WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #1

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF PUBLIC HEARING ON A PROPOSED RULE

Workers' Compensation Division

AGENCY: Bureau of Employment Programs TITLE NUMBER: 85

RULE TYPE: Exempt Legislative ; CITE AUTHORITY §21A-2-6(1),-6(2) &-6(14); §21A-2-19; §21A-3-7(b) &-7(c); §23-1-1; §23-4-3(a)(1) &-3(a)(2) §23-4-3(a)(3)

AMENDMENT TO AN EXISTING RULE: YES___ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 21

TITLE OF RULE BEING PROPOSED: Guidelines for Controlled Substances

There will be two(2) public hearings.

DATE OF PUBLIC HEARING: April 10 & 13, 1995 TIME: 10:00 a.m.

LOCATION OF PUBLIC HEARING: Jerry West Lounge, WVU Coliseum, Morgantown-April 10, 1995

Room 202, Charleston Civic Center, Charleston-April13, 1995

COMMENTS LIMITED TO: ORAL___, WRITTEN___, BOTH X

COMMENTS MAY ALSO BE MAILED TO THE FOLLOWING ADDRESS: Until May 1, 1995.

Lisa M. Kern, Counsel
Legal Services Division
P.O. Box 3922
Charleston, WV 25339-3922

The Department requests that persons wishing to make comments at the hearing make an effort to submit written comments in order to facilitate the review of these comments.

The issues to be heard shall be limited to the proposed rule.

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Andrew N. Richardson

Andrew N. Richardson

4.20

Summary of Proposed Exempt Legislative Rule

Guidelines for Controlled Substances

Title 85, Series 21

This proposed legislative rule was developed by the Health Care Advisory Panel through deliberations of the Health Care Advisory Panel's Pharmacy Sub-Panel and information developed by the Washington State Medical Association.

The guidelines are for use by the physician in the management of chronic nonmalignant pain. The guidelines are not intended to be applied uniformly to every patient, but rather are to serve as a framework for physician use in providing case-by-case care to individuals who are candidates for the use of controlled substances in the course of treatment.

The rule provides guidelines for the prescription of Controlled Substances Schedules II - IV. It provides recommendations for the documentation of controlled substances prescribed within the guidelines. The rule contains a list of contraindications for the use of controlled substances. It also lists the additional documentation required for authorization for treatment beyond the guidelines. Finally, in addition to providing the DEA Schedules for Controlled Substances, there is a section regarding the proper use of controlled substances.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Guidelines for Controlled Substances

Type of Rule: Exempt
X Legislative ___Interpretive ___Procedural

Agency: Workers' Compensation Division, Bureau of Employment Programs

Address: P. O. Box 3922

Charleston, WV 25339-3922

1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	$139,822	$826,857	$136,492	$141,036	$146,253
PERSONAL SERVICES	450	0	450	450	450
CURRENT EXPENSE	136,492	0	136,492	140,586	145,803
REPAIRS & ALTERNATIONS	0	0	0	0	0
EQUIPMENT	0	0	0	0	0
OTHER	2,880	0	2,880	0	0

2. Explanation of above estimates:

Increase in estimated cost is the amount paid to process pharmacy bills on the Point-of-Sale computer system for the first year. While this system has saved us money, we are estimating a 3% increase in this cost per year (next and thereafter). This is less than the 6 1/2% medical increase we have seen in the overall program since 1987. The decrease represents the medical savings we have realized by not allowing controlled substances to be filled in injury claims beyond medical norms without an explanation from the treating physician. The personal services cost represents the time spent by the Division's Consulting Pharmacist on issues involving controlled substances and these guidelines. The cost marked as "other" represents a one time training expense to train Division staff on the utilization of these guidelines.

3. Objectives of these rules:

These guidelines are intended to standardize the usage of prescribed controlled substances. Long-term use of controlled substances for chronic nonmalignant pain is contraindicated and may be detrimental to the patient. Use of these guidelines are intended to assist the health care provider to identify at risk patients and to manage medication use appropriately.

Rule Title: Guidelines for Controlled Substances

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

The Division must bear the cost of the implementation and maintenance of the Point-of-Sale pharmacy computer system to administer these guidelines. The Division also receives the benefit of cost savings in the pharmacy program as noted above, as well as hidden savings by decreasing the need for detoxification treatment, and other services that would arise from the over utilization of controlled substances in the Workers' Compensation program.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

The medical community will spend an unspecified time (cost) reviewing these guidelines and becoming familiar with them. However, improved care and reduced problems with extended use of controlled substances should more than offset this unspecified cost. The savings realized by reducing inappropriate pharmacy costs and subsequent medical treatment (i.e., detoxification) will be passed on to the employer community by positively effecting Workers' Compensation premiums.

C. Economic Impact on Citizens/Public at Large.

Injured workers will receive better, more appropriate medical care under these guidelines, and should have fewer complications due to over utilization of controlled substances.

Date: March 1, 1995

Signature of Agency Head or Authorized Representative

Andrew N. Richardson

Andrew N. Richardson
Commissioner, Bureau of Employment Programs

TITLE 85
EXEMPT LEGISLATIVE RULES
BUREAU OF EMPLOYMENT PROGRAMS
WORKERS' COMPENSATION DIVISION

SERIES 21
Guidelines for Controlled Substances

§85-21-1. General.

1.1. Scope. -- These rules implement the provisions of West Virginia Code, §23-4-3(a)(1) & -3(a)(2).

1.2. Authority. -- West Virginia Code, §21A-2-6(1), -6(2) & -6(14); §21A-2-19; §21A-3-7(b) & -7(c); and §23-1-1; and §23-4-3(a)(1) & -3(a)(2) §23-4-3(a)(3). Pursuant to West Virginia Code, §21A-3-7(c), rules adopted by the compensation programs performance council and the commissioner are not subject to legislative approval as would otherwise be required under West Virginia Code, §29A-3-1 et seq. Public notice requirements of that chapter and article, however, must be followed. Pursuant to Enrolled Committee Substitute for House Bill 4030, Regular Session, 1994, the Department of Commerce, Labor and Environmental Resources was abolished. Pursuant to that same bill and to Executive Order No. 5-94 by the Governor, the Commissioner of the Bureau of Employment Programs is empowered to promulgate rules and regulations without the consent or approval of a departmental secretary.

1.3. Filing Date. --

1.4. Effective Date. --

§85-21-2. Purpose of these rules.

The purpose of these rules is to implement the provisions of West Virginia Code, §23-4-3(a)(1) & -3(a)(2) and §23-4-3(a)(3) and with regard to providing guidelines to physicians for the use of controlled substances. These rules are also to be utilized by workers' compensation in its capacity as monitor of claims.

§85-21-3. Definitions.

As used in these rules, the following terms have the stated meanings unless the context of a specific use clearly indicates another meaning is intended.

3.1. "Commissioner" means the Commissioner of the Bureau of Employment Programs pursuant to West Virginia Code, §21A-2-1, and West Virginia Code, §23-1-1, and any deputies designated pursuant to West Virginia Code, §21A-2-12 & -13.

3.2. "Division" means the Workers' Compensation Division within the Bureau of Employment Programs as provided for by West Virginia Code, §21A-1-4, and West Virginia Code, §23-1-1 et seq.

4.1. The guidelines are for use by the physician in the management of chronic nonmalignant pain. Chronic nonmalignant pain is defined as pain persisting beyond the expected normal healing time for an injury, for which traditional medical approaches have been unsuccessful.

4.1.1. The guidelines cannot apply uniformly to every claimant. The guidelines cannot be the sole determining basis for identifying claimants at risk for a drug use problem. Mere application of the guidelines cannot substitute for a thorough assessment of the claimant or medical chart by qualified health care professionals. Workers' Compensation claimants that are presently receiving medication treatment beyond the guidelines must be addressed on a case-by-case basis.

4.2. Guidelines for the prescription for controlled substances schedules II - IV (refer to table §85-21-A for controlled substances schedule)

4.2.1. Schedule II drugs should be prescribed on an outpatient basis for no longer than two weeks after initial injury or following a subsequent operative procedure.

4.2.2. Schedule III drugs should be prescribed on an outpatient basis for no longer than six weeks after initial injury or following a subsequent operative procedure.

4.2.3. Schedule IV opioid drugs should be prescribed on an outpatient basis for no longer than six weeks after initial injury or following a subsequent operative basis.

4.2.4. Schedule IV sedative and anxiolytic drugs should be prescribed on an outpatient basis for no longer than six months after initial injury or following a subsequent operative procedure.

4.2.5. To prescribe medications beyond the above guidelines, authorization must be obtained from the workers' compensation division. Authorization requests must include documentation as described in Sections 4.3. and 4.5. It is recommended that providers utilize less potent medications when continued use is indicated. See Section 4.6.

4.3. Documentation recommendations for controlled substances prescribed within the guidelines.

4.3.1. A thorough medical history, physical examination, diagnosis and treatment plan should be documented, with particular attention focused on determining the cause(s) of the claimant's pain, sleeplessness or anxiety.

4.3.2. The treatment plan should include the following information:

a. A list of all current medications (with doses), including medications prescribed by other physicians (whenever possible);

b. Therapies and procedures other than medications to manage/relieve pain;

c. Consultations with health care professionals;

d. Further planned diagnostic evaluation; and

e. Follow-up plan to assess progress.

4.3.3. The above standards for documentation are being recommended for inclusion in the provider's records. These records should be submitted to the Workers' Compensation Division.

4.4. Relative contraindications for the use of controlled substances.

4.4.1. History of alcohol or other substance abuse or dependence;

4.4.2. History of chronic, high dose benzodiazepine use or prolonged opioid use;

4.4.3. History of "doctor-shopping" (seeking care for multiple physicians or history of frequent change of physicians);

4.4.4. Active alcohol or other substance abuse or dependence; and

4.4.5. Off work for more than six (6) months.

4.4.6. When special circumstances warrant the use of these drugs in the types of claimants noted above, it should be justified in the medical record, and the risks and benefits must be weighed.

4.5. Additional documentation required for authorization for treatment beyond the guidelines.

4.5.1. Documentation should include:

a. Description of reported pain, insomnia, or anxiety relief from each medication;

b. Justification of the continued use of controlled substances beyond the guidelines;

c. Documentation of attempts at weaning and/or tapering dosage;

d. If weaning attempts have failed (include history of contraindications); and

e. Alternative treatments under consideration.

4.5.2. Informed consent should be obtained from the claimant and include the risks and benefits of prescribed medications. The explanation should be documented, along with expected outcomes, duration of treatment, and prescribing limitations.

4.5.3. The treatment plan should be revised as new information develops which alters the plan.

4.5.4. When the provider requests authorization for surgical procedures that are likely to require medication use beyond the guidelines, please address the need for extended use in the initial authorization request so that the authorization will be reviewed prior to surgery.

4.6. Proper use of controlled substances.

4.6.1. Pain medication (opioids):

a. Adequate doses of medication in appropriate strength and frequency to control acute pain;

b. Fixed dosage schedules rather than PRN will enhance compliance and minimize the risk of addiction; and

c. Progressive use of less potent medication, tapering of doses and diminishing frequency of dosing should be used to wean the claimant off of narcotics.

4.6.2. Sedatives and anxiolytic medication;

a. The use of sedatives and anxiolytic medications for six weeks or less can be effective. Benzodiazepines are preferred;

b. Use beyond several weeks should trigger exploration of depression and consultation with a mental health professional; and

c. Use for anxiety should not be continued beyond three months. Tapering is usually required.

§85-21-5. Severability

5.1. If any provision of these rules or the application thereof to any entity or circumstance shall be held invalid, such invalidity shall not effect the provisions or the applications of these rules which can be given affect without the invalid provisions or application and to this end the provisions of these rules are declared to be severable.

Table §85-21-A

a. The Controlled Substances Act of 1970 regulates the manufacturing, distribution and dispensing of drugs that have abuse potential. The Drug Enforcement Administration (DEA) within the US Department of Justice is the chief federal agency responsible for enforcement.

A. DEA Schedules: Drugs under jurisdiction of the Controlled Substances Act are divided into five schedules based on their potential for abuse and physical and psychological dependence. All controlled substances listed in Drug Facts and Comparisons are identified by schedule as follows:

Schedule I (C-I)	High abuse potential and no accepted medical use (eg, heroin, marijuana, LSD).
Schedule II (C-II)	High abuse potential with severe dependence liability (eg, narcotics, amphetamines, dronabinol, some barbiturates).
Schedule III (C-III)	Less abuse potential than schedule II drugs and moderate dependence liability (eg, nonbarbiturate sedatives, nonamphetamine stimulants, limited amounts of certain narcotics).
Schedule IV (C-IV)	Less abuse potential than schedule III drugs and limited dependence liability (eg, some sedatives, antianxiety agents, non-narcotic analgesics).
Schedule V (C-V)	Limited abuse potential. Primarily small amounts of narcotics (codeine) used as antitussives or antidiarrheals. Under federal law, limited quantities of certain c-v drugs may be purchased without a prescription directly from a pharmacist if allowed under specific state statutes. The purchaser must be at least 18 years of age and must furnish suitable identification. All such transactions must be recorded by the dispensing pharmacist.

Bureau of Employment Programs
Legal Services Division
Post Office Box 3922
Charleston, West Virginia 25339-3922

Gaston Caperton
Governor
Andrew N. Richardson
Commissioner

M E M O R A N D U M

TO: Interested Persons

FROM: Lisa M. Kern, Counsel
Legal Services Division

DATE: March 1, 1995

RE: Filing of Proposed Rules

You are receiving this notice either because you previously requested to be placed on the Workers' Compensation Division's interested person's mailing list or because we believe you will be interested in these proposed rules. The division has filed for public comment a proposal for three exempt legislative rules titled: "Protocols and Guidelines for the Treatment of Workers' Compensation Injuries," Title 85, Series 20, "Guidelines for Controlled Substances," Title 85, Series 21 and "Guidelines for Psychiatric Permanent Impairment, Evaluations, Evidence and Ratings of Psychiatric Impairment Due to Workers' Compensation Injuries," Title 85, Series 22.

A summary of each rule is enclosed for your reference. Series 20 provides treatment guidelines for eleven types of injuries. It also has a section regarding physical therapy and a section providing guidelines for physical medicine. Series 21 provides guidelines for use by a physician in the management of chronic nonmalignant pain. Series 22 provides guidelines for psychiatric impairment ratings, evaluations and evidence.

Public comments are being solicited on these proposals. The division will hold two (2) public hearings on the rules as noted on the cover sheet. Both meetings will start at 10:00 a.m. on the dates indicated and at the locations noted. We suggest that you file written comments along with any oral comments that you wish to make at the hearing. In lieu of attendance at a hearing, you may mail written comments to me at the address noted above until 5:00 p.m. on Monday, May 1, 1995. Copies of the rules can be obtained through the Secretary of State's Office.

These are exempt legislative rules which means they do not have to have the approval of the Legislature before they become effective. Following the receipt of the comments, the Compensation Programs Performance Council will review the comments, adopt such changes as they may find appropriate, and then vote to either accept or reject each proposed rule. If accepted, the rule will become effective thirty (30) days after final filing with the Secretary of State.

Your comments are invited.