Summary of

MEDICAID ANTI-DISCRIMINATORY DRUG PRICE AND PATIENT BENEFIT RESTORATION ACT OF 1990
September 1990

Senator David Pryor (D-Ark)

CONDITIONS OF COVERAGE OF DRUG PRODUCTS UNDER MEDICAID

The legislation requires that in order to be placed on a Medicaid prescription drug formulary (the State's covered drug list) or to be covered by a state Medicaid program, a prescription drug manufacturer must provide the Medicaid program the same substantial discounts it is now giving to other purchasers of its medications. (Currently, many manufacturers are providing in excess of 40 to 60 percent discounts to hospitals, HMOs, the Department of Defense and the Department of Veterans Affairs for the very same drugs purchased by Medicaid).

The required discounts, provided to the States through a rebate system, apply to the single source and innovator multiple source drug products of the brand name drug companies.

If a manufacturer fails to give such discounts to any one State, no Federal matching dollars will be provided for that drug manufacturer's medication in all States. (This provision has the effect of denying manufacturers' access to the Medicaid market, which usually constitutes 10-15% of the average manufacturer's business; such an approach should protect smaller States from being denied access to discounts).

DEFINITION OF ACCEPTABLE MEDICAID REBATES

The value of the acceptable discount for single source and innovator multiple source drugs is equal to the difference between the price that manufacturers charge wholesalers to buy their products (known as the Average Manufacturers' Price, or AMP) and the "best price" that the manufacturer offers to any other purchaser of these drug products (AMP minus best price = value of the rebate). The AMP is the price that the manufacturer charges pharmaceutical wholesalers to buy their products.

To ensure that Medicaid continues to receive the lowest price in the marketplace, the "best price" is defined as the lower of the "best price" in the marketplace during the calendar quarter in which the drug is dispensed or the "best price" in place in the market as of September 1, 1990, indexed to the consumer price index (CPI). The definition of "best price" excludes those prices that are merely nominal in amount that manufacturers offer to special purchasers, such as the sale of birth control pills for a penny a pack to Planned Parenthood.

The indexing mechanism is absolutely necessary because cost estimators, such as CBO and OMB, are highly unlikely to project significant savings for any proposal that would allow manufacturers to eliminate or significantly reduce current discounts.

In addition, when a voluntary manufacturer rebate approach was tried for cans of infant formula provided by the WIC program, the manufacturers tried to eliminate the rebates by significantly raising their "best prices".

The total aggregate value of the discount payment collected by each state Medicaid agency from each drug manufacturer can be no less than 10% of total state expenditures under Medicaid that are attributable to ingredient costs (AMPs) for drug products sold by the manufacturer. Manufacturers who are now discounting at drugs at significantly high levels (some are discounting in excess of 60%) have argued that freezing such discounts would leave them no alternative but to not participate in Medicaid progam. To counter any drug manufacturer argument that it cannot afford to participate in Medicaid, the total amount that the manufacturer will be required to rebate will be capped at 25% of the total state expenditures attributable to their drugs.

The rebates are paid quarterly by the manufacturer to each state Medicaid plan. The agreements are for one-year and are automatically renewable unless terminated by the manufacturer or the Secretary. The Secretary can bar a manufacturer from participating in the Medicaid program for one year if an agreement is terminated with any state.

For non-innovator multiple source drug products (generics), the manufacturer is required to rebate a flat 10% of the total aggregate expenditures for all that manufacturers' drug products as a condition of Medicaid coverage.

QUALITY OF CARE IMPROVEMENTS FOR MEDICAID PATIENTS

1. Access to Prescription Drugs Expanded: The bill will significantly expand Medicaid beneficiary access to a wide range of FDA-approved prescription drug products and biologicals. In addition, physicians will be assured that they can prescribe these products for "off-label" indications if such use is supported by medical compendia.

To insure that Medicaid beneficiaries have access to all FDA-approved drug products, those drug products not subject to the discount (and hence not on the state formulary) can still be obtained if the physician obtains prior approval from the state Medicaid program. The bill insures that the final control over the drug product selected for the patient is retained with the patient's physician. There are no provisions in this bill for therapeutic substitution or therapeutic interchange of drug products by pharmacists.

2. Reform of Prior Approval Programs: To make prior approval programs more responsive to physicians needs, states can only operate these programs if they meet certain minimal standards: they must be available to physicians 24 hours/day, 7 days a week, and provide a response to the physician's request which must be received by the inquiring physician immediately.

3. Drug Utilization Review: The bill establishes a comprehensive system of drug use review (DUR) that encourages pharmacists to counsel patients on the proper use of their medications and requires state medical assistance programs to implement a program to avert inappropriate patterns of prescribing and dispensing of drug products.

NO COVERAGE FOR DRUG PRODUCTS SOLD ONLY WITH EXCLUSIVE PATIENT MONITORING SERVICES

The bill does not require the state medical assistance plan to cover those drug products of manufacturers which require that, a condition of sale of the product, the manufacturer be compensated for associated tests or services associated with the use of the product which are provided exclusively by the manufacturer or its designee. Serious questions have been raised by the medical community about the appropriateness of such a requirement. Thus, the state does not have to cover a drug of this type if it is included among the products of a manufacturer that has entered into an acceptable rebate agreement. An example of this is Clozaril, the antischizophrenic that can only be obtained if exclusive patient monitoring services are purchased from the manufacturer.

MEDICAID PRESCRIPTION CLAIMS PROCESSING: State medical assistance plans are given incentives to develop and implement a cost-saving on-line pharmacy-based electronic system to process Medicaid prescription drug claims. The encouragement given to the states is in the form of a 90/10 FFP match.

RESTORATION FOR PHARMACY REIMBURSEMENT CUTS: For approximately three years after enactment, some of the cuts that have been made in pharmacy reimbursement over the past decade are restored by setting aside 10% of the rebates received each year by the state for this purpose. Pharmacies will receive a fixed rebate for each prescription that they dispense to Medicaid beneficiaries in an annual lump-sum payment.

REFORMATION OF MEDICAID PHARMACY REIMBURSEMENT SYSTEM:

The bill would effect reforms in the current pharmacy reimbursement system. After the three year pharmacy restoration expires (as described above), states would be required to update pharmacy dispensing fees each year based on the results of an annual study. In addition, the bill places a two-year moratorium on any further reduction in drug product cost reimbursement for brand-name drug products and instructs the Secretary to develop a "look behind" program to provide better enforcement of the HCFA "brand medically necessary" requirement designed to promote generic substitution.

PRESCRIPTION DRUG POLICY REVIEW COMMISSION: Provides for the establishment of an 11-member Prescription Drug Policy Review Commission to advise federal and state policy makers on policy and financing matters relating to publicly-funded prescription drug benefit programs, including Medicaid and Medicare.

DEMONSTRATION PROJECTS: Provides for a demonstration project on the effectiveness of on-line prospective drug utilization review in pharmacists' fulfilling patient counseling requirements and a demonstration project on the cost-effectiveness of pharmacists' providing cognitive services to patients.

STUDIES: Requires that a study be done on the scientific and clinical foundation for the concept of therapeutic interchangeability among drug products.

Further information about the bill can be obtained from Chris Jennings or John Coster at the staff of the Senate Aging Committee, X-45364.