

**SUBSTITUTE FOR
SENATE BILL NO. 1241**

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 SUPPLIES MEDICALLY NEC-
7 ESSARY TO ADMINISTER THE DRUG.
- 8 (2) COVERAGE FOR A DRUG UNDER SUBSECTION (1) APPLIES IF ALL
9 OF THE FOLLOWING CONDITIONS ARE MET:
- 10 (A) THE DRUG IS APPROVED BY THE FEDERAL FOOD AND DRUG
11 ADMINISTRATION.

1 (B) THE DRUG IS PRESCRIBED BY AN ALLOPATHIC OR OSTEOPATHIC
2 PHYSICIAN FOR THE TREATMENT OF EITHER OF THE FOLLOWING:

3 (i) A LIFE-THREATENING CONDITION SO LONG AS THE DRUG IS MEDICALLY
NECESSARY TO TREAT THAT CONDITION AND THE DRUG IS ON THE PLAN FORMULARY
OR ACCESSIBLE THROUGH THE HEALTH PLAN'S FORMULARY PROCEDURES.

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

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

10 (i) THE AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS.

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

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

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

21 (3) UPON REQUEST, THE PRESCRIBING ALLOPATHIC OR OSTEOPATHIC
22 PHYSICIAN SHALL SUPPLY TO THE INSURER OR HEALTH MAINTENANCE
23 ORGANIZATION DOCUMENTATION SUPPORTING COMPLIANCE WITH
24 SUBSECTION (2).

25 (4) THIS SECTION DOES NOT PROHIBIT THE USE OF A COPAYMENT,
DEDUCTIBLE, SANCTION,
26 OR A MECHANISM FOR APPROPRIATELY CONTROLLING THE UTILIZATION OF A
27 DRUG THAT IS PRESCRIBED FOR A USE DIFFERENT FROM THE USE FOR

SB 1241, As Passed Senate, May 22, 2002

Senate Bill No. 1241 as amended May 22, 20020

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1 WHICH THE DRUG HAS BEEN APPROVED BY THE FOOD AND DRUG
2 ADMINISTRATION. THIS MAY INCLUDE PRIOR APPROVAL OR A DRUG UTILI-
3 ZATION REVIEW PROGRAM. ANY COPAYMENT, DEDUCTIBLE, SANCTION, PRIOR
4 APPROVAL, DRUG UTIL-
5 IZATION REVIEW PROGRAM, OR MECHANISM DESCRIBED IN THIS SUBSECTION
6 SHALL NOT BE MORE RESTRICTIVE THAN FOR PRESCRIPTION COVERAGE
7 GENERALLY.

8 (5) AS USED IN THIS SECTION:

9 (A) "CHRONIC AND SERIOUSLY DEBILITATING" MEANS A DISEASE OR
10 CONDITION THAT REQUIRES ONGOING TREATMENT TO MAINTAIN REMISSION
11 OR PREVENT DETERIORATION AND THAT CAUSES SIGNIFICANT LONG-TERM
12 MORBIDITY.

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

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

Enacting section 1. This amendatory act takes effect 180 days after
the date this amendatory act is enacted.