SB1108/744033/1

BY: Education, Health, and Environmental Affairs Committee

AMENDMENTS TO SENATE BILL 1108
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 2, strike "Exemptions –" and substitute "Definition of "Compounding" and Exemption for"; in line 4, after the first "of" insert "altering the definition of "compounding" for purposes of provisions of law governing sterile compounding to exclude certain acts performed by or under the supervision of certain individuals and in accordance with certain directions;"; in line 9, after the first "a" insert "licensed health care practitioner who performs sterile compounding in a"; in line 10, strike "appropriate" and substitute "respective"; in line 11, strike "defining a certain term;"; in the same line, strike "exemptions from the"; and in line 12, strike "permit requirement" and substitute "permits".

AMENDMENT NO. 2

On page 1, in line 15, after "Section" insert "12-4A-01 and"; and after line 20, insert:

"12-4A-01.

(a) In this subtitle the following words have the meanings indicated.

(b) **(1)** "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug only:

[(1)**]** **(I)** As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient relationship in the course of professional practice;

(Over)

[(2)**]** **(II)** For the purpose of, or incidental to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device; or

[(3)**]** **(III)** In anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

(2) "COMPOUNDING" DOES NOT INCLUDE MIXING, RECONSTITUTING, OR OTHER ACTS PERFORMED:

(I) BY, OR UNDER THE SUPERVISION OF, AN ONCOLOGIST OR A HEMATOLOGIST WHO ADMINISTERS CHEMOTHERAPY, BIOLOGIC THERAPY, SUPPORTIVE CARE MEDICATION, OR ANY OTHER THERAPY IN THE TREATMENT OF CANCER OR A BLOOD CONDITION; AND

(II) IN ACCORDANCE WITH:

1. DIRECTIONS CONTAINED IN APPROVED LABELING PROVIDED BY THE PRODUCT'S MANUFACTURER; AND

2. OTHER MANUFACTURER DIRECTIONS CONSISTENT WITH THE LABELING.

(c) "Designee" means a public agency or private entity approved by the Board to conduct inspections of sterile compounding facilities or entities that prepare sterile drug products.

(d) "Sterile compounding" means compounding of biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797, must be prepared using aseptic techniques.

(e) "Sterile compounding facility" means a pharmacy, a health care practitioner's office, or any other setting in which sterile compounding is performed.

(f) "Sterile drug product" means a drug product that:

(1) Must be prepared using aseptic techniques; and

(2) Is not required to be prepared in response to a patient specific prescription.

(g) "USP 797" means the standards set forth in the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations".".

On page 2, strike beginning with "**(1)**" in line 3 down through "**LABELING.**" in line 11; in lines 12 and 27, in each instance, strike "**(2)**" and substitute "**(1)**"; and in line 26, strike "**(3)**" and substitute "**(2)**".

On page 3, in lines 1 and 5, strike "**(4)**" and "**(5)**", respectively, and substitute "**(3)**" and "**(4)**", respectively; in line 6, strike "**(2)**" and substitute "**(1)**"; in line 7, after "**797,**" insert "**THE LICENSED HEALTH CARE PRACTITIONER WHO PERFORMS STERILE COMPOUNDING IN**"; and in line 8, strike "**APPROPRIATE**" and substitute "**RESPECTIVE**".