SOAH Docket Nos. 454-21-3024; 454-21-3104; 454-21-3139; 454-21-3164; 454-21-3168; 454-21-3169; 454-21-3253; 454-21-3254; 454-21-3255; 454-21-3103; 454-21-3105; 454-21-3167
Suffix: M4-NP

MRD Nos. _____

BEFORE THE STATE OFFICE OF ADMINISTRATIVE HEARINGS

ZURICH AMERICAN INSURANCE COMPANY; BAPTIST HOSPITALS OF SOUTHEAST TEXAS; AND OLD REPUBLIC INSURANCE CO.,
PETITIONERS
V.
MEMORIAL COMPOUNDING PHARMACY
RESPONDENT

DECISION AND ORDER

Zurich American Insurance Company, Baptist Hospitals of Southeast Texas, and Old Republic Insurance Company (collectively, Carriers) separately challenged twelve decisions of the Texas Department of Insurance, Division of Workers' Compensation (the Division) awarding reimbursement to Memorial Compounding Pharmacy (Memorial)(Provider) primarily for drugs created through compounding.[1] Based on common issues of fact and law, the cases were joined for hearing.

[1] Compounding is defined in Texas Occupations Code section 551.003(9) as "the preparation, mixing, assembling, packaging, or labeling of a drug or device" See also Tex. Admin. Code § 134.500. Although "compound drug" and "compound" are not defined terms in the Texas Workers Compensation Act or Division rules, the phrase "compounded drug" as used in this Decision and Order is shorthand for "any prescription drug created through compounding."

After considering the evidence in the context of the applicable law, the drugs dispensed by Memorial were not approved by the Food and Drug Administration (FDA) and were considered investigational or experimental. Because Memorial did not seek and obtain preauthorization under the Division's rules, the Administrative Law Judge (ALJ) finds that Carriers met their burden of proof on all twelve claims and Memorial is not entitled to reimbursement.

I. NOTICE, JURISDICTION, AND PROCEDURAL HISTORY

There are no contested notice issues in any of the twelve dockets.[2] Following notifications by the Carriers that they were denying reimbursement for the compounds, Memorial requested medical fee dispute resolution with the Medical Fee Dispute Resolution (MFDR) department of the Division. The MFDR decisions were in Memorial's favor, and Carriers requested de novo contested case hearings before the State Office of Administrative Hearings (SOAH).

The joined cases convened for hearing on July 26, 2022, via Zoom videoconference. At the start of the hearing, Memorial's counsel requested a continuance based on personal circumstances. Memorial's counsel also contended he was not prepared to cross-examine the Carriers' expert witness. Memorial's request for continuance was granted in part and denied in part. All of Carriers' exhibits were admitted, and in lieu of live testimony, the ALJ converted the case for consideration on written submission and allowed the Carriers to present expert testimony with the written closing brief. A briefing schedule was ordered with the record close date set for September 6, 2022.

[2] As an alternative argument on the merits, the Carriers contend that there is no jurisdiction in nine of the dockets (454-21-3139, 454-21-3103, 454-21-3104, 454-21-3168, 454-21-3169, 454-21-3024, 454-21-3253, 454-21-3255, and 454-21-3164) because retrospective medical necessity disputes and the extent of the injuries in the underlying claims were unresolved at the Division. As discussed below, the ALJ determines there is no jurisdiction to consider the dispute in 454-21-3164. Because the Carriers prevailed on the merits and it is dispositive of the claims in this case, the ALJ declines to reach the alternative jurisdictional argument.

Memorial submitted a written closing brief and included an affidavit of KU, which was signed on December 10, 2018. The affidavit was not exchanged, referenced, or submitted before or during the July 26, 2022 setting. Ms. U also did not appear at the hearing and was not offered as a witness. The Carriers objected to the affidavit on several grounds. The objections to the affidavit are well-taken and sustained. Accordingly, Ms. U's affidavit is not admitted as evidence and the ALJ has considered only the arguments in Memorial's response brief.

II. DISCUSSION

A. APPLICABLE LAW

An employee under the Texas Workers' Compensation system who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed, including investigational or experimental services.[3] "Health care reasonably required" means health care that is clinically appropriate and considered effective for the injured employee's injury and provided according to best practices consistent with evidence-based medicine or, if evidence-based medicine is not available, then generally accepted standards of medical practice recognized in the medical community.[4] The Commissioner of the Division is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused, and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care.[5] Accordingly, the Division has adopted treatment guidelines known as the Official Disability Guidelines (ODG) in 28 Texas Administrative Code section 137.100.[6] Further, Texas Labor Code section 413.014 authorizes the Division to adopt rules regarding preauthorization.

---

[3] Tex. Labor Code §408.021; *see* 38 Tex. Reg. 918 (February 15, 2013) ("TDI's position is that, based upon Labor Code § 408.021, an injured employee is entitled to health care reasonably required by the nature of the injury as and when needed, including experimental and investigational health care services").

[4] Tex. Labor Code § 401.011 (22-a).

[5] Tex. Labor Code § 413.011(e).

[6] All references to "Division Rule" refer to the Divisions' rules found in Texas Administrative Code, Title 28, Part 2.

Relevant here, the Division has published the ODG Workers' Compensation Drug Formulary (Closed Formulary).[7] By definition, the Closed Formulary consists of all available FDA-approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, subject to specific exclusions.[8] A provider is not required to obtain preauthorization for drugs contained in the Closed Formulary, but the following categories are excluded from the Closed Formulary and require preauthorization from the carrier:[9]

> (A) drugs identified with a status of "N" in the current edition of the Official Disability Guidelines (ODG);[10]
>
> (B) 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;
>
> (C) any prescription drug created through compounding prescribed and dispensed on or after July 1, 2018; and
>
> (D) 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 Texas Labor Code section 413.014(a).[11]

---

[7] 28 Tex. Admin. Code § 134.500(3); *see also* 28 Tex. Admin. Code § 134.502; Tex. Labor Code § 408.028(b).

[8] 28 Tex. Admin. Code §§ 134.500(3), .502, .530((b)(1)(A)-(D); *see also* Tex. Labor Code § 413.014(a) (defining "investigational or experimental drug").

[9] 28 Tex. Admin. Code §§ 134.530(e), .540(e) (restating requirement for preauthorization of pharmaceuticals not in the Closed Formulary for certified and non-certified networks); *see also* 28 Tex. Admin. Code § 134.600(p)(11).

[10] Drugs listed in the Closed Formulary are assigned "Y" or "N" status. Drugs assigned "Y" status may be dispensed without preauthorization and do not require utilization review. Drugs assigned "N" status require preauthorization.

[11] 28 Tex. Admin. Code §§ 134.500(3), .502, .530((b)(1)(A)-(D).

The resolution of a fee dispute is regulated by the Division's billing, audit, and payment rules.[12] In an appropriate case, a medical provider, such as Memorial, may dispute the amount paid by an insurance carrier, and in those cases, the Division's authority is limited to resolving "the amount due for services determined to be medically necessary and appropriate."[13] On the other hand, issues regarding medical necessity and appropriateness (i.e., not payment) for workers' compensation matters are not resolved through the Division and instead are resolved by utilization review through an Independent Review Organization (IRO) process.[14]

If it is determined in utilization review that the healthcare services provided or proposed to be provided to an injured employee are not medically necessary or appropriate, the provider receives an "Adverse Determination."[15] In the context of a group health insurance policy, the utilization review process resolves the question of whether a particular medical service is investigational or experimental.[16] Unlike the group health context, however, utilization review in a workers' compensation matter is not required to assign an investigational or experimental status to any drug (including a compounded drug) because the definition of "Adverse Determination" expressly excludes that determination.[17] When a provider contests an Adverse Determination, the provider must appeal the Adverse Determination within 45 days of receipt of the decision.[18]

---

[12] *See* 28 Tex. Admin. Code ch. 133.

[13] 28 Tex. Admin. Code § 133.307; Tex. Labor Code § 413.031(c).

[14] 28 Tex. Admin. Code § 19.2009.

[15] 28 Tex. Admin. Code § 19.2003(b)(1).

[16] Tex. Ins. Code § 4201.206.

[17] 28 Tex. Admin. Code § 19.2003(b)(1) ("(1) Adverse determination--A determination by a URA made on behalf of a payor that the health care services provided or proposed to be provided to an injured employee are not medically necessary or appropriate. The term does not include a denial of health care services due to the failure to request prospective or concurrent utilization review. **For the purposes of this subchapter, an adverse determination does not include a determination that health care services are experimental or investigational.**") (emphasis added).

[18] 28 Tex. Admin. Code § 133.308(a)(3), (g), (h).

B. EVIDENCE

There are several undisputed facts in the twelve claims:

- Memorial dispensed compounded drugs in ten of the twelve disputes.
- All of the compounded drugs at issue in this case were prescribed before July 1, 2018.
- The compounded drugs at issue in eleven of the twelve claims were not approved by the FDA.
- Memorial did not seek preauthorization for the preparation and provision of any of the drugs.
- All the ingredients in the compounded drugs contained only drugs identified with the letter "Y" in the Closed Formulary.
- None of the individual ingredients in the compounded drugs were approved for topical application.
- The Carriers issued Adverse Determinations for each claim.

In their closing brief, the Carriers presented the expert testimony of Suzanne Novak, M.D., Ph.D.[19] Dr. Novak is board-certified in Anesthesiology by the American Board of Anesthesiology. Dr. Novak also has a doctoral degree in Pharmacy Administration and is a Clinical Assistant Professor in the College of Pharmacy at the University of Texas at Austin. She is also the author of the Topical Analgesic entry in the Pain Chapter in the ODG.

According to Dr. Novak, the general concept of compounded drugs is to prepare customized medication formulations that are not available for individual patients who have specialized needs. For example, a patient may need the oral pill/capsule formulation of a drug to be in liquid form, or a patient who is allergic to the FDA formulation may need a compounded drug without the allergic component.

---

[19] Addendum 6 to Carriers' Closing Brief.

Dr. Novak testified that the FDA approves specific topical agents (as a gel, cream, or solution) that are identified in the Closed Formulary, but in the claims involved here the compounded drugs created by Memorial were not verified by the FDA for safety, effectiveness, or quality before being marketed; accordingly, the compounded drugs were not FDA-approved. As of July 1, 2018, there were only six topical drugs identified in the Closed Formulary and none of them were included in the compounded drugs at issue:[20]

Drug Class	Generic Name	Brand Name	Generic Equivalent	Status
Topical analgesics	Capsaicin, topical	Qutenza	No	N
Topical analgesics	Diclofenac Sodium Gel	Voltaren® Gel	Yes	Y
Topical analgesics	Dimethylsulfoxide	DMSO	Yes	N
Topical analgesics	Ketamine, topical	Ketamine	Yes	N
Topical analgesics	Lidocaine, topical	Lidoderm®	Yes	N
Topical analgesics	Salicylate topicals	Ben-Gay	Y-OTC	Y

According to Dr. Novak, the compounded drugs created by Memorial were investigational or experimental and thus "not recommended" based on several factors including : the use (i.e., topical application of the compounded drug for eleven of twelve of the claims); the form of the drug(s); and the medium used (solution, gel, cream, ointment, etc.). Dr. Novak also referenced the medical records of the patients involved, which demonstrated that for several claims, there was simultaneous prescription(s) of the oral form of the same or similar drugs contained in the topical compound, which resulted in the inability to determine what drugs or class of drugs and in what amount were actually being delivered to the patient. Dr. Novak also noted the following:

[20] Appendix A, ODG Workers' Compensation Drug Formulary.

- ODG recommendations do not allow for use of FDA-approved oral and topical NSAIDs simultaneously;
- The compounded drugs include duplication of classes of drugs in the compound (i.e., including two to three NSAIDs);
- The compounded drugs duplicated an ingredient from the compounded drug with an oral drug the claimant was taking;
- In numerous cases, if the individual drug was prescribed orally (i.e., as an FDA-approved oral formulation), it would not even be indicated for the work injury in question; and
- Reasonably expected adverse reactions from combining the component drugs had not been investigated.

Finally, Dr. Novak stated that, because many of the component drugs in the compounded drug have conflicting effects, additive effects, and/or no known effects in topical applications, the combination of factors rendered the compounded drugs experimental. The following is a summary of the patient information in the twelve claims with a reference to the specific ingredients of the compounded formulations.[21]

Cause Number/ Patient Identifier	Injury	Compound Ingredients	Additional considerations
454-21-3105 A.T.	Shoulder strain/sprain	• Meloxicam (non- steroidal anti-inflammatory drug (NSAID)) • Flurbiprofen (NSAID) • Tramadol (opioid) • Cyclobenzaprine (muscle relaxant) • Bupivacaine (local anesthetic)	Duplication of classes of drugs; duplicate of a compound drug with oral drug prescription; local anesthetic would not be indicated for a work injury.

[21] *See also* Addendum 1 to Carriers' Closing Brief.

Cause Number/ Patient Identifier	Injury	Compound Ingredients	Additional considerations
454-21-3139 D.B.	Lower back strain	• Meloxicam (NSAID) • Flurbiprofen (NSAID) • Tramadol (opioid) • Cyclobenzaprine (muscle relaxant) • Bupivacaine (local anesthetic)	Duplication of classes of drugs; D.B. also prescribed several oral medications in same classes, including methocarbamol (a muscle relaxant), Lidoderm patches (FDA-approved topical),and oxycodone; local anesthetic would not be indicated for a work injury.
454-21-3103 T.J.	Right knee sprain	• Meloxicam (NSAID) • Flurbiprofen (NSAID) • Tramadol (opioid) • Cyclobenzaprine (muscle relaxant) • Bupivacaine (local anesthetic)	Duplication of classes of drugs; duplicate of a compound drug with oral drug prescription Compound applied as cream rather than gel. Number of NSAIDs increases risk of gastrointestinal adverse events.

Cause Number/ Patient Identifier	Injury	Compound Ingredients	Additional considerations
454-21-3014 T.J. (same patient as above)		• Meloxicam (NSAID) • Flurbiprofen (NSAID) • Mefenamic Acid (NSAID) • Baclofen (muscle relaxant)	Duplication of classes of drugs; no evidence as to how much, if any, of the individual Meloxicam is actually delivered.
454-21-3168 T.J. (same patient as above)		• Meloxicam (NSAID) • Flurbiprofen (NSAID) • Mefenamic Acid (NSAID) • Baclofen (muscle relaxant)	Same as above.
454-21-3169 T.J.(same patient as above)		Same as 454-21-3168	Same as above.
454-21-3024 C.D.	Tarsal tunnel syndrome and complex regional pain syndrome	• Meloxicam (NSAID) • Flurbiprofen (NSAID) • Tramadol (opioid) • Cyclobenzaprine (muscle relaxant) • Bupivacaine (local anesthetic)	Duplication of classes of drugs.

Cause Number/ Patient Identifier	Injury	Compound Ingredients	Additional considerations
454-21-3253 J.P.	Failed back syndrome, lower back pain, lumbar radiculopathy, lumbar facet syndrome, and muscle spasm	• Baclofen (muscle relaxant) • Amantadine HCl (movement disorders) • Gabapentin (anticonvulsant) • Bupivacaine (local anesthetic) • Amitrityptyline HCl (anti-depressant)	J.P. also on oral tramadol and ibuprofen; duplicate of a compound drug with oral drug prescription
454-21-3254 J.P. (same patient as above)		• Tramadol tabs • Ibuprofen tabs	This date of service was a prescription for two oral medications between two fills of the topical compound in 454-21-3253 and 454-21-3255; tramadol was stopped on 12/4/7 because it made the claimant lightheaded.
454-21-3255 J.P. (same patient as above)		Same as 454-21-3253	

Cause Number/ Patient Identifier	Injury	Compound Ingredients	Additional considerations
454-21-3164 C.H.	Lumbar strain; aggravation of disc "protrusion"	• Tramadol tab (opioid) • Cyclobenzaprine tab (muscle relaxant)	Division determined the compensable injury did not extend to conditions the Carrier claimed were unrelated
454-21-3167 B.W.	Contusion to left knee; sprain of medial collateral ligament of left knee	• Meloxicam (NSAID) • Flurbiprofen (NSAID) • Tramadol (opioid) • Cyclobenzaprine (muscle relaxant) • Bupivacaine (local anesthetic)	Duplication of classes of drugs; no research to support the topical use of cyclobenzaprine. The drug relieves muscle spasm centrally (possibly in the brain stem) with no direct action on the muscle.

C. Analysis

As Memorial acknowledges, previous SOAH Decisions and Orders (all involving claims by Memorial) uniformly concluded that a carrier is relieved of liability for reimbursement when the provider has failed to seek and/or receive preauthorization for compounded drugs (topical or otherwise) that are not in the Closed Formulary.[22] The claims in dispute here are no different from the prior matters—in many cases the ingredients in the compounded drugs are identical—and Memorial re-urges the same arguments from prior cases before SOAH that remain unpersuasive.

[22] *See* Decisions and Orders in 454-18-3324.M4.Np, 454-18-4177.M4-NP, 454-18-4955.M4-NP, 454-19-0171.M4-NP, 454-16-4910.M4-NP, and 454-16-1844.M4-NP

Memorial again contends that because the ingredients of the compounded drugs in dispute were all "Y" drugs, the resulting compounded drug should be considered in the Closed Formulary. Citing 28 Texas Administrative Code sections 134.500(3)(c) and .530(b)(3), Memorial also asserts that the Division's rules regarding pharmaceutical benefits did not require preauthorization for compounded drugs containing "Y" drugs until after July 1, 2018. However, when the Division clarified its rules to note that all compounded drugs were subject to preauthorization, it did not absolve Memorial of the existing requirement to demonstrate the medical necessity and appropriateness of its compounded drugs.

Memorial concedes that the FDA does not recognize or approve that two or more of any of the individual ingredients be mixed and administered in topical form. Memorial does not dispute that all of the "Y" drugs/ingredients contained in the compounded drugs were FDA-approved only for oral use, and none of the compounded drugs included any of the approved topical drugs in the Closed Formulary (i.e., Voltaren Gel and Ben-Gay). Under the combination of oral medications and compounded creams prescribed to each patient, Dr. Novak persuasively opined that no one could reasonably predict how much of each drug class would be delivered and reasonably expected adverse reactions had not been investigated (another point that Memorial does not dispute). As Dr. Novak noted, there is no scientific analysis of the compounded drugs at issue, and they have not been accepted as the prevailing standard of care. Consistent with Dr. Novak's testimony, when Memorial combined multiple ingredients—none of which were approved for topical use—into a single topical formulation, the result was a new, non-FDA approved and non-recognized drug that was experimental and investigational. Accordingly, except for the oral medications in SOAH Docket Nos. 454-21-3254 and 454-21-3164, discussed below, the compounded drugs were not in the Closed Formulary, and Memorial was required to seek preauthorization, which was not obtained.

Regarding SOAH Docket No. 454-21-3254, this date of service was a prescription for two oral medications (tramadol and ibuprofen) prescribed between two fills of the topical compounds in SOAH Docket Nos. 454-21-3253 and 454-21-3255, both of which had Adverse Determinations. The Carriers demonstrated by a preponderance of the evidence that there was no reason for prescribing as the patient had already indicated lightheadedness from tramadol. This drug regimen reasonably falls into the investigational or experimental categories and required preauthorization,

which was not obtained. Regarding SOAH Docket No. 454-21-3164, the Division determined the compensable injury did not extend to conditions identified for the drug. This Adverse Determination was not appealed by Memorial within 45 days. Accordingly, there is no jurisdiction to consider that dispute. In sum, Memorial is not entitled to reimbursement on any of its claims.

III. FINDINGS OF FACT

1. Zurich American Insurance Company, Baptist Hospitals of Southeast Texas, and Old Republic Insurance Company (collectively, Carriers) separately challenged twelve decisions of the Texas Department of Insurance, Division of Workers' Compensation (the Division) awarding reimbursement to Memorial Compounding Pharmacy (Memorial) for certain drugs created through compounding (also referred to as compounded drugs).

2. Following notifications by the Carriers that they were denying reimbursement for the compounds, Memorial requested medical fee dispute resolution with the Medical Fee Dispute Resolution (MFDR) department of the Division. The MFDR decisions were in Memorial's favor, and Carriers requested de novo contested case hearings before an Administrative Law Judge (ALJ) of the State Office of Administrative Hearings (SOAH). Based on common issues of fact and law, the cases were joined for hearing only.

3. The cases convened for hearing on July 26, 2022, via Zoom videoconference before ALJ Vasu Behara. A briefing schedule was ordered with the record close date set for September 6, 2022.

4. SOAH Docket No. 454-21-3105 - Memorial dispensed a compounded drug to Patient A.T. for shoulder strain/pain that included the following ingredients: meloxicam (non-steroidal anti-inflammatory drug (NSAID)); flurbiprofen (NSAID); tramadol (opioid); cyclobenzaprine (muscle relaxant); and bupivacaine (local anesthetic).

5. SOAH Docket No. 454-21-3139 - Memorial dispensed a compounded drug to Patient D.B. for lower back string that included meloxicam (NSAID); flurbiprofen (NSAID); tramadol (opioid); cyclobenzaprine (muscle relaxant); and bupivacaine (local anesthetic).

6. SOAH Docket No. 454-21-3103 - Memorial dispensed a compounded drug to Patient T.J. for a right knee sprain that included meloxicam (NSAID); flurbiprofen (NSAID); tramadol (opioid); cyclobenzaprine (muscle relaxant); and bupivacaine (local anesthetic).

7. SOAH Docket No. 454-21-301 - Memorial dispensed a compounded drug to Patient T.J. for a right knee sprain that included meloxicam (NSAID); flurbiprofen (NSAID); mefenamic Acid (NSAID); and baclofen (muscle relaxant).

8. SOAH Docket No. 454-21-3168 - Memorial dispensed a compounded drug to Patient T.J. for a right knee sprain that included meloxicam (NSAID); flurbiprofen (NSAID); mefenamic Acid (NSAID); and baclofen (muscle relaxant).

9. SOAH Docket No. 454-21-3169 - Memorial dispensed a compounded drug to Patient T.J. for a right knee sprain that included meloxicam (NSAID); flurbiprofen (NSAID); mefenamic Acid (NSAID); and baclofen (muscle relaxant).

10. SOAH Docket No. 454-21-3024 - Memorial dispensed a compounded drug to Patient C.D. for tarsal tunnel syndrome and complex regional pain syndrome that included meloxicam (NSAID); flurbiprofen (NSAID); tramadol (opioid); cyclobenzaprine (muscle relaxant); and bupivacaine (local anesthetic).

11. SOAH Docket No. 454-21-3253 - Memorial dispensed a compounded drug to Patient J.P. for failed back syndrome, lower back pain, lumbar radiculopathy, lumbar facet syndrome, and muscle spasm. The compounded drug included Baclofen (muscle elaxant); amantadine HCl (movement disorders); Gabapentin (anticonvulsant); Bupivacaine (local anesthetic); and amitrityptyline HCl (anti-depressant).

12. SOAH Docket No. 454-21-3254 - Memorial dispensed Tramadol and Ibuprofen tabs to Patient J.P. for failed back syndrome, lower back pain, lumbar radiculopathy, lumbar facet syndrome, and muscle spasm. Tramadol had been ceased previously because it made Patient J.P. lightheaded.

13. SOAH Docket No. 454-21-3255 - Memorial dispensed a compounded drug to Patient J.P. for failed back syndrome, lower back pain, lumbar radiculopathy, lumbar facet syndrome, and muscle spasm. The compounded drug included baclofen (muscle relaxant); mantadine HCl (movement disorders); gabapentin (Anticonvulsant); bupivacaine (local anesthetic); and amitrityptyline HCl (Anti-depressant).

14. SOAH Docket No. 454-21-3164 - Memorial dispensed a tramadol (opioid) tab and cyclobenzaprine Tab (muscle relaxant) to Patient C.H. for lumbar strain and aggravation of disc "protrusion." The Division determined the conditions were not related to the compensable injury and the Adverse Determination was not appealed by Memorial within 45 days.

15. SOAH Docket No. 454-21-3167 – Memorial dispensed a compounded drug to Patient B.W. for a contusion to the left knee and sprain of the medial collateral ligament of the left knee. The ingredients included meloxicam (NSAID), flurbiprofen (NSAID), tramadol (opioid), cyclobenzaprine (muscle relaxant), and bupivacaine (local anesthetic).

16. The Carriers issued Adverse Determinations for each of the twelve claims.

17. All of the compounded drugs at issue in the ten of twelve claims were prescribed before July 1, 2018.

18. All the ingredients in the compounded drugs contained only drugs identified with the letter "Y" in the Division's Office of Disability Guidelines Workers' Compensation Drug Formulary (Closed Formulary).

19. All of the "Y" drugs/ingredients contained in the compounded drugs were approved by the Food and Drug Administration (FDA) only for oral use.

20. As of July 1, 2018, there were only six topical drugs identified in the Closed Formulary and none of them were included in the compounded drugs dispensed by Memorial.

21. The compounded drugs created by Memorial were not verified by the FDA for safety, effectiveness, or quality before being marketed; accordingly, the compounded drugs were not FDA approved.

22. The compounded drugs included duplication of classes of drugs in the compound (i.e., including two to three NSAIDs).

23. The compounded drugs contained an ingredient that duplicated an oral drug the claimant was taking.

24. Reasonably expected adverse reactions from combining the component drugs had not been investigated.

25. There is no scientific analysis of the compounded drugs at issue and they have not been accepted as the prevailing standard of care.

26. The Official Disability Guidelines (ODG) recommendations do not allow for use of FDA approved oral and topical NSAIDs simultaneously.

27. Memorial allowed for simultaneous prescription(s) of the oral form of the same or similar drugs contained in the topical compound, which resulted in the inability to determine what drugs or class of drugs and in what amount are actually being delivered to the patient.

28. The compounded drugs at issue were investigational or experimental and required preauthorization.

29. Memorial did not seek preauthorization for the preparation and provision of any of the drugs for the twelve claims.

IV. CONCLUSIONS OF LAW

1. SOAH has jurisdiction over these proceedings, 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. Claimants appealing from a denial of coverage must appeal the insurance carrier's denial within 45 days of denial or the claim is waived. 28 Tex. Admin. Code § 133.308(h).

4. The Division has published the ODG Workers' Compensation Drug Formulary (Closed Formulary). Tex. Labor Code § 408.028(b); 28 Tex. Admin. Code §§ 134.500(3), .502.

5. A provider is not required to obtain preauthorization for drugs contained in the Closed Formulary. 28 Tex. Admin. Code §§ 134.530(e), .540(e), .600(p)(11).

6. A medication that is excluded from the closed formulary requires preauthorization. 28 Tex. Admin. Code § 134.450(e).

7. The Closed Formulary consists of all available FDA-approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, subject to specific exclusions. 28 Tex. Admin. Code §§ 134.500(3), .502, .530((b)(1)(A)-(D); see also Tex. Labor Code § 413.014(a).

8. A compounded drug that is not FDA-approved is not part of the Closed Formulary. 28 Tex. Admin. Code § 134.500(3).

9. The following category is also excluded from the Closed Formulary: 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 Texas Labor Code section 413.014(a). 28 Tex. Admin. Code §§ 134.500(3), .502, .530((b)(1)(D).

10. Memorial is not entitled to reimbursement on any of the twelve claims.

V. ORDER

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

VI. NONPREVAILING PARTY DETERMINATION

Texas Labor Code section 413.0312(g) and 28 Texas Administrative Code section 133.307(h) require the nonprevailing party to reimburse the Division for the cost of services provided by SOAH. Texas Labor Code section 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 NOVEMBER 2, 2022.

Vasu Behara,
Presiding Administrative Law Judge