

**SOAH DOCKET NO. 454-16-1884.M4-NP**  
**DWC NO. \_\_\_\_\_**

<b>TRAVELER’S INDEMNITY COMPANY</b>	<b>§</b>	<b>BEFORE THE STATE OFFICE</b>
<b>OF CONNECTICUT,</b>	<b>§</b>	
<b>Petitioner</b>	<b>§</b>	
	<b>§</b>	<b>OF</b>
<b>v.</b>	<b>§</b>	
	<b>§</b>	
<b>AMERICAN SPECIALTY PHARMACY,</b>	<b>§</b>	<b>ADMINISTRATIVE HEARINGS</b>
<b>Respondent</b>		

**DECISION AND ORDER**

Traveler’s Indemnity Company of Connecticut (Traveler’s) challenges a decision of the Texas Department of Insurance, Division of Worker’s Compensation (Division) that awarded American Specialty Pharmacy (American) reimbursement for a combination of several drugs compounded into a topical cream. Traveler’s appeared at the hearing and presented evidence in support of its position that, by compounding multiple ingredients into a single cream, American created a new drug that the Food and Drug Administration (FDA) has not recognized or approved. Consequently, the cream is considered investigational or experimental, thus requiring preauthorization under the Division’s rules. Although notified of the hearing, American did not appear. Based on the evidence, the Administrative Law Judge (ALJ) concludes that American is not entitled to reimbursement.

**I. JURISDICTION, NOTICE, AND PROCEDURAL HISTORY**

There are no issues of notice or jurisdiction. Therefore, these matters are addressed in the Findings of Fact and Conclusions of Law without further discussion.

Following the notification by Traveler’s that it was denying reimbursement for the compound cream, American requested medical fee dispute resolution with the Medical Review Division (MRD) of the Division. The Division’s Medical Fee Dispute Resolution Findings and Decision (MRD Decision) granted American reimbursement in the amount of \$1,612.95. In response, Traveler’s timely requested a hearing before the State Office of Administrative Hearings (SOAH) to contest the decision. A hearing convened and closed before Administrative Law Judge Gary Elkins on April 11, 2016, at SOAH’s facilities in Austin, Texas. Traveler’s appeared and was represented by attorney William Weldon. Despite receiving notice of the hearing, American did not appear.

## **II. DECISION**

In support of its position that American was not entitled to reimbursement in light of its failure to secure the required preauthorization for the compounded cream, Traveler's presented the testimony of Suzanne Novak, M.D. Dr. Novak, a board-certified anaesthesiologist with a PhD in pharmacology and the author of the pain chapter of the Official Disability Guidelines published by the Work Loss Data Institute, testified that the topical medication compounded by American (consisting of Fluriprofen POW, Cyclobenzaprine POW HCL, Baclofen POW, Ethoxy Liq Diglycol, Propylene Liq Glycol, and Versapro cream) was not medically necessary and not within the accepted standard of care. She explained that a topical analgesic such as the one involved in this case is not a medically necessary treatment for carpal tunnel syndrome, the ailment for which the topical cream compound was prescribed. Describing the mix of drugs as apparently having been "grabbed out of air," Dr. Novak explained that, with a compound, there is no way to know how much of the drugs the patient is actually receiving. She added that the use of a topical cream should be limited to those approved by the FDA.

Consistent with Dr. Novak's testimony, Traveler's asserts that 28 Texas Administrative Code § 134.530(b)(1)(C) requires preauthorization for "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 broadly accepted as the prevailing standard of care as defined in Labor Code § 413.014(a)." Because the compound constituted a new, non-approved and non-recognized drug that combined multiple ingredients into a single cream, Traveler's argues, it is considered investigational or experimental. Consequently, it required preauthorization, which was not obtained.

Based on the evidence and argument presented, Traveler's established that no reimbursement is warranted, as set out in the Findings of Fact and Conclusions of Law.

## **III. FINDINGS OF FACT**

1. Traveler's Indemnity Company of Connecticut (Traveler's) challenges a decision of the Texas Department of Insurance, Division of Worker's Compensation (Division) that awarded American Specialty Pharmacy (American) reimbursement in the amount of \$1,612.95 for a combination of several drugs compounded into a topical cream and provided to an injured worker.
2. Following the notification by Traveler's that it was denying reimbursement for the compound cream, American requested medical fee dispute resolution with the Division.

3. The Division's Medical Fee Dispute Resolution Findings and Decision (MRD Decision) granted American reimbursement in the amount of \$1,612.95.
4. In response to the MRD Decision, Traveler's timely requested a hearing before the State Office of Administrative Hearings (SOAH) to contest the decision.
5. On January 14, 2016, the Division issued a Notice of Hearing to the parties. The notice informed the parties of the date, time, and location of the hearing; the matters to be considered; the legal authority under which the hearing would be held; and the statutory provisions applicable to the matters to be considered.
6. A hearing convened and closed before Administrative Law Judge Gary Elkins on April 11, 2016, at SOAH's facilities in Austin, Texas. Traveler's appeared and was represented by attorney William Weldon. Despite being notified of the hearing, American did not appear.
7. The topical cream compounded by American, and for which American seeks reimbursement, contained Fluriprofen POW, Cyclobenzaprine POW HCL, Baclofen POW, Ethoxy Liq Diglycol, Propylene Liq Glycol, and Versapro cream.
8. By compounding multiple ingredients into a single cream, American created a new drug.
9. The Food and Drug Administration has not recognized or approved the topical cream compounded by American.
10. The topical cream is an investigational or experimental drug, and it has not been broadly accepted as the prevailing standard of care.
11. The topical cream was not a medically necessary treatment for carpal tunnel syndrome, the ailment for which the compound was prescribed.

#### **IV. CONCLUSIONS OF LAW**

1. SOAH has jurisdiction over this proceeding, including the authority to issue a decision and order, pursuant to Texas Labor Code § 413.0312 and Texas Government Code ch. 2003.
2. Adequate and timely notice of the hearing was provided in accordance with Texas Government Code §§ 2001.051 and 2001.052.

3. Because the topical cream was investigational or experimental in nature and has not been accepted as the prevailing standard of care, its use required preauthorization. 28 Texas Administrative Code § 134.530(b)(1)(C).
4. American did not obtain preauthorization for the topical cream.
5. The topical cream was not medically necessary.
6. American is not entitled to any reimbursement for the topical cream.

**ORDER**

**IT IS ORDERED** that American is not entitled to reimbursement for the topical cream provided to the injured worker.

**NONPREVAILING PARTY DETERMINATION**

Texas Labor Code § 413.0312(g) and 28 Texas Administrative Code § 133.307(h) require the nonprevailing party to reimburse the Division for the cost of services provided by SOAH. Texas Labor Code § 413.0312(i) requires SOAH to identify the nonprevailing party and any costs for services provided by SOAH in its final decision. For purposes of Texas Labor Code § 413.0312, American Specialty Pharmacy is the nonprevailing party. The costs associated with this decision are set forth in Attachment A to this Decision and Order and are incorporated herein for all purposes.

**SIGNED June 2, 2016.**

  
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**GARY W. BLKINS**  
**ADMINISTRATIVE LAW JUDGE**  
**STATE OFFICE OF ADMINISTRATIVE HEARINGS**