JOHN J. H. SCHWARZ, M.D.
24TH DISTRICT
P.O. BOX 30036
LANSING, MICHIGAN 48909-7536
OFFICE: (517) 373-3447
FAX: (517) 373-5849
DISTRICT TOLL-FREE: (877) 868-8353
TDD: (517) 373-0543
E-MAIL: senjschwarz@senate.state.mi.us

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LANSING, MICHIGAN

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SENATE FISCAL AGENCY
GOVERNING BOARD

FOR IMMEDIATE RELEASE

Contact: Suzann Ruch
(517) 373-3447

Schwarz Legislation on Off-Label Drugs Passes Senate

Expansion of Insurance Coverage Increases Access to Cutting Edge Treatments

May 22, 2002 – Legislation was passed by the Michigan Senate today requiring health insurance plans to provide coverage, if a patient has existing prescription coverage, for the off-label use of a Federal Food and Drug Administration (FDA) approved drug, Senator John J.H. Schwarz, M.D., R-Battle Creek, announced.

"The science of medicine is outpacing the FDA's ability to review drugs and label them for use in treating a specific diagnosis," Schwarz said. "Insurance coverage for off-label drugs is a major break-through for doctors and their patients, giving them access to cutting edge medical treatment."

Senate Bills 1241 and 1242, sponsored by Schwarz, amend the Nonprofit Health Care Corporation Reform Act and the Insurance Code to require insurance coverage for the off-label use of certain FDA approved drugs.

The term "off-label" refers to the use of a drug for clinical indications other than those stated in the labeling approved by the FDA.

(More)

"Without insurance coverage for off-label drugs, many patients simply cannot afford these new, and potentially, life-saving drug therapies," Schwarz said.

The legislation gives insurers the ability to seek documentation ensuring the following:

- The drug is prescribed by a physician to treat a life-threatening condition or a chronic and seriously debilitating condition.
- The drug is recognized for treatment of the prescribed condition by the American Medical Association Drug Evaluation; the American Hospital Formulary Service Drug Information; the U.S. Pharmacopoeia Dispensing Information; Volume 1, "Drug Information For the Health Care Professional"; or in two articles from major peer-reviewed medical journals that presented data supporting the proposed off-label use or uses as generally safe and effective.

Senate Bills 1241 and 1242 do not prohibit insurance providers from requiring a co-payment, a deductible, prior authorization, or a drug utilization review program, as long as they are no more expensive or stringent then those applied to regular "on-label" drugs.

The legislation will now be sent to the House for consideration.

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