



**ANALYSIS** 

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House Bill 5649 (Substitute H-1 as passed by the House)

Sponsor: Representative Nancy Jenkins

House Committee: Health Policy Senate Committee: Health Policy

Date Completed: 9-23-14

## **CONTENT**

The bill would amend the Public Health Code to provide that a health care provider's recommendation or treatment provided under the proposed Right to Try Act, and a health facility's cooperation in such treatment, would not be grounds for disciplinary action by the Department of Licensing and Regulatory Affairs (LARA).

The bill is tie-barred to Senate Bill 991, which would create the "Right to Try Act" to provide for access by an eligible patient (i.e., a patient who has an advanced illness) to drugs, biological products, and medical devices not yet approved by the U.S. Food and Drug Administration for general use.

Under House Bill 5649 (H-1), except in the case of gross negligence or willful misconduct as determined by LARA, a health care provider's recommendation or treatment provided as authorized under the proposed Right to Try Act would not be grounds for LARA to investigate or for disciplinary action against a licensee.

(The Code requires LARA, with regard to a health care provider, to investigate any allegation that certain grounds requiring disciplinary action by a subcommittee exist. After finding that one or more of the prescribed grounds exist, the disciplinary subcommittee must impose certain sanctions, including probation; limitation, denial, suspension, or revocation of the person's license; restitution; or a fine.)

The bill also provides that a health facility's cooperation in a treatment recommended by a health professional under the proposed Right to Try Act, alone, would not be grounds for LARA to take any action against a licensee, except in the case of gross negligence or willful misconduct.

(Under the Code, after providing notice and an opportunity for a hearing, LARA may deny, limit, suspend, or revoke the license or certification of a health facility, or impose an administrative fine on a licensee, if certain grounds exist.)

The bill would define "gross negligence" as conduct so reckless as to demonstrate a substantial lack of concern for whether serious injury to a person would result. "Willful misconduct" would mean conduct committed with an intentional or reckless disregard for the safety of others, as by failing to exercise reasonable care to prevent a known danger.

Proposed MCL 333.16221a & 333.20165a. Legislative Analyst: Julie Cassidy

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## **FISCAL IMPACT**

The bill would have no fiscal impact on State or local government.

Fiscal Analyst: Josh Sefton

 $\underline{\text{S1314} \setminus \text{s5649sa}}$  This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.