GUIDELINE 1G
DISPENSING PRESCRIPTION MEDICATION

May 1986 • Revised June 2008

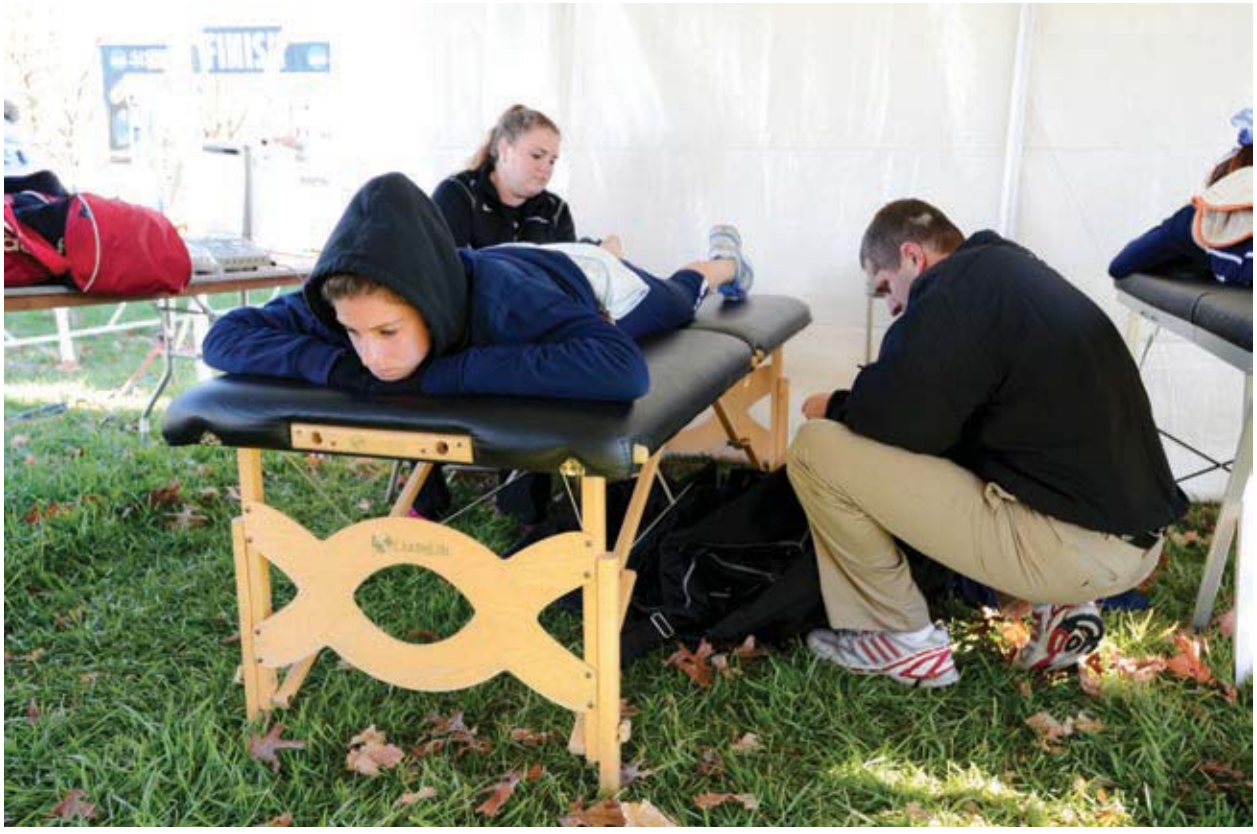
Research sponsored by the NCAA has shown that prescription medications have been provided to student-athletes by individuals other than people legally authorized to dispense such medications. This is an important concern because the improper dispensing of both prescription and nonprescription drugs can lead to serious medical and legal consequences.

Research also has shown that state and federal regulations regarding packaging, labeling, record keeping and storage of medications have been overlooked or disregarded in the dispensing of medications from the athletic training facility. Moreover, many states have strict regulations regarding packaging, labeling, record keeping and storage of prescription and nonprescription medications. Athletics departments must be concerned about the risk of harm to the student-athletes when these regulations are not followed.

Administering drugs and dispensing drugs are two separate functions. Administration generally refers to the direct application of a single dose of drug. Dispensing is defined as preparing, packaging and labeling a prescription drug or device for subsequent use by a patient. Physicians **cannot** delegate to athletic trainers the authority for dispensing prescription medications under current medication-dispensing laws, since athletic trainers are not authorized by law to dispense these drugs under any circumstances. The improper delegation of authority by the physician or the dispensing of prescription medications by the athletic trainer (even with permission of the physician) places both parties at risk for legal liability.

If athletics departments choose to provide prescription and/or nonprescription medications, they must comply with the applicable state and federal laws for doing so. It is strongly encouraged that athletics departments and their team physicians work with their on-site or area pharmacists to develop specific policies.

The following items form a minimal framework for an appropriate drug-distribution program in a college-athletics environment. Since there is extreme variability in state laws, it is imperative for each institution to consult with legal counsel in order to be in full compliance.



1. Drug-dispensing practices are subject to and should be in compliance with all state, federal and Drug Enforcement Agency (DEA) regulations. Relevant items include appropriate packaging, labeling, counseling and education, record keeping, and accountability for all drugs dispensed.

2. Certified athletic trainers should not be assigned duties that may be performed only by physicians or pharmacists. A team physician cannot delegate diagnosis, prescription-drug control or prescription-dispensing duties to athletic trainers.

3. Drug-distribution records should be created and maintained where dispensing occurs in accordance with appropriate legal guidelines. The record should be current and easily accessible by appropriate medical personnel.

4. All prescription and over-the-counter (OTC) medications should be stored in designated areas that ensure proper environmental (dry with temperatures between 59 and 86 degrees Fahrenheit) and security conditions.

5. All drug stocks should be examined at regular intervals for removal of any outdated, deteriorated or recalled medications.

6. All emergency and travel kits containing prescription and OTC drugs should be routinely inspected for drug quality and security.

7. Individuals receiving medication should be properly informed about what they are taking and how they should take it. Drug allergies, chronic medical conditions and concurrent medication use should be documented in the student-athlete's medical record and readily retrievable.

8. Follow-up should be performed to be sure student-athletes are complying with the drug regimen and to ensure that drug therapy is effective.

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GUIDELINE 2M
THE USE OF LOCAL ANESTHETICS

June 1992 • Revised June 2004

The use of local injectable anesthetics to treat sports-related injuries in college athletics is primarily left to the discretion of the physician treating the individual, since there is little scientific research on the subject. This guideline provides basic recommendations for the use of these substances, which commonly include lidocaine (Xylocaine), 1 or 2 percent; bupivacaine (Marcaine), 0.25 to 0.50 percent; and mepivacaine (Carbocaine), 3 percent. The following recommendations do not include the use of corticosteroids.

It is recommended that:

1. These agents should be administered only by a qualified clinician who is licensed to perform this procedure and who is familiar with these agents' actions, reactions, interactions and complications. The treating clinician should be well aware of the quantity of these agents that can be safely injected.

2. These agents should only be administered in facilities equipped to handle any allergic reaction, including a cardiopulmonary emergency, which may follow their use.

3. These agents should only be administered when medically justified, when the risk of administration is fully explained to the patient, when the use is not harmful to continued athletics activity and when there is no enhancement of a risk of injury.

The following procedures are not recommended:

1. The use of local anesthetic injections if they jeopardize the ability of the student-athlete to protect himself or herself from injury.

2. The administration of these drugs by anyone other than a qualified clinician licensed to perform this procedure.

3. The use of these drugs in combination with epinephrine or other vasoconstrictor agents in fingers, toes, earlobes and other areas where a decrease in circulation, even if only temporary, could result in significant harm.

GUIDELINE 2N
INJECTABLE CORTICOSTEROIDS IN SPORTS INJURIES

June 1992 • Revised June 2004

Corticosteroids, alone or in combination with local anesthetics, have been used for many years to treat certain sports-related injuries. This guideline is an attempt to identify specific circumstances in which corticosteroids may be appropriate and also to remind both physicians and student-athletes of the inherent dangers associated with their use.

The most common reason for the use of corticosteroids in athletics is the treatment of chronic overuse syndromes such as bursitis, tenosynovitis and muscle origin pain (for example, lateral epicondylitis). They have also been used to try to prevent redevelopment of a ganglion and to reduce keloid scar formation. Rarely is it appropriate to treat acute syndromes such as acromioclavicular (AC) joint separations or hip pointers with a corticosteroid.

There is still much to be learned about the effects of intra-articular, intraligamentous or intratendinous injection of corticosteroids. Researchers have noted reduced synthesis of articular cartilage after corticosteroid administration in both animals and human models. However, a causal relationship between the intra-articular corticosteroid and degeneration of articular cartilage has not been established. Research also has shown that a single intraligamentous or multiple intra-articular injections have the potential to cause significant and long-lasting deterioration in the mechanical properties of ligaments and collagenous tissues in animal models. Finally, studies have shown significant degenerative changes in active animal tendons treated with a corticosteroid as early as 48 hours after injection.

This research provides the basis for the following recommendations regarding the administration of corticosteroids in college-athletics.

It is recommended that:

1. Injectable corticosteroids should be administered only after more conservative treatments, including nonsteroidal anti-inflammatory agents, rest, ice, ultrasound and various treatment modalities, have been exhausted.

2. Only those physicians who are knowledgeable about the chemical makeup, dosage, onset of action, duration and potential toxicity of these agents should administer corticosteroids.

3. These agents should be administered only in facilities that are equipped to deal with allergic reactions, including cardiopulmonary emergencies.

4. Repeated corticosteroid injections at a specific site should be done only after the consequences and benefits of the injections have been thoroughly evaluated.

5. Corticosteroid injections only should be done if a therapeutic effect is medically warranted and the student-athlete is not subject to either short- or long-term significant risk.

6. These agents should only be administered when medically justified, when the risk of administration is fully explained to the student-athlete, when the use is not harmful to continued athletics activity and when there is no enhancement of a risk of injury.

The following procedures are not recommended:

1. Intra-articular injections, particularly in major weight-bearing joints. Intra-articular injections have a potential softening effect on articular cartilage.

2. Intratendinous injections, since such injections have been associated with an increased risk of rupture.

3. Administration of injected corticosteroids immediately before a competition.

4. Administration of corticosteroids in acute trauma.

5. Administration of corticosteroids in infection.

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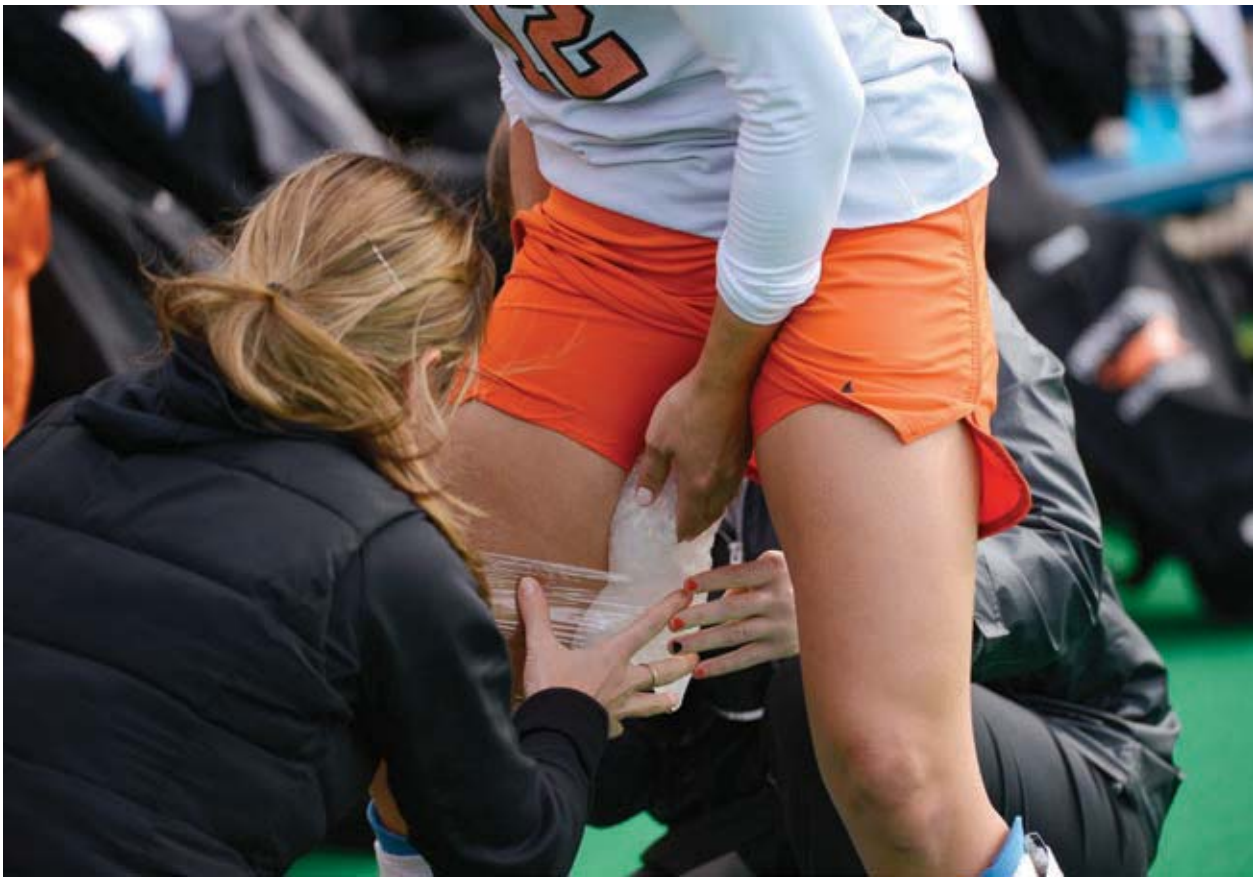

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Consensus Statement:

Managing Prescriptions and Non-Prescription Medication in the Athletic Training Facility

Athletic trainers routinely manage prescription and over-the-counter medication under the supervision, advice and consent of a physician. Establishing recommendations for managing these medications in the athletic training setting is necessary to ensure proper protocols are followed by all involved in the process of storage, packaging, tracking and disseminating both prescription (as ordered by a physician) and OTC medications (per manufacturer directions).

Execution of these recommendations occurs at a facility managed by athletic training staff at an intercollegiate institution, professional sports team facility, international competition center, private clinical setting or related venue.

Brief Overview of Laws

Because individual state laws vary and federal laws may overlap or override a state's statutes, it is essential the athletic trainer is aware of all state and federal laws and regulations that impact the facility.

Federal entities such as the Food and Drug Administration are concerned with appropriate labeling. The Drug Enforcement Agency oversees prescription and controlled substances, while the Occupational Safety and Health Administration provides standards for contamination. State agencies such as the state board of medicine or pharmacy regulate those respective practices and are concerned with the acquisition of medication.

Each governing body has a stake in establishing and enforcing laws pertaining to prescription and OTC medication. It is important to note that a DEA license is required by federal law if there are any controlled substances received, stored, administered or dispensed at the facility. When an athletic trainer travels internationally with medications, the protocol must comply with international laws as well as import/export applications from the FDA and DEA.

Additional information is available at www.fda.gov, www.usdoj.gov/dea/index.htm and www.osha.gov.

Should any athletic trainer have a question about applicable law, s/he should consult counsel (including counsel for his/her team or employer). Lack of knowledge of applicable laws is not acceptable.

Roles and Responsibilities

Successful implementation of these suggestions involves a team effort. This team includes:

- **Athletic Trainer:** The athletic trainer is responsible for the management of all prescription and OTC medications in the athletic training facility. It is possible that athletic training students may be involved in the conveyance of OTC medications.
- **Physician:** Prescription medication may be prescribed by the team or institution's physician or a patient's personal physician.
- **Pharmacist:** Prescription medication for the athletic training facility should be ordered and obtained through a licensed pharmacy or FDA-licensed drug re-packager.
- **Employment Administrator:** The athletic trainer's administrator should conduct an annual review of the athletic training facility's medication procedures.
- **Patient/Athlete:** All patients should be given precise instructions for medication use. Caution should be exercised when providing prescription or OTC medication to a minor patient.
- **Non-Athletic Trainer** (clinical administrators, athletic training students, coaching staff): A written protocol should be kept on file to define the roles of non-credentialed personnel in accessing and dispensing medications.

Description of an Athletic Training Facility

The athletic training facility is defined as any space in which athletic training services are provided. The most common athletic training facilities are the formal athletic training room, the field of practice and ancillary facilities associated with travel (i.e. bus, plane, hotel, etc.).

Prescription and non-prescription medications are to be secured at each of these venues. In formal athletic training facilities, prescription medications are to be secured by a licensed physician according to state, federal and DEA regulations for dispensing (defined as preparing, packaging and labeling). The required components include appropriate packaging, labeling, counseling and education, record keeping, and tracking of all medications. Additionally, prescription medications for use during field treatments are to be secured and accessed only by the licensed physician. As

with field treatment, ancillary facilities provide a unique challenge because the dispensing physician is responsible for securing and dispensing all prescription medications.

Non-prescription medications can be administered (defined as the direct application of a single does of a drug) by the certified athletic trainer under the direction of a physician. Non-prescription medications may include OTCs both oral and topical. All non-prescription medications should be administered only for the conditions for which they are designated. Each individual receiving the medication should be informed of the medication and how s/he should take it. Over-the-counter medications that are stored in traditional areas or travel kits should be inspected routinely for quality, integrity and security.

Recommendations

An athletic training facility is not required to store or distribute prescription and/or OTC medication. However, for those facilities that opt to have medications on hand, suggestions for the management of both prescription and OTC medications are enumerated below. It is suggested that athletic training facilities develop a *Policy and Procedure of Medication Use* document that includes these recommendations for managing medication.

Storage: All OTC and prescription medications should be stored in a locked metal cabinet that is environmentally controlled (dry temperature between 59 – 86° F) and secured by tamper-proof locks. Controlled substances must be stored separately from other medications within the locked cabinet, as must manufacturers' samples. This storage area should be inaccessible to athletes (and other unauthorized individuals), with access (keys) limited to the facility's authorized personnel (certified athletic trainers and physicians).

Verification: Each athletic training facility should have a DEA certificate identifying the physician responsible for the prescription medication on hand. A DEA certificate is not required, but it establishes the athletic training facility as a specific location where the physician conducts his/her practice. For the purpose of receiving, storing, administering or dispensing controlled substances, it is absolutely necessary. A facility may not own medications. Only a licensed individual (physician) or entity (pharmacy) may do so.

Packaging/Labeling: OTC medications should be maintained in single-dose packets, complete with information required by the FDA's 7-point label guideline[1]:

1. The name of the product
2. The name and address of the manufacturer, packer or distributor
3. The net contents of the package
4. The established name of all active ingredients and the quantity of certain other ingredients, whether active or not
5. The name of any habit-forming drug contained in the preparation
6. Cautions and warnings needed to protect the consumer
7. Adequate directions for safe and effective use

Prescription ointments, creams and inhalers should be individualized. Because OTC and prescription medications should not be repacked by a certified athletic trainer, the purchase of unit-of-use packages may be preferred over bulk containers (which may be inappropriate for athletic trainers due to the need to repackage). Repackaging brings concerns of accountability, contamination and legality with federal and state practice acts.

Distribution: All prescription and non-prescription medication should be distributed under the advice and consent of the prescribing physician. In cases where the physician is not accessible, there should be a standard written protocol in place from the physician that an athletic trainer can follow. Treatment protocols with iontophoresis or phonophoresis are commonly drafted to allow athletic trainers to administer topical medications under the direction of a physician. Documentation for the prescribing physician's records should be placed in the individual's chart. Distribution of OTC medication should follow the manufacturer's instructions and guidelines, as well as the protocols established by the facility. This is especially important when minors are involved. If instructed by the physician, the athletic trainer can *assist* with the dispensing process.

Documentation: Distribution of both prescription and OTC medication should be recorded at the athletic training facility to maintain inventory control. Information on the log sheet should include the patient's name, injury/illness, medication given, dose, quantity, lot number (if possible), and the date administered or dispensed. All patient-specific information should be transferred to the individual's chart. Iontophoresis or phonophoresis medications should be prescribed specifically to the patient/athlete receiving treatment and the details should be noted in the individual patient's daily treatment log.

Audit/Inventory Control: Inventory of OTC and prescription medications should be taken on a regular basis to reconcile the amount of medication distributed and ordered with the current amount available, as outlined in the institution's *Policy and Procedure of Medication Use.*

Emergency Medications: Use of medications intended for emergency applications should be reviewed by a physician who advises and consents to the athletic trainer's distribution of such medication. Approved usage of these medications should be outlined in the *Policy and Procedure of Medication Use*, as well as any emergency planning documents (i.e. *Emergency Action Plan*). It is appropriate and legal to use "physician's office stock" (i.e. prescription medication dispensed to the physician's own patients) for treatment of multiple individuals as long as the supply is properly labeled and stored.

Team Travel: Athletic trainers who travel domestically should carry a formulary signed by an advising physician that identifies each OTC and prescription medication managed by the athletic trainer. The formulary should also include the preferred means of communication between the athletic trainer and prescribing physician while travelling. In cases of international travel, the athletic trainer and physician should coordinate medication management with the appropriate government agencies.

Disposal: Expired prescription and OTC medication should be disposed of properly, as recommended by the pharmacist from whom the medication was ordered. It is advisable to avoid simply flushing or removing for personal use any medication, but especially controlled substances. The disposal process should be outlined in the institution's *Policy and Procedure of Medication Use.*

Samples: Sample medication provided to a physician must be distributed only by that physician and not by a certified athletic trainer. Records of acquisition, reconciliation and distribution should be maintained. Samples are not appropriate for travel bags and must be stored separately from other medication.

Samples must be labeled properly for the person for whom they are intended.

Special Considerations

— **Minors**

It is generally accepted that minors are not provided over-the-counter medications without parental consent.

Some colleges and universities have studied the denial of prescription medication for underage students, with the decision to require a note from home to prescribe any type of medication. For instance, Arizona's House Bill 2707 does not allow physicians to prescribe pills to minors without either written or oral permission from a parent.[2]

— **Epi-Pens and Short-Acting Beta-Agonist Inhalers**

These should be prescribed and dispensed by a licensed physician directly to the patient. Appropriate education on use occurs at the time of dispensation from physician and/or pharmacist.

Athletic training facilities that have established protocols for use of such emergency medications under the direct supervision of a physician (see general guidelines above) may allow for administration by an athletic trainer when conditions require. In addition, a DEA certificate is recommended.

— **Other**

Phoresis treatments and topical applications should follow these guidelines:

Athletic trainers may administer medications by phoretic means under the direction of a licensed physician where permitted by law. Stock medications stored on site and used to treat multiple individuals must be properly labeled in the name of the licensed physician responsible for the athlete's medical care. A protocol detailing proper procedures should be maintained on file in the athletic training facility. The administration or use of medications ordered for specific individuals should also be addressed in the *Policy and Procedure of Medication Use* document. In addition a DEA certificate is recommended.

Consequences of Non-Compliance

Consequences for non-compliance with the management and administration of medications in the athletic training facilities range in severity. Both state and federal laws and DEA regulations can be used to determine non-compliance and any penalties or discipline derived thereof. Specific federal regulations include the Prescription Drug Marketing Act 21 CFR; Food, Drug, and Cosmetic Act 21 USC and 15 USC; and the Federal Controlled Substance Act 21 USC. State laws can also dictate the consequences of non-compliance.

Additional consequences beyond state and federal law may be extended through the Board of Certification, Inc., and the state licensure board. This Consensus Statement should not be relied upon as legal advice, but rather as a guideline for best practices and a tool to help avoid foreseeable pitfalls.

Conclusion

Ultimately, the decisions associated with management of prescription medication are up to athletic trainers and physicians, who offer advice and consent to managing medications. These recommendations should not be considered mandates, but rather a template for the athletic trainer to apply to his/her individual setting. A *Policy and Procedure of Medication Use* document may not protect an athletic trainer completely in the event of outside scrutiny associated with medication management, but having a written protocol in place may help ensure that a good faith and meaningful effort to involve all concerned parties has been made.

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Disclaimer

The National Athletic Trainers' Association and the Inter-Association Task Force to Develop Guidelines Regarding Prescription and OTC Medication in the Athletic Training Room advise individuals, schools, athletic training facilities and institutions to carefully and independently consider each of the recommendations. The information contained in the statement is neither exhaustive nor exclusive to all circumstances or individuals. Variables such as institutional human resource guidelines, state or federal statutes, rules, or regulations, as well regional environmental conditions, may impact the relevance and implementation of these recommendations. The NATA and the Inter-Association Task Force advise their members and others to carefully and independently consider each of the recommendations (including the applicability of same to any particular circumstance or individual). The foregoing statement should not be relied upon as an independent basis for care, but rather as a resource available to NATA members or others. Moreover, no opinion is expressed herein regarding the quality of care that adheres to or differs from any of NATA's Position Statements. The NATA and the Inter-Association Task Force reserve the right to rescind or modify their statements at any time.

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

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Eight Important Principles for Managing Prescription Medications in the Athletic Training Room

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.

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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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