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REPORT BY THE

Comptroller General

OF THE UNITED STATES

RELEASED

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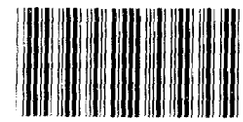
Programs To Control Prescription Drug Costs Under Medicaid And Medicare Could Be Strengthened

In August 1976 the Department of Health and Human Services (HHS) put into effect two programs to control the costs of prescription drugs under Medicaid and Medicare. One program--Maximum Allowable Cost (or MAC)--was designed to take advantage of competition in the drug market by establishing price limits for drugs available from more than one source. This, in turn, involved substituting a lower cost generic drug with the same therapeutic effect for a brand-name drug.

Although GAO did not attempt to settle the scientific disagreements over drug quality and therapeutic equivalence, it did conclude that MAC has resulted in savings under the State-operated Medicaid outpatient drug programs.

This savings could have been greater, however, if (1) States had implemented the limits in a more timely manner, (2) HHS had systematically updated the limits, and (3) HHS had encouraged States to implement or expand their own MAC programs. MAC has had little impact on the cost of drugs under Medicare because those covered under the program are not purchased in large quantities by hospitals.



HRD-81-36
DECEMBER 31, 1980

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-201437

The Honorable Bob Eckhardt
Chairman, Subcommittee on Oversight
and Investigations
Committee on Interstate and Foreign
Commerce
House of Representatives

Dear Mr. Chairman:

This report discusses Department of Health and Human Services efforts to control the costs of prescription drugs paid for under the Medicare and Medicaid programs and makes several recommendations to improve these programs. The report also discusses the potential impact of State drug substitution laws on the costs of prescription drugs to the public. The Subcommittee requested this review in October 1978.

As requested by your office, we did not obtain the Department's comments on this report. As arranged with your office earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies to interested parties and make copies available to others on request.

Sincerely yours,

Milton J. Socolar

Acting Comptroller General
of the United States

REPORT BY THE
COMPTROLLER GENERAL
OF THE UNITED STATES

PROGRAMS TO CONTROL PRESCRIPTION DRUG COSTS UNDER MEDICAID AND MEDICARE COULD BE STRENGTHENED

D I G E S T

Medicaid (a Federal/State-financed activity) pays over $1 billion a year for outpatient prescription drugs for the poor. Medicaid and Medicare (a Federal activity that provides certain health benefits to the aged and some disabled) pay about $750 million a year for prescription drugs provided to hospital inpatients.

Effective August 1976, the Department of Health and Human Services (HHS) established two programs to contain the costs of prescription drugs under Medicaid and Medicare by setting upper limits on the amounts that could be reimbursed. One program, called Maximum Allowable Cost (MAC), pertains to multiple-source drugs and is applicable to Medicaid and Medicare. The other program, called Estimated Acquisition Cost (EAC), pertains to all drugs and is applicable only to Medicaid.

GAO looked into the effectiveness of these programs in five States (California, Florida, Georgia, New Jersey, and Texas) and also obtained information on the effectiveness of State drug substitution laws 1/ nationwide.

1/These laws either permit or require pharmacists to dispense a less costly, but therapeutically equivalent, product under certain circumstances when a brand-name drug is prescribed and pass along all or part of the savings to the customer.

MAC'S EFFECTIVENESS

The MAC program has resulted in savings of about $1.4 million a year under Medicaid for outpatient drugs in the five States; however, the savings could have been greater if:

--States had implemented the MAC limits on a more timely basis and/or, in accordance with regulations, had not claimed Federal sharing for savings lost due to delays in implementation. (See p. 12.)

--HHS had a formal mechanism for systematically updating the limits. GAO analysis showed that about one-third of the MAC limits in effect in June 1979 could have been lower. (See p. 17.)

Although HHS has established an elaborate Medicare regulatory and administrative structure for enforcing the MAC limits for inpatient hospital drugs, the related enforcement requirements have not been adhered to. GAO believes that, even if the program was enforced, it would have little impact on costs because the forms or types of drugs covered by MAC do not appear to be those purchased in large quantities by hospitals. GAO also believes the program could affect costs if it focused on drugs with the greatest cost saving potential in the hospital inpatient setting. (See p. 20.)

EAC'S EFFECTIVENESS

This program was to establish reimbursement limits based on pharmacists' Estimated Acquisition Costs of drugs. One of its objectives was to move the States away from using the published Average Wholesale Prices of drugs for setting such limits. HHS believed that such published prices were from 15 to 18 percent higher than the prices at which druggists could obtain drugs.

GAO found that the States were still using the published wholesale prices to set limits, but the effect of the EAC program's failure to meet its objective is difficult to assess because:

--The HHS data provided to help States establish the EAC often produced limits very similar to the Average Wholesale Prices. (See p. 33.)

--States had their own MAC programs and other special programs for a number of drugs which resulted in lower limits. (See p. 35.)

GAO believes that encouraging State MAC programs and other special EAC programs likely would produce lower drug costs under Medicaid than the EAC program as currently established. Also, some States have reduced drug costs under the EAC program by applying the lower prices for larger package sizes frequently purchased by druggists (see p. 37) and by applying their own MAC limits which were lower than the Federal MACs. (See p. 35.)

IMPACT OF STATE DRUG SUBSTITUTION LAWS

State substitution laws have the potential for significant savings to all consumers. Estimates of such savings nationwide range from $323 million to $817 million a year, depending on the assumptions used. However, actual savings have been less because substitutions have not been made wherever possible.

The States have recognized the potential benefits of substitution laws. As of December 31, 1979, 45 States and the District of Columbia permitted or required substitution under certain circumstances, with over half the States having such statutes since 1976. (See ch. 4.)

RECOMMENDATIONS

HHS should:

--Recover from California and Florida the Federal share of excess costs GAO identified that were due to delays in implementing the MAC limits.

--Require State claims processing systems to identify costs in excess of the MAC limits which are ineligible for Federal sharing.

--Provide for the systematic and formal updating of the MAC limits.

--Reevaluate the applicability of the MAC program to the inpatient hospital setting with the view toward (1) eliminating the existing regulatory and administrative structure which is not being enforced or (2) focusing on the forms or types of drugs which would make the structure worthwhile.

--Encourage the States to (1) review their EAC drug limits to identify drugs that would be suitable for the MAC multiple-source pricing approach on a statewide basis, (2) review the Federal MAC limits to determine whether a lower statewide MAC would be appropriate, (3) determine the package sizes most commonly purchased by pharmacists and adjust their EAC reimbursement limits accordingly, and (4) determine drugs for which it is appropriate to establish EACs based on direct purchase prices and then do so.

As requested by the office of the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, which asked for this review, GAO did not obtain HHS comments on this report.

Contents

ABBREVIATIONS

AWP	Average Wholesale Price
EAC	Estimated Acquisition Cost
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
MAC	Maximum Allowable Cost

CHAPTER 1

INTRODUCTION

The Medicare and Medicaid programs incur substantial costs for prescription drugs. Medicare covers the costs of drugs provided to eligible beneficiaries in hospitals and long-term care facilities. Medicaid also covers the cost of drugs received by eligible recipients on an inpatient basis and, in addition, covers outpatient drugs in all but two States. Both programs are administered at the Federal level by the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS). 1/

HCFA estimates that in 1979 about 3 percent of total inpatient hospital costs were for drugs. During 1979, Medicare and Medicaid paid hospitals about $25 billion for the costs of inpatient hospital services. During fiscal year 1978, Medicaid costs for outpatient drugs were about $1.1 billion, or about 6 percent of its total costs of $18.6 billion.

Medicare, which began on July 1, 1966, is the Federal health insurance program for the aged, certain disabled persons, and most people with chronic kidney disease. Medicare has two parts. Part A, Hospital Insurance, covers inpatient hospital services and posthospital care in skilled nursing facilities or the beneficiary's home. Eligibility for part A is based on entitlement to benefits under Social Security's Old-Age Retirement, Survivors and Disability Insurance program. Part B, Supplementary Medical Insurance, covers physician, outpatient hospital, home health care, and certain other medical services. Part B does not cover prescription drugs unless administered in a doctor's office.

Medicaid, which began on January 1, 1966, is a Federal/State program providing health services to recipients of cash assistance under the welfare programs and to other persons whose income and resources are not sufficient to pay for their health services. The States decide whether to have a Medicaid program and design and operate it within

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1/Until May 4, 1980, HCFA was part of the Department of Health, Education, and Welfare. On that day a Department of Education commenced operating, and the remainder of the former Department, including HCFA, became HHS.

broad Federal requirements. The Federal Government pays from 50 to 78 percent of the cost of health services provided, depending on the State's per capita income. All States except Arizona have Medicaid programs, as do the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands. All jurisdictions with Medicaid programs cover inpatient drugs, and all but Alaska and Wyoming cover outpatient drugs.

States either administer Medicaid themselves or contract with firms (called fiscal agents) for assistance. HCFA contracts with organizations such as Blue Cross, called intermediaries, to administer Medicare benefits provided by institutions such as hospitals.

THE MAXIMUM ALLOWABLE COST/ ESTIMATED ACQUISITION COST DRUG PRICING PROGRAMS

On July 31, 1975, HHS revised its regulations relating to payments for prescription drugs under the Medicare and Medicaid programs. The revised regulations which became effective August 1976 established the Maximum Allowable Cost (MAC) program, which places a ceiling on the amount of payment allowed for certain high-volume drugs that are available in therapeutically equivalent forms from more than one source. A particular drug's MAC is set at the lowest price at which the drug is widely and consistently available to drug providers nationwide. Once a MAC is established, it applies to drugs furnished under Medicare and Medicaid.

The revised Medicaid regulations also required States to establish an Estimated Acquisition Cost (EAC) program for checking the reasonableness of prices charged for drugs provided to Medicaid recipients on an outpatient basis. States are required to establish EACs for all drugs covered under Medicaid at prices that reasonably estimate what pharmacists actually pay for drugs. EAC does not apply to Medicare.

States are also required to establish reasonable dispensing fees for outpatient drugs under Medicaid. The dispensing fee is meant to cover the reasonable costs to the drug provider of dispensing a prescription plus a reasonable profit.

For inpatient drugs provided to Medicare beneficiaries, the upper limit on payment is the lowest of the drug's actual cost; the MAC, if one is established; or the amount a prudent and cost-conscious buyer would pay for the drug. The facility's reasonable costs of dispensing the drug are also paid. States generally follow Medicare reimbursement policies when paying hospitals so the same limits would normally apply.

For outpatient drugs provided to Medicaid recipients, HHS regulations limit payments to the lowest of

--MAC plus a reasonable dispensing fee,

--EAC plus a reasonable dispensing fee, or

--the provider's usual and customary charge to the public.

The objective of these restrictions is to contain the cost of providing pharmaceutical services to Medicare and Medicaid eligibles. However, it is important to note that the MAC/EAC programs do not establish the level of reimbursement. Rather, they establish procedures for determining the maximum payment the Government will allow for a given drug (a drug product having a specific dosage form and strength).

There are four major components to be considered in establishing the maximum drug reimbursement level: (1) the MAC level for multiple-source drugs, (2) the EAC level for all drugs, (3) the dispensing fee for providers, and (4) the usual and customary charges. The Federal Government establishes the first component, the individual State Medicaid agencies are primarily responsible for establishing the next two components, and pharmacists determine the last.

The establishment of MAC reimbursement ceilings involves two entities at the Federal level: the Pharmaceutical Reimbursement Board and the Food and Drug Administration (FDA). The Board is composed of six HHS employees, with the director of HCFA's Bureau of Program Policy, or his/her designee, serving as a member and as chairman. The Board has a small support and research staff.

The Board identifies multiple-source drugs for which significant Federal funds are or may be expended and

for which there are or may be significant price differences among alternative suppliers. HHS regulations define a multiple-source drug as

> "* * * a drug marketed or sold by two or more formulators or labelers or a drug marketed or sold by the same formulator or labeler under two or more different proprietary names or both under a proprietary name and without such a name."

Multiple-source drugs selected by the Board are reviewed by FDA to determine if there are any problems that may warrant a delay in establishing a MAC for the drug. Once FDA has cleared the drug, the Board establishes the lowest unit price at which the drug is widely and consistently available in the package size most frequently purchased by providers.

When the Board decides to establish a MAC, the findings are published for comment in the Federal Register. Based upon a formal written request, the Board may conduct public hearings if, in its judgment, they will be useful in its deliberations on the final establishment of the MAC. After considering any written comments, public hearings, and other evidence included as part of the hearing record, the Board sets the final MAC price and publishes it in the Federal Register.

FDA's role in the MAC process is detailed in appendix I.

As of November 1, 1980, MAC limits had been established for 39 drug entities involving 18 different drugs. About 40 additional drug entities are considered to be candidates for MAC limits in fiscal year 1981.

While the MAC/EAC programs are aimed primarily at reducing the Government's share of drug costs, other efforts in progress are designed to reduce drug costs for both the Government and the public. Among these is the Government's strong support of the passage of drug substitution laws by the States. Basically, these laws either permit or require pharmacists to substitute lower cost, therapeutically equivalent drugs on prescriptions written for higher cost brand-name drugs when certain conditions are met. As of December 31, 1979, 45 States and the District of Columbia had passed such laws.

In January 1979, HHS and the Federal Trade Commission (FTC) jointly announced the development of a model generic drug substitution law which HHS said could save consumers $400 million a year if adopted by States. At that time, FDA announced that it had compiled a list of therapeutically equivalent drugs that would be distributed to the Nation's pharmacists. Chapter 4 discusses State drug substitution laws.

DEFINITION OF TERMS

The following definitions are used in this report.

1. Brand-name drug--the drug produced by the manufacturer that held the original patent on the drug.

2. Generic drug--a drug not covered by patent which is sold by more than one manufacturer or labeler.

3. Branded generic--a generic version of a drug which the manufacturer or labeler is marketing under its own trade name (as opposed to the generic name of the drug).

4. Drug entity--a particular strength and form of a specific drug (any drug may have several entities).

A drug entity may fall in one, two, or all of the first three categories. For example, for the drug Meprobamate, 200 mg tablets, in addition to the original brand-name version, there are at least five generic versions and four branded generic versions. Commonly, the original brand-name version of the drug is the most expensive; the branded generics, the second most expensive; and the generics, the least expensive.

OBJECTIVES, SCOPE, AND METHODOLOGY

Our review was made in response to an October 1978 request from the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, which asked us to look into (1) the effectiveness of the MAC and EAC programs to limit reimbursement levels for prescription drugs and (2) the effectiveness (including estimates of dollar savings projected and realized) of drug substitution laws in States that allow or require substitution of generic for brand-name drugs.

To meet the first objective, we focused our approach on the Medicaid outpatient drug benefits of five States because available data indicated that the impact of the MAC program was the greatest for this benefit. The States were California, Florida, Georgia, New Jersey, and Texas. 1/ The methodology followed and its limitations, which are explained in greater detail in chapter 2, featured comparisons of amounts paid before and after a MAC was established. We also considered other available studies on the MAC program's effectiveness. Similar analysis was performed on the EAC program.

To meet the second objective, we obtained and evaluated various studies on drug substitution done by the private sector and obtained information on all the States' laws to measure the extent that substitution is currently allowed or prohibited.

1/These States were selected in part to accommodate the second objective because of differences in their drug substitution laws.

CHAPTER 2

THE MAC PROGRAM: SAVINGS HAVE BEEN REALIZED BUT MANAGEMENT NEEDS IMPROVEMENT

The MAC program has resulted in savings under the Medicaid outpatient drug program. However, the savings could have been greater if:

--States had implemented the MAC limits in a more timely manner and/or, consistent with regulations, had not claimed Federal sharing for savings lost due to delays in implementation.

--HHS had a formal mechanism for systematically updating the limits. Our analysis of more current data showed that about one-third of the MAC limits tested could have been lower.

Regarding Medicare and Medicaid inpatient drug costs, there was no mechanism to assure that hospitals complied with the MAC limits; however, whether or not there was such compliance, we doubt that the program would have much impact on costs because of the small quantities of MAC drugs purchased by the hospitals we visited. We believe the MAC program could affect inpatient costs if HHS focused on drugs that hospitals purchase in large quantities.

Also, our review of FDA's procedures for clearing a drug for MAC and an FTC study did not support the view that the program has lowered the quality of the drugs dispensed.

HOW MAC WORKS

About half of the 100 drugs most commonly prescribed in the United States are available from only a single source. Those available from multiple sources often have widely differing prices. Historically, the lower cost versions of multiple-source drugs have been marketed by relatively small manufacturers. In recent years, however, the growing trend toward generic prescribing has encouraged major manufacturers to market generic and branded generic drugs with prices below those of the original brands.

The MAC program was designed to capitalize on the increasing price competition in the multiple-source drug market by having the Government establish limits on what would be paid for drugs available from more than one source. From the inception of the program in 1976, HHS believed that the MAC program would generate significant savings. For example, for the program's first year, HHS estimated that MAC would save $22.7 million.

Because of lawsuits and other reasons (such as the time required to respond to about 2,600 comments received from interested parties concerning the overall program), the MAC program got off to a slow start. The program regulations were effective in August 1976, but the first MAC limit was not established until June 26, 1977. As of November 1, 1980, the number of drug entities (strengths, forms, and package sizes) covered by MAC limits had increased to 39, 1/ with about 40 additional drug entities to be considered for MAC limits during the remainder of fiscal year 1981. According to HHS officials, all the drugs that were candidates for MAC limits when the program began will have been considered by the end of fiscal year 1981, and drugs coming off patents will be the candidates for most MAC limits thereafter.

From the inception of the MAC program to December 1979, MAC limits had been revised five times, and all the revisions had been decreases. For example, the MAC limit for 250 mg ampicillin capsules was set at $.0725 per capsule on June 26, 1977, and was decreased to $.0595 on January 25, 1979.

HHS regulations require States to establish EACs for all drug entities reimbursed under Medicaid, even drug entities with a MAC limit. In the States visited, except for one drug entity in Georgia, drugs with MAC limits also had EAC limits. As required by HHS regulations, drugs were generally being reimbursed at the lowest of the MAC limit, the EAC limit, or the amount charged by the pharmacist.

1/This excludes the MAC limits on three drug entities that had been suspended as of November 1980 because the alternate supplier had increased its price.

MEDICAID SAVINGS HAVE RESULTED FROM MAC

Sufficient information was not available to determine the precise savings that have resulted from the MAC program in the five review States. The available data did show that savings amounting to about $1.4 million a year were being realized.

The States we visited, as do almost all States, instruct pharmacists to bill Medicaid their usual and customary charges. 1/ Thus, the States receive claims showing the pharmacist's total charge covering both the cost of the drugs dispensed and the pharmacist's charge for dispensing them. Therefore, we had to estimate what the pharmacist was charging Medicaid for the cost of the drugs themselves. To do so we obtained data on each State's costs for all versions of a drug covered by the MACs in effect as of December 31, 1978, (1) for a period (normally a quarter) immediately before the MAC's effective date and (2) for a period (normally a quarter) after the effective date. The second period was chosen to begin several months after the MAC's effective date so that most pharmacy claims for drugs dispensed before the effective date would have been processed through the claims payment system. We also determined the total number of Medicaid prescriptions for each MAC drug entity during each of the two periods and the total number of units dispensed. We then computed a unit cost for each period by subtracting from total costs the amount of the State's dispensing fee times the number of prescriptions filled and dividing the remainder by the quantity of drugs dispensed. To estimate savings, we multiplied the difference in the per unit cost before and after MAC by the number of units dispensed during the period after MAC.

This analysis does not take into account whether the savings were realized because (1) pharmacists were dispensing lower cost drugs or (2) the actual amount received by pharmacists as compensation for dispensing the drug (that is, their effective dispensing fee) was lower after the MAC was implemented. Regardless of which reason resulted in the lowered prescription drug costs, we attributed the reduction to the MAC program. The results of our analysis of savings attributable to the MAC program are presented in the following table.

1/The amount the pharmacist normally charges the public for the drug in question.

Estimated Annual Savings Resulting From the Application of MAC to the Medicaid Program in Five States

State	Number of drugs on which savings based	Period for which savings were calculated	Estimated savings	Percentage by which MAC limits reduced cost	Estimated savings projected for 1 year
California	6	3 months	$ 81,522	26.1	$ 326,088
Florida	9	3 months	4,066	9.8	16,264
Georgia	11	6 months	133,139	45.6	266,278
New Jersey	15	3 months	74,806	29.0	299,224
Texas	15	3 months	131,003	41.3	524,012
					$1,431,866

California had its own MAC program, which resulted in 9 of the 15 drug entities having costs below the Federal MAC limits before they were established. Therefore, information is given only for six drugs.

We did not analyze four drug entities in Georgia because of an acknowledged problem with the data base. Because of pharmacists' coding errors, claims for the capsule form of drugs were coded as the liquid form and vice versa. Thus, the data for each form were incorrect.

In Florida, four drug entities were not analyzed because of incomplete records relating to them. Also, two drug entities were not considered because the State had not implemented the MAC limits in time to permit analysis. The amount of savings in Florida was relatively less than the other States because it had preexisting State MAC limits which were only slightly higher than the Federal MAC limits on seven of the nine drugs analyzed.

The estimated savings do not take into account any increased administrative costs related to implementing a MAC program. None of the five States maintained statistical information on these costs, but we believe they are minimal. In two States (Florida and Georgia), officials estimated the cost of implementation to be less than $500. California officials said their costs were negligible. Also, regardless

of whether or not a MAC program existed, States' claims processing systems would include edits for the reasonableness of drug charges. In the case of a MAC drug, the MAC is such an edit.

Abt Associates, Inc., of Cambridge, Massachusetts, has also made a study of the MAC program under contract with HCFA. Phase I of the study, which was completed in September 1979, involved establishing background information on all the States' prescription drug programs. A methodology for evaluating the MAC program was developed and tested in Massachusetts. Phase II, which was incomplete as of October 1980, carried the methodology into four other States.

For Massachusetts, Phase I of the study showed the following ranges of savings resulting from the MAC program.

	Minimum	Maximum
April 1978 - March 1979 (actual)	$166,976	$194,964
April 1979 - March 1980 (projected)	203,710	237,228

The Phase I report stated that:

> "There should no longer be any doubt about the cost-savings potential of the MAC program. The fledgling first-efforts of the MAC program are clearly shown to have saved substantial amounts in Massachusetts and we have no reason to believe that experience elsewhere will be any different."

As of December 1979 no study had been completed giving an adequate assessment of the nationwide savings resulting from the MAC program.

Savings from MAC appear to result from reduced ingredient costs

Although reductions in Medicaid drug costs have clearly resulted from the MAC program, the question arises of whether these reductions result from reduced drug ingredient costs or from a reduction in the amount pharmacists actually receive as compensation for dispensing the drug. Data we developed indicate that the reductions have generally come from reduced ingredient costs.

Using the same methodology, drug entities, and time periods as our estimate of MAC savings, we determined the amount paid for the three highest volume generic versions and brand-name/branded generic versions of each drug entity with a MAC. We analyzed the drugs for four States. Sufficient data were not obtained from California to permit analysis. We compared the amounts paid by Medicaid to the EAC and MAC limits for the drugs. A total of 271 comparisons were possible, and they showed that:

--For 96 comparisons, the MAC for the drug entity was higher than the EAC for the supplier's version of the drug. The upper limit for these drug entities is the EAC. Thus, because the MAC was more than the upper limit, we assumed that, even if the pharmacists did not get their usual and customary charges, it was not attributable to the MAC.

--For 113 comparisons, the EAC was higher than the MAC so the MAC was the upper limit. Prices paid ranged from 0 to 61 percent below the MAC and averaged 10 percent less than the MAC. Because the prices paid were below the upper limit (the MAC), some pharmacists had to be charging less than the MAC. Therefore, on the average pharmacists' dispensing fees were not being lowered because of the MAC.

--For 62 comparisons, the EAC was higher than the MAC so the MAC was the upper limit. However, because of overrides, the MAC limit was exceeded.

Overall, we believe that the foregoing data indicate that lower Medicaid prescription drug costs have not resulted from lower compensation to pharmacists for their dispensing services.

SAVINGS FROM MAC PROGRAM NOT REALIZED BECAUSE STATES DID NOT PROMPTLY IMPLEMENT LIMITS

On the effective date of a MAC, it becomes the maximum amount a State can request Federal sharing in the costs for

the covered drug entity. 1/ We found that States were not promptly implementing MAC limits and as a result were overclaiming Federal sharing.

None of the States we visited were consistently implementing MACs by their effective dates. However, Georgia, New Jersey, and Texas generally managed to implement MAC limits within 30 days of their Federal effective dates. California and Florida were even less timely.

In California, implementing a MAC limit took about 7 months. This lengthy delay is due to the fact that California's Administrative Procedures Act requires that any new regulation (or MAC limit) must go through a process of hearings and other administrative actions before it can become effective. The entire process has required up to 8 months to complete. This administrative process cannot be bypassed unless a change can be justified as being required on an emergency basis. The fact that a change, such as a new MAC limit, has already received Federal approval has no bearing under State law. State officials are reluctant to use the emergency procedure approval because of their experience with the unpredictability of court decisions should those procedures be challenged. The officials pointed out, however, that this approach is regularly used in connection with changes to California's Maximum Allowable Ingredient Cost program, a State version of the MAC program. Changes to the State program require about 3 months to implement.

We determined that through July 1979 the Federal Government had incurred drug costs in California of about $33,700 more than what would have been incurred had MAC limits been implemented under the regulations in a more timely manner. HHS should recoup these excess costs from the State.

Florida has also had excessive delays in implementing MAC limits, as shown in the following table.

1/The only exception is when the prescribing physician has properly overridden the MAC by requiring the dispensing of a drug costing more than the MAC limit based on medical necessity.

Drug Entities for Which Florida Had Not Implemented a MAC Limit or the Limit Was Implemented More than 45 Days After the Effective Date

Drug entity	Federal effective date	Florida's effective date	Months delay
Ampicillin, oral, 250 mg/5 cc	10-25-77	6-1-78	8
Ampicillin, oral, 125 mg/5 cc	10-25-77	6-1-78	8
Penicillin VK, 250 mg tablets	10-25-77	6-1-78	8
Penicillin VK, 500 mg tablets	10-25-77	6-1-78	8
Penicillin VK, oral liq., 250 mg/5 cc	10-25-77	6-1-78	8
Penicillin VK, oral liq., 500 mg/5 cc	10-25-77	6-1-78	8
Doxepin HCl, 10 mg capsules	1-25-79	(a)	At least 13
Doxepin HCl, 25 mg capsules	1-25-79	(a)	At least 13
Doxepin HCl, 50 mg capsules	1-25-79	(a)	At least 13
Erythromycin Stearate, 250 mg	1-25-79	(a)	At least 13
Erythromycin Stearate, 500 mg	1-25-79	(a)	At least 13

a/Not implemented as of 3-6-80.

For MAC limits that were implemented late, Florida officials attributed the delay to the State's Medicaid program being in a transitional period. Specifically, they said that the State changed fiscal agents and the new agent did not understand the MAC program. Further, the new agent lacked the capability to implement the MAC limits. Florida officials also blamed HHS for the delays, claiming that it kept changing the effective dates for some of the MAC limits. HHS officials said this situation had occurred only once and involved two drug entities. Effective dates for the MAC limits on these two entities were withdrawn when FDA, because of bioequivalency problems, withdrew approval of the drugs as MAC candidates.

Regarding the MAC limits for the three entities of Doxepin Hydrochloride and two entities of Erythromycin Stearate that had not been implemented as of March 1980, Florida officials provided the following explanations. For Doxepin Hydrochloride, they stated they had determined that many pharmacists in the State could not obtain the drug at the MAC limits. They said this was particularly true in south Florida. We telephoned seven drug wholesalers and found two in the Miami area that said they could supply the drug at or below the MAC limits. State officials then advised us (in October 1979) that they would reevaluate their position. Nevertheless, in March 1980 the limits on Doxepin still had not been implemented. Concerning Erythromycin Stearate, officials told us that, because the drug was on the Florida negative formulary, brand substitution was prohibited by State law. As long as a Federal MAC is in effect but has not been implemented by the State, the State should not claim Federal sharing in costs exceeding the MAC.

Inadequate records precluded us from determining the total additional costs incurred by the Federal Government as a result of Florida's failure to implement MAC limits in a timely manner. We did, however, determine that, for the three entities of Doxepin Hydrochloride, the additional costs incurred from the Federal effective date of the MAC limits to October 1979 were about $8,500. HHS should recover the identified excess costs from the State.

HHS officials at the headquarters level were unaware that Florida officials were not enforcing certain MAC limits although, according to a February 12, 1979, State memorandum, HHS had been so informed. HHS officials were aware, however, of other violations of the MAC regulations. For example, they told us that Pennsylvania did not implement the MAC program until 1-1/2 years after it was mandated. The officials added that there may be other States that have not implemented all or part of the program. HHS headquarters officials believed this was a compliance problem that should be handled by HHS regional offices. They said HHS had not recovered from the States any Federal sharing paid in excess of the MAC limits.

In our view this issue presents two problems to HHS. One involves the basic issue of noncompliance with the regulations that preclude the claiming of Federal sharing for costs exceeding the MAC limits. The second involves the time and effort and related cost to HHS of identifying and

establishing the amounts of unallowable costs claimed when States do not comply--particularly where records are inadequate.

We believe that the solution to both problems lies in providing reasonable assurance that States' claims processing systems regularly identify for exclusion from claims for Federal sharing the ineligible costs associated with noncompliance with MAC regulations.

MAC limits generally enforced after implementation

The five States, after implementing the MAC limits, generally enforced compliance. In three States the average amounts paid for some drug entities during specific periods of time exceeded the MAC limit. In all three States, officials attributed the condition to physician overrides, a subject discussed in the next section. Sufficient records were not available to determine the validity of this hypothesis.

In all the States we visited, drug claims were computer processed, and limits, such as the MAC and EAC limits, were programed so that the computer would not permit payments exceeding the limits without a manual review.

Authorized exception to MAC limits (overrides)

According to MAC regulations, the only way a MAC limit can be overridden is by the prescribing physician certifying in his own handwriting that a particular brand of drug is medically necessary for the patient.

California records reflected only three physician overrides in 18 months, an insignificant number. Prescriptions for MAC drugs analyzed for specific periods in Florida, New Jersey, and Texas showed 2.5 percent, 0.35 percent, and 2.6 percent physician overrides, respectively. In Georgia records were insufficient to determine the number of physician overrides. In New Jersey physician overrides were not being certified in accordance with HHS regulations. New Jersey has a drug substitution law which requires every prescription form to be preprinted "substitution permissible" and "do not substitute." When the prescribing physician places his or her initials by the latter words, State law prohibits the pharmacist from substituting for the drug

prescribed. These procedures may not be consistent with HHS regulations, which state that a procedure for checking a box next to a preprinted statement does not constitute an acceptable certification. Because of the low percentage of physician overrides in New Jersey (0.35 percent), we believe the dollar effect of this possible noncompliance problem is negligible.

Until June 1979, Florida had permitted Medicaid recipients to override a MAC limit. If the recipient requested the pharmacist to dispense a prescription as written (that is, by brand name), the pharmicist could do so and be paid an amount exceeding the MAC limit. Federal regulations do not permit recipient overrides. HHS regional officials identified this practice in September 1977 and informed the State in February 1978 that the practice was contrary to Federal regulations and should be stopped. Florida complied 16 months later.

Our analysis showed that, for the quarter ended December 31, 1978, Florida had 4,080 overrides on prescriptions involving MAC drugs. Of these, only 665 (or 16 percent) were authorized physician overrides. The total amount paid for prescriptions with patient overrides was $21,045; however, we were unable to determine the actual excess cost to the Federal Government that resulted from the unauthorized patient overrides because the State did not have adequate records.

SYSTEMATIC METHOD FOR UPDATING MAC LIMITS NEEDED

Savings produced by the MAC program could be increased if HHS would more frequently update the MAC limits to consider more recent pricing data.

In establishing a MAC, the Pharmaceutical Reimbursement Board first identifies multiple-source, high-volume drugs with significant price differences. FDA then advises the Board of any pending regulatory activity or problem of bioequivalence (rate at which the drugs are absorbed into the body systems) that would warrant a delay in establishing a MAC. (See app. I for details on FDA's role.) For those drugs cleared by FDA, the Board determines the lowest price at which the drug is widely and consistently available to providers. This price is then published in the Federal Register as the proposed MAC. After considering any written comments received on the proposed MAC, the presentations made at a public hearing, and other evidence, the Board makes a final determination.

A small group within HCFA's Division of Medical Services Reimbursement is responsible for assisting the Board by gathering market and price data and by identifying multiple-source drugs and estimating potential savings. In accumulating information for the Board's use, the HCFA personnel use several source materials, including IMS America, Ltd. (a private corporation) market data, Drug Topics Redbook and the Bluebook (listings of wholesale drug prices), Physicians Desk Reference, and others. In identifying market volume and most commonly purchased package sizes, the IMS data are the only source material used.

While the MAC program has produced savings, we believe these savings have not been maximized because HHS has no systematic procedure for keeping MAC limits updated. HHS officials told us they "eyeball" the statistics received monthly from IMS to determine if a drug can still be obtained at the MAC limit. These statistics stratify what about 1,600 pharmacists across the Nation pay for the largest selling 300 drugs during a selected period. For example, for December 1979, the statistics would show the amount at or below which 10 percent of the 1,600 pharmacists purchased a particular drug, 20 percent purchased the same drug, and so on through the 90th percentile.

HHS officials normally consider that, if the 70th percentile shows at least two or three major manufacturers from which the drug can be purchased at the MAC limit or less, the existing MAC limit is sufficiently high to assure availability of the drug entity. HHS has never raised a MAC limit, but several limits have been lowered. However, as of November 1980, HHS had suspended the MAC limits on three drug entities because the alternative supplier had increased its price.

We compared the IMS statistics at the 70th percentile with 30 of the 31 MAC limits existing as of June 1979. One MAC limit was excluded because the drug entity it covered was not listed in the IMS statistics. If at least three major manufacturers sold the drug at prices below the MAC limit, we considered that the highest of the three prices would be a reasonable MAC limit. If this price was below the existing limit, the MAC could be lowered. If fewer than three manufacturers sold the drug at prices below the existing MAC limit, the limit may need to be raised. Of 30 MAC limits reviewed, 9 could be lowered by applying the informal HHS criteria and 5 others could possibly be lowered. For these

five, the IMS statistics showed three or more major manufacturers with prices below the MAC limits; however, the IMS prices were based on larger package sizes than were used for the MAC limits. MAC limits are supposed to be established based on the most frequently purchased package size, and the IMS data indicated that the larger size was the most frequently purchased. Also, one of the existing MAC limits could have been raised. The following schedule details the results of our analysis.

Drug	Existing MAC limit per capsule, tablet, or cc	Amount of MAC limit using informal criteria	Percent decrease (+ increase)
1. Ampicillin capsules, 250 mg, 500s (note a)	$ .0595	$ .0439	-26.2
2. Ampicillin capsules, 500 mg, 100s	.1103	.1090	-1.2
3. Ampicillin oral liquid, 125 mg/5 cc, 100 cc	.0145	.0110	-24.1
4. Ampicillin oral liquid, 250 mg/5 cc, 200 cc (note a)	.0205	.0134	-34.6
5. Penicillin VK tablets, 250 mg, 100s	.0535	.0370	-30.8
6. Penicillin VK tablets, 500 mg, 100s	.1025	.0619	-39.6
7. Penicillin VK oral liquid, 125 mg/5 cc, 100 cc	.0120	.0115	-4.2
8. Penicillin VK oral liquid, 250 mg/5 cc, 200 cc (note a)	.0160	.0116	-27.5
9. Tetrocycline HCl. capsules, 250 mg, 1,000s (note a)	.0250	.0159	-36.4
10. Tetrocycline HCl. capsules, 500 mg, 100s	.0465	.0395	-15.1
11. Chlordiozepoxide HCl. capsules, 10 mg, 500s (note a)	.0378	.0179	-52.6
12. Chlordiazepoxide HCl. capsules, 25 mg, 100s	.0640	.0438	-31.6
13. Erythromycin stearate tablets, 250 mg, 100s	.0697	.0551	-20.9
14. Amoxicillin capsules, 250 mg, 100s	.2108	.2084	-1.1
15. Meprobamate tablets, 400 mg, 100s	.0117	.0135	(+15.4)

a/These are the package sizes reflected in the IMS statistics. The existing MAC limit was based on a package size of 100 cc or 100 capsules. There is some question about the ability to split 200 cc package sizes into smaller dispensing quantities which could affect the ability to set the MAC on the larger size. However, no such problem exists for the larger package sizes of capsules.

When informed of the results of our test, HHS officials told us they did not have the necessary staff to keep the MAC limits as current as they should be.

The amount of savings that can accrue from the MAC program, and the fairness of the program to drug providers, depends directly on the reasonableness of the MAC limits. We believe HHS should have a formal and consistently applied mechanism for keeping MAC limits current.

MAC PROGRAM HAS LITTLE APPLICABILITY FOR INPATIENT DRUGS

The MAC program has had little if any impact on inpatient hospital costs because (1) Medicare was not enforcing MAC limits and (2) even if it did, the types of drugs covered by MAC do not appear to be those with the greatest cost saving potential in the hospital inpatient setting.

MAC limits apply to drugs provided to Medicare and Medicaid patients in hospitals and nursing homes. To determine if savings have resulted in the inpatient drug program, we reviewed Medicare's enforcement of MAC limits. Because Medicaid generally follows Medicare's hospital reimbursement policies, we believe our findings regarding Medicare hospital drug costs should generally apply also to Medicaid.

We did not review Medicare enforcement of MAC limits in nursing homes because relatively little is spent on this benefit. In most cases, drugs provided to Medicaid patients in nursing homes are supplied by community pharmacies and are billed and paid in the same manner as Medicaid outpatient drugs. Therefore, the findings discussed on pages 9 to 12 include drugs provided to Medicaid patients in nursing homes.

HHS administers the Medicare inpatient hospital program through contracts with intermediaries that reimburse hospitals on the basis of their reasonable costs of providing covered services to Medicare patients. HHS policy states that drugs will be reimbursed on a reasonable cost basis to be determined by what "a prudent and cost-conscious buyer would pay" for the drug. For drugs with a MAC limit, reasonable cost is defined as the lowest of actual cost, the amount a prudent and cost-conscious buyer would pay, or the MAC limit. One exception exists: the MAC limit may be exceeded if a physician certifies that a specific brand of drug, the cost of which exceeds the MAC, is medically necessary for the patient.

Intermediaries are required to determine the sources from which hospitals obtain their drugs. If a hospital obtains drugs from manufacturers or a recognized wholesale outlet, the intermediary is not required to make a special audit to determine if the MAC regulations are being complied with. The intermediary may, however, check for MAC compliance during other provider reviews. If a hospital does not have its own pharmacy, it will generally obtain drugs under arrangements with a local pharmacy. For example, a small hospital may have an arrangement with a local pharmacist to supply its drug needs. For these situations the Medicare instructions call for periodic evaluations of drug costs by the intermediary. Specific guidance is given in the instructions for carrying out these evaluations.

Guidelines are being implemented in different ways or ignored

Intermediaries we visited implemented the guidelines differently; as a result, some are not bothering to determine the source from which some or all of the hospitals purchase drugs. For example, one intermediary followed the practice that, if a provider purchases 90 percent or more of its drugs from wholesalers or manufacturers, the guidelines applicable to purchases from this source apply. If the percentage is less than 90, the procedures applicable to "arrangement" purchases are applied. Another intermediary in the same State completely ignored the requirements to identify the source of providers' drug purchases. In all five States we visited, intermediary officials said they did not perform any specific audit steps to check for compliance with MAC limits.

Hospitals are purchasing drugs at costs above the MAC limits but excess costs appear minimal

We reviewed drug purchases in three hospitals in each of four States covered by our review and five hospitals in the fifth State. In 14 of the 17 hospitals, some MAC drugs had been purchased for amounts exceeding MAC limits. Of a total of 93 drug purchases reviewed, 35 involved costs that exceeded the MAC limits, as shown in the following table.

State	Number of hospitals visited	Number of hospitals where purchases exceeded MAC limits	Number of purchases reviewed	Number of purchases where cost exceeded MAC limits	Total cost over MAC	Time period
California	5	4	34	15	$ 809	1 year
Florida	3	2	12	3	40	3 months
Georgia	3	3	13	3	199	3 months
New Jersey	3	2	16	3	7	(a)
Texas	3	3	18	11	315	6 months
Total	17	14	93	35	$1,370	

a/Based on most recent purchase.

In an earlier review of hospital purchasing of routine supply items including drugs, 1/ we obtained the prices paid by 37 hospitals in six cities across the Nation for four drugs covered by MACs, as well as other items. Of 80 purchases of the four MAC drugs that were reviewed, 14 (17.5 percent) involving 6 of the 37 hospitals exceeded the MAC limits by between 15 and 81 percent. On the other hand, on an annual basis the total amount paid over the MAC limits by the six hospitals was only $1,100.

None of the intermediaries included in the earlier review were checking hospital compliance with MAC limits. Reasons given by the intermediaries, and HHS, for not adhering to program requirements were (1) the MAC limits were set so high that it was improbable that any hospital would exceed them and (2) checking compliance would not be cost effective. We believe the results of our earlier review and this review indicate that hospitals often do purchase drugs at prices exceeding MAC limits. However, because of the relatively small excess costs associated with the MAC drugs, our findings tended to support the intermediaries' and HHS' second rationale for not enforcing the MAC program as presently focused.

1/"Hospitals in the Same Area Often Pay Widely Different Prices for Comparable Supply Items" (HRD-80-35, Jan. 21, 1980.

The low excess costs resulted because of the small quantities of MAC drugs bought by the hospitals. For example, MAC drugs accounted for only about 0.5 percent of total drug purchases in the three Texas hospitals visited. Historically, drugs were put under MAC based on their use in the outpatient setting. However, hospitals do buy certain drug entities in volume, and placing MACs on such drugs could be worthwhile because Medicare and Medicaid do pay substantial amounts for inpatient drugs. 1/

For example, our earlier hospital procurement review identified intravenous solutions, irrigating solution, and barium sulfate--all prescription drugs--as good candidates for price monitoring because of the large price variances and the large quantities purchased by hospitals in certain cities.

DRUG QUALITY ISSUES AFFECTING SUBSTITUTION UNDER THE MAC PROGRAM AND UNDER STATE DRUG SUBSTITUTION LAWS

According to proponents, the chief benefit of the MAC program and of State drug substitution laws (see ch. 4) is their potential for significant savings for the Government and for consumers without adverse effect on quality of care. Pharmacists have greater opportunities to exercise their professional judgment by selecting lower cost products for inventory and by substituting a generic product for the prescribed brand. Critics of these programs assert that, for various reasons, all products within the same drug entity are not of equal quality and, therefore, would not have the same therapeutic effect. They also question FDA's ability to ensure equivalence. For example, in a May 1979 position paper, the Pharmaceutical Manufacturers Association, a trade association representing about 133 drug manufacturing firms, stated:

1/About 3 percent of total hospital costs are for drugs. During 1979 Medicare and Medicaid paid hospitals about $25 billion for inpatient hospital services. Assuming the same ratio, the costs to these programs for drugs were about $750 million.

"FDA's capability to assess technical equivalence is also suspect since investigations by the GAO and the House Appropriations Committee found FDA deficient in performing plant inspections and enforcing good manufacturing practices."

We made no attempt to settle scientific disagreements over drug quality. 1/ However, we made a limited analysis of (1) how often FDA inspected selected drug manufacturing firms and (2) drug recall data.

FDA is required by law to inspect drug manufacturing firms every 2 years. We reviewed the inspection files for 13 randomly selected drug manufacturers. Twelve were generic drug manufacturers, and one was a major brand-name manufacturer. All firms had been inspected by FDA within 2 years preceding our review, and most had been inspected more often.

We also reviewed recall data on file at FDA. These data indicated that, while manufacturing problems exist, they are not limited to the generic or small manufacturers. The following schedule summarizes recalls for 1973-78.

Year	Total recalls	Number attributable to 27 nationally known brand-name manufacturers
1973	384	23
1974	332	35
1975	488	29
1976	308	45
1977	348	16
1978	336	26
Total	2,196	174 (7.9%)

1/For a discussion of pertinent issues, see the FTC report, "Drug Product Selection"--Staff Report to the Federal Trade Commission, prepared by the Bureau of Consumer Protection, January 1979.

While the percentage of recalls for major manufacturers appears relatively small, this can be misleading. According to FDA Quality Assurance officials, the individual recalls for the large firms may be more significant in terms of dollars and health hazards than those of the smaller firms because of the volume of drugs involved.

The following discussion sets forth several factors which, according to FTC and HHS, mitigate the concerns over drug quality.

In both the MAC program and in all State drug substitution laws, physicians retain ultimate authority over the product selected through their prerogative to require that prescriptions be filled with a specific brand if, in their judgment, it is necessary for a particular patient. According to FTC, drug substitution laws only make it more convenient for physicians who customarily prescribe by brand name to delegate product selection authority to pharmacists. The laws do not require such delegation. Further, FDA believes that, if one therapeutically equivalent drug product is substituted for another with due professional regard for the individual patient, there is no substantial reason to believe that the patient will receive a drug product that is different in terms of therapeutic effect.

In its search FTC failed to identify a single lawsuit or insurance claim against a pharmacist who legally substituted. The executive director of the American Pharmaceutical Association knew of no liability suit against a pharmacist concerning substitution that had been successfully litigated. He added that a pharmacist's professional liability insurance premium is only about $25 a year. An FDA official said that a recent study showed that the cost of liability insurance for pharmacists was very low.

In addition to the physician's control over product selection and the lack of litigation against pharmacists, HHS maintains that under the MAC program it exercises care in selecting only drugs specifically cleared on a quality basis by FDA. When the Pharmaceutical Reimbursement Board is considering a drug for a MAC limit, it seeks FDA's advice about any pending or anticipated regulatory activity which, in FDA's opinion, would warrant a delay of Board action.

Appendix I outlines the specific steps FDA follows in reviewing drugs proposed for MAC limits. Among these are

--verifying that manufacturers of the drug have had their plants inspected in the last year and, when last inspected, were in compliance with FDA's Good Manufacturing Practices regulations;

--determining whether any change in the drug standard is pending; and

--ensuring that there are no known bioequivalence problems.

As of October 1979, the Pharmaceutical Reimbursement Board had submitted seven groups of MAC candidate drugs to FDA for review. The following table summarizes FDA's review of these groups.

Group number	Number of drug entities		
	Submitted	Approved	Rejected
1	6	6	0
2	5	5	0
3	9	7	2
4	10	7	3
5	20	15	5
6	26	15	11
7	38	8	30
Total	114 (100%)	63 (55%)	51 (45%)

These statistics indicate that FDA's approval of MAC drugs has not been a rubber stamp operation. HHS officials informed us that FDA has taken a conservative approach in reviewing MAC drug candidates. The reasons for rejection of the 51 drug entities vary widely; the most common was bioequivalency (drug absorption) related problems.

We reviewed HHS' file for all drug entities in drug group number 4 to determine if FDA had actually performed all the steps required. We observed no compliance deficiencies.

CONCLUSIONS

For the five States reviewed, we projected annual savings of about $1.4 million under the Medicaid outpatient drug program which could be reasonably attributed to MAC. An HCFA-financed study in another State projected annual savings of from $204,000 to $237,000.

The MAC limits were not being implemented in a timely manner by the States. In two States we quantified excess costs of at least $42,200 for which the States improperly claimed and were paid Federal sharing. The Federal share of these excess payments should be recovered. A larger issue, however, involves a general compliance problem under the MAC program and the extent to which HHS can reasonably be expected to expend its resouces to identify and quantify such noncompliance. We believe it would be preferable for the States to systematically identify such ineligible costs and, if they believe delays in implementation are justified or unavoidable, request HHS to grant a waiver. In any event, we believe that HHS should focus its corrective action on assuring that States' claims processing systems systematically identify and quantify the payments in excess of MAC limits not eligible for Federal participation. 1/

We also believe that the savings under the Medicaid outpatient drug program could be greater if HHS systematically updated the MAC limits because, by applying an informal criterion for testing the reasonableness of the limits, we found about one-third of the MAC limits as of June 1979 could have been lower using the more current data.

1/On October 7, 1980, the Congress enacted Public Law 96-398, the Mental Health Systems Act, which included a provision that would provide a vehicle for implementing such an approach. Essentially the amendment would require all States--unless waived--to install computerized claims processing and information retrieval systems within specified deadlines which meet performance standards and system requirements established by HHS or be subject to financial penalties. We believe that the capability to identify ineligible payments in excess of the MAC limits would be a reasonable requirement.

Concerning inpatient hospital drugs, HHS has an elaborate regulatory and administrative structure for implementing the MAC program which is not operative and apparently focuses on the wrong drugs to be cost effective in an inpatient setting. We believe that HHS should either (1) eliminate the regulatory and administrative requirements that are not being adhered to or (2) enforce the existing MAC requirements, but refocus them on the types of drugs that hospitals buy in sufficient quantity to make the enforcement effort worthwhile. Otherwise, HHS will continue to have superfluous regulatory and administrative requirements on the books.

RECOMMENDATIONS

We recommend that the Secretary of HHS direct the Administrator of HCFA to:

- Recover from California and Florida the Federal share of excess costs attributed to the delays in implementing the MAC limits.

- Require State claims processing systems to identify costs ineligible for Federal sharing through implementation of the recently enacted amendment in S. 1177 or under existing authority.

- Provide for the systematic and formal updating of the MAC limits.

- Reevaluate the applicability of the MAC program to the inpatient hospital setting with the view toward eliminating the existing regulatory and administrative structure which is not being enforced or focusing on the forms or types of drugs which would make the structure worthwhile.

CHAPTER 3

STATE EAC PROGRAMS: INTENDED EFFECT IS NOT BEING FULLY REALIZED

The EAC program was designed to move the States away from using Average Wholesale Prices (AWPs) 1/ as a basis for establishing drug reimbursement limits. HHS had estimated that AWPs typically were 15 to 18 percent higher than the prices at which pharmacists could obtain drugs. The five States reviewed still used AWPs as the primary data source to set limits, and other studies have reported similar conditions in other States; however, the effect of the EAC program's failure to meet this objective is difficult to measure because:

--The data HHS furnished to help States establish the EAC limits often produced amounts very similar to the AWPs.

--States (particularly California) had their own MAC programs for many drug entities and had other special EAC programs which resulted in lower reimbursement limits. The State MACs produced much lower reimbursement limits than those priced on a brand-name basis using either the HHS-furnished EAC data or the AWPs.

Overall, we believe HHS encouragement of State MAC programs and other types of special EAC programs likely would produce lower drug costs under Medicaid than its efforts to monitor the existing EAC program.

THE EAC PROGRAM

The EAC program differs from the MAC program primarily in that EAC reimbursement limits

--are established for all drugs, both single- and multiple-source (even if the drug has a MAC),

--are set by each State as opposed to HHS establishing one nationwide limit, and

--apply only to Medicaid.

1/Average Wholesale Prices are published in such documents as the "Drug Topic Redbook."

Before the requirement that States establish EAC programs to contain Medicaid drug costs, HHS directed the States to establish "upper limits" above which payments for drugs would not be made. The regulations gave the States considerable latitude in establishing and running their programs and did not require uniform procedures among States.

HHS became concerned because State reimbursement limits were being based on published AWPs that reportedly exceeded by 15 to 18 percent the amounts at which pharmacists could obtain drugs. HHS' position, published in the Federal Register on July 31, 1975, was

> "Average wholesale price is not currently determined by surveying drug marketing transactions (i.e., by determining the actual price a pharmacist pays to a manufacturer or wholesaler for a particular drug product), and thus published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers."

HHS proposed regulations that would have limited reimbursement to the lowest of (1) the MAC limit, if any, plus a reasonable dispensing fee, (2) the pharmacist's actual acquisition cost plus a reasonable dispensing fee, or (3) the provider's usual and customary charge to the public. However, numerous comments were received opposing adoption of an actual acquisition cost requirement because of the difficulty of administration. As a result, HHS dropped that requirement and replaced it with a program based on estimates of pharmacy acquisition costs. Each State was required to make its own estimates, which were supposed to be as close as possible to the prices generally and currently paid for drugs by pharmacists. These estimates also were to be consistent with price information that HHS would furnish the States.

In February 1976, HHS began supplying States with invoice level price data furnished under contract by IMS America. The

data, which are obtained monthly, are the drug prices charged to a nationwide sample of about 1,000 pharmacists. 1/

HHS suggested that States use the 70th percentile of these data as a "benchmark" for evaluating their EAC limits. HHS guidance said that States found to be reimbursing at levels above the 70th percentile would be expected to provide evidence that their reimbursement levels were closer to the pharmacists' actual cost than the HHS-supplied data.

MANY STATES STILL BASE EACs ON AVERAGE WHOLESALE PRICES

Although the EAC program was intended to move States away from basing drug reimbursement limits on the AWP, it has not been fully successful in doing so. A study of 45 States and the District of Columbia performed in 1979 by Abt Associates, 2/ under contract with HHS, showed that in 1977 and 1978, 28 and 27 States, respectively, still used the AWP to some extent in establishing reimbursement limits for ingredient costs. One State (West Virginia) was reported to use the AWP exclusively as a basis for reimbursement, and another State (Arkansas) reimbursed at the lower of the AWP or the provider's usual and customary charge.

All five States included in our review based their EAC limits on the AWP to some extent. Three of the five States had "Special EACs" or "Direct Purchase EACs" (special methods for determining EACs for some drugs). Three States also had State MAC programs. The following table summarizes the methodologies used by the five States in setting their EACs and State MAC limits.

1/The IMS statistics are based on a sample of about 1,600 pharmacies. However, before providing the data to the States, HHS refines the sample to about 1,000 pharmacies. This is done to provide a better balance in the statistics between large and small pharmacies.

2/"Evaluation of the Maximum Allowable Cost (MAC) for Drugs Program; Phase I Report--Final Design Report and Report of Pilot Study Analysis"; Abt Associates, Cambridge, Massachusetts; September 28, 1979.

State Methodologies Used to Establish EAC Limits

	Description of methodologies			
	Basic EAC	State MAC	Special EAC	Direct purchase EAC
California	AWP as listed in Redbook or Bluebook for all drugs not covered by a Federal MAC, State MAC, Special EAC, or Direct Purchase EAC.	Established in accordance with State procedures, which are similar to Federal procedures for establishing MACs.	For drugs that are usually purchased in larger package sizes: --AWP for a large package size or --the direct price of the larger package size if it is manufactured by 1 of the 11 manufacturers for which the State uses the direct purchase price.	The direct purchase price as listed in Redbook or Bluebook if the product is manufactured by any of the 11 manufacturers for which the State uses the direct purchase price.
Florida	The wholesale price of a major wholesaler who supplies Florida providers or, if this information is unavailable, --the AWP from Redbook, or --a determination of AWP based on manufacturers bulletins or other available sources.	Established in accordance with State procedures which are similar to Federal procedures for establishing MACs.	For 47 drugs that are usually purchased in larger package sizes, the AWP for the larger package size.	
Georgia	The wholesale price of two wholesalers who supply Georgia providers, or, if this information is unavailable, --the AWP from Redbook or --a determination of AWP based on manufacturers bulletins or other available sources.	Established in accordance with State procedures, which are similar to Federal procedures for establishing MACs.		
New Jersey	AWP as listed in Redbook. This is reduced by a graduated discount of up to 6 percent, depending on the pharmacy's prescription volume.			
Texas	AWP as listed in Redbook. The provider must indicate that the drug dispensed was purchased from a wholesaler if this limit is to be applied.			The direct purchase price as listed in Redbook if the drug can be purchased directly from the manufacturer is applied unless the provider indicates that the drug dispensed was purchased from a wholesaler.

The methodology used to derive the "Basic EAC," which represents the vast majority of drugs (except for California), was normally the AWP. All five States had taken some action to set the limits on some drugs below the AWP. Some of these efforts, such as the State MAC programs in Florida, Georgia, and California, produced limits that were lower than those based on the AWP.

HHS' SUGGESTED "BENCHMARK" IS NEAR AVERAGE WHOLESALE PRICES

HHS supplies invoice level price statistics (the IMS America data) to the States for use in evaluating their EAC limits. The statistics are based on invoice prices and do not reflect several types of discounts--such as end-of-year discounts, prompt payment discounts, total order discounts, and any other discounts, rebates, or free goods that do not appear on the pharmacists' invoice.

For the 85 most frequently prescribed brand-name/branded generic drugs, we compared the 50th, 70th (HHS' suggested benchmark), and 90th percentile of the IMS data for the last half of 1978 to the AWP as published in the January 1979 Drug Topics Redbook. The 85 drugs had a total of 683 different drug entities (different strengths, forms, and package sizes); however, IMS statistics were available for only 211 of these entities. The results of our comparisons are summarized in the following table.

	Percentile of IMS invoice price					
	50th		70th		90th	
	Number	Percent	Number	Percent	Number	Percent
IMS higher than AWP	2	0.9	27	12.8	81	38.4
IMS equal to AWP	57	27.1	55	26.1	49	23.2
IMS lower than AWP	152	72.0	129	61.1	81	38.4
Total	211	100.0	211	100.0	211	100.0

In 39 percent of the cases we examined, IMS data at the 70th percentile equaled or exceeded the AWP. In another 20 percent, IMS data were not more than 5 percent less than the AWP. Thus, in 59 percent of the cases, IMS price data at the 70th percentile were no more than 5 percent less than the AWP. This comparison tends to contradict HHS' view that the AWP exceeded the price at which pharmacists could obtain drugs by 15 to 18 percent. The AWP/IMS comparison indicates that either (1) HHS' position on the reasonableness of AWPs was not (or is no longer) correct or (2) IMS data at the 70th percentile are not an adequate substitute for the AWP.

Our results are similar to those of a 1979 study sponsored by a grant from Roche Laboratories which compared the Redbook AWP with the 70th percentile of the IMS statistics for 222 drugs entities. 1/ It reported that, for over half (119) of the drugs examined, the 70th percentile of the IMS data was equal to the AWP. For another 32 drugs, the 70th percentile of IMS exceeded the AWP, and for only about a third (71) of those drugs examined was the 70th percentile of IMS less than the AWP.

A 1978 study 2/ suggested that the IMS data were at least 60 and perhaps 90 days out of date when the States receive them and that most States simply ignored them. A 1979 study, 3/ based on questionnaire responses from 47 State Medicaid agencies, found that only 9 States used the IMS statistics to any extent in setting EAC limits and that these States usually based their limits on the 70th percentile or higher.

1/"Federal Control of Pharmaceutical Costs, the MAC Experience," report prepared for Roche Laboratories Division of Hoffman La Roche, Inc. (May 1979), Jean Paul Gasnon and Raymond Jang, pp. 56-59.

2/"An Analysis of State Reimbursement Programs to Identify and Develop MAC Program Evaluation Options," reported by Applied Management Sciences, Inc. (HEW Contract No. HRA 230-77-0077), June 1, 1978, Robert T. Deane, Roger J. McClung, and Douglas E. Skinner, p. 4.12.

3/"Evaluation of the Maximum Allowable Cost (MAC) for Drug Programs," report by Abt Associates, Inc. (HEW Contract No. 500-78-0019), September 28, 1979, A. James Lee, Dennis Hefner, and Ralph Hardy, Jr., p. 84.

STATE MAC PROGRAMS SUPERSEDE EAC LIMITS

Three of the five States we reviewed had their own MAC programs which had the effect of superseding the conventional EAC limits for a number of drugs. This in turn resulted in wide differences among the States in their reimbursement limits and average amounts paid. Also the States used larger package sizes for establishing their limits, which also resulted in lower limits and payment levels.

State MAC programs

A number of States (at least 16 as of 1978), including 3 of 5 we visited, have had or still have their own version of a MAC program for Medicaid. Most of these States initiated their programs before the Federal MAC program became effective in August 1976.

As discussed in chapter 2, California had its own MACs on 9 of 15 drug entities that had Federal MACs as of December 1978. Of these nine, seven had State MACs below the Federal MACs. Also, California had established MACs for 87 drug entities that did not have Federal MACs. 1/

Reimbursement limits and rates of payment for selected drugs vary widely among the States

We compared the EAC limits and the average amount paid by the five States for the various entities of the 85 most frequently prescribed drugs. The average amount paid was determined in the same manner as for our MAC analysis (see p. 9), which excludes dispensing fees. The results of the comparison for 10 selected drugs, which are fairly representative of all the comparisons, are presented in the following table.

1/We analyzed cost data for 13 of these 87 drug entities (using the same methodology as used for our analysis for savings from Federal MACs). The analysis showed annualized savings of about $629,000.

Comparison of Reimbursement Limits and Average Payments for Selected Drugs

Drug/form/ strength/ package size	Limit/average payment per package size indicated: California	Florida	Georgia	New Jersey (note a)	Texas (note b)	Percent difference between lowest and highest
Benadryl, capsules, 25 mg, bottle of 100	c/$1.26	d/$3.51	$4.31	$3.94	$4.10	242
	.77	2.56	3.03	3.12	3.82	396
Butisol Sodium, tablets, 15 mg, bottle of 100	c/.53	d/2.22	2.22	2.13	2.22	319
	.20	1.90	1.87	1.86	2.16	980
Esidrix, tablets, 50 mg, bottle of 1,000	c/2.60	c/4.00	c/3.36	6.00	6.07	134
	1.95	3.47	2.98	5.47	4.49	180
E-Mycin, tablets, 250 mg, bottle of 100	c/6.97	16.23	16.23	15.55	16.24	133
	6.42	12.20	13.52	14.69	14.04	129
Hydrodiuril, tablets, 50 mg, bottle of 5,000	c/2.60	c/4.00	(f)	6.16	5.70	137
	1.95	2.37	(f)	5.61	4.65	188
Mellaril, tablets, 200 mg, bottle of 1,000	24.00	22.80	22.80	23.04	22.80	5
	23.07	18.33	20.91	22.13	22.50	26
Premarin, tablets, 0.625 mg, bottle of 1,000	(f)	5.34	5.34	5.08	4.97	7
	(f)	2.34	3.49	4.38	4.62	97
Thorazine, tablets, 100 mg, bottle of 100	c/3.45	5.85	5.85	5.62	5.85	68
	3.26	4.96	5.03	5.08	5.85	79
Triavil-25, tablets, 4 mg, bottle of 100	e/14.25	16.51	16.92	16.24	16.92	19
	13.93	14.94	15.44	15.82	16.03	15
Valium, tablets, 5 mg, bottle of 500	e/9.87	10.79	11.46	11.24	11.39	16
	9.05	8.48	9.09	9.95	10.60	25

a/New Jersey establishes its EACs at the AWP and adjusts the EAC for each pharmacy by reducing it by up to 6 percent based on the pharmacy's Medicaid volume. The figure given here is the AWP reduced by 4 percent, which the State said was the average reduction.

b/Texas establishes two types of EACs. One is for drugs purchased from wholesalers, and the other is for drugs purchased from manufacturers. The EAC shown is the one for wholesalers. Data on amounts the State paid for prescriptions do not distinguish between which EAC was used, so the average price paid presented here represents the average of the amount paid under both EACs.

c/The State has established a MAC for this drug that may be less than what the pharmacist actually paid for the brand listed. If so, the number of prescriptions filled with the listed brand name is normally quite low.

d/The State established its EAC based on a package size larger than 100 tablets or capsules.

e/The State established its EAC based on the direct purchase price from the manufacturer.

f/The drug was not covered under the State's Medicaid program or data were not available.

Both the EAC limits and the average amounts paid vary widely. Most of the large variations can be explained by one or more States having a MAC on the drug in question; thus, the MAC supersedes the EAC unless the physician overrides. Other variations are partially explained by one or more States having used another special procedure, such as direct purchase price or larger package sizes, to establish the EAC for the drug entity.

Setting reimbursement limits on larger package sizes

In a 1974 study of the California Medicaid program, we found that certain high-volume drugs were being purchased by pharmacists primarily in larger package sizes (500 or 1,000 capsules or tablets) because of the substantial discounts available. The State was basing its Medicaid reimbursement limits for these drugs on the higher cost package size of 100 capsules or tablets. We estimated that the State officials could save over $800,000 annually by basing reimbursements on the larger package sizes of the top 10 drugs and suggested that they do so. Medicaid regulations call for basing reimbursements on the price of the most frequently purchased package sizes, which our data showed were the larger sizes.

On March 6, 1977, California began basing reimbursements for 11 drug entities on larger package sizes. In analyzing State data, we found that over $611,000 in savings resulted from the change during the first year. California added 10 additional drugs to this program on July 1, 1979, and estimated that additional annual savings of over $886,000 would result.

Florida also bases its EAC reimbursement limits for 47 drug entities on larger package sizes. State officials had not attempted to determine the savings resulting from this policy. We believe the savings should be worthwhile, however, because of the significant discounts available to pharmacists from purchasing in larger package sizes.

CONCLUSIONS

Because HHS believed that the AWPs were too high, a primary objective of the EAC program was to get the States away from using this source as the basis for establishing upper reimbursement limits under their Medicaid drug programs.

Although this objective has not been met, we cannot conclude that the adverse effect has been significant because our analysis of the HHS-furnished data designed to help States establish the EAC limits showed that the two prices were often very similar. Other studies have reported the same condition.

On the other hand, when a State like California, in effect, supersedes the EAC limits and applies the MAC multiple-source drug approach to a wide number of drugs, the resulting lower limits appear very significant. Further, some States have modified and lowered their EAC limits to recognize the quantity discounts realized by pharmacies by buying drugs in larger package sizes.

We believe California's experience shows that a State can reduce Medicaid drug costs by superseding the EACs and establishing MACs for drugs that may not meet the criteria for establishing a Federal MAC nationwide, but can justify a statewide MAC. California's experience also shows that States may be able to establish MACs at levels below the Federal MAC and thereby obtain additional savings. This can result because of the existence of regional drug suppliers selling drugs at prices below which the drug is available nationwide, the criterion HHS uses in establishing a Federal MAC. Thus, HHS should encourage the States to establish their own MACs where it is cost effective. HHS should also give the States technical assistance to enable them to do so and help the States obtain the information necessary for determining the MACs. In effect, a State MAC program is the State's EAC program for the drug entities covered.

In addition, HHS should encourage States to establish their EACs based on larger package sizes or on direct purchase prices when such actions are appropriate so that the savings available from those approaches can be realized.

RECOMMENDATIONS

We recommend that the Secretary of HHS direct the Administrator of HCFA to encourage the States to:

--Review their EAC drug limits to identify drugs that would be suitable for the MAC multiple-source approach on a statewide basis.

--Review the Federal MAC limits to determine whether a lower statewide MAC would be reasonable and appropriate.

--Determine the package sizes most commonly purchased by pharmacists and adjust their EAC levels accordingly.

--Determine drugs for which it is appropriate to establish EACs based on direct purchase prices and then do so.

CHAPTER 4

STATE SUBSTITUTION LAWS COULD SUBSTANTIALLY REDUCE DRUG COSTS FOR ALL CONSUMERS

Over the past few years, increasing emphasis has been given to controlling drug costs to the public. A primary effort in this direction has been the States' enactment of drug product selection laws, commonly known as substitution laws. These laws either permit or require pharmacists to dispense a less costly, but therapeutically equivalent product, when a brand-name drug is prescribed by a physician and to pass along all or part of the resulting savings to the consumer. As of December 31, 1979, 45 States and the District of Columbia permitted drug substitution with more than half allowing it only since 1976.

Because of the recency of most substitution laws, their effectiveness has not been thoroughly studied. We reviewed the studies that have been performed and obtained some data on our own. This information indicates that substantial savings to the public (including the Medicaid program) can be realized through effective drug substitution programs.

BACKGROUND ON SUBSTITUTION LAWS

After World War II the number of prescription drugs marketed by manufacturers increased dramatically. The prescription drug market shifted from one dominated by products compounded by the pharmacist to one where premanufactured products became the norm. Many imitations of the brand-name drugs of the major manufacturers appeared. Controls over drug manufacturers were not very stringent, and several serious health problems resulted from substituting nonquality imitations.

In 1952 the American Pharmaceutical Association, the National Association of Boards of Pharmacy, the American College of Apothecaries, and the National Conference of State Pharmaceutical Association Secretaries jointly recommended enactment of laws and regulations requiring pharmacists to dispense drugs exactly as prescribed by the physician. These groups jointly condemned "as unethical the dispensing of a pharmaceutical preparation or brand thereof other than that ordered or prescribed." Every State subsequently enacted antisubstitution laws or regulations. Only the District of Columbia did not.

Over the years stricter Federal controls over drug products and manufacturers were instituted, and the need for antisubstitution laws was questioned. In 1970 the American Pharmaceutical Association committed itself to seeking the repeal of antisubstitution laws. In 1971 it made three principal points in favor of substitution laws:

--The prescribing of a brand-name drug cannot be taken as a conscious selection by the physician of a source of supply.

--Pharmacists should be allowed to exercise their professional expertise in selecting a source of supply.

--Permitting pharmacists to substitute would lower drug prices to the consumer.

CHARACTERISTICS OF SUBSTITUTION LAWS

The specific provisions of substitution laws vary from State to State. 1/ However, a number of characteristics are shared by all or most of the laws. First, a substitution law may be mandatory or discretionary. Nine States require pharmacists to substitute a lower cost generic drug whenever possible, while 36 States merely permit substitution.

Most (27) of the substitution laws include a provision for a formulary. Eight States have formularies that list drugs for which substitution is not permitted, 14 States and the District of Columbia list drugs for which substitution is allowed, and 4 States have some other type of formulary.

All substitution laws allow physicians to prohibit substitution. Twenty States and the District of Columbia require the physician to add a phrase on the prescription form, such as "dispense as written," "brand necessary," or "medically necessary," to preclude the pharmacist from substituting for a brand-name drug. Twenty-five States require the physician to consent to substitution by signing or checking one of the alternative instructions preprinted on the prescription form, such as "substitution permitted" and "dispense as written." If the physician does nothing, substitution is prohibited in

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1/The information contained in this report regarding the provisions of State drug substitution laws was extracted from the FTC staff report on "Drug Product Selection," prepared by its Bureau of Consumer Protection, January 1979.

25 States but permitted by 20 other States and the District of Columbia. Twenty-seven States require that the patient be told that substitution has taken place, and 18 of these also require that the patient agree to the substitution.

Most substitution laws also deal with how savings are apportioned between the pharmacist and the consumer. Many of these laws are difficult to interpret. However, after studying them, the National Pharmaceutical Council concluded that 15 States require the pharmacist to pass on all savings to the consumer while 18 permit the pharmacist to share in the savings.

Finally, some substitution laws have provisions relating to other areas associated with substitution, such as limiting physicians' liability or specifying labeling and recordkeeping requirements.

Appendix II lists by State the key provisions of substitution laws.

INTEREST IN SUBSTITUTION

In January 1979 FTC issued a report on drug product selection, 1/ completing a 2-year study to determine whether price competition for multiple-source prescription drugs is unduly restricted by State antisubstitution laws that prohibit pharmacists from selecting lower cost sources of drugs. In its study, FTC sought information from numerous sources, including major brand-name drug manufacturers, trade associations, pharmacy and medical associations, the deans of all the Nation's colleges of pharmacy, consumer groups, State pharmacy boards, associations and formulary commissions, other Federal agencies, and business organizations. In addition, FTC commissioned (1) an economic assessment on the potential impact of substitution on manufacturers' research and development incentives and (2) an opinion survey of pharmacists' attitudes toward their State's substitution law.

The FTC report concluded that antisubstitution laws impose substantial unwarranted costs on consumers by unduly restricting price competition in the multiple-source prescription drug market and that repealing these laws would produce

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1/Ibid, p. 24.

significant consumer benefits without compromising the quality of health care. To remedy the situation FTC recommended that States adopt the Model Drug Product Selection Act, which is jointly endorsed by FTC and HHS. HHS estimated consumers would save $400 million per year if the model law was adopted by all States.

At the same time, FDA announced that it had compiled a list of therapeutically equivalent drugs to promote public education, foster containment of health costs, and help States administer their substitution laws. The list contains about 5,000 single- and multiple-source prescription drugs that FDA estimated to be about 30 percent of all prescription drug products and about 75 to 80 percent of the sales volume of prescription drugs. The list shows all manufacturers of approved, therapeutically equivalent generic drugs. FDA anticipated publishing the list annually with periodic updates. The list was prepared in response to States' requests for assistance in preparing formularies for substitution laws.

FDA considers pharmaceutically equivalent drug products to be therapeutically equivalent if they are approved for safety and effectiveness, are manufactured in accordance with current Good Manufacturing Practice regulations, meet the same or equivalent standards, and in instances where positive evidence of bioavailability is necessary, are shown to be bioequivalent to an appropriate standard. FDA believes this policy is consistent with the prevailing opinion of experts and with general experience through the years.

SAVINGS FROM SUBSTITUTION LAWS ARE SUBSTANTIAL BUT PRECISE FIGURES ARE ELUSIVE

We were unable to identify any nationwide studies of savings resulting from substitution laws; however, studies of particular States exist. For example, the Goldberg studies 1/ provide calculations based on actual prescribing and dispensing information derived from an audit over a 3-year period of more than 154,000 prescriptions in Michigan

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1/A series of studies on various aspects of drug product selection laws in Wisconsin and Michigan by Theodore Goldberg, Ph.D., Wayne State University, published during 1976, 1977, and 1978.

and Wisconsin. A Delaware study 1/ collected data on 12 commonly prescribed multiple-source products from 30 of Delaware's 130 pharmacies. A Florida study 2/ audited nearly 12,000 prescriptions from August 1 through November 30, 1977.

In Michigan, for prescriptions where substitution occurred, Goldberg calculated that average savings of $1.15 (20 percent) per prescription were realized. However, the actual reduction in the cost of prescribed drugs in Michigan as the result of substitution was estimated to be only between $200,000 and $300,000 a year because substitution occurred only about 1.5 percent of the time. For seven very popular multiple-source products in Delaware, Fink calculated savings of from about $.03 to $.13 per dosage. These savings were considered to be statistically significant. In Florida the savings were estimated at $1.92 per prescription.

The rate of substitution identified in these studies varied, as shown below.

Rate of substitution	Goldberg (Michigan)	Fink (Delaware)	University of Florida (Florida)
	(percent)		
For multiple-source prescriptions	1.5	24.0	a/6.0
For all prescriptions	.7	11.2	2.3

a/This rate is based on multiple-source drugs prescribed by brand name which are not on Florida's negative formulary.

1/"Effectiveness of Drug Product Selection Legislation in Delaware," Joseph L. Fink III, B.S. Pharm., J.D., and Maven J. Myers, J.D., Ph.D., Philadelphia College of Pharmacy and Science, May 1978.

2/"Drug Product Selection: The Florida Experience," George J. Vuturo, P.Ph., Jeffrey P. Krischer, Ph.D., and William C. McCormick, Ph.D., University of Florida, January 1979.

Since about 50 percent of prescriptions are written for multiple-source products, considerable opportunity exists for increased substitution and savings. The FTC report concluded that the various studies, though different in methodology and scope, provide the clear message that the potential for consumer savings is substantial.

Dr. Fink explained that the high rate of substitution in Delaware compared to Michigan is in part the result of the Delaware study being confined by budgetary constraints to only a few very popular multiple-source drugs. Dr. Goldberg cited a confusing and controversial "purchaser request" provision in the original act as a possible reason for the low Michigan rates. Dr. Goldberg explained that, although this provision has since been eliminated, sufficient time had not elapsed for measuring the effect of the change. The opportunity to retain some of the savings may induce Florida pharmacists to stock and dispense generic lines which they can sell at lower prices.

Several authorities agree that potential substitution rates and savings are substantial. Goldberg's estimate of savings for Michigan alone ranged from $11,730,000 to $15,295,000 annually if substitution occurred whenever possible. The FTC Bureau of Economics estimated annual savings nationwide of from $444 million to $817 million depending on alternative price assumptions. The Pharmaceutical Manufacturers Association, the Nation's association of major brand-name drug manufacturers, estimated minimum annual savings of about $323 million.

Nationwide increases in generic prescriptions and comments of wholesalers in the States we reviewed indicate that substitution laws are affecting the use of generic drugs. According to an April 1979 "Pharmacy Times" analysis of prescription data for retail pharmacies, from 1977 to 1978 initial generic prescriptions increased about 11.7 percent and initial and refill generic prescriptions increased about 8.7 percent. In 1978 generic prescriptions constituted about 11.6 percent and brand-name prescriptions about 88.4 percent of all prescriptions. Of the top 200 drugs, 17 were prescribed generically.

Sample data from California on six drugs revealed that a greater percentage of prescriptions were filled with generic drugs in 1978 than in 1975. The following drugs from this analysis demonstrate this point.

	October 1975 Prescriptions		October 1978 Prescriptions		Increase in percent of generics (Col. 4 minus col. 2)
	Number (1)	Percent (2)	Number (3)	Percent (4)	
Meprobamate, 400 mg:					
Generic	650	(50.7)	1,165	(67.5)	16.8
Brands	631	(49.3)	560	(32.5)	
	1,281	(100.0)	1,725	(100.0)	
Chlordiazepoxide 10 mg:					
Generic	52	(1.2)	459	(10.2)	9.0
Brands	4,145	(98.8)	4,028	(89.8)	
	4,197	(100.0)	4,487	(100.0)	
Chlorpromazine, 25 mg:					
Generic	27	(5.6)	500	(66.6)	61.0
Brands	458	(94.4)	251	(33.4)	
	485	(100.0)	751	(100.0)	

Further, wholesalers we interviewed in Florida, Georgia, New Jersey, and Texas said they are stocking more generic products now than they have in the past. In Texas, the primary reason cited for the increase is heightened public awareness of the availability of generic drugs.

Based on its work, FTC recommended to States (and HHS concurred) that certain key provisions be included in their substitution laws. These provisions are listed in appendix III, which also gives the rationale for including these provisions and evidence supporting them.

CONCLUSIONS

Substitution laws have the potential for significant consumer savings. Estimates of nationwide savings range

from $323 million to $817 million annually, depending on the assumptions employed. Actual substitution rates and resulting consumer savings have not reached their potential. The States have recognized the potential benefits of substitution laws, and as of December 31, 1979, 45 States and the District of Columbia permit substitution.

The Federal Government has encouraged the passage and/or strengthening of State drug substitution laws. Continued public education of drug substitution benefits by HHS and FTC should ensure that consumers and health care providers become better informed.

FDA REVIEW OF DRUGS PROPOSED FOR MAC LIMITS

FDA uses the following procedures in reviewing drugs proposed for MAC limits:

1. FDA reviews the specific drug and dosage form proposed for listing under the MAC program (e.g., tetracycline hydrochloride, 250 mg capsules).

2. FDA determines whether the drug is a new drug or an antibiotic.

3. For new drugs and antibiotics, FDA:

   a. Prepares a list of all firms with approved New Drug Applications, Abbreviated New Drug Applications, Form 5's, or Form 6's.

   b. Reviews the "plant profiles" for each manufacturer to assure that the plant has been inspected within the past year and, when last inspected, was in compliance with the Good Manufacturing Practices regulations.

   c. Reviews the compendial specifications for the drug, if any, and determines by inquiry to the appropriate compendium whether any significant change in the standard is pending. For antibiotics, a similar review is made of the applicable antibiotic regulations.

   d. Assures that a field enforcement program has been operating effectively to remove any products being marketed without FDA approval.

   e. Assures that no bioequivalence proposal or petition to establish a requirement is proposed or pending before the agency before a recommendation is made to list the drug under MAC.

   f. Searches the drug quality assurance files, the drug recall list, and the drug product defect reporting system to determine whether any unresolved problem requiring enforcement action may exist.

4. For drugs that are not new drugs or antibiotics and, therefore, may be legally marketed without approved New Drug Applications or antibiotic forms, the same basic procedures are followed.

5. On the basis of the above review, FDA must make the following positive determinations before a drug can receive a MAC:

   a. The regulatory programs conducted under the Food, Drug, and Cosmetic Act pertinent to the particular drug are in force and current.

   b. FDA does not have evidence that any currently marketed products of particular drugs, or their manufacturers, are not in compliance with the Food, Drug, and Cosmetic Act; or if such evidence is available, timely enforcement action is being taken to assure compliance.

   c. There are no important pending changes in regulatory status of the drug; i.e., there is no pending significant change in new drug/not new drug status, labeling, bioequivalence requirements, compendial specifications, or manufacturing requirements specific to the particular drug.

   d. There is no other reason known to FDA for believing that all marketed products of the particular drug fail to meet the same standards or are otherwise not in compliance with the law.

6. If these positive determinations can be made, a statement is sent by FDA to the MAC Board saying that FDA has no reason, from a quality assurance standpoint, to recommend against the establishment of a MAC. A summary supporting this statement is furnished to the Board.

7. If these positive determinations cannot be made, a statement is sent by FDA to the MAC Board recommending against the establishment of a MAC, giving the reason for this recommendation and the estimated date at which the matter can be reconsidered.

STATES HAVING DRUG SUBSTITUTION LAWS

AS OF AUGUST 1, 1979, AND THEIR KEY PROVISIONS

State	Year enacted (amended)	Formulary limitations	Discretionary (D) or Mandatory (M)	How substitution can be prevented*	Pharmacy record keeping required	Cost savings pass-on required	Patient/ customer consent required
Alabama	1979	None	D	A	Yes	No	No
Alaska	1976	None	D	C	No	Yes	Yes
Arizona	1978 (1979)	None	D	A	Yes	Yes	Yes
Arkansas	1975	Negative	D	B	No	Yes	No
California	1975	Negative	D	B	No	Yes	No
Colorado	1976	None	D	B	No	Yes	No
Connecticut	1976	None	D	B	Yes	Yes	Yes
Delaware	1976	Negative	D	A	Yes	Yes	No
Dist. of Col.	1976	Positive	D	B	Yes	No	No
Florida	1974 (1975)	Negative	2/M	B	Yes	Yes	Yes
Georgia	1977	None	D	A	Yes	No	No
Idaho	1978	None	D	A	Yes	Yes	Yes
Illinois	1977	Positive	D	A	Yes	No	Yes
Iowa	1976	Negative	D	B	No	Yes	No

APPENDIX II

State	Year enacted (amended)	Formulary limitations	Discretionary (D) or Mandatory (M)	How substitution can be prevented*	Pharmacy record keeping required	Cost savings pass-on required	Patient/ customer consent required
Kansas	1978	None	D	4/A	No	No	No
Kentucky	1972 (1976)	Positive	M	B	Yes	No	No
Maine	1975 (1978)	None	D	B	No	No	No
Maryland	1977 (1979)	Positive	D	B	Yes	Yes	No
Massachusetts	1976 (1977)	Positive	M	A	No	No	No
Michigan	1975 (1976)	None	D	B	No	Yes	No
Minnesota	1974	None	D	5/B	No	Yes	Yes
Mississippi	1979	None	D	4/A	No	Yes	Yes
Missouri	1978	Negative	D	A	Yes	Yes	Yes
Montana	1977	None	D	B	No	Yes	No
Nebraska	1977	Negative	D	B	No	Yes	No
Nevada	1979	Positive	D	A	Yes	Yes	Yes
New Hamphire	1973	Positive	D	6/A	No	No	Yes

APPENDIX II

State	Year enacted (amended)	Formulary limitations	Discretionary (D) or Mandatory (M)	How substitution can be prevented*	Pharm keepi requi
New Jersey	1977	Positive	M	B	No
New Mexico	1976	Fed. Mac List	D	B	No
New York	1977	Positive	M	A	Yes
North Carolina	1979	None	D	4/A	Yes
North Dakota	1979	None	D	7/A	Yes
Ohio 1977		Community Pharmacy	D	B	Yes
Oregon	1975	None	D	B	Yes
Pennsylvania	1976	Positive	M	A	Yes
Rhode Island	1976 (1978)	Positive	M	A	Yes
South Carolina	1978	None	D	A	Yes
South Dakota	1978	None	D	A	Yes
Tennessee	1977	Positive	D	A	Yes
Utah	1977	1/Negative	D	B	Yes
Vermont	1978	Positive	M	N	Yes

State	Year enacted (amended)	Formulary limitations	Discretionary (D) or Mandatory (M)	How substitution can be prevented*	Pharmacy record keeping required	Cost savings pass-on required	Patient/ customer consent required
Virginia	1977 (1978)	Positive	D	A	Yes	Yes	No
Washington	1977 (1979)	1/Negative or positive or none	M	A	Yes	Yes	No
West Virginia	1978	Negative	3/M	A	Yes	Yes	Yes
Wisconsin	1976	Positive	D	B	No	Yes	No
Wyoming	1979	No	D	A	Yes	Yes	No

APPENDIX II

*Legend:

A. Prescriber must give express prior approval by signing on the appropriate line on the prescription for substitution to take place.

B. Pharmacist is automatically authorized to substitute unless the prescriber indicates express disapproval, such as by writing "dispense as written," "no substitution," "brand necessary," or "medically necessary."

C. In Alaska the prescriber must permit or deny substitution, but authority to substitute is denied if the prescriber fails to make any indications. Two-line prescription forms are optional.

1/Board of Pharmacy is empowered but not required to adopt negative or positive formulary.

2/The pharmacist "shall," unless requested otherwise by the purchaser, and in the absence of the prescriber's designation "medically necessary," substitute a less expensive generic equivalent drug product from a formulary of substitutable drug products established by each community pharmacist.

3/The pharmacist "shall * * *, unless in his professional judgment * * *."

4/Two signature lines on the prescription are optional. If a prescription form without the two lines is used, the prescriber must handwrite "dispense as written" to prevent substitution.

5/When the actual manufacturer of the product to be substituted is the same as the prescribed name brand, the physician may not prevent substitution.

6/Substitution is permitted only if the prescriber directs orally or in writing "or its generic equivalent drug listed in the New Hampshire Drug Formulary."

7/Law requires the words "brand necessary" to be written on title XIX prescriptions in addition to signing the "dispense as written" side of the prescription form.

APPENDIX III

HHS/FTC MODEL SUBSTITUTION LAW

Recommended provisions	FTC's rationale	Evidence cited by FTC
Discretionary; that is, pharmacist decides whether to substitute.	Provides economic incentives. Lessens resistance to government intrusion.	FTC study found a significantly lower rate, as identified by the pharmacists themselves, of substitution in Pennsylvania, which has a mandatory law, than in several other States with discretionary laws. Pharmacy surveys by two newspapers in Kentucky indicated a lack of compliance with that State's mandatory law.
Handwritten physician statement to prohibit substitution.	Recognizes the absolute authority of the prescriber. Requires conscious choice by prescriber to prohibit substitution.	Studies show that when prescribers are required to sign either a line designated "dispense as written" or one designated "substitution permitted," they prohibit substitution half the time or more. Numerous studies show that physicians rarely (generally less than 5 percent of the time) find it necessary to use the "medically necessary" designation.
Pharmacist and consumer share savings.	Provides economic incentive for pharmacist to stock and dispense lower cost product. Provides some cost savings to the consumer.	Many pharmacists responding to the FTC survey said that mandatory pass-ons of all cost savings would deter them from substituting as often as they would otherwise. Enforcement of pass-on of all savings would be difficult because of the comparison of an actual transaction with a hypothetical one.
Patient notification and consent.	Allows patient right to insist on prescribed brand. Encourages patient education about substitution.	Responses to the FTC survey indicate that the increased time spent with patients because of such provisions does not unduly burden pharmacists.
State established formulary of drugs which may be substituted.	Because of some problems with bio-inequivalence, a list based on scientific information should be made available. The greatest degree of substitution occurs in States with a drug formulary. FDA will provide the basic list because of its expertise and to reduce costs to the individual States.	Several studies, including the one conducted for FTC, have found the greatest degree of substitution in States with a drug formulary. Goldberg's preliminary analysis of 1977-78 data in Wisconsin, which has a positive formulary, indicates an 18- to 20-percent rate of substitution compared to a 1.5-percent rate of substitution in Michigan, which has no formulary.
Other provisions --labeling, --recordkeeping, and --public education.	Both labeling and record-keeping requirements should apply to all prescriptions, not only those which have been substituted. Assess the need and, if appropriate, provide education to inform consumers so they encourage pharmacists to select lower cost generic drug products more frequently.	

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