

HB 1218 -- INVESTIGATIONAL ACCESS ORGANIZATIONS

SPONSOR: Neely

This bill repeals a requirement that an investigation drug, biological product, or device be used to treat a patient's terminal illness.

This bill allows investigational access organizations, which are entities licensed to manufacture, produce, and distribute investigational drugs, biological products, or devices to make the drug, product, or device available to certain patients with a terminal illness.

The bill prohibits a state agency from taking action against an investigational access organization's license based solely on the organization's sale of an investigational drug, biological product, or device to a patient with a terminal illness.

Any person who recommends an investigational drug or device to a patient with a terminal illness will not be liable for injury.

Any agent of the state who blocks access of a patient to an investigational drug, biological product, or device is guilty of a class A misdemeanor.

Any sponsor of a placebo-controlled clinical trial for patients with terminal illnesses must provide trial participants with a list of physicians or investigational access organizations that may provide the patient with the trial drug, product, or device outside of the trial. If the manufacturer does not provide the investigational drug, product, or device outside of the trial, the investigational access organization can manufacture and distribute the drug, product, or device.

The Department of Health and Senior Services must issue an investigational access organization license if the entity meets the requirements for licensure.

Any company or health benefit plan that provides coverage for assisted-suicide drugs or procedures in any state must provide coverage for investigational drugs, biological products, and devices on a basis no less favorable than the assisted-suicide drugs or procedures.

Coverage of investigational drugs, biological products, and devices will be subject to any prior authorization, dollar limit, co-payment, deductible, and other out-of-pocket expenses that do not apply to assisted-suicide drugs, unless the health benefit plan is

a high deductible health plan, in which case the provision will only apply after the person's deductible has been satisfied for the year.