ASSEMBLY, No. 3088

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED FEBRUARY 24, 2020

Sponsored by: Assemblyman JOHN F. MCKEON District 27 (Essex and Morris)

SYNOPSIS

Regulates Internet pharmacies and electronic prescriptions.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 2/24/2020)

1	AN	ACT	cond	cerning	Inte	ernet	pharmacies	and	elec	ctronic
2	pı	rescripti	ions,	amendii	ng a	and s	upplementing	g P.L.2	003,	c.280
3	((C.45:14	-40 et	seq.).						

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

- 1. (New section) As used in this act:
- "Board" means the New Jersey State Board of Pharmacy.

"Electronic prescription" means a prescription which is transmitted by a computer device in a secure manner, including computer to computer and computer to facsimile transmissions.

"Facsimile prescription" means a prescription which is transmitted by a device which sends an exact image to the receiver.

"Internet" means the international network of interconnected government, educational and commercial computer networks.

"Internet pharmacy" means a pharmacy located in the United States which maintains an Internet site for the purpose of soliciting and receiving prescription drug orders to be delivered to the patient by means of the United States Postal Service or other delivery service.

"New Jersey patient" means a person who resides in New Jersey and requests delivery of a prescription drug order to an address in New Jersey.

"Practitioner" means a duly licensed physician, dentist, optometrist, veterinarian, certified nurse midwife, advanced practice nurse or physician assistant, or other health care practitioner licensed or approved to write prescriptions.

"Prescription" or "prescription drug order" means any order for drugs and related items which meets the definition of "prescription" as that term is defined in section 2 of P.L.2003, c.280 (C.45:14-41) and includes a facsimile and electronic prescription.

"Prescription drug" means a drug the label of which bears a statement that it is to be dispensed only by or on the prescription of a person licensed to prescribe drugs, or words of similar or like import, or a drug that requires a prescription or order by an authorized prescriber in order to be dispensed.

"Professional judgment" means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the prescriber.

2. (New section) a. An Internet pharmacy shall not dispense or deliver prescription drugs to a New Jersey patient unless the

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

- pharmacy applies to the board and obtains a pharmacy permit to dispense and deliver prescription drugs in New Jersey in accordance with this act.
- b. The provisions of this act shall not apply to an Internet pharmacy certified under the Verified Internet Pharmacy Practice Sites Certification Process of the National Association of Boards of Pharmacy, provided that the pharmacy has submitted a copy of its certification to the board.
 - c. The provisions of this act shall not apply to a pharmacy practice site located in this State to which a duly authorized permit has been issued by the board pursuant to N.J.A.C.13:39-4.16.

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- 3. (New section) The board shall issue a permit to an Internet pharmacy that satisfactorily meets the following requirements:
 - a. has its corporate headquarters in the United States;
- b. submits an application to the board on the form that the board requires;
- 18 c. submits a copy of the most recent inspection report resulting 19 from an inspection conducted by the regulatory or licensing agency 20 of the state in which the pharmacy is located;
 - d. provides certification that it is licensed and in good standing in the state in which it is located;
 - e. provides the names, titles and addresses of all principal corporate officers;
 - f. provides the names and addresses of all of its pharmacists and certification that the pharmacists are registered and in good standing in the state where they work;
 - g. provides all other information deemed necessary by the board to ensure that the Internet pharmacy is qualified to dispense or deliver prescription drugs to New Jersey patients; and
 - h. pays any necessary application and permit fees as are required by the board.
 - The permit shall be renewed annually in accordance with regulations adopted by the board.

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- 4. (New section) An Internet pharmacy issued a permit in this State shall:
 - a. comply with the laws of the state in which it is located;
- b. within 30 days after a change of office, corporate officer, or pharmacist, disclose to the board the location, names and titles of all principal corporate officers and all pharmacists who are dispensing prescriptions for drugs or devices for delivery into this State;
- c. comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which the pharmacy is located and all requests made by the board pursuant to this section;

- d. maintain at all times a valid, unexpired permit to operate a pharmacy in compliance with the laws of the state in which it is located;
 - e. ensure that all prescription drug orders for New Jersey patients are filled by pharmacists licensed and in good standing in the state where the prescription is filled;
 - f. maintain in readily-retrievable form the records of New Jersey patients;
- g. provide a toll-free telephone number for consultations between New Jersey patients and a licensed pharmacist who has ready access to the patient's records. The toll-free telephone number must be answered during normal business hours for a minimum of 48 hours, six days per week. The toll-free telephone number must be on the label of every prescription drug delivered to New Jersey and prominently displayed on the pharmacy's Internet site;
 - h. comply with the laws of this State relating to the confidentiality of prescription records if there are no laws relating to the confidentiality of prescription records in the state in which the Internet pharmacy is located; and
 - i. dispense drugs for delivery into this State pursuant to a prescription electronically transmitted only if the transmission is an electronic prescription or facsimile prescription conforming to the requirements of the board.

- 5. (New section) An Internet pharmacy issued a permit in this State shall not:
- a. disclaim, limit or waive any liability to which a retail pharmacy in New Jersey is subject;
- b. disclaim, limit or waive the jurisdiction of the courts of the State of New Jersey; or
- 32 c. disclaim, limit or waive the application of the laws of the33 State of New Jersey.
- Any disclaimer, limitation or waiver in violation of this section is void.

- 6. (New section) The following are violations of this act:
- a. Dispensing, or arranging for the dispensing of a prescription drug to a consumer unless the person or business that packages, delivers, or otherwise furnishes the drug for use by the consumer:
 - (1) has a valid pharmacy license issued by the board; or
- (2) is a health care professional acting within the scope of his license within this State.
- b. Soliciting, assisting or enabling consumers to obtain a prescription via the Internet without a bona-fide existing practitioner-patient relationship. For purposes of this section, a bona-fide existing practitioner-patient relationship means:

the practitioner has conducted an examination, which shall be appropriately documented in the patient record. As part of the patient examination, the practitioner shall:

- (1) perform an appropriate history and physical examination;
- (2) make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;
- (3) formulate a therapeutic plan and discuss that plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and
- (4) ensure the availability of the physician or coverage for the patient for appropriate follow-up care.

- 7. (New section) a. A violation of this act is an unfair or deceptive trade practice in this State. Persons or businesses violating this act shall be subject to a civil penalty of \$25,000 for each occurrence and a pharmacist is subject to a civil penalty of \$5,000 for each occurrence. The Attorney General may bring an action in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.), to enforce this section and to collect the civil penalties authorized herein.
- In addition to such other penalties as may apply, a consumer aggrieved by violation of this act may:
- (1) obtain an injunction or such equitable relief as the court may find to be appropriate; and
- (2) obtain liquidated damages of \$10,000 per violation, in addition to court costs, attorney fees, and the reasonable costs of litigation.
- In addition to such penalties as may apply, a consumer who is injured by a prescription drug purchased through the Internet may bring an action for compensatory damages against a person who violated this act with respect to the purchase of that prescription drug by the consumer. Attorneys fees, court costs, and reasonable costs of litigation may be awarded by the court.
- b. A violation of any of the provisions of this act shall be grounds for revoking or refusing to issue a permit to an Internet pharmacy as provided in this act.
- c. Nothing in this act shall be construed to prevent or limit the board, the Director of the Division of Consumer Affairs in the Department of Law and Public Safety or the Attorney General from taking any other action permitted by law against an Internet pharmacy.
- d. Nothing in this act shall be construed to prevent or limit the board from taking any action permitted by law against a person, other than a pharmacy, violating the provisions of this act for aiding and abetting the unlawful practice of pharmacy.

8. (New section) Whenever a pharmacist has reason to question the validity of an electronic prescription or a facsimile

- prescription for a New Jersey patient, the pharmacist shall verify the prescription directly with the prescribing practitioner. The pharmacist shall refuse to fill a prescription if, in his professional judgment:
 - a. the prescription is outside the scope of practice of the license of the prescriber;
 - b. the pharmacist has sufficient reason to question the validity of the prescription; or
 - c. refusal to fill the prescription is necessary to protect the health and welfare of the patient.

9. (New section) No Internet pharmacy acting pursuant to a permit issued under this act shall fill a prescription for any schedule II, III, IV or V controlled dangerous substances in any manner other than in writing signed by the practitioner.

- 10. Section 34 of P.L.2003, c.280 (C.45:14-73) is amended to read as follows:
- 34. Any pharmacy located in another state, other than a pharmacy that is solely an Internet pharmacy, which ships, mails, distributes or delivers in any manner, legend drugs or devices pursuant to a prescription into this State, shall register with the board and provide the board with the following information:
- (1) The location, names and titles of all principal corporate officers of the pharmacy. A report containing this information shall be made on an annual basis and within 30 days after any change of office or corporate officer; and
- (2) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. As a prerequisite to registering with the board, the pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

The annual registration fee shall be established by the board and shall not exceed \$500 annually.

Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this State and **[a]** pharmacists at a pharmacy who **[has]** <u>have</u> access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this State. (cf: P.L.2003, c.280, s.34)

11. (New section) The New Jersey State Board of Pharmacy, in consultation with the State Board of Medical Examiners, shall

promulgate, in accordance with the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), such rules and regulations as may be necessary to effectuate the purposes of this act.

12. This act shall take effect on the 180th day after enactment; however, the board may take such action in advance as shall be necessary for the implementation of the act.

STATEMENT

This bill regulates Internet pharmacies which dispense or deliver prescription drugs to patients living in New Jersey.

Under its provisions, Internet pharmacies are required to obtain a pharmacy permit from the New Jersey State Board of Pharmacy prior to dispensing or delivering prescription drugs in New Jersey and to provide the board with certain information, as specified in the bill, to qualify for the permit. An Internet pharmacy must have its corporate headquarters in the United States to receive a permit under the bill's provisions.

The bill prohibits Internet pharmacies from disclaiming: any liability to which a retail pharmacy in New Jersey is subject; jurisdiction of the courts of New Jersey; or application of the laws of the State of New Jersey.

Before dispensing or delivering prescription drugs in accordance with an electronic prescription, the bill requires an Internet pharmacy or pharmacist to have a valid pharmacy license issued by the board or be a health care professional acting within the scope of his or her license within this State. It is a violation of this bill for any person to solicit, assist, or enable consumers to obtain a prescription via the Internet without a bona-fide existing practitioner-patient relationship.

As provided by the bill, a bona-fide existing practitioner-patient relationship means the practitioner has conducted an examination, appropriately documented in the patient record. As part of this examination, the practitioner is required to:

- (1) perform an appropriate history and physical examination;
- (2) make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;
- (3) formulate a therapeutic plan and discuss that plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and
- (4) ensure the availability of the physician or coverage for the patient for appropriate follow-up care.

Violations of the bill may result in a civil penalty of \$25,000 for each occurrence by a pharmacy and \$5,000 for each occurrence by a pharmacist. Consumers aggrieved by a violation of the bill may obtain equitable relief and liquidated damages of \$10,000 for each

- 1 violation. Additionally, consumers injured by a prescription drug
- 2 purchased through the Internet may recover compensatory damages.
- A permit issued pursuant to the bill may be revoked as a result of a
- 4 violation as well.

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- The bill requires pharmacists with reason to question the validity of an electronic or facsimile prescription to verify the prescription with the prescribing practitioner and to refuse to fill any prescription which, in his or her professional judgment, is beyond the scope of practice of the license of the prescriber, is of questionable validity, or is necessary to protect the health and welfare of the patient.
- An Internet pharmacy certified under the Verified Internet Pharmacy Practice Sites Certification Process of the National Association of Boards of Pharmacy is exempted from the bill's provisions, provided that it has submitted a copy of its certification to the board. Also exempt from the bill's provisions are pharmacy practice sites to which a duly authorized permit has been issued by the board pursuant to N.J.A.C.13:39-4.16.
- Under the provisions of the bill, an Internet pharmacy acting pursuant to a permit issued under the bill is prohibited from filling a prescription for any schedule II, III, IV or V controlled dangerous substances in any manner other than in writing signed by the practitioner.
- In addition, the bill authorizes the New Jersey State Board of Pharmacy, in consultation with the State Board of Medical Examiners, to promulgate rules and regulations necessary to effectuate the purposes of this act.