GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 2005

H **3**

HOUSE BILL 1493

Committee Substitute Favorable 5/31/05

Senate Health Care Committee Substitute Adopted 8/10/05

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:

"Article 4B.

"Pharmacy Quality Assurance Protection Act.

"**§ 90-85.45. Legislative intent.**

It is the intent of the General Assembly to require 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 or incorporated under Chapter 55A of the General Statutes that evaluates the quality of pharmacy services and alleged medication errors and incidents 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. 90-85.21(a) to evaluate the quality of pharmacy services and alleged medication errors and incidents 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 Chapter 122C, 131D, or 131E of the General Statutes that includes evaluation of the quality of pharmacy services and alleged medication errors and incidents 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. 90-85.21(a), 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 alleged medication errors and incidents.

(3) Pharmaceutical care outcomes.

(4) Possible improvements for the practice of pharmacy.

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

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

(1) A pharmacy, pharmacist, pharmacy technician, or other person or any agent or representative of a pharmacy, pharmacist, pharmacy technician 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, pharmacy technician, 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 pharmacy, pharmacist, or pharmacy technician 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. 90-85.21(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 error or incident 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 any of the following:

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

b. Hospitalization requiring an overnight stay or longer.

c. A 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 error or incident 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.

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

SECTION 4. This act becomes effective January 1, 2006.

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