

APA-1  
6/93

**TRANSMITTAL SHEET FOR  
NOTICE OF INTENDED ACTION**

Control 540 Department or Agency Alabama State Board of Medical Examiners  
 Rule No. Chapter 540-X-8-.11  
 Rule Title: Prescriptions and Medication Orders by Certified Registered Nurse Practitioners  
 New     X    Amend     Repeal     Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? YES

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

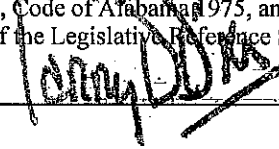
Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

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 Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

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 Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer   
 Date: February 19, 2015

APA-2  
6/93

**ALABAMA STATE BOARD  
OF MEDICAL EXAMINERS**

**NOTICE OF INTENDED ACTION**

**AGENCY NAME:** Alabama State Board of Medical Examiners

**RULE NO. & TITLE:** Chapter 540-X-8-.11, Prescriptions and Medication Orders by Certified Registered Nurse Practitioners

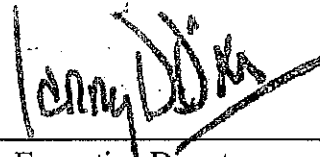
**INTENDED ACTION:** To amend the rule

**SUBSTANCE OF PROPOSED ACTION:** To amend the rule to specify conditions upon use of non-FDA approved products

**TIME, PLACE, MANNER OF PRESENTING VIEWS:** All interested persons may submit data, views, or arguments concerning the proposed new rule(s) orally or in writing to: Patricia E. Shaner, General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including Friday, April 3, 2015. Persons wishing to obtain copies of the text of this rule and submit data, views, or comments or arguments orally should contact Patricia E. Shaner, by telephone (334-242-4116) during said period in order to set up an appointment for a hearing respecting such oral data, views, or arguments.

**FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:** April 3, 2015

**CONTACT PERSON AT AGENCY:** Patricia E. Shaner



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Larry D. Dixon, Executive Director

540-X-8-.11 Prescriptions and Medication Orders by Certified Registered Nurse

Practitioners.

(1) Certified registered nurse practitioners engaged in collaborative practice with physicians may be granted prescriptive authority upon submission of evidence of completion of an academic course in pharmacology or evidence of integration of pharmacology theory and clinical application in the certified registered nurse practitioner curriculum.

(2) Certified registered nurse practitioners practicing under protocols approved in the manner prescribed by Code of Alabama 1975, as amended, § 34-21-80, et. seq., may prescribe legend drugs to their patients, subject to the following conditions:

(a) The drug shall be included in the formulary recommended by the Joint Committee and adopted by the Board of Nursing and the State Board of Medical Examiners.

(b) The drug type, dosage, quantity prescribed, and number of refills shall be authorized in an approved protocol signed by the collaborating physician and the certified registered nurse practitioner. This requirement may be met if written prescriptions adhere to the standard recommended dosages of legend drugs as identified in the Physicians Desk Reference or Product Information Insert, and do not:  
to

1. Exceed the recommended treatment regimen periods.

2. Include United States Food and Drug Administration (FDA) non-approved supplements, drug products, medication, and off label medications.

(c) Drugs and medications that do not have FDA approval may be prescribed through protocol registration in a United States Institutional Review Board or Expanded Access authorized clinical trial.

(d) "Off label" use or prescription of FDA-approved medications for uses other than that indicated by the FDA is permitted when such practices are:

1. Within the current standard of care for treatment of disease or condition.
2. Supported by evidence-based research.
3. Approved by the collaborating physician and entered into the patient record.

~~(b) The drug shall be included in the formulary recommended by the Joint Committee and adopted by the Board of Nursing and the Board of Medical Examiners.~~

(3) A certified registered nurse practitioner may not initiate a call-in prescription in the name of a collaborating physician for any drug, whether legend or controlled substance, which the certified registered nurse practitioner is not authorized to prescribe under the protocol signed by the collaborating physician and certified registered nurse practitioner and approved under this section unless the drug is specifically ordered for the patient by the physician, either in writing or by a verbal order which has been transcribed in writing, and which has been signed by the physician within seven working days or as otherwise specified by the Board of Nursing and the Board of Medical Examiners.

(4) A written prescription for any drug that the certified registered nurse practitioner is authorized to prescribe may be called in to a pharmacy, provided the prescription is entered into the patient's record and signed by the certified registered

nurse practitioner.

(5) The certified registered nurse practitioner in collaborative practice with prescriptive privileges shall not engage in prescribing for:

- (a) Self.
- (b) Immediate family members.
- (c) Individuals who are not patients of the practice.

(6) The certified registered nurse practitioner who is in collaborative practice and has prescriptive privileges may receive and sign for samples of legend drugs that are authorized in the approved formulary for the collaborative practice, provided the certified registered nurse practitioner complies with all applicable state and federal laws and regulations.

(7) When prescribing legend drugs a certified registered nurse practitioner shall use a prescription form which includes all of the following:

(a) The name, medical practice site address and telephone number of the collaborating physician or covering physician.

(b) The certified registered nurse practitioner's name printed below or to the side of the physician's name;

(c) The medical practice site address and telephone number of the certified registered nurse practitioner if different from that of the collaborating physician;

(d) The certified registered nurse practitioner's registered nurse license number and identifying prescriptive authority number assigned by the Board of Nursing.

(e) The words "Product Selection Permitted" printed on one side of the prescription form directly beneath a signature line;

(f) The words "Dispense as written" printed on one side of the prescription form directly beneath a signature line.

(g) The date that the prescription is issued to the patient.

**Author:** Alabama Board of Medical Examiners.

**Statutory Authority:** Code of Alabama 1975, as amended, §§ 34-24-53 and 34-21-86.

**History:** This new Chapter 8 - Advanced Practice Nurses: Collaborative Practice replaces Chapter 8 - Nurse Midwives. This chapter is being filed as a joint effort by the Alabama Board of Nursing and the Alabama Board of Medical Examiners. Amended/Approved For Publication: March 20, 1996.

Approved/Adopted: June 19, 1996. Effective Date: July 25, 1996.

Amended/Approved for Publication: May 21, 2003. Approved/Adopted: August 20, 2003. Effective Date: September 30, 2003. Amended/Approved for Publication: February 18, 2015.