

SOAH DOCKET NOS. 454-19-0171.M4-NP *et al.* (See Attachment A)
MRD NOS. _____ *et al.* (See Attachment A)

STATE OFFICE OF RISK MANAGEMENT, Petitioner	§	BEFORE THE STATE OFFICE
	§	
	§	
	§	
v.	§	OF
	§	
MEMORIAL COMPOUNDING PHARMACY, Respondent	§	ADMINISTRATIVE HEARINGS

**DECISION AND ORDER
ON MOTIONS FOR SUMMARY DISPOSITION**

Petitioner, the State Office of Risk Management (SORM), and Respondent, Memorial Compounding Pharmacy (Memorial) both filed Motions for Summary Disposition in these cases. SORM’s Motion is **GRANTED**; Memorial’s is **DENIED**. The Administrative Law Judge (ALJ) determines that Memorial should not be reimbursed for the amounts at issue.

I. JURISDICTION AND PROCEDURAL HISTORY

There are no contested issues of jurisdiction in this case. That matter is addressed in the conclusions of law.

SORM challenges several decisions of the Texas Department of Insurance, Division of Workers’ Compensation (Division) that awarded Memorial reimbursement for compound topical creams prepared by Memorial and provided to workers’ compensation claimants.¹

Memorial requested reimbursement for the compound creams, which was denied by SORM. SORM asserted that because the compound creams were not drugs approved by the Food and Drug Administration (FDA), they required preauthorization, which had not been requested. Memorial filed for medical fee dispute resolution with the Division’s Medical Review

¹ The case numbers are listed in Attachment A to this Decision and Order.

Division (MRD). The MRD's Medical Fee Dispute Resolution Findings and Decisions awarded Memorial reimbursement. SORM timely requested hearings before the State Office of Administrative Hearings (SOAH). The cases were consolidated and were set for joint hearing on February 27, 2019. Before that date, Memorial filed a motion to abate, citing the pendency in the 250th District Court of *Memorial Compounding Pharmacy v. State Office of Risk of Management*, Cause No. D-1-GN-18-007510, which was an appeal of the State Office of Administrative Hearings (SOAH) decision in Docket Nos. 454-18-3323.M4-NP *et al.*, which involved the same parties and type of compound creams as these cases and determined that preauthorization was required for reimbursement for the types of compound creams at issue. SORM opposed abatement and filed its Motion for Summary Disposition on the grounds that the issues had already been determined by SOAH. Memorial opposed the motion and filed its own Motion for Summary Disposition on both the preauthorization issue and a separate issue--that utilization review should have been, but was not, conducted in these cases. Oral argument was heard June 27, 2019, and the cases were abated until October 9, 2020, when the ALJ ordered the parties to file an update regarding the court proceedings. SORM filed an update on October 20, 2020; that update stated that although the declaratory judgment aspect of those cases have been dismissed, the merits remain on appeal.²

II. UNDISPUTED FACTS

In addition to the facts set forth above, it is undisputed that all the ingredients in the compound creams at issue contained only drugs identified with the letter "Y" in the Official Disability Guidelines (ODG) Workers' Compensation Drug Formulary, that the compound creams at issue were not approved by the FDA, and that Memorial did not seek preauthorization for the preparation and provision of any of the compound creams at issue. It is also undisputed that no utilization reviews were requested or conducted.

² Memorial did not file an update.

III. DISCUSSION

Summary disposition of a contested case may be granted, in full or in part, without the necessity of a hearing on the merits, if the pleadings, the motion for summary disposition, and the summary disposition evidence, show that there is no genuine issue of any material fact and that the moving party is entitled to decision in its favor as a matter of law on all or some of the issues expressly set out in the motion.³

These cases have been abated for a significant amount of time, with no prospect for imminent resolution of the court proceedings related to Docket Nos. 454-18-3323.M4-NP *et al.* The ALJ has determined that resolution of the pending motions for summary disposition is warranted rather than allow them to linger further at SOAH. If the parties desire, these cases can be consolidated with Docket Nos. 454-18-3323.M4-NP *et al.* on appeal.

A. Preauthorization Requirement

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.⁴ Pursuant to 28 Texas Administrative Code § 134.540(e), a drug that is excluded from the closed formulary requires preauthorization. Drugs with a status of “Y” are not specifically excluded from the closed formulary, but FDA approval is still required. In Docket Nos. 54-18-3323.M4-NP, *et al.*, SORM argued that the compound cream dispensed by Memorial to those claimants was excluded from the closed formulary on the basis that it was not FDA-approved. As in these cases, the ingredients in the compound cream each had a designated status of “Y,” but the compound cream itself was not FDA-approved and was not addressed in the formulary. Memorial argued that the compound cream at issue was not excluded from the closed formulary because each active ingredient within the compound cream was FDA approved. Furthermore, Memorial 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.

³ 1 Tex. Admin Code §155.505.

⁴ 28 Tex. Admin. Code § 134.502(b) (emphasis added).

The ALJ in Docket Nos. 454-18-3323.M4-NP, *et al.* concluded that because the compound cream was not FDA-approved and thus not part of the closed formulary, preauthorization was required under 28 Texas Administrative Code § 134.540(e), but was not obtained. As a result, he determined, Memorial was not entitled to reimbursement.

Docket Nos. 454-18-3323.M4-NP, *et al.* involved the same parties and the same issues as these cases. The ALJ concludes that the preauthorization issue has been decided, that summary disposition should be rendered in SORM'S favor on that issue, and that Memorial's motion for summary disposition on that issue should be denied.

B. Utilization Review

Memorial contends that SORM was barred from denying reimbursement on the basis that the compound creams were investigational or experimental drugs, because SORM failed to request utilization review under Texas Insurance Code § 4201.206. That section states:

Sec. 4201.206. OPPORTUNITY TO DISCUSS TREATMENT BEFORE ADVERSE DETERMINATION.

- (a) Subject to Subsection (b) and the notice requirements of Subchapter G, before an adverse determination is issued by a utilization review agent who questions the medical necessity, the appropriateness, or the experimental or investigational nature of a health care service, the agent shall provide the health care provider who ordered, requested, provided, or is to provide the service a reasonable opportunity to discuss with a physician licensed to practice medicine the patient's treatment plan and the clinical basis for the agent's determination.
- (b) If the health care service described by Subsection (a) was ordered, requested, or provided, or is to be provided by a physician, the opportunity described by that subsection must be with a physician licensed to practice medicine.

In response, SORM contends that because preauthorization was required for the non-FDA-approved compound creams, utilization review was not required. If utilization review had been requested, the results of that review would be moot, because Memorial still did not request preauthorization before dispensing the compound creams and reimbursement would still be denied.

The ALJ agrees with SORM. It has already been established that the compound creams at issue required preauthorization because they were not FDA-approved. Regardless of whether they are characterized as investigational or experimental, any request for utilization review would be moot, because the compound creams were not reimbursable. Memorial's motion for summary disposition on that basis should be denied.

IV. FINDINGS OF FACT

1. Petitioner, the State Office of Risk Management (SORM), challenges several decisions of the Texas Department of Insurance, Division of Workers' Compensation (Division) that awarded Respondent, Memorial Compounding Pharmacy (Memorial) reimbursement for compound topical creams prepared by Memorial and provided to workers' compensation claimants. Those cases are listed in Attachment A.
2. Memorial requested reimbursement for the compound creams, which was denied by SORM.
3. SORM asserted that because the compound creams were not drugs approved by the Food and Drug Administration (FDA), they required preauthorization, which had not been requested.
4. Memorial filed for medical fee dispute resolution with the Division's Medical Review Division (MRD). The MRD's Medical Fee Dispute Resolution Findings and Decisions awarded Memorial reimbursement.
5. SORM timely requested hearings before the State Office of Administrative Hearings (SOAH).
6. The cases were consolidated and were set for joint hearing on February 27, 2019. Before that date, Memorial filed a motion to abate, citing the pendency in the 250th District Court of *Memorial Compounding Pharmacy v. State Office of Risk of Management*, Cause No. D-1-GN-18-007510, which was an appeal of the SOAH decision in Docket Nos. 454-18-3323.M4-NP *et al.*, which involved the same parties and types of compound creams as these cases and determined that preauthorization was required for reimbursement for the types of compound creams at issue.
7. SORM opposed abatement and filed its Motion for Summary Disposition on the grounds that the issues had already been determined by SOAH. Memorial opposed the motion and filed its own Motion for Summary Disposition on both the preauthorization issue and a separate issue--that utilization review should have been, but was not, conducted in these cases.
8. Oral argument was heard June 27, 2019, and the cases were abated until October 9, 2020, when the Administrative Law Judge (ALJ) ordered the parties to file an update regarding the court proceedings. SORM filed an update on October 20, 2020.

9. All the ingredients in the compound creams at issue contained only drugs identified with the letter “Y” in the Official Disability Guidelines (ODG) Workers’ Compensation Drug Formulary.
10. The compound creams at issue were not approved by the FDA.
11. Memorial did not seek preauthorization for the preparation and provision of any of the compound creams at issue.
12. No utilization reviews were requested or conducted.

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 chapter 2003.
2. Summary disposition of a contested case may be granted, in full or in part, without the necessity of a hearing on the merits, if the pleadings, the motion for summary disposition, and the summary disposition evidence, show that there is no genuine issue of any material fact and that the moving party is entitled to decision in its favor as a matter of law on all or some of the issues expressly set out in the motion. 1 Tex. Admin Cod §1555.505.
3. The ALJ in Docket Nos. 454-18-3323.M4-NP, *et al.* concluded that because the compound cream was not FDA-approved and thus not part of the closed formulary, preauthorization was required under 28 Texas Administrative Code § 134.540(e), but was not obtained. As a result, he determined, Memorial was not entitled to reimbursement.
4. The preauthorization issue has been decided and summary disposition should be rendered in SORM’s favor on that issue. Memorial’s motion for summary disposition on that issue should be denied.
5. Any request for utilization review under Texas Insurance Code § 4201.206 would be moot, because the compound creams were not reimbursable. Memorial’s motion for summary disposition should be denied.

ORDER

The Motion for Summary Disposition filed by the State Office of Risk Management is **GRANTED**. The Motion for Summary Disposition filed by Memorial Compounding Pharmacy (Memorial) is **DENIED**. Memorial is not entitled to reimbursement for the compound creams it provided to workers’ compensation claimants.

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, Memorial Compounding Pharmacy is the nonprevailing party. The costs associated with this decision are set forth in Attachment B to this Decision and Order and are incorporated herein for all purposes.

SIGNED November 3, 2020.

**HENRY D. CARD
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS**

ATTACHMENT A

454-19-0171.M4-NP	MRD NO. _____
454-19-0257.M4-NP	MRD NO. _____
454-19-0318.M4-NP	MRD NO. _____
454-19-0387.M4-NP	MRD NO. _____
454-19-0822.M4-NP	MRD NO. _____
454-19-0823.M4-NP	MRD NO. _____
454-19-0824.M4-NP	MRD NO. _____
454-19-1088.M4-NP	MRD NO. _____
454-19-1521.M4-NP	MRD NO. _____
454-19-1522.M4-NP	MRD NO. _____
454-19-1523.M4-NP	MRD NO. _____
454-19-1524.M4-NP	MRD NO. _____
454-19-1525.M4-NP	MRD NO. _____
454-19-1526.M4-NP	MRD NO. _____
454-19-1527.M4-NP	MRD NO. _____
454-19-1528.M4-NP	MRD NO. _____
454-19-1529.M4-NP	MRD NO. _____