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SESSION 2013

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HOUSE BILL 675
Committee Substitute Favorable 5/9/13
Third Edition Engrossed 5/13/13

Short Title: Amend Pharmacy Laws.

(Public)

Sponsors:

Referred to:

April 10, 2013

1 A BILL TO BE ENTITLED
2 AN ACT AMENDING LAWS PERTAINING TO THE REGULATION OF PHARMACY
3 TECHNICIANS, PHARMACY AUDITS, AND PRESCRIPTIONS FOR SCHEDULE II
4 SUBSTANCES.

5 The General Assembly of North Carolina enacts:

6 **SECTION 1.** G.S. 90-85.3 is amended by adding a new subsection to read:

7 "(q3) "Certified pharmacy technician" means a pharmacy technician who (i) has passed a
8 nationally recognized pharmacy technician certification board examination, or its equivalent,
9 that has been approved by the Board and (ii) obtains and maintains certification from a
10 nationally recognized pharmacy technician certification board that has been approved by the
11 Board."

12 **SECTION 2.** G.S. 90-85.15A reads as rewritten:

13 "(a) ~~Registration.~~ Registration, Generally. – A registration program for pharmacy
14 technicians is established for the purposes of identifying those persons who are employed or are
15 eligible for employment as pharmacy technicians. The Board must maintain a registry of
16 pharmacy technicians that contains the name of each pharmacy technician, the name and
17 location of ~~the a~~ pharmacy in which the pharmacy technician works, the pharmacist-manager
18 who employs the pharmacy technician, and the dates of that employment.

19 (a1) Registration of Noncertified Pharmacy Technicians. – The Board must register a
20 pharmacy technician who pays the fee required under ~~G.S. 90-85.24~~ G.S. 90-85.24, is employed
21 by a pharmacy holding a valid permit under this Article, and completes a required training
22 ~~program~~ program provided by the supervising pharmacist-manager as specified in subsection
23 (b) of this section. A pharmacy technician must register with the Board within 30 days after the
24 date the pharmacy technician completes a training program ~~conducted~~ provided by the
25 ~~pharmacy technician's~~ supervising pharmacist-manager. The registration must be renewed
26 annually by paying a registration fee.

27 (a2) Registration of Certified Pharmacy Technicians. – The Board must register a
28 certified pharmacy technician who pays the fee required under G.S. 90-85.24 and provides
29 proof of current certification. The registration must be renewed annually by paying a
30 registration fee and providing proof of current certification.

31 (b) Responsibilities of ~~Pharmacist-Manager.~~ Pharmacist-Manager to Noncertified
32 Pharmacy Technicians. – A pharmacist-manager may hire a person who has a high school
33 diploma or equivalent or is currently enrolled in a program that awards a high school diploma
34 or equivalent to work as a pharmacy technician. Pursuant to G.S. 90-85.21, a
35 pharmacist-manager must notify the Board within ~~30~~ 21 days of the date the pharmacy



1 technician began employment. The pharmacist-manager must provide a training program for a
2 pharmacy technician that includes pharmacy terminology, pharmacy calculations, dispensing
3 systems and labeling requirements, pharmacy laws and regulations, record keeping and
4 documentation, and the proper handling and storage of medications. The requirements of a
5 training program may differ depending upon the type of employment. The training program
6 must be provided and completed within 180 days of the date the pharmacy technician began
7 ~~employment unless the pharmacy technician is registered with the Board. If the pharmacy~~
8 ~~technician is registered with the Board, then the completion of the training program is optional~~
9 ~~at the discretion of the pharmacist-manager employment.~~

10 (b1) Responsibilities of Pharmacist-Manager to Certified Pharmacy Technicians. – A
11 pharmacist-manager may hire a certified pharmacy technician who has registered with the
12 Board pursuant to subsection (a2) of this section. Pursuant to G.S. 90-85.21, a certified
13 pharmacy technician shall notify the Board within 10 days of beginning employment as a
14 pharmacy technician. The supervising pharmacist-manager and certified pharmacy technician
15 shall be deemed to have satisfied the pharmacy technician training program requirements of
16 subsection (b) of this section.

17 (c) Supervision. – A pharmacist may not supervise more than two pharmacy technicians
18 unless the pharmacist-manager receives written approval from the Board. The Board may not
19 allow a pharmacist to supervise more than two pharmacy technicians unless the additional
20 pharmacy technicians ~~have passed a nationally recognized pharmacy technician certification~~
21 ~~board exam, or its equivalent, that has been approved by the Board~~are certified pharmacy
22 technicians. The Board must respond to a request from a pharmacist-manager to allow a
23 pharmacist to supervise more than two pharmacy technicians within 60 days of the date it
24 received the request. The Board must respond to the request in one of three ways:

- 25 (1) Approval of the request.
- 26 (2) Approval of the request as amended by the Board.
- 27 (3) Disapproval of the request. A disapproval of a request must include a
28 reasonable explanation of why the request was not approved.

29 (d) Disciplinary Action. – The Board may, in accordance with Chapter 150B of the
30 General Statutes and rules adopted by the Board, issue a letter of reprimand or suspend, restrict,
31 revoke, or refuse to grant or renew the registration of a pharmacy technician if the pharmacy
32 technician has done one or more of the following:

- 33 (1) Made false representations or withheld material information in connection
34 with registering as a pharmacy technician.
- 35 (2) Been found guilty of or plead guilty or nolo contendere to a felony involving
36 the use or distribution of drugs.
- 37 (3) Indulged in the use of drugs to an extent that it renders the pharmacy
38 technician unfit to assist a pharmacist in preparing and dispensing
39 prescription medications.
- 40 (4) Developed a physical or mental disability that renders the pharmacy
41 technician unfit to assist a pharmacist in preparing and dispensing
42 prescription medications.
- 43 (4a) Been negligent in assisting a pharmacist in preparing and dispensing
44 prescription medications.
- 45 ~~Willfully violated~~Failed to comply with the laws governing pharmacy
46 technicians, including any provision of this Article- Article or rules adopted
47 by the Board governing pharmacy technicians.

48 (e) Exemption. – This section does not apply to pharmacy students who are enrolled in
49 a school of pharmacy approved by the Board under G.S. 90-85.13.

50 (f) Rule-Making Authority. – The Board may adopt rules necessary to implement this
51 section."

1 **SECTION 3.** G.S. 90-85.50(b) is amended by adding new subdivisions to read:

2 "(21) Not to be subject to recoupment on any portion of the reimbursement of
3 dispensed product of the prescription, except in cases of fraud or other
4 intentional and willful misrepresentation evidenced by a review of the claims
5 data, statements, physical review, or other investigative methods.

6 (22) Recoupment of claims shall be based on the actual financial harm to the
7 entity or on the actual overpayment or underpayment. A finding of an
8 overpayment that is the result of dispensing in excess of the benefit design,
9 as established by the plan sponsor, shall be calculated as the difference
10 between what was dispensed in accordance with the prescriber's orders and
11 the dispensing requirements as set forth by the benefit design. Calculations
12 of overpayments shall not include dispensing fees unless one of the
13 following conditions is present:

14 a. A prescription was not actually dispensed.

15 b. The prescriber denied authorization.

16 c. The prescription dispensed was a medication error by the pharmacy.
17 For purposes of this subdivision, a medication error is a dispensing of
18 the wrong drug or dispensing to the wrong patient or dispensing with
19 the wrong directions.

20 d. The identified overpayment is based solely on an extra dispensing
21 fee.

22 e. The pharmacy was noncompliant with Risk Evaluation and
23 Mitigation Strategies (REMS) program guidelines.

24 f. There was insufficient documentation, including electronically stored
25 information, as described in this subsection.

26 (23) To have an audit based only on information obtained by the entity
27 conducting the audit and not based on any audit report or other information
28 gained from an audit conducted by a different auditing entity. This
29 subdivision does not prohibit an auditing entity from using an earlier audit
30 report prepared by that auditing entity for the same pharmacy. Except as
31 required by State or federal law, an entity conducting an audit may have
32 access to a pharmacy's previous audit report only if the previous report was
33 prepared by that entity.

34 (24) To be informed of the identity of the responsible party on whose behalf the
35 audit is being conducted without having to request this information. If the
36 audit is conducted by a vendor or subcontractor, that entity is required to
37 identify the responsible party on whose behalf the audit is being conducted
38 without having this information being requested.

39 (25) To use any prescription that complies with State laws and regulations to
40 validate a claim in connection with a prescription, prescription refill, or a
41 change in a prescription."

42 **SECTION 4.** G.S. 90-85.52 reads as rewritten:

43 "**§ 90-85.52. Pharmacy audit recoupments.**

44 (a) ~~Recoupments of any disputed funds shall occur only after~~ The entity conducting an
45 audit shall not recoup any disputed funds, charges, or other penalties from a pharmacy until (i)
46 the deadline for initiating the appeals process established pursuant to G.S. 90-85.51 has elapsed
47 or (ii) after the final internal disposition of an audit, including the appeals process as set forth in
48 G.S. 90-85.51, whichever is later, unless fraud or misrepresentation is reasonably suspected.

49 (b) Recoupment on an audit shall be refunded to the responsible party as contractually
50 agreed upon by the parties.

1 (c) The entity conducting the audit may charge or assess the responsible party, directly
2 or indirectly, based on amounts recouped if both of the following conditions are met:

3 (1) The responsible party and the entity conducting the audit have entered into a
4 contract that explicitly states the percentage charge or assessment to the
5 responsible party.

6 (2) A commission or other payment to an agent or employee of the entity
7 conducting the audit is not based, directly or indirectly, on amounts
8 recouped."

9 **SECTION 5.** G.S. 90-106(a) reads as rewritten:

10 "(a) Except when dispensed directly by a practitioner, other than a pharmacist, to an
11 ultimate user, no controlled substance included in Schedule II of this Article may be dispensed
12 without the written prescription of a practitioner. No Schedule II substance shall be dispensed
13 pursuant to a written prescription more than six months after the date it was prescribed."

14 **SECTION 6.** This act becomes effective October 1, 2013. Sections 2 and 5 apply
15 to acts occurring, and Sections 3 and 4 apply to audits commencing, on or after that date.