NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES NOTICE OF PUBLIC HEARING

August 5, 2020 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 adoption of Title 172, Chapter 130 of the Nebraska Administrative Code (NAC) – *Mail Service Pharmacy Licensure*. This proposed new chapter of regulations governs the credentialing of mail service pharmacies operating outside of the State of Nebraska. The regulations set forth the definitions; outline licensing, renewal, and reinstatement requirements; clarifies inspection criteria; and set forth fees.

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

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, 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, respectively.

Due to the current public health crisis, the agency will enforce any Directed Health Measure Order on the size of gatherings that is in effect at the time of the hearing. 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 via phone conference line by calling 888-820-1398; Participant code: 3213662#.

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.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services				
Title:172	Prepared by: Jesse Cushman			
Chapter: 130	Date prepared: 06/25/2020			
Subject: Mail Service Pharmacy	Telephone: (402) 471-4915			

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(🗵)	(⋈)	(🗵)
Increased Costs	(🗆)	(🗆)	(🗆)
Decreased Costs	(🗆)	(🗆)	(🗆)
Increased Revenue	(🗆)	(🗆)	(🗆)
Decreased Revenue	(🗆)	(🗆)	(🗆)
Indeterminable	(🗆)	(🗆)	(🗆)

Provide an Estimated Cost & Description of Impact:

State Agency: No Change

Political Subdivision: No Change

Regulated Public: There is no change in fees to the regulated public.

If indeterminable, explain why:

TITLE 172 PROFESSIONAL AND OCCUPATIONAL LICENSURE

CHAPTER 130 MAIL SERVICE PHARMACY LICENSURE

- 001. SCOPE AND AUTHORITY. These regulations govern the credentialing of mail service pharmacies and the practice of pharmacy under the Mail Service Pharmacy Licensure Act, Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-2406 to 71-2409; the Pharmacy Practice Act Neb. Rev. Stat. §§ 38-2801 to 38-28,116; the Health Care Facility Licensure Act Neb. Rev. Stat. §§ 71-401 to 71-475; and the Uniform Controlled Substances Act Neb. Rev. Stat. §§ 28-401 to 28-456.01 and 28-458 to 28-475.
- <u>002.</u> <u>DEFINITIONS.</u> <u>Definitions set out in the Pharmacy Practice Act, the Health Care Facility Licensure Act, the Uniform Controlled Substances Act, the Uniform Credentialing Act, and 175 <u>Nebraska Administrative Code (NAC) 8 apply to this chapter.</u></u>
- <u>003.</u> MAIL SERVICE PHARMACY LICENSE REQUIREMENTS. To receive a license, an applicant must submit a complete application provided by the Department, meet the requirements of Neb. Rev. Stat. § 71-2407, 175 NAC 8-005 and 175 NAC 8-006, and provide the following:
 - (A) A copy of the current active pharmacy license, including all disciplinary action taken on that license;
 - (B) A copy of all disciplinary action taken against the pharmacy in any other jurisdiction in which the pharmacy is licensed;
 - (C) A copy of the current active pharmacist license of the Pharmacist in Charge;
 - (D) A declaration that designates the Secretary of State as the Agent for Service of Process in this state:
 - (E) The name and license number of at least one designated pharmacist who holds a current unrestricted Nebraska pharmacist license; and
 - (F) A copy of the two most recent inspection reports.
- 004. RENEWAL. All mail service pharmacy licenses expire annually on July 1. To renew, a licensee must submit a completed application provided by the Department and provide documentation demonstrating that the licensee continues to meet the requirements of 172 NAC 130-003.
- <u>005.</u> REINSTATEMENT. An applicant requesting reinstatement of an expired license must submit a complete application provided by the Department and provide documentation demonstrating that the applicant meets the requirements of 172 NAC 130-003.
 - 005.01 REINSTATEMENT FROM DISCIPLINE. An applicant requesting reinstatement after discipline must submit a complete application provided by the Department and the following:
 - (A) The reinstatement fee listed in 172 NAC 130-006.02;

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

172 NAC 130

- (B) An explanation of the events the led to discipline;
- (C) Documentation that the issues that resulted in disciplinary action have been addressed;
- (D) A copy of all inspections since the discipline and all correspondence from the appropriate jurisdiction addressing such issues; and
- (E) Documents showing the applicant meets the requirements set out in 172 NAC 130-005.

006. FEES. Fees are set out in this chapter.

006.01 INITIAL AND RENEWAL FEE. The initial and renewal fees are set at \$625.00.

006.02 REINSTATEMENT FEE. The reinstatement fee is set at \$35.00 plus the renewal fee.