

# HOUSE BILL No. 4454

March 16, 2011, Introduced by Rep. Genetski and referred to the Committee on Health Policy.

A bill to amend 1956 PA 218, entitled "The insurance code of 1956," by amending section 3406q (MCL 500.3406q), as amended by 2003 PA 88.

**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 that provides  
5 pharmaceutical coverage shall provide coverage for an off-label use  
6 of a federal food and drug administration approved drug and the  
7 reasonable cost of supplies medically necessary to administer the  
8 drug.

9           (2) Coverage for a drug under subsection (1) applies if all of  
10 the following conditions are met:

1 (a) The drug is approved by the federal food and drug  
2 administration.

3 (b) The drug is prescribed by an allopathic or osteopathic  
4 physician for the treatment of either of the following:

5 (i) A life-threatening condition so long as the drug is  
6 medically necessary to treat that condition and the drug is on the  
7 plan formulary or accessible through the health plan's formulary  
8 procedures.

9 (ii) A chronic and seriously debilitating condition so long as  
10 the drug is medically necessary to treat that condition and the  
11 drug is on the plan formulary or accessible through the health  
12 plan's formulary procedures.

13 (c) The drug has been recognized for treatment for the  
14 condition for which it is prescribed by 1 of the following:

15 ~~(i) The American medical association drug evaluations.~~

16 ~~(ii) The American hospital formulary service drug information.~~

17 ~~(iii) The United States pharmacopoeia dispensing information,~~  
18 ~~volume 1, "drug information for the health care professional".~~

19 (i) ~~(iv) Two~~ **EXCEPT AS OTHERWISE PROVIDED IN SUBPARAGRAPH (ii), 2**  
20 articles from major peer-reviewed medical journals that present  
21 data supporting the proposed off-label use or uses as generally  
22 safe and effective unless there is clear and convincing  
23 contradictory evidence presented in a major peer-reviewed medical  
24 journal.

25 **(ii) FOR CANCER TREATMENT, 2 ARTICLES FROM MAJOR PEER-REVIEWED**  
26 **MEDICAL JOURNALS RECOGNIZED BY THE CENTERS FOR MEDICARE AND**  
27 **MEDICAID SERVICES THAT PRESENT DATA SUPPORTING THE PROPOSED OFF-**

1 LABEL USE OR USES AS GENERALLY SAFE AND EFFECTIVE UNLESS THERE IS  
2 CLEAR AND CONVINCING CONTRADICTORY EVIDENCE PRESENTED IN A MAJOR  
3 PEER-REVIEWED MEDICAL JOURNAL.

4 (iii) THE AMERICAN HOSPITAL FORMULARY SERVICE DRUG INFORMATION.

5 (iv) NATIONAL COMPREHENSIVE CANCER NETWORK DRUGS AND BIOLOGICS  
6 COMPENDIUM.

7 (v) THOMSON REUTERS MICROMEDEX DRUGDEX.

8 (vi) CLINICAL PHARMACOLOGY.

9 (vii) OTHER AUTHORITATIVE COMPENDIA AS IDENTIFIED BY THE  
10 SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN  
11 SERVICES AND AS CERTIFIED BY THE COMMISSIONER.

12 (3) Upon request, the prescribing allopathic or osteopathic  
13 physician shall supply to the insurer or health maintenance  
14 organization documentation supporting compliance with subsection  
15 (2).

16 (4) This section does not prohibit the use of a copayment,  
17 deductible, sanction, or a mechanism for appropriately controlling  
18 the utilization of a drug that is prescribed for a use different  
19 from the use for which the drug has been approved by the **FEDERAL**  
20 food and drug administration. This may include prior approval or a  
21 drug utilization review program. Any copayment, deductible,  
22 sanction, prior approval, drug utilization review program, or  
23 mechanism described in this subsection shall not be more  
24 restrictive than for prescription coverage generally.

25 (5) As used in this section:

26 (a) "Chronic and seriously debilitating" means a disease or  
27 condition that requires ongoing treatment to maintain remission or

1 prevent deterioration and that causes significant long-term  
2 morbidity.

3 (b) "Life-threatening" means a disease or condition where the  
4 likelihood of death is high unless the course of the disease is  
5 interrupted or that has a potentially fatal outcome where the end  
6 point of clinical intervention is survival.

7 (c) "Off-label" means the use of a drug for clinical  
8 indications other than those stated in the labeling approved by the  
9 federal food and drug administration.