BERC-356-P

P874605

COMMENTS OF THE BUREAUS OF ECONOMICS,
CONSUMER PROTECTION AND COMPETITION OF THE
FEDERAL TRADE COMMISSION
Washington, D.C. 20580
October 20, 1986

Introduction

The staff of the Federal Trade Commission ("FTC") is pleased to offer comments on the Notice of a Proposed Rule published by the Health Care Financing Administration ("HCFA") of the U.S. Department of Health and Human Services.[1] HCFA requests comments on three alternative systems for determining the maximum level of federal funding for state reimbursement of retail pharmacies for drugs dispensed to Medicaid customers. In fiscal year 1984, Medicaid program expenditures on prescription drugs totalled about $2 billion.[2]

The FTC has a long-term interest in the development of competition in the prescription drug market, as reflected in a number of FTC studies assessing competitive conditions in that market.[3] Further, the FTC and the

---

[1] On the subject of Limits on Payments for Drugs in the Medicaid Program, file code BERC-356-P, 51 F.R. 29,560 (August 19, 1986) (hereafter referred to as the "Notice"). These comments represent the views of the Bureaus of Economics, Consumer Protection and Competition and do not necessarily reflect the views of the Federal Trade Commission or any individual Commissioner. The Commission, however, has authorized the filing of these comments. Inquiries regarding these comments should be directed to John Woodbury, Bureau of Economics.

[2] R. Helms, "Statement by the Acting Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Before the House Subcommittee on Health and the Environment" (July 15, 1985), p. 2.

[3] These studies include R. Bond and D. Lean, Promotion and Product Differentiation in Two Prescription Drug Markets (FTC, February 1977); Bureau of Consumer Protection, FTC, Drug Product Selection (FTC, 1979) (hereafter, "BCP"); and A. Masson and R. Steiner, Generic Substitution and Prescription Drug Prices (FTC , October 1985) (hereafter, "Masson and Steiner").

Food and Drug Administration ("FDA") jointly developed a model state law that would permit pharmacists to substitute lower-priced versions of a drug for more expensive versions.[4] It is against the background of our experience and expertise in examining the prescription drug market that we offer these comments to HCFA.

In section I, we describe the current reimbursement scheme and the proposed alternatives. Section II discusses the goals against which the alternative proposals should be evaluated. In sections III, IV and V, we assess the extent to which the proposed alternatives are likely to attain these goals. In section VI, we summarize our conclusions and recommendations.

In brief, the touchstone of our analysis is economic efficiency. No reimbursement scheme should unnecessarily skew marketplace outcomes to the detriment of Medicaid and non-Medicaid consumers alike. Unfortunately, the current reimbursement scheme may have unduly hindered competition by limiting the incentive to dispense the lower-cost versions of drugs. This may have occurred because relatively few of the drug categories with multiple versions of the drug available were included in the current scheme that encourages pharmacists to dispense lower-cost versions of the drug to Medicaid consumers. We therefore endorse HCFA's intention under each alternative to expand the number of drug categories for which there is an incentive to dispense lower-cost versions of the drug. Further, we suggest that HCFA consider complementing the pharmacist's incentive to dispense lower-priced versions in a drug category with an incentive (namely, a

---

[4] See BCP, pp. 273-288.

percentage copayment) for Medicaid consumers to search among pharmacies for lower-cost drugs.

However, none of the proposals permit Medicaid consumers to register their preferences for a particular version of a drug, including a brand name. As a result, the proposals may unnecessarily discourage the development of brand-name reputations and non-price differences among therapeutically-equivalent drug products. Brand names may provide consumers with valuable information regarding non-price differences among versions in a particular drug category. We therefore suggest that in whatever scheme is adopted, HCFA permit Medicaid consumers to purchase the version of a drug they prefer if they are willing to pay the difference between the price of the preferred version and the reimbursement level determined by HCFA.

For each proposal, we also suggest that HCFA carefully consider what the most efficient distribution system for the delivery of prescription drugs to Medicaid consumers might be. A lower reimbursement level will reduce the costs of the program to the government. However, the number and quality (for example, locational convenience) of participating pharmacies may fall as the reimbursement level is reduced. Consequently, the accessibility of pharmacies to Medicaid consumers may decline. In selecting the reimbursement level that yields the most efficient distribution system, we suggest that HCFA balance the gain in government savings from lower reimbursement levels against the costs of reduced accessibility of pharmacies to Medicaid consumers.

While we offer a number of suggestions concerning reimbursement schemes, a lack of available data prevents us from determining which of

the proposed alternatives is best. We suggest the kind of further analysis that might be undertaken to eliminate these information gaps.

I. THE CURRENT AND PROPOSED MEDICAID REIMBURSEMENT SYSTEMS FOR DRUGS

While the states are directly responsible for implementing Medicaid programs, the rules governing federal reimbursement of state Medicaid expenditures exert a strong influence on the state programs. The purpose of the current federal-state program is to reimburse the retail pharmacist for the entire cost of a Medicaid prescription drug beyond the small fixed copayment that may be paid by the consumer.[5] States set many rules, which may include the consumer's copayment, a list of drugs for which reimbursement will be made, mandatory substitution of lower cost versions of a drug for higher cost versions, and the amounts of reimbursement. The state in turn is reimbursed by federal monies, in accordance with HCFA regulations. It is these HCFA regulations that are now to be revised.

The federal Medicaid drug reimbursement system currently in place is a composite of several interlocking elements. The HCFA regulations for the reimbursement for multisource drug categories (i.e, drug categories with two or more therapeutically-equivalent versions available)[6] requires payment by

---

[5] Twenty-two states currently require a fixed copayment, most frequently $.50 or $1.00. Drug Topics (March 24, 1986), p. 29. For some drug categories with multiple versions of the drug available, these typical copayments amount to 9 percent and 18 percent respectively of the average price of the lower-priced versions. The price data used is from Professional Management Associates, Inc., Interim Report on Medicaid Reimbursement Policies (September 8, 1986), Table 1, Column 1. The imposition and magnitude of copayments are governed by 42 U.S.C. Section 1396(o).

[6] Multisource drug categories are those with two or more products containing the same active chemical ingredients. Many multisource drug categories contain products that are both chemically and therapeutically equivalent. In this Comment, we confine our attention to that class of multisource drug categories that contain chemically and therapeutically

HCFA of the lowest of a) the usual and customary retail price of the individual pharmacist in question for the exact product dispensed, b) the sum of a dispensing fee and the Estimated Acquisition Cost (to the retail pharmacy) ("EAC") of the drug product or c) the sum of a dispensing fee and the Maximum Allowable Cost ("MAC") of the drug. The MAC system was designed to encourage pharmacists to dispense low-cost generic drug products. For multisource drugs for which no MAC limit has been established, reimbursement is the lower of (a) or (b).[7]

In place of the current scheme, HCFA proposes to adopt one of three alternatives for multisource drug reimbursement: (a) a revised MAC program; (b) a Pharmacists Incentive Program ("PhIP"); or (c) a Competitive Incentive Program ("CIP"). For all three alternatives, the list of drugs to be included in the special multisource reimbursement schemes would encompass all drug categories that are deemed by the FDA to contain therapeutically equivalent

---

equivalent drug products. Within that class, we often refer to "generic" versions of a drug, products chemically and therapeutically equivalent to the leading or pioneer versions of the drug. Finally, the discussion below focuses only on schemes which reimburse the pharmacist for dispensing particular products in a multisource drug category when the pharmacist has the discretion to select the particular product dispensed. The FTC's expertise is most extensive in the assessment of competition in the multisource drug categories.

[7] The prescription dispensing fee is set in each state after pharmacies' costs of dispensing are surveyed and analyzed. Dispensing fees are updated occasionally. The EAC is established by the states by reference to published sources of advertised wholesale prices for individual products. Finally, the MAC system applies to a small list of multisource drugs for which the maximum allowable cost for each drug category is currently established at the 70th percentile of actual wholesale invoice costs of pharmacists as determined from survey data. Thus, pharmacies dispensing a drug under the MAC system receive a fixed level of reimbursement regardless of the particular manufacturer's product actually dispensed, provided that the EAC of the drug product dispensed is greater than the MAC. The list of multisource drugs for which MAC limits are determined is set by HCFA after a period of public comment and in consultation with the FDA. The MAC limits are also established by HCFA after a period of public comment.

products[8] and for which the advertised wholesale prices of at least three suppliers are included in the most current edition of the Red Book or Blue Book, standard industry sources.

The MAC limits in the revised MAC proposal would be determined in streamlined administrative proceedings. EAC and the dispensing fee would continue to be determined as in the current program.

Under the PhIP proposal, reimbursement of multisource drugs would be a specific percentage (for example, the HCFA - proposed 150 percent) of the lowest price advertised in each multisource drug category in the most current Red Book or Blue Book, plus an estimated reasonable dispensing fee. However, HCFA also proposes to limit the payment to no more than $4.00 and no less than $1.50 above the lowest price advertised in each multisource drug category.

Under CIP, HCFA proposes to use as the basis of its reimbursement limits for all (not just multisource) drugs the actual price charged by the pharmacist to its non-Medicaid customers, less a discount of 5 or 10 percent. However, if the pharmacist chooses to dispense a higher-priced leading brand when a lower priced generic version could have been dispensed, the discount rises to 25 percent. HCFA is also proposing that in no case would the CIP reimbursement exceed 125 percent of the median retail price in the state for a particular manufacturer's product.

---

[8] The list includes all drug products in a specific drug category that are identical in terms of their active chemical ingredients, dosage form and strength and that have been classified as "A" in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.

II. GOALS OF REVISION

In assessing the proposed schemes as well as the reasons for HCFA's dissatisfaction with the current MAC program, we begin by noting that any reimbursement program should contribute to a number of sometimes conflicting goals.

A. Economic efficiency.

First, any scheme of prescription drug reimbursement should contribute to economic efficiency. Thus, the scheme should not hinder the development of market mechanisms that assist consumers (i.e., reduce their costs) in making product choices; that facilitate the least-costly distribution of goods to consumers; and that promote price competition or, in a dynamic market environment, promote the production of new goods and product attributes desired by consumers. A scheme that unnecessarily impedes the use or development of such mechanisms or otherwise unnecessarily distorts marketplace outcomes may impose costs on Medicaid and non-Medicaid consumers that must be weighed against any resulting administrative or reimbursement cost savings to the government.

For example, in many economic markets, firms have an incentive to develop a brand name reputation. While consumers may pay a higher price for brand name goods, brand names often have value to consumers because they may indicate that the expected quality of a product is higher than that for non-branded products, and the existence of brand names reduces the costs of consumer search for products that best satisfy consumer demands. Brand names provide an incentive for firms to develop product attributes that consumers value and to compete along these and other non-price dimensions, for example, by communicating these non-price differences (as

well as price differences) to consumers via advertising. The information contained in advertising is valuable to consumers not only directly but also indirectly because it may facilitate entry by new suppliers and thus advances competition.

Thus, the selected reimbursement scheme should not unduly hinder new product introduction, brand name differences and other non-price dimensions of competition, just as it should not hinder price competition.

B. Incentive to dispense the lowest-cost generic product.

One significant reason why HCFA is considering replacing the current reimbursement scheme is to reduce the government's reimbursement costs by encouraging Medicaid consumers to seek out and pharmacists to dispense the lowest cost generic drug products. This goal will be easier to attain as the number of multisource drug categories that fall within this incentive scheme increases. If multisource drug products were reimbursed at a fixed level, the structure of the current MAC program would yield incentives for low-cost generic drug dispensing for drugs on the MAC list: in dispensing a MAC drug, the pharmacist could retain the difference between his actual acquisition plus dispensing costs and the MAC plus the estimated dispensing cost. However, it is our understanding from discussions with HCFA staff that, at least for some MAC drug products, the EAC is less than the MAC.[9] Consequently, the incentive to dispense the lowest cost generic drug product

---

[9] This can occur because each MAC is determined by reference to the range of wholesale prices for all drug products within a particular drug category. By contrast, the EAC is established for each specific drug product.

may be reduced under the current MAC scheme.[10] Even if this were not the case, the current administrative machinery has proven costly and cumbersome for determining which multisource drug categories should have MAC limits and what those limits should be. Consequently, only a relatively small number of multisource drug categories have HCFA - determined MAC limits.

The opportunity for government savings through enhancing the incentive for low-cost generic use is large.[11] Approximately two-thirds of all prescriptions written in the U.S. are for multisource drug categories. The difference between the price of the leading brand in a prescription drug entity and the price of alternative brands in the same entity is typically large.[12] Savings depend not only on whether the pharmacist dispenses a generic drug product but also on which generic is selected because of the wide variation in the cost to the pharmacist of different generic versions of

---

[10] For example, consider two versions, A and B, in the same drug category. The MAC for both is $5 and the (correctly estimated) dispensing fee for both is $3. The EAC for A is $5.50 while that for B is $4.50. The actual wholesale price to the pharmacist is $4.00 for A and $3.75 for B. If the pharmacist dispenses the lowest-cost version (B), the amount of reimbursement is $7.50 (EAC plus dispensing fee), leaving the pharmacist with a profit of $.75 ($7.50 less dispensing costs less the wholesale cost). If instead A is dispensed, the reimbursement would be $8.00 (MAC plus dispensing fee), leaving the pharmacist with a $1.00 profit.

[11] One indication of the savings potential from restoring the incentive to use generic drug products in the Medicaid program is an estimate of savings due to states' allowing generic substitution. An FTC staff report estimated the annual reduction in consumer expenditures attributable to state policies that permit generic substitution to be $44 million to $80 million in 1980 and perhaps three times that in 1984. Masson and Steiner, p. 183.

[12] A 1980 average price across 37 leading multi-source drugs, weighted by number of prescriptions sold, was $8.22 for the leading brand and $6.22 for the average of other brands, a difference of $2.00, or nearly 25 percent of the leading brand price. Masson and Steiner, pp. 5, 356-36.

the same drug.[13] Thus government savings can be increased if pharmacists choose low-cost rather than high-cost generics.

C. Pharmacy participation

A third goal is the selection of the most efficient set of pharmacies to handle Medicaid drugs.[14] The level of Medicaid reimbursement will affect not only the number of pharmacies that opt to participate but also the "quality" of such pharmacies. Other things being equal (for example, the number and types of Medicaid prescriptions dispensed, the incentive for the pharmacist to dispense the lowest-cost generic product, and the administrative costs), a lower reimbursement level will not only reduce government costs but also reduce pharmacy participation and accessibility of participating pharmacies to Medicaid consumers.[15] The Notice describes HCFA's concern that in fact many pharmacists have had difficulty in acquiring drugs at or below the MAC levels in the current scheme.

---

[13] In the 1984 Red Book, for example, the wholesale price per 100 tablets/capsules of allopurinol, other than the leading brand, ranged from $14.65 to $33.68; for amoxicillin from $8.95 to $27.25; for metronidazole from $28.75 to $54.40; for amitriptyline from $2.10 to $10.48. The extent of price dispersion among generic products is puzzling. One would expect that pharmacists would be knowledgeable about the therapeutic equivalence of generic products and therefore that competition among generic product manufacturers for the patronage of pharmacists would greatly reduce the degree of price dispersion. One possible explanation is that the dispersion among transactions prices is far less than that for advertised prices. Alternatively, these price differences may reflect real non-therapeutic differences among generic products.

[14] Our understanding from discussions with HCFA officials is that most U.S. pharmacies currently participate in the Medicaid program.

[15] To the extent that many pharmacies depend upon Medicaid consumers for purchases of drugs and other goods, such pharmacies might exit the industry if the reimbursement level is not sufficient to profitably maintain their participation in the Medicaid program.

D. Administrative costs

A fourth goal of any reimbursement scheme is to reduce the administrative costs, including any costs required to insure that the reimbursement limits accurately reflect changing market conditions. As noted above, the current administrative process for determining MAC limits has proven unwieldy.

III. EFFICIENCY EVALUATION

All three proposals encourage greater use of generic drug products by expanding the set of multisource drugs for which the dispensing of generic drug products would be encouraged from the present relatively short MAC list to a much larger FDA list.[16] The FDA therapeutic equivalence list reflects the fact that for many multisource drugs there is now substantial agreement that no serious therapeutic inequivalence problems exist.[17]

Under the current administrative scheme, neither the pharmacist nor the customer has the incentive to dispense or use the lowest cost version of

---

[16] Compared to PhIP or CIP, the universe for possible generic substitutions at any given time might be somewhat smaller under the revised MAC plan simply because of delays in adding new products or new generic entities. The revised MAC system requires publication of notices of proposed actions, with a comment period to follow, before a drug is added to the MAC list. However, the revised MAC proposal would streamline the current administrative process.

[17] However, two same-strength products in the same generic entity, containing the same active chemical ingredients in identical proportions, may not always have the same effects in a patient, because differences in inactive ingredients used for binding or coloring may modify the effects of the active ingredients or create their own unintended side effects. Further, therapeutically equivalent products may differ with respect to flavoring, color, shape, packaging, and shelf life. FDA, Approved Prescription Drug Products with Therapeutic Equivalence Evaluations (1985), pp. I-2, I-3. For a more extensive discussion of these and other differences, see M. Lieberman, The Essential Guide to Generics (Harper and Row, 1986), pp. 4-11.

a multisource drug in many multisource drug categories.[18] This government-induced indifference in the current scheme regarding which non-MAC multisource drug is dispensed may have unduly limited the extent of competition among generic drug products and between generic and brand name drug products, thereby raising the cost of the Medicaid program to the government and the costs for non-Medicaid consumers as well. However, because the three multisource reimbursement proposals focus exclusively on encouraging the dispensing of low-cost generic products, they appear to veer too far in discouraging the development of brand names and non-therapeutic differences among drug products. Between these two extremes, we propose a straightforward middle ground.

A. Benefits from encouraging pharmacists to dispense lower-cost drug products

Information about American consumers in general suggests that many feel ill-informed about generic drug products.[19] This conclusion is supported by a recent FTC study which points to consumers' lack of information as a major cause of reluctance to accept a generic drug product.[20] For example,

---

[18] For non-MAC multisource drugs, the pharmacist is currently reimbursed at EAC plus the estimated dispensing fee. If these estimated costs were accurate, the pharmacist would have no incentive to dispense a lower cost product instead of a higher cost product to Medicaid customers. Because Medicaid customers bear at most a small fixed dollar copayment for the purchase of the drug, they also have no incentive to request a lower cost product.

[19] According to the CBS Consumer Model, a national survey done in 1983, consumers rate themselves as being either "not very informed" (29 percent of the sample) or "somewhat informed" (25 percent of the sample) on the effectiveness of generic prescription drugs; 45 percent said they were "not at all informed". On brand versus generic prescription costs, the typical consumer was less than somewhat informed. The CBS survey used a national probability sample of households. The CBS Consumer Model, 1984, p. 14.

[20] Masson and Steiner, pp. 5-7.

the study shows that consumers are more likely to accept generic drug products if they feel their doctor has certified their appropriateness.[21] The most likely explanation of this behavior is that consumers (and pharmacists) interpret the fact that physicians specify a brand as a strong preference on the physician's part for that particular brand, even when the physician has not chosen to exercise the legal option to prohibit substitution explicitly, an option available on every prescription. The physician may not, in fact, have a strong preference, but the consumer's uncertainty deters acceptance of a substitute brand.[22]

---

[21] Consumers accept generic substitutions at the pharmacy only a small fraction of the time when the physician has named a brand (on 7.3 percent of prescriptions on which substitution was permitted in 1980), yet they accept generics nearly all the time (89 percent in 1980) when the physician prescribes generically. Masson and Steiner, pp. 27, 116-117. In the U.S. market as a whole, use of generic drug products is increasing rapidly. The market share of generic drug products in 1980 was about 25 percent of 45 leading multisource drugs dispensed. Masson and Steiner, p. 117. Officials at the Pharmaceutical Manufacturers Association report that a drug-by-drug analysis of the market share of generic drug products shows substantial increases between 1980 and 1986, citing increases of 20 percentage points in some instances. These increases are consistent with a heightened consumer understanding of the therapeutic equivalence of lower-priced generic products and the higher-priced brand names. The rise in the market share of generic drug products may also reflect recent changes in state laws that now permit the pharmacist to substitute generic drug products on a prescription written for a brand name (provided that the prescribing physician does not explicitly prohibit such substitution). Masson and Steiner, p. 1. As a result of these changes in state laws, the percentage of brand-written multisource prescriptions on which substitutions were made nearly doubled from 5.1 percent to 9.5 percent between 1980 and 1984. Stephen C. Chappell, "1st 6 Months of '84: Independents & Drug Chains Dispensed 775.7 Million Prescriptions." Pharmacy Times, October 1984, pp. 25-31.

[22] HCFA notes that it intends to retain the requirement that any physician veto or override of substitution must be certified in the physician's own handwriting. We endorse retention of this requirement. Previous research has consistently demonstrated that the format of the physician's prescription pad has a substantial impact on the incidence of physician overrides. For example, one study found that substitution was 18 percentage points higher for formats requiring more physician effort to override substitution than for other formats. See Masson and Steiner, pp. 89-97; 100-

HCFA is of course fully aware of the therapeutic equivalence between lower-cost generic products and higher-priced brand names. Yet, by reimbursing non-MAC multisource drugs dispensed at EAC, HCFA's scheme provides no incentive for pharmacists to dispense lower-cost drug products.[23] This may have adverse consequences for consumers (including non-Medicaid consumers) by reducing the availability of generic products, by reducing downward pressure on prices, and by slowing the diffusion of information to consumers about therapeutic equivalence.

By expanding the number of multisource drug categories for which there are incentives for pharmacists to dispense lower-cost drug products, the three proposals ameliorate these inefficiencies. The resulting increase in competition may cause generic drug prices to decline.

In each of the proposed alternatives, these benefits could be magnified if the pharmacist's incentive to dispense lower cost generic products were complemented by incentives for the Medicaid consumer to request these products and to shop among pharmacies for the lowest-priced version in each drug category. We would therefore suggest that HCFA consider a requirement that Medicaid consumers pay a percentage copayment. We recognize that HCFA must weigh the efficiency benefits of a copayment

---

101; and 106-107. See also, C. DeVito, W. Dickson, and J. Gabel, "Evaluating Kentucky's Generic Substitution Law" in Generic Drug Laws: A Decade of Trial--A Prescription for Progress (U.S. Department of Health and Human Services, June 1986), pp. 401-402.

[23] Indeed, the pharmacist may in fact be inclined to dispense brand names rather than generic drug products under EAC. For example, consider a Medicaid prescription written generically or for a brand name but which permits the pharmacist to substitute a generic drug product. If the pharmacist were to dispense the generic product, the pharmacist might have to bear the cost of explaining to the Medicaid patient that the generic product dispensed is therapeutically equivalent to the brand name product.

against any income distributional considerations, particularly the possibility that for very expensive drugs, a copayment may be onerous for the Medicaid consumer.[24]

We note, however, that the three proposals are not identical with respect to the pharmacist's incentives to dispense the lowest-cost products in any particular drug category. PhIP clearly creates an incentive for the lowest cost generic drug product to be dispensed because the pharmacist can retain the difference between the PhIP limit plus the estimated dispensing fee and the pharmacist's true wholesale and dispensing costs. Because the EAC of many products within each multisource drug category may be below the MAC, the revised MAC proposal may not create as much incentive for the pharmacist to dispense the lowest-cost generic product.

The proposed 25 percent brand-name discount in the CIP proposal will certainly encourage the pharmacist to dispense a lower-priced generic product instead of a brand name product.[25] However, we can detect no

---

[24] One way of ameliorating this particular concern would be a graduated copayment schedule. For example, on any prescription the Medicaid consumer might provide a copayment of 20 percent on the first $20 and 5 percent on anything over $20. We recognize that implementation of this recommendation would require statutory changes.

[25] We note that under CIP, prices for multisource products other than the leading brand would be discounted by 5 or 10 percent. There seem to be three reasons for this particular discount. First, data show that EAC levels are approximately 10 percent below retail prices to private pay customers. (New results from HHS contractor's analysis, as reported by Walt Francis of HCFA.) This suggests that, in the absence of a Medicaid discount, reimbursement levels would be higher than current reimbursement levels. Second, pharmacies often provide "senior citizens" discounts of 10 percent. Third, through Medicaid the government is a volume buyer. Volume discounts appropriately reflect real savings when it is cheaper to deal with one large buyer than with several smaller ones. However, Medicaid transactions occur individually. It is difficult to argue that the real costs to the pharmacy are lower because the prescriptions are for Medicaid customers. On the contrary, pharmacies' costs may be higher for Medicaid prescriptions than for cash-paying customers because of paperwork

mechanism in CIP that would encourage the pharmacist to dispense the lowest-priced generic.[26]

B. Costs of excessively discouraging use of brand-name drug products

While the current multisource reimbursement scheme may have unnecessarily hindered competition between brand name and generic products, at least two of the three alternatives (PhIP and CIP) appear to discourage the potentially efficient development of brand-name reputations and non-price differences among therapeutically-equivalent drug products.[27] A policy actively discouraging brand-name dispensing is predicated on the assumption that informed consumers will be indifferent between two drug products that

---

and delays in reimbursement. Therefore, if volume purchases under Medicaid were the proferred basis for the discount, we would recommend elimination of this discount.

[26] In a recent supplementary Notice, HCFA expressed concern about an apparent anomaly in the CIP proposal. HCFA noted that CIP might generate a reimbursement level for the highest-priced generic product dispensed that is greater than the brand-name reimbursement level (after the 25 percent discount is applied to the brand-name product). Federal Register (September 18, 1986), pp. 33086-33087. HCFA considers two alternatives to reduce the incidence of this anomaly. The first is to supplement the 25 percent brand-name discount with a limit on the reimbursement for any generic product, the limit being no more than 75 percent of the median leading brand price. While this proposal, if adopted, may have the advantage of both discouraging the unilateral dispensing of higher-priced generic products by the pharmacist and of limiting the extent of the anomaly, CIP as modified would still not provide incentives for dispensing the lowest-priced generic product. HCFA's second alternative would be to raise the reimbursement level for brand name products. Raising the reimbursement level for brand-name products would not reduce the pharmacist's incentives to dispense brand-name products. Other things equal, the first alternative seems preferable.

[27] Because it sets a fixed reimbursement level, PhIP encourages the dispensing of lowest cost generic products. Under CIP, the pharmacist would receive only 75 percent of the retail price charged if a brand name were dispensed. The incentives in the revised MAC are less clear if the EAC of many drug products falls below the MAC level. The marginal profit from dispensing a brand-name product could be greater or less than that from dispensing a generic product.

are therapeutically equivalent. This may not in fact be the case. To use an extreme example, a Yugo and a Rolls Royce may be "transportationally equivalent" but they are not homogeneous in the view of consumers.

Therapeutically-irrelevant product differences might include, for example, the incidence of side effects that are annoying to consumers without posing health hazards, the size and shape of the tablet, and taste. A brand name or the development of a reputation for quality may signify to the consumer that the probability of experiencing annoying side effects is lessened.

By focusing on price as the only important difference among drug products, HCFA may discourage the development of therapeutically equivalent drugs that differ in important dimensions to consumers. Similarly, HCFA may discourage advertising to doctors and pharmacists and the development of brand names in prescription drugs even if these brand names convey useful information to consumers. Further, if the current virtual FDA ban on direct consumer advertising of individual prescription drugs were relaxed, the incentive of drug manufacturers to provide information via such advertising may be diminished under any of the HCFA schemes.[28]

We are not aware of any evidence that would indicate the extent to which consumer perceptions of non-price differences among therapeutically equivalent drugs are important. Experience in other markets, however, clearly suggests the importance of non-price differences to consumers. For

---

[28] Evaluating the role of brand names and thus the source of price differences between brand name and generic drug products in a multisource drug environment is difficult in part because of the virtual FDA ban on direct consumer advertising of prescription drugs and therefore the lack of this particular source of consumer information on the products of individual drug manufacturers. See A. Masson and P. Rubin, "Plugs for Drugs," Regulation (September/October 1986), pp. 37-43 ff.

example, following airline deregulation, a hitherto unknown variety of price-service options available to consumers began to flourish. With the advent of the advertising of legal services, a number of "no-frills" and low priced services were offered to consumers. Brand names have played an important role in efficiently guiding consumer choice in products ranging from appliances to fast-food chains.

We recommend that in the reimbursement scheme adopted by HCFA, Medicaid consumers have the option of purchasing any multisource drug provided they pay the pharmacist the difference between the market price of the purchased drug and HCFA's reimbursement level.[29]

C. Conclusion.

In sum, the current HCFA reimbursement scheme for multisource drugs may artificially inhibit competition between generic drug products and brand name products as well as among generic drug products. The multisource coverage of the current MAC scheme is limited, and neither pharmacists nor Medicaid consumers have an incentive to select the lower-cost generic

---

[29] For this reason, we recommend that the 25 percent brand-name discount in the CIP plan be replaced with a less costly alternative. For Medicaid consumers that wish to purchase a higher-cost version of a drug in the CIP plan, we suggest that such consumers pay the difference between the price of the lowest cost product dispensed by the pharmacist and the higher cost product. The pharmacist, in turn, would be reimbursed by the government for the price of the lowest-cost generic dispensed. Should HCFA choose to retain the 25 percent discount, then we would suggest that the Medicaid consumer requesting a brand name product pay the pharmacist 25 percent of the brand name price. In either case, the pharmacist will be discouraged from choosing to dispense a brand-name product to a Medicaid consumer unless the consumer values the higher priced drug sufficiently.

Because the CIP reimbursement rules as originally proposed distinguish between leading brand and generic products, we note that the leading brand in each drug category must be unambiguous. Yet HCFA offers no definition of a leading brand. We suggest that HCFA consider defining the leading brand product as the pioneer product. HCFA might also require that a leading brand be defined as any product named by physicians on at least, for example, 30 percent of all prescriptions in the particular drug category.

products in many cases. Consequently, fewer generic alternatives may be available, the prices for available generic drug products may be higher, and the price of the brand name drug product may be higher than would be efficient. Because of the greater rate of generic product introduction expected as a result of the streamlined FDA approval process mandated in the Hatch-Waxman Act, the costs of limits on the dispensing of generic drug products in the future would be enormous. Because all three proposed alternatives will expand the number of multisource drug categories included under a reimbursement scheme designed to promote greater use of generic drug products, all are improvements over the current scheme. However, only PhIP appears to create unambiguous incentives for the pharmacist to dispense the lowest-cost generic product.

However, we note that the assumption that therapeutic equivalence implies product homogeneity in the view of consumers may not be correct. We would therefore urge HCFA to modify whatever scheme is adopted in order to avoid unnecessarily discouraging the use of brand name products by consumers willing to pay the higher price and thereby avoid discouraging the development of non-therapeutic differences across drugs, investment in brand names, and non-price competition.

Within the framework of the efficiency goal, we would also suggest that HCFA compare its current and proposed schemes of prescription drug reimbursement and distribution to those developed by private insurance companies. Those firms have profit incentives to pick the efficient structure of distribution and reimbursement levels, ceilings on total reimbursement, and

incentives to encourage both pharmacists and consumers to select the lowest-cost drug products.[30]

IV. PHARMACY PARTICIPATION

Each of the proposed multisource reimbursement proposals will likely have different effects on pharmacy participation rates unless the average reimbursement level for Medicaid prescriptions dispensed were identical in each.[31] As previously observed, HCFA has noted the complaints of some pharmacists that they are unable to acquire MAC drugs at or below the MAC limit. In a recently-released study conducted for HCFA, the revised MAC proposal is estimated to result in the highest average per-prescription reimbursement level, followed by PhIP and CIP.[30] Yet, there is no evidence that HCFA has considered the effect of the reimbursement level on the pharmacy participation rate in setting the rates at which pharmacies will be paid under each of the three proposals.

---

[30] However, subsidies to employer-financed schemes provided by the tax system may encourage excessive insurance coverage.

[31] This assumes that each proposal provides an equal incentive for pharmacists to dispense lower-cost generic products.

[30] Professional Management Associates, Interim Analysis of the Medicaid Reimbursement Policies (September 4, 1986), Tables 2, 3, and 12. We note that among other difficulties, the definition of multisource drug categories in the report is different from that described in the Notice. Further, while the reported reimbursement levels for revised MAC and PhIP may be reliable indicators for analysis of pharmacy participation, that for CIP may not. Unlike PhIP or MAC that establish a single reimbursement level for all pharmacies, the reported reimbursement levels for CIP reflects pharmacy-specific prices as well as the effect of the 125 percent screen that determines the maximum reimbursement level. Thus, the average per-prescription reimbursement level for CIP includes drug products whose retail prices are less than the screen as well as those whose prices are at or above the screen. For assessing pharmacy participation, it is only this maximum CIP level (the screen level) that is relevant.

Because, in principle, any desired reimbursement level can be attained under any of the three alternatives,[31] the reimbursement level, and the participation rate implied by that level, should not be used as a basis for choosing one proposal rather than another. Rather, the choice of reimbursement mechanism should be made on other grounds, such as the plan's effect on economic efficiency and its administrative costs. After the plan is selected, attention should then be directed to selecting the reimbursement level that will induce the most efficient number and types of pharmacies to participate in the program.[32]

In considering the efficient level of pharmacy participation, we note that designing a system of Medicaid drug distribution that includes most operating pharmacies may result in excessively high reimbursement costs.

---

[31] The choice of the MAC limit for each drug category (plus the estimated dispensing fee) in the revised MAC program will determine that scheme's reimbursement level. The percentage and dollar multiples of the Red Book's or Blue Book's lowest cost generic product in each drug category (plus the estimated dispensing fee) will determine PhIP's reimbursement level. The 125 percent screen will similarly establish CIP's maximum reimbursement level.

We also note that the Notice proposes that the PhIP ceiling (excluding dispensing fee) be set at 150 percent of the lowest published wholesale list price, but that the ceiling reimbursement (excluding dispensing fee) be no less than $1.50 and no more than $4.00 above that lowest price. This approach seems more arbitrary than necessary. HCFA might consider a somewhat less arbitrary mechanism that preserves the central principle of the plan -- tying the reimbursement to a low-ranked wholesale price -- but is simpler: choosing the third lowest (or the median) price as the PhIP level. An advantage would be the elimination of need for minimum and maximum dollar incentives and the percentage multiple. Their elimination would remove two problems. First, since prescription prices will change along with the level of prices in general, any minimum and maximum dollar figures would have to be inflation-adjusted over time. Second, the specification of any dollar minimum or maximum incentive or a percentage multiple might for some drugs be either insufficient to assure availability of low cost products or much more than necessary to assure their availability.

[32] Thus HCFA can adjust the details in each of the three schemes to attain any desired level of savings in government reimbursement costs.

For the same drug dispensed in any given dosage form, the price variation among drug stores in any given geographic area is usually substantial.[33] Further, for each pharmacy participating in the Medicaid program, there may be a fixed administrative cost borne by HCFA. Thus, the higher HCFA's reimbursement level for prescription drugs dispensed to Medicaid patients, the greater will be the number of participating pharmacies of any given quality (cost) and the higher will be the government's reimbursement and administrative costs.

In choosing the number and quality of participating pharmacies, HCFA must also consider the accessibility of these pharmacies to Medicaid customers. The lower the number of participating pharmacies, the less accessible participating pharmacies will be to Medicaid customers. The optimum distribution system is one that just balances the additional government reimbursement costs of increasing the number and type of participating pharmacies with the additional benefits of increasing Medicaid customers' access to participating pharmacies.

We do not have sufficient information to conduct this balancing. Without knowing how various classes of pharmacies will decrease their participation in response to a lower reimbursement level and how those decreases affect accessibility to Medicaid consumers, we cannot provide HCFA with even a cursory discussion of each proposal's effects on pharmacy participation.

---

[33] See D. Kreling, Developing A Prescription Drug Reimbursement Formula For Texas, unpublished Ph.D. Dissertation (University of Texas (Austin), 1984).

V. ADMINISTRATIVE COSTS

All three proposals entail substantial costs of administration. All require pharmacists to file claims and states to review and pay them. All require analysis of data to set acceptable reimbursement levels.

As compared to the current MAC program, the revised MAC proposal envisions a streamlined "notice and comment" procedure by which HCFA would determine MAC limits for multisource drugs covered by the reimbursement scheme. Nonetheless, HCFA staff would still have to monitor FDA therapeutic evaluations, prepare notices for the Federal Register, and evaluate comments. Private firms would incur costs in responding to the request for comments for setting the initial MAC limit and for changes in those limits. HCFA's availability survey and the states' dispensing fee surveys would be retained. HCFA would continue to purchase and analyze invoice cost data in order to determine the MAC reimbursement level for each drug category. Further, HCFA proposes to set regional MAC limits to insure availability of multisource drugs to pharmacists, an added administrative burden. Finally, the states would still be required to set the EAC for each product and the dispensing fee. This process promises to be expensive, but we have no data on what the actual administrative costs might be or how they might compare with current costs.

As in the current and revised MAC, the PhIP proposal would require periodic surveys by the states of pharmacists' dispensing costs,[34] as well as

---

[34] Actually, the Notice seems to suggest that these surveys would be continued even under CIP. We can see no usefulness of dispensing cost surveys if CIP is adopted.

the EAC for each product.[35] PhIP would also require an analysis of list price data for multisource drugs. Because the data are now computerized and updated monthly by the publishers, and the programming required for determining any reimbursement level tied to a low-ranked price as well as changes in that level is simple, the costs of this procedure would be moderate. The administrative costs of PhIP may be substantially lower than those of the revised and current MAC.

For a number of reasons, the administrative costs of the CIP proposal are more difficult to evaluate than those of the other proposed schemes. Unlike the current or revised MAC or PhIP, CIP does not require an estimate of the EAC or the dispensing fee. Nor is an availability survey required. However, in order for the 125 percent screen to reflect actual retail prices, we presume that periodic surveys by states would be required, an added administrative burden.

We also suggest that an additional monitoring and enforcement cost may have to be incurred with CIP. Any scheme that bases reimbursement on the prices charged by individual pharmacists may create an incentive for pharmacists to charge the government (i.e., Medicaid customers) higher prices than other customers. To the extent that the 125 percent screen typically exceeds the price charged to retail customers, pharmacists will have an incentive to charge Medicaid consumers the screen price while charging non-Medicaid consumers a lower competitive price. First, pharmacists know who their Medicaid customers are. Second, Medicaid customers do not care what price is charged for the prescription since their copayment, when required,

---

[35] In the PhIP as in the current and revised MAC, products which do not fall into a multisource drug category would be reimbursed at the product's EAC plus estimated dispensing costs.

is a fixed dollar amount. Thus, pharmacists can charge Medicaid customers inflated prices and the Medicaid customers will have no incentive to seek a new pharmacist.[36] Further, unless the screen were defined in terms of private pay prices only, the screen itself might also rise.

The invitation to engage in dual pricing would affect all Medicaid prescriptions. Were dual pricing to be unchecked, the added cost to the Medicaid program could be substantial. Although HCFA would require that the screen be determined by the prices paid by non-Medicaid customers in each state, HCFA might find it cost-effective to audit the Medicaid and non-Medicaid prices of at least some individual pharmacists.[37]

In sum, while PhIP clearly has lower administrative costs than the revised MAC, a lack of data does not permit us to compare either PhIP or the revised MAC to CIP.

VI. CONCLUSION.

We would urge HCFA to adopt a scheme that is designed to be economically efficient. In this regard, we endorse HCFA's intention to expand the number of drug categories subject to multisource drug reimbursement. This will reduce or eliminate any inefficient use of brand-name drugs that results from the limited coverage of the current MAC

---

[36] A percentage copayment by Medicaid customers would restore some of the consumer's incentive to search for lower prices and thus reduce the likely extent of dual pricing.

[37] Some pharmacies ("Medicaid mills") may evade the intent of such an audit by restricting their clientele to Medicaid customers. These pharmacies would then have no prices charged non-Medicaid customers against which the prices charged Medicaid consumers could be compared. One possible solution is the proposed 125 percent screen. While such a screen will reduce the profitability and possibly the incidence of Medicaid mills, we are unable to evaluate how effective a deterrent such a screen might be. We do note that a screen will also likely reduce the number of pharmacies participating in Medicaid.

program. However, because each of the proposed alternatives would provide strong disincentives to dispensing brand-names when a generic drug product is available, and because of some uncertainty regarding the significance of current or potential non-therapeutic differences among drugs, we would urge HCFA to permit Medicaid consumers to purchase the brand-name products if they choose to pay the difference between the price of the brand name and the maximum reimbursement level for a generic drug product. We would also suggest consideration of a percentage copayment by Medicaid customers to provide them with an incentive to seek the lowest-cost drug available.

We are unable to completely rank the proposals against the other goals of a reimbursement scheme. We would suggest that to facilitate such a ranking HCFA consider drawing a random sample of multisource and single-source drugs, and compare the estimated likely reimbursement levels and administrative costs, given the efficient selection of pharmacy participation. But we would also suggest that HCFA examine a variety of market-tested private insurance schemes to assess the means by which reimbursement levels are determined. There may be information available in the private sector regarding reimbursement program design that HCFA may find particularly useful in developing its Medicaid scheme.

With respect to the efficient distribution of prescription drugs to Medicaid consumers, we would similarly suggest that an examination of market-tested private reimbursement schemes would be useful. One approach that could be employed with any of the three proposed schemes would rely on market responses to eliminate the arbitrary nature of the proposed reimbursement levels and simultaneously result in the lowest-cost distribution systems consistent with HCFA's mandate. HCFA could in effect auction off

the right for pharmacies to participate in the Medicaid program.[38] First, HCFA (or the states) would have to determine the efficient number and the efficient quality of the Medicaid-drug distribution system. Such quality aspects might include the distances of the pharmacies from Medicaid consumers, hours of operation, average waiting time, and the like. HCFA (or the states) might then conduct regional auctions based upon the selected reimbursement scheme (for example, PhIP).[39] In each region, HCFA would then announce that Medicaid drugs under PhIP would be reimbursed at the lowest-cost generic drug product in the Red Book or Blue Book minus, say, 10 percent. If the number and mix of pharmacies agreeing to participate falls short of HCFA's goals, a second auction would be undertaken, by announcing, for example, that Medicaid reimbursement would be at the lowest-cost generic drug product minus, say, 5 percent. HCFA would continue to revise the announced reimbursement limits until the number and mix of participating pharmacies was efficient.

This type of auction scheme is attractive because it eliminates the need for arbitrarily establishing the upper limits of reimbursement. While we are unsure of the magnitude of the administrative costs entailed, the proposal might require some monitoring to insure that in fact the quality of the services provided by the participating pharmacies is maintained. Further, under this scheme there would be no incentive to develop either Medicaid "mills" or dual pricing schemes.

---

[38] It is our understanding that the Department of Justice will be proposing a variant of the auction scheme. While we are not aware of the precise details of the proposal and therefore cannot endorse the proposal, we believe this novel proposal merits consideration.

[39] We use PhIP for illustrative purposes only. The described auction could be used in conjunction with any of the proposals.