This is an amendment to 16.19.8 NMAC, Section 9, 11, 15, 17, 20, 21 and 22 effective 10/10/2023

Explanatory paragraph: Subsections B through I of 16.19.8.9 NMAC were not published as there are no changes. Subsections B through D of 16.19.8.11 NMAC were not published as there are no changes. Subsections B through H of 16.19.8.15 NMAC were not published as there are no changes. Subsections B through E of 16.19.8.17 NMAC were not published as there are no changes. Subsections B through H of 16.19.8.20 NMAC were not published as there are no changes. Subsections A and B of 16.19.8.21 NMAC were not published as there are no changes.

16.19.8.9 MINIMUM REQUIRED INFORMATION FOR WHOLESALE DRUG DISTRIBUTION LICENSURE:

A. Every wholesale distributor who engages in the wholesale distribution of drugs shall be licensed with the board by submitting an application and providing information required by the board on an application approved by the board including [~~but not limited to~~]:

(1) applicant's full name; all trade or business names used by the licensee (includes "is doing business as" and "formerly known as") which cannot be identical to the name used by another unrelated wholesale distributor, third-party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including;

(a) if a person, the name, address, social security number or Federal Employer Identification Number (FEIN), and date of birth;

(b) if other than a person, the name, address, social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c) if a corporation, the state of incorporation; and

(d) if a publicly traded corporation, the information in Subparagraph (b) of this paragraph is not required for corporate officers and corporate directors;

(e) any other relevant information that the board requires;

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the distribution of drugs;

(5) evidence of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(6) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the wholesale drug distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess and distribute drugs;

(7) a list of all disciplinary actions or any other sanction by state and federal agencies against the wholesale distributor as well as any such actions against principals, owners, directors or officers;

(8) a full description of each facility and warehouse located in New Mexico, including all locations utilized for drug storage or distribution; the description must include the following:

(a) square footage;

(b) security and alarm system descriptions;

(c) terms of lease or ownership;

(d) address and;

(e) temperature and humidity controls;

(9) a description of the wholesale distributor's drug import and export activities;

(10) a copy of the wholesale distributor's written policies and procedures as required in Subsection I of 16.19.8.13 NMAC, (**Written policies and procedures)**;

(11) a facility located outside of New Mexico shall submit a copy of a current satisfactory inspection report issued by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such wholesale distributor, or by the board;

(12) the information collected pursuant to Paragraphs (5), (8) and (10) of this subsection shall be made available only to the board, and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.

(13) renewal applications shall be on a form furnished by the board.

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[16.19.8.9 NMAC - Rp, 16.19.8.9 NMAC, 11-28-2017; A, 10/10/2023]

16.19.8.11 PERSONNEL: As a condition of receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained by law. Each person that is issued an initial or renewal license as a wholesale distributor whether in state or out of state must designate in writing on a form required by the board a person for each facility to serve as the designated representatives of the wholesale distributor.

A. To be certified as a designated representative a person must:

(1) submit an application on a form furnished by the board and provide information that includes [~~but is not limited to~~]:

(a) evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;

(b) date of birth and social security number;

(c) occupations, positions of employment and offices held during the past seven years;

(d) whether the person during the past seven years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating and state or federal laws regulating the possession, control or wholesale distribution of prescription drugs or devices, together with details of such events;

(e) whether the person has been during the past seven years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature of the proceeding and the disposition of the proceeding;

(f) description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, which manufactured, administered, prescribed, wholesale distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

(g) description of any criminal offense (not including minor traffic violations) of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere; if the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition; and

(h) any other information the board deems relevant;

(2) may serve as the designated representative for only one wholesale distributor at any one time, except where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;

(3) be actively involved in and aware of the actual daily operations, purchasing and inventory control of the wholesale distributor;

(a) employed full-time in a managerial position by the wholesale distributor;

(b) physically present at the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence;

(c) aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale distributor.

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[16.19.8.11 NMAC - Rp, 16.19.8.11 NMAC, 11-28-2017; A, 10/10/2023]

16.19.8.15 MINIMUM REQUIRED INFORMATION FOR THIRD-PARTY LOGISTICS PROVIDER LICENSURE:

A. Every third-party logistics provider, located in New Mexico or located in another state and not licensed as a third-party logistics provider by the FDA, who engages in third-party logistics activities involving product shall be licensed with the board, by submitting an application and providing information required by the board on an application approved by the board, including [~~but is not limited to~~]:

(1) applicant's full name; all trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated wholesale distributor, third-party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including;

(a) if a person, the name, address, social security number or FEIN, and date of birth;

(b) if other than a person, the name, address, social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c) if a corporation, the state of incorporation; and

(d) if a publicly traded corporation, the information in Subparagraph (b) of this paragraph is not required for corporate officers and corporate directors.

(e) any other relevant information that the board requires;

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the third-party logistics provider that engages in the distribution of drugs;

(5) evidence of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(6) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the third-party logistics provider by any other state and federal authority that authorizes the third-party logistics provider to possess and distribute drugs;

(7) a list of all disciplinary actions or any other sanction by state and federal agencies against the third-party logistics provider as well as any such actions against principals, owners, directors or officers;

(8) a full description of each facility and warehouse located in New Mexico, including all locations utilized for drug storage or distribution; the description must include the following:

(a) square footage;

(b) security and alarm system descriptions;

(c) terms of lease or ownership;

(d) address and;

(e) temperature and humidity controls;

(9) a description of the third-party logistics provider's drug import and export activities;

(10) a copy of the third-party logistics provider's written policies and procedures as required in Subsection D of 16.19.8.18 NMAC;

(11) a facility located outside of New Mexico shall submit a copy of a current satisfactory inspection report issued by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such third-party logistics provider, or by the board;

(12) the information collected pursuant to Paragraphs (5), (8) and (10) of this subsection shall be made available only to the board, and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.

(13) renewal applications shall be on a form furnished by the board.

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[16.19.8.15 NMAC - Rp, 16.19.8.15 NMAC, 11-28-2017; A, 10/10/2023]

16.19.8.17 PERSONNEL: As a condition of receiving and retaining a third-party logistics provider license, the licensee shall require each person employed in any prescription drug third-party logistics activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained by law. Each person that is issued an initial or renewal license as a third-party-logistics provider

whether in state or out of state must designate in writing on a form required by the board a person for each facility to serve as the designated representatives of the third-party logistics provider.

A. To be certified as a designated representative a person must:

(1) submit an application on a form furnished by the board and provide information that includes [~~but not limited to~~]:

(a) evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;

(b) date of birth and social security number;

(c) occupations, positions of employment and offices held during the past seven years;

(d) whether the person during the past seven years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating and state or federal laws regulating the possession, control or wholesale distribution of prescription drugs or devices, together with details of such events;

(e) whether the person has been during the past seven years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature of the proceeding and the disposition of the proceeding;

(f) description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, which manufactured, administered, prescribed, distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

(g) description of any criminal offense (not including minor traffic violations) of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere; if the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition;

(h) any other information the board deems relevant;

(2) may serve as the designated representative for only one third-party logistics provider at any one time, except where more than one licensed third-party logistics provider is co-located in the same facility and such third-party logistics providers are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;

(3) be actively involved in and aware of the actual daily operations and inventory control of the third-party logistics provider;

(a) employed full-time in a managerial position by the third-party logistics provider;

(b) physically present at the third-party logistics provider during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence;

(c) aware of and knowledgeable about all policies and procedures pertaining to the operations of the third-party logistics provider.

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[16.19.8.17 NMAC - Rp, 16.19.8.17 NMAC, 11-28-2017; A, 10/10/2023]

16.19.8.20 MINIMUM REQUIRED INFORMATION FOR REPACKAGER LICENSURE:

A. Every repackager who engages in the distribution of product shall be licensed with the board by submitting an application and providing information required by the board on an application approved by the board, including [~~but not limited to~~]:

(1) applicant's full name; all trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated wholesale distributor, third-party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including;

(a) if a person, the name, address, social security number or FEIN, and date of birth;

(b) if other than a person, the name, address, social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c) if a corporation, the state of incorporation; and

(d) if a publicly traded corporation, the information in Subparagraph (b) of this paragraph is not required for corporate officers and corporate directors.

(e) any other relevant information that the board requires;

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the repackager that engages in the distribution of drugs;

[~~**(5)** evidence of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;~~]

[~~(6)~~] **(5)** proof of valid registration as a drug establishment with the FDA;

[~~(7)~~] **(6)** a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the repackager by any other state and federal authority that authorizes the repackager to purchase, possess, repackage and distribute drugs;

[~~(8)~~] **(7)** a list of all disciplinary actions or any other sanction by state and federal agencies against the repackager as well as any such actions against principals, owners, directors or officers;

[~~(9)~~] **(8)** a full description of each facility and warehouse located in New Mexico, including all locations utilized for drug storage or distribution; the description must include the following:

(a) square footage;

(b) security and alarm system descriptions;

(c) terms of lease or ownership;

(d) address and;

(e) temperature and humidity controls;

[~~(10)~~] **(9)** a description of the repackager's drug import and export activities;

[~~(11)~~] **(10)** a copy of the repackager's written policies and procedures as required in Subsection D of 16.19.8.23 NMAC;

[~~(12)~~] **(11)** a facility located outside of New Mexico shall submit a copy of a current satisfactory inspection report issued by the FDA, or State licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such repackager, or by the board.

[~~(13)~~] **(12)** the information collected pursuant to Paragraphs [~~(5), (9)~~] (8) and [~~(11)~~] (10) of this subsection shall be made available only to the board, and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.

(13) renewal applications shall be on a form furnished by the board.

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[16.19.8.20 NMAC - Rp, 16.19.8.20 NMAC, 11-28-2017; A, 10/10/2023]

16.19.8.21 MINIMUM QUALIFICATIONS:

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[~~**C.** The board shall consider the results of a criminal and financial background check and fingerprinting of the applicant and designated representative, to determine if an applicant or others associated with the ownership, management or operations of the repackager have committed criminal acts that would constitute grounds for denial of licensure.~~]

[~~**D.**~~] **C.** The applicant shall provide and attest to a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

[~~**E.**~~] **D.** The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based upon factors and qualifications that are directly related to the protection of the public health and safety.

[16.19.8.21 NMAC - Rp, 16.19.8.21 NMAC, 11-28-2017; A, 10/10/2023]

16.19.8.22 PERSONNEL: As a condition of receiving and retaining a repackager license, the licensee shall require each person employed in any repackaging or distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained by law. Each

person that is issued an initial or renewal license as a repackager whether in state or out of state must designate in writing on a form required by the board a person for each facility to serve as the designated representatives of the repackager.

[~~**A.** To be certified as a designated representative a person must:~~

~~**(1)** submit an application on a form furnished by the board and provide information that includes but is not limited to;~~

~~**(a)** evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;~~

~~**(b)** date of birth and social security number;~~

~~**(c)** occupations, positions of employment and offices held during the past seven years;~~

~~**(d)** whether the person during the past seven years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating and state or federal laws regulating the manufacturing, possession, control or distribution of prescription drugs or devices, together with details of such events;~~

~~**(e)** whether the person has been during the past seven years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature of the proceeding and the disposition of the proceeding;~~

~~**(f)** description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, which manufactured, administered, prescribed, distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;~~

~~**(g)** description of any criminal offense (not including minor traffic violations) of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere; if the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition;~~

~~**(h)** any other information the board deems relevant;~~

~~**(2)** may serve as the designated representative for only one repackager at any one time, except where more than one licensed repackager is co-located in the same facility and such repackagers are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;~~

~~**(3)** be actively involved in and aware of the actual daily operations, purchasing and inventory control of the repackager;~~

~~**(a)** employed full-time in a managerial position by the repackager;~~

~~**(b)** physically present at the repackager facility during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence;~~

~~**(c)** aware of and knowledgeable about all policies and procedures pertaining to the operations of the repackager.~~

~~**B.** The criminal and financial information collected pursuant to this section shall be made available only to the board, a third party recognized by the board, and to state and federal law enforcement officials. The board and a third party recognized by the board shall make provisions for protecting the confidentiality of the information collected under this section.~~

~~**C.**~~] **A.** Each licensed repackager located outside of this state that distributes prescription drugs in this state shall designate a registered agent in this state for service of process. Any licensed repackager that does not so designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed repackager growing out of or arising from such manufacture or distribution. A copy of any such service or process shall be mailed to such repackager by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed repackager has designated on its application for licensure in this state. If any such repackager is not licensed in this state, service on the secretary of state only shall be sufficient service.

[~~**D.**~~] **B.** A designated representative must complete training programs that address applicable state and federal laws and are provided by qualified in-house specialists, outside counsel or counseling specialists with capabilities to help ensure compliance.

[16.19.8.22 NMAC - Rp, 16.19.8.22 NMAC, 11-28-2017; A, 10/10/2023]