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HOUSE BILL 675
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PROPOSED SENATE COMMITTEE SUBSTITUTE H675-PCS70499-RF-32

Short Title: Amend Pharmacy Laws.

(Public)

Sponsors:

Referred to:

April 10, 2013

A BILL TO BE ENTITLED

AN ACT AMENDING LAWS PERTAINING TO THE REGULATION OF PHARMACY
TECHNICIANS, PHARMACY AUDITS, AND PRESCRIPTIONS FOR SCHEDULE II
SUBSTANCES.

The General Assembly of North Carolina enacts:

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

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

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

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

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

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

(b) Responsibilities of ~~Pharmacist-Manager.~~ Pharmacist-Manager to Noncertified Pharmacy Technicians. – A pharmacist-manager may hire a person who has a high school diploma or equivalent or is currently enrolled in a program that awards a high school diploma or equivalent to work as a pharmacy technician. Pursuant to G.S. 90-85.21, a



1 pharmacist-manager must notify the Board within ~~30~~21 days of the date the pharmacy
2 technician began employment. The pharmacist-manager must provide a training program for a
3 pharmacy technician that includes pharmacy terminology, pharmacy calculations, dispensing
4 systems and labeling requirements, pharmacy laws and regulations, record keeping and
5 documentation, and the proper handling and storage of medications. The requirements of a
6 training program may differ depending upon the type of employment. The training program
7 must be provided and completed within 180 days of the date the pharmacy technician began
8 employment ~~unless the pharmacy technician is registered with the Board. If the pharmacy~~
9 ~~technician is registered with the Board, then the completion of the training program is optional~~
10 ~~at the discretion of the pharmacist manager employment.~~

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

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

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

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

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

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

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

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

5 "(21) Not to be subject to recoupment on any portion of the reimbursement for the
6 dispensed product of a prescription, unless otherwise provided in this
7 subdivision.

8 a. Recoupment of reimbursement, or a portion of reimbursement, for
9 the dispensed product of a prescription may be had in the following
10 cases:

11 1. Fraud or other intentional and willful misrepresentation
12 evidenced by a review of the claims data, statements, physical
13 review, or other investigative methods.

14 2. Dispensing in excess of the benefit design, as established by
15 the plan sponsor.

16 3. Prescriptions not filled in accordance with the prescriber's
17 order.

18 4. Actual overpayment to the pharmacy.

19 b. Recoupment of claims in cases set out in sub-subdivision a. of this
20 subdivision shall be based on the actual financial harm to the entity
21 or the actual underpayment or overpayment. Calculations of
22 overpayments shall not include dispensing fees unless one of the
23 following conditions is present:

24 1. A prescription was not actually dispensed.

25 2. The prescriber denied authorization.

26 3. The prescription dispensed was a medication error by the
27 pharmacy. For purposes of this subdivision, a medication
28 error is a dispensing of the wrong drug or dispensing to the
29 wrong patient or dispensing with the wrong directions.

30 4. The identified overpayment is based solely on an extra
31 dispensing fee.

32 5. The pharmacy was noncompliant with Risk Evaluation and
33 Mitigation Strategies (REMS) program guidelines.

34 6. There was insufficient documentation, including
35 electronically stored information, as described in this
36 subsection.

37 7. Fraud or other intentional and willful misrepresentation by
38 the pharmacy.

39 (22) To have an audit based only on information obtained by the entity
40 conducting the audit and not based on any audit report or other information
41 gained from an audit conducted by a different auditing entity. This
42 subdivision does not prohibit an auditing entity from using an earlier audit
43 report prepared by that auditing entity for the same pharmacy. Except as
44 required by State or federal law, an entity conducting an audit may have
45 access to a pharmacy's previous audit report only if the previous report was
46 prepared by that entity.

47 (23) If the audit is conducted by a vendor or subcontractor, that entity is required
48 to identify the responsible party on whose behalf the audit is being
49 conducted without having this information being requested.

1 (24) To use any prescription that complies with federal or State laws and
2 regulations at the time of dispensing to validate a claim in connection with a
3 prescription, prescription refill, or a change in a prescription."

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

5 **"§ 90-85.52. Pharmacy audit recoupments.**

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

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

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

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

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

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

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

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