

SENATE BILL REPORT

SB 5458

AS OF FEBRUARY 9, 1993

Brief Description: Regulating insurance coverage of drugs that have not received federal drug administration approval.

SPONSORS: Senators Wojahn and Sheldon

SENATE COMMITTEE ON HEALTH & HUMAN SERVICES

Staff: Martin Lovinger (786-7443)

Hearing Dates: February 19, 1993

BACKGROUND:

Obtaining federal Food and Drug Administration (FDA) approval for use of a drug is very expensive and time consuming. Some drugs have taken \$50 million, 10 years and the filing of over 100,000 sheets of paper. After a drug has been approved for a specific use and is marketed, other potential uses for the drug are discovered. The manufacturer has no reason to go back to the FDA for approval of the new use, because it already can market the drug. No other party will spend the money and time to apply for approval for the new use, because the manufacturer has the patent to sell it. In some cases a drug approved for one condition will be used to treat other conditions for years before these other uses will be included in the official labeling, despite the fact that such use is recognized or recommended in health care literature.

Some health insurance programs are now screening prescription claims to see if they are for uses approved by the FDA and rejecting claims as inappropriate if the use is not FDA approved.

SUMMARY:

Disability insurance companies, group disability insurance companies, health care service companies and health maintenance entities are prohibited from rejecting prescription claims based on the use of the drug, if the use is recognized as appropriate by equivalent practitioners or is a recognized or recommended use in the health care literature.

Disability insurance companies, group disability insurance companies, health care service companies and health maintenance entities are prohibited from requiring contract provisions that violate federal or state laws.

Appropriation: none

Revenue: none

Fiscal Note: requested February 3, 1993

Effective Date: The bill contains an emergency clause and takes effect immediately.