RENEWAL NOTICE

DHHS – DIVISION OF PUBLIC HEALTH LICENSURE UNIT STATE OF NEBRASKA PO Box 94986 Lincoln NE 68509-4986 PH: (402) 471-2118

<u>LATE PAYMENT PENALTY</u> – There is a \$100.00 late renewal fee for renewals postmarked after July 1, 2025. A Final renewal notice will be sent if payment is not received by July 1, 2025. However, payment must be received by August 1, 2025, to avoid revocation of the license.

<u>AMENDMENTS</u>—If you have had or will have a change in the name of the wholesale drug distributor or designated representative, you are required to complete an Application for Amendment. You may make the changes on this form, but these changes will not be shown on the renewed license until the Application for Amendment has been processed. You may obtain the Application for Amendment at: https://dhhs.ne.gov/licensure/Documents/WhslDrugAmendApp.pdf. You do not have to wait until the license has been amended in order to submit your renewal.

<u>PLEASE NOTE:</u> With the passing of the Drug Quality and Security Act (DQSA) by the Food & Drug Administration (FDA), Nebraska is no longer requiring a state license for those entities whose business is limited solely to that of a Manufacturer or Third Party Logistics Provider (3PL). As a result, the current Nebraska licenses for Manufacturers and 3PLs will be allowed to expire, and renewal will <u>NOT</u> be required for those facility license types.

<u>CHANGE OF OWNERSHIP OR ADDRESS</u> – A license is not transferable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. You must apply for a new wholesale drug distributor license. Please contact our office at 402/471-2118 to request an application.

YOU MUST ANSWER THE FOLLOWING QUESTIONS:

If you fail to answer these questions about your Wholesale Drug Distributor license and the designated representative, your renewal <u>WILL NOT</u> be processed and will be returned to you as incomplete.

1.	Has any license of the facility in another state been revoked, suspended, limited, or	Yes	No
	disciplined in any manner, since you last renewed this license?		
2.	Since initial licensure or since your last renewal, has the designated representative of		
	the facility been (doesn't apply to manufacturers or medical gas distributors):		
	a. The subject of any proceeding for the revocation of any license. If yes, provide	Yes	No
	the nature of the proceeding and its disposition.		
	b. Either temporarily or permanently enjoined by a court of competent jurisdiction	Yes	No
	from violations of any federal or state law regulating the possession, control, or		
	distribution of prescription drugs. If yes, provide the details of such order.		
	a Involved in any lawayita regarding the manufacture, administration, distribution	Yes	No
	 c. Involved in any lawsuits regarding the manufacture, administration, distribution or storage of prescription drugs. 	165	INO
	of storage of prescription drugs.		
	d. Convicted of any felony. If yes, provide the details relating to such conviction.	Yes	No
	a. Controlled of any followy. If you, provide the detaile folding to each controller.	. 30	1,0

If you answered "Yes" to any of the above questions, you must submit the following documents:

• If any felony conviction(s) of the designated representative of the licensee or any disciplinary action was taken against the licensee by another state, an official copy of the disciplinary action or court records, including charges and disposition.

Wholesale Drug Distributors are required to submit the following:

- Proof of a bond as defined in 172 NAC 131-002 (the Department does not provide a bond form).
- Proof of an acceptable inspection completed within the previous three years.
- Renewal fee of \$550.00

Medical Gas Distributors are required to submit a copy of an inspection completed within the previous three years or proof of accreditation, but are not required to submit a bond.

Please submit the following:				
FOR WHOLESALE DRUG DISTRIBUTORS:				
Print the Name of Designated Representative				
Print the Name of Designated Representative's Supervisor				
FOR MEDICAL GAS DISTRIBUTORS:				
Print the Name of Corporate Officer in Charge of Licensing				
Questions about this license renewal can be sent to the Office of Medical and Specialized Health at dhhs.medicaloffice@nebraska.gov or you can call 402/471-2118.				
YOU MUST COMPLETE THIS CERTIFYING INFORMATION: I hereby attest that I am the person designated by the applicant to fill this application on their behalf. I am of good character. That my response and the information provided on this form are true, complete and accurate.				
Signature of the Designated Representative or Corporate Officer Date				