IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

January 2015 Term

FILED

February 5, 2015 released at 3:00 p.m. RORY L. PERRY II, CLERK SUPREME COURT OF APPEALS OF WEST VIRGINIA

No. 12-1127

JENNIFER MOORE, Claimant Below, Petitioner

v.

K-MART CORPORATION, Employer Below, Respondent

Appeal from the Workers' Compensation Board of Review No. 2046853

REVERSED AND REMANDED

Submitted: January 14, 2015 Filed: February 5, 2015

George Zivkovich, Esq. Parkersburg, West Virginia Counsel for Petitioner Michael A. Kawash, Esq. Robinson & McElwee PLLC Charleston, West Virginia Counsel for Respondent

CHIEF JUSTICE WORKMAN delivered the Opinion of the Court.

SYLLABUS BY THE COURT

1. "Interpreting a statute or an administrative rule or regulation presents a purely legal question subject to *de novo* review." Syl. Pt. 1, *Appalachian Power Co. v. State Tax Dep't of W.Va.*, 195 W.Va. 573, 466 S.E.2d 424 (1995).

2. "One of the basic purposes of workmen's compensation legislation is to impose upon industry the cost of medical expenses incurred in the treatment and rehabilitation of workers who have suffered injuries in the course of and as a result of their employment[.]" Syl. Pt. 2, in part, *Ney v. State Workmen's Comp. Com'r*, 171 W.Va. 13, 297 S.E.2d 212 (1982).

3. "Any rules or regulations drafted by an agency must faithfully reflect the intention of the Legislature, as expressed in the controlling legislation. Where a statute contains clear and unambiguous language, an agency's rules or regulations must give that language the same clear and unambiguous force and effect that the language commands in the statute." Syl. Pt. 4, *Maikotter v. Univ. of W.Va. Bd. of Trs.*, 206 W.Va. 691, 527 S.E.2d 802 (1999).

4. West Virginia Code of State Rules § 85-20-62.2 (2006), which provides, in part, that "[t]he Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable, will not reimburse for IV chelation therapy performed in office[,]" unreasonably denies reimbursement when such treatment is medically necessary, in contravention of the Workers' Compensation Act, West Virginia Code § 23-4-3 (2010), and it is therefore invalid.

Workman, Chief Justice:

In this workers' compensation appeal, the claimant/petitioner, Jennifer Moore ("Petitioner"), challenges the validity of a regulation insofar as it denies reimbursement for medically necessary intravenous chelation therapy when the therapy is performed in a physician's office. Having studied the record and reviewed the arguments of the parties in consideration of applicable legal authority, we conclude the portion of the regulation challenged is unreasonable and inconsistent with the Workers' Compensation Act, specifically West Virginia Code § 23-4-3 (2010), and hereby invalidate it. We reverse the order of the Workers' Compensation Board of Review ("BOR") and remand this matter for entry of an order directing that Petitioner's reasonable expenses for medically necessary chelation therapy be reimbursed.

I. FACTUAL AND PROCEDURAL HISTORY

Petitioner worked for the K-Mart Corporation ("Respondent") for more than thirty years. During the course of her employment, Petitioner used belt sanders and grinders to refurbish furniture. She worked in a small room with poor ventilation and was exposed to furniture dust and metal dust. Petitioner developed symptoms of tingling and numbness in her feet.¹ Following medical testing, her treating physician, Jonathan Murphy, M.D., an internal medicine specialist familiar with the principles of toxicology,

¹ Petitioner testified at deposition that she began having problems with her feet in June of 2006. Her symptoms included burning and tingling that felt like crushed ice coming out of the bottom of her feet. Over time, Petitioner's symptoms grew worse.

diagnosed Petitioner with peripheral neuropathy due to toxic exposure to heavy metals at the workplace.² Petitioner filed a claim for workers' compensation and following litigation, the claim was ruled compensable.³

In 2008, Dr. Murphy began treating Petitioner with intravenous chelation therapy and her symptoms have improved. In layman's terms, the process of chelation therapy is simple: it is a chemical process in which a synthetic solution is injected into the bloodstream to help remove heavy metals⁴ and/or minerals from the body.⁵ Dr. Murphy has extensive experience performing this therapy in his office; he states there are no

⁴ "The so-called heavy metals [include] . . . lead, cadmium, zinc, mercury and iron and, while aluminum is not a heavy metal, aluminum may be considered as such for the purposes hereinafter mentioned as it tends to some extent to be chelated by the processes concerned." *U.S. v. Evers*, 453 F.Supp. 1141, 1143 n.4 (1978).

⁵ During chelation therapy, a patient receives intravenous injections of the chelating drug, usually disodium ethylenediamine tetraacetic acid ("EDTA"). *Evers*, 453 F.Supp. at 1143. The chelating drug binds to the harmful metals and they are passed out of the body through the kidneys. EDTA intravenous treatment is often recommended for lead poisoning and other diseases requiring removal of heavy metals from the body. *Rogers v. State Bd. of Med. Exam'rs*, 371 So.2d 1037, 1039 (Fla. 1979).

² Petitioner's urine toxicology revealed elevated levels of heavy metals including aluminum, lead, and nickel.

³ Petitioner protested the claim administrator's order of July 3, 2008, which denied compensability of the claim. In support of her protest, Petitioner submitted various medical records including diagnostic test reports from Dr. Murphy's office. She also submitted her deposition testimony and the deposition testimony of Dr. Murphy. An Administrative Law Judge with the Workers' Compensation Office of Judges reviewed this evidence and found the claim compensable by decision dated April 29, 2010. Respondent appealed, and by order dated December 15, 2010, the BOR affirmed the decision of the Administrative Law Judge, with modifications.

chelation programs in hospitals in West Virginia that treat chronic heavy metal toxicity. The record is undisputed that this treatment is medically necessary to treat Petitioner's compensable condition.⁶ In this appeal, Petitioner is seeking reimbursement for these medical expenses.

Petitioner appeals the August 29, 2012, order of the BOR, which denied her request for reimbursement for medical expenses for intravenous chelation therapy from May 1, 2008, through October 15, 2010.⁷ The BOR denied reimbursement for these medical expenses pursuant to West Virginia Code of State Rules § 85-20-62.2 (2006) which provides, in part, that: "The Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable, will not reimburse for IV chelation therapy performed in office."⁸

(continued . . .)

⁶ The danger associated with the harmful metals remaining in the blood is that the blood vessels may become clogged, disallowing free passage of the blood through the blood vessels causing stroke, senility because of inadequate blood supply to the brain, gangrene resulting from failure of sufficient blood in the limbs, and various degrees of numbness, dizziness and pain associated with poor circulation. *Evers*, 453 F.Supp. at 1144.

⁷ At his deposition in September of 2009, Dr. Murphy testified that Petitioner had undergone approximately thirty treatments and her peripheral neuropathy symptoms improved. Dr. Murphy recommended that in the future, Petitioner have four intravenous chelation therapy treatments per year.

 $^{^{8}}$ The full text of West Virginia Code of State Rules § 85-20-62.2, reads as follows:

In so ruling, the BOR reversed a decision of an Administrative Law Judge ("ALJ") with the Workers' Compensation Office of Judges ("OOJs"). The ALJ had reversed the claim administrator's order denying reimbursement for chelation therapy, concluding that reimbursement was appropriate because "[t]he Claim Administrator must provide medically related and reasonably required medical treatment, health care or healthcare goods and services under the W.Va. Code §23-4-3 and 85 CSR 20."

II. STANDARD OF REVIEW

Petitioner contends the BOR erred in reversing the OOJs' order granting reimbursement for medically necessary intravenous chelation therapy. Our review of workers' compensation appeals is guided by the criteria set forth in West Virginia Code § 23-5-15 (2010):

(b) In reviewing a decision of the board of review, the Supreme Court of Appeals shall consider the record provided

All chelation therapy (oral and IV) requires prior authorization and consultation with a Board Certified Medical Toxicologist, an occupational medicine specialist, or general internist familiar with principals of toxicology, prior to initiation of the therapy. In the rare incident, in which acute encephalopathy occurs as the result of heavy metal toxicity, a consultation with the Poison Control Center will serve as confirmation of the need for such chelation therapy. The Commission, Insurance Commissioner, private carrier or selfinsured employer, whichever is applicable, will not reimburse for IV chelation therapy performed in office.

The record reflects that Petitioner was unable to receive prior authorization for chelation therapy, as required by the regulation, because the claim was held non-compensable at the time she began this treatment. *See* footnote 3, supra.

by the board and give deference to the board's findings, reasoning and conclusions, in accordance with subsections (c) and (d) of this section.

. . . .

(d) If the decision of the board effectively represents a reversal of a prior ruling of either the commission or the Office of Judges that was entered on the same issue in the same claim, the decision of the board may be reversed or modified by the Supreme Court of Appeals only if the decision is in clear violation of constitutional or statutory provisions, is clearly the result of erroneous conclusions of law, or is so clearly wrong based upon the evidentiary record that even when all inferences are resolved in favor of the board's findings, reasoning and conclusions, there is insufficient support to sustain the decision. The court may not conduct a de novo re-weighing of the evidentiary record. If the court reverses or modifies a decision of the board pursuant to this subsection, it shall state with specificity the basis for the reversal or modification and the manner in which the decision of the board clearly violated constitutional or statutory provisions, resulted from erroneous conclusions of law, or was so clearly wrong based upon the evidentiary record that even when all inferences are resolved in favor of the board's findings, reasoning and conclusions, there is insufficient support to sustain the decision.

Resolution of this matter requires us to interpret a provision contained in the West Virginia Code of State Rules and our review is therefore de novo. "Interpreting a statute or an administrative rule or regulation presents a purely legal question subject to *de novo* review." Syl. Pt. 1, *Appalachian Power Co. v. State Tax Dep't of W.Va.*, 195 W.Va. 573, 466 S.E.2d 424 (1995); *Hale v. W.Va. Office of Ins. Com'r*, 228 W.Va. 781, 784, 724 S.E.2d 752, 755 (2012). With these principles in mind, we consider the arguments of the parties.

III. DISCUSSION

The sole issue we address in this appeal is whether Petitioner is entitled to receive reimbursement for medically necessary intravenous chelation therapy when the therapy was performed in her physician's office. Petitioner urges this Court to invalidate the challenged portion of West Virginia Code of State Rules § 85-20-62.2 as arbitrary and capricious. She maintains the BOR's decision is tantamount to a denial of medical treatment in contravention of West Virginia Code § 23-4-3,⁹ which requires the claim

(1) Sums for health care services, rehabilitation services, durable medical and other goods and other supplies and medically related items as may be reasonably required. The commission, and effective upon termination of the commission, all private carriers and self-insured employers or their agents, shall determine that which is reasonably required within the meaning of this section in accordance with the guidelines developed by the health care advisory panel pursuant to section three-b [§ 23-4-3b] of this article: Provided, That nothing in this section shall prevent the implementation of guidelines applicable to a particular type of treatment or service or to a particular type of injury before guidelines have been developed for other types of treatment or services or injuries: Provided, however, That any guidelines for utilization review which are developed in addition to the guidelines provided for in section three-b of this article may be used by the commission, and effective upon termination of the commission, all private carriers and self-insured employers or their agents, until superseded by (continued . . .)

⁹ West Virginia Code § 23-4-3, provides, in part, that:

The commission, and effective upon termination of the commission, all private carriers and self-insured employers or their agents, shall disburse and pay for personal injuries to the employees who are entitled to the benefits under this chapter as follows:

administrator provide medically related and reasonably required medical treatment, healthcare or healthcare goods and services. Respondent, conversely, argues the medical treatment at issue should be denied consistent with the regulatory bounds of the workers' compensation system.

We begin by recognizing the Workers' Compensation Act provides benefits to workers who have "received personal injuries in the course of and resulting from their covered employment[.]" W.Va. Code § 23-4-1 (2010). Under the Act, the term "personal injury" includes occupational disease. W.Va. Code § 23-4-1(b). "One of the basic purposes of workmen's compensation legislation is to impose upon industry the cost of medical expenses incurred in the treatment and rehabilitation of workers who have suffered injuries in the course of and as a result of their employment[.]" Syl. Pt. 2, in part, *Ney v. State Workmen's Comp. Com'r*, 171 W.Va. 13, 297 S.E.2d 212 (1982).

> guidelines developed by the health care advisory panel pursuant to said section. Each health care provider who seeks to provide services or treatment which are not within any guideline shall submit to the commission, and effective upon termination of the commission, all private carriers, selfinsured employers and other payors, specific justification for the need for the additional services in the particular case and the commission shall have the justification reviewed by a health care professional before authorizing the additional services. The commission, and effective upon termination of the commission, all private carriers, self-insured employers and other payors, may enter into preferred provider and managed care agreements which provides for fees and other payments which deviate from the schedule set forth in this subsection.

Pursuant to West Virginia Code § 23-4-3b (2010), the Workers' Compensation Commission established guidelines for health care treatment reasonably required for various types of injuries and occupational diseases. W.Va. Code § 23-4-3b(1). *See* Syl. Pt. 10, *Simpson v. W.Va. Office of the Ins. Comm'r*, 223 W.Va. 495, 678 S.E.2d 1 (2009) (upholding constitutionality of statute whereby Legislature specifically delegated its rule-making authority for medical management of workers' compensation claims and awards of disability).

According to the agency regulation at issue, a claimant will be denied reimbursement for intravenous chelation therapy performed in an office. W.Va. Code of State Rules § 85-20-62.2. However, an administrative regulation is not, itself, the equivalent of a statute. "To be valid, a regulation promulgated by an administrative agency must carry out the legislative intent of its governing statutes." *Hale*, 228 W.Va. at 785, 724 S.E.2d at 756. As a rule of statutory construction, we have repeatedly held that

[a]ny rules or regulations drafted by an agency must faithfully reflect the intention of the Legislature, as expressed in the controlling legislation. Where a statute contains clear and unambiguous language, an agency's rules or regulations must give that language the same clear and unambiguous force and effect that the language commands in the statute.

Syl. Pt. 4, *Maikotter v. Univ. of W.Va. Bd. of Trs.*, 206 W.Va. 691, 527 S.E.2d 802 (1999). The "[p]rocedures and rules properly promulgated by an administrative agency with authority to enforce a law will be upheld so long as they are reasonable and do not enlarge, amend or repeal substantive rights created by statute." *Hale*, 228 W.Va. at 786,

724 S.E.2d at 757 (quoting Syl. Pt. 4, *State ex rel. Callaghan v. W.Va. Civil Serv. Comm'n*, 166 W.Va. 117, 273 S.E.2d (1980)); *see also, Anderson & Anderson Contractors, Inc. v. Latimer*, 162 W.Va. 803, 807-08, 257 S.E.2d 878, 881 (1979) ("Although an agency may have power to promulgate rules and regulations, the rules and regulations must be reasonable and conform to the laws enacted by the Legislature.").

At the outset of this Court's analysis, it is imperative to acknowledge what arguments Respondent *fails* to advance. Importantly, Respondent does not argue the regulation was promulgated for health and safety concerns. Based on our review of the record, we discern no medical rationale for the distinction between chelation therapy performed in an office and chelation therapy performed elsewhere. We would be extremely hesitant to invalidate the regulation if there was any medical justification contained in the regulation or the record to support the distinction. The record reflects that Dr. Murphy has treated dozens of patients in his office for heavy metal toxicity. He has not experienced any patient suffering complications from the treatments, nor has he encountered a patient who has not benefited from the removal of the heavy metals through chelation therapy.

Furthermore, Respondent does not argue that the regulation was promulgated to promote economic efficiency. In fact, we discern no cost-saving rationale for the distinction between chelation therapy performed in an office and chelation therapy performed elsewhere. To the contrary, Dr. Murphy reported that chelation therapy generally costs \$400 per unit and he provides this medical treatment in office at the discounted rate of \$105 per unit.

Respondent does not articulate any rational basis to deny reimbursement for medically necessary chelation therapy treatment when performed in an office. Even so, Respondent argues the BOR properly applied the regulation to discourage chelation therapy due to the controversial nature of the therapy. This contention lacks merit both factually and legally. The controversy in the medical community surrounding chelation therapy has to do with the use of that therapy for other medical problems including arteriosclerosis (hardening of the arteries), not when the therapy is used to treat heavy metal toxicity.

Chelation therapy has been approved by the federal Food and Drug Administration (FDA) only as a means for the removal of heavy metals from the body. However, non-FDA-approved, or "off-label," use of medications by physicians is not prohibited by the FDA and is generally accepted in the medical profession. . . Approximately 1,000 physicians in the United States engage in the off-label use of chelation therapy to treat arteriosclerosis and other vascular conditions. Of these 1,000 United States-based physicians, 750 belong to the American College for Advancement in Medicine (ACAM), which has 1,000 members worldwide and which endorsed chelation therapy as a valid course of treatment for occlusive vascular and degenerative diseases associated with aging. To that end, ACAM developed a protocol . . . for using chelation therapy to treat such diseases.

State Bd. of Registration for Healing Arts v. McDonagh, 123 S.W.3d 146, 149-50 (Mo.

2003) (citations and footnotes omitted). See also Friedrich v. Sec. of Health and Human

Servs., 894 F.2d 829, 838 (6th Cir. 1990) (upholding validity of regulation denying

Medicare Part B reimbursement for chelation therapy to treat arteriosclerosis because Secretary of Health and Human Services found it to be not reasonable and necessary for the treatment of that illness).

Respondent states the regulation does not require that the chelation therapy be performed in a hospital; it just prohibits reimbursement when performed in an office. This point only highlights the arbitrary nature of this portion of the regulation. Applying the plain language of the regulation, Dr. Murphy could travel to Petitioner's home to administer the chelation therapy and the cost would be reimbursable. Ostensibly, Dr. Murphy could walk out of his office and meet Petitioner in the parking lot of his medical practice to administer the chelation therapy and the cost would be reimbursable; this asinine example reveals the absence of any rational basis for the challenged portion of West Virginia Code of State Rules § 85-20-62.2. Nevertheless, we are not asked in this case to say whether we think this regulation is wise. We are asked to hold if it violates the Act. And that, we do.

To the extent Respondent argues the regulation furthers the legitimate goal of ensuring chelation therapy is used only to treat appropriate medical conditions, its position is nonsensical. Medical necessity and appropriateness of treatment have always been prerequisites to a worker's recovery of medical benefits.¹⁰ Dr. Murphy administers chelation therapy to Petitioner to treat her symptoms of neuropathy related to heavy metal toxicity. There is no evidence Petitioner ever received chelation therapy as treatment for arteriosclerosis or any other non-compensable condition. Consequently, we fail to see how Petitioner's chelation therapy treatment is in any way controversial.

The primary reason Respondent's argument lacks merit is because it ignores the fundamental purpose of workers' compensation legislation. There is no rational basis to *discourage* medically necessary treatment; this reasoning is wholly incompatible with the Act's benevolent objectives. One of the overriding purposes of the Act is to provide reasonable and necessary medical treatment to employees who are injured on the job. W.Va. Code § 23-4-1. The regulation is discordant with West Virginia Code § 23-4-3, which provides the claim administrator must provide medically related and reasonably required medical treatment, healthcare or healthcare goods and services. *See generally, Riley Family Trust v. Hood*, 874 P.2d 503, 504 (Colo. App. 1994) (affirming payment of reasonable and necessary massage therapy prescribed by treating physician and performed by certified massage therapist even though regulation required

 $^{^{10}}$ In addition to their obligation as medical professionals, physicians have financial incentives to provide appropriate medical treatment under the workers' compensation system because the commission may suspend or permanently terminate their right to obtain payment for services if the "commission finds that the health care provider is regularly providing to injured employees health care that is excessive, medically unreasonable or unethical[.]" W.Va. Code § 23-4-3c(1) (2010).

therapy be administered by or under on-site supervision of a physician or registered physical therapist).

The challenged portion of the regulation is also contradicted by other statutes, namely West Virginia Code § 23-1-1(b) (2010), which provides the Act shall "be interpreted so as to assure the quick and efficient delivery of indemnity and medical benefits to injured workers at a reasonable cost to the employers[.]" In addition, West Virginia Code § 23-5-13 (2010), provides: "[i]t is also the policy of this chapter to prohibit the denial of just claims of injured or deceased workers or their dependents on technicalities." Therefore, finding no legitimate justification for the challenged portion of the regulation at issue, we conclude it is unreasonable to deny reimbursement for medically necessary chelation therapy to treat heavy metal toxicity simply because the therapy was performed in a physician's office.

Based on the foregoing, we hold that West Virginia Code of State Rules § 85-20-62.2 (2006), which provides, in part, that "[t]he Commission, Insurance Commissioner, private carrier or self-insured employer, whichever is applicable, will not reimburse for IV chelation therapy performed in office[,]" unreasonably denies reimbursement when such treatment is medically necessary, in contravention of the Workers' Compensation Act, West Virginia Code § 23-4-3 (2010), and it is therefore invalid. Petitioner suffers from peripheral neuropathy due to toxic exposure to heavy metals at the workplace. She is entitled to receive reasonable and necessary medical

benefits to treat this compensable condition whether she receives such treatment in her physician's office or elsewhere.

IV. CONCLUSION

For the reasons set forth above, the August 29, 2012, order of the BOR is reversed, and this matter is remanded for entry of an order directing that Petitioner's reasonable expenses for medically necessary chelation therapy be reimbursed.

Reversed and remanded.