Evaluation of the Maximum Allowable Cost Program

by A. James Lee, Dennis Hefner, Allen Dobson, and Ralph Hardy, Jr.

This article summarizes an evaluation of the Maximum Allowable Cost (MAC)-Estimated Acquisition Cost (EAC) program, the Federal Government's cost-containment program for prescription drugs.[1] The MAC-EAC regulations which became effective on August 26, 1976, have four major components: (1) Maximum Allowable Cost reimbursement limits for selected multisource or generically available drugs; (2) Estimated Acquisition Cost reimbursement limits for all drugs; (3) "usual and customary" reimbursement limits for all drugs; and (4) a directive that professional fee studies be performed by each State. The study examines the benefits and costs of the MAC reimbursement limits for 15 dosage forms of five multisource drugs and EAC reimbursement limits for all drugs for five selected States as of 1979.

Background

Market Characteristics

The pharmaceutical manufacturing industry is commonly portrayed as an oligopolistic industry in which advertising or promotion is used to differentiate products by focusing on minor product differences in order to avoid direct price competition (see Henderson and Quandt, 1971). The marketing of "brand name" drugs in a generic market can be seen as an extreme case of such product differentiation. The manufacturer typically dwells on therapeutically irrelevant differences (for example, taste, packaging, and dosage form) or more substantive differences such as stringent manufacturing and quality standards (for example, bonding of aspirin). Frequently, physicians acting as consumer agents for their patients cannot easily assess whether or not such "quality" differences are therapeutically significant. Thus, physicians may prescribe higher-priced brand names to protect their patients from the uncertain risk entailed by potentially lower-quality generic equivalent products. In this sense, physicians "trust" the manufacturer either on the basis of satisfactory experience with the manufacturer in the past or on the basis of the manufacturer's general reputation, visibility, and prior exposure to scrutiny.

Drug manufacturer advertising is especially effective for the brand name manufacturer because the government grants exclusive patent rights for a period of 17 years on new drug developments, in order to give the innovator an opportunity to recoup research and development costs. During this interval of patent protection, a drug manufacturer sets the price in excess of "marginal cost" in order to obtain a return on its research and development investment. The manufacturer is legally protected from direct competition, although there may be indirect competition from other manufacturers that are marketing products which are close therapeutic substitutes. Nevertheless, brand name drugs usually continue earning an excess return after expiration of patent and entry of direct generic competition because of brand recognition and habit persistence factors. Brand name familiarity is developed when products are prescribed by brand name while still under patent. After patent expiration, it is common for a multisource drug (drugs available from more than one manufacturer after expiration of patent protection) to be referred to by brand name rather than by its generic drug class name. This tendency is augmented by the fact that generic names are typically lengthy and unpronounceable. Brand names are, by design, more tractable and memorable, in addition to being more prominently exhibited by promotional advertising.

[1]The study was made pursuant to Contract No. 500-78-0019 between the Office of Research and Demonstrations/Health Care Financing Administration and Abt Associates, Inc. For a full report, see Lee *et al.*, 1981.

A key characteristic of the pharmaceutical manufacturing industry resulting from the above factors is that substantial variation persists in prices charged by different manufacturers for essentially the same product (within a generic class). The central tenet of MAC reimbursement is that all available products within many generic classes are therapeutically equivalent—as attested by the Food and Drug Administration (FDA)—and that product selection for government patients should be based on price only. That is, except for certain dosage forms, nonprice differences within a generic class are deemed to be irrelevant and the government can thereupon limit reimbursement to the cost of the lowest price generic alternative available without harm to its beneficiaries.

MAC-EAC Program Development

Hearings by the late Senator Estes Kefauver (1959-1962) and subsequently by Senator Gaylord Nelson (1967-1970) brought the existence of price differentials in the drug marketplace to the public's attention. In 1969, the Federal Task Force on Prescription Drugs (U.S. Department of Health, Education and Welfare, 1969) organized to consider a drug benefit program for Medicare, recommended the implementation of a "MAC-type" program. The Task Force estimated that 5 to 8 percent of drug costs for the elderly could be saved through such a generic prescription program.

However, conditions in the late 1960's were not favorable for the Federal adoption of a MAC-type program. The major pharmaceutical manufacturers argued that lower-priced generic drugs were not equivalent to their own brand name drugs. They contended that the physician could not be sure of the pharmacological action of a generic drug in a patient and that the use of generic drugs is tantamount to treatment based on price and not quality. During the late 1960's, perhaps these arguments had some validity. However, during the decade of the 1970's these types of arguments lost much of their force for a variety of reasons.

Of course, the emergence of substitutes for branded products was important. The greater the number of multisource drugs, the greater the opportunity to achieve savings. In the early 1970's, practically all major drugs enjoyed patent protection. However, this situation has changed dramatically. Some 117 of the top 200 products in 1973 are now off patent. Following patent expiration, major companies then entered the generic market, thus providing generic substitutes for previously protected products. As mentioned previously, the result of this market entry is that almost identical drugs are sold at greatly different prices.

While the existence of generic substitutes was a necessary condition for the existence of a MAC program, it was by no means a sufficient condition. The public and the medical profession needed assurance that generic substitutes are therapeutically equivalent to higher priced brand name drugs. The introduction of generic lines by well-known, reputable manufacturers did much to allay concerns about the quality of generic substitutes. Additionally, the FDA developed new good manufacturing practice (GMP) requirements (22 C.F.R. SS210, 211, 1977) and bioavailability regulations (42 Fed. Reg. 1624, 1636, 1977). The bioavailability regulations, first proposed in 1975 and made final on January 7, 1977, confirm FDA's determination to assure the equivalence of drugs. The FDA specifies both those drugs with bioavailability problems and those that have no such problem. As a further commitment to equivalency, the FDA recently developed and issued a list of interchangeable drugs (Food and Drug Administration, 1979).

Directly related to the quality issue are laws relating to substitution. With equivalence no longer looked upon as a major problem, State legislatures, supported by the American Pharmaceutical Association and many consumer groups, no longer saw the need for antisubstitution legislation and felt that through substitution the consumer would have the opportunity to purchase multisource products at lower cost. At this writing 43 States and the District of Columbia have adopted laws permitting pharmacists to dispense a chemically equivalent drug product for a drug prescribed by trade name. Substitution, and concomitantly, prescribing of generics have become acceptable and public programs have been developed to promote them.

Of course, the pressures for health care cost containment have also heightened considerably since 1970. In 1976, (the year MAC regulations became effective) national expenditures for drugs and related products were approximately $11.2 billion. Of this amount, Federal, State, and local government drug expenditures were an estimated $3.4 billion—30 percent of the total. In this same year, Medicaid payments for prescription drugs amounted to $957 million, about 6.8 percent of the total Medicaid benefit expense.

The fact that substantial variation existed in the prices charged by different pharmacies for the same prescription and that substantial variation also existed in prices charged by different manufacturers led the States of California (in 1961) and Tennessee (in 1972) to establish programs to control drug reimbursements for Medicaid.[2] These State programs, and recommendations made by a Federal Task Force on Prescription Drugs in 1969 served as a basis for Federal regulations proposed by HEW in 1973 and finalized in July of 1975 to control drug reimbursements by Federal programs.

The MAC-EAC Program

The MAC-EAC program regulations (Weinberger, 1975), which became effective on August 26, 1976, contain four major components: (1) Maximum Allowable Cost (MAC) reimbursement limits for selected multisource or generically available drugs, (2) Estimated Acquisition Cost (EAC) reimbursement limits for all drugs, (3) usual and customary reimbursement limits for all drugs, and (4) a directive that professional fee studies be performed by each State.

The MAC provision takes advantage of the price differentials between brand name products and their lower-priced generic competition; it limits ingredient cost reimbursement to the lowest price at which a generically-available drug is "widely and consistently" available.[3] The EAC portion of the program limits ingredient cost reimbursement to the pharmacy's estimated acquisition cost. The regulations state that the "estimated acquisition cost" should be "The State's closest estimate of the price generally and currently paid by providers." Whereas pre-EAC ingredient cost reimbursement levels were thought to be too high, it was also suggested that dispensing fee levels were too low.

In response to this concern, the MAC-EAC regulations also required that the States conduct cost studies and establish reasonable cost-related dispensing fees. Finally, the "usual and customary" provision constrains reimbursement to be no greater than the pharmacy's usual and customary charge to the general public—that is, the price that a nongovernment-reimbursed customer would be charged for the prescription. Thus, allowable reimbursement under the MAC and EAC is the *lowest* of the following: (1) the MAC reimbursement limit (if any) plus the dispensing fee, (2) the EAC reimbursement limit plus the dispensing fee, or (3) the usual and customary charge to the general public.

The MAC and EAC are described in somewhat greater detail below.

Maximum Allowable Cost

A MAC limit can be established for any multisource drug for which significant amounts of Federal funds are expended and for which there are significantly different market prices. The regulation requires that "the Board (Pharmaceutical Reimbursement Board—PRB) determine the lowest unit price at which the drug is widely and consistently available from any formulator or labeler. This determination will be based on the package size of the drug most frequently purchased by providers (Weinberger, 1975, p.32302)."

In establishing a MAC limitation, the PRB first establishes that a product is available from multiple sources, determines the lowest unit price at which it is available, and estimates the potential savings to the government from the MAC limit. The FDA Bureau of Drugs then advises the PRB, "whether there is any regulatory action, either pending or under consideration, bearing upon the marketability or the establishment of bioequivalence that in the judgment of the FDA may be a reason for delaying or withholding the establishment of a MAC for a drug (Weinberger, 1975)." Following FDA approval of the drug, the PRB conducts public hearings and makes the final decision, with assistance from consultants as needed. To the extent that the low-price generic equivalents were stocked by pharmacies prior to MAC implementation—that is, were widely and consistently available

[2] In 1961, under its Public Assistance Medical Care Program, California established maximum allowable costs for 10 multisource drugs. The program continued through initiation of Medi-Cal in 1966. In 1972, Medi-Cal extended and modified the program. However, the modified program was successfully challenged in court, and in 1973 a successive program was implemented. In 1972 Tennessee Medicaid also adopted a State MAC program; and the University of Tennessee ran bioavailability tests to assure quality. A total of 12 States had adopted MAC-type programs prior to implementation of the Federal program.

[3] Because of wide variability in market prices for the same manufacturer's products and a presumed lack of competition, especially in the absence of widespread price advertising, State Medicaid programs have traditionally sought to reimburse prescriptions at cost. Furthermore, they have taken a "value-added" approach in doing so by setting reimbursement equal to the ingredient cost plus the estimated cost of actually dispensing the product—that is, the dispensing fee.

from the providers—the government is merely choosing, as a prudent buyer, to purchase what it perceives to be a homogeneous commodity at the lowest price available. As such, the government is not exercising any incremental market power.[4]

Estimated Acquisition Cost

In many States the allowable ingredient cost reimbursement had been taken as the Average Wholesale Price (AWP). However, because of various kinds of purchasing discounts, the actual prices paid by pharmacies were estimated by the Task Force on Prescription Drugs to be 15 to 18 percent lower than the listed wholesale prices. The EAC component of the MAC program requires that all States use actual price data in setting ingredient cost reimbursement levels. The regulations state that EAC reimbursement limits should "be the State's closest estimate of the price generally and currently paid by providers. Such estimates shall be based on the package size most frequenty purchased by providers. To aid States in making cost estimates, the Department makes information available on a current basis on acquisition costs of the most frequently purchased package size of drugs. These data will cover the majority of the most frequently prescribed drugs (Weinberger, 1975)."[5]

An additional activity of the MAC program is to prepare and issue a guide to economical drug selection. It is believed that providing comparative drug price information to physicians will alter prescribing patterns, and save money for both Medicaid and the general public. The guide (Health Care Financing Administration, 1980) is now being distributed to physicians, hospital pharmacies and community pharmacies on a periodic basis. It shows differences in therapy cost for different brands of the same drug and for drugs having the same therapeutic effect.

Early Estimates of MAC-EAC Savings Potential

Prior to actual implementation of the MAC-EAC program, two major evaluations of the benefits and costs were conducted. One was prepared by the Federal Government (U.S. Department of Health, Education and Welfare, 1975) and the other prepared for the pharmaceutical industry. Both studies focus almost exclusively on cost-savings potential.

The Federal study estimated that if MAC had been in force for the most common multisource drugs, the savings in drug cost would have been $37.2 million in fiscal year 1975. It was likewise estimated that the EAC provision of the MAC program would have saved $23.1 to $38.4 million; however, State administrative costs were estimated to be an additional $3.5 million in the first year and $0.3 million annually thereafter. The total net savings was projected to range between $55.3 and $70.8 million. These figures imply benefit to cost ratios of approximately 11 to 1 to 14 to 1.

An independent evaluation of the prospective MAC program conducted for Eli Lilly and Company (Trapnell, 1975) came up with an altogether different assessment. In fact, this study concluded that the MAC portion of the MAC-EAC program would actually increase costs. Furthermore, it concluded that there was no money to be saved on EAC. The study argues that pre-EAC price levels fairly reflected the costs of doing business and, that in the short run, losses of income due to EAC would simply be passed on to the general public in the form of higher prices for non-Medicaid prescriptions. However, in the long run (for example, five years) it was thought that the pharmacies would organize and renegotiate earlier (pre-EAC) price levels for Medicaid reimbursement.

[4]To the extent that the low-price generics were not formerly available, the government is exercising at least some additional market power. In such cases, participating pharmacies would either have to dispense a higher cost product at the lower reimbursement level or incur additional inventory and other transaction expense in stocking the lower-cost product. Although such exercise of public market power is commonly perceived as a form of regulation, it is not regulation in the technical sense inasmuch as it does not involve coercion. Pharmacies have the option of participating or not participating in the Medicaid drug programs and dispensing or not dispensing prescriptions according to the Medicaid price schedule and in accordance with other program conditions. As such, the Medicaid drug programs are not formally different from the nongovernmental third-party plans and they depend upon the same normal market forces that the United Federation of Teachers in New York City used in negotiating lower prices for its members. (*American Druggist*, 1979, p. 17.)

[5]The Office of Pharmaceutical Reimbursement (OPR) in HCFA collects this information under a contract with IMS America, Ltd., and disseminates it to the States. IMS provides OPR the results of a continuing survey of all purchases for drugs in 1,000 pharmacies. The survey gives the invoice level prices for the 300 most frequently purchased chemical entities and the most frequently purchased dosage forms and strengths.

Study Methods and Data Sources

Benefit-to-Cost Analysis: A Five-State Study

Primary Study Hypothesis and Study Structure

It was not possible in the context of this study to reliably measure, much less value, all potential benefits and costs of the MAC-EAC program. Thus, the study primarily focuses on the testing of a more limited or partial hypothesis: Do reimbursement savings to the Medicaid program exceed incremental administrative costs, and, if so, by how much? Inasmuch as the MAC and EAC parts of the MAC-EAC program could, in principle, have been implemented separately, separate estimates are given for the cost savings potential of each.[6] In 1977, Medicaid payments for prescription drugs amounted to $1.2 billion or 5.9 percent of total Medicaid benefit expenses. Thus, the potential for savings is considerable.

Because of data limitations and resource constraints, this study primarily relied upon Medicaid data drawn from a sample of five States—Arkansas, Maine, Massachusetts, Minnesota and Tennessee—to estimate reimbursement savings. These States were selected to provide a general representation of program sizes and geographic regions. These States also had stable programs over the observation period, "clean" prescription records and a history of cooperation with Federal studies regarding data collection, availability of State staff, and records. The study was conducted in two phases. In Phase I, a profile of State programs was prepared, and the evaluation methodology was developed and pretested in one study State (Massachusetts). In Phase II, data were collected from the four other study States and all analyses completed.

The study examines experience for calendar year 1979 with the five initial MAC products:

- ampicillin,
- chlordiazepoxide HCl (Librium),
- penicillin VK,
- propoxyphene HCl (Darvon), and
- tetracycline HCl.

Between September 1976 and February 1978, MAC reimbursement limits were placed on 15 dosage forms of these multisource drugs. The five MAC products for which MAC savings and costs are calculated represent about 5 percent of total prescription drug sales. Since the study was conducted, MAC limits have been set on 37 dosage forms of 20 additional multisource drugs.

[6]For practical purposes, the "EAC part" is understood to also include the usual and customary reimbursement limit and the dispensing fee mandate provision.

Benefit-to-Cost Methodology

MAC-EAC benefits (program reimbursement savings) are estimated by using pre-MAC-EAC prescription drug reimbursement levels and associated rates of change to estimate the "expected" reimbursement levels which would have existed if the MAC-EAC program had not been implemented. By subtracting actual post-MAC-EAC reimbursement levels from expected levels, an estimate of reimbursement savings is achieved.

Before benefits could be estimated, reimbursement of ingredient costs had to be estimated. Our data came directly from Medicaid drug reimbursement files in each of the study States. The numbers of prescriptions, numbers of units dispensed, and amounts paid were aggregated by product, dosage form, and manufacturer for the 9, 10, or 11 most recent six-month time intervals.[7] While the average amount paid per prescription or per unit could be readily calculated from these data, the portion of this amount allowed for reimbursement of ingredient cost (as opposed to the dispensing fee) had to be estimated. Two alternative techniques were available for doing so. One approach, the dispensing fee approach, involves subtracting a dispensing fee allowance from the total reimbursement amount. The other approach involves multiplying the total number of units dispensed by the program's actual per-unit ingredient cost reimbursement limits, the allowable ingredient cost approach. Of course, if all prescriptions were reimbursed on the basis of the allowable ingredient cost plus the dispensing fee, these two techniques would yield identical estimates. Different results are obtained to the extent that the "usual and customary" price (that is, the price charged to non-Medicaid customers) is lower than the ingredient cost limit and the pharmacies actually claim the lower amount as reimbursement. The results are also different to the extent that physicians specify "brand necessary" and override the MAC reimbursement limits. Although the results obtained were generally quite similar, we have used the average of the two estimates whenever possible.

Data in Table 1 indicate the nature of the study's reimbursement data using propoxyphene HCl, 65 MG CAPS, in Minnesota. The table shows the time trend in per-unit and per-prescription ingredient cost reimbursement by manufacturer and again in the aggregate, as well as information on the percentage distribution of the market across manufacturers.[8] There is an abrupt decline in ingredient cost reimbursement, both per unit and per prescription, that begins in the 4/78-9/78 period. It was during this period that the

[7]Such information is reported in one of the standard Medicaid Management Information System reports, the *Drug Usage Report* or *Drug Analysis Profile*.

[8]Tennessee uses a generic drug code that does not distinguish manufacturer. Thus, only aggregate information was available for that State.

TABLE 1

Cost Per Unit, Cost Per Prescription, and Percent Represented by Brands of Propoxyphene HCl 65 Mg. Compound Capsules: Minnesota

Product/Manufacturer Time Period	Cost/ Unit	Cost/ Prescription	Percent of Ingredient Cost	Percent of Units	Percent of Prescription
Darvon/Lilly					
Apr. '75-Sept. '75	$0.0668	$3.1817	96.04%	94.36%	95.18%
Oct. '75-Mar. '76	0.0670	3.2110	96.52	94.92	95.15
Apr. '76-Sept. '76	0.0682	3.2040	96.74	95.15	95.18
Oct. '76-Mar. '77	0.0682	3.2504	96.91	95.20	95.26
Apr. '77-Sept. '77	0.0692	3.2202	96.97	94.60	95.31
Oct. '77-Mar. '78	0.0694	3.2650	96.38	93.65	94.03
Apr. '78-Sept. '78	0.0533	2.4032	74.36	64.77	65.33
Oct. '78-Mar. '79	0.0427	1.7978	48.80	40.63	43.45
Apr. '79-Sept. '79	0.0477	2.0870	41.79	33.42	34.82
Dolene/Lederle					
Apr. '75-Sept. '75	0.0405	1.9198	1.26	1.80	1.82
Oct. '75-Mar. '76	0.0373	1.9237	1.27	1.97	1.84
Apr. '76-Sept. '76	0.0408	1.6607	1.40	1.94	2.24
Oct. '76-Mar. '77	0.0469	1.6077	1.06	1.26	1.75
Apr. '77-Sept. '77	0.0432	1.9414	0.73	1.00	1.04
Oct. '77-Mar. '78	0.0390	1.7210	0.84	1.23	1.32
Apr. '78-Sept. '78	0.0369	1.7379	3.06	3.51	3.39
Oct. '78-Mar. '79	0.0344	1.6220	8.71	8.73	8.31
Apr. '79-Sept. '79	0.0352	1.6602	9.41	9.57	9.25
SK-65 Cmpd. SKF					
Apr. '75-Sept. '75	0.0364	1.5755	1.14	1.70	1.89
Oct. '75-Mar. '76	0.0357	1.4429	0.95	1.39	1.65
Apr. '76-Sept. '76	0.0360	1.3973	0.78	1.14	1.38
Oct. '76-Mar. '77	0.0357	1.7244	0.91	1.45	1.43
Apr. '77-Sept. '77	0.0360	1.8214	1.22	1.97	1.83
Oct. '77-Mar. '78	0.0323	1.7222	1.31	2.32	2.05
Apr. '78-Sept. '78	0.0304	1.3635	6.26	7.93	8.05
Oct. '78-Mar. '79	0.0300	1.4545	12.70	13.91	12.91
Apr. '79-Sept. '79	0.0312	1.3852	14.04	14.96	15.38
Miscellaneous					
Apr. '75-Sept. '75	0.0495	4.5875	1.55	2.14	1.11
Oct. '75-Mar. '76	0.0474	2.8943	1.26	1.72	1.35
Apr. '76-Sept. '76	0.0398	2.7354	1.09	1.77	1.21
Oct. '76-Mar. '77	0.0319	2.0451	1.12	2.09	1.55
Apr. '77-Sept. '77	0.0247	1.5489	1.09	2.43	1.81
Oct. '77-Mar. '78	0.0282	1.4337	1.48	2.79	2.59
Apr. '78-Sept. '78	0.0250	1.1642	16.33	23.80	23.23
Oct. '78-Mar. '79	0.0245	1.1438	29.80	36.73	35.32
Apr. '79-Sept. '79	0.0265	1.2556	34.76	42.05	40.56
Totals					
Apr. '75-Sept. '75	0.0655	3.1475	100.00	100.00	100.00
Oct. '75-Mar. '76	0.0657	3.1567	100.00	100.00	100.00
Apr. '76-Sept. '76	0.0669	3.1422	100.00	100.00	100.00
Oct. '76-Mar. '77	0.0668	3.1843	100.00	100.00	100.00
Apr. '77-Sept. '77	0.0673	3.1544	100.00	100.00	100.00
Oct. '77-Mar. '78	0.0671	3.1703	100.00	100.00	100.00
Apr. '78-Sept. '78	0.0439	1.9977	100.00	100.00	100.00
Oct. '78-Mar. '79	0.0333	1.4964	100.00	100.00	100.00
Apr. '79-Sept. '79	0.0353	1.6108	100.00	100.00	100.00

MAC reimbursement limit on propoxyphene became effective. The average ingredient cost reimbursement declined sharply from 6.7¢ per unit to 4.4¢ per unit over a 12-month interval. Furthermore, the average ingredient cost reimbursement per prescription fell from $3.17 to $2.00. However, it is not appropriate to simply take such "price" reductions as measuring the MAC-related savings in ingredient cost reimbursement. Due to increased competition and other market factors, the prices of many generically available drugs are declining over time anyway. Furthermore, in some cases (for example, tetracycline), market shares are shifting toward the less expensive generic substitutes. We therefore sought to take account of any such exogenous price trends by fitting a linear relationship between the pre-MAC reimbursement levels and the number of the time period, and then using this relationship to project the time period reimbursement levels that would have been expected had MAC not been implemented.[9]

Except for chlordiazepoxide, this could not be done in Arkansas. Reimbursement data on the four other MAC products being studied were available for only two six-month time intervals prior to introduction of State MAC limits. Thus, the pre-MAC reimbursement levels were also taken as the projected reimbursement levels for these products in Arkansas. Furthermore, Tennessee's State MAC limits on propoxyphene, ampicillin, and tetracycline were implemented prior to the beginning of the study interval for which data had been collected. Thus, we did not have any baseline data for these products. The price levels projected for the States of Massachusetts, Maine, and Minnesota were averaged together and used as the projected values for Tennessee. In all cases, differences between expected values and the actual per-unit or per-prescription reimbursement levels were taken to measure the per-unit and per-prescription savings in ingredient cost reimbursement.

[9]Whereas a trend model is clearly inadequate to explain the dynamics of pharmaceutical pricing, the evaluation findings are rather insensitive to such considerations. The estimated program effects on drug reimbursement levels are must too large and systematic to be attributed to other criteria. Curvilinear relationships including a time-squared term were also estimated from the data in several States. However, the resulting projections were sometimes implausible (for example, price increases were occasionally projected for products with prices that declined consistently over the course of the study interval).

The annual reimbursement savings in each instance were estimated by simply doubling the estimates developed for the most recent six-month study interval unique to 1979. State savings estimates are influenced by: (1) pre-existing differences in generic market share—that is, differences in the percentage of prescriptions that were already being filled with lower-price brands (that is, generic brands) prior to MAC implementation; (2) differences in the prevalence of "brand necessary" overrides of MAC regulations; (3) regional differences in average prescription size; and (4) the fact that Tennessee's MAC limit was relatively low.

The EAC-related reimbursement cost savings were estimated by EAC product category, using the same "expected" value methodology used to estimate MAC-related savings.

The costs of administering the MAC-EAC program were estimated, not only in the five study States but also at the Federal level. However, additional costs attributable to the MAC-EAC program encompass not only State and Federal "incremental" costs but also the loss of State and Federal income tax revenue, and for the EAC program, estimated increases in dispensing fees associated with State professional fee studies. Benefits are compared to costs in terms of net benefits (benefits less costs) and benefit-to-cost ratios.

Survey and Econometric Studies

In addition to the five-State study, a time series of State drug program data across all States was compiled for cross section/time series econometric analysis. This time series (1974-1978) information was gathered by a survey which focused on managers of State programs concerning State Medicaid program characteristics. The econometric study based on these survey data was helpful in generalizing EAC-related results from the sample States to the nation as a whole. However, methodological and data problems precluded econometric estimation of MAC-related effects. The econometric analyses attempted to determine statistical relationships between aggregate State reimbursement experience in terms of the average number of prescriptions per Medicaid recipient and State drug program characteristics. By and large, this investigation was primarily exploratory in nature. The study's conclusions are thus principally drawn from the analysis of the five States described above. However, some of the findings presented are based on survey information and econometric results.

Findings

MAC-Related Savings and Costs

The estimated annual reimbursement savings for each of the 15 initial MAC product-dosage forms in each study State are shown in Table 2. The total reimbursement savings estimated for all five study States is also given for each MAC product. Reimbursement savings were greatest for chlordiazepoxide and propoxypene, approximately $300,000 each per year, and smallest for tetracycline, about $30,000 per year.

Table 2 indicates that MAC-related reimbursement savings across the initial five MAC products amounted to more than $900,000 per year in the five study States. This is nearly one percent of total Medicaid drug reimbursement expense in these States. If the same level of savings were achieved by Medicaid drug programs in other States, almost $11 million dollars per year would be saved nationwide on only the first five MAC products. The estimated rates of reimbursement savings in the five States range from 0.54 percent of drug program cost in Minnesota to 1.40 percent of the cost in Arkansas. Using this range of estimates, the savings achieved nationwide range between $6 and $15 million dollars.

TABLE 2

Projected Annual Reimbursement Savings on the Five Initial MAC Products, by State

Product	State					Total
	Arkansas	Maine	Massachusetts	Minnesota	Tennessee	
Chlordiazepoxide HCl						
5 MG CAPS	$ 2,830	$ 3,646	$ 18,882	$ 3,890	$ 8,334	$ 37,592
10 MG CAPS	23,304	17,264	81,298	12,114	75,878	209,858
25 MP CAPS	3,646	7,802	32,856	4,862	29,208	78,374
						$325,824
Propoxyphene HCl						
65 MG CAPS	7,358	10,998	38,630	9,458	82,336	148,780
65 MG CMPD CAPS	32,378	8,258	75,458	22,810	NA	138,904
						$287,684
Ampicillin						
250 MG CAPS	40,380	10,580	(7,314)	7,790	20,168	71,604
500 MG CAPS	52,744	1,184	(12,740)	13,674	17,614	72,476
125 MG LIQ	3,566	828	(2,668)	472	15,828	18,026
250 MG LIQ	6,420	3,022	(4,692)	(768)	15,782	19,764
						$181,870
Penicillin VK						
250 MG CAPS	16,316	11,246	1,870	12,620	13,604	55,656
500 MG CAPS	12,140	2,962	1,700	4,648	10,760	32,210
125 MG LIQ	2,384	816	(536)	876	1,702	5,242
250 MG LIQ	1,840	3,022	(6,956)	3,036	4,722	5,664
						$ 98,772
Tetracycline HCl						
250 MG CAPS	10,648	6,952	(7,916)	2,910	11,842	24,436
500 MG CAPS	4,974	1,206	(4,162)	2,064	3,028	7,110
						$ 31,546
Total	$220,928	$89,786	$203,710	$100,456	$310,816	$925,696
Percent of Total Medicaid Drug Reimbursement Expense	1.40	1.26	0.73	0.54	1.01	0.99

Table 3 contains the study's principal MAC-related findings. For 1979, total MAC-related savings on the five products for the five study States are estimated at $925,696. Savings estimates range from a high of $310,816 in Tennessee to a low of $89,786 in Maine.

Incremental State costs of administering the MAC part of the MAC-EAC program were quite modest, virtually insignificant in three of the five study States. For the other two States, costs amounted to $9,268 per year in Minnesota and $700 in Arkansas.[10] The Federal costs of implementing and operating the combined MAC-EAC program totaled just under $3 million for the five-year interval between 1975 and 1979. About 60 percent of this amount was spent on MAC program staff and FDA staff activity. The remainder is primarily attributable to the cost of data-related contracts.

[10]Although not shown in Table 3, the one-time State costs of originally implementing the MAC-EAC program were somewhat larger, averaging about $22,000 per State: Arkansas $47,952, Maine $11,600, Massachusetts $15,000, Minnesota $12,491, Tennessee $22,000, total $109,043. However, only a small percentage of implementation costs should be said to be MAC-related. The largest part of these costs, almost 75 percent, were incurred in conducting the mandated dispensing fee surveys. Such implementation costs were "sunk costs" at this point, and as an allocational matter, are irrelevant for evaluating whether or not the MAC-EAC program should be continued. Furthermore, if either the State or the Federal implementation costs were amortized or depreciated over a 30-year period, the allocated expense would amount to less than $4,000 per year.

Although it was not possible to distinguish between implementation and operating costs, total Federal MAC-EAC program costs appear to be stabilizing at about $700,000 per year. The study team estimated that only half of this annual expense is MAC-related, that is, about $350,000 per year. Apportioning this annual cost on the basis of drug program size, the prorated share of the five study States amounts to approximately $31,500 per year. The net MAC-related reimbursement savings, that is, the reimbursement savings net of State and Federal administrative costs for the initial five MAC products, amounts to about $884,185 per year in the five study States. The implicit benefit-to-cost ratio of net savings to administrative costs is 22 to 1.

The savings in drug reimbursement might also be offset by the reduction in tax revenue to Federal, State and local governments. Based on unpublished 1970 data, the average tax rate on net earnings in the pharmaceutical industry was 18.4 percent. Thus, the net governmental savings amounted to $713,857—calculated as 1 minus the tax rate times the savings in ingredient cost reimbursement. This implies a benefit-to-cost ratio of 17 to 1.[11]

[11]Note, however, that from the perspective of society it is not clear that the tax loss is a cost that should be attributed to the program. Taxes are merely transfer payments within the society-at-large and do not constitute a real cost from the taxpayers' perspective.

TABLE 3

MAC-Related Savings on Five Products and the MAC-Related Costs in Five Study States, Annual Projections, 1979

	State	Arkansas	Maine	Massachusetts	Minnesota	Tennessee	TOTAL
(1)	MAC-Related Savings on Five Products[1]	$220,928	$89,786	$203,710	$100,456	$310,816	$925,696
(2)	Incremental State Administrative Costs	700	0	0	9,268	0	9,968
(3)	Prorated Share of Federal Administrative Costs	5,086	2,282	8,976	5,976	9,223	31,543
(4)	Net Savings [(1)-(2 + 3)]	215,142	87,504	194,734	85,212	301,593	884,185
(5)	Reduction in Federal and State Income Taxes [.184(1)]	40,651	16,521	37,483	18,484	57,190	170,328
(6)	Net Governmental Savings [(4)-(5)]	174,491	70,983	157,251	66,728	244,403	713,857

[1]Ampicillin, chlordiazepoxide HCl, penicillin VK, propoxyphene HCl and tetracycline HCl.

EAC-Related Savings and Costs

EAC-related reimbursement savings in the five study States amounted to about $2.3 million per year. However, these savings were achieved in only two of the five study States, Maine and Massachusetts. The total annual EAC-related reimbursement savings amounted to about $2 million in Massachusetts and about $300,000 in Maine.

The Medicaid programs in Arkansas, Minnesota, and Tennessee have not changed their drug reimbursement programs in response to the EAC requirement. Although the standards for assessing EAC compliance are somewhat unclear, the pre-existing approaches to determining ingredient cost reimbursement in Minnesota and Tennessee appear to satisfy the EAC requirement. However, the current approach to ingredient cost reimbursement in Arkansas probably does not satisfy the requirement, and additional EAC-related savings may eventually be achieved in Arkansas.

Neither Maine nor Massachusetts, the two States that responded to the EAC requirement, are incurring additional administrative cost due to the EAC-related changes in drug reimbursement.[12] The newly-adopted approaches to establishing ingredient cost reimbursement limits in these two States are neither more nor less expensive than the approaches they replaced. However, it is estimated that the Federal expense of administering and supporting the EAC-part of the MAC-EAC program is currently about $350,000 per year. By apportioning the Federal expense on the basis of program size, the prorated share of the five study States is about $31,000 per year. Such expenses are not explicitly allocated to States unaffected by the EAC requirement, therefore State-specific estimates are not given.

An increase in dispensing-fee reimbursement represents by far the largest cost component attributed to EAC. The average per-prescription dispensing fee increased over the 5-year study interval as shown in Table 4.

[12]States did incur some expense at time of implementation.

TABLE 4

The Five-Year Trend in National Average Dispensing Fees, 1974-1978

	Year	Average Fee	Change	% Change
Pre-EAC	1974	$1.96		
	1975	2.04	+ 8¢	+ 4.08%
	1976	2.11	+ 7¢	+ 3.43%
Post-EAC	1977	2.28	+ 17¢	+ 8.06%
	1978	2.45	+ 17¢	+ 7.45%

In the two years prior to EAC, the average dispensing fee increased at the rate of 3.76 percent per year. However, in the two years subsequent to EAC, the average fee increased at the rate of 7.76 percent per year. The average fee in 1978 was 17.2 cents higher than if the pre-EAC trend had continued. The greater post-EAC rates of fee increases, appear to be linked to the mandate for reassessment of dispensing fees.

Although it is not clear that the full amount of the incremental fee differential above pre-EAC trends should be attributed to EAC, we have chosen to do so even though the post-EAC rate of fee increase is still no greater than the rate of increase in the drug consumer price index.[13] If fee increases were uniquely tied to the general inflation rate, one would have expected the pre-EAC rate of fee increase to parallel the general inflation rate. This is clearly not the case. One explanation is that the market is shifting toward higher volume, lower cost pharmacies—that is, the chains are expanding and "corner" drug stores are closing. There is reason to believe that input price inflation is being substantially offset by efficiency gains.[14]

Attributing the full amount of the fee differential to the program represents a $2.8 million increase in dispensing fee reimbursement for the five study States. This implies that the EAC-part of the program is actually incurring a net loss, equal to about half a million dollars per year in the five study States. This general finding—namely, that no savings have been achieved by EAC—was also supported by econometric analysis of the aggregate drug reimbursement experience in all States.

The above finding tends to support a hypothesis put forward by program critics, namely, that there was simply no money to be saved by the EAC-provision of the MAC-EAC program. It had been argued that pre-EAC price levels fairly reflected the costs of doing business and that EAC-related savings in ingredient cost reimbursement would be offset by increases in dispensing fee reimbursement. Whereas current evidence is clearly consistent with that hypothesis, it is premature to either accept or deny it on the basis of the highly idiosyncratic EAC experience in our five study States. However, even if EAC is not found to save money, such finding would not preclude favorable evaluation of the EAC provision. To the extent that EAC rationalizes pharmacy reimbursement, by setting reimbursement limits that more nearly reflect the differential costs of different prescriptions, it furnishes more appropriate price incentives and may lead to a more efficient allocation of resources in the long run.

[13]It is possible that fee surveys may have simply catalyzed the adjustment of long-run disequilibrium problems and fee increases might have been imminent.

[14]This conclusion was also supported by econometric analysis. After controlling for other relevant differences (for example, wage levels and recipient characteristics), dispensing fees were estimated to increase unexpectedly by 17.6 cents per prescription in 1978.

Other Findings

Among other MAC- and EAC-related findings from the study were the following:

- No evidence was found that pharmacy participation rates have fallen in response to the MAC-EAC program. However, reliable information on pharmacy participation could be obtained in only two study States, Maine and Tennessee.
- In 1979, a significant percentage of the prescriptions for propoxyphene HCl (Darvon), and chlordiazepoxide HCl (Librium), were still being filled with the higher-priced brands. Thus, part of the MAC-related savings are temporarily coming from pharmacy losses as opposed to manufacturer profits.
- No evidence was found of MAC-related shifts toward prescribing of sole source, therapeutically-equivalent substitutes for the MAC products. Nevertheless, it appears that non-MAC products are gradually being substituted for at least some of the MAC products over time and therefore reimbursement savings may be expected to decline over time.
- Brand-necessary overrides were not a significant factor in any of the study States except Minnesota. Although Minnesota did not then have a mechanism for monitoring overrides, about 22 percent of the chlordiazepoxide prescriptions were reimbursed at the brand-name (Librium) price level.
- Some evidence was found that manufacturers of the higher-priced brands of the MAC products have reduced their prices in response to the MAC program. There was also some, albeit a much less strong, indication that the manufacturers of lower-priced brands have increased their prices to the MAC level and that manufacturers have increased price levels on sole-source substitutes.

The following findings come from econometric investigation:

- Usual and customary reimbursement limits were estimated to reduce reimbursement by 27 cents per prescription.
- Substitution laws were found to reduce reimbursement by 33 to 37 cents per prescription.
- A closed formulary (that is, a listing of drug products for which the Medicaid program reimburses) was found to reduce reimbursement by 32 cents per prescription.
- The results generally confirm the cost-savings potential of other types of program restrictions, especially copayments.

Implications

There should no longer be much doubt about the cost-savings potential of the MAC portion of the MAC-EAC program. The first efforts of the MAC program are clearly shown to have saved substantial amounts in the five study States, and there is no reason to believe that experience elsewhere will be different.

Moreover, the MAC-related reimbursement savings measured in this study represent merely the "tip of the iceberg" because the reimbursement savings were estimated for only the initial five MAC products. MAC reimbursement limits have now been established for 20 additional products. Furthermore, the number of multisource products available for MAC reimbursement will increase sharply in the near future, as bioequivalency standards are met by additional multisource products, and as more patents expire on sole-source products.

The cost-savings potential of the EAC portion of the MAC-EAC program is considerably less certain. Results indicate that EAC-related savings on ingredient cost reimbursement are offset by EAC-related increases in dispensing fee levels. However, it is premature to draw any strong conclusions on the basis of the highly idiosyncratic EAC experience across the five study States. In any event, the use of actual cost data for estimating ingredient cost and pharmacy dispensing costs levels provides a more rational mechanism for establishing reimbursement levels.

Acknowledgments

We wish to thank the pharmacist consultants in the five study States—George Levey in Massachusetts, Michael O'Donnell in Maine, John Bush in Minnesota, Herbert Bates, Jr., in Tennessee, and Debbie Dodson in Arkansas. We also thank those who assisted in preparing the data—John Tripoddi at Pilgrim Health Systems (Massachusetts), John Campbell at Health Systems Institute (Maine), and Charles Federspiel and Wayne Ray at Vanderbilt University (Tennessee).

We thank the present and former MAC program staff—Vince Gardner, Peter Rodler, Charles Spaulding, and Thomas Fulda—for furnishing various information and data. We also thank James Morrison at the Food and Drug Administration.

Steven Edberg and Michael Schwartz gave superb systems analytic support. Katherine Howard and Henry Goldberg provided critical administrative and other assistance.

Feather Davis was the initial HCFA Project Officer. Our debt to Dr. Davis is immense.

References

American Druggist. "Use of Consumer Leverage to Reduce Prescription Costs." November 1979, p.17.

Food and Drug Administration. *Approved Drug Products with Proposed Therapeutic Equivalence Evaluations*, January 1979.

Health Care Financing Administration. *Guide to Prescription Drug Costs*, April 1980.

Henderson, James M. and Richard E. Quandt. *Microeconomic Theory.* McGraw Hill, Inc., 1971.

Lee, A. James, *et al.* "Evaluation of the Maximum Allowable Cost (MAC) for Drugs Program: Final Report," *Health Care Financing Grants and Contracts Reports.* Pub. No. 03102. Health Care Financing Administration, April, 1981.

Trapnell, Gordon R. "Estimated Cost of Implementing the Regulations Limiting Payment under Federal Health Programs to Maximum Allowable Costs (MACs) and Estimated Acquisition Costs (EACs)." Unpublished, November 21, 1975.

U.S. Department of Health, Education, and Welfare. "Inflation Impact Statement on CFR Title 45, Subtitle A, Part 19—Limits on Payment or Reimbursement of Drugs." July 25, 1975.

U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs. *Final Report*, 1969.

Weinberger, Casper W. "Rules and Regulations, Part 19: Limitations on Payment or Reimbursement for Drugs." *Federal Register*, 40(148): 32284-32303, July 31, 1975.