

equivalent products, demand for the product, and ability of the manufacturer to produce quality drugs.

Sixth, it should be recognized that the price of a prescription at the retail level is composed of two parts: cost of the drug and the cost of the overhead and profit of the drug dispenser. Both parts account for approximately equal portions of the final price of the prescription to the consumer. Maximum cost savings can only be achieved by controlling both elements. Therefore, the regulation will have to address ways to deal with both of these problems.

Seventh, in discussing the implementation of the Maximum Allowable Cost (MAC) policy, apprehension has been expressed with regard to the possibility that, in the event that the physician, for valid medical reasons, insists that a drug be used which is priced above the MAC level, his patient receiving services under the medicare or medicaid programs would have to pay the difference between the MAC price and the cost of the drug he prescribed. In this regard it should be noted that Title XIX, Section 1902(a)(14) of the Social Security Act stipulates that individuals receiving benefits under the medicaid programs cannot now be required to pay additional costs resulting from, in this instance, the use of drugs costing more than the MAC price. In view of the legal prohibitions against passing the cost to the patient, we believe that, in those instances where an exception is requested for medically valid reasons, the program should pay the added cost. We believe it would also be appropriate for the medicare program to pay these added costs for its beneficiaries.

Senator NELSON. How do you determine whether it is for a valid reason? How do you handle a matter like this: Somebody prescribes Darvon as an analgesic, although aspirin is more effective and much cheaper. Will the doctors have to tell you that the reason is the patient is allergic to aspirin or some special medical reason? How do you handle that?

Dr. EDWARDS. As I will note later in my statement, the physician would be required to state on an appropriate form why the patient needs a specific brand of product and this form would accompany the prescription and it would be retrospectively reviewed.

Senator NELSON. Please proceed.

Dr. EDWARDS. As I said, the physician would be required to state on an appropriate form why the patient needs a specific branded product. This form would accompany the prescription. The pharmacist would file one copy with the prescription and the other would be submitted with his request for payment to the Federal program. These would be reviewed retrospectively and enforcement would be by utilization review committees or PSROs. In those instances where no medical justification has been presented, these programs will not pay the additional cost.

Senator NELSON. Wouldn't that present a complicated paperwork problem?

Dr. EDWARDS. I don't know, Mr. Chairman. I think this is one of those things we are going to have to try. I think just the fact that they have to fill out a form will probably eliminate most doctors