

**Eight Important Principles
For Managing Prescription Medications
In the Athletic Training Room**

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Over the last ten years, the use of prescription and over the counter medications in the athletic training room has increased exponentially. This is due, in part, to new medications being introduced to the marketplace specifically designed for sports medicine, an increased economy affording a wider variety of services for athletes, more physicians specializing in team sports and older athletic training rooms being updated, remodeled and/or rebuilt to include physician offices, exam rooms and dispensing areas. These increases in drug usage should be incrementally reflected in management systems for ordering, storage, dispensing and administration of medications. There have been many changes over the last ten years to the state and federal regulations concerning the handling of medications for team physicians wishing to administer or dispense medication in the athletic training room (Table 1).

The purpose of this article is to suggest some general principles or guidelines that every professional or college/university sports medicine department should add to their existing policies and programs. These suggestions should be considered minimum criteria; an aggressive program could incorporate up to ten times this number.

The Problem

There have been many reports and allegations from across the country against professional teams and colleges/universities, with regards to the inappropriate handling of prescription and over-the-counter medications. State and federal rules and regulations have been violated. In some cases, arrests, fines and citations have been levied. In most cases, those involved have lost their jobs or had their position dramatically changed.

If you are currently working as a certified athletic trainer, athletic training student, physical therapist or team physician in an athletic training room (also referred to as an athletic training medical office), it is vital that your facility implement policies and procedures to help manage the handling of prescription medications. State and federal regulations are applicable whether or not the facility has an inventory of one medication or an entire team physician pharmacy.

According to the Kahanov, et al. 2003 study investigating the adherence to drug dispensation and administration laws and guidelines for collegiate athletic training rooms, we have not seen an improvement in the handling of medications at the university and college level over the last ten years.¹ This may be due to the fact that quite often the "old guard" is teaching the "new guard" without implementing many of the new regulations approved by our government on an ongoing basis. It could be due to the fact we are not properly educating and informing our athletic and medical directors, we are not teaching the fundamentals in school to our future certified

athletic trainers or the team physicians do not comprehend the full scope of the responsibly placed upon their license. We believe that pushing forward with educating and informing those involved in the management of prescription medications is a primary way to serve our industry.

Eight Principles

We suggest the following eight principles be implemented in universities and colleges across the country as an initial step toward the establishment of practice standards for the management of prescription medications in athletic training rooms.

Develop an Ongoing Revision of a Policy and Procedure Manual (PPM)

The PPM is the first step toward managing prescription and over-the-counter medications. It is used as the “road map” and instruction guide for all athletic trainers, medical staff, and team physicians authorized to assist with the prescription medication management . The PPM should include policies and procedures describing the systems for ordering, receiving, storage, security, dispensing, administering, treating, transportation, disposal, inventory and audit and reconciliation. The PPM should be renewed, reviewed and updated annually, and signed by the athletic director, head team physician, head athletic trainer, and team pharmacist.

Follow Federal Regulations for Controlled Substances

The second principle involves federal law and controlled substances. If controlled substances such as Vicodin[®], Tylenol with codeine[®], Ambien[®], codeine cough syrup, morphine etc., are maintained in the athletic training room for any reason whatsoever, there are specific federal controlled substances regulations to follow. If any team physician orders, stores, receives, administers or dispenses controlled substances, he/she must maintain a separate and unique DEA certificate listing the exact physical address of the location where the controlled substances are stored. In some cases, controlled substances may be stored in the athletic training room, as well as at the game stadium, practice arena or summer/spring camp. This regulation would, in fact, dictate the team physician to maintain multiple certificates. There is a significant difference between the team physician’s current DEA certificate to prescribe and additional certificates for the physician to store controlled substances on site and subsequently dispense and/or administer the medications.

Identify Proper Chain of Command

In most cases, the team physician is not directly employed by the organization or university, he/she generally does not directly employ the certified athletic trainer(s) as part of his/her medical staff, a proper chain of command and communication detailing specific duties of discretionary and non-discretionary decision making must be developed. A list of these duties and responsibilities, delegated to the medical staff and authorized by the team physician, must be signed annually and kept on file for a period of at least three years. Likewise,

additional signature forms for drug usage, audit and reconciliation, pharmacy authorization, HIPPA regulations, in-house treatments, PPM and reconciliation of sample medications should also be signed annually and maintained on file.

Maintain Proper Records

Proper record maintenance is a vital function for any facility choosing to dispense, administer or treat patients with prescription medications. According to federal law, prescription drug records must be kept ready and retrievable for a minimum of three years. The records should include all inventory received; all medications administered, dispensed or used for treatments; a current balance of inventory on hand; and an audit and reconciliation performed on a consistent basis. The reconciliation should be signed and dated by all members of the medical staff involved in the audit. Records should be consistent, legible and complete.

Monitor for Expired or Contaminated Medications

Expired or contaminated medications (whether or not they are over-the-counter, supplements or prescription) must be removed from the general stock. The medications should be immediately quarantined to prevent access by medical staff, athletes or team physicians. A damaged or expired medication should never be dispensed, administered or used for treatments on a patient for any reason. Quarantined medications should be itemized, packed and shipped back to the pharmacy for destruction. Prescription and non-prescription medications should not be disposed of in the athletic training room.

Correct Label Designation

Medications not yet designated for the end user should be listed in the name of the licensed entity (in most cases, this would be the head team physician). The medication label should never be in the team name, certified athletic trainer's name or any other name other than the team physician or end user (athlete). It is a violation of federal law to give a medication to anyone other than to whom it was originally prescribed. If a medication is dispensed to an athlete and subsequently returned, the medication should be placed in quarantine and sent to the team pharmacy for destruction. A general rule is that prescription medications can only go from one licensed entity to another or from a licensed entity to the end user.

Secure Prescription Medications

Prescription medication security is critical to the success of a proper audit and reconciliation. Missing, lost or stolen medications must be acknowledged and dealt with in a consistent and formal manner according to the PPM on file. According to federal law, all prescription medications must be locked and secured at all times. There must be a chain of command designed by the team physician to control keys to the locked medication cabinet. The medications should be stored in a locked and secure cabinet or container inside the team physician office or another room designated solely for medication storage. Other good ideas to implement in your facility are an alarm on the medication cabinet, a perimeter

alarm with central monitoring and re-keying the locks after changes in employment status of those previously authorized access.

Account for Sample Medications

If your athletic training room policy and procedure manual allows sample medications to be brought in by the team physician, there are very specific regulations that must be followed. Sample medications are required to have a receipt and a paper trail leading to where the sample medications came from. When sample medications are received, a log needs to be generated listing all information about the transfer of the sample medication including the lot number, name and strength of medication, quantity, date and name of transferring physician. Another area often overlooked with sample medications is understanding the difference between an administered and a dispensed dose of medication. If enough samples are given to the athlete to exceed a 24 hour therapeutic dose, then dispensing laws come into place which include, labeling, packaging, record keeping, etc. Remember, only a physician can receive, store or administer sample medications.

The concepts of a team pharmacy and team pharmacist are critical to the success of a good prescription drug management program. The best person on your sports medicine staff to help with the policies and procedures, labeling requirements, and related functions is your team pharmacist. Be sure to choose wisely and find a sports pharmacist with experience and expertise in the industry.

Summary

This article should be saved and kept as a reference guide and starting point for your organization to establish internal systems for the management of prescription and over the counter medications in the athletic training room. Medication handling is very serious and worthy of public and media attention, especially when it involves athletes and sports. We urge you to immediately begin to establish a program at your facility. The above guidelines are only a small list of possibilities to be included in your organization's policy and procedure manual.

For more information, please contact the author of this article.
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References

1. Kahanov L, Furst D, Johnson S, Roberts J. Adherence to Drug-Dispensation and Drug-Administration Laws and Guidelines in Collegiate Athletic Training Rooms. *Journal of Athletic Training*. 2003;38(3):252-258.

Table 1. Federal Regulations specific to the management of prescription medications in the athletic training medical facility.

Prescription Drug Marketing Act

- 21 CFR 5.115 - Sample medication control
- 21 CFR 1301.23(1) - DEA certificate required for separate locations
- 21 C.F.R. 1301.75 - Storage of controlled substances
- 21 C.F.R. 1301.44 - DEA certificate readily retrievable
- 21 C.F.R. 1301.90 - Security of personnel for handling of controlled substances
- 21 C.F.R. 1304.4 - Record-keeping requirements for controlled substances
- 21 C.F.R. 1304.02(d) - Defines a physician which prescribes administers and dispenses controlled substances.
- 21 C.F.R. 1304.11-12(b) - Inventory requirements for controlled substances
- 21 C.F.R. 1304.13 - Reconciliation requirements for controlled substances
- 21 C.F.R. 1305.12 - Reporting a theft of a controlled substance
- 21 C.F.R. 1301.92 - Responsibility to report drug diversion

Food, Drug, and Cosmetic Act

- 21 U.S.C. 360(g) - Requirement to utilize a FDA licensed pharmacy repackager
- 21 U.S.C. 353(b)(2) - Labeling of prescription medications

Poison Prevention Packaging Act,

- 15 U.S.C. 1471 - Packaging of controlled substances and prescription medications
- 15 U.S.C. 1473 (b) - Exception to PPPA for prescriber dispensing of non-child safety container.

Federal Controlled Substance Act

- 21 U.S.C., 824(a)(f) - DEA certificate required
- 21 U.S.C. 802(10) - Prescriber dispensing
- 21 U.S.C. 823 (f) - DEA certificate required for separate locations
- 21 U.S.C. 802(10) - Defines a dispensing physician vs. an individual practitioner
- 21 U.S.C. 827[©](1)(A)(B) - Acquisition and Disposition record keeping requirements for individual practitioners dispensing controlled substances.

Bios

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