SUBSTITUTE FOR

SENATE BILL NO. 1242

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:

SEC. 416C. (1) A HEALTH CARE CORPORATION GROUP OR NONGROUP CERTIFICATE THAT PROVIDES PHARMACEUTICAL COVERAGE SHALL PROVIDE COVERAGE FOR AN OFF-LABEL USE OF A FEDERAL FOOD AND DRUG ADMINISTRATION APPROVED DRUG AND THE REASONABLE COST OF SUPPLIES MEDICALLY NECESSARY TO ADMINISTER THE DRUG.

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

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

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

(*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.

(*ii*) A CHRONIC AND SERIOUSLY DEBILITATING 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.

(C) THE DRUG HAS BEEN RECOGNIZED FOR TREATMENT FOR THE CONDITION FOR WHICH IT IS PRESCRIBED BY 1 OF THE FOLLOWING:

(*i*) THE AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS.

(*ii*) THE AMERICAN HOSPITAL FORMULARY SERVICE DRUG INFORMATION.

(*iii*) THE UNITED STATES PHARMACOPOEIA DISPENSING INFORMATION, VOLUME 1, "DRUG INFORMATION FOR THE HEALTH CARE PROFESSIONAL".

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

(3) UPON REQUEST, THE PRESCRIBING ALLOPATHIC OR OSTEOPATHIC PHYSICIAN SHALL SUPPLY TO THE HEALTH CARE CORPORATION DOCUMENTATION SUPPORTING COMPLIANCE WITH SUBSECTION (2).

(4) THIS SECTION DOES NOT PROHIBIT THE USE OF A COPAYMENT, DEDUCTIBLE, SANCTION, OR A MECHANISM FOR APPROPRIATELY CONTROLLING THE UTILIZATION OF A DRUG THAT IS PRESCRIBED FOR A USE DIFFERENT FROM THE USE FOR WHICH THE DRUG HAS BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION. THIS MAY INCLUDE PRIOR APPROVAL OR A DRUG UTILIZATION REVIEW PROGRAM. ANY COPAYMENT, DEDUCTIBLE, SANCTION, PRIOR APPROVAL, DRUG

UTILIZATION REVIEW PROGRAM, OR MECHANISM DESCRIBED IN THIS SUBSECTION SHALL NOT BE MORE RESTRICTIVE THAN FOR PRESCRIPTION COVERAGE GENERALLY.

(5) AS USED IN THIS SECTION:

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

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

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

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