GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 2005

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HOUSE BILL 1493
Committee Substitute Favorable 5/31/05

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. The notice shall include the specific reason for the investigation."

SECTION 2. Chapter 90 of the General Statutes is amended by adding the following new Article to read:

"Article 4B.

"Pharmacy Quality Assurance Protection Act.

"**§ 90-85.45. Legislative intent.**

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

"**§ 90-85.46. Definitions.**

The following definitions shall apply in this Article:

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

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

a. A pharmacy association created under G.S. 90-85.4 and incorporated under Chapter 55A of the General Statutes that evaluates the quality of pharmacy services and medication errors and makes recommendations to improve the quality of pharmacy services.

b. A program established by a person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A to evaluate the quality of pharmacy services and medication errors and make recommendations to improve the quality of pharmacy services.

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

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

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

(1) The quality of the practice of pharmacy.

(2) The cause of medication errors.

(3) Pharmaceutical care outcomes.

(4) Possible improvements for the practice of pharmacy.

(5) Methods to reduce medication error occurrences.

(b) There shall be no monetary liability on the part of, or no cause of action for damages arising against, any member of a duly appointed pharmacy quality assurance program or any pharmacy or pharmacist furnishing information to a pharmacy quality assurance program or any person, including a person acting as a witness or incident reporter to or investigator for a pharmacy quality assurance program, for any act or proceeding undertaken or performed within the scope of the functions of the pharmacy quality assurance program.

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

(d) Except as provided in this subsection, the proceedings and records of a pharmacy quality assurance program shall not be subject to discovery or be introduced into evidence in any civil action, administrative proceeding, or investigation arising out of matters that are the subject of evaluation and review by the pharmacy quality assurance program; nor shall any person in attendance at a meeting of a pharmacy quality assurance program be permitted or required to testify in any civil action, administrative hearing or Board investigation as to any evidence or other matters produced or presented during the proceedings of the pharmacy quality assurance program regarding any findings, recommendations, evaluations, opinions, or other actions of a pharmacy quality assurance program or any members of the program. However, the information, documents, or records otherwise available from original sources shall not be construed as prohibited from discovery for use in any civil action merely because they were presented during proceedings of a pharmacy quality assurance program; nor shall any person testifying before a pharmacy quality assurance program or member of a pharmacy quality assurance program be prevented from testifying as to matters within the person's or member's knowledge; provided that, the witness shall not be asked about his or her testimony before a pharmacy quality assurance program or opinions formed by the witness as a result of the pharmacy quality assurance program. Confidential information may be used under the following circumstances:

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

(2) A pharmacy, pharmacist, other person participating on the committee, or any person or organization named as a defendant in a civil action, a respondent in an administrative proceeding, or a pharmacist subject to a Board investigation as a result of participation in the pharmacy quality assurance program may use otherwise privileged, confidential information in the pharmacy quality assurance program or person's own defense. A plaintiff in the civil action or the agency in the administrative proceeding may disclose records or determinations of or communications to the pharmacy quality assurance program in rebuttal to information given by the defendant, respondent, or pharmacist subject to Board investigation.

(e) Upon the Board providing written notice to the pharmacy permittee's designated agent under G.S. 90-21(a) and pharmacist of an investigation against the pharmacist, including the specific reason for the Board investigation, the pharmacy permittee's designated agent shall compile and provide documentation within 10 days of the receipt of the notice of any alleged medication incident or error committed by the pharmacist in the 12 months preceding the receipt of the notice, that the pharmacy permittee has knowledge of, when:

(1) The alleged medication error or incident resulted in: (i) an emergency room visit attributed to the alleged medication incident or error; (ii) hospitalization requiring an overnight stay or longer; or (iii) fatality.

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

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

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

SECTION 2. This act is effective when it becomes law.