



New Mexico Regulation and Licensing Department

BOARDS AND COMMISSIONS DIVISION

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

OUTSOURCING FACILITY APPLICATION

FEE: \$2000.00 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 application form and form of payment for future reference.

NAME & MAILING ADDRESS:

PHYSICAL LOCATION NAME & STREET ADDRESS:

PHONE NO: _____

FAX NO: _____

EMAIL: _____

WEB ADDRESS _____

Contact Person Name and Title: _____ Telephone Number _____

Check Appropriate Box: NEW CHANGE OF OWNERSHIP

I, (we) the undersigned, hereby apply for a license to operate an Outsourcing Facility 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 New Mexico Board of Pharmacy (NMBOP) 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 outsourcing facility location.

Please make sure 1-7 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) DEA Manufacturer Reg. No. _____ (attach a copy)
 - b) Resident state license, permit or registration to operate an outsourcing facility No. _____ (attach a copy).
 - c) Resident State Controlled Substance Registration No. _____ (attach a copy)
 - d) A New Mexico Controlled Substance registration is required for shipping/ mailing controlled substances into New Mexico.
2. Circle the Letter beside appropriate classification: **(If b, c, or d please attach list on a separate sheet 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 a copy of the most recent facility inspection report, dated within the last 12 months. Inspection must have been conducted by the resident state regulatory or licensing agency, or the FDA. **(Include documentation of corrective action if applicable.)**
4. Company name as registered on FDA website as an Outsourcing Facility:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm>
5. List all other states where licensed, license number and expiration date. **(attach list)**
6. Attach a letter describing in detail the nature of your business in the State of New Mexico.
7. 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 nolo 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

PRINTED NAME AND TITLE

DATE

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

SIGNATURE

PRINTED NAME AND TITLE

DATE

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

I (we) attest under penalty of perjury that the information given on this form is true and accurate.

SIGNATURE

PRINTED NAME AND TITLE

DATE

Pharmacist-In-Charge must complete the Outsourcing Facility Self-Assessment form on the back of this application.



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Outsourcing Facility Application Self-Assessment Form

The Pharmacist-In-Charge* is responsible for completing this self-assessment form.
Please check the correct answer. Return the completed form.

ENSURE CORRECT ATTESTATION(S) ARE SIGNED

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 distribute or 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 facility compound non-patient specific product for distribution into NM? Y N
A. Are you compliant with current good manufacturing practices (cGMP) requirements? Y N
B. Are products labeled correctly per NMAC 16.19.37.10 (D)? Y N
C. Do you operate in compliance with NMAC 16.19.37? Y N
4. Does (or will) your facility compound patient specific preparations for dispensing to NM residents? Y N
A. If yes you must first be registered with the NMBOP as a Pharmacy (NMBOP license # PH _____)
B. Are you compliant with cGMP requirements? Y N
C. Are products only labeled for use on a specific patient? Y N

If you would like to make any written comments about the content on the form, please write on the back of this form or attach a separate sheet of paper.

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

(QUESTIONS 1, 2, 3)

The registrant/licensee operates in compliance with 503B requirements including cGMP. Non patient-specific products are not sold for resale. The registrant/licensee operates 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 [*Pharmacist-In-Charge per NMAC 16.19.37.7 (K)]

DATE

PRINTED NAME-PHARMACIST-IN-CHARGE

PHONE NUMBER & E-MAIL

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

(QUESTION 4)

Producers of patient-specific preparation(s): The registrant/licensee operates in compliance with cGMP requirements, and only dispenses medication pursuant to a valid prescription as defined in NMSA 61-11-2(CC). The registrant/licensee operates 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