

Act No. 538
Public Acts of 2002
Approved by the Governor
July 25, 2002
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July 26, 2002
EFFECTIVE DATE: January 22, 2003

**STATE OF MICHIGAN
91ST LEGISLATURE
REGULAR SESSION OF 2002**

**Introduced by Senators Schwarz, Van Regenmorter, McManus, Hart, Gast, Steil, Hammerstrom, North,
Byrum, Leland, Emerson and Garcia**

ENROLLED SENATE BILL No. 1241

AN ACT to amend 1956 PA 218, entitled "An act to revise, consolidate, and classify the laws relating to the insurance and surety business; to regulate the incorporation or formation of domestic insurance and surety companies and associations and the admission of foreign and alien companies and associations; to provide their rights, powers, and immunities and to prescribe the conditions on which companies and associations organized, existing, or authorized under this act may exercise their powers; to provide the rights, powers, and immunities and to prescribe the conditions on which other persons, firms, corporations, associations, risk retention groups, and purchasing groups engaged in an insurance or surety business may exercise their powers; to provide for the imposition of a privilege fee on domestic insurance companies and associations and the state accident fund; to provide for the imposition of a tax on the business of foreign and alien companies and associations; to provide for the imposition of a tax on risk retention groups and purchasing groups; to provide for the imposition of a tax on the business of surplus line agents; to provide for the imposition of regulatory fees on certain insurers; to provide for assessment fees on certain health maintenance organizations; to modify tort liability arising out of certain accidents; to provide for limited actions with respect to that modified tort liability and to prescribe certain procedures for maintaining those actions; to require security for losses arising out of certain accidents; to provide for the continued availability and affordability of automobile insurance and homeowners insurance in this state and to facilitate the purchase of that insurance by all residents of this state at fair and reasonable rates; to provide for certain reporting with respect to insurance and with respect to certain claims against uninsured or self-insured persons; to prescribe duties for certain state departments and officers with respect to that reporting; to provide for certain assessments; to establish and continue certain state insurance funds; to modify and clarify the status, rights, powers, duties, and operations of the nonprofit malpractice insurance fund; to provide for the departmental supervision and regulation of the insurance and surety business within this state; to provide for regulation over worker's compensation self-insurers; to provide for the conservation, rehabilitation, or liquidation of unsound or insolvent insurers; to provide for the protection of policyholders, claimants, and creditors of unsound or insolvent insurers; to provide for associations of insurers to protect policyholders and claimants in the event of insurer insolvencies; to prescribe educational requirements for insurance agents and solicitors; to provide for the regulation of multiple employer welfare arrangements; to create an automobile theft prevention authority to reduce the number of automobile thefts in this state; to prescribe the powers and duties of the automobile theft prevention authority; to provide certain powers and duties upon certain officials, departments, and authorities of this state; to provide for an appropriation; to repeal acts and parts of acts; and to provide penalties for the violation of this act," (MCL 500.100 to 500.8302) by adding section 3406q.

The People of the State of Michigan enact:

Sec. 3406q. (1) An expense-incurred hospital, medical, or surgical policy or certificate delivered, issued for delivery, or renewed in this state that provides pharmaceutical coverage and a health maintenance organization contract 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 insurer or health maintenance organization 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.

This act is ordered to take immediate effect.

Carol Morey Viventi

Secretary of the Senate.

Ray E. Randall

Clerk of the House of Representatives.

Approved _____

Governor.