CHAPTER 61-04-08
LIMITED PRESCRIPTIVE PRACTICES

61-04-08-01. Purpose. The purpose of these rules is to implement limited prescriptive practices provisions of the North Dakota Century Code.

History: Effective December 1, 1996.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-02. Definitions. For purposes of this chapter:

1. "Collaborative agreement" means the written document signed by a ~~physician~~ practitioner and a pharmacist which describes the limited prescribing authority granted the pharmacist under North Dakota Century Code section 43-15-31.4.

2. "Immediate notification" means interactive two-way communication between the pharmacist and ~~physician~~ practitioner within twenty-four hours of the initiation or modification of drug therapy, unless specific reference is made in the collaborative agreement to situations in which a notification time limit of up to seventy-two hours is appropriate.

3. "Initiate drug therapy" means to begin administering for the first time a prescribed drug therapy for treating a patient with an existing diagnosis. A licensed ~~physician~~ practitioner shall make any diagnosis required.

4. "Medical record" means a written record of clinical care developed and maintained by a patient's ~~physician~~ practitioner which contains information and data about a patient's condition sufficient to justify the diagnosis and subsequent treatment. The record must contain further appropriate information as described in section 33-07-01.1-20.

5. "Modify drug therapy" means to change, within the same therapeutic class of drugs, a specific drug, the dosage, or route of delivery of a drug currently being administered for an existing diagnosis.

~~6. "Pharmacist in an institutional setting" means a pharmacist who:~~

~~a. Has a written agreement to provide daily or regular pharmaceutical services within a hospital, physician clinic, skilled nursing facility, swing-bed facility, or long-term care facility; and~~
~~b. Is physically present in the facility when exercising prescriptive practices under the terms of a collaborative agreement.~~

6. "Practitioner" means a licensed physician or advanced practice registered nurse.

7. "Supervision" means the active role taken by the ~~physician~~ practitioner to oversee the pharmacist throughout the provision of drug therapy to patients under the terms of a collaborative agreement.

History: Effective December 1, 1996; amended effective December 1, 2003, amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-03. Eligibility and approval.

1. A ~~physician~~ practitioner and a pharmacist who are licensed and practicing their respective professions in this state are eligible, provided the conditions of this section and any applicable statutes are met, to enter into the collaborative agreement allowing the pharmacist to provide prescription drug therapy to patients ~~in an institutional setting on a limited basis~~.

2. The practitioner and the pharmacist must have access to the patient's appropriate medical records. The care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the practitioner.

~~2. A physician may have a collaborative agreement with no more than three eligible pharmacists unless the physician's licensing board specifies otherwise based on individual circumstances. A pharmacist may have a collaborative agreement with one or more physicians, the number of which may be limited by the board based on individual circumstances.~~

3. ~~The collaborative agreement serves as a formal arrangement between an individual pharmacist and an individual collaborative supervising physician and is operative only within the institutional setting identified on the collaborative agreement form.~~ The collaborative agreement may be between a medical director and pharmacist-in-charge. The medical director and pharmacist-in-charge shall report to the respective board of any practitioner and pharmacist covered under the agreement.

4. Each individual collaborative agreement must be reviewed by the board of ~~medical examiners~~ medicine or the board of nursing and the board of pharmacy, and will not become effective until ~~both~~ the respective boards grant approval and notify the parties. Each agreement must be reviewed at least every ~~two~~ four years or when modifications to the scope of the pharmacist's prescriptive practices are proposed by the parties, and must receive continued approval from both boards in order to remain in effect. Removal or addition of either practitioners or pharmacists involved in the agreement shall be communicated to all respective boards. Unless deemed necessary, a change in personnel does not necessitate board approval of the collaborative agreement.

5. A collaborative agreement may be terminated by ~~either~~ any of the involved boards for good cause, including adverse action taken against either licensee. Noncompliance with the terms of these rules or of a collaborative agreement may be considered evidence of unprofessional conduct by ~~either~~ any of the involved boards.

6. Either party of a collaborative agreement may terminate the agreement at will by notifying either board of their desire to do so.

7. Neither party to a collaborative agreement may seek to gain personal financial benefit by participating in any incentive-based program that influences or encourages therapeutic or product changes.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-04. Procedures. A ~~physician~~ practitioner who has signed an approved collaborative agreement with a pharmacist shall remain responsible for the care of the patient following initial diagnosis ~~and assessment~~, and for the supervision of the pharmacist as prescriptive authority is exercised. The ~~physician~~ practitioner shall remain available to receive immediate notification from the pharmacist regarding prescriptive drug therapy being provided. The parties may modify as necessary, within the practice guidelines described in the collaborative agreement, their relationship in the joint provision of care to each patient as the requirements of the patient or drug therapy change.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-05. Initiation of drug therapy. To initiate drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating ~~physician~~ practitioner. ~~A pharmacist may initiate drug therapy only if the pharmacist has obtained a doctor of science, doctor of philosophy in clinical pharmacy, master of science, or doctor of pharmacy degree, has been certified a~~

~~fellow by the board of pharmaceutical specialties, or has completed an accredited pharmacy fellowship or residency, and has been authorized to do so within the collaborative agreement. Verification of these credentials must be provided by the pharmacist.~~ The pharmacist must provide immediate notification to the ~~physician~~ practitioner when the pharmacist initiates drug therapy.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-06. Modification of drug therapy.

1. To modify drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating ~~physician~~ practitioner. A pharmacist may modify drug therapy as warranted to assure an appropriate course of treatment for the patient. The pharmacist must provide immediate notification to the ~~physician~~ practitioner when the pharmacist modifies drug therapy.

2. The ~~physician~~ practitioner and pharmacist entering into a collaborative agreement must have indicated on the form the scope and authority to be exercised by the pharmacist and the type or class of drugs or drug therapy to be utilized or prohibited under the agreement. Authority to prescribe schedule II drugs may not be delegated to a pharmacist. The parties may also indicate the type of medical diagnoses to be included or excluded within the collaborative relationship.

3. The current medical record of each patient receiving drug therapy must be readily accessible to the pharmacist and ~~physician~~ practitioner ~~within the facility setting~~. The pharmacist, unless ~~physician~~ the practitioner ~~or facility policy~~ directs otherwise, shall provide timely documentation and indications for all drug therapies initiated or modified by the pharmacist as part of the medical record.

4. Contingency treatment should be addressed for treating allergic or acute adverse drug reactions.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-07. Form.

1. The collaborative agreement form utilized under this section is attached as an appendix to these rules as approved by the board of ~~medical examiners~~ medicine, board or nursing, and board of pharmacy. Upon request, ~~either~~ a board shall supply a copy of the rules and form to any interested party.

2. A copy of each collaborative agreement and subsequent amendments approved by the boards shall remain on file with the boards. Each party shall retain the original or a copy of the agreement and amendments, and either party shall provide a copy to ~~the~~ a facility within which ~~the~~ an agreement is operative.

3. Either board may disseminate a current listing of the individual parties who are practicing under an approved collaborative agreement.

4. More details may be provided. Further stipulations or details shall be supplied on a separate page.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

APPENDIX

COLLABORATIVE AGREEMENT FORM

The pharmacists and ~~physicians~~ practitioners listed below are parties to this collaborative agreement, through which the pharmacist receives limited prescriptive authority under the supervision of the ~~physician~~ practitioner in accordance with North Dakota Century Code section 43.15-31.4 and administrative rules.

~~Institution~~Facility	Facility
Address	Address
Telephone	Telephone

Pharmacist Name	License Number	~~Physician~~ Practitioner Name	License Number
Pharmacist Name	License Number	~~Physician~~ Practitioner Name	License Number
Pharmacist Name	License Number	~~Physician~~ Practitioner Name	License Number
		~~Physician~~ Practitioner Name	License Number

[Please review the administrative rules governing collaborative agreements which accompany this form before proceeding.]

1. Describe the scope and authority to be exercised by the pharmacist. (If requesting authority to initiate drug therapy, pharmacist must include credential verification.)
2. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement. (Note: Schedule II drugs are excluded by these rules.)
3. If appropriate, indicate any diagnosis which are specifically included or excluded under this agreement.
4. Attach any protocols or guidelines to be used in decision making or other activities contemplated under this agreement. This must include a protocol for treating acute allergic or other adverse reactions related to drug therapy.
5. Describe approved situations, if any, in which the notification time limit may be extended beyond twenty-four hours (not to exceed seventy-two hours).

Attach additional sheets if necessary.

Pharmacist Signature	Date	~~Physician~~ Practitioner Signature	Date
Pharmacist Signature	Date	~~Physician~~ Practitioner Signature	Date
Pharmacist Signature	Date	~~Physician~~ Practitioner Signature	Date
		~~Physician~~ Practitioner Signature	Date
State Board of Pharmacy	Approval Date	State Board of ~~Medical Examiners~~ Medicine	Approval Date
		State Board of Nursing	Approval Date