

NORTH DAKOTA ADMINISTRATIVE CODE
SECTION 33-07-01.1-22 (LABORATORY SERVICES IN HOSPITALS)
REGULATORY ANALYSIS

Fiscal Note (NDCC 28-32-08.2): A fiscal note is not required as these rules have no fiscal effect.

Regulatory Analysis (NDCC 28-32-08(2)):

1. **Describe the classes of people likely to be affected by the proposed rule, including the classes bearing the cost of the proposed rule and classes benefiting from the proposed rule:** The rules were revised upon the request of the regulated community and to be consistent with current standards of practice. The individuals likely to be affected by the proposed rule changes are the laboratory services in hospitals and related staff and consumers. There is no anticipated increase in cost related to the implementation of the proposed rules.
2. **Describe the probable impact, including the economic impact, of the proposed rule:** The probable impact of the proposed rule is the decrease in the frequency of some tissue testing dependent upon hospital policy. Other changes in the rules were consistent with current practice by laboratory services in hospitals consistent with federal laboratory requirements. As a result, the cost is anticipated to slightly decrease with implementation of the proposed rules.
3. **Describe the estimated cost to the agency of implementation and enforcement of the proposed rule and any anticipated effect on state revenue:** There is no estimated additional costs to the agency for implementation of the proposed rules.
4. **Describe any alternative methods of achieving the purpose of the proposed rule that were considered by the agency and the reasons why the methods were rejected in favor of the proposed rule:** No other alternative method for achieving the proposed rules were considered as the change in tissue testing requested provides more flexibility by the hospital as requested by the industry, and the other hospital laboratory requirements addressed are mandated by federal law.

Takings Assessment (NDCC 38-32-09): A takings assessment is not required as the rule did not result in a taking in the context of NDCC 28-32-09.

Small Entity Regulatory Analysis:

- 1. Was establishment of less stringent compliance and reporting requirements for small entities considered? To what result?** The requirements for tissue testing in the proposed rules are less stringent and established through hospital policy with the implementation of the proposed rule revision. We do not have the authority to change the federal law related to laboratory services. What is proposed is less stringent than previous rules to the extent possible. Reporting will continue consistent with federal requirements.
- 2. Was establishment of less stringent schedules or deadline for compliance or reporting requirements considered for small entities? To what result?** There is no change in the reporting requirements as they are determined by federal requirements that apply to laboratory services.
- 3. Was consideration or simplification of compliance or reporting requirements for small entities considered? To what result?** The requirements for tissue testing have been changed to be consistent with facility policy. Other laboratory services compliance and reporting requirements have been reviewed to ensure they are the minimum necessary to comply with the federal requirements.
- 4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rule? To what result?** The requirements for tissue testing were changed to be consistent with facility policies. The remainder of the requirements are consistent with federal requirements which remain unchanged.
- 5. Was exemption of small entities from all or any part of the requirements in the proposed rule considered? To what result?** Laboratory services are a required service of a licensed hospital and need to be federally certified for operation, therefore, no exemptions were considered.

Small Entity Impact Statement:

1. **Which small entities are subject to the proposed rules?** Laboratory services in hospitals throughout North Dakota.
2. **What are the administrative and other costs required for compliance with the proposed rule?** There should be no additional administrative or other costs for Laboratory Services in Hospitals as the testing of tissues was changed to by facility policy, and the federal requirements are currently being met by Laboratory Services in Hospitals.
3. **What is the probable cost and benefit to private persons and consumers who are affected by the proposed rule?** The proposed rule revision related to tissue testing was at the request of the industry and should result in less frequent testing of tissue as determined by the medical provider. Other changes in the rules decrease duplication with federal requirements and are consistent with standards of practice. There should be a benefit to hospitals and consumers of care related to the decreased requirements for tissue testing with no additional cost.
4. **What is the probable effect of the proposed rule on state revenues?** Overall, no increase or decrease in state revenue will occur based on proposed rule.
5. **Is there any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule?** No less intrusive or less costly alternative method of achieving the purpose of the proposed rules was identified.

33-07-01.1-22. Laboratory services.

1. General acute hospitals shall have a well-organized, adequately supervised, clinical laboratory service available with the necessary space, facilities, and equipment and qualified, licensed staffing to perform these services commensurate with the hospital's needs for its patients. At a minimum, the hospital must adhere to the following:
 - a. Laboratory services must be provided in accordance with the clinical laboratory improvement amendments (CLIA) at 42 code of federal regulations (CFR) part 493.
 - ~~a. The medical director of laboratory service must be a physician who is a member of the medical staff with delineated clinical privileges for interpretation of diagnostic studies.~~
 - ~~b. The medical director of the laboratory service shall assure procedures and tests are within the scope of education, training, and experience of the individuals employed to perform technical procedures in the laboratory. Only personnel designated as qualified by the medical staff by education, experience, and training may perform and report laboratory test results.~~
 - b. e. Provisions must be made to assure twenty-four-hour availability of emergency laboratory services either directly or through contract.
 - ~~d. Examination in the fields of hematology, chemistry, microbiology, sero-immunology, clinical microscopy, and other services necessary to meet patient care needs must be provided within the hospital or by contractual agreement.~~
 - c. -e. All clinically relevant surgically removed tissues must be examined by a pathologist consistent with hospital policy and signed reports must be included in the patient's medical record. If the hospital provides Anatomical pathology services, such may be provided either by the hospital directly or per contractual arrangement with a certified laboratory. Written policies and procedures must be established through the medical staff and pathologist governing prompt transportation of specimens and submission of reports.
 - f. ~~There must be a quality control assurance program designed to ensure reliability of the laboratory data and which includes written provisions for no less than:~~
 - ~~(1) The method of quantitative and qualitative testing and the frequency of control performance, including control data and evaluation criteria.~~
 - ~~(2) The frequency, and method, and evaluation criteria of quality control testing and calibration of instruments, equipment, and commercially prepared testing kits.~~
 - ~~(3) A preventive and corrective maintenance program for instruments and equipment involved in laboratory testing.~~
 - ~~(4) Participation in an approved external proficiency testing program if one is available, as applicable.~~
 - ~~(5) Maintenance of records documenting all quality control and related activities.~~

- d. g. An autopsy service must be provided either directly by the hospital or by contractual arrangement with another institution having an approved laboratory. Hospitals providing the service directly must have adequate space, equipment, and personnel for services provided.
 - e. h. Each hospital shall provide appropriate facilities and equipment for the procurement, storage, safekeeping, and administration of whole blood and blood products either directly or through contractual arrangement. ~~participation in a multifacility community blood collection, storage, and processing system.~~ Written policies and procedures for all phases of operation of blood banks and transfusion services must be established and revised as needed.
 - i. ~~Reports indicating the name and address of the testing laboratory must be authenticated, dated, and clearly indicate the results of all pathological and clinical laboratory examinations, including autopsies, and made part of the patient's medical record.~~
2. The Primary care hospitals are subject to the laboratory services requirements for general acute hospitals in this section. ~~shall maintain, or have available through contract, clinical laboratory services adequate to fulfill the needs of its patients and meeting the following:~~
- a. ~~The hospital, at a minimum, shall provide basic laboratory services essential to immediate diagnosis and treatment, including:~~
 - (1) ~~Chemical examinations of urine by stick or tablet methods, or both (including urine ketones).~~
 - (2) ~~Hemoglobin or spun hematocrit.~~
 - (3) ~~Blood sugar by whole blood testing device.~~
 - (4) ~~Examination of stool specimens for occult blood.~~
 - (5) ~~Primary culturing for transmittal to a certified laboratory.~~
 - b. ~~The hospital shall provide or have a contractual agreement with a certified laboratory for, any additional laboratory services that are needed by a patient.~~
 - c. ~~Emergency provision of basic laboratory services must be available twenty-four hours a day.~~
 - d. ~~The hospital shall assign personnel to direct and conduct the laboratory services.~~
 - e. ~~Only personnel designated as qualified by the medical staff by virtue of education, experience, and training may perform and report laboratory test results.~~
 - f. ~~Each hospital shall provide appropriate facilities and equipment for the procurement, storage, safekeeping, and administration of whole blood and blood products either directly or through participation in a multifacility community blood collection, storage, and processing system. Written policies and procedures for all phases of operation of blood banks and transfusion services must be established and periodically revised.~~
3. Specialized hospitals shall provide laboratory services to meet the needs of patients served consistent with the laboratory services requirements for general acute hospitals in this section. If onsite laboratory services are not necessary to meet the needs of

patients served, ~~such as in hospitals serving only psychiatric or substance abuse patients,~~ the laboratory services may be provided through a contractual agreement with a certified laboratory.

History: Effective April 1, 1994.; amended effective

General Authority: NDCC 23-01-03(3), 28-32-02

Law Implemented: NDCC 23-16-06