



# TEXAS DEPARTMENT OF INSURANCE

## Division of Workers' Compensation - Medical Fee Dispute Resolution (MS-48)

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### MEDICAL FEE DISPUTE RESOLUTION FINDINGS AND DECISION

#### GENERAL INFORMATION

**Requestor Name**

American Specialty Pharmacy

**Respondent Name**

Texas Mutual Insurance Company

**MFDR Tracking Number**

M4-15-3111-01

**Carrier's Austin Representative**

Box Number 54

**MFDR Date Received**

May 22, 2015

#### REQUESTOR'S POSITION SUMMARY

**Requestor's Position Summary:** Submitted documentation does not include a position statement from the requestor.

**Amount in Dispute:** \$399.90

#### RESPONDENT'S POSITION SUMMARY

**Respondent's Position Summary:** "...The requestor billed for a Medrox Patch, which is a compound of Capsaicin and Menthol. ODG indicates Capsaicin has an 'N' status as a topical. The requestor provided the compounded drug anyway without obtaining preauthorization as required by Rule 134.540.

...The requestor billed for filling a prescription of Theramine to the claimant. ODG in its Pain chapter does not recommend the use of Theramine."

**Response Submitted by:** Texas Mutual Insurance Company

#### SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
January 22, 2015	Medical Foods – Theramine	\$130.40	\$0.00
January 22, 2015	Prescription Compound Medication – Medrox 0.038%/5% Patch	\$269.50	\$0.00

#### FINDINGS AND DECISION

This medical fee dispute is decided pursuant to Texas Labor Code §413.031 and applicable rules of the Texas Department of Insurance, Division of Workers' Compensation.

**Background**

1. 28 Texas Administrative Code §133.305 defines the terms used for medical disputes.
2. 28 Texas Administrative Code §133.307 sets out the procedures for resolving medical fee disputes.
3. 28 Texas Administrative Code §134.1 sets out the general medical reimbursement guidelines for non-

network care.

4. 28 Texas Administrative Code §134.500 defines specific terms associated with pharmaceutical services.
5. 28 Texas Administrative Code §134.503 sets out the fee guidelines for pharmaceutical services.
6. 28 Texas Administrative Code §134.540 sets out the guidelines for use of the closed formulary for claims subject to certified networks.
7. Texas Insurance Code §1305.101 defines the duties of networks to provide medical treatment.
8. The insurance carrier reduced payment for the disputed services with the following claim adjustment codes:
  - CAC-45 – Charge exceeds fee schedule/maximum allowable or contracted/legislated fee arrangement.
  - 784 – Service exceeds recommendations of treatment guidelines (ODG)

### Issues

1. Is Theramine addressed in the division's pharmacy fee guidelines?
2. Did the requestor receive an out-of-network referral from the injured employee's treating doctor that has been approved by the network pursuant to §1305.103?
3. Is Theramine eligible for medical fee dispute resolution pursuant to 28 Texas Administrative Code §133.307?
4. Is Medrox 0.038%/5% Patch eligible for medical fee dispute resolution pursuant to 28 Texas Administrative Code §133.307?
5. Is the insurance carrier's reason for denial of payment for Medrox 0.038%/5% Patch supported?

### Findings

1. In resolving disputes over the amount of payment due for services determined to be medically necessary and appropriate for treatment of a compensable injury, the role of the division's medical fee dispute resolution program is to adjudicate the payment given the relevant statutory provisions and rules. 28 Texas Administrative Code §134.1 titled *Medical Reimbursement* states in pertinent part that

- (e) Medical reimbursement for health care not provided through a workers' compensation health care network shall be made in accordance with:
  - (1) the Division's fee guidelines;
  - (2) a negotiated contract; or
  - (3) in the absence of an applicable fee guideline or a negotiated contract, a fair and reasonable reimbursement amount as specified in subsection (f) of this section.

Provision at Rule §134.1(e)(1) is first considered. The requestor billed the service in dispute using a DWC Form-066 Statement of Pharmacy Services. The rules and regulations for pharmacy services are found at Texas Administrative Code Title 28, Part 2, Chapter 134, Subchapter F, with fee guidelines for pharmacy services found in §134.503. According to the medical bill, the disputed services include Theramine. Available information about Theramine indicates that it is a medical food. For example, Theramine is found in the Official Disability Guidelines under the procedure/topic "Medical Food."

To determine whether a fee guideline for medical foods is found in Subchapter F, the division examines the applicability portions of 28 Texas Administrative Code §134.503, amended to be effective October 23, 2011 (36 TexReg 6949), along with relevant definitions of terms pursuant to 28 Texas Administrative Code §134.500, adopted to be effective January 17, 2011 (35 TexReg 11344). Rule §134.503 states, in pertinent part:

- (a) Applicability of this section is as follows:
  - (1) This section applies to the reimbursement of **prescription drugs** [emphasis added] and **nonprescription drugs or over-the-counter medications** [emphasis added] as those terms are defined in §134.500 of this title (relating to Definitions) for outpatient use in the Texas workers' compensation system

The definition of those terms under Rule §134.500 are as follows:

- (8) Nonprescription drug or over-the-counter medication--A non-narcotic **drug** [emphasis added] that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law...

(12) Prescription **drug** [emphasis added] -- (A) A substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public; (B) A **drug** [emphasis added] that under **federal law** [emphasis added] 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 (C) A **drug** [emphasis added] 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.

That is, only substances considered prescription drugs, nonprescription drugs, or over-the-counter drugs by federal law are addressed in the fee guideline Rule §134.503. Additionally, the definition of closed formulary at Rule §134.500(3) clarifies that substances approved by the Food and Drug Administration (FDA) as prescription and nonprescription drugs form the basis for the pharmacy closed formulary. The FDA is therefore the federal program that the division relies upon in order determine whether a medical food, such as Theramine, is categorized as a prescription drug, nonprescription drug, or an over-the-counter drug for the purposes of the formulary and application of fees pursuant to Rule §134.503.

Information found on the FDA's website indicates that Medical foods are **not** regulated as drugs. Under the FDA's [Compliance Program Guidance Manual \(CPGM\)](#), medical foods are categorized under and regulated as "Food and Cosmetics." Specifically, under the Food Compliance Program numbered 7321.002 titled *Medical Foods – Import and Domestic*, implemented on August 24, 2006, the FDA states that "Only food regulations apply to medical foods." The division therefore concludes that Theramine, a medical food included in the disputed services, is not addressed in Texas Administrative Code Title 28, Part 2, Chapter 134, Subchapter F because it is not regulated as a drug by the FDA. Consequently, fees for these disputed services cannot be established pursuant to 28 Texas Administrative Code §134.503.

2. The requestor filed this medical fee dispute to the Division asking for resolution pursuant to 28 Texas Administrative Code §133.307. The authority of the Division of Workers' Compensation is to apply Texas Labor Code statutes and rules, including 28 TAC §133.307, is limited to the conditions outlined in the applicable portions of the Texas Insurance Code, Chapter 1305. Neither the insurance carrier nor the requestor asserted the network status of the health care provider. Through available information on the Texas Star Network website, the division finds that pharmacies, including the requestor, are not part of the Texas Star Network.

Because the dispute includes services that do not meet the definition of a drug subject to the division pharmacy exclusion in Texas Insurance Code §1305.101(c), these services are subject to TIC §1305.153(c) which provides that "Out-of-network providers who provide care as described by Section 1305.006 shall be reimbursed as provided by the Texas Workers' Compensation Act and applicable rules of the commissioner of workers' compensation."

Texas Insurance Code §1305.006(3) states, "health care provided by an out-of-network provider pursuant to a referral from the injured employee's treating doctor that has been approved by the network pursuant to Section 1305.103."

The requestor therefore has the burden to prove that the condition(s) outlined in the Texas Insurance Code §1305.006 were met in order to be eligible for dispute resolution for the services in question. Texas Insurance Code §1305.103 requires that:

- (e) A treating doctor shall provide health care to the employee for the employee's compensable injury and shall make referrals to other network providers, or request referrals to out-of-network providers if medically necessary services are not available within the network. Referrals to out-of-network providers must be approved by the network. The network shall approve a referral to an out-of-network provider not later than the seventh day after the date on which the referral is requested, or sooner if circumstances and the condition of the employee require expedited approval. If the network denies the referral request, the employee may appeal the decision through the network's complaint process under Subchapter I.

The requestor has the burden to prove that it obtained the appropriate approved out-of-network referral for the out-of-network healthcare it provided. Review of the submitted documentation does not find a

referral was from the treating doctor and approved by the network to treat the injured employee. The Division concludes that the requestor has therefore failed to meet the requirements of Texas Insurance Code §1305.103.

3. The Division finds that the requestor failed to prove in this case that the requirements of Texas Insurance Code §1305.006(3) were met. Consequently, the disputed service, Theramine, is not eligible for medical fee dispute resolution pursuant to 28 Texas Administrative Code §133.307.
4. Review of the submitted documentation finds that the dispute includes Medrox 0.038%/5% Patch, which is a compound medication including Methyl Salicylate, Menthol, and Capsaicin. Texas Insurance Code §1305.101 (c) states,

Notwithstanding any other provision of this chapter, prescription medication or services, as defined by Section 401.011(19)(E), Labor Code, **may not, directly or through a contract, be delivered through a workers' compensation health care network.** Prescription medication and services shall be reimbursed as provided by Section 408.0281, Labor Code, other provisions of the Texas Workers' Compensation Act, and applicable rules of the commissioner of workers' compensation [emphasis added].

The Preamble of 28 Texas Administrative Code §134.540, effective January 17, 2011, 35 TexReg 11344, states that the rule “concerns the requirements for the use of the pharmacy closed formulary for claims subject to certified networks.” In addition, “the Division notes the closed formulary applies to both certified network and non-network claims, and may not be amended by system participants.”

While the claim is part of a certified network, Medrox 0.038%/5% Patch may not be delivered through a health care network and is subject to the fee guidelines found in 28 Texas Administrative Code §134.503 and the closed formula guidelines found in 28 Texas Administrative Code §134.540. Further, because prescription medications may not be delivered through a workers' compensation health care network, this fee dispute involving Medrox 0.038%/5% Patch is subject to dispute resolution in accordance with 28 Texas Administrative Code §133.307.

5. The insurance carrier denied disputed services with claim adjustment reason code 784 – “SERVICE EXCEEDS RECOMMENDATIONS OF TREATMENT GUIDELINES (ODG).” 28 Texas Administrative Code §134.500 establishes the closed formulary, the applicable treatment guidelines for pharmaceutical services, as all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, with the exception of the following services that require preauthorization in accordance with 28 Texas Administrative Code §134.540(b):

- (1) drugs identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp (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' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary*, and any updates;** [emphasis added] 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 broadly accepted as the prevailing standard of care as defined in Labor Code §413.014(a).

Review of the submitted documentation finds that the dispute involves a compound drug that includes the ingredients Methyl Salicylate, Menthol, and Capsaicin. The *ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary* in effect on the date of service finds that Capsaicin is an “N” status drug. Therefore, the compound requires preauthorization.

Review of the submitted documentation does not indicate that a preauthorization was requested or obtained. The insurance carrier's denial reason is supported. Additional reimbursement cannot be recommended.

### **Conclusion**

For the reasons stated above, the Division finds that the requestor has not established that additional reimbursement is due. As a result, the amount ordered is \$0.00.

**ORDER**

Based upon the documentation submitted by the parties and in accordance with the provisions of Texas Labor Code §413.031, the Division has determined that the requestor is entitled to \$0.00 reimbursement for the disputed services.

**Authorized Signature**

_____	_____ Laurie Garnes _____	_____ December 17, 2015 _____
Signature	Medical Fee Dispute Resolution Officer	Date

***YOUR RIGHT TO APPEAL***

Either party to this medical fee dispute has a right to seek review of this decision in accordance with 28 Texas Administrative Code §133.307, 37 *Texas Register* 3833, applicable to disputes filed on or after June 1, 2012.

A party seeking review must submit a **Request to Schedule a Benefit Review Conference to Appeal a Medical Fee Dispute Decision** (form **DWC045M**) in accordance with the instructions on the form. The request must be received by the Division within **twenty** days of your receipt of this decision. The request may be faxed, mailed or personally delivered to the Division using the contact information listed on the form or to the field office handling the claim.

The party seeking review of the MFDR decision shall deliver a copy of the request to all other parties involved in the dispute at the same time the request is filed with the Division. **Please include a copy of the *Medical Fee Dispute Resolution Findings and Decision*** together with any other required information specified in 28 Texas Administrative Code §141.1(d).

**Si prefiere hablar con una persona en español acerca de ésta correspondencia, favor de llamar a 512-804-4812.**