REPRINT

SUBSTITUTE FOR

SENATE BILL NO. 1242

(As passed the Senate May 22, 2002)

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 NONGROUP
- 2 CERTIFICATE THAT PROVIDES PHARMACEUTICAL COVERAGE SHALL PROVIDE
- 3 COVERAGE FOR AN OFF-LABEL USE OF A FEDERAL FOOD AND DRUG ADMINIS-
- 4 TRATION APPROVED DRUG AND THE REASONABLE COST OF SUPPLIES MEDI-
- 5 CALLY NECESSARY TO ADMINISTER THE DRUG.
- 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.
- 10 (B) THE DRUG IS PRESCRIBED BY AN ALLOPATHIC OR OSTEOPATHIC
- 11 PHYSICIAN FOR THE TREATMENT OF EITHER OF THE FOLLOWING:

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2.

- i (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.
- 2 (ii) A CHRONIC AND SERIOUSLY DEBILITATING CONDITION SO LONG
- 3 AS THE DRUG IS MEDICALLY NECESSARY TO TREAT THAT CONDITION AND
- 4 THE DRUG IS ON THE PLAN FORMULARY OR ACCESSIBLE THROUGH THE
- 5 HEALTH PLAN'S FORMULARY PROCEDURES.
- 6 (C) THE DRUG HAS BEEN RECOGNIZED FOR TREATMENT FOR THE CON-
- 7 DITION FOR WHICH IT IS PRESCRIBED BY 1 OF THE FOLLOWING:
- 8 (i) THE AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS.
- 9 (ii) THE AMERICAN HOSPITAL FORMULARY SERVICE DRUG
- 10 INFORMATION.
- 11 (iii) THE UNITED STATES PHARMACOPOEIA DISPENSING INFORMA-
- 12 TION, VOLUME 1, "DRUG INFORMATION FOR THE HEALTH CARE
- 13 PROFESSIONAL".
- 14 (iv) TWO ARTICLES FROM MAJOR PEER-REVIEWED MEDICAL JOURNALS
- 15 THAT PRESENT DATA SUPPORTING THE PROPOSED OFF-LABEL USE OR USES
- 16 AS GENERALLY SAFE AND EFFECTIVE UNLESS THERE IS CLEAR AND CON-
- 17 VINCING CONTRADICTORY EVIDENCE PRESENTED IN A MAJOR PEER-REVIEWED
- 18 MEDICAL JOURNAL.
- 19 (3) UPON REQUEST, THE PRESCRIBING ALLOPATHIC OR OSTEOPATHIC
- 20 PHYSICIAN SHALL SUPPLY TO THE HEALTH CARE CORPORATION DOCUMEN-
- 21 TATION SUPPORTING COMPLIANCE WITH SUBSECTION (2).
- 22 (4) THIS SECTION DOES NOT PROHIBIT THE USE OF A COPAYMENT, DEDUCTIBLE, SANCTION,
- 23 OR A MECHANISM FOR APPROPRIATELY CONTROLLING THE UTILIZATION OF A
- 24 DRUG THAT IS PRESCRIBED FOR A USE DIFFERENT FROM THE USE FOR
- 25 WHICH THE DRUG HAS BEEN APPROVED BY THE FOOD AND DRUG
- 26 ADMINISTRATION. THIS MAY INCLUDE PRIOR APPROVAL OR A DRUG
- 27 UTILIZATION REVIEW PROGRAM. ANY COPAYMENT, DEDUCTIBLE, SANCTION, PRIOR APPROVAL, DRUG

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- 1 UTILIZATION REVIEW PROGRAM, OR MECHANISM DESCRIBED IN THIS
- 2 SUBSECTION SHALL NOT BE MORE RESTRICTIVE THAN FOR PRESCRIPTION

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- 3 COVERAGE GENERALLY.
- 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.

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