ASSEMBLY, No. 410

STATE OF NEW JERSEY

Introduced Pending Technical Review by Legislative Counsel

PRE-FILED FOR INTRODUCTION IN THE 1996 SESSION

By Assemblywoman HECK

AN ACT providing for pharmaceutical manufacturer rebates and supplementing Title 30 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. As used in this act:

"Commissioner" means the Commissioner of Human Services.

"Covered outpatient drugs" means those outpatient, single source drugs covered by the State Medicaid program that are subject to manufacturer rebates pursuant to 42 U.S.C.§1396r-8.

"International wholesaler" means a person, other than a manufacturer, who sells, resells or distributes pharmaceutical products, either directly or through an agent, to purchasers in any one or more of the following countries: Australia, Austria, Belgium, Canada, Denmark, the Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

"Manufacturer" means an entity defined pursuant to 42 U.S.C.§1396r-8(k).

"Manufacturer's retail price" means the certified retail acquisition cost for a manufacturer's covered outpatient drugs.

"Medicaid" means the State Medicaid program established pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.).

2. a. The Medicaid program shall limit the coverage of pharmaceutical products to manufacturers who agree to provide rebates to the State pursuant to this act. The commissioner shall contract with manufacturers of pharmaceutical products to provide rebates for pharmaceutical products pursuant to this act. The rebate agreements entered into pursuant to this act shall take effect on January 1, 1996 and shall be retroactive to that date if entered into after January 1, 1996.

b. A manufacturer shall submit to the commissioner by January 31

of each year following the effective date of this act, in a form and manner specified by the commissioner, a written statement by a resident corporate officer or agent, certifying the following:

(1) the quarterly average manufacturer's retail price available to purchasers in the State for the manufacturer's covered outpatient drugs; and

(2) the quarterly lowest manufacturer's retail price available to purchasers by international wholesalers for the manufacturer's covered outpatient drugs.

c. A manufacturer which participates in the Medicaid program shall provide to the commissioner such other information as he may request to carry out the purposes of this act.

3. a. A manufacturer shall remit to the commissioner, in a manner specified by the commissioner, an annual rebate with respect to each dosage form and strength of drug, in an amount equal to the greater of:

a. the rebate required pursuant to 42 U.S.C.§1396r-8; or

b. the product of the total number of units subject to rebate and the difference between the average manufacturer's retail price made available to purchasers in the State and the lowest manufacturer retail price made available to purchasers in foreign countries by international wholesalers.

c. A manufacturer shall annually remit an additional rebate to the commissioner that reflects increases in the price of drugs in excess of increases in the consumer price index for all urban consumers. The amount of the rebate shall be calculated in the same manner as provided for in 42 U.S.C.§1396r-8(c)(2).

4. A manufacturer who knowingly provides false information is subject to a civil penalty not to exceed $10,000 for each item of false information. The penalty shall be sued for and recovered pursuant to "the penalty enforcement law," N.J.S.2A:58-1 et seq.

5. This act shall take effect on January 1, 1996, but the commissioner may take such anticipatory administrative action in advance as may be necessary for the implementation of the act.

STATEMENT

The purpose of this bill is to ensure that the State, through the Medicaid program, pays no more than the lowest price charged in foreign countries by pharmaceutical manufacturers for outpatient drugs covered by the State program.

Accordingly, this bill requires manufacturers of pharmaceutical

products that participate in the Medicaid program, as a condition of participation, to pay to the Department of Human Services a rebate based on the amount of that manufacturer's outpatient drugs sold to Medicaid recipients that is the greater of: the rebate required under federal law (42 U.S.C.§1396r-8), or the product of the total number of units subject to rebate and the difference between the average manufacturer's retail price made available to purchasers in the State and the lowest manufacturer retail price made available to purchasers in foreign countries by international wholesalers.

Consumers in this country are subsidizing low prices that pharmaceutical manufacturers offer only to purchasers in designated foreign countries. Brand name, single source prescription drugs are marketed worldwide, but pharmaceutical manufacturers charge acquisition prices for their products in the United States that are 50% to 60% higher than prices charged for the same products in designated foreign countries. These foreign countries have provided relief for their consumers by enacting laws that mandate reasonably justifiable prescription drug pricing. This bill provides similar relief for New Jersey's taxpayers.

Requires pharmaceutical manufacturers to provide rebates to Medicaid for lower drug prices in foreign countries.