SENATE, No. 1264

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED FEBRUARY 3, 2020

Sponsored by:
Senator JAMES BEACH
District 6 (Burlington and Camden)

SYNOPSIS

"Compounding Pharmacy Quality Assurance Act"; requires accreditation of compounding pharmacies.

CURRENT VERSION OF TEXT

As introduced.

AN ACT concerning the regulation of compounding pharmacies and supplementing Title 45 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. This act shall be known and may be cited as the "Compounding Pharmacy Quality Assurance Act."

2. The Legislature finds and declares that:

a. There may be as many as 3,000 compounding pharmacies in the United States that create customized versions of prescription medications that are not available through pharmaceutical manufacturers;

b. The lack of adequate regulatory oversight of these pharmacies has received national attention in the wake of a wave of reports of death and illness among patients who were exposed to fungal meningitis as a result of receiving contaminated spinal steroid injections from a compounding pharmacy in Massachusetts;

c. It is unclear at this point who is ultimately responsible, among state regulators, the federal Food and Drug Administration, and the pharmaceutical industry, for providing effective oversight of compounding pharmacies throughout the United States, and so there is an urgent need to address this regulatory void in order to ensure the safety and effectiveness of medications made by these pharmacies;

d. The intent of this act is to ensure the safety and effectiveness of medications dispensed by compounding pharmacies in New Jersey by requiring that these pharmacies document to the New Jersey State Board of Pharmacy that they meet the nationally accepted quality assurance, quality control, and quality improvement standards required for accreditation by the Pharmacy Compounding Accreditation Board, or PCAB;

e. In order to demonstrate compliance with PCAB standards and earn PCAB accreditation, a pharmacy must voluntarily participate in an evaluation process that includes: verification by PCAB that the pharmacy is not on probation for issues related to compounding quality, public safety, or controlled substances; verification that the pharmacy is properly licensed in each state in which it does business; and an extensive on-site evaluation by a PCAB surveyor who is a compounding pharmacist trained in evaluating compliance with PCAB quality standards;

f. The quality standards adopted by PCAB, which have been developed by a standards committee of compounding pharmacists, academics, and experts, include requirements that accredited pharmacies use only high-quality chemicals and equipment, ensure that their compounding pharmacists and technicians are provided with regular and specialized training, conduct testing to evaluate the

quality of their preparations, and maintain an effective recall mechanism that allows them to identify which patients received a particular compound;

g. PCAB requires a minimum 90-day history of compliance with its standards before a pharmacy is eligible for accreditation;

h. PCAB performs a routine on-site survey of its accredited pharmacies every three years, and may select any of these pharmacies for an unannounced survey at any time during their accreditation cycle;

i. PCAB was founded by the leading pharmacy organizations in this nation, which comprise its board of directors, including the American College of Apothecaries, the National Community Pharmacists Association, the American Pharmacists Association, the National Alliance of State Pharmacy Associations, the International Academy of Compounding Pharmacists, the National Home Infusion Association, the National Association of Boards of Pharmacy, and the United States Pharmacopeial Convention; and

j. The enactment of this act will serve the interests of the public health by ensuring that compounding pharmacies adhere to rigorous standards and prepare quality medications for dispensing or administration to New Jersey patients.

3. As used in this act:

"Board" means the New Jersey State Board of Pharmacy.

"Compounded medication" means a sterile or nonsterile compounded formulation for dispensing or administration pursuant to a prescription, which is prepared for a patient with needs that cannot be met by a commercially available prescription drug.

"Compounding pharmacy" means a licensed pharmacy operating in this State that engages in the preparation of compounded medications, or a pharmacy located in another state that ships, mails, distributes, or delivers in any manner, compounded medications pursuant to a prescription into this State.

4. The board shall require:

a. a compounding pharmacy that engages in the preparation of compounded medications on the effective date of this act to furnish evidence to the board of its accreditation by the Pharmacy Compounding Accreditation Board, in a manner prescribed by the board, no later than one year after the effective date of this act, as a condition of that pharmacy's continued authorization to dispense compounded medications in this State; and

b. a compounding pharmacy that commences its engagement in the preparation of compounded medications after the effective date of this act to furnish evidence to the board of its accreditation by the Pharmacy Compounding Accreditation Board, in a manner prescribed by the board, no later than six months after the pharmacy commences its engagement in the preparation of compounded

medications, as a condition of that pharmacy's continued authorization to dispense compounded medications in this State.

5. The board, in consultation with the Pharmacy Compounding Accreditation Board and pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt rules and regulations as necessary to effectuate the purposes of this act.

6. This act shall take effect on the first day of the third month next following the date of enactment, but the board may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.

STATEMENT

This bill, which is designated as the "Compounding Pharmacy Quality Assurance Act," requires compounding pharmacies in New Jersey to be accredited by the Pharmacy Compounding Accreditation Board (PCAB).

Under this bill, the State Board of Pharmacy is to require a compounding pharmacy that engages in the preparation of compounded medications on the effective date of the bill to furnish evidence to the State board of the pharmacy's accreditation by PCAB, in a manner prescribed by the State board, no later than one year after the effective date of the bill, as a condition of that pharmacy's continued authorization to dispense compounded medications in New Jersey.

In addition, the State Board of Pharmacy is to require a compounding pharmacy that commences its engagement in the preparation of compounded medications after the effective date of the bill to furnish evidence to the State board of the pharmacy's accreditation by PCAB, in a manner prescribed by the State board, no later than six months after the pharmacy commences its engagement in the preparation of compounded medications, as a condition of that pharmacy's continued authorization to dispense compounded medications in this State.

The bill defines:

"compounded medication" to mean a sterile or nonsterile compounded formulation for dispensing or administration pursuant to a prescription, which is prepared for a patient with needs that cannot be met by a commercially available prescription drug; and

"compounding pharmacy" to mean a licensed pharmacy operating in this State that engages in the preparation of compounded medications, or a pharmacy located in another state that ships, mails, distributes, or delivers in any manner, compounded medications pursuant to a prescription into this State.

The bill takes effect on the first day of the third month following its enactment, but it authorizes the State Board of Pharmacy to take prior anticipatory administrative action as necessary for the bill's implementation.