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Synopsis of Senate Committee Amendments

(This synopsis does not address amendments that may have been adopted on the Senate Floor.)

H.B. 73 of the 135th General Assembly

Senate Health

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Limits the bill's application to off-label drugs and specifies that they must be approved for human use.

Eliminates provisions specifying that a prescriber or pharmacist is not required to obtain a test result before issuing a prescription for or dispensing the drug. Also eliminates a provision that stated that the patient is not required to have had a positive screen for, or exposure to, a particular disease, illness, or infection before the prescription is issued or the drug is dispensed.

Narrows the provision requiring pharmacists to dispense off-label drugs to pharmacists practicing in hospitals or inpatient facilities. Also narrows this provision by specifying that it applies only during a public health emergency or the period in which a local or state health order is in effect.

Prohibits a person from prescribing, dispensing, or administering any of the following off-label drugs if the person knows, or has reasonable cause to know, that the off-label drug is any of the following: a controlled substance that is not intended for a medical purpose; a drug subject to a federal Food and Drug Administration Risk Evaluation and Mitigation Strategy; a cross-sex hormone or puberty-blocking drug to be used in violation of the law regarding gender transition services for minors; and a drug to be used for euthanasia.

Eliminates provisions granting immunity to the hospital, inpatient facility, or its pharmacist with an objective, good faith, and scientific objection to the administration or dosage of an off-label drug, but who were required under the House-passed bill to dispense it, or allow its dispensing, instead establishing such an objection as an additional exception to the bill's mandatory dispensing.

Maintains the process by which an outpatient physician prescriber may seek temporary privileges at the hospital to prescribe the off-label drug to the patient, but removes provisions (1) prohibiting the process from exceeding five days and (2) allowing a physician denied privileges to file a complaint with ODH. Also prohibits the hospital bylaws for privileges from being more restrictive for such an outpatient physician than for others. Also requires the outpatient physician

with privileges to make a good faith effort to maintain ongoing consultation with the patient's care team.

Modifies the bill's informed consent requirement to define informed consent and require the physician to provide all of the following information: the patient's diagnosis, if known; nature and purpose of the recommended drug, treatment, or intervention; the burdens, risks, and expected benefits of all drug, treatment, or intervention options, including the option of forgoing treatment; and any conflicts of interest the physician may have regarding the recommended drug, treatment, or intervention.

States that the ultimate decision to accept an off-label drug or continue its use is for the patient, minor patient's parent or guardian, or person holding the patient's health care power of attorney, including in the case of a disagreement between the outpatient physician and in-house care team.

If the off-label drug is not authorized by insurance or the patient does not want to wait for authorization, requires the patient to be notified of estimated, out-of-pocket costs for the off-label drug and to be offered the drug at that cost. Also permits a hospital or inpatient facility to require payment before ordering the off-label drug.

Extends to a licensed health care professional (other than a pharmacist or prescriber) practicing in a hospital or inpatient facility immunity from administrative and civil liability for any harm that arises from the patient's use of the off-label drug prescribed by an outpatient physician (Maintains House-passed provisions granting this immunity to in-house pharmacists and physicians and to hospitals and inpatient facilities).

For purposes of the foregoing immunity provision, defines ***gross negligence*** to mean intentional failure to perform an apparent duty in reckless disregard of the consequences concerning the life or property of another.

Also extends to licensed health professionals other than pharmacists or physicians protection from licensing board discipline for actions taken under the bill.

Rather than protect health care professionals from disciplinary action for expressing medical opinions, as under the House-passed version, instead protects medical opinions about off-label prescribing.

Rather than prohibit a political subdivision, public official, or state agency from enforcing any federal government-issued rule or order, as under the House-passed version, instead prohibits enforcing or using any state funding to implement or incentivize any guideline, mandate, recommendation, or rule issued by the World Health Organization, including one that prohibits issuing a prescription for, or dispensing, an off-label drug.

Adds a severability provision.

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