

SOAH DOCKET NO. 454-18-3323.M4-NP
DWC NO. _____

SOAH DOCKET NO. 454-18-3545.M4-NP
DWC NO. _____

SOAH DOCKET NO. 454-18-4105.M4-NP
DWC 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 Workers' Compensation (Division) that awarded Healthcare Provider (HCP) a \$1,688.74 reimbursement for a compound topical cream prepared by HCP. Carrier argued that because the compound cream was not a drug approved by the Food and Drug Administration (FDA), it required preauthorization. The Administrative Law Judge (ALJ) concludes HCP is not entitled to reimbursement because preauthorization was not obtained.

I. JURISDICTION, NOTICE, AND PROCEDURAL HISTORY

There are no contested issues of notice or jurisdiction in this case. Those matters are addressed in the findings of fact and conclusions of law. On (Date of Injury), (Claimant) sustained a compensable workers' compensation injury. On three separate dates in 2017, HCP dispensed a compound cream to Claimant to treat the injury. HCP's request for reimbursement was denied by Carrier, and HCP requested medical fee dispute resolution with the Division of Worker's Compensation's Medical Review Division (MRD).

The MRD's Medical Fee Dispute Resolution Findings and Decision (MRD Decision) awarded HCP reimbursement in the amount of \$1,688.74. Carrier timely requested a hearing before the State Office of Administrative Hearings (SOAH). On September 5, 2018, ALJ Steven

M. Rivas convened a hearing at SOAH in Austin, Texas. Carrier appeared and was represented by attorney JT. HCP appeared and was represented by attorney BM. The record closed the same day.

II. APPLICABLE LAW

The Division has adopted a “closed formulary” defined at 28 Texas Administrative Code § 134.500(3) as all available FDA approved prescription and nonprescription drugs prescribed and dispensed for outpatient use.¹ Excluded from the closed formulary are the following:

- drugs identified with a status of “N” in the current edition of the *Official Disability Guidelines* (ODG);
- any prescription drug created through compounding prescribed before July 1, 2018, that contains a drug identified with a status of “N” in the current edition of the ODG;
- any prescription drug created through compounding prescribed and dispensed on or after July 1, 2018; and
- 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).²

Pursuant to 28 Texas Administrative Code § 134.540(e), a drug that is excluded from the closed formulary requires preauthorization.

III. DISCUSSION

Carrier argued that the compound cream dispensed by HCP was excluded from the closed formulary on the basis that it was not FDA approved. In support of its position, Carrier emphasized that rule 134.500(3) mandates only FDA approved drugs be included in the closed formulary. Carrier also cited a prior SOAH Decision in *(Carrier) v. (Healthcare Provider)*,

¹ 28 Tex. Admin. Code § 134.502(b).

² 28 Tex. Admin. Code § 134.500(3)(A)-(D).

SOAH Docket No. 454-16-4910.M4-NP.³ In that case, (Healthcare Provider) sought reimbursement for a compound cream that the FDA had not recognized or approved. The ALJ in *(Carrier) v. (Healthcare Provider)*, SOAH Docket No. 454-16-4910.M4-NP concluded, among other things, that the compound cream was not recognized or approved by the FDA. As such, it required preauthorization; and because preauthorization was not obtained, the ALJ denied reimbursement.⁴

In this case, HCP argued that the compound cream was not excluded from the closed formulary because each active ingredient within the compound cream was FDA-approved. Furthermore, HCP argued, the current edition of the ODG assigned each active ingredient a “Y” status, meaning the drug was classified as being part of the closed formulary.⁵ The active ingredients in the compound cream dispensed by HCP on each date of service are as follows:

Date of Service	Ingredients	Reimbursement ordered
June 29, 2017	Meloxicam, Flurbiprofen, Tramadol, Cyclobenzaprine, and Bupivacaine	\$566.53
July 14, 2017	Meloxicam, Flurbiprofen, Tramadol, Cyclobenzaprine, and Bupivacaine	\$566.53
July 26, 2017	Baclofen, Amantadine, Gabapentin, Bupivacaine, and Amitriptyline	\$555.68
Total		\$1,688.74

HCP is correct that each individual drug that comprised the compound cream is FDA approved. That being the case, HCP argued, the compound cream should be included in the closed formulary. Carrier argued, however, that HCP’s reasoning fails to consider three important distinctions. First, each drug that was used to manufacture the compound cream was

³ Carrier Ex. 3. Decision issued by ALJ Gary Elkins on February 2, 2017.

⁴ *Id.*

⁵ Drugs assigned with an “N” status are not part of the closed formulary and would require preauthorization.

FDA approved only as an injectable or by tablet (oral) dosage form.⁶ None of the drugs at issue were FDA approved to be taken or applied in a topical dosage form.⁷ Second, Carrier argued, the FDA does not recognize or approve the resulting mixture or compound of two or more of the drugs at issue in any dosage form, be it oral, topical, or otherwise. Third, Carrier argues, the compound cream itself, in its final (topical dosage) form is not FDA approved. Hence, because the compound cream is not FDA approved, it is not part of the closed formulary and requires preauthorization.

The ALJ agrees with Carrier's position. The FDA does not recognize or approve the compound cream in its final state. Similarly, the FDA does not recognize or approve that any of the individual ingredients that make up the compound cream to be taken in a topical dosage form. Finally, the FDA does not recognize or approve that two or more of the compound cream's individual ingredients be mixed and taken in any dosage form.

Because the compound cream and its ingredients, are not FDA approved and thus not part of the closed formulary, preauthorization was required under 28 Texas Administrative Code § 134.540(e), but it was not obtained. As a result, HCP is not entitled to reimbursement.

IV. FINDINGS OF FACT

1. Carrier challenges three decisions of the Texas Department of Insurance, Division of Workers' Compensation (Division) that awarded HCP a reimbursement for a compound cream HCP prepared and provided to (Claimant) on three occasions.
2. HCP dispensed compound cream to Claimant on June 29, 2017, which was comprised of Meloxicam, Flurbiprofen, Tramadol, Cyclobenzaprine, and Bupivacaine.
3. HCP dispensed compound cream to Claimant on July 14, 2017, which was comprised of Meloxicam, Flurbiprofen, Tramadol Cyclobenzaprine, and Bupivacaine.
4. HCP dispensed compound cream to Claimant on July 26, 2017, which was comprised of Baclofen, Amantadine, Gabapentin, Bupivacaine, and Amitriptyline.

⁶ Carrier Ex. 6. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

⁷ *Id.*

5. HCP sought reimbursement from Carrier for the compound cream it dispensed on the three dates of service, but Carrier denied each request for reimbursement.
6. HCP requested medical fee dispute resolution with the Division of Worker's Compensation's Medical Review Division (MRD).
7. The MRD's Medical Fee Dispute Resolution Findings and Decision (MRD Decision) found in favor of HCP and awarded a total reimbursement amount of \$1,688.74.
8. Carrier timely requested hearings before the State Office of Administrative Hearings (SOAH) to contest the MRD Decisions.
9. The Division issued timely Notices of Hearing to the parties.
10. Each Notice of Hearing contained a statement of the time, place, and nature of the hearing; a statement of the legal authority and jurisdiction under which the hearing was to be held; a reference to the particular sections of the statutes and rules involved; and either a short, plain statement of the factual matters asserted or an attachment that incorporates, by reference, the factual matters asserted in the complaint or petition filed with the state agency.
11. On September 5, 2018, Administrative Law Judge Steven M. Rivas convened a hearing at SOAH in Austin, Texas. Carrier was represented by attorney JT. HCP was represented by attorney BM. The record closed the same day.
12. The compound cream HCP dispensed is not approved by the Food and Drug Administration (FDA).
13. The FDA has not recognized or approved topical cream as the dosage form for any of the ingredients identified in Findings of Fact Nos. 2, 3, and 4.
14. The FDA has not recognized or approved that a mixture or compound of any of the ingredients identified in Findings of Fact Nos. 2, 3, and 4, be taken in any dosage form.
15. HCP did not seek preauthorization for the compound cream.

V. 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-.052.

3. Compound cream that is not FDA approved is not part of the Division's closed formulary. 28 Tex. Admin. Code § 134.500(3).
4. A medication that is excluded from the closed formulary requires preauthorization. 28 Tex. Admin. Code § 134.450(e).

ORDER

HCP is not entitled to reimbursement for the compound cream it provided to Claimant.

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 of Workers' Compensation for the cost of services provided by SOAH. Texas Labor Code § 413.0312(i) requires that SOAH 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 2, 2018.

STEVEN M. RIVAS
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS