**TITLE 856 INDIANA BOARD OF PHARMACY**

**Emergency Rule**
LSA Document #12-435(E)

DIGEST

Temporarily adds guidelines and definitions to establish standards that allow pharmacies and other health care providers to run ongoing prescription drug take back programs for return and destruction of unused and unwanted medications consistent with the requirements of the Indiana Code as added by P.L.119-2011, SECTION 4. Statutory authority: IC 25-26-23-2. Effective July 23, 2012.

SECTION 1. **(a) This document establishes standards applicable to any:**
**(1) prescription drug take back program;**
**(2) entities that may participate in prescription drug take back programs; and**
**(3) guidelines and standards for prescription drug take back programs.**

**(b) This document and these guidelines are not intended to prohibit or otherwise curtail activities taking place through existing take back programs or events being run by statutorily authorized law enforcement agencies or municipal (or state and federal) solid waste programs.**

SECTION 2. **The following definitions are adopted for use in this document:**
**(1) All terms which are defined in IC 25-26-13-2, IC 16-42-19, and IC 16-42-20 shall have the same meanings as they are so defined when used in the rules and regulations of the Indiana board of pharmacy found in Article 7 of Title 856 of the Indiana Administrative Code.**
**(2) As used in this document, "board" or "Board" means the Indiana board of pharmacy established under IC 25-26-13-3.**
**(3) As used in this document, "Take Back Program" refers to a program or service intended to collect unused or unwanted medication from consumers or patients, and established and run under the guidelines and standards as laid out in this document.**
**(4) As used in this document and as authorized by IC 25-26-23-2, "return of unused medication" refers to medications that are collected under the auspices of an eligible Take Back Program as established under this document. This does not include medication that is returned for credit, resale, and redistribution. This also does not include drugs that are listed in Schedule 1 controlled substances under Indiana law.**
**(5) For purposes of this document, "entities" shall mean those licensed facilities that are eligible to run a legal Take Back Program under Indiana law. Licensed facilities included in this definition are all pharmacies licensed under IC 25-26 listed as active and in good standing and health care facilities licensed under IC 16-28 listed as active and in good standing.**
**(6) As used in this document, "vendor" means a contracted party that is providing services to the entity that is running a Take Back Program established under this document. A vendor can perform any of the services that are part of the program so long as those services are defined in the contract established between that vendor and the entity. The vendor assumes the liabilities and responsibilities as established in the contract and policies and procedures that apply in each relationship.**
**(7) For purposes of this document, "unused or unwanted medication" could mean all drugs that fall under the definition of drug as defined in IC 16-42-19. Entities that run Take Back Programs may further define or limit what drugs they are capable or willing to accept for destruction purposes. They are not required or mandated to take all drugs in order to maintain eligibility as a Take Back Program.**
**(8) As used in this document, "drug storage device" means the device in which the returned prescription drugs are stored after return by the consumer and before disposal.**
**(9) As used in this document, "drug return receptacle" means the receptacle into which the consumer places the returned prescription drugs, whether or not it is the drug storage device.**

SECTION 3. **Responsibilities of entities who accept unused or unwanted medications:**
**(1) Entities that run a Take Back Program must have licensed personnel that directly manage and have oversight for implementation and the day-to-day activities of the program and services. The individual responsible for managing the program or services must have an active and in good standing license issued by the Indiana professional licensing agency under IC 25.**
**(2) Entities that run a Take Back Program must have documented policies and procedures that address all the requirements of IC 25-26-23 and this document.**

**(3) Entities that run a Take Back Program must maintain a documented contract that provides for the roles and responsibilities of each party performing services related to transportation, destruction, and security, and that is available for review by the board. This SECTION does not require that the contract or services be approved by the board and does not require a contract where the entity is eligible to perform this services independent of a third party vendor.**

**(4) The ultimate responsibility for management of the vendor relationship falls to the licensed entity that is running the Take Back Program. Any issues of liability, indemnification, or responsibility on the vendor's part should be addressed in the contractual relationship.**

**(5) Unused or unwanted medications collected by an entity running a Take Back Program shall not be returned to saleable inventory nor made available for subsequent relabeling and redispensing unless otherwise permitted by applicable law (see IC 25-26-13-25).**

SECTION 4. **(a) Policy regarding record keeping. Requirement to keep records. Entities that engage in a Take Back Program shall be required to keep a record of the following:**

**(1) Policies and procedures.**

**(2) Personnel involved with or who have access to returned medications.**

**(3) Dates when medications were collected by the party responsible for destruction; and**

**(4) Personnel responsible for destruction, transportation, and security.**

**This information may be maintained in conjunction or as part of the policies and procedures being utilized by the entity running the Take Back Program.**

**(b) A proper record validation process must include a documented signature and audit trail that includes review and/or witness by two (2) separate individuals, both of which are employed by the entity, one (1) of which must be a licensed individual and will ultimately be responsible for ensuring that drug storage devices are properly sealed, secured, and disposed of, either by means provided by the participating pharmacy or the contracted party. The intent of this process is to ensure safeguards against diversion, misuse, and/or improper disposal. Additional details on specific policies and procedures are provided in the section concerning access and security.**

**(c) Model record keeping logs may be obtained from the board. While an entity is not required to use these forms, the board provides them as guidance for participating entities as models of an acceptable record keeping mechanism.**

**(d) Access to records. Records shall be made available for review to the board, board personnel, and other entities as may be determined by the board.**

**(e) In instances where an entity that runs a Take Back Program is capable of maintaining records in an electronic format, including any logs, receipts, or other records that might be required under this document, those records may be maintained in an electronic format. However, if maintained electronically, those records must be accessible, readily retrievable, secure (similar to how other pharmacy records are maintained), be backed up in the event of disaster, and available for board inspection upon request. This SECTION is intended to apply to all aspects of this document.**

**(f) Record retention requirements. Entities that engage in Take Back Programs are required to maintain the relevant records for a period of two (2) years from the date of destruction or delivery/shipment to the party responsible for destruction.**

SECTION 5. **Requirement for destruction:**

**(1) Drugs collected by a Take Back Program being implemented under this document are required to be destroyed and may not be resold, reused, redistributed, or otherwise interfered with in any way that might present an opportunity for harm, misuse, or diversion.**

**(2) Required time period for destruction. The frequency of drug destruction can be determined by the entity that runs the Take Back Programs as determined by need and volume, but destruction must occur at least on a quarterly basis to ensure drugs are not stored indefinitely and do not pose a threat to public health and safety.**

**(3) Acceptable methods of destruction. Entities that run Take Back Programs must use a means of destruction that results in incineration of the drugs ensuring that those destroyed drugs do not pose a risk to public health and safety and ensure that the drugs or drug remains do not pose an unacceptable level of risk or harm to water systems or landfills. Entities that run Take Back Programs that utilize their own means to destroy collected drugs must be able to evidence that their incinerator or destruction method is capable of safely destroying drugs and rendering them harmless to the**

**public.**

**(4) Entities that do not destroy the collected drugs on-site or within their own company must have a contract in place with a vendor that will manage the destruction. Such contract must include documented policies and procedures that address destruction. Those policies and procedures must at least include a discussion of the transportation, security, and destruction means which would otherwise comply with section 1. A system of receipt and/or logs that evidence each destruction, the total weight of the drugs destroyed (not quantity or type), and the date it occurred must be included as a part of this contract.**

**(5) Entities that wish to utilize a different method of destruction not otherwise listed or discussed above, may petition the board to approve another documented and proven destruction process. Such process must include documented policies and procedures that at least address the following issues:**

**(A) public health and safety;**

**(B) diversion; and**

**(C) environmental hazards.**

SECTION 6. **Privacy protocols and safeguards:**

**(1) Privacy policy generally. An entity that runs a Take Back Program shall be responsible for ensuring that their Take Back Program does not violate the privacy rights of patients and customers and is consistent with what is otherwise required by state and federal law for protecting the privacy rights of patients.**

**(2) If an entity running a Take Back Program contracts with vendors to assist in accomplishing components of their programs, the entities shall ensure that privacy rights are protected and addressed in their contract with appropriate indemnification and liability provisions to ensure that those privacy rights are protected.**

**(3) Requirement to establish privacy protocols and policies. An entity that runs a Take Back Program shall be responsible for providing documented policies and procedures that outline how they protect patient privacy consistent with state and federal laws. This policy shall be documented and be a part of the larger set of policies and procedures made available for board inspection.**

**(4) An entity shall provide privacy training to all staff involved with a Take Back Program and have documentation of said training available for board inspection.**

**(5) Requirement to provide notice to patients or customers. An entity that runs a Take Back Program is required to provide a notice to consumers and/or patients a copy of their privacy policy and how they protect consumers' private health information from being disclosed. The notice and policy should include a statement to how the drugs are collected, the security safeguards, and the method of destruction. This notice may be posted or provided in any one (1) of the following ways:**

**(A) pamphlets or leaflets that describe the policy available to the public upon request;**

**(B) a notice posted on the box or device where the drugs are collected; or**

**(C) a notice posted in the area where take back occurs and is reasonably accessible to view by patients and other consumers.**

SECTION 7. **Security standards:**

**(1) Requirement for a storage device or drug return receptacle. An acceptable storage device or drug return receptacle will meet the following criteria:**

**(A) does not allow for the removal of contents except by authorized personnel;**

**(B) is secured in a manner that will only allow authorized personnel to remove the contents of the container; and**

**(C) utilizes a design that is tamper resistant and will not represent a risk to patient or customer safety.**

**(2) Proper location of storage device or drug return receptacle. If the storage device is movable, the device and/or receptacle must be located in the pharmacy department and must be capable of being monitored by whatever security features or personnel that pharmacy department utilizes.**

**(3) If the storage device is stationary and secure, than the device and/or receptacle may be located anywhere in the interior of the building housing the pharmacy, but only personnel included within this document and as provided for in the policies and procedures of the entity running the Take Back Program may have access to that storage device or receptacle.**

**(4) Secure method of drop-off. It is not required that licensed personnel physically facilitate the placement of the drugs by the patient or customer into the storage device or receptacle. If done by the patient into a secure device, then no other involvement or documentation need occur. If pharmacy staff is involved in assisting with the drop-off and collection of drugs, the personnel involved (one (1) of which shall be licensed) will witness and document that the drop-off and**

**placement of the drugs into the storage device or receptacle occurred. All that needs to be included in this acknowledgement and documentation is the date and time the drop-off occurred, the names of the personnel that facilitated and witnessed the drop-off, and that the drugs were placed into the appropriate storage device and receptacle for destruction. (The board does not intend that this documentation include the name of the patient, the drugs accepted, or any physical count or inventory of the product.)**

**(5) Access to contents. Only personnel designated in the policies and procedures governing the Take Back Program for each individual entity and program shall have access to remove the storage device(s) from the receptacle where the drugs are collected or to transfer the device to the party performing the destruction services (be that party internal or external). When the device is accessed for removal of the storage device to transport or facilitate the contents for destruction, the process will involve two (2) personnel for witness and acknowledgment purposes, one (1) of which will be a licensed member of the pharmacy staff.**

**(6) Requirement for documented policies and procedures. Any entity which chooses to run a one-time or ongoing Take Back Program is required to maintain documented policies and procedures that will address all the requirements of this document.**

**(7) Maintenance, monitoring, and emptying. The drug receptacle into which drugs are placed or returned must be maintained in such a way as to prevent unintended access, diversion, or harm to the personnel or patients/customers that might use or be in the vicinity of the receptacle.**

**(8) The storage device and drug receptacle should be monitored in accordance with the security provisions discussed in this document. The level of monitoring should correspond to the location and permanence of the device and should be focused on reasonably preventing diversion, inappropriate access, and harm to patients and/or customers. In no instance should the receptacle used to facilitate a Take Back Program be located outside the facility or be left in an area incapable of being monitored via security cameras or live personnel.**

**(9) Emptying the device and receptacle shall be done in accordance with the provisions provided above and utilize a log or receipt schedule capable of being audited and maintained as a part of the program's record retention requirements.**

**(10) In the event that the device being used to accept returned medications is full or exceeds capacity, personnel involved in managing the Take Back Program may remove the contents to the extent necessary to secure the returned medications until such time as personnel can arrange for destruction. Whatever contents are removed must be secured in an area separate from merchandise or prescriptions available for sale to customers or patients. Any additional storage area shall also only be accessible to the personnel named in this document and specified in the entity's policies and procedures. Additionally, if an entity maintains additional storage space, this process and space shall be addressed in their policies and procedures (for example, referenced as "Overflow Policy").**

**(11) Requirement for notice or signage of acceptable returns. If an entity engaged in a Drug Take Back Program chooses to limit those drugs which are acceptable for return under that program, such limitations shall be clearly and conspicuously placed on or near the drug receptacle in plain view of the patient/customer returning prescription drugs.**

SECTION 8. **Transportation standards for transporting returned drugs:**

**(1) Use of a contracted carrier. An entity engaged in a Drug Take Back Program which utilizes a vendor for any part of the return and disposal process, such entity shall cause the vendor to sign and adhere to a written contract detailing the relationship between the entity and the vendor, including, but not limited to, the duties, processes, and responsibilities of both the entity and the vendor.**

**(2) It is acceptable for entities (or their vendors) that run Take Back Programs to utilize a common carrier, such as, but not limited to, FedEx, the United States Postal Service, and UPS, that are known carriers that have implemented security and privacy protocols and currently used as part of the wholesale or mail order drug supply chain.**

**(3) Entities or vendors that run Take Back Programs may also utilize entities licensed and accredited as wholesale distributors or reverse distributors under Ind. Code § 25-26-14 to the extent those distributors are capable of providing the destruction and/or transportation services that satisfy the criteria outlined in this document.**

**(4) Minimum standards. The following minimum standards shall apply to the transportation solutions utilized by entities that run Take Back Program or the contracted provider they use:**

**(A) an appropriate level of security that protects against diversion;**

**(B) insurance and liability coverage similar to that maintained by common carriers or reverse distributors;**

**(C) does not utilize a vehicle or mode of transportation that is primarily used for personal nonbusiness uses; and**

**(D) the minimum level of driver licensure required by the state to operate a commercial vehicle for business purposes.**

**(5) Compliance with state and federal laws and regulations. Entities that run Take Back Programs shall comply with applicable state and federal laws and regulations that pertain to transport of prescription drugs for destruction to the extent that they are not addressed in this document.**

SECTION 9. **Liability and immunity for entities operating a Take Back Program. Liability and immunity defined. Any person or entity which exercises reasonable care in collecting dispensed drugs or devices for disposal pursuant to this SECTION shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.**

SECTION 10. This document expires 90 days from the effective date on which it was filed.

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