ARKANSAS SENATE

90th General Assembly - Regular Session, 2015

Amendment Form

Subtitle of Senate Bill No. 4

CONCERNING TERMINALLY ILL PATIENT ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES; AND TO CREATE THE RIGHT TO TRY ACT.

Amendment No. 2 to Senate Bill No. 4

Amend Senate Bill No. 4 as engrossed, S1/22/15 (version: 01/22/2015 11:53:16 AM):

Page 2, line 17, delete ", and devices" and substitute ", or devices"

AND

Page 2, delete lines 34 through 36 and substitute "(4) "Terminal illness means an incurable and irreversible condition that without the administration of life-sustaining treatment will, in the opinion of the patient's physician, result in death within a relatively short time."

AND

Page 3, delete lines 7 through 9 and substitute the following:

"(2) Has a determination from a qualified physician that the patient has no comparable or satisfactory treatment options approved by the United States Food and Drug Administration available to treat the terminal illness and that the probable risk to the patient from the investigational drug, biological product, or device is not greater than the probable risk from the terminal illness;"

AND

Page 3, line 14, delete "prescription or recommendation" and substitute "prescription"

AND

Page 3, delete lines 30 through 35 and substitute the following:

"(a) A manufacturer of an investigational drug, biological product, or device may:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(2)(A) Require an eligible patient to pay the costs associated

with the manufacture of the investigational drug, biological product, or device.

(B) As used in this section, "costs associated with the manufacture of the investigational drug, biological product, or device" means the actual out-of-pocket costs incurred in providing the investigational drug, biological product, or device to the patient in the specific case.

(b) If a patient dies while being treated by an investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt to the manufacturer related to the investigational drug, biological product, or device."

AND

Page 4, delete lines 2 through 3 and substitute the following:

"An insurance company:

(1) May, but is not required to, provide coverage for an investigational drug, biological product, or device; and

(2) Shall not deny coverage for an item or service that is:

(A) Otherwise covered by an insurance contract between the eligible person and an insurance company; and

(B) Used separately or in conjunction with an investigational drug, biological product, or device."

AND

Page 4, line 5 through 9 and substitute the following:

"20-15-2008. Prohibited sanctions.

The recommendation, prescription, treatment, or participation in the treatment of a terminal illness with an investigational drug, biological product, or device shall not permit:

(1) A licensing board to revoke a license, fail to renew a license, or take any other action against a physician's license;

(2) A state agency or licensing board to revoke a license, fail to renew a license, or take any other action against:

(A) A medical professional licensed under state law; or

(B) A hospital licensed under § 20-9-213; or

(3) An action against a hospital's Medicare certification."

AND

Page 4, delete lines 12 through 14 and substitute the following:

"The counseling, advice, or recommendation by a medical professional who is licensed under the state law is not a violation of this subchapter."

AND

Page 4, delete lines 17 through 24 and substitute the following:

"(a) Except in the case of gross negligence or willful misconduct, a person or entity that manufacturers, imports, distributes, prescribes, dispenses, administers, or is otherwise involved in the care of an eligible patient using an investigational drug, biological product, or device is immune from civil liability for any loss, damage, or injury arising out of,

relating to, or resulting from the investigational drug, biological product, or device so long as the person or entity is substantially complying in good faith with this subchapter.

(b) This subchapter does not require a medical professional who is licensed under the laws of this state to counsel, advise, prescribe, dispense, administer, or otherwise be involved in the care of an eligible patient using an investigation drug, biological product, or device.

(c) This subchapter does not require a hospital licensed under § 20-9-213 to provide any service related to an investigational drug, biological product, or device."

The Amendment was read the first time, rules suspended and read the second time and _____

By: Senator J. Cooper

JMB/JMB - 01-27-2015 10:43:15 _____

JMB106 **Secretary**