Rule 4729:5-10-06 | ~~Donor and recipient forms.~~ Required forms and record keeping.

(A) Each donor must sign a form stating that the donor is the owner of the drug and intends to voluntarily donate the drug to the drug repository program. The donor form must be completed prior to any donation and include at least the following:

(1) The name of the person that was originally dispensed the drugs or the name of the terminal distributor of dangerous drugs or drug distributor that owns the drugs.

~~(2) The signature of the donor, which may include the person designated by durable power of attorney, a guardian, an individual responsible for the care and well-being of a patient, the signature of the responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor.~~

(2) The full name, contact phone, and signature of the donor, which may include any of the following:

(a) The person designated by durable power of attorney, a guardian, an individual responsible for the care and well-being of a patient;

(b) The responsible person or the responsible person's designee of a terminal distributor of dangerous drugs or a drug distributor; or

(c) The licensed prescriber or pharmacist responsible for the oversight of the entity donating the drugs.

(3) The address of the donor or the entity donating the drug.

(~~3~~ **4**) The date the form was signed.

(B) The following donor information must also be documented. This information may be documented on the original signed donor form or on an alternate record **created by the repository program**. If an alternate record is used, the record must include the name of the donor in addition to the required information in this paragraph.

(1) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#).

(2) The strength of the drug donated.

(3) The quantity of the drug donated.

(4) The date the drug was donated.

(C) Prior to receiving donated drugs from a drug repository program, each recipient must sign a form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code.

(D) Donor forms must be maintained for a minimum of three years in a readily retrievable manner by the repository program.

(E) Recipient forms must be maintained for a minimum of three years in a readily retrievable manner by the repository program.

(F) A prescriber must document the distribution of a personally furnished donated repository program drug to the prescriber's patient pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code and a pharmacy must document the dispensing of a donated repository program drug pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code. Such records must indicate that the drug distributed to a patient was from a repository program. If recipient forms are used with each dispensing or personal furnishing, this information may be documented on the recipient form.

Rule 4729:5-10-07 | ~~Record keeping,~~ Occasional sales and handling fee.

NOTE: Since more than 50% of the rule is being deleted, the rule will be repealed and replaced starting with the new text in proposed paragraph (A).

~~(A) Donor forms must be maintained for a minimum of three years in a readily retrievable manner by a terminal distributor of dangerous drugs, a distributor of dangerous drugs, or an institutional facility.~~

~~(B) Recipient forms must be maintained for a minimum of three years in a readily retrievable manner by a pharmacy, hospital, or nonprofit clinic.~~

~~(C) An invoice must be created by the donor location, which includes a terminal distributor of dangerous drugs, a distributor of dangerous drugs, or an institutional facility where the donor resides. The invoice must include the following information:~~

~~(1) The name and address of the donor location.~~

~~(2) The brand name or generic name of the drug donated and either the name of the manufacturer or the national drug code number (NDC#).~~

~~(3) The strength of the drug.~~

~~(4) The quantity of the drug.~~

~~(5) The date the drug was sent to the pharmacy, hospital, or nonprofit clinic.~~

~~(6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic.~~

~~(D) A prescriber must document the distribution of a personally furnished donated repository program drug to the prescriber's patient pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code and a pharmacy must document the dispensing of a donated repository program drug pursuant to the applicable record keeping rules of division 4729:5 of the Administrative Code. Such records must indicate that the drug distributed to a patient was from a repository program. If recipient forms are used with each dispensing or personal furnishing, this information may be documented on the recipient form.~~

~~(E) A copy of the invoice must be maintained for a minimum of three years in a readily retrievable manner by both the donor location, which includes a terminal distributor of dangerous drugs, a distributor of dangerous drugs, or an institutional facility, and the recipient location, which includes a pharmacy, hospital, or nonprofit clinic.~~

(~~**F**~~**A**) A pharmacy, hospital, or nonprofit clinic may charge the recipient of a donated drug a handling fee up to twenty dollars to cover restocking and dispensing costs. If a drug repository program chooses to charge a handling fee, then the fees collected in any given year shall not exceed the program's total restocking and dispensing costs for that given year.

(B) A charitable pharmacy, hospital, or nonprofit clinic that operates a drug repository program may conduct occasional sales at wholesale of drugs that have been donated or given to the program if all of the following apply:

(1) The receiving location is a charitable pharmacy, hospital, or nonprofit clinic that operates a drug repository program in this state or an entity participating in a drug repository program operated by another state subject to the laws of that state;

(2) The seller maintains a record of or sale that shall contain the name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, the date of transfer or sale;

(3) The seller provides a copy of the record of sale as outlined in this paragraph to the receiver; and

(4) The seller and receiver maintain a record of the sale for three years from the date of creation in a readily retrievable manner.

Rule 4729:5-3-09 | Occasional sale and drug transfers.

(A) The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a commercially manufactured dangerous drug to a person licensed in accordance with section 4729.52 of the Revised Code, terminal distributor of dangerous drugs or any entity or person exempted from licensure as a terminal distributor of dangerous drugs by **any of the following** ~~either~~:

(1) A pharmacy licensed as a terminal distributor of dangerous drugs; ~~or~~

(2) A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only as authorized in section 4729.51 of the Revised Code~~.~~**; or**

(3) A drug repository program pursuant to rule 4729:5-10-07 of the Administrative Code.

(B) The dosage units of all dangerous drugs distributed by the pharmacy pursuant to this rule shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year.

(C) The limits set forth in this rule do not apply to the following:

(1) A licensed terminal distributor of dangerous drugs as described in paragraph (A)(2) of this rule; ~~and~~

(2) Pharmacies that are also licensed to conduct sales of dangerous drugs in accordance with section 4729.52 of the Revised Code~~.~~**; and**

(3) Drug repository programs pursuant to rule 4729:5-10-07 of the Administrative Code.

(D) The requirements of this rule do not apply to the transfer of dangerous drugs pursuant to paragraph (E) of this rule.

(E) 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.

(F) Occasional sales by a licensed terminal distributor shall comply with the reporting requirements set forth in division 4729:8 of the Administrative Code.

(G) "Drug shortage," with respect to an occasional sale, means a drug on the United States food and drug administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.