

RIGHT TO TRY EXPERIMENTAL TREATMENTS FOR COVID-19

Phone: (517) 373-8080
<http://www.house.mi.gov/hfa>

House Bill 5637 as reported from committee
Sponsor: Rep. Mary Whiteford
Committee: Health Policy
Complete to 2-22-22

Analysis available at
<http://www.legislature.mi.gov>

SUMMARY:

House Bill 5637 would amend the Right to Try Act to allow eligible patients to use certain experimental treatments in the treatment of COVID-19.

Enacted in 2014, the Right to Try Act allows eligible patients to access yet-unapproved drugs that successfully completed Phase 1 of a U.S. Food and Drug Administration (FDA)-approved clinical trial. Among other things, the act protects health care providers from licensing sanctions or loss of Medicare certification that would otherwise ensue from recommendation of the experimental drug and absolves the manufacturer and provider from civil liability.

Section 2 of the act allows a manufacturer of an *investigational drug, biological product, or device* to make the drug, product, or device available to an *eligible patient* and allows an eligible patient to request the drug, product, or device available. However, it expressly does not require a manufacturer to make the drug, product, or device available to an eligible patient.

Eligible patient means an individual who meets all of the following conditions:

- Has an advanced illness, attested to by the patient's treating physician.
- Has considered all other treatment options currently approved by the FDA.
- Has received a recommendation from his or her physician for an investigational drug, biological product, or device.
- Has given written, informed consent for the use of the investigational drug, biological product, or device.
- Has documentation from his or her physician that he or she meets these requirements.

The bill would extend the act's provisions so that, during a *COVID-19 pandemic emergency*, an *investigational drug, biological product, or device* would, in addition to its typical definition, include both of the following:

- A drug, biological product, device, or other treatment that remains under investigation in an FDA-approved clinical trial and that a physician recommends as a remedy for COVID-19.
- A drug, biological product, or device normally prescribed as a remedy to treat an illness other than COVID-19 that a physician recommends as a remedy for COVID-19.

COVID-19 pandemic emergency would mean a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services resulting from COVID-19.

MCL 333.26451

BRIEF DISCUSSION:

During committee testimony, proponents advanced the bill as a way to give patients a chance to try experimental treatments or courses of treatment that have not been approved for COVID when conventional treatments had been exhausted. According to the bill sponsor, the bill seeks to leave these medical decisions to the specific doctor and patient and to allow the patient to assume the risk (and the doctor, manufacturer, and provider to be absolved from sanctions or civil liability). If experimental treatments offer some hope where conventional treatments have failed, why shouldn't patients have that option?

Others questioned whether drugs such as ivermectin and hydrochloroquine, which have been advanced as treatments during the COVID pandemic but whose efficacy and safety have been questioned, would or should be legitimized by legislation such as this. Among other effects, this could result in shortages in certain drugs for their approved uses because of demand for unapproved uses.

FISCAL IMPACT:

House Bill 5637 would have no direct fiscal impact on the state or local units of government, as section 3 of the Right to Try Act states that governmental agencies are not required to pay for the cost associated with the treatment.

Legislative Analyst: Jenny McInerney
Fiscal Analyst: Kevin Koorstra

■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations and does not constitute an official statement of legislative intent.