ARIZONA STATE SENATE

Fifty-Fifth Legislature, First Regular Session

AMENDED

FACT SHEET FOR S.B. 1353

~~anti-rabies vaccination; rabies titer~~
(NOW: terminally ill patients; compounding; pharmacy)

As passed by the Senate, S.B. 1353 allowed a licensed veterinarian to administer a rabies antibody titer to determine whether to administer a rabies booster vaccine to a dog.

The House of Representatives adopted a strike-everything amendment that does the following:

Purpose

Establishes the right for chronically and terminally ill patients to determine courses of treatment through the use of medications and treatments obtained from compounding pharmacies.

Background

According to the Food and Drug Administration (FDA) compounding is generally a practice in which a licensed pharmacist, a licensed physician or a person under the supervision of a licensed pharmacist combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient (FDA). A drug may be compounded for a patient who cannot be treated with an FDA-approved medication, and practitioners in hospitals, clinics and other health care facilities can provide compounded drugs to patients when an FDA-approved drug is not medically appropriate to treat the patient. Compounded drugs are not FDA-approved and the FDA does not review or evaluate compounded drugs for safety, effectiveness or quality before being offered to patients.

In 2012, the U.S. Congress passed the Drug Quality and Security Act (DQSA) which made various updates to the Federal Food, Drug and Cosmetic Act (FD&C Act) regarding human drug compounding, including eliminating provisions concerning advertising of compounded drugs that had been found to be unconstitutional. Additionally, the FD&C Act describes the conditions under which compounded human drug products are exempt from requirements regarding pre-marketing approval, manufacturing practices and directions for use labeling. Further, the DQSA and FD&C Act outline requirements for compounding in state-licensed pharmacies and by doctors, as well as compounding in outsourcing facilities (P.L. 113-54, 113th Congress, 2013; FD&C Act § 503A).

There is no anticipated fiscal impact to the state General Fund associated with this legislation.

Provisions

1. Establishes the right for chronically and terminally ill patients to determine, with assistance from and guidance of their health care providers, individual courses of treatment through the use of medications and treatments obtained from a compounding pharmacy.

2. Grants licensed compounding pharmacies access to active pharmaceutical ingredients that meet U.S. pharmacopeia monographs for use in compounding in order to provide chronically and terminally ill patients with a prescribed individual course of treatment, including medications, dietary supplements and amino acids that are already utilized in Arizona, if the active pharmaceutical ingredient:
   a) is prepared for use by a U.S. FDA-registered manufacturer or packager;
   b) is shipped according to Arizona law; and
   c) arrives in Arizona with a certificate of analysis detailing quality specifications.

3. Specifies that the use of a treatment or medication that is intended to cause death is prohibited.

4. Defines relevant terms.

5. Becomes effective on the general effective date.

House Action

COM	3/23/21	DPA/SE	9-0-0-1
3rd Read	4/08/21		58-0-2

Prepared by Senate Research
April 8, 2021
CRS/gs