

TO BE RESCINDED

4729-9-12

Verification of license as a distributor of dangerous drugs or exempt status of a prescriber.

(A) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code or may utilize the board's online registry to confirm licensure.

(1) The purchaser shall furnish a copy of the certificate of license as a terminal distributor to the wholesale distributor of dangerous drugs or the wholesale distributor may utilize the board's online registry to confirm licensure. If the certificate of license indicates a limited category I, II, or III license, the terminal distributor shall furnish the wholesale distributor a copy of the current license addendum listing those drugs the purchaser is authorized to possess.

(2) If no certificate of license or confirmation of licensure as a terminal distributor is obtained or furnished before the sale, both the seller and the purchaser shall be considered to be in violation of section 4729.60 of the Revised Code.

(B) Before a terminal distributor of dangerous drugs may make a purchase of dangerous drugs at wholesale, the purchaser must obtain from the seller or the board's online registry either the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code or the terminal distributor license number for occasional wholesale sales conducted in accordance with rule 4729-9-10 of the Administrative Code.

(1) The seller shall furnish the wholesale distributor registration number and registration expiration date to the terminal distributor of dangerous drugs or the purchaser may utilize the board's online registry to confirm licensure.

(2) If no registration number of the wholesale distributor is obtained or furnished before the purchase, both the purchaser and the seller shall be considered to be in violation of section 4729.60 of the Revised Code.

(C) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a prescriber as defined in division (I) of section 4729.01 of the Revised Code, the wholesale distributor must obtain:

(1) A copy of the current certificate of license as a terminal distributor from the prescriber pursuant to division (A) of section 4729.60 of the Revised Code or the wholesale distributor may utilize the board's online registry to confirm

licensure as a terminal distributor of dangerous drugs and, if the license is limited, a copy of the addendum listing the drugs the licensee is authorized to purchase and possess; or

- (2) Unless the prescriber meets the terminal distributor of dangerous drugs licensing requirements in section 4729.541 of the Revised Code, copies of all documents required to establish that the prescriber is exempt from licensure as a terminal distributor of dangerous drugs pursuant to divisions (B)(1)(a), (B)(1)(j), and (B)(1)(k) of section 4729.51 of the Revised Code and is authorized by federal and state laws to purchase the dangerous drugs for use in the course of his/her professional practice. The required documents are as follows:
- (a) An individual prescriber doing business as a sole proprietor (not incorporated in any manner) as set forth in division (B)(1)(a) of 4729.51 of the Revised Code, an individual prescriber doing business as a sole shareholder of a corporation or a limited liability company pursuant to division (B)(1)(j) of section 4729.51 of the Revised Code, and a dentist pursuant to division (B)(1)(k) of 4729.51 of the Revised Code must provide a copy of his/her current license to practice and the license must authorize the use of the drugs requested from the wholesaler in his/her practice. Also, a prescriber doing business as a sole shareholder of a corporation or a limited liability company must also provide official documentation that states he/she is the sole shareholder;
 - (b) The address of all sites of practice where the drugs will be delivered to and stored for use by the prescriber in his/her professional practice pursuant to federal and state laws;
 - (c) Verification from the licensing board that the prescriber's license is in good standing and that there are no restrictions on his/her license to practice and use drugs in his/her practice. If the license has been restricted by the licensing board, a copy of the official documents restricting the license to practice and use drugs in the course of professional practice must be furnished to the wholesaler and maintained by the wholesaler with all other documents establishing the prescriber's exemption from licensure as a terminal distributor of dangerous drugs;
 - (d) If an exempted prescriber wishes to purchase and possess dangerous drugs which are also controlled substances, the prescriber must submit a copy of his/her current registration with the federal drug enforcement administration and provide verification that the DEA registration and authority to use controlled substances in the course of professional

practice has not been restricted by the appropriate professional licensing board or the federal drug enforcement administration.

- (D) Dangerous drugs may not be shipped by a wholesale distributor of dangerous drugs to any address other than those listed by a prescriber and filed with the wholesale distributor in accordance with paragraph (C) of this rule. Controlled substances may only be shipped to those addresses registered with the federal drug enforcement administration for the purpose of storing controlled substances.
- (E) All documents establishing the fact that a prescriber is exempt from licensure as a terminal distributor of dangerous drugs shall be current and maintained for a period of three years by the wholesale distributor of dangerous drugs.
- (F) Copies of licenses to practice and verification that there are no restrictions on a prescriber's license by either the appropriate professional licensing board or the federal drug enforcement administration shall be obtained within fifteen days of the date of renewal of such licenses. No dangerous drugs may be sold and delivered to a prescriber until the required documentation has been obtained by the wholesale distributor.
- (G) Each wholesale distributor of dangerous drugs registered with the state board of pharmacy shall report any suspicious purchases of any dangerous drugs by a prescriber exempted from licensure as a terminal distributor of dangerous drugs. A suspicious purchase includes, but is not limited to, any drugs that the prescriber is not authorized to use in the course of his/her professional practice.
- (H) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729-16-07 of the Administrative Code, the terminal distributor of dangerous drugs must confirm a current certificate of license as a terminal distributor from the purchaser. The seller may utilize the board's online registry to confirm licensure.
- (I) Before a wholesale distributor of dangerous drugs may purchase a dangerous drug from another wholesale distributor of dangerous drugs, the purchaser must confirm the seller has a current license as a wholesale distributor of dangerous drugs. The purchaser may utilize the board's online registry to confirm licensure.
- (J) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729-9-10 of the Administrative Code, the seller must confirm the purchaser has a current certificate of license as a terminal distributor from the purchaser or the purchaser is exempted from licensure as a terminal distributor of dangerous drugs pursuant to section 4729.51 of the Revised Code. The seller may utilize the board's online registry to confirm licensure.

- (K) Use of the board's online registry pursuant to this rule shall be documented and such documentation shall be maintained for a period of three years by the wholesale or terminal distributor of dangerous drugs.
- (L) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following:
- (1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control.
 - (2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer of a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

Effective:

Five Year Review (FYR) Dates: 8/17/2018

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 3719.04, 4729.60, 4729.541, 4729.54, 4729.51
Prior Effective Dates: 10/01/1971, 03/19/1987, 07/01/1991, 03/13/1995,
01/10/1996, 03/01/1999, 01/01/2009, 10/05/2015,
03/01/2017