IN THE COURT OF APPEALS OF TENNESSEE
AT NASHVILLE
Assigned on Briefs April 2, 2020

THOMAS K. BALLARD, III, M.D. ET AL v. TENNESSEE DEPARTMENT OF HEALTH

Appeal from the Chancery Court for Davidson County
No. 17-0931-I Patricia Head Moskal, Chancellor

No. M2019-01101-COA-R3-CV

Appellants, a doctor and a medical clinic, challenge a final order of the Tennessee Commissioner of Health imposing monetary fines and costs. The order followed the investigation and prosecution of numerous violations of state statutes and regulations governing pain management clinics. After review of an initial decision from an administrative law judge, the Commissioner's Designee found three additional violations and increased the assessment of civil penalties and costs issued in the initial ruling. Appellants argue that the new violations were not supported by substantial and material evidence and were arbitrary and capricious under the Uniform Administrative Procedures Act. Further, they argue that the increase in penalties and costs was arbitrary and capricious. Because the decision appealed was supported by substantial and material evidence and neither arbitrary nor capricious, we affirm.

Tenn. R. App. P. 3 Appeal as of Right; Judgment of the Chancery Court Affirmed and Remanded

J. STEVEN STAFFORD, P.J., W.S., delivered the opinion of the court, in which RICHARD H. DINKINS, and THOMAS R. FRIERSON, II, JJ., joined.

Fetlework S. Balite-Panelo and Stephen W. Elliott, Nashville, Tennessee, for the appellants, Thomas K. Ballard, III, and Ballard Clinic, P.C.

Herbert H. Slatery, III, Attorney General and Reporter; Andrée Sophia Blumstein, Solicitor General; Sue A. Sheldon, Senior Assistant Attorney General, for the appellee, State of Tennessee, Department of Children's Services.

OPINION

BACKGROUND

Thomas K. Ballard, III, M.D., ("Dr. Ballard") operated Ballard Clinic, P.C. ("the Clinic," and together with Dr. Ballard, "Appellants") in Jackson, Tennessee. Dr. Ballard was the sole medical provider working at the Clinic. In March 2012, Dr. Ballard applied for and received a pain management clinic certificate from the Tennessee Department of Health ("the Department"). Appellants were first audited by the Department on May 19, 2015. Two subsequent audits occurred on November 3, 2015 and August 22, 2016. Over the course of those three audits, the Department alleged that Appellants failed to comply with the state's Pain Management Clinic Act and related Department regulations in several ways, including failure to post a medical license or pain management clinic certificate, failure to use risk management tools before prescribing controlled substances, failure to maintain records for personnel files or for continuing education, and keeping a dog on the back of the Clinic's property. The audit also noted a sign posted in the Clinic waiting room that stated that cash and money orders were accepted for the self-payment of clinic services. Most notably, Appellants failed to maintain written policies, programs, and procedures for pain management patients, health and safety requirements for the Clinic, patient access to records, or infection control. While an Occupational Safety and Health Administration ("OSHA") manual was located in the Clinic, its contents had not been updated since approximately 1994. The Clinic also had kept its biohazardous waste on site for approximately five years without proper disposal. In response to these allegations, Dr. Ballard stated that he was the only medical practitioner at the Clinic and also claimed that he maintained verbal policies for medication counts.

During the May 2015 audit, Dr. Ballard also admitted to distributing controlled substances given to him by other patients in the past. He also estimated that 80% of his practice involved pain management in May 2015. While Dr. Ballard said that he reduced this figure to less than 50% by the August 2016 audit ("the final audit"), he did not provide any documentation to verify his claims. A review of billing policies also indicated the Clinic failed to maintain adequate billing records, which only listed insurance coverage and the date of insurance payments and did not list amounts of co-pays and other information required by state law, discussed in detail, *infra*. Dr. Ballard later stated that he remedied the billing records issues before a subsequent audit. The Clinic's Pain Management Clinic certificate was renewed in March 2016.

During the final audit, officials with the Department discovered that Dr. Ballard was no longer eligible to serve as a medical director of a pain management clinic under state law that took effect on July 1, 2016.[1] As a result, the Clinic operated without a

[1] Three letters from the Department were sent to the Clinic informing them of the impending

statutorily required medical director for fifty-two days. Dr. Ballard claimed that the Clinic stopped operating as a pain management clinic during this period, but was simply unaware he was required to complete paperwork to that effect. After being provided with the documents to terminate the Clinic's pain management certificate, Dr. Ballard relinquished the Clinic's certificate during the final audit.

On December 19, 2016, the Department filed an administrative Notice of Hearing and Charges and Memorandum for Assessment of Civil Penalties and Costs against Appellants. In the Notice, the Department alleged that Appellants violated eight separate statutes and regulations. In particular, the Department alleged that Appellants failed to have a pain management specialist on staff, failed to establish quality assurance policies and procedures, failed to conduct all financial transactions in accordance with state law, failed to accept payments via credit card or check, failed to establish a written infection control program, failed to establish written health and safety policies, failed to ensure that patients could access their medical records, and failed to post the Pain Management Clinic certificate to be clearly visible to patients. The Department sought civil penalties against Appellants and called for the Commissioner of Health or his designee to determine whether Dr. Ballard's certificate should be suspended, revoked, or disciplined. In response to the allegations, Appellants argued that the Clinic was a family practice clinic that never operated as a "pill mill." Further, they alleged that the State did not provide substance or information upon which the penalties sought by the Department would be appropriate.

The matter was heard on January 19, 2017, before an administrative law judge ("ALJ") sitting for the Commissioner of the Department of Health. The auditor who investigated the Clinic testified at the hearing, while another Department official testified about the Clinic's certification via affidavit. Neither Dr. Ballard nor any of his employees testified. Following the hearing, the ALJ entered an order on March 9, 2017. Therein, the ALJ found that the Department's audit revealed the following deficiencies at the Clinic:

> a. Failure to post its pain management certificate in a conspicuous location;
> b. Failure to provide written policies and procedures for chronic pain management patients including medication counts, written drug screening and compliance plans;
> c. Failure to maintain a written infection control program;
> d. Failure to maintain a current OSHA manual;
> e. Failure to have a written policy for returning medical records to patients in the event of closure of the clinic;
> f. The acceptance of cash payments and money orders for pain

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statutory change.

management treatment;

g. Failure to maintain current documentation of required pain management continuing education for health care providers and required documentation in personnel files.

Further, the ALJ found that Dr. Ballard operated the Clinic without being qualified as a pain management specialist, which did not comply with state statute. Appellants also failed to show that the Clinic's caseload was altered to ensure less than 50% of patients received chronic pain treatment after Dr. Ballard lost his ability to operate a pain management clinic. Therefore, the ALJ held that the Department carried its burden of proof that Appellants violated a variety of state statutes and regulations governing pain management clinics. While the ALJ found that Dr. Ballard had no ill intent, "the record does demonstrate a blatant disregard by Dr. Ballard of the legal requirements for the operation of a pain management clinic." The ALJ assessed Appellants $3,500.00 in civil penalties[2] and ordered that the Clinic's Pain Management Clinic certificate be permanently revoked. Dr. Ballard was also ordered to pay all court costs for the matter not to exceed $5,000.00.

Following the initial order, the Department appealed the ruling to the Department's Commissioner as permitted under Tennessee Code Annotated section 4-5-315. The Department requested that the penalties against Appellants be increased to $48,500.00 and that Appellants be obligated to pay the Department's costs to prosecute the matter not to exceed $10,000.00. The Department argued that the penalty imposed by the initial order would not serve as a financial deterrent and did not match the actions taken by Dr. Ballard in operating the Clinic, which the Department argued had created a significant public health risk. The Commissioner appointed a separate designee to determine whether the appeal should be granted and, if so, to enter a final order for the matter. *See* Tenn. Code Ann. § 4-5-315 (allowing initial orders to be appealed to the agency, which may "in the exercise of discretion conferred by statute or rule of the agency . . . [d]elegate[] its authority to review the initial order to one (1) or more persons"). Appellants opposed the appeal, submitting that the Department never clearly established why the ALJ's ruling was improper and why the penalties in the case should be increased.

The Commissioner's Designee issued a final order on June 5, 2017. In addition to finding that the ALJ was correct to find the previously discussed violations by Appellants, the Commissioner's Designee included three additional findings of fact in support of further violations by Appellants:

[2] The ALJ assessed 15 individual penalties in the amount of $100.00 against Appellants for each month that the Clinic did not comply with state statutes and regulations. The ALJ also assessed a $2,000.00 penalty for every month that the Clinic operated without a pain management specialist.

h. Failure to establish a means of evaluating and monitoring the quality of patient care, identifying and correcting deficiencies, or opportunities to improve quality of care;

i. Failure to maintain adequate billing records;

j. The dispensing of unused controlled medications received from patients which were then repackaged and distributed to other patients.

The Commissioner's Designee also increased the civil penalty against Appellants to $9,300.00[3] and ordered them to pay up to $10,000.00 in the Department's costs. While the Commissioner's Designee also placed Dr. Ballard's medical license on probation in her initial order, an amendment to her order ("Amended Final Order") later removed that penalty.

Appellants filed a Petition for Judicial Review of the Department's actions of August 28, 2017 in Davidson County Chancery Court ("the trial court"). Appellants' petition argued that the increased penalties made by the Commissioner's Designee were arbitrary and capricious and not supported by substantial and material evidence. After the submission of briefs and oral argument, the trial court affirmed the penalties assessed by the Commissioner's Designee. In an order entered February 22, 2019, the trial court held that the civil penalties imposed by the Commissioner's Designee had adequate evidentiary support, were within the Commissioner's authority and discretion, and were not arbitrary and capricious. Appellants timely filed this appeal.

ISSUES PRESENTED

Appellants raise two issues on appeal, which we restate as follows:

1. Whether the three additional findings of fact provided by the Commissioner's Designee in the Amended Final Order are not supported by substantial and material evidence and added in an arbitrary and capricious manner by the Commissioner's Designee.
2. Whether the Commissioner's Designee acted arbitrarily and capriciously by increasing the penalties and costs assessed against Dr. Ballard and the Ballard Clinic in the Amended Final Order.

STANDARD OF REVIEW

Disciplinary actions against medical licensees take place in accordance with the state's Uniform Administrative Procedures Act ("the UAPA"). Tenn. Code Ann. § 63-6-

[3] The Commissioner's Designee assessed ten penalties of $100.00 for each violation identified in the May 2015 audit and sixteen penalties of $300.00 for each month that elapsed between the May 2015 audit and the final audit. Further, thirty-five penalties of $100.00 were assessed for each day that the Clinic operated without a pain management specialist.

216. Codified in Tennessee Code Annotated section 4-5-101 *et seq.*, the UAPA limits our scope of review "to a 'narrow and statutorily prescribed review of the record made before the administrative agency.'" ***Crawford v. Dep't of Fin. & Admin.***, No. M2011-01467-COA-R3-CV, 2012 WL 219327, at *5 (Tenn. Ct. App. Jan. 24, 2012) (quoting ***Metro Gov't v. Shacklett***, 554 S.W.2d 601, 604 (Tenn. 1977)). This Court's review of an agency decision "shall be confined to the record." Tenn. Code Ann. § 4-5-322(g). The decision of an administrative agency may be modified or reversed if the agency's findings, inferences, conclusions, or decisions are:

> (1) In violation of constitutional or statutory provisions;
> (2) In excess of the statutory authority of the agency;
> (3) Made upon unlawful procedure;
> (4) Arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion; or
> (5)(A) Unsupported by evidence that is both substantial and material in the light of the entire record.
> (B) In determining the substantiality of evidence, the court shall take into account whatever in the record fairly detracts from its weight, but the court shall not substitute its judgment for that of the agency as to the weight of the evidence on questions of fact.

Tenn. Code Ann. § 4-5-322(h).

Additionally, "[n]o agency decision pursuant to a hearing in a contested case shall be reversed, remanded or modified by the reviewing court unless for errors that affect the merits of such decision." Tenn. Code Ann. § 4-5-322(i). The same standard of review that is utilized by the trial court is applicable here. *See* ***Estate of Street v. State Bd. of Equalization***, 812 S.W.2d 583, 585 (Tenn. Ct. App. 1990) ("The scope of review in this Court is the same as in the trial court, to review findings of facts of the administrative agency upon a standard of substantial and material evidence."). Indeed, the trial court "may not substitute its judgment concerning the weight of the evidence for that of the Board[,]" and "the same limitations apply to that of the appellate court." ***Roy v. Tennessee Bd. of Med. Examiners***, 310 S.W.3d 360, 364 (Tenn. Ct. App. 2009) (citing ***Humana of Tennessee v. Tennessee Health Facilities Comm'n***, 551 S.W.2d 664, 668 (Tenn. 1977); ***Jones v. Bureau of TennCare***, 94 S.W.3d 495, 501 (Tenn. Ct. App. 2002)). "Thus, when reviewing a trial court's review of an administrative agency's decision, this court is to determine 'whether or not the trial court properly applied the ... standard of review' found at Tenn. Code Ann. § 4-5-322(h)." ***Id.*** (citing ***Jones***, 94 S.W.3d at 501 (quoting ***Papachristou v. Univ. of Tennessee***, 29 S.W.3d 487, 490 (Tenn. Ct. App. 2000))).

DISCUSSION

The present case is an appeal of various violations of the Tennessee Pain Management Clinic Act ("the Act") and the regulations promulgated to enforce that statute. *See* Tenn. Code Ann. § 63-1-301 *et seq*; Tenn. Comp. R. & Regs. 1200-34-01-.01 *et seq.*; Tenn. Comp. R. & Regs. 1200-34-01-.12(1) (referring to sections 63-1-301 *et seq.*, as the "Tennessee Pain Management Clinic Act").[4] These statutes established "a framework for state oversight of those clinics that were largely treating chronic pain with opioids, whose patient populations were therefore potentially at risk of poor outcomes, including dependence and overdose." Melissa McPheters, Mary K. Bratton, *The Right Hammer for the Right Nail: Public Health Tools in the Struggle Between Pain and Addiction*, 48 U. Mem. L. Rev. 1299, 1328 (2018). Thus, the Act generally governs the operation of "pain management clinics."

The Act defines a pain management clinic as "a privately-owned clinic, facility or office in which any health care provider licensed under this title provides chronic nonmalignant pain treatment to a majority of its patients for ninety (90) days or more in a twelve-month period" or "a privately-owned clinic, facility or office which advertises in any medium for pain management services of any type." Tenn. Code Ann. § 63-1-301(8)(A)−(B) (2016). *But see* Tenn. Code Ann. § 63-1-302 (noting some exceptions to the general definition not applicable in this case). In turn, "chronic nonmalignant pain treatment" is defined as "prescribing or dispensing opioids, benzodiazepines, barbiturates or carisoprodol for ninety (90) days or more in a twelve-month period for pain unrelated to cancer or palliative care[.]" Tenn. Code Ann. § 63-1-301(3) (2016). The Act directs the Department to promulgate rules governing the operation of pain management clinics. Tenn. Code Ann. § 63-1-303(b)–(c); *see also* Tenn. Code Ann. § 63-1-306(k) (2016) ("The department shall have the authority to adopt rules, including emergency rules if deemed necessary, to implement this part for which the department has responsibility."). The regulations promulgated under the Act can cover a variety of topics, including the licensure of clinics, the operation of the clinics, patient records, and standards for patient quality care. *See generally* Tenn. Code Ann. § 63-1-303(a)(2)(c). Among other regulations discussed in detail *infra*, the regulations provide an apparatus for obtaining a certificate to operate a pain management clinic. *See* Tenn. Comp. R. & Regs. 1200-34-01-.03 (2012) ("Beginning January 1, 2012, in order to obtain a certificate as a pain management clinic, an applicant shall submit the following to the Department . . . .").[5]

In order to ensure compliance with its requirements, inspections of pain

[4] The Act and its regulations have been substantively amended since the notice of charges was filed in December 2016. Unless otherwise specifically noted, we apply the statutes and regulations in effect at the time the notice of charges was filed.

[5] Current regulations provide for any pain management clinic to obtain a license before operating. *See* Tenn. Comp. R. & Regs. 1200-34-01-.02(1) ("Before operating or practicing in a pain management clinic as defined in T.C.A. § 63-1-301 (7) on or after July 1, 2017, the Medical Director of that clinic shall first obtain a Pain Management Clinic License from the Department, except as provided in Rule 1200-34-01-.04(2).").

management clinics are also authorized by the Act and the corresponding regulations. Tennessee Code Annotated section 63-1-304 specifically provides that

> Each board shall have the authority to inspect a pain management clinic which utilizes the services of a practitioner licensed by that board. During such inspections, the authorized representatives of the board may inspect all necessary documents and medical records to ensure compliance with this part and all other applicable laws and rules.[6]

The Act further provides for investigations as to violations of the Act or its corresponding regulations:

> Each board shall have the authority to investigate a complaint alleging a violation of this part, or a rule adopted under this part, by a pain management clinic utilizing the services of a healthcare practitioner licensed by that board. Each board shall also have the authority to investigate a complaint alleging that a pain management clinic utilizing the services of a healthcare practitioner licensed by that board is not properly licensed by the department as required by this part.

Tenn. Code Ann. § 63-1-305. The regulations also contemplate inspections directly by "the boards regulating the health care providers working for or at the clinic" Tenn. Comp R. & Regs. 1200-34-.05(1) (2012).[7]

At the time the notice of charges was filed, the Act provided that the Department had authority to discipline pain management clinics for violation of the Act or its related regulations:

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[6] The boards referred to in section 63-1-304 are the licensure boards of the different types of healthcare providers, as section 63-1-303 provides that "[e]ach licensed healthcare practitioner who provides services at a pain management clinic shall continue to be regulated only by the board which has issued a license to that practitioner." Tenn. Code Ann. § 63-1-303(a)(1). These boards include "the board of medical examiners, the board of osteopathic examination, the board of nursing, and the committee on physician assistants[.]" Tenn. Code Ann. § 63-1-303(a)(2)(b).

[7] The medical boards which regulate the health care providers are established under the umbrella of the Tennessee Department of Health, which conducted this investigation. *See generally* Tenn. Code Ann. § 68-1-101(a)(7). Appellants have not argued, either in the trial court or on appeal, that the Department lacked authority to conduct the audits and investigations at issue in this case.

The current version of the pain management clinic regulations expressly provides that the Department may conduct inspections and investigations of pain management clinics "[u]pon application for licensure as a pain management clinic." Tenn. Comp. R. & Regs. 1200-34-01-.08(a). Because licenses must be renewed every two years, *see* Tenn. Comp. R. & Regs. 1200-34-01-.04(1)(a), the regulations make clear that inspections by the Department are authorized at least every two years. *See* Tenn. Comp. R. & Regs. 1200-34-01-.08(2) (noting the fees that must be paid for the "biennial inspection").

> If the department finds that a pain management clinic which was issued a certificate no longer meets any requirement of this part, including, but not limited to, any violation of any rule promulgated by the department pursuant to this part, the department may impose lawful disciplinary action against the pain management clinic, including, but not limited to, the revocation or suspension of its certificate, and the imposition of a civil penalty of up to one thousand dollars ($1,000) per day for each day of continued violation. The pain management clinic shall be entitled to a hearing pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. Further, the department has the discretion to lift the suspension of a certificate when the clinic demonstrates compliance to the department.

Tenn. Code Ann. § 63-1-306 (2015).[8]

Here, much of the facts and findings of the Commissioner's Designee are undisputed for purposes of appeal. For example, Appellants do not argue that the Act is inapplicable to their practice or that they were not operating a pain management clinic during the relevant time. Appellant likewise do not question the Department's authority to audit or impose discipline on them for violations of the Act and its related regulations. Nor do Appellants' challenge any of the violations of the Act and regulations found by the ALJ or the ALJ's imposition of discipline, including the fact that they operated without a proper medical director for a period of time. Rather, the only dispute in this appeal concerns the additional violations found by the Commissioner's Designee and her decision to impose additional penalties on Appellants as a result. Thus, we will consider each finding from the Commissioner's designee, along with the relevant statutory provision or regulation, along with the evidence presented supporting the finding and fairly detracting from it, to determine whether substantial and material evidence supports the violation.[9]

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[8] The current version of the statute provides that licensing boards may impose discipline and thereafter must inform the Department. *See generally* Tenn. Code Ann. § 63-1-306(c). Regulations that are currently applicable continue to provide that the Department has authority to impose discipline. *See* Tenn. Comp. R. & Regs. 1200-34-01-.12(1) ("Upon a finding that a pain management clinic is in violation of any provision of the Tennessee Pain Management Clinic Act (T.C.A. §§ 63-1-301, et seq.) or the rules promulgated pursuant thereto, the Commissioner may impose [discipline as outline in the regulation]."); *see also* Tenn. Comp. R. & Regs. 1200-34-01-.01(6) (defining "Commissioner" as "the Commissioner of Health or his designee").

[9] While Appellants used their statement of the issues to argue that the inclusion of these findings of fact by the Commissioner's Designee was arbitrary and capricious, no further argument was made to support their assertion. When an issue is raised in a statement of the issues, it must be supported with citation to authorities. *See* Tenn. R. App. Pro. 27(a)(7)(A) (Arguments must set forth "the contentions of the appellant with respect to the issues presented, and the reasons therefor, including the reasons why the contentions require appropriate relief, with citations to the authorities and appropriate references to the record . . . ."). As discussed *infra*, however, a decision may be found to be arbitrary and capricious where

In addressing this issue, it is important to remember that we review only the final decision of the agency, i.e., the Amended Final Order. The Commissioner's Designee was not bound by any of the findings in the initial order in rendering her decision:

> In Tennessee's administrative decision-making hierarchy, like the hierarchy in most states, the agencies remain superior to the hearing officers and administrative judges. An agency's decision-making authority is not circumscribed in any way by an initial order. Because an agency possesses its own fact-finding authority, it may make its own factual determinations, and it may substitute its judgment for that of the hearing officer or administrative judge. Thus, when an agency reviews an initial order, it renders its own decision, and it is the agency's final order, not the initial order, that is the subject of judicial review.

McEwen v. Tennessee Dep't of Safety, 173 S.W.3d 815, 822 (Tenn. Ct. App. 2005) (internal citations and footnotes omitted). Thus, the fact that the Commissioner's Designee found additional violations by Appellants is not in error unless those findings were unsupported by substantial and material evidence or arbitrary and capricious.

We first consider whether substantial and material evidence was present to justify the additional violations that were found by the Commissioner's Designee. The term "substantial and material evidence" is not defined in the statute. Rather, this Court has held that substantial and material evidence is "such relevant evidence as a reasonable mind might accept to support a rational conclusion" and establish that the decision in question was reasonably sound. ***Jackson Mobilphone Co. v. Tenn. Pub. Serv. Comm'n***, 876 S.W.2d 106, 110–11 (Tenn. Ct. App. 1993); *see also* ***City of Memphis v. Civil Service Cmm'n of City of Memphis***, 216 S.W.3d 311, 316 (Tenn. 2007). "In general terms, the standard requires something less than a preponderance of the evidence, but more than a scintilla or glimmer." ***Wayne Cty. v. Tennessee Solid Waste Disposal Control Bd.***, 756 S.W.2d 274, 280 (Tenn. Ct. App. 1988) (citation omitted) (citing ***Consolo v. Federal Maritime Comm'n***, 383 U.S. 607, 620, 86 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1966); ***Pace v. Garbage Disposal Dist.***, 54 Tenn. App. 263, 267, 390 S.W.2d 461, 463 (Tenn. Ct. App. 1965)). While this Court must consider evidence in the record that can fairly detract from the weight of the evidence, we cannot substitute our judgment or re-weigh the evidence in the matter. ***Pittman v. City of Memphis***, 360 S.W.3d 382, 388 (Tenn. Ct. App. 2011) (citing ***City of Memphis***, 216 S.W.3d at 316). Even if the evidence could support another result, we may reject an agency's ruling "only if a reasonable person necessarily would reach a different conclusion based on the evidence." ***Id.*** Decisions considered to be arbitrary and capricious also lack substantial

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is it is not supported by material evidence. As such, we will review the Amended Final Order to determine whether it was supported by sufficient evidence.

and material evidence. ***City of Memphis***, 216 S.W.3d at 316 (citing ***Jackson Mobilphone Co.***, 876 S.W.2d at 110). In addition, a ruling can be arbitrary and capricious "if caused by a clear error in judgment." ***Id.***

Appellants first challenge whether substantial and material evidence exists to find a failure to establish a means of evaluating and monitoring the quality of patient care, identifying and correcting deficiencies, or opportunities to improve quality of care. At the time that the Department filed its notice of charges, the Department's pain management clinic regulations stated that a clinic's medical director was required to establish quality assurance policies and procedures that included "evaluating and monitoring the quality and appropriateness of patient care, the methods of improving patient care as well as identifying and correcting deficiencies, and the opportunities to improve the clinic's performance and quality of care[.]" Tenn. Comp. R. & Regs. 1200-34-01-.07(iv) (2012). Appellants argue that the Department could only prove that the Clinic could not provide a written policy for chronic pain management patients and written programs for drug screening and infection control. Further, Appellants argue that the Department never observed Dr. Ballard's practice and never indicated that there were problems and concerns with his practice.

However, a cursory review of the record and hearing transcript shows that the Department's auditor asked Dr. Ballard about quality assurance policies regarding patient care, ways to identify and correct deficiencies, or opportunities to improve quality of care during multiple audits. According to the auditor's testimony, "Dr. Ballard stated that they were redoing all forms and trying to make sure that things were done every single time on every patient, but there was no written policy." In at least two audit forms, the Department found that Appellants did not have the proper quality assurance policies and procedures as outlined by the regulations. Even by the time of the final audit, Dr. Ballard still had no written policy and Appellants were still creating new paperwork to be provided to patients outlining certain directives applicable to pain management clinics. In addition, Appellants never produced any version of its quality policies, written, verbal, or otherwise, to the Department, the Commissioner's Designee, the trial court, or this Court. As the Department produced records and testimony indicating that Appellants did not possess the required quality assurance policies, and nothing has been produced to rebut their claims, a reasonable mind could accept this evidence and rationally conclude that Appellants did not comply with the Department's regulations. *See* ***Pittman***, 390 S.W.3d at 388 (holding that courts "may reject an agency's determination only if a reasonable person necessarily would reach a different conclusion based on the evidence"). As such, we conclude that substantial and material evidence existed to establish the additional charge of failing to establish a means of evaluating and monitoring the quality of patient care, identifying and correcting deficiencies, or opportunities to improve quality of care. The Commissioner's Designee's addition of this finding of fact was therefore neither arbitrary nor capricious.

Appellants further question whether substantial and material evidence exists for the Commissioner's Designee to find that adequate billing records were not kept in the Clinic. In 2015, the Department's audit established that the Clinic's billing records were not kept on site and that the Clinic's statements did not list the amounts paid for co-pay or the remainder of services. Instead, the billing statements only listed insurance coverage and the date of any insurance payment. The records were also prepared electronically, and statements were only sent to insurers, not patients. When the notice of charges was filed, pain management clinics were required to keep billing records with "(a) the amount paid for the co-pay and/or remainder of services; (b) method of payment; (c) date of delivery of services; (d) date of payment; and (e) description of services." Tenn. Comp. R. & Regs. 1200-34-01-.08(1) (2012). Further, the Clinic accepted cash, checks, and money orders for the services it provided. State statute, however, provides that pain management clinics "may accept only a check or credit card in payment for services provided at the clinic" unless cash is used to pay "for a co-pay, coinsurance or deductible when the remainder of the charge for the services will be submitted to the patient's insurance plan for reimbursement." Tenn. Code Ann. § 63-1-310.[10]

While Appellants claim that any billing issues found by the Department's auditor were eventually cured, Appellants provide no caselaw or citations to statutes or regulations to support a claim that an admitted, but later corrected, violation of relevant directives cannot serve as a basis for discipline. Rather, we have previously held that the admission of improper behavior under state regulations can be enough to establish substantial and material evidence of an administrative violation. *See* ***Miller v. Tenn. Bd. of Nursing***, 256 S.W.3d 225, 230 (Tenn. Ct. App. 2007) (holding that substantial and material evidence was established when a nurse admitted she did not notify her supervisor that she was leaving her shift, thereby abandoning her patients without sufficient notice). Appellants admitted to not keeping billing records on site and not sending records to patients for a period of time. In addition, records were provided that showed that the billing statements sent to insurers failed to meet the state's regulatory requirements, as they did not include amounts of payments or methods of payments.

[10] When charges were filed in the present case, state regulations that regulate pain management clinics stated that the clinic's certificate holder shall ensure that all transactions comply with Tennessee Code Annotated section 63-1-310, "which provides that a pain management clinic may accept only a check, credit card, or money order in payment for services provided at the clinic[.]" Tenn. Comp. R. & Regs. 1200-34-01-.08(6) (2012). While a previous version of Tennessee Code Annotated section 63-1-310 allowed money orders to be accepted, the statute was amended in 2013 to disallow the use of money orders. *See* 2013 Tenn. Pub. Acts c. 430, § 10. As such, the regulation and the statute did not match when charges were filed. When a regulation does not match a statute, the statute is controlling. ***Wright v. Tenn. Peace Officer Standards and Training Comm'n***, 277 S.W.3d 1, 15 (Tenn. Ct. App. 2008) (citing ***Hobbs v. Hobbs***, 27 S.W.3d 900, 903 n.1 (Tenn. 2000)). The regulation was amended in 2017 to reflect the amended language of the statute. There is no dispute in this case that if shown by sufficient evidence, Appellant's use of money orders would constitute a basis for discipline due to a violation of section 63-1-310.

Further, it is not clear that all billing issues were in fact resolved when the Department filed its notice of charges. While the Department's auditor testified generally that all billing issues were corrected by the final audit, Dr. Ballard admitted during the final audit that the Clinic continued to accept money orders. A sign posted in the office at the time of the final audit also confirmed that the clinic would accept only money orders for "self-pay" for office visits and drug screens. Clearly, this practice conflicts with the plain language of section 63-1-310 to only allow cash payments in limited circumstances. *See* Tenn. Code Ann. § 63-1-310(b). When an undisputed violation occurred when charges were filed by an administrative agency, attempts to later cure that violation may not be effective. ***County of Shelby v. Tompkins***, 241 S.W.3d 500, 508 (Tenn. Ct. App. 2007) (holding that a firefighter who attempted to move into Shelby County after he was accused of living outside of the county could not resolve the issue). As Appellants admitted to several billing violations, and since at least one improper practice continued when charges were filed, substantial and material evidence existed for the Commissioner's Designee and the trial court to find a failure to maintain adequate billing records under state statutes and regulations. As substantial and material evidence existed, the action by the Commissioner's Designee was not arbitrary and capricious.

Appellants also challenge whether substantial and material evidence existed for the Commissioner's Designee to find that Dr. Ballard dispensed controlled substances to his patients. Appellant's argument is directed toward the following finding of fact included in the order of the Commissioner's Designee: "The dispensing of unused controlled medications received from patients which were then repackaged and distributed to other patients." As state statute makes clear, physicians in pain management clinics are not permitted to distribute controlled substances to their patients. Tenn. Code Ann. § 63-1-313(a) ("[N]o pain management clinic or medical doctor . . . shall be permitted to dispense controlled substances. . . ."). There is no dispute that during the final audit, Dr. Ballard told the Department's auditor that he repackaged controlled substances from some patients and gave them to others; Dr. Ballard claimed, however, that he only rarely did so and that he had not done so for years before the auditor's review. Thus, while Dr. Ballard attempts to minimize his violations of the relevant statute, we must conclude that substantial and material evidence was presented to establish that controlled substances were distributed by Dr. Ballard in violation of statutes applicable to pain clinics. *Cf.* ***Miller***, 256 S.W.3d at 230 (concluding that substantial and material evidence was presented that a nurse was convicted of a crime when the nurse admitted to pleading guilty). The Commissioner's Designee therefore did not act in an arbitrary and capricious manner by finding that fact in its Amended Final Order. Further, the trial court correctly upheld the finding of the Commissioner's Designee.

Finally, Appellants challenge whether the decision by the Commissioner's Designee to increase the civil penalty and costs against the Appellants was arbitrary and capricious. In the present case, Appellants argue that the Commissioner's Designee acted arbitrarily and capriciously by increasing the civil penalty from $3,500.00 to $9,300.00

and by increasing the potential costs assessed against them from $5,000.00 to $10,000.00.[11] The Department counters that the civil penalty against the Appellants was properly modified to account for the nature and scope of the violations proven in the administrative matter.

"A decision of an administrative agency is arbitrary or capricious when there is no substantial and material evidence supporting the decision." ***StarLink Logistics Inc. v. ACC, LLC***, 494 S.W.3d 659, 669 (Tenn. 2016) (citing ***Pittman v. City of Memphis***, 360 S.W.3d 382, 389 (Tenn. Ct. App. 2011)) (involving a different statute that also applies the substantial and material evidence standard). As described otherwise, "a decision is arbitrary or capricious if it 'is not based on any course of reasoning or exercise of judgment, or . . . disregards the facts or circumstances of the case without some basis that would lead a reasonable person to reach the same conclusion.'" ***Smith v. White***, 538 S.W.3d 1, 11 (Tenn. Ct. App. 2017) (citing ***City of Memphis***, 216 S.W.3d at 316). Further, "a clear error of judgment can also render a decision arbitrary and capricious notwithstanding adequate evidentiary support[,]" and "[i]n the broadest sense, the arbitrary and capricious standard requires the court to determine whether the administrative agency has made a clear error in judgment." ***Id.***; ***Wade v. Tennessee Dep't of Finance and Admin.***, 487 S.W.3d 123, 131 (Tenn. Ct. App. 2015) (citing ***Jackson Mobilphone Co., Inc.***, 876 S.W.2d at 110-11).

In its argument, Appellants cite ***Rawdon v. Tennessee Board of Medical Examiners***, No. M2012-02261-COA-R3-CV, 2013 WL 5874779 (Tenn. Ct. App. Oct. 30, 2013), where this Court affirmed a decision vacating a $6,355,000.00 administrative penalty assessed by the state's Board of Medical Examiners. ***Id.***at *3–4. The penalty, which was based on the estimated number of patients a doctor saw for approximately 18 years, was not based on precise evidence presented in the case and was not supported by a consideration or articulation of regulatory factors tied to the proper penalty. ***Id.*** Appellants argue that the same reasoning would apply here, as the Commissioner's Designee insufficiently provided evidence or developed reasoning based on state regulations to support her decision. We disagree.

As stated *supra*, substantial and material evidence existed for the Commissioner's Designee to include additional violations to the amended final order, much less for the host of violations that were in the ALJ's original order. According to the Department's regulations in place when the notice of charges was filed, the following factors could be used to determine the amount of a civil penalty assessed against a pain management clinic:

(a) Whether the amount imposed will be a substantial economic

[11] After the Commissioner's Designee assessed the new penalties, the Department's costs related to this matter were $7,048.03.

deterrent to the violator;
(b) The circumstances leading to the violation;
(c) The severity of the violation and the risk of harm to the public;
(d) The economic benefits gained by the violator as a result of noncompliance;
(e) The interest of the public; and
(f) The willfulness of the violation.

Tenn. Comp. R. & Regs. 1200-34-01-.10(3) (2012).

In her Amended Final Order, the Commissioner's Designee stated that she considered these factors and expressly mentioned the severity and willfulness of the violations in this case. Unlike ***Rawdon***, the violations referenced in the final order were specific, and the factors that could be considered in assessing a penalty were referenced. Further, the increase in the civil penalty assessed against Appellants was justified considering the facts and circumstances of the case. Scholarly articles have noted that "'[t]he misuse and abuse of prescription drugs, along with the associated morbidity and mortality, has been identified as one of the most serious and costly issues facing Tennesseans today.'" Julie A. Warren, *Defining the Opioid Crisis and the Limited Role of the Criminal Justice System Resolving It*, 48 U. Mem. L. Rev. 1205, 1214 (2018) (quoting *Naloxone Training Information*, Tenn. Dep't of Health, https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html (last updated Jan. 2018)). In response, the Tennessee General Assembly enacted "changes to the law [to] additionally restrict[] and create[] oversight for both prescribing physicians and pharmacists." ***Id.*** at 1222. Thus, Appellants' violations of the Pain Management Clinic Act have serious implications for public health.

Moreover, the Commissioner's Designee awarded fines in an amount tens of thousands of dollars less than what the Department sought. Finally, as Appellants conceded in their brief, the determination of penalties in an administrative action is "peculiarly within the discretion of the agency." ***McClellan v. Bd. of Regents of State Univ.***, 921 S.W.2d 684, 693 (Tenn. 1996). While Appellants state that the ALJ's opinion was not thoughtfully considered by the Commissioner's Designee and the trial court, the Department is allowed to call for an initial order to be reconsidered or appealed. *See* Tenn. Code Ann. § 4-5-315. Moreover, the Commissioner and its Designee are permitted to substitute their judgment for that of a hearing officer or administrative judge. *See* ***McEwen***, 173 S.W.3d at 822. The Commissioner's Designee was therefore not required to give the decision of the ALJ any deference whatsoever in issuing its final order.. Here, the Commissioner's Designee assessed a penalty that was reasonable in a case where the violations themselves were largely undisputed and not remedied more than a year after the Department first noted them. As the decision was rooted in the facts and circumstances of the case and stayed within a scope of reasonable judgment, we cannot

conclude that the increase in civil penalties from the Commissioner's Designee was arbitrary and capricious.

In addition, we do not agree with Appellants' claims that the increase in potential costs was arbitrary and capricious under the UAPA. Agencies under the authority of the Department which discipline a medical license or certificate holder have the discretion to require that license or certificate holder "to pay the actual and reasonable costs of the investigation and prosecution of the case." Tenn. Code Ann. 63-1-144(a). Here, the Commissioner's Designee increased the maximum that Appellants could pay in costs from $5,000.00 to $10,000.00. By the time the case reached the Commissioner's Designee, the Department's costs for investigating and prosecuting the case was $7,048.03, which was nearly 50% more than the cap imposed by the ALJ. Moreover, the Department was successful in its appeal of the initial order, which resulted in additional discipline to Appellants. Given the Department's success, it was within the Commissioner's Designee's discretion to order Appellants to pay the additional costs incurred on review. In sum, increasing the amount of costs Appellants were required to pay was not unreasonable, particularly given the discretion the Department, and by extension the Commissioner's Designee, possessed in assessing the costs of investigation and prosecution by the Department. We conclude that there is no clear error or arbitrary or capricious action due to the increase in costs that resulted from the increased violations and increased discipline that resulted from review of the initial order. Consequently, the trial court did not err in affirming the ruling of the Commissioner's Designee in full.

CONCLUSION

The judgment of the Davidson County Chancery Court is affirmed in full. This cause is remanded to the trial court for all further proceedings as may be necessary and consistent with this Opinion. Costs of this appeal are taxed to the Appellants, Thomas K. Ballard, III, M.D., and Ballard Clinic, P.C., for which execution may issue if necessary.

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J. STEVEN STAFFORD, JUDGE