

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 329 Session of  
1999

INTRODUCED BY BEBKO-JONES, READSHAW, GEORGE, PESCI, BISHOP,  
M. COHEN, THOMAS, YOUNGBLOOD, YEWIC, SCRIMENTI, BELFANTI,  
LAUGHLIN, CURRY, MYERS, BELARDI, MELIO, PISTELLA, CORRIGAN,  
WOJNAROSKI, TRELLO, DeLUCA, RAMOS, SHANER, WASHINGTON,  
SEYFERT, TRICH, WILLIAMS, MAHER, HARHAI, JOSEPHS, HORSEY,  
STEELMAN AND DAILEY, FEBRUARY 8, 1999

REFERRED TO COMMITTEE ON INSURANCE, FEBRUARY 8, 1999

AN ACT

1 Requiring health insurance providers which furnish coverage for  
2 prescription drugs to extend coverage to off-label use of  
3 drugs; and imposing a penalty.

4 The General Assembly of the Commonwealth of Pennsylvania  
5 hereby enacts as follows:

6 Section 1. Short title.

7 This act shall be known and may be cited as the Off-label Use  
8 of Drugs Coverage Act.

9 Section 2. Definitions.

10 The following words and phrases when used in this act shall  
11 have the meanings given to them in this section unless the  
12 context clearly indicates otherwise:

13 "Food and Drug Administration." The Food and Drug  
14 Administration within the United States Department of Health and  
15 Human Services.

16 "Health insurance." Any policy, contract or plan which

1 provides medical coverage on an expense-incurred service or  
2 prepaid basis or an employee welfare benefit plan issued or  
3 subject to any of the following laws:

4 (1) The act of May 17, 1921 (P.L.682, No.284), known as  
5 The Insurance Company Law of 1921.

6 (2) The act of December 29, 1972 (P.L.1701, No.364),  
7 known as the Health Maintenance Organization Act.

8 (3) The act of May 18, 1976 (P.L.123, No.54), known as  
9 the Individual Accident and Sickness Insurance Minimum  
10 Standards Act.

11 (4) The act of December 14, 1992 (P.L.835, No.134),  
12 known as the Fraternal Benefit Societies Code.

13 (5) 40 Pa.C.S. Ch. 61 (relating to hospital plan  
14 corporations) or 63 (relating to professional health services  
15 plan corporations).

16 (6) The Employee Retirement Income Security Act of 1974  
17 (P.L. 93-406, 88 Stat. 829).

18 "Medical literature." A peer-reviewed, national medical or  
19 scientific journal.

20 "Off-label use of drugs." Prescribing a drug for treatment  
21 of a condition other than a condition specifically approved for  
22 treatment by the Food and Drug Administration.

23 "Standard reference compendia." The American Medical  
24 Association Drug Evaluation, the American Hospital Formulary  
25 Service Drug Information or the United States Pharmacopeia Drug  
26 Information.

27 Section 3. Coverage for off-label use of drugs required.

28 Health insurance that provides coverage for prescription  
29 drugs shall not exclude coverage of a drug for a particular  
30 indication on the grounds that the drug has not been approved by

1 the Food and Drug Administration for that indication if the drug  
2 is recognized for treatment of the indication in one of the  
3 standard reference compendia or in medical literature.

4 Section 4. Review of off-label uses of drugs.

5 The Secretary of Health shall appoint a panel of eight  
6 qualified medical experts to review off-label uses of drugs not  
7 included in the standard reference compendia or medical  
8 literature. The panel shall advise the Insurance Commissioner  
9 whether a particular off-label use is medically appropriate and  
10 shall make recommendations regarding payment of off-label use.

11 Section 5. Enforcement.

12 The Insurance Commissioner shall enforce the provisions of  
13 this act.

14 Section 6. Penalty.

15 A provider of health insurance which violates this act shall  
16 pay a civil penalty of \$1,000.

17 Section 7. Construction of act.

18 Nothing in this act shall be construed to require coverage  
19 for experimental drugs not otherwise approved for any indication  
20 by the Food and Drug Administration.

21 Section 8. Effective date.

22 This act shall take effect in 60 days.