IN THE INTERMEDIATE COURT OF APPEALS OF WEST VIRGINIA

JUDITH MILLER,
Claimant Below, Petitioner

v.) No. 24-ICA-85 (JCN: 2019008366)

WHEELING HOSPITAL, INC.,
Employer Below, Respondent

FILED
December 6, 2024
ASHLEY N. DEEM, CHIEF DEPUTY CLERK
INTERMEDIATE COURT OF APPEALS
OF WEST VIRGINIA

MEMORANDUM DECISION

Petitioner Judith Miller appeals the January 31, 2024, order of the Workers' Compensation Board of Review ("Board"). Respondent Wheeling Hospital, Inc., (Wheeling Hospital) filed a response.[1] Ms. Miller did not reply. The issue on appeal is whether the Board erred in affirming the claim administrator's order that denied authorization for a compound cream medication.

This Court has jurisdiction over this appeal pursuant to West Virginia Code § 51-11-4 (2024). After considering the parties' arguments, the record on appeal, and the applicable law, this Court finds that there is error in the Board's decision but no substantial question of law. This case satisfies the "limited circumstances" requirement of Rule 21(d) of the Rules of Appellate Procedure for reversal in a memorandum decision. For the reasons set forth below, the Board's decision is vacated, and this case is remanded for further proceedings consistent with this decision.

On October 8, 2018, while employed by Wheeling Hospital, Ms. Miller injured her left foot at work. It is undisputed that a diagnosis of complex regional pain syndrome ("CRPS") of the left lower extremity was added as a compensable condition in the claim in 2019. Trent Emerick, M.D., and Nicole Lukaszewicz, CRNP, with UPMC Pain Management, began treating Ms. Miller's CRPS in January 2021. By order dated September 1, 2021, the claim administrator authorized the compound cream, finding that Dr. Emerick's request was supported by official disability guidelines ("ODG") for pain control and that it was reasonably related and appropriate treatment for CRPS. Further, the claim administrator noted that Ms. Miller received 70% relief from pain while using a

[1] Ms. Miller is self-represented. Wheeling Hospital is represented by Elizabeth R. McCadden, Esq.

previous compound cream, and the current request switched the muscle relaxer component to baclofen. The approved compound cream consisted of Ketamine 10%, baclofen 2%, Gabapentin 6%, and tetracaine 2% in a compound base; 240 grams of the cream were prescribed with no refills. However, the claim administrator also commented that the cream was "excessive in cost at $2000 per prescription."

At the request of the claim administrator, Heidi Dufrene, PharmD., of Carlisle Medical, performed a Case Management Prescription Review regarding the request for the compound cream on August 30, 2023. Pharmacist Dufrene reported that 240 units of the compound cream cost $2,119.93, although a cream compounded by Carlisle Medical would only cost $573.75. Pharmacist Dufrene also reported cost savings if other medications were substituted for the compound cream. Further, Pharmacist Dufrene commented that compounded topical prescriptions are not often medically necessary, and she opined that commercially available alternatives should be considered first. Pharmacist Dufrene recommended that Ms. Miller try lidocaine patches or capsaicin cream to treat her neuropathic pain and she also noted that the oral form of Lyrica (pregabalin) may be an option, although she cautioned that Ms. Miller's medication allergies needed to be considered.

On August 31, 2023, the claim administrator issued an order notifying Ms. Miller that, based on the ODG, it would discontinue paying for the compound medication on October 1, 2023. Ms. Miller protested this order to the Board and asserted, among other things, that the compound cream met the ODG criteria based on the guidelines she received from the claim administrator.

On September 13, 2023, the claim administrator wrote a letter to Ms. Miller, explaining that it was the workers' compensation administrator for Wheeling Hospital, the self-insured employer in the claim. The claim administrator indicated that a copy of "the ODG used in the determination of the denial of [the] compound cream" was enclosed with the letter. However, the enclosure included with this letter consists of an unsigned, single-page document containing several statements that the author attributes to the ODG.[2] The author of this document also opined that the medication was not recommended because it was "not supported through evidence-based medicine." Further, the author states that the ODG "notes that <u>any compounded product that contains at least one drug (or drug class) that is not recommended topically is not recommended for topical compounded agents</u>" and that the ODG "notes that there is no evidence for topical use" of the following medications: Gabapentin, an anti-epilepsy drug; Baclofen and other muscle relaxants; and Ketamine, which is reserved as a treatment for neuropathic pain in refractory cases in which other treatments have been exhausted. Further, according to the document, topical

[2] It is unclear whether the unknown author of the document is quoting the ODG or if the statements are simply the author's impressions.

lidocaine (Lidoderm patch) has been designated for "orphan status" by the FDA for neuropathic pain and it is generally not recommended for non-neuropathic pain. Lastly, the unknown author asserts that according to the ODG, "topical analgesics are 'largely experimental in use with few randomized controlled trials to determine efficacy or safety.'"

In a letter dated October 5, 2023, Nurse Practitioner Lukaszewicz commented that it was against her medical opinion for Ms. Miller to be taken off the compound cream since it had been an effective treatment. Further Nurse Lukaszewicz explained that the oral forms of Gabapentin, Cymbalta, Pamelor, Flexeril, Baclofen, and Zanaflex, caused intolerable side effects in Ms. Miller, but the topical compound cream was both effective and without side effects.

On January 31, 2024, the Board issued an order affirming the claim administrator's order of August 31, 2023. In its order, the Board acknowledged that the claim administrator based the denial of the medication on the ODG. Further, the Board noted that Ms. Miller argued that the compound cream met the ODG criteria because all other treatments/medications were ineffective and her medical need could not be met by other FDA-approved oral medications due to side effects. Also, the Board acknowledged Nurse Practitioner Lukaszewicz's opinion that the topical compound cream effectively controlled Ms. Miller's pain. However, the Board upheld the denial of the compound cream for the following reasons:

> 1) West Virginia Code of State Rules § 85-20-51.6(a) (2006) does not list topical compound creams as a treatment option for CRPS;
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> 2) West Virginia Code of State Rules § 85-20-16.1 provides that "[s]ervices investigative or experimental in nature or unsafe and not accepted by the general medical community are not reimbursable by the . . . private carrier or self-insured employer, whichever is applicable" and "[a]ccording to the ODG summary submitted by the claimant, the use of compounded agents and topical analgesics is not supported by evidence-based medicine and is considered largely experimental." Also, Pharmacist Dufrene's opinion that such compounds are often not medically necessary, supports the experimental nature of the requested compound cream;
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> 3) West Virginia Code of State Rules § 85-20-6.2 provides that a treating physician should use the least costly mode of treatment and less expensive options should be exhausted before a more expensive medication is requested. Pharmacist Dufrene noted several less expensive alternative treatments that should have been considered; and

> 4) West Virginia Code of State Rules § 85-20-17.2 permits the authorization of a trial period, and authorization of a compound cream on a one-time basis did not preclude the claim administrator from denying authorization of a new request.

Thus, the Board determined that the request for the compound cream was not supported by West Virginia Code of State Rules § 85-20 (2006) ("Rule 20"). Ms. Miller now appeals the Board's order.

Our standard of review is set forth in West Virginia Code § 23-5-12a(b) (2022), in part, as follows:

> The Intermediate Court of Appeals may affirm the order or decision of the Workers' Compensation Board of Review or remand the case for further proceedings. It shall reverse, vacate, or modify the order or decision of the Workers' Compensation Board of Review, if the substantial rights of the petitioner or petitioners have been prejudiced because the Board of Review's findings are:
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> (1) In violation of statutory provisions;
> (2) In excess of the statutory authority or jurisdiction of the Board of Review;
> (3) Made upon unlawful procedures;
> (4) Affected by other error of law;
> (5) Clearly wrong in view of the reliable, probative, and substantial evidence on the whole record; or
> (6) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

Syl. Pt. 2, *Duff v. Kanawha Cnty. Comm'n*, 250 W. Va. 510, 905 S.E.2d 528 (2024).

On appeal, Ms. Miller raises four assignments of error on appeal, which we will address in turn. As her first assignment of error, Ms. Miller asserts that the Board erred in finding that West Virginia Code of State Rules § 85-20-51.6(a) does not include compound creams as a treatment option for CRPS.

We agree with Ms. Miller that the Board erred in finding that West Virginia Code of State Rules § 85-20-51.6(a) does not include topical compounds as a treatment option for CRPS. [3] This rule neither excludes nor includes compound creams as a treatment option

[3] W. Va. Code of State Rules § 85-20-51.6 provides as follows:

for CRPS. Instead, the rule lists five classes of medications that may be used to treat CRPS. The rule does not list specific medications, and except for opioid and steroid medications (for which the rule only allows the oral forms), the rule does not restrict the form in which the medication must be administered (i.e., orally, topically, etc.) In applying this rule, the Board should have considered whether the medications in the compound cream were, for instance, anticonvulsants, tricyclic antidepressants, nonsteroidal anti-inflammatory drugs, etc. Thus, we must vacate and remand the claim to the Board for a proper analysis.

Additionally, regarding the Board's analysis of the treatment issue in general, we note that the claim administrator based its denial of the compound cream on the ODG, and Ms. Miller, in turn, in her protest to the Board, focused on ODG provisions. However, in its order, the Board primarily relied on several subsections of Rule 20, instead of the ODG.[4] The Board did not address whether Wheeling Hospital's workers' compensation program operates under an approved managed care plan that allows it to utilize the ODG instead of Rule 20 treatment guidelines. West Virginia Code of State Rules § 85-20-63 only allows employers, private carriers, or self-insured employers to use other treatment guidelines to establish such things as medical treatment protocols if they "are part of a managed care plan otherwise approved by the [Insurance Commissioner] . . . pursuant to W. Va. Code § 23-4-3(b)(2)(2003)." On remand, the Board is directed to determine whether the ODG or Rule 20 treatment guidelines apply to this claim and apply the correct guidelines.

Further, we disagree with Wheeling Hospital's assertion that the ODG sections Ms. Miller included in her Appendix are "additional evidence" that should not be considered on appeal. The ODG was the stated basis of the claim administrator's order, and the claim administrator sent these pertinent sections to her. Nevertheless, we do not rely on either of

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> Treatment for compensable complex regional pain syndrome type 1 (reflex sympathetic dystrophy) should be directed at providing pain control in an effort to promote participation in a directed physical and/or occupational therapy program to restore use and function of the injured extremity. Treatment options include:
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> a. Pharmacologic Agents.
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> 1. Nonsteroidal anti-inflammatory drugs.
> 2. Tricyclic antidepressants.
> 3. Anticonvulsants.
> 4. Oral opioids.
> 5. Oral steroids.

[4] The single exception being a reference Board makes to an "ODG summary" which was the enclosure included with the letter from September 13, 2023.

the two ODG sections that Ms. Miller included in her Appendix. Wheeling Hospital did not address whether it has an approved managed care plan that allows it to use the ODG. If it does have a managed care plan that relies on the ODG or other guidelines, the Board should obtain and consider the relevant provisions of the plan and ODG (or other incorporated guidelines).

In her second assignment of error, Ms. Miller contends that the Board erred by agreeing with Wheeling Hospital that less expensive alternative medications should be tried before an expensive medication is requested. Ms. Miller argues that the evidence presented to the Board showed that the compound medication may be available at a lower cost through a different medical network according to Pharmacist Dufrene. It is Ms. Miller's opinion that the cost of the medication is at the root of the claim administrator's denial. The Board relied upon the West Virginia Code of State Rules § 85-20-6.2 when it determined that less expensive alternative treatments should have been considered before Dr. Emerick prescribed the compound cream. However, because it is unclear whether Wheeling Hospital has an approved managed care plan, and if so, what cost guidelines apply, it is not possible to determine whether the Board erred. Thus, we must vacate and remand the claim to the Board for a proper analysis of this issue.

Third, Ms. Miller asserts that the Board erred by ruling in favor of Wheeling Hospital whose attorney misquoted West Virginia Code of State Rules § 85-20-54.3. Although it is unclear whether Rule 20 applies to this claim, the Board's ruling did not rely on this subsection. Thus, we disagree with Ms. Miller that the Board erred with regard to the application of this rule.

Ms. Miller's fourth and final assignment of error addresses the Board's determination that the claim administrator's authorization of the compound cream on a one-time basis did not obligate it to continue its authorization on an ongoing basis. Ms. Miller argues that the Board erred by ignoring a letter from Nurse Lukaszewicz, and failing to consider that her first authorization of the compound cream was in June of 2021, and the claim administrator continued to authorize it for more than two years. Thus, she argues that the Board erred in not recognizing that the claim administrator authorized and paid for twenty-eight prescription refills between June 2021 and August of 2023.[5] Further, Ms. Miller contends that her trial of the compound cream was in accordance with the ODG criteria for Compound Drugs and that the claim administrator authorized the medication because it was a medically appropriate and reasonably related treatment for CRPS.

[5] Wheeling Hospital does not dispute Ms. Miller's assertion that the claim administrator continued to authorize the medication until August 2023.

We note that the Board determined that a one-time authorization of the medication did not obligate the claim administrator to "authorize every subsequent request for the medication." The Board relied on the West Virginia Code of State Rules § 85-20-17.2 for this conclusion.[6] First, we note that Ms. Miller's arguments are, at least partly, based on the ODG. Again, it is unclear whether the ODG should have been applied in the claim. We agree with Ms. Miller that the Board erred in determining that the claim administrator merely authorized the cream on a "one-time" basis and by citing a rule applicable to a trial authorization. However, we also agree with the Board's proposition that "each treatment request must be considered and determined based upon the medical evidence available at that time." That being said, we note that in its order dated September 1, 2021, the claim administrator authorized the medication as it determined that the request was supported by the ODG for pain control. Then, in its order dated August 31, 2023, the claim administrator relied on the ODG to cease coverage of the compound cream.

Based on our review of the record, we conclude that the Board was clearly wrong in holding that the West Virginia Code of State Rules § 85-20-51.6(a) does not include topical compounds as a treatment option for CRPS. We also find that the Board was clearly wrong in determining that the claim administrator only authorized the compound cream on a one-time basis. Thus, we vacate the Board's order and remand the claim for further analysis consistent with this decision. Also, on remand, it will first be necessary for the Board to determine whether the ODG or Rule 20 guidelines apply to this claim. This ruling must be made prior to a ruling on the merits of the claim administrator's order, and due process requires that the parties be provided notice of the ruling so that, if necessary, they can formulate proper arguments to the Board regarding the merits of the case.

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[6] West Virginia Code of State Rules § 85-20-17.2 provides that:

> New or experimental therapies always require prior authorization from the Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable. The Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable, will require a detailed, credible and otherwise sufficient explanation of the anticipated outcomes of the proposed therapy. The Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable, may authorize a trial of the therapy, for a duration identified by the Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable, prior to acceptance of any modality. Approval of new or experimental therapies is within the sole discretion of the Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable.

Accordingly, we vacate the Board's January 31, 2024, order and remand the claim for further proceedings consistent with this decision.

Vacated and Remanded.

ISSUED: December 6, 2024

CONCURRED IN BY:

Chief Judge Thomas E. Scarr
Judge Charles O. Lorensen
Judge Daniel W. Greear