June 2004.

[4] Ibid.

[5] National Governor's Association and National Association of State Budget Officers. "Fiscal Survey of States," page 3. June 2005.

[6] Centers for Medicare & Medicaid Services. "A Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Drug Coverage." May 2, 2005. Available online at www.cms.hhs.gov/medicarereform/strategyforduals.pdf.

[7] Centers for Medicare & Medicaid Services. "2003 CMS Statistics." Available online at www.cms.hhs.gov/researchers/pubs/03cmsstats.pdf.

[8] Centers for Medicare & Medicaid Services. "A Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Drug Coverage." May 2, 2005. Available online at www.cms.hhs.gov/medicarereform/strategyforduals.pdf.

[9] Food and Drug Administration. "What are Generic Drugs?" Available online at www.fda.gov/cder/ogd/#Introduction. Accessed January 18, 2006.

[10] National Association of Chain Drug Stores. "Issue Brief: Retail Prescription Prices for Generic Drugs." October 2004. Available at www.nacds.org/user-assets/pdfs/gov_affairs/issuebriefs/.

[11] For example: Centers for Medicare & Medicaid Services. "Safe and Effective Approaches to Lowering Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs." September 9, 2004. Also, "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much, 2004": Hearing Before the Subcommittee on Oversight and Investigations of the Senate Committee on Energy and Commerce, 108th Congress, 2nd Session.

[12] "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much, 2004": Hearing Before the Subcommittee on Oversight and Investigations of the Senate Committee on Energy and Commerce, 108th Congress, 2nd Session.

[13] National Pharmaceutical Council. Pharmaceutical Benefits Under State Medical Assistance Programs, 2003.

[14] National Pharmaceutical Council. Pharmaceutical Benefits Under State Medical Assistance Programs, 2003.

Crowley, Jeffrey; Ashner, Deb; Elam, Linda. Kaiser Commission on Medicaid and the Uninsured. Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003. December 2003. Page iv.

Centers for Medicare & Medicaid Services. Medicaid Prescription Reimbursement by State – Quarter Ending March 2005. Available online at www.cms.gov/meidcaid/drugs/pre0305.pdf. Accessed August 22, 2005.

[15] In some States, pharmacists must inform and/or obtain the consumer's permission to make this substitution. Additionally, such substitution at the pharmacy counter may be requested by the consumer

in order to save money on copays, coinsurance, or out-of-pocket drug costs.

[16] Food and Drug Administration. "Drug Shortages." Available online at www.fda.gov/cder/drug/shortages. Accessed August 18, 2005.

[17] Centers for Medicare & Medicaid Services. "Safe and Effective Approaches to Lowering Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs." September 9, 2004.

[18] Ibid.

[19] The 340B Drug Discount Program is a Federal discount program that requires pharmaceutical manufacturers to lower outpatient drug prices for qualified Federal grantees including Community Health Centers and Disproportionate Share Hospitals.

[20] Centers for Medicare & Medicaid Services. Statistical Compendium: Medicaid Pharmacy Benefit Use and Reimbursement in 1999. Exhibit 3.

[21] Generic drugs that receive an A rating have been found by FDA to be pharmaceutically and therapeutically equivalent to the brand name product. All A-rated products either have no known or suspected bioequivalence problems (codes AA, AN, AO, AP, and AT), or any suspected bioequivalence problems have been resolved with *in vivo* or *in vitro* evidence (code AB).

Food and Drug Administration, The Orange Book, page xii. Available online at www.fda.gov/cder/orange/obannual.pdf. Accessed February 9, 2006.

[22] Centers for Medicare & Medicaid Services. "Safe and Effective Approaches to Lowering Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs." September 9, 2004.

[23] Managed Care Week. "Some Insurers Say Pharmacy Costs Could Help Drive Medical Cost Growth in 2004." May 24, 2004. Available online at www.aishealth.com/ManagedCare/GenBus/MCWSomeInsure.html.

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[24] Ibid.

KEY TERMS

Single source drug: A brand name drug with no generic equivalent.

Multisource brand drug: A brand name drug with at least one generic equivalent. Medicaid's technical term for these drugs is "innovator multiple-source" drugs.

Generic drug: A drug that is a chemical copy of a brand name drug. Medicaid's technical term for these drugs is "non-innovator multiple-source" drugs. All generic drugs are considered multisource drugs, since a brand version was available first.

Generic utilization rate: The percentage of all prescriptions filled that were generics.

Generic substitution: Substituting a generic drug for its brand name equivalent.

Generic substitution rate: The percentage of prescriptions for all multisource drugs (both multisource brand and generic) that are dispensed as generics. This indicator measures how often a generic is dispensed when a generic version of the prescribed drug exists. It is sometimes referred to as the generic "penetration" or "efficiency" rate.

Single source drug prescribing rate: The percentage of all prescriptions that are written for single source drugs. This indicator measures how often providers write a prescription for a drug that has no generic equivalent.

Therapeutic substitution: Substituting one drug for another that is chemically different but treats the same medical condition.

Active ingredient: A substance in a drug that gives the drug its pharmaceutical effect. A multisource brand name drug and its generic equivalent(s) share the same active ingredient.

Inactive ingredient: A substance in a drug that does not impact its pharmaceutical effect, such as dyes or fillers. A multisource brand name drug and its generic equivalent(s) may have different inactive ingredients.

Therapeutic class: A group of drugs that treat the same medical condition.

National drug code (NDC): A unique numeric identifier for each drug that includes information about the manufacturer, strength, dosage, and package size.

Step therapy: A cost control mechanism that requires patients to try a less expensive (often generic) drug for their condition before a more expensive (often brand name) drug will be covered.

Counter-detailing: Educational outreach to health care providers.

GENERIC DRUG UTILIZATION INDICATORS BY STATE

Table 2 presents the following rates for each State Medicaid program.

- Generic substitution rate: the percentage of all prescriptions for drugs with generic equivalents that were dispensed as generics.
- Single source prescribing rate: the percentage of all prescriptions that were for single source drugs, which have no generic equivalent.
- Generic utilization rate: the percentage of all prescriptions filled that were generics.

Table 2: Generic Drug Utilization in State Medicaid Programs, 2004

State	Generic Substitution Rate	Single Source Prescribing Rate	Generic Utilization Rate
Alabama	90%	35%	61%
Alaska	85%	48%	46%
Arkansas	88%	44%	52%
California	83%	46%	50%
Colorado	89%	40%	55%
Connecticut	90%	46%	49%
Delaware	89%	46%	49%
District of Columbia	91%	44%	52%
Florida	92%	45%	51%
Georgia	89%	43%	52%
Hawaii	92%	34%	60%
Idaho	89%	46%	49%
Illinois	89%	36%	59%
Indiana	90%	36%	59%
Iowa	89%	39%	57%
Kansas	90%	42%	53%
Kentucky	90%	37%	59%
Louisiana	89%	43%	52%
Maine	84%	42%	53%
Maryland	90%	47%	48%
Massachusetts	90%	38%	58%
Michigan	90%	40%	55%
Minnesota	91%	39%	56%
Mississippi	90%	43%	52%
Missouri	90%	38%	56%

Source: Office of Inspector General analysis of 2004 State Medicaid drug utilization data, 2006.

Generic Drug Utilization in State Medicaid Programs, 2004 *Continued*

State	Generic Substitution Rate	Single Source Prescribing Rate	Generic Utilization Rate
Montana	88%	40%	56%
Nebraska	89%	36%	59%
New Hampshire	88%	39%	56%
New Jersey	89%	50%	44%
New Mexico	86%	36%	58%
New York	87%	45%	50%
Nevada	90%	41%	54%
North Carolina	88%	45%	49%
North Dakota	88%	41%	53%
Ohio	87%	42%	54%
Oklahoma	90%	37%	58%
Oregon	90%	35%	60%
Pennsylvania	88%	43%	51%
Rhode Island	91%	43%	52%
South Carolina	89%	45%	49%
South Dakota	88%	45%	50%
Tennessee	90%	39%	56%
Texas	90%	40%	55%
Utah	89%	39%	56%
Vermont	91%	43%	51%
Virginia	88%	39%	56%
Washington	90%	34%	61%
West Virginia	89%	39%	55%
Wisconsin	90%	39%	56%
Wyoming	87%	45%	51%

Source: Office of Inspector General analysis of 2004 State Medicaid drug utilization data, 2006.

ANALYSIS OF THE IMPACT ON MEDICAID GENERIC DRUG UTILIZATION OF DUAL ELIGIBLES' 2006 SHIFT TO MEDICARE

In 2006, dual eligibles began receiving prescription drug coverage through Medicare. Dual eligibles made up approximately 15 percent of Medicaid beneficiaries in 2004, and their transfer from Medicaid to Medicare will affect Medicaid's overall prescription drug expenditures. However, excluding dual eligibles from our analysis made little difference in patterns of generic drug utilization. Table 3 displays 2004 average generic substitution, single source prescribing, and generic utilization rates for all Medicaid beneficiaries and for nondually eligible beneficiaries.

Table 3: 2004 Indicators of Generic Drug Utilization: All Medicaid Beneficiaries vs. Nondually Eligible Beneficiaries

	Generic Substitution Rate	Single Source Prescribing Rate	Generic Utilization Rate
All Medicaid Beneficiaries	89%	41%	54%
Nondually Eligible Beneficiaries	88%	43%	53%
Percentage Point Difference	(-1)	+2	(-1)

Source: Office of Inspector General analysis of 2004 State Medicaid drug utilization data, 2006.

AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

MAY 24 2006

200 Independence Avenue SW
Washington, DC 20201

TO: Daniel R. Levinson
Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Generic Drug Utilization in State Medicaid Programs" (OEI-05-05-00360)

Thank you for the opportunity to review and comment on the above OIG Draft Report. This OIG report assesses the extent to which State Medicaid programs use generic drugs. The Centers for Medicare & Medicaid Services (CMS) strongly encourages the dispensing of generic drugs. We are pleased that State Medicaid agencies have a high rate of generic dispensing and we hope that States will review the results of this report to identify yet more opportunities to further raise their generic dispensing rates.

The report found that, on average, 89 percent of prescriptions were filled with a generic drug when a generic product was available. Fifty-four percent of all prescriptions were filled with a generic. The difference between percentages in generic substitution and overall generic usage occurs because 41 percent of prescriptions were written for drugs that do not have a generic substitute. The report notes that the high use of generic drugs in many States leaves little room for improvement.

The report also notes that States vary in their use of generic drugs by therapeutic classes. In some instances this difference is substantial. In light of this finding, the report suggests that CMS assist States to identify and target these differences in order to increase the use of generic drugs. The report further suggests that CMS share with States its expertise on therapeutic interchangeability gained through the oversight of formularies of Medicare Part D Prescription Drug Plans.

As the report notes, CMS strongly encourages States to maximize the use of generic drugs. We will share this report with States and encourage them to review their generic drug use by therapeutic class. While we would be happy to share CMS' expertise on therapeutic interchangeability, we note that States have pharmaceutical and therapeutics committees that should be equally qualified to make these determinations.

Finally, we want to point out that, on occasion, States achieve better prices on brand name drugs than on generic drugs through aggressive rebates offered by some drug manufacturers. While we understand that OIG's analysis did not address State policies or rebates obtained, this fact could account for the lower use of generic drugs in some States for certain therapeutic classes of drugs and lower overall rates of generic use.

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