

SENATE BILL No. 1241

April 23, 2002, Introduced by Senators SCHWARZ, VAN REGENMORTER, MC MANUS, HART, GAST, STEIL, HAMMERSTROM, NORTH, BYRUM, LELAND, EMERSON and GARCIA and referred to the Committee on Health Policy.

A bill to amend 1956 PA 218, entitled
"The insurance code of 1956,"
(MCL 500.100 to 500.8302) by adding section 3406q.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 SEC. 3406Q. (1) AN EXPENSE-INCURRED HOSPITAL, MEDICAL, OR
2 SURGICAL POLICY OR CERTIFICATE DELIVERED, ISSUED FOR DELIVERY, OR
3 RENEWED IN THIS STATE THAT PROVIDES PHARMACEUTICAL COVERAGE AND A
4 HEALTH MAINTENANCE ORGANIZATION CONTRACT SHALL PROVIDE COVERAGE
5 FOR AN OFF-LABEL USE OF A FEDERAL FOOD AND DRUG ADMINISTRATION
6 APPROVED DRUG AND THE REASONABLE COST OF ITS ADMINISTRATION.

7 (2) COVERAGE FOR A DRUG UNDER SUBSECTION (1) APPLIES IF ALL
8 OF THE FOLLOWING CONDITIONS ARE MET:

9 (A) THE DRUG IS APPROVED BY THE FEDERAL FOOD AND DRUG
10 ADMINISTRATION.

1 (B) THE DRUG IS PRESCRIBED BY A LICENSED HEALTH CARE
2 PROFESSIONAL, OR FOR AN ENROLLEE BY A PARTICIPATING OR AFFILIATED
3 LICENSED HEALTH CARE PROFESSIONAL, FOR THE TREATMENT OF EITHER OF
4 THE FOLLOWING:

5 (i) A LIFE-THREATENING CONDITION.

6 (ii) A CHRONIC AND SERIOUSLY DEBILITATING CONDITION SO LONG
7 AS THE DRUG IS MEDICALLY NECESSARY TO TREAT THAT CONDITION AND
8 THE DRUG IS ON THE PLAN FORMULARY OR ACCESSIBLE THROUGH THE
9 HEALTH PLAN'S FORMULARY PROCEDURES.

10 (C) THE DRUG HAS BEEN RECOGNIZED FOR TREATMENT FOR THE CON-
11 DITION FOR WHICH IT IS PRESCRIBED BY 1 OF THE FOLLOWING:

12 (i) THE AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS.

13 (ii) THE AMERICAN HOSPITAL FORMULARY SERVICE DRUG
14 INFORMATION.

15 (iii) THE UNITED STATES PHARMACOPOEIA DISPENSING INFORMA-
16 TION, VOLUME 1, "DRUG INFORMATION FOR THE HEALTH CARE
17 PROFESSIONAL".

18 (iv) TWO ARTICLES FROM MAJOR PEER-REVIEWED MEDICAL JOURNALS
19 THAT PRESENT DATA SUPPORTING THE PROPOSED OFF-LABEL USE OR USES
20 AS GENERALLY SAFE AND EFFECTIVE UNLESS THERE IS CLEAR AND CON-
21 VINING CONTRADICTORY EVIDENCE PRESENTED IN A MAJOR PEER-REVIEWED
22 MEDICAL JOURNAL.

23 (3) UPON REQUEST, THE PRESCRIBING HEALTH CARE PROFESSIONAL
24 SHALL SUPPLY TO THE INSURER OR HEALTH MAINTENANCE ORGANIZATION
25 DOCUMENTATION SUPPORTING COMPLIANCE WITH SUBSECTION (2).

26 (4) THIS SECTION DOES NOT PROHIBIT THE USE OF A CO-PAYMENT
27 OR SIMILAR MECHANISM FOR APPROPRIATELY CONTROLLING THE

1 UTILIZATION OF A DRUG THAT IS PRESCRIBED FOR A USE DIFFERENT FROM
2 THE USE FOR WHICH THE DRUG HAS BEEN APPROVED BY THE FOOD AND DRUG
3 ADMINISTRATION.

4 (5) AS USED IN THIS SECTION:

5 (A) "CHRONIC AND SERIOUSLY DEBILITATING" MEANS A DISEASE OR
6 CONDITION THAT REQUIRES ONGOING TREATMENT TO MAINTAIN REMISSION
7 OR PREVENT DETERIORATION AND THAT CAUSES SIGNIFICANT LONG-TERM
8 MORBIDITY.

9 (B) "LIFE-THREATENING" MEANS A DISEASE OR CONDITION WHERE
10 THE LIKELIHOOD OF DEATH IS HIGH UNLESS THE COURSE OF THE DISEASE
11 IS INTERRUPTED OR THAT HAS A POTENTIALLY FATAL OUTCOME WHERE THE
12 END POINT OF CLINICAL INTERVENTION IS SURVIVAL.

13 (C) "OFF-LABEL" MEANS THE USE OF A DRUG FOR CLINICAL INDICA-
14 TIONS OTHER THAN THOSE STATED IN THE LABELING APPROVED BY THE
15 FEDERAL FOOD AND DRUG ADMINISTRATION.