SOAH DOCKET NO. 454-18-2743.M4-NP MRD NO. _____

CARRIER,	§	BEFORE THE STATE OFFICE
Petitioner	§	
	§	
v.	§	OF
	§	
HEALTHCARE PROVIDER,	§	
Respondent	§	ADMINISTRATIVE HEARINGS

DECISION AND ORDER

Carrier challenges a decision of the Texas Department of Insurance, Division of Worker's Compensation (Division) that awarded Healthcare Provider (HCP) reimbursement for a combination of several drugs compounded into a topical cream. Carrier appeared at the hearing and presented evidence in support of its position that, by compounding multiple ingredients into a single cream, HCP 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. Based on the evidence, the Administrative Law Judge (ALJ) concludes that HCP 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 Carrier that it was denying reimbursement for the compound cream, HCP 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 HCP reimbursement in the amount of \$12,612.98. In response, Carrier 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 Rudy Calderon on September 24, 2018, at SOAH's facilities in Austin, Texas. Carrier appeared and was represented by attorney BJ. Despite receiving notice of the hearing, HCP did not appear.

II. DECISION

In support of its position that HCP was not entitled to reimbursement in light of its failure to secure the required preauthorization for the compounded cream, Carrier presented the testimony of NT, M.D. Dr. T, a board-certified orthopaedic surgeon, testified that the topical medication compounded by HCP (consisting of Propylene Glycol, Gabapentin, Fluticasone Propionate, Pracasil Plus-Base AWP cream, Naproxen, and Methyl Salicylate) was not medically necessary and not within the accepted standard of care. He explained that a topical analgesic such as the one involved in this case is not a medically necessary treatment for scar tissue, the condition for which the topical cream compound was prescribed. Dr. T explained that, with a compound, there is no way to know how much of the drugs the patient is actually receiving and the efficacy of the individual components to treat the scarring.

Consistent with Dr. T's testimony, Carrier 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, Carrier argues, it is considered investigational or experimental. Consequently, it required preauthorization, which was not obtained.

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

III. FINDINGS OF FACT

- 1. Carrier challenges a decision of the Texas Department of Insurance, Division of Worker's Compensation (Division) that awarded HCP reimbursement in the amount of \$12,612.98 for a combination of several drugs compounded into a topical cream and provided to an injured worker.
- 2. Following the notification by Carrier that it was denying reimbursement for the compound cream, HCP requested medical fee dispute resolution with the Division.
- 3. The Division's Medical Fee Dispute Resolution Findings and Decision (MRD Decision) granted HCP reimbursement in the amount of \$12,612.98.

- 4. In response to the MRD Decision, Carrier timely requested a hearing before the State Office of Administrative Hearings (SOAH) to contest the decision.
- 5. On March 19, 2018, 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 Rudy Calderon on September 24, 2018, at SOAH's facilities in Austin, Texas. Carrier appeared and was represented by attorney BJ. Despite being notified of the hearing, HCP did not appear.
- 7. The topical cream compounded by HCP, and for which HCP seeks reimbursement, contained Propylene Glycol, Gabapentin, Fluticasone Propionate, Pracasil Plus-Base AWP cream, Naproxen, and Methyl Salicylate.
- 8. By compounding multiple ingredients into a single cream, HCP created a new drug.
- 9. HCP did not obtain preauthorization for the topical cream.
- 10. The Food and Drug Administration has not recognized or approved the topical cream compounded by HCP.
- 11. The topical cream is an investigational or experimental drug, and it has not been broadly accepted as the prevailing standard of care.
- 12. The topical cream was not a medically necessary treatment for scar tissue, the condition 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. The topical cream was not medically necessary.

5. HCP is not entitled to any reimbursement for the topical cream.

ORDER

IT IS ORDERED that HCP 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, HCP 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 November 26, 2018.

RUDY CALDERON ADMINISTRATIVE LAW JUDGE STATE OFFICE OF ADMINISTRATIVE HEARINGS