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Notice ID(s): 2332
File Date: 6/22/15

Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Tennessee Department of Labor and Workforce Development
Division:	Workers' Compensation
Contact Person:	Troy Haley
Address:	220 French Landing Drive 1-B
Phone:	615-532-0179
Email:	troy.haley@tn.gov

Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	Troy Haley
Address:	220 French Landing Drive 1-B
Phone:	615-532-0179
Email:	troy.haley@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	220 French Landing Drive		
Address 2:	Side 1-A Tennessee Room		
City:	Nashville, TN		
Zip:	37243		
Hearing Date :	08/25/15		
Hearing Time:	2:00 p.m.	_X_ CST/CDT	___ EST/EDT

Additional Hearing Information:

Revision Type (check all that apply):

___ Amendment
_X_ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
0800-02-25	Workers' Compensation Medical Treatment Guidelines
Rule Number	**Rule Title**
0800-02-25-.01	Purpose and Scope
0800-02-25-.02	Definitions

0800-02-25-.03	Treatment Guidelines
0800-02-25-.04	Drug Formulary

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

0800-02-25-.01 Purpose and Scope

(1) Purpose: To provide guidelines for the diagnosis and treatment of commonly occurring workers' compensation injuries.

(2) Scope: To include guidelines for diagnostic and treatment decisions including pharmaceuticals and pain management.

Authority: §50-6-124.

0800-02-25-.02 Definitions

(1) "Act" means the applicable Workers' Compensation Law in effect.

(2) "Administrator" means the chief administrative officer of the Tennessee Bureau of Workers' Compensation, or the Administrator's designee.

(3) "Authorized Treating Physician" means the practitioner chosen from the panel required by T.C.A. 50-6-204, or a practitioner who has received a referral from the original authorized treating physician if the employer has not provided an alternative referral within three business days. "Authorized Treating Physician" also means any practitioner specifically authorized by the employer.

(4) "Bureau" means the Tennessee Bureau of Workers' Compensation attached for administrative purposes to the Tennessee Department of Labor and Workforce Development.

(5) "Employee" means an employee as defined in T.C.A. § 50-6-102, but also includes the employee's representative or legal counsel.

(6) "Employer" means an employer as defined in T.C.A. § 50-6-102, but also includes an employer's insurer, third party administrator, self-insured employers, self-insured pools and trusts, as well as the employer's representative or legal counsel, as applicable.

(7) "Health care provider" includes, but is not limited to, the following: licensed individual chiropractor, dentist, physical therapist, physician, surgeon, group of practitioners, hospital, free standing surgical outpatient facility, health maintenance organization, industrial or other clinic, occupational healthcare center, home health agency, visiting nursing association, laboratory, medical supply company, community mental health center, and any other facility or entity providing treatment or health care services for a work-related injury.

(8) "Medical Director" means the Medical Director of the Tennessee Bureau of Workers' Compensation appointed by the Administrator pursuant to T.C.A. § 50-6-126, or the Medical Director's designee chosen by the Administrator to act on behalf of the Medical Director.

(9) "Medically necessary" or "medical necessity" means healthcare services, including medications, that a physician (or other healthcare provider acting within their scope of practice), exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

(a) In accordance with generally accepted standards of medical practice; and

(b) Clinically appropriate, in terms of type, frequency, extent, site and duration; and considered effective for the patient's illness, injury or disease. Treatment primarily for the convenience of the patient, physician, or other healthcare provider does not constitute medical necessity.

(10) "Treatment guideline" means the Institute of Medicine (2011) definition of a "clinical practice guideline,": "statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefit and harms of alternative care options."

(11) "Utilization review" means a system for prospective and/or concurrent review of the necessity and appropriateness in the allocation of health care resources and services, including medications, given or proposed to be given to an individual within this state;

(a) "Utilization review" does not include elective requests for clarification of coverage, referral from or to, or consultations, or second opinions from physicians or other providers, or office visits.

(b) "Utilization review" does include the efficiency and quality of medical services based upon medically accepted and evidenced based standards, provided, that the 'utilization review' does not include the establishment of approved payment levels or a review of medical bills or fees.

(c) "Utilization review" does not include analysis of or opinions regarding medical causation or compensability.

Authority: §§50-6-102, 50-6-122, 50-6-124, 50-6-126, and 50-6-233. 56-6-703, 56-61-102.

0800-02-25-.03 Treatment Guidelines

(1) Effective January 1, 2016, the Tennessee Bureau of Workers' Compensation adopts the current edition of the Work Loss Data Institute ODG Guidelines as published by the Work Loss Data Institute, 169 Saxony Road Suite 101, Encinitas, California, 92024, and the Chronic Pain Guidelines of the State of Tennessee, Department of Health, and any other related appendices to the above-referenced guidelines adopted by the Administrator.

(2) Medical treatment provided by or at the direction of the authorized treating physician, or other healthcare provider, in accordance with the ODG Guidelines listed in section 1) above is presumed to be reasonable and necessary and not subject to utilization review.

(3) It is recognized that each individual clinical situation and patient is unique. The guidelines are not a standard or a mandate. Exceptions to and the proper application of the guidelines require judgment. The Utilization Review and prior approval/authorization procedures and timeframes remain in effect. See Utilization Review Rule 0800-02-06. A mechanism for the timely appeal for these exceptional situations is set forth in Rule 0800-02-06-.07 Appeals.

(4) The employer shall not deny treatment based solely on the determination that the treatment falls outside of the guideline.

(a) If a provider makes a written request by fax or e-mail (and gets acknowledgement of receipt of the request) for authorization for a treatment 21 business days in advance of the anticipated date that treatment is to be delivered and has not been notified in writing or confirmed telephone call or confirmed fax at least 7 business days in advance of the date of the proposed treatment, it is presumed to be medically necessary, a covered service, and to be paid by the employer.

(b) If a provider makes a verbal request for authorization, the burden of proof for showing that authorization was granted by the employer rests with the provider.

(5) The employer shall not be responsible for charges for medical treatment that is not in accord with the guidelines unless:

(a) it was provided in a medical emergency,

(b) it was authorized by the employer,

(c) it was approved through the appeal process by the Medical Director.

(6) As new information becomes available, the Administrator may direct the Medical Director to publish or post on the Division's website, advisory or explanatory updates or bulletins to the guidelines. Print copies will be made available by request to the Medical Director. The Medical Advisory Committee may be consulted at the Administrator's discretion.

(7) The Bureau of Workers' Compensation subscribes to the Tennessee Department of Health "Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant Pain" as updated periodically by the Department of Health.

(8) As there are special circumstances in workers' compensation, the Bureau has adopted and published on its website an "Appendix" to the Department of Health guidelines. Updates to these documents will be addressed as new information warrants.

(9) As of January 1, 2016, physicians and other providers dispensing drugs required to be reported in the Tennessee Controlled Substances Monitoring Database (CSMD) from their offices or clinics must report these medications in the Tennessee Controlled Substances Monitoring Database (CSMD) within one business day of the dispensing of those medications. These provisions are in accord with T.C.A. §53-10-305, T.C.A. §53-10-307 and T.C.A. §53-10-310 as amended.

Authority: T.C.A. §§50-6-122, 50-6-124, 50-6-126, 50-6-233.

0800-02-25-.04 Drug Formulary

(1) The purpose of the drug formulary is to facilitate the safe and appropriate use of medications for injured workers, and is a specific part of the Treatment Guidelines set forth in subsection .03 of this rule.

(2) The Bureau adopts the ODG Drug Formulary published and updated by the Work Loss Data Institute.

(3) Initial prescriptions presented to a pharmacy for an alleged or accepted workers' compensation claim may be filled for a maximum of seven (7) days, even if the drug is status "N." The employer is responsible for the payment, subject to a final determination of the compensability of the alleged claim.

(a) The Formulary shall be posted on the Division's website.

(b) Medications with the status "N" in the formulary require prior approval..

(c) Compounded medications and topical applications are "N" and subject to prior approval.

(d) "Y" drugs and "N" drugs substituted with a "Y" drug, prescriptions should be filled without delay if they are approved as appropriate for the nature of the injury being treated.

(e) For compensation claims with a date of injury (DOI) on or after January 1, 2016, and for new medication prescriptions for dates of injury prior to January 1, 2016, the formulary applies to all drugs that are prescribed or dispensed for outpatient use on or after July 1, 2016.

(f) For refill prescriptions and medications being used for dates of injury (DOI) before January 1, 2016, the formulary will be effective on January 1, 2017.

(h) Retrospective review of medications will not be allowed. Once the prescription is filled, the employer is responsible for the payment of the initial prescription.

(i) If the authorized treating physician believes there to be a legitimate danger to the patient by a change or discontinuation of a medication, then the physician may appeal using the procedure outlined under (5) below, a request for expedited determination.

(4) The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

(a) "Brand name drug" means a drug marketed under a proprietary, trademark-protected name.

(b) "Closed Formulary" means all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, and applies to the categories listed below that require prior approval:

1. drugs identified with a status of "N" in the current edition of the Official Disability Guidelines Treatment in Workers' Compensation (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates;

2. any compound that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Compensation (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates; and

3. any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet accepted as the prevailing standard of care.

(c) "Compounding", "compound" or "compounded" medication or preparation means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

1. as the result of a practitioner's prescription drug order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

2. for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

3. in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or

4. for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing.

(d) "Generically equivalent" means a drug that, when compared to the prescribed drug, is:

1. "Pharmaceutically equivalent" or drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendia or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium; and

2. "Therapeutically equivalent" or pharmaceutically equivalent drug products that, if administered, will provide the same therapeutic effect, identical in duration and intensity.

(e) "Medical emergency" means the sudden onset of a medical condition manifested by acute symptoms of sufficient severity, including severe pain that in the absence of immediate medical attention could reasonably be expected to result in:

1. Placing the patient's health or bodily functions in serious jeopardy; or

2. Serious dysfunction of any body organ or part.

(f) "Nonprescription drug" or "over-the-counter medication" means a non-narcotic drug that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law.

(g) "Open Formulary" means all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but does not include drugs that lack FDA approval, or non-drug items.

(h) "Prescribing Doctor" means a physician or dentist who prescribes prescription drugs or over the counter medications in accordance with the physician's or dentist's license and state and federal laws and rules. For purposes of this chapter, prescribing doctor includes an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders, who prescribes prescription drugs or over the counter medication under the physician's supervision and in accordance with the health care practitioner's license and state and federal laws and rules.

(i) "Prescription" means an order for a prescription or nonprescription drug to be dispensed, in accordance with the applicable federal definition and T.C.A. §53-10.

(j) "Prescription drug" means:

1. A substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

2. A drug that under federal law is required, before being dispensed or delivered, to be labeled with the statement: "Caution: federal law prohibits dispensing without prescription;" "Rx only;" or another legend that complies with federal law; or

3. A drug that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a prescribing doctor only.

(k) "Statement of Medical Necessity" means a written statement from the prescribing doctor to establish the need for treatments or services, or prescriptions, including the need for a brand name drug where applicable. A statement of medical necessity shall include:

1. The injured employee's full name;

2. Date of injury;

3. Social security number;

4. Bureau's State File Number, if known;

5. Diagnosis code(s);

6. Whether the drug has previously been prescribed and dispensed, if known, and whether the inability to obtain the drug poses an unreasonable risk of a medical emergency; and

7. How the prescription treats the diagnosis, promotes recovery, or enhances the ability of the injured employee to return to or retain employment.

(l) "Substitution" means the dispensing of a drug or a brand of drug other than the drug or brand of drug ordered or prescribed.

(m) "Topical" means a prescription substance or substances, not injected or ingested, that are used on the skin or other membranes, or are applied to exterior or exposed surfaces. This category includes "inhalers."

(5) The provider may appeal to the Bureau's Medical Director for an expedited decision, a request for an expedited determination.

(a) The purpose of this section is to provide a prescribing doctor or pharmacy the ability to obtain an expedited determination from the Bureau's Medical Director in instances where a preauthorization denial of a previously prescribed and dispensed drug(s) excluded from the Closed Formulary poses an unreasonable risk of a medical emergency as defined in this title.

(b) The request for an expedited determination from the Medical Director shall contain the following information:

1. Injured employee name;

2. Date of birth of injured employee;

3. The injured employee's Social Security Number.

4. Tennessee Bureau of Workers' Compensation state file or claim number;

5. Date of injury;

6. Prescribing doctor's name;

7. Prescribing doctor's DEA number;

8. Name of drug and dosage;

9. Requestor's name (pharmacy or prescribing doctor);

10. Requestor's contact information;

11. A statement that the prior approval request for a previously prescribed and dispensed drug(s), which is excluded from the closed formulary, has been denied by the insurance carrier, accompanied by the denial letter if available;

12. A statement that an independent review request or request for reconsideration has already been submitted to the insurance carrier or the insurance carrier's utilization review agent;

13. A statement that the prior approval denial poses an unreasonable risk of a medical emergency and justification from a medical perspective such as withdrawal potential or other significant side effects or complications;

14. A statement that the potential medical emergency has been documented in the prior approval process;

15. A statement of justification from a medical perspective of the potential medical emergency such as withdrawal potential or other significant side effects or complications;

16. A statement that the insurance carrier has been notified that a request for an expedited determination is being submitted to the Bureau; and

17. The signature of the requestor and the following certification by the requestor for paragraphs 10 to 14 of this subsection, "I hereby certify under penalty of law that the previously listed conditions have been met."

(c) A complete request for an expedited determination under this section shall be processed and approved by the Medical Director of the Bureau in accordance with this section. At the discretion of the Medical Director of the Bureau, an incomplete request or a request with incomplete information for an expedited determination under this section may be considered in accordance with this section.

(d) The request for an expedited determination may be submitted on the designated form available on the Bureau of Workers' Compensation website. In the event the Bureau form is not available, the written request must contain the provisions of subsection (b) of this section.

(e) The requestor shall provide a copy of the request to the insurance carrier, prescribing doctor, injured employee, and dispensing pharmacy, if known, on the date the request is submitted to the Bureau.

(f) An expedited determination shall be effective retroactively to the date of the original prescription.

(6) A request for reconsideration of a prior approval denial is not required prior to a request for an expedited determination under this section. If a request for reconsideration or an expedited determination request is not initiated within 15 business days by the provider to the employer, carrier of Utilization Review Agent, from the initial prior approval denial, then the opportunity to request an expedited determination under this section does not apply.

(7) If pursuing an expedited determination after denial of a reconsideration request, a complete request shall be submitted within five business days of the notification of the reconsideration denial.

(a) An appeal of the utilization review organization decision relating to the medical necessity and reasonableness of the drugs contained in the expedited determination shall be submitted in accordance with these rules.

(b) The Medical Director's determination shall continue in effect until the later of:

1. Final determination of a medical dispute regarding the medical necessity and reasonableness of the drug;

2. Expiration of the period for a timely appeal; or

3. Agreement of the parties.

(c) Withdrawal or the request for an expedited determination by the requestor constitutes acceptance of the prior approval denial.

(d) All parties shall comply with an expedited determination issued in accordance with this section and the insurance carrier shall reimburse the pharmacy or other payer for prescriptions dispensed in accordance with the determination of the Medical Director.

(e) The insurance carrier shall notify the prescribing doctor, injured employee, and the dispensing pharmacy once reimbursement is no longer required because of the denial by the Medical Director of a request for an expedited determination.

(f) A decision issued by a Utilization Review organization is not a Bureau or Administrator decision.

(g) A party may seek to reverse or modify the Medical Director's determination issued under this section if:

1. A final determination of medical necessity has been rendered; and

2. The party requests a hearing in accordance with the procedures of the Court of Workers' Compensation Claims.

3. The insurance carrier may dispute the request for expedited determination or the Medical Director's determination entered under this title by filing a written request for a hearing in accordance with the Court of Workers' Compensation Claims procedures.

Authority: T.C.A. §50-6-124.

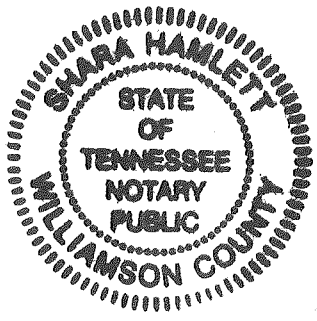
I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: June 22, 2015

Signature: Abbie Hudgens

Name of Officer: Abbie Hudgens

Title of Officer: Administrator, Bureau of Workers' Compensation



Subscribed and sworn to before me on: June 22, 2015

Notary Public Signature: Shara Hamlett

My commission expires on: 1/24/16

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Filed with the Department of State on: 6/22/15

Tre Hargett
Secretary of State