



Technical Bulletin #18-008
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Pharmacies and the Use of Key Boxes

Referenced Codes and Standards: R.C. § 4729.27
R.C. § 4729.55(B)
O.A.C. § 1301:7-7-5(F)(1); O.F.C. § 506.1
O.A.C. § 4729-9-11(A)(2)(d)
O.A.C. § 4729-9-11(A)(3)

The Ohio Department of Commerce, Division of State Fire Marshal (SFM) has been asked if Ohio Fire Code (O.F.C.) provisions allow fire code officials to require the installation of key boxes at pharmacy locations. Although the O.F.C. does allow fire code officials to require the installation of key boxes at certain locations, the answer to whether or not they can be required for a building that contains a pharmacy depends on how the pharmacy is physically set up.

O.F.C. section 506 does provide, in part:

506.1 Where required. Where access to or within a structure or an area is restricted because of secured openings or where immediate access is necessary for life-saving or fire-fighting purposes, the fire code official is authorized to require a key box to be installed in an approved location.

However, other Ohio statutory requirements set forth rules specifically regarding pharmacies and how they must be secured.

The Ohio Revised Code (O.R.C.) states a pharmacist “shall be personally in full and actual charge of the pharmacy” and, for licensure purposes, must demonstrate they will “maintain supervision and control over the possession and custody of dangerous drugs.” See O.R.C. sections 4729.27 and 4729.55(B), respectively. The Ohio Administrative Code (O.A.C.) provides “only a pharmacist may have access to the prescription department or stock of dangerous drugs or assume responsibility for the security of dangerous drugs.” See O.A.C. section 4729-9-11(A)(2)(d). The O.A.C. further states “no person may be within the physical confines of the area designated for the dispensing, compounding, and storage of dangerous drugs unless under the personal supervision of a pharmacist.” O.A.C. section 4729-9-11(A)(3).

These provisions clearly state a pharmacist must be in actual control of the location at all times and only the pharmacist can have access to the area in a pharmacy where dangerous drugs are stored or kept. There are no exceptions to these provisions for emergency response personnel. Therefore, even though the O.F.C. states fire code officials are authorized to require a key box to be installed to gain entry to secured locations for life-saving and fire-fighting purposes, the O.F.C. cannot be construed in a way that would frustrate the more specific security requirements for pharmacy locations.

If keys were placed in a key box and fire officials could use those keys to access the pharmacy or that portion of the pharmacy where the dangerous drugs are kept, the intent and purpose of the above pharmacy security provisions would be circumvented. This is not permissible. For example, if a pharmacy is located in a freestanding building containing only the pharmacy, a key box could not be required since access would give fire officials access to that portion of the pharmacy that must be secured and must be controlled by the pharmacist. This is particularly true because such access would generally be for a time when the pharmacist would not be on the premises. Likewise, if a pharmacy is located in a strip mall with its own dedicated entrance, the fire code official could not require a key box for access to the pharmacy.

However, if a pharmacy is located within a portion of a larger occupancy, a key box could be required for access to the larger occupancy itself. But, that portion of the store where the pharmacy is located and dangerous drugs are stored would still need to remain separately secured. For example, many grocery stores and superstores, such as Kroger, Walmart, Meijer, Walgreens, CVS, etc., have pharmacy areas inside the store. In these types of locations, a fire code official could require a key box on the outside of the store (i.e., for access into the Kroger or the Meijer, etc.). In this instance, though, the pharmacy/pharmacy area where dangerous drugs are stored would have to remain locked and secured from entry even by first responders. The fire code official cannot require keys or access to that portion of the store that constitutes the pharmacy. Key box access to the separately secured part of the premises that houses the pharmacy would not be allowed.

To reiterate, if a pharmacy is located within a portion of a larger store, O.F.C. provisions do permit a fire code official to require the use of a key box on the exterior building for the storage of keys that will allow general entry to the store itself. However, the fire code official cannot require a key box for or keys to the pharmacy area within that store. Likewise, the fire code official cannot require a key box for or keys to a pharmacy when the pharmacy is located in its own dedicated occupancy or structure.

For additional resources on this topic, please contact the State Board of Pharmacy (<https://www.pharmacy.ohio.gov/contact>) or see its Sept. 28, 2018 guidance document entitled ***“Use of Key Boxes by First Responders to Obtain Access to a Pharmacy,”*** which can be found [here](#).

This Technical Bulletin is intended only as an informational tool. Affected individuals and code enforcement officials should consult their legal advisor to determine specific requirements, their applicability, and courses of action that should be taken to ensure compliance with all applicable requirements and standards.

OHIO REVISED CODE

CHAPTER 4729: PHARMACISTS; DANGEROUS DRUGS

Sec. 4729.27 Pharmacist must be in full and actual charge of pharmacy.

A person not a pharmacist, who owns, manages, or conducts a pharmacy, shall employ a pharmacist to be in full and actual charge of such pharmacy. Any pharmacist who owns, manages, or conducts a pharmacy shall be personally in full and actual charge of the pharmacy, or shall employ another pharmacist to be in full and actual charge of the pharmacy.

Sec. 4729.55 Terminal distributor license requirements.

No license shall be issued to an applicant for licensure as a terminal distributor of dangerous drugs unless the applicant has furnished satisfactory proof to the state board of pharmacy that:

(B) A pharmacist, licensed health professional authorized to prescribe drugs, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant.

OHIO ADMINISTRATIVE CODE

Chapter 1301:7-7 Division of State Fire Marshal - Ohio Fire Code

1301:7-7-05 Fire Service Features Sec. 506 Key Boxes

506.1 Where required. Where access to or within a structure or an area is restricted because of secured openings or where immediate access is necessary for life-saving or fire-fighting purposes, the fire code official is authorized to require a key box to be installed in an approved location. The key box shall be of an approved type listed in accordance with UL 1037 as listed in rule 1301:7-7-80 of the Administrative Code, and shall contain keys to gain necessary access as required by the fire code official.

Chapter 4729-9 State Board of Pharmacy - Dangerous Drugs

Sec. 4729-9-11 Security and control of dangerous drugs.

A pharmacist, prescriber, and responsible person pursuant to rule 4729-5-11 of the Administrative Code shall provide supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws as required in section 4729.55 of the Revised Code, by the following procedures:

(A) In a pharmacy:

(1) Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion;

(2) Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:

(a) The prescription department or stock of dangerous drugs must be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time the pharmacist is not present. Such a barrier, before being put into use, must be approved by the state board of pharmacy.

(b) The prescription department must contain all dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist.

(c) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the prescription department.

(d) Except as provided in rule 4729-17-03 of the Administrative Code, only a pharmacist may have access to the prescription department or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, exempt narcotics, hypodermics, poisons, and any other item or product that requires the personal supervision or sale by a pharmacist.

(e) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product that requires the personal supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the prescription department is closed.

(f) New or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.

(g) If a pharmacy utilizes a board approved delivery system that securely stores and releases a dispensed prescription drug to a patient the pharmacy must be open for business and a pharmacist must be physically present and available for consultation, unless otherwise authorized by the board.

(h) Any designated area outside the prescription department at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, exempt narcotics, hypodermics, poisons, records relating to the distribution of dangerous drugs except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:

(i) The designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. Such a barrier, before being put into use, must be approved by the state board of pharmacy.

(ii) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy.

(iii) Authorized personnel may have access if there is on-site supervision by a pharmacist.

(3) Areas designated for the dispensing, compounding, and storage of dangerous drugs shall meet the security requirements in rule 4729-9-05 of the Administrative Code. No person may be within the physical confines of the area designated for the dispensing, compounding, and storage of dangerous drugs unless under the personal supervision of a pharmacist.

(B) In other terminal distributors of dangerous drugs, including but not limited to, emergency medical services pursuant to division (C) of section 4729.54 of the Revised Code, first-aid departments pursuant to rule 4729-9-03 of the Administrative Code, approved laboratories pursuant to paragraph (D) of rule 4729-13-01 of the Administrative Code, and animal shelters

pursuant to paragraph (A) of rule 4729-14-01 of the Administrative Code, shall comply with all of the following:

(1) Dangerous drugs, exempt narcotics, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, hypodermics and poisons must be stored in an area secured by either a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access;

(2) All records relating to the dispensing, distribution, personal furnishing and sale of dangerous drugs shall be maintained on-site under appropriate supervision and control to restrict unauthorized access.

(3) Paragraph (B)(1) of this rule does not apply to hypodermics at veterinary facilities if all of the following conditions are met:

(a) During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access;

(b) During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections.

(C) A pharmacist, prescriber, or responsible person for a terminal distributor of dangerous drugs license pursuant to rule 4729-5-11 of the Administrative Code who has signed as being responsible for a terminal distributor of dangerous drugs license is responsible to monitor for suspicious orders, unusual usage, or questionable disposition of dangerous drugs.

(D) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board. Records relating to the distribution of dangerous drugs shall be maintained in a secure manner that ensures the integrity of the information.

(E) Only individuals authorized under state laws or rules shall have unsupervised access to dangerous drugs.