

1 21 NCAC 32B .1350 is amended, **with changes**, as published in 28:22 NCR pages 2725 - 2727 as follows:

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3 **21 NCAC 32B .1350 REINSTATEMENT OF PHYSICIAN LICENSE**

4 (a) **Reinstatement** "**Reinstatement**" is for a physician who has held a North Carolina License, but whose license
5 either has been inactive for more than one year, or whose license became inactive as a result of disciplinary action
6 (revocation or suspension) taken by the Board. It also applies to a physician who has surrendered a license prior to
7 charges being filed by the Board.

8 (b) All applicants for reinstatement shall:

- 9 (1) submit a completed **application, application which can be found on the Board's website in the**
10 **application section at <http://www.ncmedboard.org/licensing>**, attesting under oath or affirmation
11 that information on the application is true and complete, and authorizing the release to the Board
12 of all information pertaining to the application;
- 13 (2) submit documentation of a legal name change, if applicable;
- 14 (3) supply a certified copy of **the** applicant's birth certificate if the applicant was born in the United
15 States or a certified copy of a valid and unexpired US passport. If the applicant does not possess
16 proof of U.S. citizenship, the applicant **must shall** provide information about **the** applicant's
17 immigration and work status which the Board **will shall** use to verify **the** applicant's ability to
18 work lawfully in the United ~~States;~~ **States. Applicants who are not present in the US and who do**
19 **not plan to practice physically in the US shall submit a written statement to that effect.**
- 20 (4) **If a graduate of a medical school other than those approved by LCME, AOA, COCA or CACMS,**
21 **shall** furnish an original ECFMG certification status report of a currently valid certification of the
22 **ECFMG. ECFMG if the applicant is a graduate of a medical school other than those approved by**
23 **LCME, AOA, COCA, or CACMS.** The ECFMG certification status report requirement shall be
24 waived if:
- 25 (A) the applicant has passed the ECFMG examination and successfully completed an
26 approved Fifth Pathway program (original ECFMG score transcript from the ECFMG
27 required); or
- 28 (B) the applicant has been licensed in another state on the basis of a written examination
29 before the establishment of the ECFMG in 1958;
- 30 (5) submit the AMA Physician Profile; and, if **the** applicant is an osteopathic physician, also submit
31 the AOA Physician Profile;
- 32 (6) submit a NPDB/HIPDB report dated within 60 days of the application's submission;
- 33 (7) submit a FSMB Board Action Data Bank report;
- 34 (8) submit documentation of CME obtained in the last three years, upon request;
- 35 (9) submit two completed fingerprint cards supplied by the Board;
- 36 (10) submit a signed consent form allowing a search of local, state, and national files to disclose any
37 criminal record;

- 1 (11) provide two original references from persons with no family or material relationship to the
2 applicant. These references **must shall** be:
3 (A) from physicians who have observed the applicant's work in a clinical environment within
4 the past three years;
5 (B) on forms supplied by the Board;
6 (C) dated within six months of submission of the application; and
7 (D) bearing the original signature of the author;
- 8 (12) pay to the Board a non-refundable fee pursuant to G.S. 90-13.1(a), plus the cost of a criminal
9 background check; and
- 10 (13) upon request, supply any additional information the Board deems necessary to evaluate the
11 applicant's qualifications.

12 (c) In addition to the requirements of Paragraph (b) of this Rule, the applicant shall submit proof that the applicant
13 has:

- 14 (1) within the past 10 years taken and passed either:
15 (A) an exam listed in G.S. 90-10.1 (a state board licensing examination; NBME; NBOME;
16 USMLE; FLEX; COMLEX; or MCCQE or their successors);
17 (B) SPEX (with a score of 75 or higher); or
18 (C) COMVEX (with a score of 75 or higher);
- 19 (2) within the past ten years:
20 (A) obtained certification or recertification of CAQ by a specialty board recognized by the
21 ABMS, CCFP, FRCP, FRCS or AOA; or
22 (B) met requirements for ABMS MOC (maintenance or certification) or AOA OCC
23 (Osteopathic continuous Certification);
- 24 (3) within the past 10 years completed GME approved by ACGME, CFPC, RCPSC or AOA; or
25 (4) within the past three years completed CME as required by 21 NCAC 32R .0101(a), .0101(b), and
26 .0102.

27 (d) All reports **must shall** be submitted directly to the Board from the primary source, when possible. **If a primary**
28 **source verification is not possible, then a third party verification shall be submitted.**

29 (e) An applicant shall be required to appear in person for an interview with the Board or its agent to evaluate the
30 applicant's competence and character if the Board needs more information to complete the application.

31 (f) An application must be complete within one year of submission. If not, the applicant shall be charged another
32 application fee plus the cost of another criminal background check.

33 (g) Notwithstanding the above provisions of this ~~rule,~~ Rule, the licensure requirements established by rule at the
34 time the applicant first received his or her equivalent North Carolina license shall apply. Information about these
35 rules is available from the Board.

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37 *History Note: Authority G.S. 90-8.1; 90-9.1; 90-10.1; 90-13.1;*
38 *Eff. August 1, 2010;*

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Amended Eff. September 1, 2014; November 1, 2013; November 1, 2011.

1 21 NCAC 32B .1360 is amended, with changes, as published in 28:22 NCR pages 2725 - 2727 as follows:

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3 **21 NCAC 32B .1360 REACTIVATION OF PHYSICIAN LICENSE**

4 (a) ~~Reactivation~~ “Reactivation” applies to a physician who has held a physician license in North Carolina, and whose
5 license has been inactive for up to one year except as set out in Rule .1704(e) of this Subchapter. Reactivation is not
6 available to a physician whose license became inactive either while under investigation by the Board or because of
7 disciplinary action by the Board.

8 (b) In order to reactivate a Physician License, an applicant shall:

- 9 (1) submit a completed ~~application,~~ application which can be found on the Board’s website in the
10 application section at <http://www.ncmedboard.org/licensing>, attesting under oath that the information
11 on the application is true and complete, and authorizing the release to the Board of all information
12 pertaining to the application;
- 13 (2) supply a certified copy of ~~the~~ applicant's birth certificate if the applicant was born in the United States
14 or a certified copy of a valid and unexpired US passport. If the applicant does not possess proof of
15 U.S. citizenship, the applicant ~~must shall~~ provide information about ~~the~~ applicant's immigration and
16 work status which the Board ~~will shall~~ use to verify ~~the~~ applicant's ability to work lawfully in the
17 United States; ~~(Note: there may be some Those~~ applicants who are not present in the US and who do
18 not plan to practice physically in the ~~US. Those applicants US~~ shall ~~submit include~~ a statement to that
19 ~~effect); effect in the application.~~
- 20 (3) submit a FSMB Board Action Data Bank report;
- 21 (4) submit documentation of CME obtained in the last three years;
- 22 (5) submit two completed fingerprint record cards supplied by the Board;
- 23 (6) submit a signed consent form allowing search of local, state, and national files for any criminal record;
- 24 (7) pay to the Board the ~~relevant,~~ a non-refundable ~~fee,~~ fee pursuant to G.S. 90-13.1(a), plus the cost of
25 a criminal background check; and
- 26 (8) upon request, supply any additional information the Board deems necessary to evaluate the applicant's
27 competence and ~~character,~~ character, if the Board needs more information to complete the application.

28 (c) An applicant may be required to appear in person for an interview with the Board or its agent to evaluate the
29 applicant's competence and character.

30 (d) Notwithstanding the above provisions of this rule, the licensure requirements established by rule at the time the
31 applicant first received his or her equivalent North Carolina license shall apply. Information about these rules is
32 available from the Board.

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34 *History Note:* Authority G.S. 90-8.1; 90-9.1; 90-12.1A; 90-13.1; 90-14(a)(11a);
35 Eff. August 1, 2010.
36 Amended Eff. September 1, 2014.
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1 21 NCAC 32B .1402 is amended, **with changes**, as published in 28:22 NCR pages 2725 - 2727 as follows:

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21 NCAC 32B .1402 APPLICATION FOR RESIDENT'S TRAINING LICENSE

(a) In order to obtain a Resident's Training License, an applicant shall:

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- (1) submit a completed ~~application,~~ **application which can be found on the Board's website in the application section at <http://www.ncmedboard.org/licensing>,** attesting under oath or affirmation that the information on the application is true and complete, and authorizing the release to the Board of all information pertaining to the application;
- (2) submit documentation of a legal name change, if applicable;
- (3) submit a photograph, two inches by two inches, affixed to the oath or affirmation which has been attested to by a notary public;
- (4) submit proof on the Board's Medical Education Certification form that the applicant has completed at least 130 weeks of medical education.
- (5) ~~If a graduate of a medical school other than those approved by LCME, AOA, COCA or CACMS,~~ furnish an original ECFMG certification status report of a currently valid certification of the ~~ECFMG.~~ **ECFMG if the applicant is a graduate of a medical school other than those approved by LCME, AOA, COCA, or CACMS.** The ECFMG certification status report requirement shall be waived if:
 - (A) the applicant has passed the ECFMG examination and successfully completed an approved Fifth Pathway program (original ECFMG score transcript from the ECFMG required); or
 - (B) the applicant has been licensed in another state on the basis of a written examination before the establishment of the ECFMG in 1958;
- (6) submit an appointment letter from the program director of the GME program or his **or her** appointed agent verifying the applicant's appointment and commencement date;
- (7) submit two completed fingerprint record cards supplied by the Board;
- (8) submit a signed consent form allowing a search of local, state, and national files for any criminal record;
- (9) pay a non-refundable fee pursuant to G.S. 90-13.1(b), plus the cost of a criminal background check;
- (10) provide proof that the applicant has taken and ~~passed;~~ **passed within three attempts:**
 - (A) the COMLEX ~~Level 1~~ **Level 1, within three attempts** and each component of COMLEX Level 2 (cognitive evaluation and performance evaluation) ~~within three attempts;~~ **and if taken, COMLEX Level 3;** or
 - (B) the USMLE Step 1 ~~within three attempts~~ and each component of the USMLE Step 2 (Clinical Knowledge and Clinical ~~Skills~~) ~~within three attempts;~~ **Skills); and if taken USMLE Step 3;** and

1 (11) upon request, supply any additional information the Board deems necessary to evaluate the
2 applicant's competence and character.

3 (b) An applicant shall be required to appear in person for an interview with the Board or its agent to evaluate the
4 applicant's competence and character, if the Board needs more information to complete the application.

5 (c) If the applicant previously held a North Carolina residency training license, the licensure requirements
6 established by rule at the time the applicant first received his or her North Carolina residency training license shall
7 apply. Information about these rules is available from the Board.

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9 *History Note: Authority G.S. 90-8.1; 90-12.01; 90-13.1;*
10 *Eff. August 1, 2010;*
11 *Amended Eff. September 1, 2014; November 1, 2013; August 1, 2012; November 1, 2011.*
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1 21 NCAC 32U .0101 is amended **with changes** as published in 28:21 NCR pages 2586 - 2590 as follows:

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3 **21 NCAC 32U .0101 ADMINISTRATION OF VACCINES BY PHARMACISTS**

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5 (a) ~~An Immunizing Pharmacist shall administer only those vaccines or immunizations permitted by [G.S.]~~
6 ~~G.S. 90-85.15B and shall do so subject to all requirements of that statute and this Rule. Purpose. The purpose of~~
7 ~~this Rule is to provide standards for pharmacists engaged in the administration of influenza, pneumococcal and~~
8 ~~zoster vaccines as authorized in G.S. 90-85.3(r) of the North Carolina Pharmacy Practice Act.~~

9 (b) **Definitions.** The following words and terms, when used in this Rule, have the following **meanings: meanings,**
10 **unless the context indicates otherwise.**

- 11 (1) ~~"ACPE" means Accreditation Council for Pharmacy Education.~~
12 (2) ~~"Administer" means the direct application of a drug to the body of a patient by injection,~~
13 ~~inhalation, ingestion, or other means by:~~
14 (A) ~~an Immunizing Pharmacist or a Pharmacy Intern [pharmacy intern] who is under the~~
15 ~~direct, in-person supervision of an Immunizing Pharmacist; a pharmacist, an authorized~~
16 ~~agent under the pharmacist's supervision, or other person authorized by law; or~~
17 (B) ~~the patient at the direction of either an Immunizing Pharmacist or a health care provider~~
18 ~~authorized by North Carolina law to prescribe the vaccine. a physician or pharmacist.~~
19 (2) ~~"Immunizing Pharmacist" shall have the meaning provided in [G.S.] G.S. 90-85.3(i1).~~
20 (3) ~~"Pharmacy Intern" [intern"] shall have the meaning provided in 21 NCAC 46~~
21 ~~.1317(28). "Antibody" means a protein in the blood that is produced in response to stimulation by a~~
22 ~~specific antigen. Antibodies help destroy the antigen that produced them. Antibodies against an~~
23 ~~antigen usually equate to immunity to that antigen.~~
24 (4) ~~"Physician" means a [currently licensed] M.D. or D.O. currently licensed with the North Carolina~~
25 ~~Medical Board who is responsible for the [on-going, continuous] supervision of the Immunizing~~
26 ~~Pharmacist pursuant to the Written Protocol between the Immunizing Pharmacist and the~~
27 ~~[physician] Physician. "Antigen" means a substance recognized by the body as being foreign; it~~
28 ~~results in the production of specific antibodies directed against it.~~
29 (5) ~~"Board" means the North Carolina Board of Pharmacy.~~
30 (6) ~~"Confidential record" means any health related record that contains information that identifies an~~
31 ~~individual and that is maintained by a pharmacy or pharmacist such as a patient medication record,~~
32 ~~prescription drug order, or medication order.~~
33 (7) ~~"Immunization" means the act of inducing antibody formation, thus leading to immunity.~~
34 (8) ~~"Medical Practice Act" means G.S. 90-1, et seq.~~
35 (9) ~~"Physician" means a currently licensed M.D. or D.O. with the North Carolina Medical Board who~~
36 ~~is responsible for the on going, continuous supervision of the pharmacist pursuant to written~~
37 ~~protocols between the pharmacist and the physician.~~

1 (10) ~~"Vaccination" means the act of administering any antigen in order to induce immunity; is not~~
2 ~~synonymous with immunization since vaccination does not imply success.~~

3 (11) ~~"Vaccine" means a specially prepared antigen, which upon administration to a person may result~~
4 ~~in immunity.~~

5 (5) RESERVED

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12 (12) ~~"Written Protocol" is a document means a physician's written order, standing medical order, or~~
13 ~~other order or protocol. A written protocol must be prepared, signed signed, and dated by the~~
14 ~~physician~~ Physician and Immunizing Pharmacist that shall pharmacist and contain the following:

15 (A) the name of the Physician ~~individual physician authorized to prescribe drugs and~~
16 ~~responsible for authorizing the Written Protocol; written protocol;~~

17 (B) the name of the Immunizing Pharmacist ~~individual pharmacist~~ authorized to administer
18 vaccines;

19 (C) the immunizations or vaccinations that may be administered by the Immunizing
20 Pharmacist; pharmacist;

21 (D) the screening questionnaires and safety procedures that shall at least include the then-
22 current minimum standard screening questionnaire and safety procedures adopted by the
23 Medical Board, the Board of [Nursing] Nursing, and the Board of Pharmacy pursuant to
24 S.L. 2013-246, [s. 6.] s. 6, and available at the North Carolina Medical Board's office and
25 on its website (www.ncmedboard.org).

26 (D)(E) the procedures to follow, including any drugs required by the Immunizing Pharmacist
27 pharmacist for treatment of the patient, in the event of an emergency or severe adverse
28 reaction event following vaccine administration;

29 (E)(F) the reporting requirements by the Immunizing Pharmacist pharmacist to the Physician,
30 physician issuing the written protocol, including content and time frame; and

31 (F)(G) the locations at which the Immunizing Pharmacist pharmacist may administer
32 immunizations or vaccinations, vaccinations; and

33 (G) the requirement for annual review of the protocols by the physician and pharmacist.

34 The Physician and the Immunizing Pharmacist [must] shall review the Written Protocol at least
35 annually and revise it if necessary.

36 (e) ~~Policies and Procedures.~~

- 1 (1) ~~Pharmacists must follow a written protocol as specified in Subparagraph (b)(12) of this Rule for~~
2 ~~administration of influenza, pneumococcal and zoster vaccines and the treatment of severe adverse~~
3 ~~events following administration.~~
- 4 (2) ~~The pharmacist administering vaccines must maintain written policies and procedures for handling~~
5 ~~and disposal of used or contaminated equipment and supplies.~~
- 6 (3) ~~The pharmacist or pharmacist's agent must give the appropriate, most current vaccine information~~
7 ~~regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal~~
8 ~~representative with each dose of vaccine. The pharmacist must ensure that the patient or legal~~
9 ~~representative is available and has read, or has had read to him or her, the information provided~~
10 ~~and has had his or her questions answered prior to administering the vaccine.~~
- 11 (4) ~~The pharmacist must report adverse events to the primary care provider as identified by the~~
12 ~~patient.~~
- 13 (5) ~~The pharmacist shall not administer vaccines to patients under 18 years of age.~~
- 14 (6) ~~The pharmacist shall not administer the pneumococcal or zoster vaccines to a patient unless the~~
15 ~~pharmacist first consults with the patient's primary care provider. The pharmacist shall document~~
16 ~~in the patient's profile the primary care provider's order to administer the pneumococcal or zoster~~
17 ~~vaccines. If the patient does not have a primary care provider, the pharmacist shall not administer~~
18 ~~the pneumococcal or zoster vaccines to the patient.~~
- 19 (7) ~~The pharmacist shall report all vaccines administered to the patient's primary care provider and~~
20 ~~report all vaccines administered to all entities as required by law, including any State registries~~
21 ~~which may be implemented in the future.~~
- 22 (d) ~~Pharmacist requirements. Pharmacists who enter into a written protocol with a physician to administer vaccines~~
23 ~~shall:~~
 - 24 (1) ~~hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the~~
25 ~~American Heart Association or the American Red Cross or an equivalent certification~~
26 ~~organization;~~
 - 27 (2) ~~successfully complete a certificate program in the administration of vaccines accredited by the~~
28 ~~Centers for Disease Control, the ACPE or a health authority or professional body approved by the~~
29 ~~Board as having a certificate program similar to the programs accredited by either the Centers for~~
30 ~~Disease Control or the ACPE;~~
 - 31 (3) ~~maintain documentation of:~~
 - 32 (A) ~~completion of the initial course specified in Subparagraph (2) of this Paragraph;~~
 - 33 (B) ~~three hours of continuing education every two years beginning January 1, 2006, which~~
34 ~~are designed to maintain competency in the disease states, drugs, and administration of~~
35 ~~vaccines;~~
 - 36 (C) ~~current certification specified in Subparagraph (1) of this Paragraph;~~
 - 37 (D) ~~original written physician protocol;~~

- (E) ~~annual review and revision of original written protocol with physician;~~
- (F) ~~any problems or complications reported; and~~
- (G) ~~items specified in Paragraph (g) of this Rule.~~

(c) ~~A pharmacist~~ An Immunizing Pharmacist who, because of physical disability, is unable to obtain a current provider level CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer vaccines in the presence of a pharmacy technician or pharmacist who holds a current provider level CPR certification.

(d) With each dose of vaccine, either the Immunizing Pharmacist or a Pharmacy Intern shall ~~[pharmacy intern must]~~ give the ~~[appropriate]~~ most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal representative. The Immunizing Pharmacist or Pharmacy Intern ~~[pharmacy intern]~~ must ensure that the patient or legal representative has the opportunity to read, or to have read to him or her, the information provided and to have any questions answered prior to administration of the vaccine.

(e) ~~Supervising Physician responsibilities. Pharmacists who administer vaccines shall enter into a written protocol with a supervising physician who agrees~~ [The] In agreeing to serve as a supervising Physician, the Physician shall ~~[must] agree to meet the following requirements:~~

- (1) be responsible for the formulation or approval and periodic review of the Written Protocol ~~physician's order, standing medical order, standing delegation order, or other order or written protocol~~ and periodically review the Written Protocol ~~order or protocol~~ and the services provided to patients ~~a patient~~ under the Written ~~[Protocol;]~~ Protocol, as set out in subsection (b)(12) of this Rule; ~~order or protocol;~~
- (2) be accessible to the Immunizing Pharmacist ~~pharmacist administering the vaccines~~ or be available through direct telecommunication for consultation, assistance, direction, and provide back-up coverage; and
- (3) ~~review written protocol with pharmacist at least annually and revise if necessary; and~~
- (4) receive a periodic status reports from the Immunizing Pharmacist, ~~report on the patient,~~ including any problems ~~problem~~ or complications ~~complication~~ encountered.

(f) Drugs. The following requirements pertain to drugs administered by an Immunizing Pharmacist; ~~a pharmacist:~~

- (1) Drugs administered by an Immunizing Pharmacist ~~a pharmacist~~ under the provisions of this Rule shall be in the legal possession of:
 - (A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination; or
 - (B) the Physician, ~~a physician,~~ who shall be responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination;
- (2) Drugs shall be transported and stored at the proper temperatures indicated for each drug;
- (3) Pharmacists, Immunizing Pharmacists, while engaged in the administration of vaccines under the Written Protocol, ~~written protocol,~~ shall have in their custody and control the vaccines identified in the Written Protocol ~~written protocol~~ and any other drugs listed in the Written Protocol ~~written protocol~~ to treat adverse events; ~~reactions;~~ and

1 (4) After administering vaccines at a location other than a pharmacy, the Immunizing Pharmacist
2 ~~pharmacist~~ shall return all unused prescription medications to the pharmacy or physician
3 Physician responsible for the drugs.

4 (g) Record Keeping and Reporting.

5 (1) ~~A pharmacist who administers any vaccine~~ An Immunizing Pharmacist shall maintain the
6 following information, readily retrievable, in the pharmacy records in accordance with the
7 applicable rules and statute regarding each administration:

8 (A) The the name, address, and date of birth of the patient;

9 (B) The the date of the administration;

10 (C) The the administration site of injection (~~e.g., (e.g.,~~ right arm, left leg, right upper arm);

11 (D) Route route of administration of the vaccine;

12 (E) The the name, manufacturer, lot number, and expiration date of the vaccine;

13 (F) Dose dose administered;

14 (G) The the name and address of the patient's primary health care provider, as identified by
15 the patient; and

16 (H) The the name or identifiable initials of the Immunizing Pharmacist, ~~administering~~
17 ~~pharmacist~~.

18 (2) ~~A pharmacist who administers vaccines~~ An Immunizing Pharmacist shall document the annual
19 review with the Physician physician of the Written Protocol as required in this Rule. ~~written~~
20 ~~protocol in the records of the pharmacy that is in possession of the vaccines administered.~~

21 (3) An Immunizing Pharmacist shall [must] report adverse events associated with administration of a
22 vaccine to either the prescriber, when administering a vaccine pursuant to [G.S.] G.S. 90-
23 85.15B(a), or the patient's primary care provider, if the patient identifies one, when administering
24 a vaccine pursuant to G.S. 90-85.15B(b).

25 (h) The Immunizing Pharmacist shall [must] maintain written policies and procedures for handling and disposal of
26 used or contaminated equipment and supplies.

27 (h) ~~Confidentiality.~~

28 (1) ~~The pharmacist shall comply with the privacy provisions of the federal Health Insurance~~
29 ~~Portability and Accountability Act of 1996 and any rules adopted pursuant to this act.~~

30 (2) ~~The pharmacist shall comply with any other confidentiality provisions of federal or state laws.~~

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32 *History Note:* Authority G.S. 90-85.3(r); 90-85.15B;
33 Emergency Adoption Eff. September 10, 2004;
34 Temporary Adoption Eff. December 29, 2004;
35 Eff. November 1, 2005;
36 Amended Eff. February 1, 2008;
37 Emergency Amendment Eff. October 9, 2009;

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Temporary Amendment Eff. December 29, 2009;
Temporary Amendment Expired on October 12, 2010.
Amended Eff. September 1, 2014; March 1, 2012.