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
Sentrix Pharmacy and Discount, L.L.C.

Respondent Name
Indemnity Insurance Company of North America

MFDR Tracking Number
M4-17-2768-01

Carrier's Austin Representative
Box Number 15

MFDR Date Received
May 18, 2017

REQUESTOR'S POSITION SUMMARY

Requestor's Position Summary: "28 TAC §134.530 clearly states that preauthorization is only required for any compound that contains a drug identified with a status of 'N' in the current edition of the ODG Workers' Compensation Drug Formulary. In the case of the claim(s) as issue, all of the ingredients are identified with a 'Y' in the March 2017 Drug Formulary. As demonstrated by the enclosed documentation, all ingredients in the compounded medications subject to the claims at issue are included on the closed formulary."

Amount in Dispute: $2,078.06

RESPONDENT'S POSITION SUMMARY

Respondent's Position Summary: "Respondent maintains it's position in the denial that the compound medication required preauthorization because, compound medications constitute a new, non-approved and non-recognized drug and is considered investigational/experimental."

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

SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
March 7, 2017	Pharmacy Service – Compound Cream	$2,078.06	$1,718.06

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 §133.307
3. 28 Texas Administrative Code Chapter 134, Subchapter F
4. 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)
5. 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
6. 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

The insurance carrier denied payment for the disputed services with the following claim adjustment codes:

- 39 – Services denied at the time authorization/pre-certification was requested.

Issues

1. Did Indemnity Insurance Company of North America support its assertion that the compound cream in dispute requires FDA approval?
2. Does the compounded cream in dispute require preauthorization because it is "investigational or experimental"?
3. Does the compounded cream in dispute require preauthorization for other reasons?
4. Is reimbursement due to Sentrix Pharmacy and Discount, L.L.C. (Sentrix) for the compound cream in dispute? If so, in what amount?

Background

On March 7, 2017, Sentrix dispensed a compound cream. Indemnity Insurance Company of North America denied the compound in question asserting that preauthorization was required but not obtained. Sentrix 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., on behalf of Indemnity Insurance Company of North America, argued:

> The State Office of Administrative Hearings (SOAH) found in SOAH Docket 454-16-1884.M4-NP that by compounding multiple ingredients into a single cream, the pharmacy created a new drug that ws 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.

Through EOBs and blanket reference to State Office of Administrative Hearings' June 2, 2016 Decision and Order, the sole contention of Indemnity Insurance Company of North America 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, requires a provider, in this case a dispensing pharmacy, to seek preauthorization under three separate circumstances.

> (b) Preauthorization for claims subject to the Division's closed formulary.
> (1) Preauthorization is only required for:
> (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).

Indemnity Insurance Company of North America relies upon a State Office of Administrative Hearings (SOAH) decision to support its position that preauthorization was required under Rule 134.530(b)(1)(C). In SOAH

decision 454-16-1884-NP the administrative law judge appears to have reasoned, and by extension Indemnity Insurance Company of North America 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 Indemnity Insurance Company of North America for lack of preauthorization is supported.

Findings and Rationale

1. *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.

   Sentrix is not registered as an outsourcing facility.[1] For this reason, 503A applies and exempts the compound cream in dispute from FDA approval. Indemnity Insurance Company of North America failed to provide case-specific information sufficient to support a conclusion to the contrary. Indemnity Insurance Company of North America therefore failed to demonstrate that the compound cream in dispute required FDA approval under Section 505.

   Review of the documentation and information presented to the division finds that Indemnity Insurance Company of North America did not support its assertion that the compound in dispute required FDA approval.

[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.gov

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

Because Indemnity Insurance Company of North America failed to demonstrate that the compounded cream in this dispute in fact 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:

> 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 of a treatment, drug or service;
- that is not yet broadly accepted as the prevailing standard of care.

Accordingly, per the text of the Act and rule, 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 different 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 Indemnity Insurance Company of North America does not clarify how it made the determination that the compounded cream in this dispute was "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."

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[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

The division concludes that Indemnity Insurance Company of North America failed to support its contention that the services in dispute required preauthorization based upon the provision at Rule §134.530(b)(1)(C).

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

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

- Provision §134.530(b)(1)(A) preauthorization requirement is not discussed because 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 Treatment in Workers' Comp (ODG) / Appendix A.
- Memorial was not required to seek preauthorization pursuant to §134.530(b)(1)(C) because Indemnity Insurance Company of North America failed to demonstrate that the compound cream in this dispute required FDA approval and failed to demonstrate that the compound cream 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 Indemnity Insurance Company of North America is not supported.

Absent any evidence that Indemnity Insurance Company of North America presented other defenses to Sentrix 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 cream is eligible for reimbursement.

4. *Is reimbursement due to Sentrix for the compound cream in dispute?*

Sentrix is seeking reimbursement for a compound dispensed on March 7, 2017, with the following ingredients:

- Salt Stable LS Base, NDC 00395602157, $572.54
- Baclofen 4%, NDC 00395803243, $342.05
- Amitriptyline 2%, NDC 00395804843, $87.55
- Ketoprofen 10%, NDC 00395805643, $250.80
- Amantadine 8%, NDC 00395805843, $465.12
- Gabapentin 5%, NDC 10695003507, $360.00

The division finds that NDC 10695003507 is not a valid national drug code (NDC) as required by 28 Texas Administrative Code §134.502(d)(1). Therefore, this ingredient will not be considered for reimbursement.

28 Texas Administrative Code §134.503 applies to the services 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). Reimbursement is calculated as follows:

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)
Salt Stable LS Base	00395602157 Brand Name	$3.36	170.4 gm	$3.36 x 170.4 x 1.09 = $624.07	$572.54	$572.54
Baclofen 4%	00395803243 Generic	$35.63	9.6 gm	$35.63 x 9.6 x 1.25 = $427.56	$342.05	$342.05
Amitriptyline 2%	00395804843 Generic	$18.24	4.8 gm	$18.24 x 4.8 x 1.25 = $109.44	$87.55	$87.55
Ketoprofen 10%	00395805643 Generic	$10.45	24.0 gm	$10.45 x 24 x 1.25 = $313.50	$250.80	$250.80
Amantadine 8%	00395805843 Generic	$24.225	19.2 gm	$24.225 x 19.2 x 1.25 = $581.40	$465.12	$465.12
					Total	$1,718.06

The total allowable reimbursement for the compound in dispute is $1,718.06. This amount is recommended.

Conclusion

The division, per its analysis of the information and documentation timely submitted by the parties, including the denial reasons appropriately raised and presented by Indemnity Insurance Company of North America to Sentrix prior to the filing of this medical fee dispute, finds that (1) compounds are generally exempt from FDA approval; (2) compounds cannot as a general proposition be considered investigational or experimental; and (3) a payment denial for lack of preauthorization based on "investigational or experimental" status must be supported on a case-by-case basis taking into consideration the applicable FDA regulations, applicable Texas State Board of Pharmacy rules and existing utilization review requirements.

Therefore, per the current text of Texas Labor Code §413.031 and Division Rule §134.530, the division finds that Indemnity Insurance Company of North America failed to support its payment denial for lack of preauthorization. The division also finds that the documentation provided by Sentrix supports that payment is due. As a result, the amount ordered is $1,718.06.

ORDER

Based on the submitted information, pursuant to Texas Labor Code Sec. 413.031, 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 $1,718.06, plus applicable accrued interest per 28 Texas Administrative Code §134.130, due within 30 days of receipt of this Order.

Authorized Signature

	Laurie Garnes	July 19, 2017
Signature	Medical Fee Dispute Resolution Officer	Date

YOUR RIGHT TO APPEAL

Either party to this medical fee dispute has a right to seek review of this decision in accordance with Rule §133.307, effective May 31, 2012, *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. **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.