

STAFF MEASURE SUMMARY

Senate Committee On Health Care

Fiscal: No Fiscal Impact

Revenue: No Revenue Impact

Action Date: 06/03/15

Action: Do Pass The A-Eng Bill. Refer To Ways And Means.

Meeting Dates: 06/01, 06/03

Vote:

Yeas: 5 - Knopp, Kruse, Monnes Anderson, Shields, Steiner Hayward

Prepared By: Zena Rockowitz, Committee Administrator

WHAT THE MEASURE DOES:

Creates and specifies providers, methods and criteria by which a health care practitioner may offer to treat patient who has a terminal illness with an investigational product that is not approved by the United States Food and Drug Administration. Defines "terminal disease." States that insurers are not required to reimburse any cost associated with the treatment. Specifies that hospice care must be determined on a patient's overall prognosis, care or treatment goals. Specifies protections of waiver of liability for health care practitioners, health care facilities, professional organizations or associations and manufacturers or suppliers of investigational products that comply with the measure.

ISSUES DISCUSSED:

- Time to develop, test and receive approval by U.S. Food and Drug Administration (FDA) for drugs
- Time to process paperwork when requesting non-FDA-approved drugs
- Compromise of clinical integrity
- Pursuit of non-FDA-approved drugs through investigational clinical studies or compassionate use
- Patient access to medication based on socioeconomic factors
- Ethical challenges for physicians
- Side effects of non-FDA-approved drugs
- Hope for patients with terminal illnesses

EFFECT OF COMMITTEE AMENDMENT:

No amendment.

BACKGROUND:

Arizona, Colorado, Louisiana, Michigan and Missouri enacted Right-to-Try laws in 2014. Right-to-Try laws generally permit a patient to have access to an experimental drug after it has passed through Phase 1 of a clinical trial, which is the initial trial testing where a drug is given to a small group of people to evaluate its safety and side effects. Proponents state that only about three percent of the sickest Americans qualify for or have access to clinical drug trials approved by the United States Food and Drug Administration. Right-to-Try legislation that has been developed by the Goldwater Institute states that insurers are not required to cover the costs of the drug or other services related to its use.