AN ACT RELATING TO PHARMACY BOARD ENFORCEMENT, PHARMACEUTICAL SUPPLY CHAIN INTEGRITY, AND REGULATORY ACCOUNTABILITY

NEW ARTICLE: PRESCRIPTION DRUGS, ACTIVE PHARMACEUTICAL INGREDIENTS, AND OVERSIGHT OF COMPOUNDING PRACTICES

SECTION 1. LEGISLATIVE INTENT

a) The Legislature finds that the integrity of the pharmaceutical supply chain, which includes the safe compounding of prescription drugs for dispensing or administering to a patient, is a matter of importance to critical public health and safety.
b) It is the intent of the Legislature to grant the Board of Pharmacy authority to protect the public health and safety from substandard pharmaceuticals being procured, compounded, dispensed, or administered in or into this State.

SECTION 2. DEFINITIONS

a) “Active Pharmaceutical Ingredient” or “API” means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.
b) “Administer” or “Administration” means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.
c) “Adulterated” has the same meaning as 21 U.S.C. § 351.
d) “Adverse Event” means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
e) "Authorized Agent” means any individual or entity identified by the Board as qualified to conduct inspections, investigations, or seizures on its behalf.
f) “Board” means the state Board of Pharmacy.
g) “Chemical” means any substance not otherwise defined by the Act that is a biologically active substance intended to produce a therapeutic effect in the body to diagnose, cure, mitigate, treat, or prevent disease.
h) “Compounding” or “Compounded” means the preparation, mixing, assembling, altering, packaging, or labeling of a drug, or device in accordance with a licensed practitioner’s prescription, medication order.

i) “Controlled substance” means a Food and Drug Administration-approved drug or other substance included in the State’s Controlled Substances Act listed in Schedule II, III, IV, or V.
j) “Counterfeit” or “Counterfeit Drug” has the same meaning as 21 U.S.C. § 321(g)(2).
k) “Dispense” or “Dispensing” means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, final verification, and delivery of a drug or device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.
l) “Drug” means an article recognized as drugs in any official compendium, or supplement thereto, or an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
m) “Facility” means any location not licensed by the Board that receives, stores, compounds, or prepares prescription drugs, APIs, controlled substances, or any other chemicals or peptides.
n) “Licensed Healthcare Professional” means an individual who has been granted the legal authority by the State to practice a particular healthcare profession.
o) “Misbranded” has the same meaning as 21 U.S.C. § 352.
p) “National Practitioner Data Bank” means the information clearinghouse created by Congress with the primary goals of improving health care quality, protecting the public, and reducing health care fraud and abuse in the United States.
q) “Peptide” means a molecule consisting of two or more amino acids covalently linked together by peptide bonds that are intended to produce a therapeutic effect in the body to diagnose, cure, mitigate, treat, or prevent disease.
r) “Person” means an individual, corporation, government, or governmental subdivision or agency, statutory trust, business trust, estate, trust, partnership, unincorporated association, or more of any of the foregoing having a joint or common interest, or any other legal or commercial entity.
s) “Practitioner” means a licensed healthcare professional who has the authority to procure, prescribe, dispense, or administer prescription drugs and devices.
t) “Prescription Drug” means a drug that is required under federal law to be labeled with “Rx Only” and must be dispensed or administered upon the order of or by a licensed practitioner authorized to prescribe prescription drugs.
u) “Responsible Person” means a licensed healthcare professional with the independent authority to procure, prescribe, dispense, or administer prescription drugs and devices and who is responsible for supervising Facility healthcare operations.

v) “Serious Adverse Event” means an adverse event that results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization, or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or congenital anomaly/birth defect.

w) “Significant Violations” include substantial deviation from compounding standards established by USP; procuring, administering, or dispensing unapproved drugs, peptides, or any other chemicals, unless the Responsible Person is engaged in a systematic research program, has obtained the necessary approvals from the Institutional Review Board and the FDA, and has obtained approval to conduct such research from the Board; other violations identified by rule of the Board.

x) “United States Pharmacopeia” or “USP” means the independent, non-profit, scientific organization that establishes public standards for the quality, purity, strength, and consistency of medicines, food ingredients, and dietary supplements.

SECTION 3. BOARD AUTHORITY: INSPECTION, INVESTIGATION, AND ENFORCEMENT

3.1 RIGHT OF ENTRY AND INSPECTION OF PREMISES

a) The Board or its authorized agents may enter and inspect, during normal business hours, any location that is operating or is suspected of operating as a Facility.

b) The inspection may include areas of the Facility where prescription drugs, APIs, controlled substances, or any other chemicals or peptides are received, stored, compounded, and prepared for dispensing or administration. The inspection shall include a review of Facility records, including, but not limited to, ownership information, invoices, purchase orders, certificates of analysis, transaction information, compounding logs, Practitioner prescription orders, or dispensing and administration information. If the Facility is engaged in compounding, the inspection shall evaluate compliance with the most current published version of the United States Pharmacopeia General Chapters <797>, <795>, and <800>, as applicable.

c) The Board or its authorized agents may investigate any location that the Board has reasonable cause to suspect that prescription drugs, APIs, controlled substances, or any other chemicals or peptides are received, stored, compounded, or prepared for dispensing or administration.

d) Inspection reports may be made available to the public pursuant to state law or the rules of the Board.

3.2 AUTHORITY TO SEIZE, QUARANTINE, AND DUE PROCESS

a) The Board or its authorized agents shall have the authority to seize and quarantine prescription drugs, APIs, FDA-approved controlled substances, or any other chemicals or peptides if the Board or its agent has probable cause to believe that the prescription drug, API, FDA-approved controlled substance, chemical, or peptide is an unapproved new drug, adulterated, misbranded, counterfeit, or is otherwise unauthorized for human use, is labeled in a manner that indicates the substance is for research use only, is not compounded in accordance with USP, or is otherwise in violation of this Chapter.
b) Upon seizure, the Board or its agent shall provide the Facility owner or the Responsible Person with a detailed, itemized inventory of all seized substances. The Board shall conduct an administrative hearing, in accordance with the state's administrative procedures act, which shall be open to the public, no later than ten (10) business days after the date of seizure, to determine the lawful disposition or return of the seized substances. The Board shall provide notice of the hearing to the Facility owner and the Responsible Person within two (2) business days of any seizure.

SECTION 4. PRESCRIPTION DRUGS, COMPOUNDING, UNAPPROVED DRUGS OR CHEMICALS, AND SUPPLY CHAIN INTEGRITY

a) It is unlawful for a Facility or person to procure, administer, or dispense prescription drugs, peptides, or any other chemicals that are intended for research-use only, unless the Responsible Person is engaged in a systematic research program, has obtained the necessary approvals from the Institutional Review Board and the FDA, and has obtained approval to conduct such research from the Board.
b) It is unlawful for a Facility or person to procure, administer, or dispense prescription drugs, peptides, or any other chemicals that are labeled not for use in humans.
c) A Facility engaged in compounding under the supervision and direction of the Responsible Person shall compound in accordance with applicable chapters of the most current version of USP for sterile and nonsterile compounding and shall only procure APIs from an FDA-registered establishment that is licensed with the state, as applicable.

SECTION 5. REPORTING REQUIREMENTS

5.1 SERIOUS ADVERSE EVENT REPORTING

a) Serious Adverse Events shall be reported to the Board in a manner and form prescribed by the Board within five business days of the Facility becoming aware of such Serious Adverse Event.

5.2 REPORTING TO AND RESPONSIBILITIES OF PROFESSIONAL LICENSING BOARDS

a) The Board shall provide the professional licensing board that has issued a professional license to the Responsible Person (e.g., Board of Medicine, Board of Nursing) with the following:
    a. Notification of refusal of entry into the Facility for inspection and investigation purposes.
    b. Inspection reports that identify any violations of this Act.
    c. Investigative material, including the original complaint, after the Board determines that the alleged violations were proven by a preponderance of the evidence. If the investigation reveals the culpability of other professionally licensed individuals, the Board shall also share the investigative material and the original complaint with the board that issued their license.
    d. Any fines levied against the Responsible Person
    e. Any unpaid fines levied against the Responsible Person.
b) The Board shall advise the professional licensing board that receives a report from the Board whether additional action is needed to protect public health and safety. Any public disciplinary action taken by professional licensing boards pursuant to this Act shall be shared with the Board and reported to the National Practitioner Data Bank.

5.3 ANNUAL REPORT TO THE GOVERNOR AND LEGISLATURE

a) The Board, upon request, no later than xx-xx of each year, shall submit a comprehensive report on its inspection and investigation findings conducted under the authority of this Act in the preceding fiscal year. The report to the Governor and Legislature shall include, but is not limited to:
    a. The total number of Facility inspections conducted.
    b. The total number of consumer complaints received against Facilities.
    c. A summary of the most significant findings related to violations of compounding, procurement of prescription drugs, and APIs.
    d. The identity and amount of any prescription drugs, controlled substances, APIs, peptides, or any other chemicals seized by the Board.
    e. A summary of serious adverse events reported to the Board.
    f. A summary of public disciplinary action taken by professional licensing boards pursuant to this Act against Responsible Persons or other licensed professionals engaged the practices identified by this Act.

g. An estimated cost to the Board for inspections and investigations activities conducted pursuant to this Act.
h. The total amount of penalties levied and collected against facilities and Responsible Individuals for violations of this Act.
i. Specific recommendations for legislative or regulatory changes, including any requests for additional enforcement powers or oversight.

SECTION 6. IMPLEMENTATION AND EFFECTIVE DATE

a) The Board may adopt rules, not inconsistent with this Act, to implement this Act.
b) This Act shall take effect upon enactment.

SECTION 7. ENFORCEMENT AND PENALTIES

a) The Board may impose a fine of up to $5000 on the Responsible Person and the owner of the Facility for refusing the Board or its authorized agent to enter the Facility under the authority of this Act.
b) The Board may impose a fine of up to $2500 on the Responsible Person for each violation of this Act.
c) Fines imposed on the Responsible Person shall not be considered discipline or reported to the National Practitioner Data Bank.
d) The Board may collect inspection and investigative fees from the facility and/or the Responsible Person for violations of this Act.
e) All fines and fees levied under the authority of this Act shall be payable to the Board within 30 calendar days. Fines and fees collected shall be retained by the Board and used to carry out its duty under the Act.