



Bear Lake - Near Jackson Hole, WY

PIC QUESTION OF THE WEEK: 7/18/11

Q: What are Pennsylvania's regulations regarding the return of prescription medications to the pharmacy?

A: In October, 2003, the Pennsylvania State Board of Pharmacy adopted its current regulations on returning unused medications to stock in the community pharmacy. This regulation is incorporated into the Pharmacy Act and does not allow drugs to be returned to stock and subsequently dispensed after they have been distributed from the pharmacy. However, after considerable confusion and discussion, the Board published a notice in 2005 that served to expand upon and clarify the regulation. The Board stated that redistribution of returned medication is permissible under the following circumstances:

- The medication is in its original *sealed* container
- The container displays the name, lot number, and expiration date of the medication
- The manufacturer's original label is intact

It is important to note that the pharmacist is ultimately responsible for ensuring that the returned medication is free of alteration and has been properly stored while in the patient's possession. This is problematic because verification of this information is based only on patient testimony. Under no circumstances should already used/unsealed containers of prescription medication be accepted AND re-dispensed. The law does not prohibit *accepting* returned medication and providing a monetary refund; however, the medication cannot be returned to stock unless the above criteria are met. Regardless of the decision to return the medication to stock, the claim to the third-party payer should be reversed. Medications that are not picked up by the patient or delivered to them are subject to different rules and regulations that generally permit varying time limits for redistribution.

Relatively similar guidelines exist in some states such as Florida and Kentucky. Many states completely forbid the return of prescription medications to stock after they have left the premises of the pharmacy. The Food and Drug Administration (FDA) supports these states on the basis that their regulations are in the interest of public safety. For additional information on these topics, the reader is encouraged to visit the Pennsylvania Code or State Board of Pharmacy websites.

References:

- Food and Drug Administration. CPG Sec. 460.300. Return of Unused Prescription Drugs to Pharmacy Stock. <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074399.htm>. Accessed July 13, 2011.
- Pennsylvania Code. 27.102 Return to Stock of Undelivered Medication - Statement of policy. <http://www.pacode.com/secure/data/049/chapter27/s27.102.html>. Accessed July 13, 2011.
- Pennsylvania State Board of Pharmacy. Special Notice: Return to stock of unused drugs. *Pennsylvania State Board of Pharmacy Newsletter*. 2005(Fall):4.

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