TEXAS DEPARTMENT OF INSURANCE
Division of Workers' Compensation - Medical Fee Dispute Resolution (MS-48)
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MEDICAL FEE DISPUTE RESOLUTION FINDINGS AND DECISION

GENERAL INFORMATION

Requestor Name
Memorial Compounding Pharmacy

Respondent Name
K-Mart Corporation

MFDR Tracking Number
M4-17-2195-01

Carrier's Austin Representative
Box Number 17

MFDR Date Received
March 20, 2017

REQUESTOR'S POSITION SUMMARY

Requestor's Position Summary: "The attached bill has been denied not timely filed. The reconsideration was sent to the carrier but denied. We are now requesting Medical Fee Dispute Resolution."

Amount in Dispute: $489.96

RESPONDENT'S POSITION SUMMARY

Respondent's Position Summary: "The compound medication required preauthorization because several of the components of the medication, specifically bupivacaine, cannot be located on the Appendix A, ODG Workers' Compensation Drug Formulary, from the Official Disability Guidelines – Treatment in Workers' Comp (ODG). DWC Rule 134.530(d)(1) states in part, prescription and nonprescription drugs included in the Division's adopted closed formulary may be dispensed without preauthorization. Three components of the compound medication in dispute are not included in the Division's adopted closed formulary; therefore, preauthorization for the entire compound medication was required.

Further, compound medication constitute a new, non-approved and non-recognized drug and is considered investigational/experimental … The State Office of Administrative Hearings (SOAH) found in SOAH Docket 454-16-1884.M4-NP that compounding multiple ingredients into a single cream, the pharmacy created a new drug that was not recognized or approved by the FDA and was not the accepted, prevailing standard of care. Because the compound medication was investigational or experimental in nature and was not accepted as the prevailing standard of care, it required preauthorization. The same applies to the medication at issue in this matter."

Response Submitted by: Downs-Stanford, P.C.

SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
April 14, 2016	Pharmacy Services - Compound	$489.96	$489.96

FINDINGS AND DECISION

This medical fee dispute is decided pursuant to Texas Labor Code §413.031 and applicable rules of the Texas Department of Insurance, Division of Workers' Compensation.

Rules and Laws

1. Texas Labor Code §413.014
2. 28 Texas Administrative Code §133.20
3. 28 Texas Administrative Code §133.210
4. 28 Texas Administrative Code §133.307
5. 28 Texas Administrative Code Chapter 134, Subchapter F
6. Federal Food, Drug and Cosmetic Act Section 503A and 503B added by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115)
7. Section 503A of the FD&C Act (21 United States Code 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist
8. Section 505 (21 United States Code 355) concerning the approval of drugs under new drug applications or abbreviated new drug applications.

Denial Reasons and Defenses Presented to Memorial Prior to MFDR

1. Explanation of Benefits (EOB) dated November 7, 2016:
    - 29 – The time limit for filing has expired
    - 937 – Service(s) are denied based on HB7 provider timely filing requirement. A provider must submit a medical bill to the insurance carrier on or before the 95th day after the date of service.
2. EOB dated February 16, 2017:
    - 947 – Upheld. No additional allowance has been recommended.
    - 5264 – Payment is denied-service not authorized.
    - 948 – Re-reviewed at providers request with additional information and documentation. Additional payment suggested.

Issues

1. Did Memorial Compounding Pharmacy (Memorial) submit a bill within 95 days in accordance with 28 Texas Administrative Code §133.20?
2. Did K-Mart Corporation support its assertion that the compound in dispute requires FDA approval?
3. Did the compounded cream in dispute require preauthorization because it is "investigational or experimental"?
4. Did the compounded cream in dispute require preauthorization for other reasons?
5. Is reimbursement due to Memorial for the compound in dispute? If so, in what amount?

Background

Memorial is seeking reimbursement of $489.96 for a compound dispensed on April 14, 2016. The following compound ingredients are included in the request:

- Gabapentin USP, NDC 38779246109, 3.6 gm
- Amitriptityline HCl, NDC 38779018904, 1.8 gm
- Baclofen, NDC 38779038809, 5.4 gm
- Amantadine HCl, NDC 38779041105, 3.0 gm
- Bupivacaine HCl, NDC 38779052405, 1.2 gm

K-Mart Corporation denied the compound in dispute asserting that preauthorization was required but not obtained. Memorial did not request or obtain preauthorization for the compound in question. At issue is

whether preauthorization is required in this case. In its response to medical fee dispute resolution, Downs-Stanford, P.C. argued on behalf of K-Mart Corporation:

> The State Office of Administrative Hearings (SOAH) found in SOAH Docket 454-16-1884.M4-NP that compounding multiple ingredients into a single cream, the pharmacy created a new drug that was not recognized or approved by the FDA and was not the accepted, prevailing standard of care. Because the compound medication was investigational or experimental in nature and was not accepted as the prevailing standard of care, it required preauthorization. The same applies to the medication at issue in this matter.

Through EOBs and blanket reference to State Office of Administrative Hearings' June 2, 2016 Decision and Order, the contention of K-Mart Corporation is that compounded medications are categorically "investigational or experimental" – thereby triggering a preauthorization requirement under the division's rule.

In general, 28 Texas Administrative Code Chapter 134, Subchapter F, Rule §134.530(b)(1), requires a provider, in this case a dispensing pharmacy, to seek preauthorization under three separate circumstances.

(A) drugs identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates;
(B) any compound that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates; and
(C) 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).

K-Mart Corporation relies, in part, upon the above SOAH decision to support its position that preauthorization was required under Rule 134.530(b)(1)(C). The administrative law judge, in that case, appears to have reasoned, and by extension K-Mart Corporation now asserts:

- that lack of FDA "recognition or approval" of the compound cream in dispute leads to the conclusion that the compounded cream was an "investigational or experimental" drug; and
- that preauthorization was therefore required pursuant to §134.530(b)(1)(C).

The division now compares the position statements, assertions, and documentation timely filed with MFDR to the applicable FDA and division pharmacy formulary provisions in order to determine whether the denial of payment by K-Mart Corporation for the stated reasons are supported.

Findings and Rationale

1. *Did Memorial Compounding Pharmacy (Memorial) submit a pharmaceutical bill within 95 days in accordance with 28 Texas Administrative Code §133.20?*

   On EOB dated November 7, 2016, Sedgwick, third party administrator for K-Mart Corporation, denied the compound in question for timely filing with claim adjustment reason codes 29 – "THE TIME LIMIT FOR FILING HAS EXPIRED," and 937 – "SERVICE(S) ARE DENIED BASED ON HB7 PROVIDER TIMELY FILING REQUIREMENT. A PROVIDER MUST SUBMIT A MEDICAL BILL TO THE INSURANCE CARRIER ON OR BEFORE THE 95TH DAY AFTER THE DATE OF SERVICE."

   This denial reason was upheld on the reconsideration EOB dated February 16, 2017. The timely filing requirement for a medical bill is found in Rule §133.20(b), which requires health care providers to submit a medical bill not later than "the 95th day after the date the services are provided."

   Rule §133.210(e) establishes the following requirement for insurance carriers and their agents:

   > It is the insurance carrier's obligation to furnish its agents with any documentation necessary for the resolution of a medical bill. The Division considers any medical billing information or documentation possessed by one entity to be simultaneously possessed by the other.

The dispensing date of the disputed compound is April 14, 2016. Review of the documentation submitted by the requestor finds a fax confirmation page dated April 20, 2016 indicating receipt by Sedgwick—the respondent's agent. The receipt date is before the 95th day after the date the service was provided.

The division concludes the requestor timely submitted the bill for the disputed compound in accordance with Rule §133.20. The respondent's denial reason regarding untimely filing is not supported.

2. *Did the carrier support its assertion that the compound cream in dispute requires FDA approval?*

To address whether compounds are recognized by the FDA, and to address whether compounds require FDA approval, the division finds it prudent to review the FDA's general, publicly available guidance pertaining to the compounding of drug products. Most of this information can be found on the *FDA's Information on Compounding* webpage at www.FDA.gov. There, one finds that the FDA not only recognizes compounds through its regulations, those same regulations also address the question of whether compounded drug products require FDA approval.

Pharmacies that are appropriately licensed to compound drug products fall into one of two categories, each with corresponding FDA regulations: (1) Pharmacies that do not register as outsourcing facilities and (2) Pharmacies/facilities that choose to register with the FDA as an outsourcing facility. These FDA regulations state, in pertinent part:

- Pharmacies that do not register as outsourcing facilities are required to meet Section 503A of the Federal Food, Drug and Cosmetic Act. See the June 2016 FDA guidance document, Revision 2, titled *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug and Cosmetic Act*.
- Pharmacies/facilities that choose to register with the FDA as an outsourcing facility are required to meet Section 503B of the Federal Food, Drug and Cosmetic Act. See the November 2014 FDA guidance document, titled *Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*.

If the pharmacy complies with the requirements outlined in the applicable regulation, the compounded drug product is exempt from Section 505 (21 United States Code 355) concerning the approval of drugs under the new drug application process. On the other hand, if the compounding pharmacy fails to meet those requirements, the compounded medication would indeed be subject to the FDA's new drug application and approval process.

Memorial is not registered as an outsourcing facility.[1] For this reason, 503A applies and thus exempts the compound cream in dispute from FDA approval. K-Mart Corporation failed to provide case-specific information sufficient to support a conclusion to the contrary. K-Mart Corporation therefore failed to demonstrate that the compound cream in dispute required FDA approval under Section 505.

Based on the submitted information, the division concludes the respondent did not support its assertion that the disputed compound required FDA approval.

3. *Does the compound cream in dispute require preauthorization because it is "investigational or experimental"?*

Because K-Mart Corporation failed to demonstrate that the compounded cream in this dispute required FDA approval, then its subsequent assertion that the compounded cream is "investigational or experimental" also fails. Under this approach, it follows that if lack of FDA recognition or approval is not determinative, then the compounded cream at issue is not necessarily "investigational or experimental."

The division now examines the terms "investigational or experimental" as they relate to compounded drug products. The terms "investigational or experimental" are collectively defined under Texas Labor Code Sec. 413.014(a) as follows:

[1] Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) www.FDA

> In this section, "investigational or experimental service or device" means a health care treatment, service or device for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, service, or device but that is not yet broadly accepted as the prevailing standard of care.

Per the language of the Act cited above and Rule §134.530(b)(1)(C), the critical definitional concepts are:

- early, developing scientific or clinical evidence demonstrating the potential efficacy
- not yet broadly accepted as the prevailing standard of care.

Accordingly, per the text of the Act and rules, on a case-by-case basis, a given compound may be characterized as "investigational or experimental" by a qualified reviewer when reliable evidence shows that the compound is the subject of developing scientific or clinical review; or that the prevailing opinion regarding the compound is that further review is necessary to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis. In the absence of any evidence of these, or related case-specific considerations, a general assertion that a given compounded medication is "investigational or experimental" fails.

It must be noted that the definition of "investigational or experimental" set forth in Texas Labor Code Sec. 413.014 (a) is far from unique to the Texas workers' compensation system. Instead, this definition is utilized broadly in the context of health care coverage. And as various systems require determination of "investigational or experimental" status for various purposes, multiple examples of similar definitional guidelines are in the public domain.[2] The relevant point for present purposes is that as the Act and division rule reflect, determination of "investigational or experimental" status for whatever purpose is a case-specific, fact-intensive exercise that does not lend itself to categorical determinations that any given device, service, treatment protocol, or drug is "investigational or experimental."

Applying the foregoing analysis and noting again the absence of case-specific evidence, the required conclusion is that the compounded cream in this case is not "investigational or experimental" and, thus, did not trigger the preauthorization requirement.

Additionally, the division notes that K-Mart Corporation did not explain how it determined the disputed compounded in this dispute to be "investigational or experimental" and whether that determination was made by a utilization review agent certified under Insurance Code, Chapter 4201. Insurance Code, Section 4201.002 defines "utilization review" to include "a system to determine the experimental or investigational nature of health care services."

Accordingly, the division concludes the respondent has failed to support its assertion that the disputed compound was "investigational or experimental." The preauthorization requirement under Rule §134.530(b)(1)(C) was therefore not triggered.

4. *Does the compound cream in dispute require preauthorization for other reasons?*

In its response to medical fee dispute resolution, Downs-Stanford, P.C. also argued:

> The compound medication required preauthorization because several of the components of the medication, specifically bupivacaine, cannot be located on the Appendix A, ODG Workers' Compensation Drug Formulary, from the Official Disability Guidelines – Treatment in Workers' Comp (ODG). DWC Rule 134.530(d)(1) states in part, prescription and nonprescription drugs included in the Division's adopted closed formulary may be dispensed without preauthorization. Three components of the compound medication in dispute are not included in the Division's adopted closed formulary; therefore, preauthorization for the entire compound medication was required.

[2] See, for example, the definitional statements found at:
http://www.aetna.com/members/individuals/health/plan_details/NewYork/experimental.pdf
https://www.unitedhealthcareonline.com/.../ExperimentalIDE_Clinical_Trials_UHCM.
https://www.priorityhealth.com/provider/manual/auths/~/media/.../91117.pdf
https://www.capbluecross.com/wps/wcm/connect/62ef6d1d-5c51-413b-b765-51eaa83b7f4f/Experimental+and+Investigational+Procedures.pdf?MOD=AJPERES

28 Texas Administrative Code §134.530(b)(1) requires preauthorization **only** for the reasons noted above. A drug's absence in the ODG, *Appendix A* does not trigger a requirement for preauthorization. On the contrary, except in the case of an "investigational or experimental" determination, a requirement for preauthorization is triggered **only** by the presence of a drug or ingredient in the ODG, *Appendix A,* listed with a status of "N."

Review of the submitted documentation finds that the compound in question does not include a drug identified with a status of "N" in the current edition of the ODG, *Appendix A*.

The division now summarizes its findings pursuant to the provisions of Rule §134.530(b)(1) which sets out the circumstances under which Memorial would have been required to obtain preauthorization.

- Provision §134.530(b)(1)(A) preauthorization requirement is not addressed as it was not asserted by either party in this dispute.
- Memorial was not required to seek preauthorization pursuant to §134.530(b)(1)(B) because none of the compounded ingredients have a status of "N" in the current edition of the ODG /Appendix A.
- Memorial was not required to seek preauthorization pursuant to §134.530(b)(1)(C) because K-Mart Corporation failed to demonstrate that the compound in this dispute required FDA approval; and failed to demonstrate that the compound in dispute is an investigational or experimental drug.

The division concludes that preauthorization was not required for the compound cream in dispute. Denial of payment by K-Mart Corporation for this reason is not supported.

5. *Is reimbursement due to Memorial for the compound in dispute? If so, in what amount?*

Absent any evidence that K-Mart Corporation presented other defenses to Memorial before medical fee dispute resolution that conform with the requirements of Title 28, Part 2, Chapter 133, Subchapter C, the division finds that the compound is eligible for reimbursement. 28 Texas Administrative Code §134.503 applies to the compound in dispute and states, in pertinent part:

> (c) The insurance carrier shall reimburse the health care provider or pharmacy processing agent for prescription drugs the lesser of:
> (1) the fee established by the following formulas based on the average wholesale price (AWP) as reported by a nationally recognized pharmaceutical price guide or other publication of pharmaceutical pricing data in effect on the day the prescription drug is dispensed:
> (A) Generic drugs: ((AWP per unit) x (number of units) x 1.25) + $4.00 dispensing fee per prescription = reimbursement amount;
> (B) Brand name drugs: ((AWP per unit) x (number of units) x 1.09) + $4.00 dispensing fee per prescription = reimbursement amount;
> (C) When compounding, a single compounding fee of $15 per prescription shall be added to the calculated total for either paragraph (1)(A) or (B) of this subsection; or
> (2) notwithstanding §133.20(e)(1) of this title (relating to Medical Bill Submission by Health Care Provider), the amount billed to the insurance carrier by the:
> (A) health care provider; or
> (B) pharmacy processing agent only if the health care provider has not previously billed the insurance carrier for the prescription drug and the pharmacy processing agent is billing on behalf of the health care provider.

The compound in dispute was billed by listing each drug included in the compound and calculating the charge for each drug separately as required by 28 Texas Administrative Code §134.502(d)(2). Each ingredient is listed below with its corresponding reimbursement amount as applicable.

Ingredient	NDC & Type	Price/ Unit	Total Units	AWP Formula §134.503(c)(1)	Billed Amt §134.503 (c)(2)	Lesser of (c)(1) and (c)(2)
Gabapentin USP	38779246109 Generic	$59.85	3.6 gm	$59.85 x 3.6 x 1.25 = $269.33	$188.10	$188.10
Amitriptyline HCl	38779018904 Generic	$18.24	1.8 gm	$18.24 x 1.8 x 1.25 = $41.04	$30.70	$30.70
Baclofen	38779038809 Generic	$35.63	5.4 gm	$35.63 x 5.4 x 1.25 = $240.50	$184.68	$184.68
Amantadine HCl	38779041105 Generic	$24.225	3.0 gm	$24.225 x 3 x 1.25 = $90.84	$38.46	$38.46
Bupivacaine HCl	38779052405 Generic	$45.60	1.2 gm	$45.60 x 1.2 x 1.25 = $68.40	$48.02	$48.02
					Total	$489.96

The total allowable reimbursement for the disputed pharmacy service is $489.96. This amount is recommended.

Conclusion

For the reasons stated above, the Division finds that the requestor has established that additional reimbursement is due. As a result, the amount ordered is $489.96.

ORDER

Based on the submitted information, pursuant to Texas Labor Code Sec. 413.031 and 413.019 (if applicable), the Division has determined that the requestor is entitled to additional reimbursement for the services in dispute. The Division hereby ORDERS the respondent to remit to the requestor the amount of $489.96, plus applicable accrued interest per 28 Texas Administrative Code §134.130, due within 30 days of receipt of this Order.

Authorized Signature

Signature	Laurie Garnes Medical Fee Dispute Resolution Officer	September 26, 2018 Date

YOUR RIGHT TO APPEAL

Either party to this medical fee dispute has a right to seek review of this decision in accordance with 28 Texas Administrative Code §133.307, 37 *Texas Register* 3833, applicable to disputes filed on or after June 1, 2012.

A party seeking review must submit a **Request to Schedule a Benefit Review Conference to Appeal a Medical Fee Dispute Decision** (form **DWC045M**) in accordance with the instructions on the form. The request must be received by the Division within **twenty** days of your receipt of this decision. The request may be faxed, mailed or personally delivered to the Division using the contact information listed on the form or to the field office handling the claim.

The party seeking review of the MFDR decision shall deliver a copy of the request to all other parties involved in the dispute at the same time the request is filed with the Division. **Please include a copy of the *Medical Fee Dispute Resolution Findings and Decision*** together with any other required information specified in 28 Texas Administrative Code §141.1(d).

Si prefiere hablar con una persona en español acerca de ésta correspondencia, favor de llamar a 512-804-4812.