

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2005

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HOUSE BILL 1493  
Committee Substitute Favorable 5/31/05  
Senate Health Care Committee Substitute Adopted 8/10/05  
Fourth Edition Engrossed 8/11/05

Short Title: Pharmacy Quality Assurance Protection Act.

(Public)

Sponsors:

Referred to:

April 21, 2005

A BILL TO BE ENTITLED

AN ACT ESTABLISHING THE PHARMACY QUALITY ASSURANCE  
PROTECTION ACT TO FACILITATE THE CONTINUOUS REVIEW OF THE  
PRACTICE OF PHARMACY.

The General Assembly of North Carolina enacts:

**SECTION 1.** G.S. 90-85.21(a) reads as rewritten:

"(a) In accordance with Board regulations, each pharmacy in North Carolina shall annually register with the Board on a form provided by the Board. The application shall identify the pharmacist-manager of the pharmacy and all pharmacy personnel employed in the pharmacy. All pharmacist-managers shall notify the Board of any change in pharmacy personnel within 30 days of the change. In addition to identifying the pharmacist-manager, a pharmacy may identify a pharmacy permittee's designated agent that the Board shall notify of any investigation of the pharmacy or a pharmacist employed by the pharmacy within 48 hours of the Board initiating an investigation. The notice shall include the specific reason for the investigation."

**SECTION 2.** G.S. 90-85.26 reads as rewritten:

**"§ 90-85.26. Prescription orders preserved.**

(a) Every pharmacist-manager of a pharmacy shall maintain for at least three years the original of every prescription order and refill compounded or dispensed at the pharmacy except for prescription orders recorded in a patient's medical record. An automated data processing system may be used for the storage and retrieval of refill information for prescriptions pursuant to the regulations of the Board.

(b) Every pharmacy permittee's designated agent shall maintain documentation of alleged medication errors and incidents described in G.S. 90-85.47(e)(1) for which the pharmacy permittee has knowledge."

**SECTION 3.** Chapter 90 of the General Statutes is amended by adding the following new Article to read:

1 "Article 4B.

2 "Pharmacy Quality Assurance Protection Act.

3 "**§ 90-85.45. Legislative intent.**

4 It is the intent of the General Assembly to require pharmacy quality assurance  
5 programs to further contribute to and enhance the quality of health care and reduce  
6 medication errors in this State by facilitating a process for the continuous review of the  
7 practice of pharmacy.

8 "**§ 90-85.46. Definitions.**

9 The following definitions shall apply in this Article:

10 (1) Board. – The North Carolina Board of Pharmacy.

11 (2) Pharmacy quality assurance program. – A program pertaining to one of  
12 the following:

13 a. A pharmacy association created under G.S. 90-85.4 or  
14 incorporated under Chapter 55A of the General Statutes that  
15 evaluates the quality of pharmacy services and alleged  
16 medication errors and incidents and makes recommendations to  
17 improve the quality of pharmacy services.

18 b. A program established by a person or entity holding a valid  
19 pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21(a)  
20 to evaluate the quality of pharmacy services and alleged  
21 medication errors and incidents and make recommendations to  
22 improve the quality of pharmacy services.

23 c. A quality assurance committee or medical or peer review  
24 committee established by a health care provider licensed under  
25 this Chapter or a health care facility licensed under Chapter  
26 122C, 131D, or 131E of the General Statutes that includes  
27 evaluation of the quality of pharmacy services and alleged  
28 medication errors and incidents and makes recommendations to  
29 improve the quality of pharmacy services.

30 "**§ 90-85.47. Pharmacy quality assurance program required; limited liability;**  
31 **discovery.**

32 (a) Every person or entity holding a valid pharmacy permit pursuant to  
33 G.S. 90-85.21 or G.S. 90-85.21(a), shall establish or participate in a pharmacy quality  
34 assurance program as defined under G.S. 90-85.46(2), to evaluate the following:

35 (1) The quality of the practice of pharmacy.

36 (2) The cause of alleged medication errors and incidents.

37 (3) Pharmaceutical care outcomes.

38 (4) Possible improvements for the practice of pharmacy.

39 (5) Methods to reduce alleged medication errors and incidents.

40 (b) There shall be no monetary liability on the part of, or no cause of action for  
41 damages arising against, any member of a duly appointed pharmacy quality assurance  
42 program or any pharmacy or pharmacist furnishing information to a pharmacy quality  
43 assurance program or any person, including a person acting as a witness or incident  
44 reporter to or investigator for a pharmacy quality assurance program, for any act or

1 proceeding undertaken or performed within the scope of the functions of the pharmacy  
2 quality assurance program.

3 (c) This section shall not be construed to confer immunity from liability on any  
4 professional association, pharmacy or pharmacist, or health care provider while  
5 performing services other than as a member of a pharmacy quality assurance program or  
6 upon any person, including a person acting as a witness or incident reporter to or  
7 investigator for a pharmacy quality assurance program, for any act or proceeding  
8 undertaken or performed outside the scope of the functions of the pharmacy quality  
9 assurance program. Except as provided in subsection (a) or (b) of this section, where a  
10 cause of action would arise against a pharmacy, pharmacist, or an individual health care  
11 provider, the cause of action shall remain in effect.

12 (d) The proceedings of a pharmacy quality assurance program, the records and  
13 materials it produces, and the materials it considers shall be confidential and not  
14 considered public records within the meaning of G.S. 132-1 or G.S. 58-2-100 and shall  
15 not be subject to discovery or introduction into evidence in any civil action,  
16 administrative hearing or Board investigation against a pharmacy, pharmacist,  
17 pharmacy technician, a pharmacist manager or a permittee or a hospital licensed under  
18 Chapter 122C or Chapter 131E of the General Statutes or that is owned or operated by  
19 the State, which civil action, administrative hearing or Board Investigation results from  
20 matters that are the subject of evaluation and review by the pharmacy quality assurance  
21 program. No person who was in attendance at a meeting of the pharmacy quality  
22 assurance program shall be required to testify in any civil action, administrative hearing  
23 or Board investigation as to any evidence or other matters produced or presented during  
24 the proceedings of the pharmacy quality assurance program or as to any findings,  
25 recommendations, evaluations, opinions, or other actions of the pharmacy quality  
26 assurance program or its members. However, information, documents, or records  
27 otherwise available are not immune from discovery or use in a civil action merely  
28 because they were presented during proceedings of the pharmacy quality assurance  
29 program. Documents otherwise available as public records within the meaning of  
30 G.S. 132-1 do not lose their status as public records merely because they were presented  
31 or considered during proceedings of the pharmacy quality assurance program. A  
32 member of the pharmacy quality assurance program may testify in a civil or  
33 administrative action but cannot be asked about the person's testimony before the  
34 pharmacy quality assurance program or any opinions formed as a result of the pharmacy  
35 quality assurance program. Nothing in this subsection shall preclude:

36 (1) A pharmacy, pharmacist, pharmacy technician, or other person or any  
37 agent or representative of a pharmacy, pharmacist, pharmacy  
38 technician or other person participating on a pharmacy quality  
39 assurance program may use otherwise privileged, confidential  
40 information for legitimate internal business or professional purposes of  
41 the pharmacy quality assurance program.

42 (2) A pharmacy, pharmacist, pharmacy technician, other person  
43 participating on the committee, or any person or organization named as  
44 a defendant in a civil action, a respondent in an administrative

1 proceeding, or a pharmacy, pharmacist, or pharmacy technician subject  
2 to a Board investigation as a result of participation in the pharmacy  
3 quality assurance program may use otherwise privileged, confidential  
4 information in the pharmacy quality assurance program or person's  
5 own defense. A plaintiff in the civil action or the agency in the  
6 administrative proceeding may disclose records or determinations of or  
7 communications to the pharmacy quality assurance program in rebuttal  
8 to information given by the defendant, respondent, or pharmacist  
9 subject to Board investigation.

10 (e) Upon the Board providing written notice to the pharmacy permittee's  
11 designated agent under G.S. 90-85.21(a) and pharmacist of an investigation against the  
12 pharmacist, including the specific reason for the Board investigation, the pharmacy  
13 permittee's designated agent shall compile and provide documentation within 10 days of  
14 the receipt of the notice of any alleged medication error or incident committed by the  
15 pharmacist in the 12 months preceding the receipt of the notice, that the pharmacy  
16 permittee has knowledge of, when:

17 (1) The alleged medication error or incident resulted in any of the  
18 following:

19 a. An emergency room visit attributed to the alleged medication  
20 incident or error.

21 b. Hospitalization requiring an overnight stay or longer.

22 c. A fatality.

23 (2) The pharmacist is the subject of disciplinary action conducted under  
24 Article 3A of Chapter 150B of the General Statutes. Unless the  
25 documentation relates to an alleged medication error or incident that  
26 was specifically the cause of the investigation, the Board may review  
27 the documentation only after the Board has made findings of fact and  
28 conclusions of law pursuant to G.S. 150B-42(a) and may use the  
29 documentation in determining the remedial action the pharmacist shall  
30 undergo as part of the disciplinary action imposed by the Board. The  
31 documentation shall be released only to the Board or its designated  
32 employees pursuant to this subsection and shall not otherwise be  
33 released except as required by law.

34 Any information provided to the Board pursuant to this subsection shall be returned  
35 to the pharmacy permittee's designated agent within 10 days after the Board has made  
36 findings of fact and conclusions of law pursuant to G.S. 150B-42(a).

37 The documentation provided to the Board shall not include the proceedings and  
38 records of a pharmacy quality assurance program or information prepared by the  
39 pharmacy solely for consideration by or upon request of a pharmacy quality assurance  
40 program.

41 (f) Nothing in this section shall preclude the Board from obtaining information  
42 concerning a specific alleged medication error or incident that is the subject of a Board  
43 investigation resulting from a complaint to the Board."

1           **SECTION 4.** This act becomes effective January 1, 2006. Section 3 of this  
2 act shall supersede all administrative rules regulating the maintenance of alleged  
3 medication error or incident records in effect as of January 1, 2006.