

# ASSEMBLY, No. 1025

## STATE OF NEW JERSEY 212th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2006 SESSION

**Sponsored by:**

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**District 5 (Camden and Gloucester)**

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**SYNOPSIS**

"Pharmacy Quality Improvement and Error Prevention Act."

**CURRENT VERSION OF TEXT**

Introduced Pending Technical Review by Legislative Counsel



**(Sponsorship Updated As Of: 1/27/2006)**

1 AN ACT concerning prescription drug-related errors and  
2 supplementing chapter 14 of Title 45 of the Revised Statutes.

3

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

6

7 1. This act shall be known and may be cited as the "Pharmacy  
8 Quality Improvement and Error Prevention Act."

9

10 2. The Legislature finds and declares that:

11 a. The number of complaints filed with the New Jersey Board of  
12 Pharmacy concerning prescription errors has more than doubled in  
13 the past eight years;

14 b. According to a 1999 report of the Institute of Medicine of the  
15 National Academies, more than 7,000 Americans die each year  
16 from medication errors, including those that occur in and out of  
17 hospitals, as compared with 6,000 deaths annually from workplace  
18 injuries; and

19 c. The essential obligation of government to protect the health  
20 and well-being of its citizens dictates the need for immediate action  
21 by this State to initiate a systematic effort to reduce the possibility  
22 of prescription errors that may have serious adverse consequences  
23 for the residents of New Jersey.

24

25 3. As used in this act:

26 "Board" means the New Jersey Board of Pharmacy in the  
27 Division of Consumer Affairs in the Department of Law and Public  
28 Safety.

29 "Medication-related error" means a preventable event related to a  
30 prescription drug, which adversely affects a person who uses that  
31 prescription drug and is potentially attributable, in whole or in part,  
32 to the procedures, actions or personnel of a pharmacy or to other  
33 persons, health care providers, or entities, including, but not limited  
34 to, the ordering, labeling; packaging, nomenclature; compounding;  
35 dispensing; furnishing; administration; monitoring, or use of, or the  
36 provision of information to a person about, that prescription drug.

37 "Pharmacy" means a pharmacy practice site as defined in section  
38 2 of P.L.2003, c.280 (C.45:14-41).

39 "Prescription" means a prescription as defined in section 2 of  
40 P.L.2003, c.280 (C.45:14-41).

41 "Task force" means the New Jersey Task Force on Medication  
42 Error Prevention as established pursuant to section 4 of P.L. , c.  
43 (C. ) (now pending before the Legislature as this bill).

44

45 4. There is established the "New Jersey Task Force on  
46 Medication Error Prevention."

47 a. The task force shall consist of 23 members as follows:

48 (1) the Director of the Division of Consumer Affairs, one

1 representative of the Board of Pharmacy, one representative of the  
2 Board of Medical Examiners, one representative of the Board of  
3 Nursing, one representative of the Board of Dentistry, and the Dean  
4 of the Ernest Mario School of Pharmacy at Rutgers or their  
5 designees, who shall serve ex officio; and

6 (2) 17 public members, who shall include:

7 (a) two persons appointed upon the recommendation of an  
8 organization representing pharmacists;

9 (b) two persons appointed upon the recommendation of an  
10 organization representing independent pharmacies;

11 (c) two persons appointed upon the recommendation of an  
12 organization representing chain drug stores;

13 (d) two persons representing pharmaceutical manufacturers;

14 (e) one person appointed upon the recommendation of an  
15 organization that represents physicians;

16 (f) one person appointed upon the recommendation of an  
17 organization that represents dentists;

18 (g) one person appointed upon the recommendation of an  
19 organization that represents nurses;

20 (h) one person appointed upon the recommendation of an  
21 organization that represents hospitals;

22 (i) one person that represents managed care carriers;

23 (j) two persons who represent the interests of health care  
24 consumers, and

25 (k) two pharmacists representing mail service pharmacy.

26 Of the 17 public members, five shall be appointed by the  
27 Governor; six shall be appointed by the President of the Senate; and  
28 six shall be appointed by the Speaker of the General Assembly.  
29 The Governor, the President of the Senate, and the Speaker of the  
30 General Assembly shall consult with each other on the appointment  
31 of the public members.

32 b. Vacancies in the membership of the task force shall be filled  
33 in the same manner provided for the original appointments. The  
34 public members of the task force shall serve without compensation  
35 but may be reimbursed for traveling and other miscellaneous  
36 expenses necessary to perform their duties, within the limits of  
37 funds made available to the task force for its purposes.

38 c. (1) The task force shall organize as soon as practicable, but  
39 no later than the 30th day after the appointment of its members, and  
40 shall select a chairperson and vice-chairperson from among the  
41 members. The chairperson shall appoint a secretary who need not  
42 be a member of the task force.

43 (2) The task force may meet at the call of the chairperson and  
44 hold hearings at the times and in the places it may deem appropriate  
45 and necessary to fulfill its charge. The task force shall be entitled  
46 to call to its assistance, and avail itself of the services of, the  
47 employees of any State, county or municipal department, board,  
48 bureau, commission or agency as it may require and as may be

1 available to it for its purposes.

2 (3) The Division of Consumer Affairs shall provide staff  
3 services to the task force.

4 d. The purpose of the task force shall be to provide guidelines  
5 for the New Jersey State Board of Pharmacy to utilize in  
6 implementing medication error prevention, pharmacy quality  
7 improvement, and consumer education programs on this topic. The  
8 guidelines provided by the task force shall address topics including,  
9 but not limited to:

10 (1) the type of situations a registered pharmacist should be  
11 required to report to the board information based upon which the  
12 pharmacist concludes that a medication-related error may have  
13 occurred. In examining this issue, the task force shall consider  
14 what constitutes serious or significant harm and the types of  
15 medication-related errors which may cause or contribute to such  
16 harm;

17 (2) information which should be required to be included in a  
18 report filed by a registered pharmacist indicating that a medication-  
19 related error may have occurred;

20 (3) appropriate time frames in which a registered pharmacist  
21 should be required to file a required report indicating that a  
22 medication-related error may have occurred;

23 (4) circumstances which should result in pharmacy personnel  
24 being required to satisfactorily complete education courses aimed at  
25 reducing medication-related error. In developing this standard, the  
26 task force shall consider the merits of requiring personnel whose  
27 actions, inactions, or procedures seem to be associated with or  
28 contribute to repeated instances of serious medication-related errors  
29 to satisfactorily complete such courses; and

30 (5) elements which should be included in required education  
31 courses for pharmacy personnel, and an acceptable time frame in  
32 which they should be completed.

33 e. The task force shall present a report of its findings and  
34 recommendations to the Governor and the Legislature no later than  
35 12 months after the date of its initial meeting, and shall be  
36 authorized to periodically issue a summary of its deliberations prior  
37 to the presentation of its report.

38

39 5. A pharmacy doing business in this State shall establish a  
40 continuous quality improvement program no later than 6 months  
41 after the date of the rules and regulations required pursuant to  
42 section 10 of P.L. , c. (C. ) (now pending before the  
43 Legislature as this bill) are adopted by the New Jersey Board of  
44 Pharmacy.

45 a. The program shall be designed to document, review and  
46 assess medication-related errors in order that the pharmacy may  
47 take appropriate action if reasonably necessary to prevent their  
48 recurrence.

1       b. The program shall also include measures that are designed to  
2 minimize the incidence of medication-related errors if reasonably  
3 necessary, including, but not limited to, compliance with the  
4 following requirements:

5       (1) pharmacy personnel shall verify the accuracy of each  
6 prescription before it is dispensed;

7       (2) the pharmacy shall adopt procedures for the receipt of  
8 electronically transmitted prescriptions as permitted pursuant to  
9 pharmacy laws and regulations; and

10       (3) the pharmacy shall prominently display, for easily accessible  
11 reference by pharmacy personnel, the information provided by the  
12 board pursuant to section 6 of P.L.     , c.     (C.     ) (now pending  
13 before the Legislature as this bill).

14       c. Records, meetings, determinations, and findings that are  
15 generated for, and maintained as a component of, a pharmacy's  
16 quality improvement program concerning medication-related errors,  
17 pursuant to subsection a. of this section, shall be considered  
18 privileged and confidential peer review documents and matters, and  
19 shall not be subject to discovery, use, subpoena, or admissible as  
20 evidence in any administrative, disciplinary, arbitration, civil or  
21 other proceeding; except that the provisions of this subsection shall  
22 not be construed to:

23       (1) prevent review of a pharmacy's quality improvement  
24 program policies and procedures and any records maintained by the  
25 pharmacy in connection with the program by the government  
26 agency with jurisdiction over the pharmacy as necessary to  
27 determine compliance with this section; except that any such review  
28 shall not be considered a waiver of any privileges or protections  
29 provided under these provisions;

30       (2) prohibit a patient from accessing his own prescription drug  
31 records; or

32       (3) affect the discoverability of any records that are not solely  
33 generated for, and maintained as a component of, a pharmacy's  
34 quality improvement program concerning medication-related errors,  
35 pursuant to subsection a. of this section.  
36

37       6. The board shall provide for the periodic distribution, to all  
38 licensed pharmacies in the State, of written information about  
39 prescription drugs that have been identified by the board, the  
40 federal Food and Drug Administration, or any other public or  
41 private entity as determined appropriate by the board, as having  
42 names that look or sound alike to the extent that they are difficult to  
43 differentiate without careful examination. This information shall be  
44 identified by the board as an "ALERT TO PHARMACIES" and  
45 formatted in a manner that clearly displays the relevant pairs of  
46 prescription drugs, such that pharmacy personnel may display this  
47 information for easily accessible reference in the pharmacy.

1       7. a. The board shall prepare an informational brochure that is  
2 designed to educate and inform consumers about their role in  
3 medication safety and error prevention. The brochure shall, at a  
4 minimum, explain:

- 5       (1) the patient's role in preventing medication-related errors;  
6       (2) actions that a patient may take to prevent a medication-  
7 related error;  
8       (3) what a patient can do if the patient suspects a medication-  
9 related error; and  
10       (4) the procedure by which a patient may report a medication-  
11 related error to the board and what actions the board will take in  
12 response to such a report.

13       b. The board shall post the brochure on its Internet web site and  
14 make a supply of the brochures available to all pharmacies  
15 registered with the board for distribution to the public.

16  
17       8. The board shall conduct a study of the feasibility of requiring  
18 by a certain date, as determined by the board, that every  
19 prescription written in this State be transmitted to a pharmacy by  
20 facsimile, telephone or electronically or in typewritten form, and  
21 shall determine the most effective means of implementing such a  
22 requirement. The board shall report its findings and  
23 recommendations to the Governor and Legislature no later than one  
24 year after the effective date of this act.

25  
26       9. a. A registered pharmacist shall file a report with the board  
27 whenever required to do so pursuant to the rules and regulations  
28 adopted by the New Jersey Board of Pharmacy pursuant to section  
29 10 of P.L.     , c.     (C.     ) (now pending before the Legislature as  
30 this bill).

31       b. A registered pharmacist who, without good cause as  
32 determined by the board, fails to report information to the board, as  
33 required pursuant to subsection a. of this section, is subject to  
34 P.L.1978, c.73 (C.45:1-14 et seq.).

35       c. A registered pharmacist who reports information to the board  
36 relating to a medication-related error, as required pursuant to  
37 subsection a. of this section, shall be immune from liability in a  
38 civil action for any injury or damages in connection with that  
39 medication-related error.

40  
41       10. The Board of Pharmacy shall adopt, pursuant to the  
42 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et  
43 seq.), rules and regulations necessary to implement this act. These  
44 rules and regulations shall be adopted no later than the first day of  
45 the seventh month following the presentation of the report by the  
46 task force established pursuant to section 4 of P.L.     , c.     (C.     )  
47 (now pending before the Legislature as this bill), and shall be based  
48 on the guidelines developed and provided by that task force. The

- 1 rules and regulations shall include, but not be limited to:
- 2 a. an outline of when a registered pharmacist shall file a report
- 3 with the board regarding medication-related errors;
- 4 b. guidelines for pharmacies' quality improvement programs;
- 5 and
- 6 c. requirements for certain pharmacy personnel to satisfactorily
- 7 complete education courses aimed at reducing medication-related
- 8 error.

9

10 11. This act shall take effect immediately, except that sections 6

11 and 7 of this act shall take effect on the first day of the seventh

12 month following enactment and section 9 of this act shall take

13 effect on the first day of the fourth month following the adoption by

14 the Board of Pharmacy of the rules and regulations required

15 pursuant to section 10 of P.L. , c. (C. ) (now pending before

16 the Legislature as this bill), but the Board of Pharmacy may take

17 such anticipatory administrative action in advance as shall be

18 necessary for the timely implementation of this act.

19

20

21 STATEMENT

22

23 This bill would enact the "Pharmacy Quality Improvement and

24 Error Prevention Act."

25 The bill establishes a 23-member "Medication Error Prevention

26 Task Force" to provide guidelines for the New Jersey State Board of

27 Pharmacy to utilize in implementing medication error prevention,

28 pharmacy quality improvement, and consumer education programs

29 on this topic. The guidelines provided by the task force are

30 required to address topics including, but not limited to:

- 31 • the type of situations in which a pharmacist should be required
- 32 to report that a medication-related error may have occurred. In
- 33 examining this issue, the task force is required to consider what
- 34 constitutes serious or significant harm and the types of
- 35 medication-related errors which may cause or contribute to such
- 36 harm;
- 37 • information which should be included in such a report;
- 38 • appropriate time frames in which such a report should be filed;
- 39 • circumstances which should result in pharmacy personnel
- 40 having to satisfactorily complete education courses aimed at
- 41 reducing medication-related error; and
- 42 • elements to be included in required education courses, and
- 43 acceptable timeframes in which they should be completed.

44 The bill requires pharmacies doing business in this State to

45 establish a continuous quality improvement program within 6

46 months of the adoption of relevant rules and regulations by the New

47 Jersey Board of Pharmacy. The programs shall be designed to

48 document, review and assess medication-related errors in order that

1 the pharmacy may take appropriate action if reasonably necessary  
2 to prevent their recurrence. The bill outlines certain aspects which  
3 the programs must incorporate, and specifies that the programs must  
4 include measures designed to minimize the incidence of  
5 medication-related errors if reasonably necessary.

6 Under the bill, program records, meetings, determinations, and  
7 findings are considered privileged and confidential peer review  
8 documents and matters, and are not subject to discovery, use, or  
9 subpoena, or admissible as evidence in any administrative,  
10 disciplinary, arbitration, civil or other proceeding, except for  
11 internal review purposes.

12 The bill requires the board to periodically provide an "ALERT  
13 TO PHARMACIES" about prescription drugs that have been  
14 identified as having names that look or sound alike to the extent that  
15 they are difficult to differentiate without careful examination, to be  
16 displayed in all pharmacies. The board is also required by the bill  
17 to prepare an informational brochure that is designed to educate and  
18 inform consumers about their role in medication safety and error  
19 prevention. The bill also requires the board to study the feasibility  
20 of requiring all prescriptions to be transmitted by facsimile,  
21 telephone, electronically, or in typewritten form.

22 Finally, the bill requires registered pharmacists to report possible  
23 errors to the board, in compliance with its regulations. The bill  
24 authorizes the board to use its existing statutory enforcement  
25 powers for failure to comply with the act. In addition, the bill  
26 provides that a pharmacist who files a report as required shall be  
27 immune from civil liability for injury or damages in connection  
28 with the medication related error.