



Storage of Records Outside of the Pharmacy Department

Updated 8-19-2016

Effective August 15, 2016, rule 4729-9-11 states:

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 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:

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

For questions regarding the requirements of this rule, please review the guidance document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting:

<http://www.pharmacy.ohio.gov/contact.aspx>.

Q1) I need additional time to secure records not stored within the pharmacy department. May I request an extension from the Board?

The Board has issued the following resolution to address this issue:

R-2017-054: The Board has received a number of inquiries from pharmacies that are currently storing patient records on-site but that do not currently meet the requirements set forth in rule 4729-9-11.

In order to assist pharmacies in meeting this specific requirement, the Board hereby grants an extension of this provision until February 1, 2017. Pharmacies must ensure that they meet this requirement by February 1, 2017 and should begin the process of securing



their on-site records storage now to allow time for approval by their local compliance agent or specialist. If a pharmacy cannot meet the February 1, 2017 deadline, they can receive a six-month extension (no later than August 1, 2017) if they submit a plan to the Board indicating how they will meet the requirements of the rule.

Adopted August 8, 2016

Q2) How to I obtain approval by the Board for records stored outside of the pharmacy department?

To obtain approval for your physical barrier and/or an electronic barrier for your records, you should contact your local compliance agent or specialist. If you do not know the name of your agent or specialist, you may call the Board office (614-466-4143) and ask to speak to the compliance department.

Q3) Am I permitted to store records off-site?

Yes. Pursuant to rules [4729-9-14](#) and [4729-9-22](#) of the Administrative Code, off-site storage is permitted with approval by the Board. A request form can be accessed here: <http://www.pharmacy.ohio.gov/records>.

Q4) Does storing my records on a high shelf or using tamper evident tape meet the security requirements for records stored outside of the prescription department?

No. The rule states the designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. It also states that the barrier, prior to being put into use, must be approved by Board of Pharmacy.

Q5) What constitutes the prescription department?

The prescription department is typically the confines of the pharmacy whereby an existing physical and/or electronic barrier to detect unauthorized entry currently exists. Areas outside of the prescription department usually consist of stock rooms (in a retail setting) and other areas of the establishment that may be readily accessible to individuals that are not authorized to have access to patient records pursuant to rule 4729-9-11.