ARC 4132C

NURSING BOARD[655]

Notice of Intended Action

Proposing rule making related to advanced registered nurse practitioners and providing an opportunity for public comment

The Board of Nursing hereby proposes to rescind Chapter 7, "Advanced Registered Nurse Practitioners," Iowa Administrative Code, and to adopt a new Chapter 7 with the same title.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 17A.3 and 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 152.

Purpose and Summary

The proposed changes included in new Chapter 7:

- Clarify definitions in the chapter.
- Add definitions to the chapter.
- Streamline the requirements and process for licensure as an advanced registered nurse practitioner (ARNP).
- Clarify the role and expectation of the ARNP per the Consensus Model and current standards of practice.
- Add language on the standards of practice for treating patients.
- Add language on the standards of practice for the prescribing and administration of controlled substances.
- Add language on the ability of the ARNP to enter into collaborative practice agreements with pharmacists.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 655—Chapter 15.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on December 11, 2018. Comments should be directed to:

Kathy Weinberg
Iowa Board of Nursing
400 S.W. 8th Street, Suite B
Des Moines, Iowa 50309
Email: kathy.weinberg@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Rescind 655—Chapter 7 and adopt the following **new** chapter in lieu thereof:

CHAPTER 7
ADVANCED REGISTERED NURSE PRACTITIONERS

655—7.1(152) Definitions.

"Advanced registered nurse practitioner" or *"ARNP"* means a person who is licensed by the board pursuant to this chapter.

"Board" as used in this chapter means the Iowa board of nursing.

"Collaboration" is the process whereby an ARNP and another health care provider or member of the health care team jointly manage the care of a client or patient.

"Controlled substance" means a drug in Schedules II through V of subchapter II of Iowa Code chapter 124.

"National professional certification organization" means the American Academy of Nurse Practitioners, the American Association of Critical Care Nurses, the American Midwifery Certification Board, the American Nurses Credentialing Center, the National Board of Certification and Recertification for Nurse Anesthetists, the National Certification Corporation, and the Pediatric Nursing Certification Board.

"Opioid" means a drug that produces an agonist effect on opioid receptors and is indicated or used for the treatment of pain.

"Prescription monitoring program database" or *"PMP database"* means a centralized database of reportable controlled substance prescriptions dispensed to patients and includes data access logs, security tracking information, and records of each individual who requests prescription monitoring program (PMP) information as operated by the board of pharmacy.

655—7.2(152) Requirements for licensure as an ARNP.

7.2(1) *Qualifications.* An applicant for an ARNP license shall meet the following qualifications:

a. Hold an active unrestricted license as a registered nurse in accordance with 655—Chapter 3.

b. Graduation from an accredited graduate or postgraduate advanced practice educational program in one of the following roles, except as provided by subrule 7.2(2):

(1) Certified nurse-midwife.

(2) Certified registered nurse anesthetist.

(3) Certified nurse practitioner.

(4) Clinical nurse specialist.

c. Current certification issued by a national professional certification organization as a certified nurse-midwife or certified registered nurse anesthetist, or as a certified nurse practitioner or clinical nurse specialist in at least one of the following population foci:

(1) Women's health/gender-related.

(2) Family (individual across the lifespan).

(3) Psychiatric mental health.

(4) Adult/gerontology.

(5) Pediatrics.

(6) Neonatal.

7.2(2) *Exception.* An applicant who has completed a formal advanced practice educational program but has not graduated from an accredited graduate or postgraduate advanced practice educational program may be licensed as an ARNP provided that the applicant possesses a current certification from a national professional certification organization as described in paragraph 7.2(1)*"c."* This exception is intended to allow for the grandfathering of ARNPs who completed educational programs before the board required graduation from an accredited graduate or postgraduate advanced practice educational program.

655—7.3(152) Application process.

7.3(1) An applicant who wishes to be licensed as an ARNP shall submit the following to the board:

a. An ARNP application for each population focus.

b. A dated copy of the applicant's current advanced level certification issued by the appropriate national professional certification organization.

c. If the applicant is not licensed as a registered nurse in Iowa, verification of an active registered nurse license in another state recognized for licensure in this state pursuant to the nurse licensure compact contained in Iowa Code chapter 152E.

d. A nonrefundable license fee of $81.

7.3(2) The applicant shall request that official transcripts be sent directly to the board from the educational program verifying the coursework, date of completion of the program, and the degree conferred.

7.3(3) The executive director of the board or the executive director's designee shall have the authority to determine if all requirements have been met for licensure of the applicant as an ARNP. If all requirements have been met:

a. The applicant shall be issued a license card and a certificate to practice as an ARNP which clearly denotes the applicant's name, title, and population focus, and the expiration date of the license.

b. The expiration date of the ARNP license shall be the same as the expiration date of the applicant's license to practice as a registered nurse.

7.3(4) Licensure completion. An applicant shall complete the ARNP licensure process within 12 months from the start of the application. The board reserves the right to destroy incomplete application materials after 12 months.

7.3(5) Renewal of licensure. An ARNP license may be renewed beginning 60 days prior to the license expiration date and ending 30 days after the expiration date. To renew, a licensee shall submit the information required by subrule 7.3(1). The expiration date assigned to a renewed ARNP license shall be the same as the expiration date of the licensee's license to practice as a registered nurse.

7.3(6) Inactive status. Failure to renew an ARNP license within 30 days after its expiration shall result in an inactive ARNP license.

a. Continuing to work as an ARNP with an inactive ARNP license may result in disciplinary action.

b. To reactivate the license, the licensee must reactivate the underlying license to practice as a registered nurse, if required, and shall complete the license renewal process for the ARNP license.

655—7.4(152) Advanced nursing practice.

7.4(1) An ARNP shall practice within the ARNP's respective population foci. An ARNP shall practice in accordance with the applicable standard of care as described in guidelines published by national professional associations or other reputable sources.

7.4(2) An ARNP must maintain current certification with a national professional certification organization at all times while the ARNP license is active.

7.4(3) An ARNP licensed by the board may prescribe, administer, or dispense prescription drugs or devices, including controlled substances, within the ARNP's role and population foci and consistent with applicable state and federal laws.

7.4(4) An ARNP shall have the authority to practice to the full extent of the ARNP's license, education, and experience in the ARNP's respective population foci. An ARNP may:

a. Assess health status;
b. Obtain a relevant health and medical history;
c. Perform physical examinations;
d. Order preventive and diagnostic procedures;
e. Formulate a differential diagnosis;
f. Develop a treatment plan;
g. Develop a patient education plan;
h. Receive third-party reimbursement;
i. Maintain hospital privileges; and
j. Promote health maintenance.

7.4(5) Supervision of fluoroscopy. An ARNP shall be permitted to provide direct supervision in the use of fluoroscopic X-ray equipment, as defined in rule 641—38.2(136C).

a. The ARNP shall provide direct supervision of fluoroscopy pursuant to the following provisions:

(1) Completion of an educational course including content in radiation physics, radiobiology, radiological safety and radiation management applicable to the use of fluoroscopy, and maintenance of documentation verifying successful completion.

(2) Collaboration, as needed, as defined in rule 655—7.1(152).

(3) Compliance with facility policies and procedures.

b. The ARNP shall complete an annual radiological safety course whose content includes, but is not limited to, the time, dose, distance, shielding and effects of radiation.

c. The ARNP shall maintain documentation of the initial educational course and all annual radiological safety updates.

d. The initial and annual education requirements are subject to audit by the board pursuant to 655—subrule 5.2(10).

655—7.5(152) Standards of practice for treating patients. An ARNP shall follow the standards of practice for the ARNP's respective population foci. Prior to treating a patient, an ARNP shall:

7.5(1) Establish a patient-provider relationship.

7.5(2) Perform and document the following, or have access to the patient's health records where all of the following have been documented by other providers in the care team:

a. Chief complaint;
b. Health history;
c. A focused assessment;
d. Diagnosis; and
e. Plan of treatment.

655—7.6(152) Standards of practice for controlled substances. In addition to following the standards of practice for treating a patient described in rule 655—7.5(152), an ARNP who prescribes or administers a controlled substance shall practice in accordance with the following:

7.6(1) The health history shall include a personal and family substance abuse risk assessment.

7.6(2) The health record must include documentation of the presence of one or more recognized indications for the use of a controlled substance.

7.6(3) An ARNP is encouraged to utilize a treatment agreement if continuously prescribing one or more controlled substances.

7.6(4) Prior to issuing a controlled substance prescription or dispensing a controlled substance, the ARNP or authorized delegate shall query the PMP. The query shall be performed within 48 hours of a prescription being issued or dispensed and shall be done for each patient, each time a controlled substance prescription is authorized or dispensed.

7.6(5) An ARNP who dispenses a controlled substance is required to report the dispensing to the PMP in accordance with 657—Chapter 37.

7.6(6) Throughout the course of the patient's treatment, the ARNP shall provide ongoing education that includes, but is not limited to, the risks of using a controlled substance, and information regarding addiction, physical dependence, substance abuse, and tolerance.

7.6(7) An ARNP shall maintain an active Drug Enforcement Administration (DEA) registration and an active controlled substance application (CSA) registration to dispense, prescribe, or administer controlled substances.

7.6(8) An ARNP shall not prescribe a controlled substance to the ARNP's self or to a family member unless the prescribing occurs in a clinical setting when an emergency situation arises and when there is no other qualified practitioner available to the patient.

7.6(9) The board may discipline an ARNP for prescribing opioids in dosage amounts that exceed what would be prescribed by a reasonably prudent ARNP in a similar population focus.

7.6(10) An ARNP who prescribes opioids is required to complete a minimum of 2 contact hours of continuing education regarding the U.S. Centers for Disease Control and Prevention guideline for prescribing opioids for chronic pain, including recommendations on limitations on dosages and the length of prescriptions, risk factors for abuse, and nonopioid and nonpharmacologic therapy options, as a condition of license renewal. These hours may count toward the 36 contact hours required for license renewal. The ARNP shall maintain documentation of these hours, which may be subject to audit.

655—7.7(152) Prescribing epinephrine auto-injectors in the name of a facility.

7.7(1) An ARNP may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code section 135.185(1), a school district, or an accredited nonpublic school.

7.7(2) An ARNP who prescribes epinephrine auto-injectors in the name of an authorized facility as defined in Iowa Code section 135.185(1), a school district, or an accredited nonpublic school, to be maintained for use pursuant to Iowa Code sections 135.185, 280.16 and 280.16A, provided the ARNP has acted reasonably and in good faith, shall not be liable for any injury arising from the provision, administration, or assistance in the administration of an epinephrine auto-injector.

655—7.8(152) Supervision of pharmacists engaged in collaborative drug therapy management. A supervising ARNP may only delegate aspects of drug therapy management to an authorized pharmacist pursuant to a written protocol with a pharmacist pursuant to the requirements of this rule. The ARNP is considered the supervisor and retains the ultimate responsibility for the care of the patient. The authorized pharmacist retains full responsibility for proper execution of pharmacy practice.

7.8(1) *Definitions.* As used in this subrule:

"ARNP" means a person who is currently licensed in Iowa to practice advanced nursing. An ARNP who executes a written protocol with an authorized pharmacist shall supervise the pharmacist's activities involved in the overall management of patients receiving medications or disease management services under the protocol. The ARNP may delegate only drug therapies that are in areas common to the ARNP's practice.

"Authorized pharmacist" means an Iowa-licensed pharmacist who meets the training requirements of the Iowa board of pharmacy (IBP) as specified in the drug therapy management criteria in rule 657—39.13(155A).

"Board" means the board of nursing of the state of Iowa.

"Collaborative drug therapy management" means participation by an ARNP and an authorized pharmacist in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

"Collaborative practice" means that an ARNP may delegate aspects of drug therapy management for the ARNP's patients to an authorized pharmacist through a written community practice protocol. "Collaborative practice" also means that a P&T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and the hospital's clinic patients through a hospital practice protocol when the clinic and the pharmacist are under the direct authority of the hospital's P&T committee.

"Community practice protocol" means a written, executed agreement entered into voluntarily between an ARNP and an authorized pharmacist establishing drug therapy management for one or more of the ARNP's patients residing in a community setting. A community practice protocol shall comply with the requirements of 657—subrule 39.13(2).

"Community setting" means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

"Hospital clinic" means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

"Hospital pharmacist" means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital's P&T committee.

"Hospital practice protocol" means a written plan, policy, procedure, or agreement that authorizes drug therapy management between ARNPs and hospital pharmacists within a hospital and its clinics as developed and determined by its P&T committee. Such a protocol may apply to all ARNPs and hospital pharmacists at a hospital or the hospital's clinics under the direct authority of the hospital's P&T committee or only to those ARNPs and pharmacists who are specifically recognized. A hospital practice protocol shall comply with the requirements of 657—subrule 39.13(3).

"IBP" means the Iowa board of pharmacy.

"P&T committee" means a committee of the hospital composed of ARNPs, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

"Therapeutic interchange" means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

7.8(2) *Community practice protocol.*

a. An ARNP shall engage in collaborative drug therapy management with a pharmacist only under a written protocol that is identified by topic and has been submitted to the IBP or a committee authorized by the IBP. Written protocols shall be made available upon request of the board or the IBP.

b. The community practice protocol shall include:

(1) The name, signature, date and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a particular patient. If more than one authorized pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal pharmacist shall be designated in the protocol.

(2) The name, signature, date and contact information for each ARNP who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The ARNP who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal ARNP.

(3) The name and contact information of the principal ARNP and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration and route of administration of the drug authorized by the patient's ARNP. The protocol shall not authorize the pharmacist to change a Schedule II drug or initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions or determine if the patient should be referred back to the patient's ARNP for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for the ARNP to secure the patient's written consent. If the ARNP does not secure the patient's written consent, the pharmacist shall secure such and notify the patient's ARNP within 24 hours.

(6) Circumstances that shall cause the pharmacist to initiate communication with the ARNP, including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests and physical findings upon which the pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy protocol to be reviewed, updated and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the ARNP.

(10) A description of the types of reports the ARNP requires the pharmacist to provide and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame in which a pharmacist shall report any adverse reaction to the ARNP.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the ARNP authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits an ARNP from delegating collaborative drug therapy management to any unlicensed or licensed person other than another ARNP or authorized pharmacist.

(17) A description of the mechanism for the pharmacist and ARNP to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

c. Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least the patient's ARNP and one authorized pharmacist.

d. Written protocols shall be made available upon request of the board or the IBP.

e. An ARNP may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the ARNP notifies, in writing, the pharmacist. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change.

f. Patient consent for community practice protocols. The ARNP or pharmacist who initiates a protocol with a patient is responsible for securing a patient's written consent to participate in drug therapy management and for transmitting a copy of the consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient needs to be

communicated to the other party at the time of securing the patient's consent. The patient's ARNP shall maintain the patient consent in the patient's medical record.

7.8(3) *Hospital practice protocol.*

a. A hospital's P&T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by its hospital pharmacists in the hospital and its clinics. Hospital clinics are restricted to outpatient care clinics operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

b. Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P&T committee.

c. The hospital practice protocol shall include:

(1) The names or groups of ARNPs and pharmacists who are authorized by the P&T committee to participate in collaborative drug therapy management.

(2) A plan for development, training, administration, and quality assurance of the protocol.

(3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration and route of administration of the drug authorized by the ARNP. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions or determine if the patient should be referred back to the ARNP for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's ARNP, including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.

(5) A statement of the medication categories and the type of initiation and modification of drug therapy that the protocol authorizes the hospital pharmacist to perform.

(6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

(7) A description of the mechanism for the hospital pharmacist and the patient's ARNP to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

These rules are intended to implement Iowa Code sections 17A.3 and 147.73 and chapter 152.