

**SOAH DOCKET NO. 454-16-4910.M4-NP**  
**DWC NO. \_\_\_\_\_**

<b>OLD REPUBLIC INSURANCE</b>	§	<b>BEFORE THE STATE OFFICE</b>
<b>COMPANY,</b>	§	
<b>Petitioner</b>	§	
	§	
<b>v.</b>	§	<b>OF</b>
	§	
<b>MEMORIAL COMPOUNDING</b>	§	
<b>PHARMACY,</b>	§	
<b>Respondent</b>	§	<b>ADMINISTRATIVE HEARINGS</b>

**DECISION AND ORDER**

Old Republic Insurance Company (Old Republic) challenges a decision of the Texas Department of Insurance, Division of Workers’ Compensation (Division) that awarded Memorial Compounding Pharmacy (Memorial) reimbursement for a compound topical cream prepared by Memorial. Old Republic argued that, because the topical cream was not recognized by the Food and Drug Administration (FDA), it would be considered investigational or experimental, thereby requiring preauthorization. Because Memorial did not obtain preauthorization, however, it was not entitled to reimbursement.

In support of its position, Old Republic cited a prior Decision issued by the State Office of Administrative Hearings (SOAH) in *Traveler’s Indemnity Company of Connecticut v. American Specialty Pharmacy*, SOAH Docket No. 454-16-1884.M4-NP. In that case, the product for which reimbursement was sought was also a compound cream that the FDA had not recognized. Consistent with the carrier’s position, this Administrative Law Judge (ALJ) concluded that the topical cream was investigational or experimental in nature and had not been accepted as the prevailing standard of care. As a result, it required preauthorization. Because preauthorization was not obtained in that case, the ALJ denied reimbursement.

Memorial argued that, although the cream it compounded was not recognized or approved by the FDA, it was not investigational due to the nature of the drugs it contained. Thus, Memorial was entitled to reimbursement for it.

The ALJ agrees with Old Republic’s position. The Division’s rules, at 28 Texas Administrative Code § 134.530(b)(1)(C), require 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).” As both parties noted, the

FDA has not recognized the cream, and there is no evidence the cream has been broadly accepted as the prevailing standard of care. Consequently, preauthorization was required under § 134.530(b)(1)(C), but it was not obtained. As a result, Memorial is not entitled to reimbursement.

## I. FINDINGS OF FACT

1. Old Republic Insurance Company (Old Republic) challenges a decision of the Texas Department of Insurance, Division of Worker's Compensation that awarded Memorial Compounding Pharmacy (Memorial) reimbursement for a topical compound cream Memorial prepared and provided to an injured worker.
2. Following the notification by Old Republic that it was denying reimbursement for the compound cream, Memorial requested medical fee dispute resolution with the Division of Worker's Compensation's Medical Review Division (MRD).
3. The MRD's Medical Fee Dispute Resolution Findings and Decision (MRD Decision) awarded Memorial reimbursement in the amount of \$489.96.
4. In response to the MRD Decision, Old Republic timely requested a hearing before the State Office of Administrative Hearings (SOAH) to contest the decision.
5. On June 29, 2016, the Division of Worker's Compensation issued a Notice of Hearing to the parties. The notice informed the parties of the date, time, and location of the hearing; the factual 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 December 5, 2016, at SOAH's facilities in Austin, Texas. Old Republic appeared and was represented by attorney John Fundis. Anna Baltazar appeared on behalf of Memorial.
7. The cream Memorial compounded, for which it seeks reimbursement, contained Baclofen Powder, Amantadine HCL, Gabapentin USP, Amityptyline HCL, and Bupivacaine HCL.
8. The Food and Drug Administration (FDA) has not recognized or approved the topical cream.
9. The topical cream is an investigational or experimental drug.
10. Memorial did not seek preauthorization for the topical cream.

## II. 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. Because the topical cream has not been recognized or approved by the FDA as the prevailing standard of care, its use required preauthorization. 28 Tex. Admin. Code § 134.530(b)(1)(C).
4. Memorial is not entitled to any reimbursement for the topical cream.


### ORDER

**IT IS ORDERED** that Memorial 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 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 A to this Decision and Order and are incorporated herein for all purposes.

**SIGNED February 2, 2017.**

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