Amendments to ALEC's Safe Compounding Act

Summary: Ensures the ability of compounding pharmacies to acquire safe active pharmaceutical ingredients necessary to compound drugs for chronically or terminally ill patients.

Section 1: Compounding Pharmacies; Certain Medications; Requirements; Definitions

A. All ~~Chronically-ill patients and terminally ill~~ patients have the right to determine, with the assistance and guidance of their health care providers, individual courses of treatment or personalized care through the use of medications and treatments obtained from a compounding pharmacy.

B. Compounding pharmacies that are licensed in this state shall have access to Active Pharmaceutical Ingredients for use in compounding that meet United States Pharmacopeia Monographs, if the Active Pharmaceutical Ingredient is:

(1) prepared for use by a United States Food and Drug Administration-registered Active Pharmaceutical Ingredient manufacturer or packager; and[Text Wrapping Break](2) shipped into this state in compliance with state law and arrives with a certificate of analysis detailing quality specifications, including any medications, dietary supplements and amino acids that are already in use by compounding pharmacies in this state, in order to provide chronically ill patients and terminally ill patients with the prescribed individual course of treatment.

C. Subsection (B) of this section does not apply if the Active Pharmaceutical Ingredient is deemed unsafe for compounding by the federal Food and Drug Administration or is placed on the Interim 503a Category II Bulk Drug Substance List. Compounding pharmacies may use substances placed on the Interim 503a Category III Bulk Drug Substance List only if the substance meets the requirements of this section.

D. This section does not allow any treatment or use of medication that is intended to cause the death of the patient.

E. Nothing in this Act shall be construed to preempt, limit, or supersede any state law, regulation, or policy governing abortion or gender-affirming hormonal treatment for the purpose of gender transition.

F. For the purposes of this section:

~~(1) "chronically ill patient" means a patient whose physician has diagnosed the patient as having a long-term disease or condition that if left untreated may cause major irreversible morbidity and who might benefit from individualized or specialized medication that is not commercially available.~~

(1) "personalized care" means medical care and related services that are tailored to the patient's unique clinical needs in which licensed providers prescribe customized medications—adjusting dosage, form, or ingredients from what is commercially available to meet each patient's unique clinical needs.[Text Wrapping Break](2) "compounding pharmacy" means a pharmacy that is classified as a 503a pharmacy by the United States Food and Drug Administration.[Text Wrapping Break](3) "monographs" means quality standards for prescription medicines and dietary supplements that articulate the quality expectations for a medicine or dietary supplement, including its identity, strength, purity and performance.[Text Wrapping Break]~~(4) "terminally ill patient" means a patient whose physician has diagnosed the patient with a disease that, taking into account the patient's medical circumstances, will cause the patient's death in a reasonably foreseeable time.~~