



New Mexico Regulation and Licensing Department
Board of Pharmacy

5500 San Antonio Drive NE, Suite C, Albuquerque, NM 87109
(505) 222-9830 Fax (505) 222-9845 (800) 565-9102
http://www.rld.state.nm.us/boards/pharmacy.aspx

NONRESIDENT STERILE PHARMACY APPLICATION

FEE: \$600.00 Biennial (Please pay by check or money order)

Our office must receive application and fees at the same time; otherwise processing time will be delayed.
Retain a copy of both the renewal form and form of payment for future references.

NAME & MAILING ADDRESS:

NAME & STREET ADDRESS:

PHONE NO:

FAX NO:

EMAIL:

WEB ADDRESS

Contact Person Name and Title: Telephone Number Email

REQUIRED TOLL FREE NUMBER FOR NEW MEXICO RESIDENTS: not less than six days a week and for a minimum of 40 hours a week

Check Appropriate Box: NEW CHANGE OF OWNERSHIP current license number PH

I, (we) the undersigned, hereby apply for a license to operate a Pharmacy under the Pharmacy Laws of the State of New Mexico and present the following statements in support of the privilege to be granted a license and represent that if such license is granted, such place will be conducted in full compliance with existing Pharmacy laws, and rules and regulations of the Board of Pharmacy unless compliance would violate the laws and regulations of the resident state.

I (we) hereby understand that the license expires December 31 of every other year, that the license is not transferable, and that a separate license is required for each pharmacy location.

Please make sure 1-11 are all answered or attached to this application before submittal, if not it will be returned.

- 1. Enter current registration numbers; "pending" if applying for; or "N/A" if not applicable.
a) Federal DEA Reg. No.
b) New Mexico Controlled Substance Registration No.
c) Resident State Controlled Substance Registration No.
d) A New Mexico Controlled Substance license is required for shipping/mailling controlled substances into New Mexico.
2. Circle the Letter beside appropriate classification: (If b, c, or d please attach list on a separate piece of paper)
a) If individual is owner, give name and address;
b) If a partnership is owner, give name and address of all partners, (attach list);
c) If a corporation or municipality, list name, address and title of all officers, (attach list);
d) If county, city, state or church is owner, give name, address and title of all officers, (attach list);
3. Attach copy of current resident state license, permit or registration to operate a pharmacy.
4. Attach a list of all pharmacists who are (or will be) dispensing prescription drugs to persons in New Mexico.
5. Attach a copy of the most recent inspection conducted by the resident state regulatory or licensing agency.
6. Attach a copy of the most recent sterile compounding operations inspection report demonstrating conformance with USP, dated within the last 12 months. Documentation of corrective action for deficiencies is required. 16.19.6.24 (C) (1) (d) NMAC
7. All applicants submit a policy & procedure manual as required by the New Mexico Board of Pharmacy Rules & Regulations. The policy and procedures manual as defined in 16.19.6.24.C (1) (e) & (D) (2) NMAC. This manual will have the following policies: Do not send entire policy manual, only the five items listed below. All items must be labeled.
a) Normal delivery protocols and times;
b) The procedures to be followed if the patient's medication is not available at the Nonresident Pharmacy, or if the delivery will be delayed beyond the normal delivery time, to include coordinating with patient and prescriber to have Rx filled at patient's local pharmacy of choice (POC) as appropriate;
c) The procedure to be followed upon receipt of a prescription for an acute illness, which policy shall include a procedure for delivery of the medication to the patient from the Nonresident Pharmacy at the earliest possible time (i.e. courier delivery), or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time, to include coordinating with patient and prescriber to have filled at patient's local POC as appropriate;
d) The procedure to be followed when the Nonresident Pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient requires interim dosage until mailed prescription drugs becomes available, to include coordinating to have filled at local POC; and
e) the procedure for ensuring proper medication storage conditions until the medication is delivered to the patient.
8. Attach a list of the name and address of a resident agent in New Mexico for service of process.
9. List all other states where licensed, license number and expiration date. (attach list)
10. Attach a letter describing in detail the nature of your business in the State of New Mexico.
11. List all trade or business names ("DBA" names) previously or currently used by same corporation or by licensee: -

I, (we) have not been arrested, investigated for, charged with, convicted of, sentenced, entered a plea of non contendere, or entered into any other legal agreements for any criminal offense in any state, territory or possession of the United States or by the federal government.*

Signature

I, (we) do not have any disciplinary actions, or any pending actions against me/the pharmacy, or to my knowledge been investigated by any professional licensing authority.*

Signature

*If the above statements are not true, explain the circumstances, include a copy of the judgment, and attach to this application.

I (we) hereby certify that the information given in this application is true and correct to the best of my (our) knowledge.

Signature Print Name & Title - Owner or Officer

Date signed

Signature Print Name of Pharmacist-in-Charge

License #

Date signed

Please complete Non Resident Self-Assessment on the back of this application.



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Non-Resident Pharmacy Self-Assessment Form

The Pharmacist-In-Charge is responsible for completing this self-assessment form.

Please **circle** the correct answer. Return the completed form.

1. Has any State Licensing or Disciplinary Board or comparable body in the Armed Service, denied your application for licensure, reinstatement or renewal, or taken any action against your license, including, but not limited to reprimand, suspension, or revocation (license of Pharmacist-In-Charge and/or facility)? **Y N**
If yes, explain and attach a copy of the relevant document(s).
2. Do (or will) you dispense controlled substances into New Mexico? **Y N**
 - A. If yes, do you have a current NM State Controlled Substance registration? **Y N**
License #: CS_____ Expiration Date: _____
3. Does (or will) your pharmacy compound preparations for NM residents? **Y N**
 - A. If yes, do you compound **sterile** preparations? **Y N**
 - a. Are you compliant with USP <797> requirements? **Y N**
 - b. Do you compound only patient specific preparations? **Y N**
 - c. Are products only labeled for use on a specific patient? **Y N**
 - d. Do you distribute or cause to be distributed into NM non-patient specific compounded product? **Y** N**
 - B. If yes, do you compound **non-sterile** preparations? **Y N**
 - a. Are you compliant with USP <795> requirements? **Y N**
 - b. Do you compound only patient specific medications? **Y N**
 - c. Are products only labeled for use on a specific patient? **Y N**
 - d. Do you distribute or cause to be distributed into NM non-patient specific compounded product? **Y** N**
4. If compounded sterile preparations (CSP) are (or will be) shipped into NM, a copy of the most recent CSP operations inspection report conducted by the regulatory or licensing agency of the resident state (or party recognized by that agency to perform such inspection, or party recognized by the board) dated within the last 12 months and demonstrating conformance with the requirements of applicable USP/NF General Chapters numbered below 1000 is required. Documentation of corrective action for deficiencies must also be submitted.

****A pharmacy cannot distribute or cause to be distributed non-patient specific compounded product into New Mexico, other than non-sterile veterinary office use preparation, consistent with 16.19.30.9 NMAC. Compliance with 16.19.37 NMAC is required in order to distribute non-patient specific compounded sterile human drug product into NM. If you answered Y to distributing into NM non-patient specific compounded product, you must attach an explanation.**

Attestation of truthful information provided and compliance with laws and regulations:

Producers of sterile preparation(s): The registrant/licensee is in compliance with USP <797> requirements, and applicable USP/NF General Chapters numbered below 1000; and only dispenses medication pursuant to a valid prescription as defined in NMSA 61-11-2(CC). The registrant/licensee is in compliance with NM Board of Pharmacy regulations, as applicable. I (we) attest under penalty of perjury that the information given on this form is true and accurate.

SIGNATURE-PHARMACIST-IN-CHARGE [16 NMAC 19.6.9(A)(8)]

DATE

PRINTED NAME-PHARMACIST-IN-CHARGE

PHONE NUMBER & E-MAIL

OR

I (we) do not produce sterile product. The registrant/licensee is in compliance with NM Board of Pharmacy regulations, as applicable. I (we) attest under penalty of perjury that the information given on this form is true and accurate.

SIGNATURE-PHARMACIST-IN-CHARGE

DATE

PRINTED NAME-PHARMACIST-IN-CHARGE

PHONE NUMBER & E-MAIL