

**NEW MEXICO BOARD OF PHARMACY
SELF-ASSESSMENT FORM
MEDICAL GAS REPACKAGER OR SELLER**

Please complete this self-assessment form and upload it with your application.

FACILITY NAME _____ NMBOP LIC# (if applying, specify pending) _____ EXP DATE _____
ADDRESS _____ CITY _____ ZIP CODE _____

If you are a manufacturer, wholesale drug distributor, or pharmacy licensed by the Board a separate medical gas license is not required.

Specify whether you are (or are applying as) a medical gas repackager or seller: **Repackager** _____ **Seller** _____

POLICY AND PROCEDURE MANUAL [16.19.14.14 A. NMAC]

- | | |
|--|--------------------|
| 1. Does the medical gas repackager or seller have a written policy and procedure manual? | Yes _____ No _____ |
| 2. Does the repackager or seller establish, maintain, and adhere to written policies and procedures for the following: | |
| a. Proper receipt | Yes _____ No _____ |
| b. Security | Yes _____ No _____ |
| c. Storage | Yes _____ No _____ |
| d. Handling | Yes _____ No _____ |
| e. Repackaging | Yes _____ No _____ |
| f. Labeling | Yes _____ No _____ |
| g. Inventory | Yes _____ No _____ |
| h. Distribution | Yes _____ No _____ |
| i. Quarantine | Yes _____ No _____ |
| j. Return or disposition of medical gases | Yes _____ No _____ |
| k. Identifying, recording, and reporting losses or thefts | Yes _____ No _____ |
| l. Correcting all errors and inaccuracies in inventories | Yes _____ No _____ |
| m. Maintenance of required drug records in proper form | Yes _____ No _____ |
| n. Handling recalls | Yes _____ No _____ |

LICENSE REQUIREMENTS [16.19.14.14 NMAC]

- | | |
|---|---------------------|
| 1. Does the repackager or seller operate from a place of residence? | Yes* _____ No _____ |
| 2. Is the <u>primary</u> business location operated out of a storage unit? | Yes* _____ No _____ |
| 3. Is the use of a storage unit consistent with accrediting body approval and allowance? | Yes _____ No _____ |
| 4. Has the person or entity been convicted of any felony for conduct relating to manufacturing or distribution, any felony violation of Subsection (i) or (k) of section 301, or any felony violation of Section 1365 of title 18, United States Code, relating to product tampering? | Yes* _____ No _____ |

***Repackagers and sellers cannot operate from a place of residence. No primary business location will be operated out of a storage unit.**

MINIMUM REQUIREMENTS [16.19.14.16 NMAC]

- | | |
|---|--------------------|
| 1. Is the facility of suitable size and construction, with adequate lighting, environmental control, quarantine, cleanliness, and pest control? | Yes _____ No _____ |
| 2. Is the facility secure from unauthorized entry? | Yes _____ No _____ |
| 3. Are (or will) all required licenses (be) publicly displayed or readily available? | Yes _____ No _____ |
| 4. Is (or will) the most recent inspection report conducted by the Board (be) publicly displayed or readily available? | Yes _____ No _____ |
| 5. Does the repackager distribute only to an entity licensed to receive medical gas? | Yes _____ No _____ |
| 6. Are inventories and records of all transactions established and maintained regarding the receipt and distribution or other disposition of medical gas. | Yes _____ No _____ |
| 7. Are all inventories and records available for inspection and copying by board inspectors for a period of at least three (3) years? | Yes _____ No _____ |

If you answered no to any of the above questions not marked by an asterisk, provide an explanation

I CERTIFY THE INFORMATION PROVIDED ON THIS FORM IS TRUE AND ACCURATE

Print name and title of representative

Signature

Date