DRUG DISPENSING IN ATHLETIC DEPARTMENTS OF COLLEGES AND UNIVERSITIES: A NEW PROPOSAL

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I. INTRODUCTION

The occurrence of illegal dispensing of prescription drugs in athletic departments of colleges and universities appears to be more common than merely isolated occurrences. Nevertheless, neither the National Collegiate Athletic Association (NCAA) nor any other governing body has adopted rules or regulations specifically designed to protect the safety and well-being of those persons receiving prescription drugs from the athletic departments. This paper reviews prescription drug dispensing related problems that have occurred within athletic departments of NCAA member institutions in recent years. This paper presents a proposal for regulating the dispensing of prescription drugs in these situations and details the rationale behind the proposal, based on these situations and federal law.

II. BACKGROUND

In January of 1994 state and federal investigators began a probe into allegations that drugs were being illegally dispensed in the athletic department at the University of Arkansas.[1] The investigators uncovered that athletic trainers and student trainers were dispensing prescription drugs, including Darvocet-N 100® and Tylenol #3® (both controlled substances) without the authorization of a licensed physician, proper labeling, or proper instructions.[2] According to the Drug Enforcement Agency, over 10,000 narcotic doses were purchased by the University of Arkansas between November 1992 and Janu-

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1. Elizabeth Caldwell, *Hunton Cure for Medical, Drug Boards Doesn't Make Changes Sought in Wake of UA Pill Scandal*, ARKANSAS DEMOCRAT-GAZETTE, Feb. 23, 1995, at 1B.

2. *Id.*

ary 1994, but the school could only account for 332 doses.[3] In particular, the situation involved athletic trainers that were purchasing prescription narcotics in bulk packages and then dispensing them to athletes without a doctor's prescription.[4] Two of the Arkansas trainers pleaded guilty to violating the Federal Controlled Substances Act by not maintaining proper narcotic dispensing records and were sanctioned to two years probation.[5]

Besides the two trainers, both the team physician and the University were required to pay fines.[6] However, no other penalties were assessed.[7] Both the Arkansas State Board of Pharmacy and the Arkansas State Board of Medicine stated that the case was not within their jurisdiction.[8] Similarly, the case was outside the Board of Pharmacy's jurisdiction because they are only authorized to penalize persons who are licensed under their authority (such as pharmacists, pharmacies, technicians).[9] The Board of Medicine also declined to exercise jurisdiction.[10] Moreover, the National Collegiate Athletic Association (NCAA) also had no jurisdiction because there were no rules or regulations against the events that occurred and, therefore, they took no action to sanction the university.[11]

The illegal dispensing of drugs at the University of Arkansas was not an isolated incident. In May of 1985 it was alleged that the University of Washington's athletic department was allowing trainers to dispense prescription drugs.[12] Both the University and the Washington State Board of Pharmacy investigated the school's drug dispensing practices and found that licensed physicians were not the sole dispensers of prescription drugs.[13] The executive secretary of the State Board stated that "[n]o state laws were violated, and there were no

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3. Zester Ledd, *Sports Notebook*, HOUSTON CHRONICLE, Jan. 21, 1995, at 10.
4. Mike Rodman, *2 Trainers get Probation, Fine in Hogs Pill Case*, ARKANSAS DEMOCRAT-GAZETTE, Jan. 21, 1995, at 1A.
5. *Id.*
6. *Id.*
7. *Id.*
8. Caldwell, *supra* note 1 at 10.
9. *Id.*
10. *Id.*
11. Rodman, *supra* note 4 at 1A.
12. *Huskies Track Coach is Cleared of Drug Allegations*, L.A. TIMES, July 25, 1985, at 11.
13. *Id.*

problems or harm to anyone because of distribution, but doctors will have to be more closely involved in distributions."[14] The executive secretary also stated that in the future, the drugs must be distributed by doctors or by pharmacists at the direction of a physician.[15]

In December of 1992, the University of Washington was again investigated concerning a number of violations, one of which included the illegal dispensing of drugs by coaches or by trainers.[16] A former football player for the university stated that "[t]here were numerous occasions when this medication [Tylenol #3®] was dispensed to me directly from the trainer with no prescription."[17] Once again, drug dispensing violations were found, but no sanctions were administered by the NCAA.[18]

In another incident of coaches or athletic trainers dispensing prescription drugs, Clemson University coaches were indicted on charges of dispensing prescription drugs illegally.[19] Ultimately, two of them pled guilty.[20] Both the pain killer phenylbutazone and anabolic steroids were dispensed by track and strength training coaches at the university.[21] As in the previous incidents, the persons who distributed the drugs were penalized, but the NCAA did not sanction the member institution for its part in the illegal dispensing of drugs.[22]

At both the University of Arkansas and Clemson University, athletes died while receiving prescription medications from the schools that had not been authorized by a physician.[23] In each case it was not clear whether the drugs ingested were the direct causes of the deaths, but they may very well have compounded the problems that eventually led to the deaths.[24]

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14. *Id.*
15. *Id.*
16. Elliot Almond, *Husky Football: A pattern of Violation?* , L.A. TIMES, Dec. 9, 1992, at C6.
17. *Id.*
18. *Id.*
19. *Jurisprudence*, WASHINGTON POST, March 26, 1985, at D2.
20. *Id.*
21. *Newswire*, L.A. TIMES, January 8, 1985, at 8.
22. *Id.*
23. Richard Harkness, *Death of Football Player Tied to Athletic Department, Drugs*, OTTAWA CITIZEN, July 31, 1995, at D8 (discussing University of Arkansas). *See also Newswire*, *supra* note 21 at 8 (discussing Clemson University).
24. *See* Harkness, *supra* note 23 at D8; *Newswire*, *supra* note 21 at 8.

The above examples of illegal drug dispensing practices in athletic departments do not appear to be isolated incidents. In 1989 an NCAA-funded study uncovered the existence of widespread problems in the dispensing of both prescription and nonprescription drugs in university athletic departments.[25] The study included 30 randomly chosen athletic departments from among 293 Division I schools.[26] The study revealed that student athletes received their prescription drugs from the training room approximately 51% of the time as compared to local pharmacies (19%), student health pharmacies (19%), and physician's offices (11%).[27] These statistics indicate a need for uniformity among NCAA member institutions to protect the health and well-being of the student athlete. The study also revealed the fact that in 77% of the schools studied, prescription drugs were routinely dispensed from the training room.[28] At 70% of the schools studied, the athletic trainers or graduate assistant trainers rather than the team physician, were allowed to dispense medication.[29] By allowing unqualified personnel to dispense prescription drugs, the students' health is compromised due to the fact that unqualified personnel are not knowledgeable enough to safely and effectively dispense medication. Dr. Robert Voy lamented that "[u]nfortunately, it's not the health professionals but coaches or trainers who often serve as sources of drug information in sports circles. And too often they underestimate or understate the dangers that drugs or other performance aids can pose."[30]

The above study also noted problems with drug stock[31] and proper dispensing.[32] Aside from the potential harms associated with allowing unqualified personnel to dispense prescription medication, the act is illegal.[33] Evidence of this was demonstrated in the University of Arkansas and Clemson Uni-

25. Audrey D. St. Jean, *Patient Care Compromised in College Athletic Programs*, AM. J. OF HOSP. PHARM., Vol. 49, July 1992, at 1590, 1590.

26. *Id.*

27. *Id.*

28. *Id.* at 1596.

29. *Id.*

30. John White, *Athletes Substance Abuse Involves More Than Cocaine*, DRUG TOPICS, April 21, 1986, at 50.

31. Expired drugs and drugs that had been recalled.

32. St. Jean, *supra* note 27 at 1596.

33. *Id.* at 1598.

versity cases discussed herein.[34] In each incident individuals were charged, convicted or pled guilty to violations of illegal dispensing of drugs and violating the Controlled Substances Act.[35] Other violations noted in the above study included violations of the Federal Food, Drug and Cosmetic Act ("FDCA").[36] The FDCA requires information such as drug name, drug strength, name of patient, and name of prescriber to appear on the label of the bottle in which the medication is dispensed.[37] Only three of the thirty schools studied met all the requirements of the FDCA.[38]

The NCAA committee on competitive safeguards and medical aspects of sports commissioned the study and were given the results in February of 1992.[39] A copy of the study was sent to the athletic directors at all member institutions.[40] In June of 1992, the committee met and drafted a set of recommendations for the member institutions to follow.[41] These drug dispensing policies for the schools are only recommendations and not requirements.[42]

Dispensing prescription drugs is illegal if done by persons other than those legally authorized to dispense and therefore the student athletes' health is jeopardized by such illicit dispension.[43] Hence, the NCAA should adopt strict regulations to provide for the best interests of the athlete and members of the coaching staff that receive prescription drugs from member institutions. The following proposed regulation addresses many of the problems found in the study funded by the NCAA and provides guidelines for the member institutions to follow aimed at alleviating the problems that have existed.

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34. *See* notes 1-11 *supra* and accompanying text; notes 19-22 *supra* and accompanying text.

35. *See* notes 1-11 *supra* and accompanying text; notes 19-22 *supra* and accompanying text.

36. 21 U.S.C. §353(b)(2).

37. *Id.*

38. St. Jean, *supra* note 27 at 1596.

39. *NCAA-Sponsored Project Examines Drug Distribution in Sports Programs*, NCAA NEWS, April 1992, at 3.

40. *Id.*

41. *Id.*

42. *Id.*

43. St. Jean, *supra* note 27 at 1598.

III. Proposed Regulations

The goal of the proposed regulation is to create an atmosphere in the controlled drug area that closely resembles a retail pharmacy setting. This goal addresses both the legal aspects of drug dispensing and provides for the best possible health care of the student athlete or coaching staff member receiving the prescription.

There are several legal aspects involved in the proposed drug dispensing regulations. First, by allowing only licensed personnel to dispense prescription medication, the coaches, trainers, and university are more apt to avoid liability from violating both federal and state laws that restrict this type of dispension. Second, the maintenance of proper prescriptions records assures that prescription drugs are dispensed only when authorized and therefore assures that no laws are violated concerning dispensing of legend drugs without a prescription. Third, the Federal Poison Prevention Packaging Act[44] requires that prescription drugs be packaged in child resistant containers and the FDCA requires that they be labeled properly.[45] The proposed regulation assures that medical personnel following the guidelines will not be in violation of these acts. The proposed regulation also specifies the information that must be kept on a patient profile and what must be communicated to the patient during counseling of proper use of the prescription. Both of these details will allow the dispensing personnel to follow the recommendations of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90).[46] This Act requires that prospective drug use review programs (monitoring patient profiles and conducting patient drug counseling) be utilized for patients receiving prescriptions paid for by Medicaid.[47] Although the OBRA '90 legislation is only applicable to prescriptions received by Medicaid patients, over one-half of the states have adopted similar requirements that are applicable to the filling of all prescriptions.[48] The use of these procedures is now widespread and the safety features that are

44. 15 U.S.C. §§1471-4.
45. 21 U.S.C. §353(b)(2).
46. Act of Nov. 5, 1995, Pub. L. No. 101-508, 104 Stat. 1388.
47. *Id.*
48. *See* Facts and Comparisons-Pharmacy Law Digest, A-50K, (1991).

incorporated in using them are abundant.[49] It would be in the best interests of the patients receiving prescriptions from the controlled drug area if these provisions were followed. Finally, making the member institutions responsible to the NCAA as well as other traditional governmental entities will assure that these institutions follow the guidelines of the regulation or risk being penalized by the NCAA through loss of scholarships, loss of revenue, or in the most extreme instance the loss of athletic programs.

Similarly, there are several health care aspects involved in the proposed drug dispensing regulations. First, by allowing personnel with a knowledge of prescription drugs to dispense them, patients are more assured of receiving the correct drug, with the correct directions for use. Second, proper drug counseling is important to patient care because it assures that the patient understands all the aspects of properly taking the medication and the precautions that may need to be considered. Last, by maintaining patient profiles, the dispensing medical personnel will be alerted to the possibility of drug interactions, potential allergic reactions, and possible drug dependence. The possibility of drug dependence is high among athletes due to both the social pressures that exist and the existence of pain from injuries that frequently need relief that is available only from narcotic pain relievers.[50] Due to both of these situations, it is important that a drug profile is reviewed by medical personnel before dispensing.

IV. Rationale for Proposed Regulation

The proposed regulation begins by offering NCAA member institutions an option of either completely following the guidelines or receiving prescription medications by conventional means such as from a retail pharmacy or student health pharmacy. This option is available in order to allow smaller schools with a small budget to have their student athletes and coaching staff members prescriptions filled in a less costly manner although at the expense of not having the convenience of maintaining prescription drugs in the athletic department.

Section (C) of the proposed regulation details which drugs

49. *Id.*

50. Mark Kram, *Athletes Often Lose To Addictions*, Fresno Bee, Jan. 6, 1995, at E1.

are allowed to be kept in the controlled drug area and the requirements relating to the physical structure. Those drugs listed in bylaw 32.2.3.1 are drugs that have been banned by the NCAA and are therefore not allowed to be kept in the controlled drug area.[51] The other class of medications that are prohibited are schedule II prescription drugs.[52]

One of the physical aspects of the controlled drug area is that it is required to be locked at all times. This requirement is meant to assure that only medical personnel will have access to the drug area and the drug stock. Further, this protects both the medical personnel responsible for the maintenance of the drug stock, athletes and others that possibly receive unauthorized medications that could be hazardous to their health. As mentioned above, only medical personnel are allowed to have access to the controlled drugs area. If any other person is in the controlled drug area in any way, the member institution is in violation of the regulation and subject to sanctions.

Accordingly, temperature control is important to assure that medications retain their efficacy. Therefore, the temperature must remain between 55 and 80 degrees Fahrenheit at all times. However, if the temperature varies from this range, the drugs have the potential to lose potency or become toxic, possibly harming the person receiving them. A requirement has been added for those institutions that prefer to keep refrigerated items to permit enough room in the controlled drug area to keep a refrigerator. This is important because like other drugs, the possibility of tampering or unauthorized use could be high. Most institutions will not keep refrigerated items because it would be a rare occasion that would require their use in an athletic setting. For those institutions that do have a refrigerator, it is mandated that no food or beverages will be allowed to be in the refrigerator at any time. This requirement is meant to assure that no medications in the controlled drug area may become contaminated.

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51. 1995-96 NCAA DRUG EDUCATION AND DRUG TESTING PROGRAM, at 9.

52. These drugs have been prohibited due to both the high potential for addiction and abuse and the increased chance of theft that would occur if these drugs were present. Schedule II drugs are the strongest pain relievers available and have the highest potential for abuse. They are therefore needed only in extreme situations. Due to these extreme situations being rare, it would be in the best interest of both the athletic departments and the medical personnel assigned to the drugs area if these medications could only be received by conventional means.

Section (D) contains the requirements involved with the actual dispensing of prescription drugs. The first part describes the conditions that must be met in order for the team physician to dispense a prescription from the controlled drug area. If the team physician is the person who authorized the medication to be dispensed, then he must write out a prescription and follow the rest of the requirements in the regulation. If a physician other than the team physician is the person authorizing the medication to be dispensed, the team physician must comply with the requirements for dispensing prescription drugs.

The second part of section (D) details the requirements that the team pharmacist or team nurse must follow in order to dispense prescriptions from the controlled drug area. When the authorization that is received for dispensing of legend drugs is written, the team pharmacist or team nurse must comply with the remainder of the regulation. However, if the authorization is oral, the dispensing medical personnel is required to immediately reduce it to writing and then follow the requirements of the rest of the regulation. By allowing medical personnel to receive oral authorization for dispensing of legend drugs, there is more flexibility allowed and student athletes or members of the coaching staff can be better treated for illnesses or injuries.

The third part of section (D) deals directly with the prescription bottle that the ultimate user receives. In accordance with the Federal Poison Prevention Packaging Act ("PPPA") of 1970 childproof containers are required.[53] The PPPA regulates certain substances (including prescription drugs) and requires that they be packaged for consumer use in special packaging that will make them significantly difficult for children under the age of five to open.[54] This requirement protects small children that may come in contact with the prescription bottle. It reduces the potential for liability for the member institution from potential accidents and from violation of the federal act. This part of the section also indicates exactly what information is required to be on the prescription label. The information is in accordance with the FDCA which assures that the drug is not misbranded if all the information is correct.[55]

Part four of section (D) limits the number of units that may

53. 15 U.S.C. §§1471-4.
54. *Id.*
55. 21 U.S.C. §353(b)(2).

be dispensed from one prescription. The limit on units is designed to keep the prescribing physician from getting around the rule that no refills are allowed and prescribing large quantities of drugs on a single prescription is not permitted.

Section (D)(5) requires dispensing medical personnel to tell the person receiving the prescription drug at the time of receipt the information listed therein. The listing of this information will allow the student athlete or member of the coaching staff taking the medication to be well informed concerning the chemicals that they are putting into their bodies. Further, it allows the most advantageous results without undergoing some of the potential problems. Moreover, this requirement is strictly to mandate the following of recommendations from both state and federal law and to protect the dispensing medical personnel from potential liability as well as to provide for the health and safety of the person receiving the medication.

Additionally, Section (E) of the proposed regulation describes the requirements for action that must be followed in the keeping of records. The receipt of legend drugs must be documented in a bound book. The aforementioned requirement is meant to ensure that all drugs coming into the controlled drug area are accounted for and make it easier to balance the drug records. The other part of the record keeping section deals with the numbering and filing of prescriptions. In order to maintain uniformity throughout the NCAA member institutions, all prescriptions for noncontrolled legend drugs will be required to be placed in one file with the beginning prescription number being 100,001. All prescriptions for legend drugs classified as schedule III, IV, or V will be required to be kept in a separate file with the beginning number being 1. The filing system is meant to as closely as possible duplicate one of the three options that are offered in order to comply with the Controlled Substances Act[56] ("CSA"). The option that the CSA requires that all prescriptions for noncontrolled legend drugs be kept in one file, all prescriptions for drugs classified as schedule II be kept in a second file, and all prescriptions for drugs classified as schedule III, IV, or V be kept in a third file.[57] Since schedule II legend drugs are prohibited in the con-

56. 21 C.F.R. §1304.04(h).
57. *Id.*

trolled drug area, maintaining the two separate files as indicated for the proposed regulation would meet the requirements of the act.[58]

Section (F) of the proposed drug dispensing regulation requires that refills on prescriptions are not allowed. This provision eases the record keeping burden on the medical personnel and ensures that each prescription received is necessary and required for the treatment of a medical problem.

Section (G) mandates that prescriptions are not allowed to be transferred into or out of the controlled drug area. A prescription is considered to be transferred when a receiving pharmacy verbally communicates with another pharmacy where the active prescription remains for a specific patient for a specific medication. The receiving pharmacy obtains all the prescription information that is required and the patient is then allowed to have the prescription filled at the receiving pharmacy. The pharmacy that gave the prescription is considered to no longer have the prescription and would be required to transfer it back if the patient wished to once again have it filled at the original pharmacy.

There are two major premises behind the rule of not allowing prescriptions to be transferred. First, the medical personnel will not be burdened with the additional rules and regulations that would be involved. Second, since prescriptions filled in the controlled drug area are not allowed to have refills, there would not be part of a prescription to transfer out. Under the same idea, if a prescription was to be transferred into the controlled drug area, it would lose what refills may have remained. Therefore, the student athletes health and best interests would be best protected by not allowing transfers.

Section (H) of the proposed regulation identifies the information that would be required in order to maintain appropriate patient profiles. Patient profiles are important because the dispensing medical personnel will be able to monitor and identify potential problems such as drug allergies, drug-drug interactions, drug-food interactions and conflicts involving the drug dispensed and other current medical conditions that could be exacerbated by receiving the new prescription drug.

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58. *Id.*

Thereafter, the patient profiles will be required to be kept for two years after the patient is no longer associated with the member institution. By retaining the profiles, the member institution will be able to serve the best interests of the patient because they can give the information contained on the profiles to other medical personnel if the need arises. Since there will be a limited number of patients that will receive prescriptions from the controlled drug area, there should be no record keeping burden placed on the member institution by requiring the length of time they must be retained. At all times, the patient profiles are required to be kept in the controlled drug area to insure that patient confidentiality is maintained.

Pursuant to Section (I), medical personnel will be required to check the drug stock and destroy all expired drugs every six months. By requiring this type of check, patients receiving prescriptions will be assured of receiving safe and effective medication. Individual member institutions are allowed to decide the proper process that the medical personnel will be required to follow to destroy drugs that are found to be out of date.

Section (J) also requires that medical personnel be required to receive product recall information to assure that there are no drugs in the controlled drug room that have been recalled by the manufacturer or by the government due to safety or effectiveness problems. This process will also provide for the health and safety of the patients receiving prescriptions. The individual member institutions will be required to adopt their own procedures for obtaining this information, and will be held to have violated the regulation if they do not. As with expired drugs, the product recalls or copies of them, will be required to be kept in a bound book. The medical personnel that performs the check to make sure that the drug that was recalled is not in the controlled drug area stock is required to sign the recall notice each time a notice is received.

Section (K) of the proposed regulation details the information that each member institution will be required to submit to the NCAA committee on safeguards and medical aspects of sports if they choose to maintain a controlled drug area. The reports are required to contain information for the year ending June 30. This date was chosen simply to obtain uniformity

throughout the institutions. All member institutions will have one month to compile the information required before it is due.

The name and total number of units of each drug dispensed is required in order to allow the committee to compare usage of individual drugs among the member institutions and determine if there is a pattern of potential over dispensing at certain institutions. The list of medical personnel having access to the controlled drug area is required to insure that only specified persons with the proper credentials have access and to identify these persons each year. Submission of the individual patient profiles is required to aid in insuring that no patients are receiving such quantities of schedule III, IV, or V drugs by the member institutions that could subject that patient to drug addictions. Submission of these profiles will also assure the committee that there are no patterns of member institutions dispensing large numbers of controlled legend drugs without the proper diagnosis. A provision has been added to require that the patients name and date of birth is removed from the profile before it is submitted. This will protect the patient's identity and insure patient confidentiality.

Pursuant to Section (L), NCAA member institutions that choose to use a controlled drug area will be subject to inspection as the committee on competitive safeguards and medical aspects of sports deems necessary. These inspections may occur at any time and may be either announced or unannounced. The inspectors will be required to look for possible violations of this regulation. Periodic unannounced inspections will insure the best possible maintenance of the controlled drug area and provide the best possible health care for the coaching staff members and student athletes.

Finally, Section (M) of the proposed regulation details the sanctions that could be imposed on any member institution that violates any section.

V. Conclusion

It is important for both the student athletes and members of the coaching staff to have access to prescription drugs at all times because injury and illness for these individuals often occur at times when conventional methods of obtaining prescription drugs are not available. However, the importance of proper health care outweighs the importance of access. As

seen in both the study performed involving drugs dispensed in athletic departments and the problems that have arisen at individual colleges in the past ten years, a uniform method of storing and dispensing prescription drugs should be required by the NCAA if its member institutions are allowed to possess them. Member institutions will not alter their current drug dispensing practices if there continues to exist a lack of responsibility to the NCAA. By adopting a regulation, rather than simply making a recommendation, the member institutions would be required to follow the guidelines of the regulation or face the possible sanctions for violations. Therefore, the NCAA should adopt a regulation such as the one proposed to insure that the proper personnel is dispensing medications and that the proper persons that are receiving those medications are protected from the potential harms that are present in the system as it exists today.

Appendix

NCAA Regulation

Purpose

To uniformly monitor and control the storage and dispensing of legend drugs at NCAA member institutions.

A. Definitions:

Coaching Staff - Persons employed as coaches, trainers, or student trainers in any part of the athletic programs offered by a college or university.

Controlled Drug Area - The area where legend drugs are kept in the athletic department.

Drug Recalls - When a drug is deemed unsafe for human use by the manufacturer who alerts the medical community to pull the drug from their stock and either return it to the manufacturer or destroy it.

Expired Drugs - Legend drugs that exhibit an expiration date earlier than the current date. For legend drugs that only have an expiration date of month and year (i.e. 10/96), the drug is deemed to have expired on the last day of the month (i.e. 10/31/96).

Legend Drugs - Drugs that have been labeled with the fed-

erally required warning: "Caution: Federal Law prohibits the dispensing of this medication without a prescription"

Medical Personnel - Any team physician, team pharmacist, or team nurse that is employed by a college or university. Athletic trainers are not included in this classification.

NCAA Member Institution - Colleges or universities that are official members of the National Collegiate Athletic Association.

Noncontrolled Legend Drugs - Legend drugs that are not classified as schedule II, III, IV, or V.

Patient - A person receiving care or treatment in the form of a prescription drug from the controlled drug area.

Schedule II Drugs - Legend drugs that have a high abuse potential and that are classified as schedule II drugs by the Controlled Substances Act.

Schedule III, IV, or V Drugs - Legend drugs that have an abuse potential and that are classified as schedule III, IV, or V by the Controlled Substances Act.

Student Athlete - Any person enrolled in classes in a college or university who also participates in one or more of the athletic programs offered by the college or university.

Team Nurse - A person who is licensed as a registered nurse in the state where the college or university that employees that person is located.

Team Pharmacist - A person who is licensed as a registered pharmacist in the state where the college or university that employees that person is located.

Team Physician - A person who is licensed to practice medicine in the state where the college or university that employees that person is located.

Transferred Prescription - The act of moving a prescription that has been filled at one pharmacy to another pharmacy so that it may be filled at the second pharmacy.

B. Conventional Means:

NCAA member institutions choosing not to comply with the following requirements or mandated by state law to do otherwise, are required to use conventional means of obtaining legend drugs for their student athletes and coaching staff. An example of a conventional means of filling a prescription would be having a prescription filled at a retail pharmacy.

C. Storage of Legend Drugs:

All legend drugs, except those in 32.2.3.1 of the regulations and those classified as schedule II, are permitted to be stored by member institutions for the use of student athletes and the coaching staff.

1. All legend drugs must be stored in the controlled drug area which is to remain locked at all times.
2. Medical personnel are the only persons who are allowed to have any form of access to the controlled drug area.
3. The temperature of the controlled drug area must remain between 55 degrees and 80 degrees F at all times.
4. If legend drugs requiring refrigeration are kept by the NCAA member institution, a refrigerator must be maintained inside the controlled drug area. No products other than medication are allowed to be in this refrigerator.

D. Dispensing of Legend Drugs:

1. The team physician may dispense legend drugs from the controlled drug area upon his own prescription or the prescription of any other physician legally authorized to prescribe legend drugs.
2. The team pharmacist or team nurse may dispense legend drugs from the controlled drug area only upon the oral or written authorization of the team physician or any other physician legally authorized to prescribe legend drugs. In the event that the authorization is oral, the receiving team pharmacist or team nurse must immediately prepare a written record of the prescription order.
3. Medical personnel dispensing legend drugs from the controlled drug area must dispense them in accordance with the Federal Poison Prevention Packaging Act in a child resistant container and label them in accordance with the Federal Food, Drug and Cosmetic Act with the following information:
   a. Patient's name;
   b. Name of drug and strength;
   c. Quantity;
   d. Directions for use;
   e. Prescribing physician's name;
   f. Date of dispensing; and

g. Prescription number.

4. Prescriptions for legend drugs classified as schedule III, IV, or V may not be filled for a quantity greater than 50 units for tablets and capsules and 180 milliliters for liquids.

5. The following information must be communicated by the dispensing medical personnel to the person receiving the prescription at the time of receipt:

a. Name of drug;

b. Specific indication for taking drug;

c. Directions for use;

d. Most common side effects;

e. Possible drug - drug interactions (both prescription and over the counter);

f. Possible drug - food interactions; and

g. Proper storage.

E. Record Keeping of Legend Drugs in the Controlled Drug Area.

1. The medical personnel receiving legend drugs into the controlled drug area must document the following in a bound book:

a. Date of receipt;

b. Drug received;

c. Quantity received; and

d. Signature of receiving medical personnel.

2. Non-controlled legend drugs shall be assigned a prescription number beginning with 100,001 and increasing by 1 for each prescription filled. Those legend drugs classified as schedule III, IV, or V shall be assigned a prescription number beginning with 1 and increasing by 1 for each prescription filled.

3. The medical personnel dispensing legend drugs from the controlled drug area must document the dispensing and comply with the Controlled Substances Act by maintaining two separate prescription files:

a. One containing prescriptions for noncontrolled legend drugs; and

b. One containing prescriptions for controlled legend drugs classified as schedule III, IV, or V.

4. All prescriptions filled in the controlled drug area must be kept by the member institution for ten years.

F. Refills:

No refills are allowed for legend drugs dispensed from the controlled drug area.

G. Transfers:

Transferring of prescriptions to or from pharmacies is not allowed.

H. Patient Profiles:

1. Individual patient profiles must be maintained by medical personnel for those student athletes or members of the coaching staff receiving prescriptions from the controlled drug area. The following information must appear on each profile:
   a. Patient's name;
   b. Patient's date of birth;
   c. Patient's gender;
   d. Drug allergies;
   e. Current medications;
   f. Drug dispensed;
   g. Quantity;
   h. Diagnosis relating to drug dispensed;
   i. Date of dispensing; and
   j. Prescription number.
2. Individual patient profiles must be kept by medical personnel of the member institution until two years after the patient is no longer associated with the member institution.

I. Expired Drugs:

Medical personnel must check for and destroy expired medication every six months. Medical personnel conducting the check must record in a bound book:

1. The date the check was performed;
2. The drug(s) destroyed;
3. The quantity of each drug destroyed; and
4. Medical personnel performing the check must sign the book.

J. Product Recalls:

Medical personnel must receive drug product recall information and check the drug stock when drug product recalls are made. All drug product recalls must be kept in a bound book. Medical personnel who performs the check for the drug product that has been recalled must sign and date each recall notice when the check is performed. Individual member institutions are required to adopt their own procedure for obtaining drug product recall information.

K. Reporting:

Member institutions that choose to maintain a controlled drug area are required to submit a yearly report covering the period ending on June 30 to the NCAA committee on competitive safeguards and medical aspects of sports which shall include:

1. Name and total number of units of each legend drug dispensed;
2. A list of medical personnel who have access to the controlled drug area; and
3. All patient profiles (excluding name and date of birth) for any student athlete or member of the coaching staff receiving more than six prescriptions for drugs classified as schedule III, IV, or V in the preceding year.

This report must be received by the committee before August 1 of each year.

L. Inspecting:

NCAA member institutions will be subject to periodic inspections of the controlled drug area by the NCAA.

M. Violations:

A violation of any section of this regulation will be considered a secondary violation as identified in 19.02.2.1 and will be subject to the penalties for a secondary violation identified in 19.6.1. Any subsequent violation of any section of this regulation that occurs within two years of the previously reported violation will be considered a major violation as identified in 19.02.2.2 and will be subject to the penalties of a major viola-

tion as identified in 19.6.2. Enforcement of this regulation is subject to the provisions of article 19 of the NCAA rules and regulations.