

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NOTICE OF PUBLIC HEARING

November 30, 2021  
10:00 a.m. Central Time  
Nebraska State Office Building – Lower Level A  
301 Centennial Mall South, Lincoln, Nebraska  
Phone call information: 888-820-1398; Participant code: 3213662#

The purpose of this hearing is to receive comments on the proposed repeal of Title 177 NAC 4 of the Nebraska Administrative Code (NAC) – *Rules and Regulations Relating to Biological Products and the Distribution of Materials Containing Live Micro Organisms*. The regulations are proposed for REPEAL in their entirety as the regulations are duplicative and are governed by Code of Federal Regulations, Title 21 Chapter I, Subchapter F, and are no longer necessary.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

In order to encourage participation in this public hearing, a phone conference line will be set up for any member of the public to call in and provide oral comments. Interested persons may provide verbal comments by participating in person or via phone conference line by calling 888-820-1398; Participant code: 3213662#.

Interested persons may provide written comments by mail, fax, or email, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or [dhhs.regulations@nebraska.gov](mailto:dhhs.regulations@nebraska.gov), respectively.

A copy of the proposed changes is available online at <http://www.sos.ne.gov>, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.



TO: Executive Board  
Room 2108 State Capitol  
Legislative Council

FROM: Marge Respeliers, Paralegal I  
Legal Services  
Department of Health and Human Services (DHHS)

DATE: October 20, 2021

RE: Notice of Rulemaking under Neb. Rev. Stat. § 84-907.06

---

The Department of Health and Human Services (DHHS) will be holding a public hearing on repealing the following regulations:

TITLE: 177 Nebraska Department of Health/Laboratory Services  
CHAPTER: 4 Rules and Regulations Relating to Biological Products and the Distribution of Materials Containing Live Micro-Organisms

These regulations are scheduled for public hearing on November 30, 2021.

The purpose of this hearing is to receive comments on the proposed repeal of Title 177 NAC 4 of the Nebraska Administrative Code (NAC) – *Rules and Regulations Relating to Biological Products and the Distribution of Materials Containing Live Micro Organisms*. The regulations are proposed for REPEAL in their entirety as the regulations are duplicative and are governed by Code of Federal Regulations, Title 21 Chapter I, Subchapter F, and are no longer necessary.

The following items are enclosed for your referral to the chair of the relevant standing committee of the Legislature:

1. A copy of the notice of public hearing;
2. A copy of the proposed regulations;
3. A copy of the Policy Pre-Review Checklist; and
4. The estimated fiscal impact of this rulemaking action on state agencies, political subdivisions or persons being regulated.

## FISCAL IMPACT STATEMENT

Agency: <b>Department of Health and Human Services</b>	
Title: 177 Health & Laboratory Services	Prepared by: Sue Medinger
Chapter: 4	Date prepared: 8/9/21
Subject: Biological Products and Distribution of Materials Containing Live Micro Organisms	Telephone: 402-471-0191

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	( <input checked="" type="checkbox"/> )	( <input checked="" type="checkbox"/> )	( <input checked="" type="checkbox"/> )
Increased Costs	( <input type="checkbox"/> )	( <input type="checkbox"/> )	( <input type="checkbox"/> )
Decreased Costs	( <input type="checkbox"/> )	( <input type="checkbox"/> )	( <input type="checkbox"/> )
Increased Revenue	( <input type="checkbox"/> )	( <input type="checkbox"/> )	( <input type="checkbox"/> )
Decreased Revenue	( <input type="checkbox"/> )	( <input type="checkbox"/> )	( <input type="checkbox"/> )
Indeterminable	( <input type="checkbox"/> )	( <input type="checkbox"/> )	( <input type="checkbox"/> )

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

~~TITLE 177 — NEBRASKA DEPARTMENT OF HEALTH/LABORATORY  
SERVICES/REGULATIONS —~~

~~CHAPTER 4 — RULES AND REGULATIONS RELATING TO BIOLOGICAL  
PRODUCTS AND THE DISTRIBUTION OF MATERIALS  
CONTAINING LIVE MICRO-ORGANISMS~~

TABLE OF CONTENTS

<u>SUBJECT</u>	<u>STATUTORY AUTHORITY</u>	<u>CODE SECTION</u>
Dating	71-1802	003
Dispensing	71-1802	002
Distribution of Materials Containing — Live Micro-Organisms	71-1802	004
Storage	71-1802	001

~~Title 177 — NEBRASKA DEPARTMENT OF HEALTH~~

~~Chapter 4 — RULES AND REGULATIONS RELATING TO BIOLOGICAL PRODUCTS AND THE DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS~~

~~001 STORAGE.~~ Toxins, toxoids, antitoxins, bacterins and bacterial vaccines shall be stored in a refrigerator at not less than 2° C (36° F) nor higher than 10° C (50° F). Freezing shall not be permitted.

~~Modified smallpox vaccine and rabies vaccine shall be refrigerated at as low a temperature as possible, preferably well below freezing temperature.~~

~~Tuberculin in tablet form (P.P.D.) and dried plasma shall be stored in a cool dry place.~~

~~002 DISPENSING.~~ Biologicals shall be dispensed only in the unopened original package in which they were placed and sealed by the manufacturer.

~~003 DATING.~~ Biologicals shall not be dispensed beyond the expiration date which has been indicated on each package by the manufacturer.

~~004 DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS.~~

~~— 004.01 Application for Permit.~~ Application for permit for the use of aforementioned materials in the prevention or control of diseases of animals shall be made to the State Veterinarian in a manner prescribed by the Department of Agriculture and Inspection. Application for permits for the use of these materials for any other purpose shall be made to the Director of Health, State Department of Health, on forms provided for that purpose. The aforementioned Departments shall keep a record of the date of issuance and other contents of all permits issued.

~~— 004.02 Distribution Prohibited Except to Individuals Possessing a Permit.~~ No vaccine, bacterin, immunogen or other material containing live micro-organisms capable of infecting humans and inciting therein any disease or pathological condition shall be transmitted by sale, gift or in any other manner except to an individual possessing a valid permit as provided by these regulations.

~~— 004.03 Form of Permits.~~ Permits shall be on forms provided by the respective State Departments. Permits for use of materials referred to herein in veterinary medicine shall be issued by the State Veterinarian; those for all other purposes by the Director of Health, State Department of Health. Permits involving the manufacture or sale of any such product used in veterinary medicine shall bear the endorsement of the State Veterinarian.

Title 177  
Chapter 4

~~004.04 Micro-Organisms Pathogenic to Humans. The following named or described micro-organisms are hereby declared to be pathogenic to humans:~~

~~004.04A Bacillus anthracis.~~

~~004.04B All varieties of malarial plasmodii including P. vivax, P. malariae and P. falciparum.~~

~~004.04C Mycobacterium tuberculosis, human, bovine and avian strains.~~

~~004.04D Erysipelathrix rhusiopathica (swine erysipelas vaccine).~~

~~004.04E Salmonellae (all species).~~

~~004.04F Newcastle Disease virus.~~

~~004.04G Any other species of micro-organism capable of inciting disease in humans, and not listed herein. Exceptions: Virus prepared for the prophylactic treatment of rabies in humans, and smallpox vaccine when manufactured according to the standards of the United States Public Health Service.~~

~~004.05 Records of Sale to be Kept. Records of all transfers by sale or otherwise of material containing such pathogens as named herein or supplementally named shall be kept by the individual distributing the pathogen. Such record shall show the date of transfer, the item or items containing pathogenic micro-organisms and the identity of the organisms, the name and address of the person receiving same, and the number of his valid permit, and shall at all times be available for inspection by an authorized representative of the Nebraska State Department of Health or an authorized representative of the state Department of Agriculture and Inspection.~~

~~004.06 Renewal of Permits. Permits shall expire on the 31<sup>st</sup> day of December of the year issued unless revoked prior to that date. Application for renewal must be in writing. In case the information furnished in the application for the original permit is still applicable, the applicant shall so state in his application for renewal. Should changes in the condition under which the original permit was issued have occurred, a new written application shall be submitted and passed on before reissuance of the permit.~~

~~004.07 Revocation of Permit. Any permit may be revoked by the Department issuing same when deemed necessary to protect the public health. The individual concerned shall be given an opportunity for a hearing, said hearing to be subject to such rules as may be adopted by the Director of the Department issuing the permit.~~

---

SOURCE: Section 71-1802