

SENATE BILL No. 1242

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 1980 PA 350, entitled
"The nonprofit health care corporation reform act,"
(MCL 550.1101 to 550.1704) by adding section 416c.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 SEC. 416C. (1) A HEALTH CARE CORPORATION, GROUP, OR NON-
2 GROUP CERTIFICATE THAT PROVIDES PHARMACEUTICAL COVERAGE SHALL
3 PROVIDE COVERAGE FOR AN OFF-LABEL USE OF A FEDERAL FOOD AND DRUG
4 ADMINISTRATION APPROVED DRUG AND THE REASONABLE COST OF ITS
5 ADMINISTRATION.

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

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

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

4 (i) A LIFE-THREATENING CONDITION.

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

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

11 (i) THE AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS.

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

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

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

22 (3) UPON REQUEST, THE PRESCRIBING HEALTH CARE PROFESSIONAL
23 SHALL SUPPLY TO THE HEALTH CARE CORPORATION DOCUMENTATION SUP-
24 PORTING COMPLIANCE WITH SUBSECTION (2).

25 (4) THIS SECTION DOES NOT PROHIBIT THE USE OF A CO-PAYMENT
26 OR SIMILAR MECHANISM FOR APPROPRIATELY CONTROLLING THE
27 UTILIZATION OF A DRUG THAT IS PRESCRIBED FOR A USE DIFFERENT FROM

1 THE USE FOR WHICH THE DRUG HAS BEEN APPROVED BY THE FOOD AND DRUG
2 ADMINISTRATION.

3 (5) AS USED IN THIS SECTION:

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

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

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