Memorandum

Date: JUL 7 1994

From: June Gibbs Brown
Inspector General

Subject: Medicaid Program Savings Through the Use of Therapeutically Equivalent Generic Drugs (A-06-93-00008)

To: Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached are two copies of our final report on our review of the potential extended use of generic outpatient prescription drugs in the Medicaid program. The purpose of our review was to study: (1) efforts taken by State Medicaid programs and selected private and public health benefit programs to encourage the use of less costly generic prescription drug products and (2) the financial impact of changing Federal regulations to limit reimbursement of brand name drugs to the amounts set by the Health Care Financing Administration (HCFA) for equivalent generic drugs.

We found that 11 State Medicaid programs have policies in place that promote the use of generic drugs beyond the current Federal requirements. We also found that use of generic drugs was being promoted by other programs that provide health benefits. Some programs require generic substitution when generic drugs are available, while others use financial incentives as part of their reimbursement policy.

We calculated that the annual cost savings to the Medicaid program could be as much as $46 million for only 37 high volume dispensed brand name drugs, if the reimbursement for those drugs is limited to the amounts set by HCFA for equivalent generic drugs. The cost savings will become even greater in the future as the Federal patents on exclusive drug manufacturing of 60 important highly used drugs with more than $10 billion in sales will expire between now and 1995. Therefore, we are recommending that HCFA identify and alert States to methods which would encourage the use of lower priced generic drug products in the Medicaid program.

In response to our draft report, HCFA stated that our report effectively described "best practices" and agreed to share our report with all State agencies. However, HCFA expressed concerns regarding our recommendation that they seek legislative authority to require States to adopt policies to encourage generic drug substitution or to limit Federal financial participation to amounts based on generic drug prices rather than brand name drug prices.
We considered HCFA's concerns and revised this recommendation. And, we are also recommending that HCFA: (1) take a more active role to encourage States to use generic drugs and provide stronger incentives for States to adopt policies that encourage use of generic drugs; and (2) monitor the States' efforts to encourage the use of lower priced generic drugs and formally assess those activities.

Please advise us within the next 60 days on actions taken or planned on our recommendations. If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 966-7104. Copies of this report are being sent to other interested Department officials.

To facilitate identification, please refer to Common Identification Number A-06-93-00008 in all correspondence relating to this report.

Attachments
MEDICAID PROGRAM SAVINGS THROUGH THE USE OF THERAPEUTICALLY EQUIVALENT GENERIC DRUGS
This report provides you with the results of our review of the potential extended use of generic outpatient prescription drugs in the Medicaid program. The purpose of our review was to study: (1) efforts taken by State Medicaid programs and selected private and public health benefit programs to encourage the use of less costly generic prescription drug products and (2) the financial impact of changing Federal regulations to limit reimbursement of brand name drugs to the amounts set by the Health Care Financing Administration (HCFA) for equivalent generic drugs.

We found that 11 State Medicaid programs have policies in place that promote the use of generic drugs beyond the current Federal requirements. We also found that use of generic drugs was being promoted by other programs that provide health benefits. Some programs require generic substitution when generic drugs are available, while others use financial incentives as part of their reimbursement policy.

We calculated that the annual cost savings to the Medicaid program could be as much as $46 million for only 37 high volume dispensed brand name drugs, if the reimbursement for those drugs is limited to the amounts set by HCFA for equivalent generic drugs. The cost savings will become even greater in the future as the Federal patents on exclusive drug manufacturing of 60 important highly used drugs with more than $10 billion in sales will expire between now and 1995. Therefore, we recommend that HCFA identify and alert States to methods which would encourage the use of lower priced generic drug products in the Medicaid program. Promising approaches, such as those discussed in this report, have the potential for reducing Medicaid expenditures without adversely impacting quality of care.

In response to our draft report, HCFA stated that our report effectively described "best practices" and agreed to share our report with all State agencies. The full text of HCFA's comments are included in Appendix B.
However, HCFA expressed concerns regarding our recommendation that they seek legislative authority to require States to adopt policies to encourage generic drug substitution or to limit Federal financial participation (FFP) to amounts based on generic drug prices rather than brand name drug prices.

We considered HCFA's concerns and revised this recommendation. And, we are also recommending that HCFA: (1) take a more active role to encourage States to use generic drugs and provide stronger incentives for States to adopt policies that encourage use of generic drugs; and (2) monitor the States' efforts to encourage the use of lower priced generic drugs and formally assess those activities.

BACKGROUND

A generic drug is an equivalent version of the pioneer or brand name drug originally manufactured. The generic drug, however, is not marketed until the brand name drug's Federal patent on exclusive manufacturing rights has expired. The Food and Drug Administration (FDA) is responsible for approving generic versions of brand name drug products. For purposes of this report, we use the term "generic" to refer only to drug products that have been categorized as "A" rated equivalents by the FDA.

In order for a generic drug to be granted a category "A" approval from the FDA, the drug must be bioequivalent to its brand name counterparts. Bioequivalency means that generic drugs must contain the same active chemical ingredients and be identical to brand name drugs in strength, dosage form, and route of administration. Also, the generic manufacturers must submit evidence to the FDA that their drugs will have the same therapeutic effect as the brand name counterparts. This means that generic products can be expected to deliver to the bloodstream, or other site where the drug does its work, the same amount of active ingredients as the original product. According to the FDA, when the same amount of active ingredients of the generic version gets into the bloodstream at the same rate as the brand name version, there is no scientific reason to believe that the effects of the two drugs will differ.

The Drug Price Competition and Patent Restoration Act of 1984 encouraged the introduction of generic competition, accelerating the approval process for generic drugs by allowing use of research undertaken on the behalf of the pioneer product to gain generic approval.

The generic drug manufacturing industry is expected to continually grow in this decade. According to Fortune magazine, the Federal patents of 60 important highly used drugs with more than $10 billion in sales will expire between now and 1995, including half of America's 10 best-selling products. The best-selling
products coming off patent include: Cardizem, Tagamet, Ceflor, Seldane, and Naprosyn. Additionally, according to the FDA, about 80 percent of the generic drug production is currently performed by brand name firms.

Prescription Drugs in the Medicaid Program

Under Medicaid, reimbursement for drugs is generally based upon ingredient costs plus a reasonable pharmacy dispensing fee. Effective October 29, 1987, Federal regulations limited the amount which Medicaid reimbursed for drugs with available generic drugs to a Federal upper limit price (FULP). This upper limit amount is 150 percent of the lowest priced generic equivalent drug that is available plus a reasonable dispensing fee. The HCFA is responsible for identifying and publishing a list of the drugs with FULPs.

Under Federal regulations, States have the flexibility to pay more for some upper limit drugs and less for others. However, States' claims for FFP cannot exceed the aggregate of the individual FULP for all upper limit drugs. Additionally, FULP limits do not apply to drug purchases where prescribing physicians certify in their handwriting on the prescription form that a specific brand is medically necessary. Physicians are not required to provide any specific medical, scientific, or diagnostic information regarding their brand name decisions. The payment limits for brand name drugs are based on estimated acquisition costs of the drugs rather than the FULP amount and are usually higher than the FULP amount.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objectives of our review were to study: (1) efforts taken by State Medicaid programs and selected private and public health benefit programs to encourage the use of less costly generic prescription drug products and (2) the financial impact of changing Federal regulations to limit reimbursement of brand name drugs to the amounts set by HCFA for equivalent generic drugs. Our objectives did not require that we identify or review any internal control systems.

We interviewed officials from the Medicaid programs of 49 States and the District of Columbia concerning the reimbursement of brand name drugs. We reviewed 10 State pharmaceutical assistance programs that provide financial assistance for prescription drugs to elderly populations. Additionally, we reviewed the 1993 drug benefits of seven fee-for-service plans and nine prepaid plans in the Federal Employees Health Benefits (FEHB) programs.
We reviewed the HCFA Federal upper limit list for generic drugs in effect as of July 29, 1993 and the drug pricing file of the Arkansas Medicaid program. The list of the top 200 drugs was obtained from Pharmacy Times and American Druggist. We obtained drug utilization information from the Medicaid Drug Rebate Database of the HCFA Data Center for the 4 quarters ending June 30, 1992. We also referred to other studies and references, which are listed at the end of this report.

For information on the savings calculation, see Appendix A.

We did not independently verify any information obtained from third party sources. Our review was conducted jointly by our Office of Audit Services field office in Little Rock, Arkansas and our Office of Evaluation and Inspections regional office in Philadelphia, Pennsylvania. The review was conducted from October 1992 to September 1993. The HCFA did not have an opportunity to comment on the second recommendation which was revised in our final report.
FINDINGS AND RECOMMENDATIONS

State Medicaid programs, as well as other health benefit programs, have taken steps to encourage the use of generic drugs. We found many different policies in place to encourage the use of generic drugs, ranging from a restriction on brand name drugs when generic drugs are available, to cost incentives for beneficiaries and for pharmacists to select generic drugs in preference to brand name drugs. We calculated that the annual cost savings to the Medicaid program could be as much as $46 million for only 37 high volume dispensed brand name drugs, if the override provision (that which allows physicians to state brand name drugs must be dispensed) for brand name drugs is totally eliminated.

State Medicaid Programs Have Taken Steps to Encourage the Use of Generic Drugs

Eleven State Medicaid programs have taken steps to encourage the use of generic drugs beyond the Federal requirement that payment for brand name drug products will not be made unless the physician certifies medical necessity. These steps include limiting Medicaid reimbursement to the FULP and requiring prior authorization for brand name products that are on the FULP list. State officials believe that their efforts have been successful in reducing expenditures. These State officials pointed to the small number of overrides processed by their States as measures of success. Two States provided annual savings estimates of $1.5 million and $5 million, respectively.

We found that two States had restrictive policies that did not allow physicians to override the FULP for brand name drugs. However, one State had recently allowed exceptions to that policy for the anticonvulsive class of drugs. Officials from the States informed us that they were not aware of any adverse medical problems encountered by their Medicaid recipients as a result of these policies.

An official from another State informed us that the State had a similarly restrictive policy in that only brand name drugs on the State’s negative formulary could be reimbursed for more than the FULP amount. The official explained how the State arrived at this policy. In 1989, the State performed an internal review which found that the utilization of brand name products appeared to be geographically limited. In fact, one county and its surrounding subdivision accounted for 86 percent of claims paid for brand name drugs certified as medically necessary and 87 percent of the total dollars statewide for medically necessary certified prescriptions while comprising only 26 percent of the Medicaid eligible population. The State calculated that discontinuing the option of brand name specification would save a minimum of $1.5 million in the one county alone.
Officials from seven States informed us that they had placed brand name drugs with FULPs on prior authorization approval. Prior authorization requires physicians to request and receive official permission before a particular drug can be dispensed. The request can be by phone, fax, or mail. In most cases, the State requires information on the patient and a medical justification as to why the generic drug cannot be dispensed. The detail of the medical justification differs among the States. For example, one State requires information on whether or not the patient had a trial of a generic drug product, and if the generic drug was tried, the results of the trial, and if the generic drug was not tried, the medical reason that such a trial would be inappropriate.

One State official reported that the State had implemented a policy that required the physician to take an additional step in order to prescribe a brand name drug with a FULP. In addition to physicians certifying that a brand name drug is medically necessary, they must also certify the reason that the brand name drug is necessary.

Additionally, some States require varying copayment amounts which can further promote the use of generic drugs.

State Pharmaceutical Assistance Programs are Promoting the Use of Generic Drugs

Nine of the 10 State pharmaceutical assistance programs for the elderly or low-income people we reviewed, mandate or provide incentives for using generic drugs over brand name products. Seven States mandate the dispensing of generic drugs in place of brand name products when available. However, six of these States will allow brand name products to be dispensed when physicians indicate there should be no substitution.

In five States with mandatory substitution, the programs provide additional incentives to encourage the use of less costly generic drugs. One State requires that prescriptions only be filled with the generic drug. Another State requires that the prescriber provide a justification for the brand name drug used. In two States, the copayment increases for brand name products. For example, in one of the two States, a copayment of $3.00 is required for generic drugs while the copayment for brand name drugs is $5.00. Finally, one State requires that the actual prescription be provided if the prescription was telephoned or faxed to the pharmacy in order to dispense a brand name drug when a generic drug is available.

In all three States without mandatory substitution, the use of generic drugs is encouraged through increased cost sharing for recipients. One State requires the recipient to pay the difference between the cost of the generic drug and the cost
of the brand name drug. The other two States require the recipient to pay a percentage of the price of the drug. Since recipient cost sharing amounts increase for higher priced drugs, there is an incentive to choose lower priced generic products. One State further encourages generic drug substitution by reimbursement incentives to pharmacies. The State pays a $1.00 dispensing fee to pharmacies for brand name products and a $5.00 dispensing fee for generic products.

FEHB Plans Encourage the Use of Generic Drugs

Eight of the 16 FEHB plans that we reviewed encouraged the use of generic drugs by requiring the beneficiary to pay more for brand name drugs. Nine of the 16 plans were prepaid health plans (e.g., a health maintenance organization) and 7 were fee-for-service health plans. The method most frequently used by both prepaid and fee-for-service health plans to encourage use of generic drugs is recipient cost sharing.

Four of the nine prepaid health plans encouraged the use of generic drugs through higher copayments for brand name drugs. The difference in copayment amounts per prescription ranged from $2.00 to $5.00. For example, one prepaid plan required a $5.00 copayment per prescription or refill for a generic drug and a $10.00 copayment per prescription or refill for brand name drugs.

All seven of the fee-for-service plans required the recipient to make copayments at the pharmacy of up to 40 percent of the cost of the prescription. Five of the seven plans have mail-order programs. Four of the mail order prescription drug programs require a higher copayment for brand name drugs.

Savings to the Medicaid Program Can Be Achieved Through Increased Use of Generic Drugs

Our estimate showed that substantial savings could be achieved in the Medicaid program by restricting the physician override for brand name drugs with FULPs. We calculated that the annual savings could be as much as $46 million for only 37 high volume brand name drugs, if the override provision is totally eliminated. While the elimination of the override provision might seem to be an extreme position, two States already have policies in place that do not permit the override of FULP drugs (with the exception of anticonvulsive drugs in one State).

Appendix A explains how our calculation was made. Our estimate, although not a scientific statistical sample projection, shows that the possible savings are substantial.
CONCLUSIONS AND RECOMMENDATION

The use of generic drugs in place of prescribing and dispensing brand name drugs is being encouraged by State Medicaid programs as well as other third party payers. While the use of generic drugs within the Medicaid program is already encouraged through HCFA’s FULP listing, 11 States have policies in place that either prohibit, or discourage the override of FULP, thereby promoting dispensing of the lower priced generic drugs. Nine of 10 State pharmaceutical assistance programs that we reviewed mandate or provide incentives for using generic drugs over brand name products. Eight of 16 FEHB plans that we reviewed promote the use of generic drugs through higher copayment requirements or reduced reimbursement.

Our estimate showed that substantial savings could be achieved in the Medicaid program by restricting the physician override for brand name drugs with FULPs. We calculated that the annual savings could be as much as $46 million for 37 high volume brand name drugs. We believe that the potential cost savings will become even greater in the future as the Federal patents of 60 important highly used drugs, with more than $10 billion in sales, will expire between now and 1995. Included in the 60 are 5 of the top 10 best-selling drugs. Therefore, in the short term, we recommend that HCFA identify and alert States to methods which would encourage the use of lower priced generic products in the Medicaid program. Promising approaches, such as those discussed in this report, have the potential for reducing Medicaid expenditures without adversely impacting quality of care.

We also recommend that HCFA: (1) take a more active role to encourage States to use generic drugs and provide stronger incentives for States to adopt policies that encourage use of generic drugs; and (2) monitor the States’ efforts to encourage the use of lower priced generic drugs and formally assess those activities. After assessment of the State efforts and results, HCFA could better determine if additional or different measures are needed to ensure that lower priced generic drugs are used whenever appropriate.

HCFA’S COMMENTS

The HCFA commented on the draft report and the full text of their comments appears in Appendix B. The HCFA generally concurred with the first recommendation but did not concur with the second recommendation contained in our draft report.

In response to our first recommendation, HCFA agreed that savings to the Medicaid program would result if States instituted programs encouraging the use
of generic drugs. The HCFA also stated that our report effectively describes "best practices" and agreed to share our report with all State Medicaid agencies.

The HCFA did not concur with the second recommendation contained in our draft report. We considered HCFA's concerns and revised our second recommendation to address those issues in this final report.

OIG'S RESPONSE

By agreeing to share our report with all of the States, we believe that HCFA has taken a positive step toward encouraging the use of lower priced generic drugs. There is a major trend taking place in both public and private health programs discouraging the use of brand name drugs and requiring the greater use of generic drugs. The HCFA's FULPs has been a successful means to limit the use of brand name drugs in the Medicaid drug program. We recognize that States currently have the flexibility to encourage the use of generic drugs and that the Omnibus Budget Reconciliation Act of 1993 has given States other means to limit the use of brand name drugs. However, most States have not taken the opportunity to use this flexibility to encourage the use of generic drugs.

In order to encourage the use of generic drugs, we are not proposing that States eliminate physician overrides for the use of brand name drugs or that prior authorization programs be established. These decisions should be left to the States' discretion in order to allow them the necessary flexibility to operate their programs. However, we believe that HCFA has an opportunity to do more. Thus, we have revised the second recommendation contained in this final report.
Calculation of Potential Savings to Medicaid Program

We selected all brand name drugs that appeared on the HCFA FULP and were listed in the top 200 drugs for 1991 by *Pharmacy Times* and *American Druggist*. There were 37 drugs that met these requirements.

After identifying the drugs, we determined the different strengths available for each drug from the 1991 *Red Book*--an annual pharmacists' reference guide for drug pricing, packaging, product identification, and manufacturer names and addresses. We then obtained the number of units dispensed for each drug by the Medicaid program of each State for the four quarters ended June 30, 1992. This utilization information is reported quarterly by the States to HCFA as part of the Medicaid drug rebate program. The information was not available for all States for all four quarters. Nevertheless, we computed our savings estimate based on the data that was available. (The savings estimate was for 46 States for the third quarter of 1991 and the first quarter of 1992, 44 States for the fourth quarter of 1991 and 47 States for the second quarter of 1992. We also excluded the two States that did not permit overrides.)

When a physician certifies that a brand name drug is necessary, the States reimburse the estimated acquisition cost of the drug rather than the FULP for the ingredient cost portion of the drug. We did not determine the actual State payment for the drug, since this information was not readily available. We did, however, survey each State to determine their reimbursement basis for the ingredient cost of drugs. Most of the States reimburse based on the average wholesale price (AWP) of a drug less some percentage. Therefore, we obtained AWP for each drug as of July 29, 1993. We then calculated the ingredient cost for each drug for each State. If a State used another reimbursement methodology, we used AWP less 10.5 percent. We used 10.5 percent because it was the most conservative percentage frequently used by the States to calculate reimbursement to pharmacies for ingredient costs.

Next, we compared the calculated ingredient cost to the FULP for each drug and multiplied the difference between the two by the number of units dispensed for each drug for each State. These calculations produced a cost savings of $93 million for the 37 drugs. However, the savings estimate does not account for any difference in drug rebates that might occur from dispensing generic drugs rather than brand name drugs.

In order to approximate the difference in drug rebates, we identified a generic drug for each of the 37 drugs. We judgmentally selected the generic drugs. After identifying the generic drugs, we obtained the unit rebate amounts for the 37 brand name drugs and the corresponding generic drugs. We used the unit rebate amounts for the first quarter of 1993, which was the latest data available. We computed the rebate difference by subtracting the
generic unit rebate amount from the brand name unit rebate amount and multiplying the difference by the total utilization for each drug for the four quarters ended June 30, 1992. These calculations showed that the rebate for the generic drugs would be $47 million less than the rebate for the brand name drugs. Therefore, our cost savings estimate of $93 million would be adjusted to $46 million after accounting for the rebates.
DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date APR 14 1994
From Bruce C. Vladeck Administrator
To June Gibbs Brown Inspector General

We reviewed the above-referenced draft report on the use of generic outpatient prescription drugs in the Medicaid program.

We offer an alternative approach to the first recommendation presented in the report. We do not concur with the second recommendation. Our detailed comments are attached.

Thank you for the opportunity to review and comment on this draft report. Please advise us if you would like to discuss our position on the recommendations at your earliest convenience.

Attachment
Recommendation 1

In the short term, the Health Care Financing Administration (HCFA) should identify and alert States to methods which would encourage the use of lower priced generic products in the Medicaid program.

HCFA Response

We agree that if States institute programs to encourage the use of generic drugs, savings to the Medicaid program could result. However, we do not believe that alerting States to the steps that some States have taken to encourage greater use of generic drug products would be fruitful. These measures are already known to State agencies. As a result of the prior approval process incorporated in the Omnibus Budget Reconciliation Acts of 1990 and 1993 (OBRA 90 and OBRA 93), State agencies are aware that they can subject any drugs which they believe are being overutilized to prior authorization. However, we believe that your report effectively describes "best practices" and will send a copy of the report to all State agencies for their information if you supply us with an electronic copy.

Recommendation 2 (See Auditor's Note below)

HCFA should seek legislative authority to require States to adopt policies to encourage generic drug substitution or to limit Federal financial participation (FFP) to amounts based on generic drug prices rather than brand name drug prices. While States could have some flexibility in which method to adopt, the Federal Government could require that such policies exist as a condition of receiving FFP, or limit FFP to the amount that would have been paid had the generic drug been dispensed.

HCFA Response

We do not concur. We believe the recommendation to seek legislative authority to require States to limit reimbursement to generic drugs is problematic for a number of reasons.

States currently have the flexibility to encourage the use of generic drugs, as specific examples in your report show. OBRA 93 reinstated States' ability to institute drug formularies so that States can exclude brand name drugs from their

Auditor's Note: Recommendation 2 that HCFA is referring to in its response has been revised in the final report due to HCFA's concerns.
formularies if certain conditions are met. One condition is that State agencies allow for the payment of these more costly brand name drugs by means of a prior authorization program. It would seem, therefore, that OBRA 93 provides a statutory basis for a program similar to that recommended in the report, i.e. a program which restricted coverage to only certain drugs when there is a range of available therapeutically equivalent (generic) alternatives, but paid for brand name drug products via the prior authorization process.

We do not believe that Congress would favorably view legislation that would prohibit payment for brand name drugs when determined to be medically necessary by physicians. A Federal Government proposal to completely eliminate the physician override would be seen as unwarranted interference with the relationship between doctor and patient and between doctor and pharmacist. Specifically, physicians would not willingly accept such legislation because it would interfere with their ability to prescribe brand name drugs for patients who are unable to tolerate specific excipients or binders as found in "equivalent drugs." Similarly, patient access to medically necessary drugs might be hindered if reimbursement was limited in the manner proposed. Although intolerance to specific pharmaceutical ingredients generally is rare, it limits drug substitution options for the segment of the population affected by this medical condition.

Finally, HCFA is currently prohibited from revising its regulations to change its physician certification exemption or drug reimbursement methodology to achieve Medicaid program savings. Section 1927(e)(1)(B) of the Social Security Act prohibits the Secretary from modifying the regulatory Federal upper limit formula through December 31. Thus, at least until the end of this calendar year, we are precluded from revising the policy which establishes FPP for certain brand name drugs, and which permits an exemption from the Federal upper limits when there is a physician certification. The OBRA 90 moratorium on changes to Medicaid reimbursement methodology expires as of December 31. After this date, States may request approval of changes that would have the effect of lowering payment rates for any prescription drugs. This further reduces the need for legislative changes.
REFERENCES

