

NORTH DAKOTA ADMINISTRATIVE CODE

Supplement 326

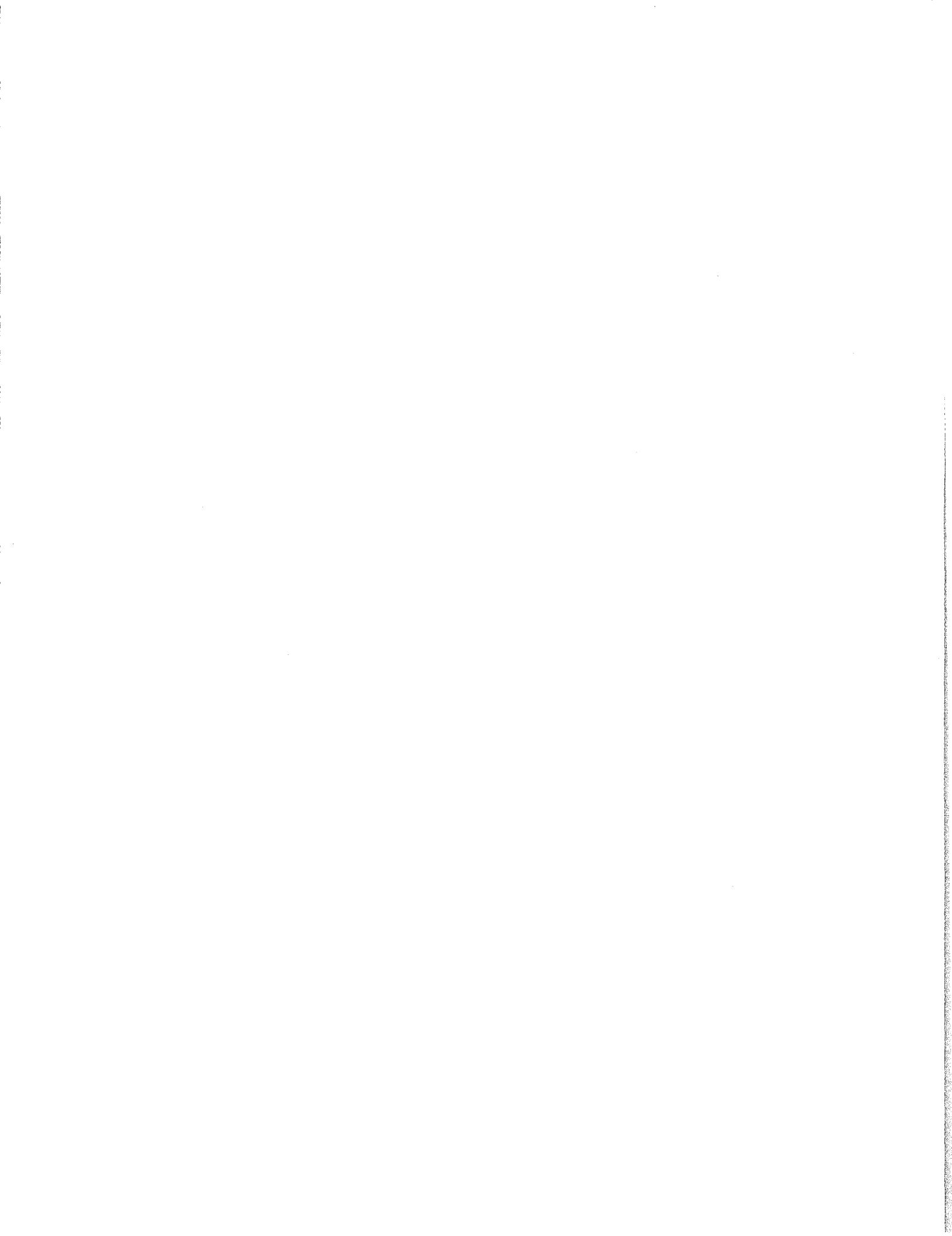
October 2007

**Prepared by the Legislative Council staff
for the
Administrative Rules Committee**



TABLE OF CONTENTS

State Board of Dental Examiners 1
State Board of Pharmacy 19



TITLE 20

STATE BOARD OF DENTAL EXAMINERS

OCTOBER 2007

CHAPTER 20-01-02

20-01-02-01. Definitions. Unless specifically stated otherwise, the following definitions are applicable throughout this title:

1. "Anxiolysis" means diminution or elimination of anxiety.
2. "Basic full upper and lower denture" means replacement of all natural dentition with artificial teeth. This replacement includes satisfactory tissue adaptation, satisfactory function, and satisfactory aesthetics. Materials used in these replacements must be nonirritating in character and meet all the standards set by the national institute of health and the bureau of standards and testing agencies of the American dental association for materials to be used in or in contact with the human body.
3. "Board certified" means the dentist has been certified in a specialty area in which there is a certifying body approved by the commission on dental accreditation of the American dental association.
4. "Board eligible" means the dentist has successfully completed a duly accredited training program or in the case of a dentist in practice at the time of the adoption of these rules has experience equivalent to such a training program in an area of dental practice in which there is a certifying body approved by the commission on dental accreditation of the American dental association.
5. "Certified dental assistant" means a dental assistant who has satisfactorily completed the educational requirements specified by the commission on dental accreditation of the American dental association for dental assistants or has two years of full-time work experience as a dental assistant, and who has passed and currently holds the dental assisting national board (DANB) certification examination for dental assistants meets the education or experience prerequisites, or both, established by the dental assisting national board and passes the dental assisting national board's certified dental assistant

examination (including radiation health and safety, infection control, and general chairside components), is currently cardiopulmonary resuscitation-certified, and continues to maintain the credential by meeting the dental assisting national board requirements.

6. "Combination inhalation - enteral conscious sedation" (combined conscious sedation) means conscious sedation using inhalation and enteral agents.

When the intent is anxiolysis only, and the appropriate dosage of agents is administered, then the definition of enteral or combined inhalation-enteral conscious sedation (combined conscious sedation), or both, does not apply.

Nitrous oxide/oxygen when used in combination or with sedative agents may produce anxiolysis, conscious or deep sedation, or general anesthesia.

7. "Complete evaluation" means an examination, review of medical and dental history, the formulation of a diagnosis, and the establishment of a written treatment plan, documented in a written record to be maintained in the dentist's office or other treatment facility or institution.
8. "Conscious sedation" means depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command and that is produced by a pharmacological or nonpharmacological method or a combination thereof. The drugs or technique, or both, should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of conscious sedation.
9. "Coronal polishing" is the mechanical polishing of clinical crowns using a rubber cup or brush only and not to include any instrumentation. Examination for calculus and instrumentation must be done by the dentist or hygienist.
10. "Deep sedation" is an induced state of depressed consciousness accompanied by partial loss of protective reflexes, including the inability to continually maintain an airway independently or to respond purposefully to physical stimulation or verbal command, and is produced by pharmacological or nonpharmacological method, or combination thereof.
11. "Dental assistant" means a person who under the direct supervision of a dentist renders assistance to a dentist or dental hygienist as described in article 20-03.

12. "Dental hygienist" means any person who is a graduate of a school of dental hygiene with a minimum of two academic years of dental hygiene curriculum approved or provisionally approved by the commission on dental accreditation of the American dental association and who is registered and licensed by the North Dakota board of dental examiners.
13. "Dental technician" means any individual who offers or undertakes to perform the fabrication or repair of corrective or prosthetic dental devices according to the written instructions of a licensed dentist. A certified dental technician is an individual who is specifically qualified through education and experience and who has successfully completed the written and practical certification examinations administered by the national board for certification, and who further maintains certification through compliance with continuing education requirements as stipulated by the national board for certification.
14. "Direct supervision" means the dentist is in the dental office or treatment facility, personally diagnoses the condition to be treated, personally authorizes the procedures and remains in the dental office or treatment facility while the procedures are being performed by the dental hygienist or dental assistant, and before dismissal of the patient, evaluates the performance of the dental hygienist or dental assistant.
15. "Evaluation" means the act or process by a dentist of assessing and determining the significance, quality or work of something such as the patient's oral health status, the progress of dental therapy, or the performance of the dental hygienist or dental assistant.
16. "General anesthesia" means an induced state of unconsciousness accompanied by a partial or complete loss of protective reflexes, including the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command, and is produced by a pharmacological or nonpharmacological method, or a combination thereof.
17. "General supervision" means the dentist has authorized the procedures and they are carried out in accordance with the dentist's diagnosis and treatment plan. The dentist is not required to be in the treatment facility. Limitations are contained in North Dakota Century Code section 43-20-03.
18. "Inactive status" means the licensee shall not engage in the practice of dentistry or dental hygiene in the state of North Dakota. The license that is placed on inactive status remains on that status until such time as the license is reinstated.
19. "Indirect supervision" means that a dentist is in the dental office or treatment facility, has personally diagnosed the condition to be treated, authorizes the procedures, and remains in the dental office

or treatment facility while the procedures are being performed by the dental hygienist or dental assistant.

20. "Local anesthesia" means the elimination of sensations in one part of the body by regional injection of drugs without causing the loss of consciousness.
21. "Modified general supervision" means that the dentist must personally evaluate the patient, diagnose the conditions to be treated, and plan and authorize treatment. The dentist must personally evaluate the patient at each visit, but need not be present when treatment is initiated or remain until procedures are completed on a patient of record who has been seen in the office in the previous twelve months.
22. "Oral hygiene treatment planning" means the process of assessing and determining, by the dentist and the hygienist, the services the dental hygienist will perform, including preventative, educational, and instrumentation. This treatment plan is an organized sequence of events that is a part of the dentist's total treatment plan. The total treatment plan and diagnosis are to be determined by the dentist.
23. "Patient of record" means a patient who has undergone a complete dental evaluation performed by a licensed dentist.
24. "Personal supervision" means a level of supervision indicating that the dentist or dental hygienist is personally treating a patient and authorizes the dental hygienist or dental assistant to aid the treatment by concurrently performing a supportive procedure.
25. "Primary practice site" means the office location that is to be considered the main location of the dental practice. This office location would be listed first on the biennial registration.
26. "Qualified dental assistant" means a dental assistant who has ~~been employed and trained as a dental assistant and has~~ received on-the-job training or instruction totaling at least six hundred fifty hours ~~of on-the-job training~~, has completed a board-approved infection control seminar and passed the x-ray and infection control portions of the dental assisting national board examination, and has applied to the board and paid the certificate fee determined by the board.
27. "Registered dental assistant" means a dental assistant who is a graduate of a dental assistant program approved or provisionally approved by the commission on dental accreditation of the American dental association, or who has received at least three thousand two hundred hours of dental assisting instruction including on-the-job training as a dental assistant and has completed dental assistant national boards, or who has completed a course in dental assisting

which is approved by the North Dakota board of dental examiners, and who is registered by the North Dakota board of dental examiners.

28. "Satellite office" means an office, building, or location used at any time by a dentist for the practice of dentistry other than the office listed on the dentist's biennial registration certificate.

History: Effective September 1, 1980; amended effective February 1, 1992; October 1, 1993; May 1, 1996; August 1, 1998; April 1, 2000; June 1, 2002; July 1, 2004; April 1, 2006; October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-20-02, 43-20-12, 43-28-06

CHAPTER 20-02-01

20-02-01-03. Nitrous oxide. A duly licensed dentist may use nitrous oxide for treating patients only when the following conditions are met:

1. Documentation has been provided by the dentist to the board that verifies completion of ~~sixteen~~ fourteen hours of instruction or continuing professional education dealing specifically with the use of nitrous oxide. In the absence of documentation of classroom training, the dentist must provide proof acceptable to the board that demonstrates three years of practical experience in the use of nitrous oxide.
2. A dentist who induces a patient into a state of psychosedation or relative analgesia using nitrous oxide shall ensure that the patient will be continually and personally monitored by a dentist. A dentist may delegate the monitoring tasks to a licensed dental hygienist or a registered dental assistant utilizing direct supervision only after the patient has been stabilized at the desired level of conscious sedation or relative analgesia by the action of the dentist. The licensed dental hygienist or registered dental assistant who is assigned the monitoring task shall remain in the treatment room with the patient at all times. A dental hygienist or a dental assistant may not initiate the administration of nitrous oxide to a patient.
3. The dentist must provide and document training for the dental hygienist or registered dental assistant in the proper and safe operation of the analgesia machine being used, including the emergency procedures to be employed if required.

History: Effective February 1, 1992; amended effective May 1, 1996; April 1, 2000; October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-28-06

20-02-01-04. Temporary license to practice dentistry. The board may grant a nonrenewable temporary license to practice dentistry in the state of North Dakota for a period not to exceed one year. The temporary license will be issued only for special purposes that are unique and cannot be satisfied by the normal means to licensure.

1. ~~The primary objective for issuing a temporary license is to facilitate the maintenance of professional care for patients when the attending dentist is suddenly incapacitated, disabled, or dies.~~
2. A temporary license to practice dentistry in North Dakota may be granted to a dentist when the ~~following conditions are met~~ dentist:

- a. ~~Applied~~ Has applied to the board in the prescribed manner and payment of the fee determined by the board as prescribed in North Dakota Century Code section 43-28-12.
 - b. ~~Successfully completed the written national board dental examinations.~~ Has paid the nonrefundable application and license fee prescribed by the board.
 - c. ~~Is already licensed to practice dentistry~~ Holds an active dental license in another state or has been a full-time student or resident of a dental program accredited by the American dental association's commission on dental accreditation within the last six months.
 - d. Has provided a statement from the licensing authority of all the states in which the dentist is licensed that the dentist's license is unencumbered, unrestricted, and that the dentist's professional record is free of blemish for professional misconduct, substandard care, or violations of the state's practice act.
 - e. Has certified that no disciplinary actions are pending in other states or jurisdictions.
 - f. Has authorized the board to seek information concerning the dentist's professional and personal background and agrees to hold harmless those individuals who may provide such information to the board.
3. 2. The board may apply such restrictions as it deems appropriate to limit the scope of the practice of dentistry under the authority of the temporary license.
4. 3. The board may restrict the licensee to engage in dental practice, as may be limited above, only at certain and specifically defined practice locations.

History: Effective February 1, 1992; amended effective October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-28-06

20-02-01-04.1. Restricted license to practice dentistry. Repealed effective October 1, 2007. ~~The board may grant a restricted license to practice dentistry at a single specific location in North Dakota, renewable annually by application to the board, when the following conditions are met:~~

- ~~1. The dentist is currently licensed in the state of Minnesota.~~
- ~~2. The dentist is actively engaged in dental practice in Moorhead, Minnesota.~~

3. ~~The dentist wishes to participate in the Fargo-Moorhead community dental emergency treatment service and see emergency dental patients as a member of the emergency call rotation schedule.~~
4. ~~The dentist agrees to treat only emergency dental patients who have been referred by the Fargo-Moorhead community dental emergency treatment service for care.~~
5. ~~The dentist has made application for a restricted dental license in the manner prescribed by the board.~~
6. ~~The dentist has paid the nonrefundable application and license fee prescribed by the board.~~
7. ~~If the Fargo-Moorhead community dental emergency treatment service ceases to function, licenses issued under provisions of this rule are automatically revoked.~~

History: Effective October 1, 1993; amended effective April 1, 2000.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-28-06

20-02-01-05. Permit for anesthesia use.

1. The rules in this chapter are adopted for the purpose of defining standards for the administration of anesthesia by dentists. The standards specified in this chapter shall apply equally to general anesthesia ~~and parenteral, deep sedation, moderate (conscious) sedation, or a combination of any of these with inhalation,~~ but do not apply to sedation administered through inhalation alone. A dentist licensed under North Dakota Century Code chapter 43-28 and practicing in North Dakota may not use ~~general anesthesia or conscious any form of sedation if the intent is beyond anxiolysis~~ on any patient unless such dentist has a permit, currently in effect, issued by the board, initially for a period of twelve months and renewable biennially thereafter, authorizing the use of such general anesthesia ~~or conscious, deep sedation, moderate (conscious) sedation, or minimal sedation when used in combination with inhalation.~~
2. An applicant may not be issued a permit initially as required in subsection 1 unless:
 - a. ~~The board of dental examiners approve~~ approves the applicant's facility after an inspection conducted by an individual or individuals designated by the dental examiners;
 - b. ~~The board of dental examiners are~~ is satisfied that the applicant is in compliance with the American dental association's most recent policy statement: THE USE OF CONSCIOUS SEDATION, DEEP

**SEDATION AND GENERAL ANESTHESIA FOR BY DENTISTS
(October 2000); and**

- c. The initial application includes payment of a fee in the amount determined by the dental examiners.
3. The board of dental examiners may renew such permit biennially, provided:
 - a. Requirements of the permit application have been met;
 - b. Application for renewal is received by the dental examiners before the date of expiration of such permit;
 - b. c. Payment of a renewal fee in the amount to be determined by the board of dental examiners is received with such application; and
 - e. d. An onsite evaluation of the dentist's facility may be conducted by an individual designated by the board of dental examiners, and the board of dental examiners must approve the results of each such evaluation.

History: Effective October 1, 1993; amended effective May 1, 1996; June 1, 2002; July 1, 2004; April 1, 2006; October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-28-06

20-02-01-06. Continuing dental education for dentists, dental hygienists, and dental assistants. Each dentist, dental hygienist, or dental assistant licensed or registered in this state shall provide evidence on forms supplied by the board that the person has attended or participated in continuing dental education in accordance with the following conditions:

1. The continuing dental education hours will accumulate on the basis of one hour of credit for each hour spent in actual teaching sessions. Subject matter directly related to clinical dentistry will be accepted by the board without limit. Limits are established for nonclinical subjects and home study courses.
2. The minimum number of hours required within a two-year cycle for dentists is thirty-two. Of these hours, a dentist may earn no more than six hours in nonclinical subjects relating to the dental profession and no more than ten hours through home study courses.
3. The minimum number of hours required within a two-year cycle for dental hygienists is sixteen. Of these hours, a dental hygienist may earn no more than three hours in nonclinical subjects relating to the dental profession and no more than five hours through home study courses.

4. The minimum number of hours for a registered dental assistant and a qualified dental assistant is eight hours annually. Of these hours, a registered dental assistant or qualified dental assistant may earn no more than three hours in nonclinical subjects relating to the dental profession and no more than two hours through home study courses.
5. Nonclinical subjects relating to the dental profession are those which cover skills relating to dental services in general which are not related to, but are nevertheless supportive of, the provision of clinical dental services. Examples of nonclinical subjects relating to the dental profession are patient management, the legal and ethical responsibilities of the dental profession, and stress management.
6. Examples of nonclinical subjects that will not be creditable to the continuing education requirement are those that deal with estate planning, financial planning, marketing, investments, and personal health.
7. Mere registration at a dental convention without specific attendance at continuing education presentations will not be creditable toward the continuing dental education requirement.
8. The infection control continuing education requirement for dentists, dental hygienists, registered dental assistants, and qualified dental assistants practicing in North Dakota is two hours biennially and is a requirement for renewal of the ~~annual~~ biennial certificate of registration. This training may be accomplished in an office setting or at a sponsored course.
9. All dentists, registered dental hygienists, dental assistants, qualified dental assistants, and registered dental assistants must hold a current cardiopulmonary resuscitation certificate of registration or its equivalent, to practice dentistry, dental hygiene, or dental assisting in the state of North Dakota (equivalent means basic life support or advanced care life support).

History: Effective October 1, 1993; amended effective May 1, 1996; August 1, 1998; June 1, 2002; April 1, 2006; October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-20-12.1, 43-28-06, 43-28-12.2

CHAPTER 20-03-01

20-03-01-03. Annual registration of dental assistants performing expanded duties.

1. Any individual engaged in performing expanded duties in the practice of dental assisting in the state of North Dakota (those duties set out in subsections 7 through 32 of section 20-03-01-01) must register with the board of dental examiners by submitting an application accompanied by a fee determined by the board. Thereafter, on a yearly basis, before expiration, every dental assistant performing expanded duties shall transmit to the board a registration fee determined by the board and evidence of completion of continuing education requirements, together with other pertinent information as required. At least thirty days before the certificate of registration expiration date, the executive director of the board shall send to every dental assistant performing expanded duties a written notice stating the amount and due date of the fee. A late fee determined by the board shall be assessed if the registration renewal application and fee are not received by the board before expiration.
2. An initial certificate of registration may be issued by the board to a dental assistant when:
 - a. The dental assistant has applied to the board and paid the registration fee determined by the board; and
 - b. The dental assistant possesses one of the following professional qualifications:
 - (1) The dental assistant is currently dental assistant certified by the dental assisting national board and has received at least three thousand two hundred hours of dental assisting instruction, including on-the-job training;
 - (2) The dental assistant has completed a course in dental assisting from a school of dental assisting accredited by the commission on dental accreditation of the American dental association; or
 - (3) The dental assistant has completed a course in dental assisting which is approved by the North Dakota board of dental examiners.
3. Every registered dental assistant performing expanded duties shall provide the board a current ~~business~~ mailing address. A registered dental assistant may not practice in this state for more than thirty days after a change of ~~business~~ address without providing the board with written notice of the new address by first-class mail.

4. Each year registered dental assistants performing expanded duties shall submit to the board with the annual registration evidence of attendance or participation in continuing dental education acceptable to the board. To remain in good standing, a registered dental assistant performing expanded duties must complete at least eight hours of continuing education each year. The board shall suspend the registration of any person who fails to comply with this section.
5. An initial certificate of qualification to take dental radiographs (allows subsections 1 through 7 in section 20-03-01-01) may be issued by the board to a dental assistant when:
 - a. The dental assistant has applied to the board and paid the certificate fee determined by the board.
 - b. The dental assistant has received six hundred fifty hours of dental assisting instruction, including on-the-job training, and been employed and trained as a dental assistant for at least six months working at least twenty-four hours per week and has received at least six hundred fifty hours of on-the-job training.
 - c. The dental assistant has completed a board-approved infection control seminar and passed the x-ray and infection control portions of the dental assisting national board examination.
6. A dental assistant who is not registered or qualified may, at the direction of a licensed dentist, perform only basic dental assisting services listed in subsections 1 through 6 of section 20-03-01-01.
7. Current certification in cardiopulmonary resuscitation and infection control shall be required for registration of all dental assistants.

History: Effective October 1, 1993; amended effective May 1, 1996; July 1, 1998; April 1, 2000; June 1, 2002; July 1, 2004; April 1, 2006; October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-28-06

20-03-01-04. Criteria for dental assistants placing sealants. A dental assistant may place sealants, if the following ~~criteria are met:~~

1. ~~The assistant is currently certified by the dental assisting national board (DANB) and registered with the North Dakota state board of dental examiners; or~~
2. ~~The assistant is a graduate within the past two years of an accredited school recognized by the commission on dental accreditation of the American dental association (CODA), or if not a graduate of a CODA accredited school within two years, if the assistant successfully completes a board-approved sealant class or course offered at an~~

accredited school dental assistant is currently registered with the North Dakota board of dental examiners and has provided documentation of a board-approved sealant course.

History: Effective June 1, 2002; amended effective April 1, 2006; October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-28-06

CHAPTER 20-05-01

20-05-01-01. Fees. The following fees apply to the services listed:

1. The nonrefundable fee to process an initial application for a license to practice for an applicant who has completed a clinical board examination within the time period allowed by the state board of dental examiners is ~~two~~ four hundred ~~twenty~~ forty dollars for a dentist and ~~fifty-five~~ two hundred dollars for a dental hygienist. The nonrefundable initial application for the registration of a registered or qualified dental assistant is sixty-five dollars.
2. The nonrefundable fee to process an application for a license by a review of the applicant's professional credentials without additional clinical examination is ~~four~~ one thousand two hundred ~~fifty~~ dollars for a dentist and ~~one~~ four hundred ~~sixty-five~~ fifty dollars for a dental hygienist.
3. The nonrefundable annual fee to process an application for a temporary license to practice dentistry is ~~one~~ two hundred ~~sixty~~ fifty dollars.
4. The fee for annual registration for registered or qualified dental assistants is ~~thirty-five~~ fifty dollars. The certificate of registration biennial renewal fee is ~~two~~ four hundred ~~twenty~~ dollars for a dentist and one hundred ~~ten~~ fifty dollars for a dental hygienist. The board may charge an administrative fee for hard copy license or registration renewal.
5. In addition to the fee for renewal, the penalty for late renewal of the biennial certificate of registration is ~~two~~ four hundred ~~twenty~~ dollars for dentists, one hundred ~~ten~~ fifty dollars for dental hygienists, and ~~thirty-five~~ fifty dollars for late renewal of the annual certificate of registration for dental assistants.
6. The fee to replace or provide a duplicate copy of a dental or dental hygiene license is forty-five dollars.
7. The fee to reactivate a retired or inactive dental or dental hygiene license is the sum of each year's annual renewal fee since the license was retired plus one hundred dollars. ~~Maximum number of years will be five (maximum fee five, not to exceed one thousand two hundred fifty dollars for dentists; three or four hundred twenty-five fifty dollars for hygienists).~~
8. ~~The nonrefundable annual fee to process an application by a Moorhead, Minnesota, dentist for a restricted dental license to treat emergency dental patients at board-approved settings is fifty dollars.~~

- ~~9. The annual registration fee for renewal of a restricted dental license to treat emergency dental patients at board-approved settings is fifty dollars.~~
- ~~40. The fee for an onsite facility inspection to obtain a permit for anesthesia use will be at a rate similar to compensation paid board members for services rendered to the state of North Dakota the sole responsibility of the anesthesia permit applicant and shall be determined as the cost incurred by the board for the site evaluation process.~~
- ~~41. The fee for initial application and biennial renewal of a permit to use general anesthesia or conscious sedation is one hundred dollars.~~
- ~~42. 9.~~ The fee for a volunteer dental license is thirty-five dollars annually.
- ~~43. 10.~~ The fee for inactive license status is thirty-five dollars annually.

History: Effective May 1, 1992; amended effective October 1, 1993; May 1, 1996; August 1, 1998; April 1, 2000; June 1, 2002; July 1, 2004; April 1, 2006; October 1, 2007.

General Authority: NDCC 43-28-06

Law Implemented: NDCC 43-28-27

TITLE 61
STATE BOARD OF PHARMACY

years for inspection and copying. This requirement applies, even though the business has been discontinued.

History: Effective October 1, 2007.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-35

61-02-01-16. Transfer of controlled substances when selling a business. The permitholder of a pharmacy discontinuing business shall notify the board of pharmacy and the nearest DEA registration field office at least fourteen days before the date of the proposed transfer of controlled substances in connection with discontinuing the business, and provide the following information:

1. The name, address, and registration number of the pharmacy discontinuing business.
2. The name, address, and registration number of the pharmacy acquiring the business.
3. The date on which the controlled substances will be transferred.

History: Effective October 1, 2007.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-35

CHAPTER 61-03-01

61-03-01-02. Approved schools. The board of pharmacy designates as approved schools all colleges of pharmacy which are members of the American association of colleges of pharmacy or maintain standards equivalent to those required for membership in that association, and have been accredited by the American accreditation council of pharmaceutical for pharmacy education.

History: Amended effective October 1, 2007.

General Authority: NDCC 43-15-15

Law Implemented: NDCC 43-15-15

CHAPTER 61-03-02

61-03-02-04. Distribution and control.

1. General. The consulting pharmacist shall establish written procedures for the safe and efficient distribution of pharmaceutical products; which shall be on hand for inspections.
2. Responsibility of consulting pharmacist. The consulting pharmacist shall be responsible for the safe and efficient distribution of, control of, and accountability of medications by developing procedures subject to the approval of the pharmaceutical services committee of the long-term care facility, to include:
 - a. Establishment of specifications for the storage, distribution, and procurement of medications and biologicals.
 - b. Participation in those aspects of the long-term care patient evaluation program which relate to drug utilization and effectiveness.
 - c. Providing information on a twenty-four-hour basis for assistance in emergency situations.
 - d. Assuring all medication shall be stored in a locked area or locked cart.
 - e. Review, evaluate, and make recommendations monthly regarding drug utilization to the pharmaceutical services committee.
 - f. Minimum standards that all provider pharmacists must meet to include the following:
 - (1) Expected delivery times for new orders and reorders.
 - (2) Procedures to ensure accountability during delivery.
 - (3) Methods to document receipt of medications by the facility.
 - (4) Procedure to obtain emergency medications and for the provider pharmacist to receive orders.
 - (5) Procedures used by the facility to reorder medications and for the provider pharmacist to receive reorders.
 - (6) Expected scope of services and medications to be provided by the provider pharmacist. If the provider pharmacist cannot provide the complete scope of services and medications, the provider pharmacist shall designate alternative sources.

- g. Procedures that allow for use of or repackaging of medications received which are not in the packaging system used by the facility.
 - h. Policy that is included as a part of the patient admissions packet that describes the responsibility of the patient or provider pharmacist to compensate a secondary pharmacist for medications or packaging services that the provider pharmacist chosen by the patient is either unwilling or unable to provide.
3. Responsibility of provider pharmacist. All provider pharmacists shall meet the minimum standards established by the consulting pharmacist.
4. Discontinued drugs.
 - a. The consulting pharmacist shall develop and implement policies and procedures to ensure that all discontinued or outdated drugs or containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Controlled drugs shall be destroyed by the consulting pharmacist subject to guidelines and approval of the state board of pharmacy.
 - b. Controlled drugs shall be destroyed at the specific institution. Noncontrolled drugs may be destroyed at the institution or returned to the provider pharmacy, for possible credit or destruction. A log must be made when the drugs are discontinued. If drugs are destroyed at the institution, two professionals must sign the destruction log.
5. Practitioner's orders. A pharmacist shall review the medication order, or a copy thereof.
 - a. Authorization. Any licensed practitioner authorized by law to prescribe drugs within the scope of the practitioner's license may prescribe for the practitioner's patient in a long-term facility.
 - b. Abbreviations. Orders employing abbreviations or chemical symbols will be only those which are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the pharmaceutical services committee of the facility.
 - c. Requirements. Orders for drugs for use by patients of the facility shall, at a minimum, contain patient name, drug name and strength, directions for use, date of order, and name of prescriber. On the facility reorder form, include all of the above except for directions.
 - d. Emergency medication order. In cases where an emergency medication order is written when pharmacy services are

unavailable, the medication order shall be reviewed by the pharmacist as soon as reasonably possible.

- e. Verification. Verification of the accuracy of any medication dispensed and of any transcriptions made of that order shall be done by handwritten initials of the pharmacist so certifying.
 - f. Duration. The prescribed medications should be for a specific time.
6. An automated dispensing system is authorized for use in long-term care facilities to store controlled bulk drugs.
- a. Drugs in the automated dispensing system are not considered dispensed until taken out by authorized personnel at the long-term care facility, once released by the pharmacy pursuant to a prescription.
 - b. Only single doses may be removed from the automated dispensing system at one time.
 - c. The pharmacy must have a separate drug enforcement administration number for the automated dispensing system at each location.
 - d. All records of dispensing must be kept at the central pharmacy.
 - e. The automated dispensing system shall permit access to only one controlled substance at each authorized entry.
 - f. Only retail pharmacies are authorized to use an automated dispensing system.
 - g. Pharmacies cannot share an automated dispensing system at a long-term care facility.
 - h. North Dakota controlled substance registration is required.
7. Controlled drug accountability. The consulting pharmacist shall establish and implement effective procedures and assure that adequate records be maintained regarding use and accountability of controlled substances which meet federal and state laws and regulations, and which shall at least specify the following:
- a. Name of drug.
 - b. Dose.
 - c. Prescriber.

- d. Patient.
 - e. Date and time of administration.
 - f. Person administering the drug.
7. ~~8.~~ Recall. The consulting pharmacist shall develop and implement a recall procedure that can readily be activated to assure the medical staff of the facility, the provider pharmacy, and the consulting pharmacist that all drugs included in the recall, located within the facility, are returned to the provider pharmacy for proper disposition.
8. ~~9.~~ Records and reports. The consulting pharmacist shall supervise the maintenance of such records and reports as are required to ensure patient health, safety, and welfare and, at a minimum, the following:
- a. Pharmacy patient profiles and medication administration records.
 - b. Reports of suspected adverse drug reactions.
 - c. Inspections of drug storage areas.
 - d. Controlled drug and accountability reports, including board of pharmacy destroyed medication forms for controlled and noncontrolled medications.
 - e. Such other and further records and reports as may be required by law and this chapter.
9. ~~10.~~ Labeling.
- a. All stock drugs intended for use within the facility shall be in appropriate containers and adequately labeled as to identify at a minimum: brand name or generic name and manufacturer, and strength. An internal code which centrally references manufacturer and lot number can be utilized.
 - b. Whenever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date, administration time and infusion rate when applicable, and name or initials of

person so adding. This excludes any single dose medication prepared and totally administered immediately.

History: Effective August 1, 1983; amended effective October 1, 1999; December 1, 2003; October 1, 2007.

General Authority: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

Law Implemented: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

CHAPTER 61-04-04

61-04-04-01. Definition of unprofessional conduct. The definition of "unprofessional conduct" for purposes of subdivision i of subsection 1 of North Dakota Century Code section 43-15-10 for disciplinary purposes includes, but is not limited to, the following:

1. The violating or attempting to violate, directly, indirectly, through actions of another, or assisting in or abetting the violation of, or conspiring to violate, any provision or term of North Dakota Century Code chapter 43-15, the Prescription Drug Marketing Act, the Robinson-Patman Act, or of the applicable federal and state laws and rules governing pharmacies or pharmacists.
2. Failure to establish and maintain effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by state or federal laws or rules.
3. Making or filing a report or record which a pharmacist or pharmacy knows to be false, intentionally or negligently failing to file a report or record required by federal or state law, or rules, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the pharmacist or pharmacy is required to make or file in the capacity as a licensed pharmacist or pharmacy.
4. Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition. A pharmacist affected under this subsection shall at reasonable intervals be afforded an opportunity to demonstrate that the pharmacist can resume the competent practice of pharmacy with reasonable skill and safety to the pharmacist's customers.
5. Knowingly dispensed a prescription drug after the death of a patient.
6. Using a facsimile machine to circumvent documentation, authenticity, verification, or other standards of pharmacy practice.
7. Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed.
8. Submits fraudulent billing or reports to a third-party payor of prescription charges.
9. Refuses to provide information or answer questions when requested to do so by the patient, which affect the patient's use of medications prescribed and dispensed by the pharmacy.

10. Does not address or attempt to resolve and document a possible prescription error or situation of potential harm to the patient when apparent or should have been apparent to the pharmacist.
11. Does not attempt to affect the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that patient may be so dependent or addicted.
12. The assertion or inference in a public manner of material claims of professional superiority in the practice of pharmacy that cannot be substantiated.
13. The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy.
14. Refusing to compound and dispense prescriptions that may reasonably be expected to be compounded or dispensed in pharmacies by a pharmacist.
15. Participation in agreements or arrangements with any person, corporation, partnership, association, firm, or others involving rebates, kickbacks, fee-splitting, or special charges in exchange for professional pharmaceutical services, including, but not limited to, the giving, selling, donating, or otherwise furnishing or transferring, or the offer to give, sell, donate, or otherwise furnish or transfer money, goods, or services free or below cost to any licensed health care facility or the owner, operator, or administrator of a licensed health care facility as compensation or inducement for placement of business with that pharmacy or pharmacist. Monetary rebates or discounts which are returned to the actual purchaser of drugs as a cost-justified discount or to meet competition are permitted if the rebates or discounts conform with other existing state and federal rules and regulations.
16. Discriminating in any manner between patients or groups of patients for reasons of religion, race, creed, color, sex, age, or national origin.
17. Disclosing to others the nature of professional pharmaceutical services rendered to a patient without the patient's authorization or by order or direction of a court or as otherwise permitted by law. This does not prevent pharmacies from providing information copies of prescriptions to other pharmacies or to the person to whom the prescription was issued and does not prevent pharmacists from providing drug therapy information to physicians for their patients.
18. Improper advertising. Prescription drug price information may be provided to the public by a pharmacy, if all the following conditions are met: No representation or suggestion concerning the drug's safety, effectiveness, or indications for use, is made. No reference is made to controlled substances listed in schedules II-V of the latest revision of the

Federal Controlled Substances Act, North Dakota Uniform Controlled Substances Act, and the rules of the state board of pharmacy.

19. Failure to report to the prescription drug monitoring program as required by North Dakota Century Code chapter 19-03.5.
20. Failure to comply with the reporting requirement of North Dakota Century Code section 43-15-42.3, including:
 - a. Actions that affect the licensee's or registrant's practice privileges in a facility.
 - b. Actions that result in the loss of the licensee's or registrant's employment or membership in a professional organization due to alleged incompetence, negligence, unethical or unprofessional conduct, or physical, mental, or chemical impairment.
 - c. Actions based on a professional liability claim against the licensee or registrant, such as an adverse judgment or settlement, a refusal to issue or renew coverage, or a cancellation of coverage.
 - d. Actions resulting in the loss of the licensee's or registrant's authorization to practice by any state or jurisdiction.
 - e. Conviction of the licensee or registrant of any misdemeanor or felony in this or any other state, territory, or jurisdiction.

Interpretation of this definition of unprofessional conduct is not intended to hinder or impede the innovative practice of pharmacy, the ability of the pharmacist to compound, alter, or prepare medications, subsequent to a practitioner's order for the appropriate treatment of patients. Further, it is not intended to restrict the exercise of professional judgment of the pharmacist when practicing in the best interest of the pharmacist's patient.

History: Effective November 1, 1991; amended effective December 1, 2003; October 1, 2007.

General Authority: NDCC 28-32-02, 43-15-10(1)(i)(12)(14)

Law Implemented: NDCC 28-32-02

