SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-1246-21

DANA SLESS, D.O.,

Petitioner-Appellant,

v.

NEW JERSEY DEPARTMENT OF HEALTH,

Respondent-Respondent.

Argued June 7, 2023 – Decided July 27, 2023

Before Judges Haas and DeAlmeida.

On appeal from the New Jersey Department of Health, Docket Nos. 01-029 and 01-054.

Louis M. Barbone argued the cause for appellant (Jacobs & Barbone, PA, attorneys; Louis M. Barbone, on the brief).

Francis X. Baker, Deputy Attorney General, argued the cause for respondent (Matthew J. Platkin, Attorney General, attorney; Melissa H. Raksa, Assistant Attorney General, of counsel; Francis X. Baker, on the brief).

PER CURIAM

Appellant Dana E. Sless, D.O. appeals from the November 22, 2021 final agency decision of the Department of Health (DOH) finding that she violated the terms of an agreement requiring her staff to be trained with respect to the storage and management of vaccines for children. We affirm.

I.

Sless is a licensed pediatrician and her practice had offices in Egg Harbor and Atlantic City. She enrolled in the Vaccine for Children (VFC) program in 2004. VFC is a federal Medicaid benefit that provides pediatric vaccines for standard childhood illnesses at no cost to eligible children through registered medical providers. DOH operates as a coordinating agency for the State VFC program.

To participate in VFC, Sless executed a Provider Enrollment Agreement (PEA) which allowed her to receive vaccines at no cost if she agreed to follow the rules of the VFC and submit to announced and unannounced onsite inspections. The PEA required Sless to comply with specific vaccine management standards including: (1) storing vaccine under proper storage conditions at all times; (2) ensuring refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices meet the VFC storage and

handling requirements; and (3) returning all spoiled/expired vaccine to the Center for Disease Control's centralized vaccine distributor within six months of spoilage/expiration.

On October 18, 2017, VFC inspector Ramona Braddock performed a scheduled onsite inspection at Sless's Atlantic City office. During the visit, Braddock reviewed the temperature logs maintained by Sless's staff for refrigerator and freezer vaccine storage units. The temperature logs included twice daily current temperature readings, the times the readings were taken, and the minimum/maximum temperatures of the unit since the previous reading. At the time, the only recording required by the VFC were the two daily current temperature readings. The minimum/maximum temperatures readings were recommended.

From January 1, 2017 to May 24, 2017, the minimum/maximum temperatures recorded for one of the Atlantic City refrigerators was fifty degrees and eighty-six degrees respectively for every day on which those recordings were made. Those temperatures are significantly over the acceptable maximum limit of forty-six degrees. The same fifty degrees/eighty-six degrees temperatures were recorded on various other days, as were other minimum/maximum temperatures such as thirty-one degrees/seventy-six

degrees. The maximum temperature of the freezer at that office was also noted to be above the maximum limit of five degrees on several days.

Under the VFC and PEA, an excursion is a temperature reading above forty-six degrees or below thirty-six degrees for refrigerated vaccines, or above five degrees or below negative fifty-eight degrees for frozen vaccines. A provider must "document all excursions and actions taken including the following: (1) Quarantine and label vaccines as 'DO NOT USE'; (2) Place vaccine[s] in a unit where they can be stored under proper conditions; (3) Contact [VFC] to report an excursion; and (4) Contact the vaccine manufacturer to obtain documentation supporting the usability of the vaccine." These steps were not taken by Sless prior to Braddock's inspection, despite numerous recorded excursions by her staff for her storage units.

On October 25, 2017, Braddock visited the Egg Harbor office, where she determined there were also temperature excursions recorded in minimum/ maximum temperatures on April 21, May 11, 12, and 15, August 25, September 14 and 15, and October 10, 2017. Based on her review of the temperature logs, Braddock quarantined the vaccines in both offices.

On October 30, 2017, Sless installed new computerized data logger thermometers in both offices so all information would be fully downloadable

and would not require manual temperature logs. After monitoring the new thermometer results, Sless determined that the refrigeration and freezer units were working properly and did not diverge from approved temperatures.

During an investigation, Sless also determined that the recorded temperature excursions in the minimum/maximum temperatures had existed at her offices in 2015 and 2016 and that during past inspections Braddock had not flagged them. Braddock explained the VFC focused on minimum/maximum temperatures in 2017 but testified providers would not have known about the new focus on minimum/maximum temperatures because it was an internal priority promulgated within the VFC.

Sless also retained an expert biomedical engineer, Dr. Robert Wetstein, to investigate her vaccine storage units. In a report, Wetstein offered the opinion that there had been no temperature excursions on any of the vaccine storage units in Sless's offices in 2017. He stated the vaccine storage units and thermometers were all properly maintained and in good condition. After speaking with the staff about their recording process and observing the "very high" minimum/maximum recordings, Wetstein explained that in addition to showing the current actual temperature of the units, there were two modes on the Fisher thermometers that were in use at Sless's offices: the alarm setting and

the high/low setting. When the thermometer was in the alarm setting, it would display the high and low temperatures that would cause the thermometer sound an alarm if the unit reached those temperatures. The high/low setting displayed the actual high/low temperatures in the time since this setting was reset. To toggle between the two settings, staff needed to press a button on the thermometer. The default alarm setting on the Fisher device was fifty degrees/eight-six degrees, the minimum/maximum temperature readings repeatedly recorded by Sless's staff.

Wetstein concluded that the staff, after recording the actual temperatures in the logs each day, was consistently looking at the numbers on the thermometer in the default alarm setting to record the minimum/maximum settings without changing to the correct setting on the thermometer. Thus, he opined that the staff accurately recorded the twice daily readings, which were in the expected range with small variability, but often recorded the default alarm settings rather than the actual minimum/maximum temperatures. He opined that it was not possible for the refrigerators to reach eighty-six degrees but also have the twice daily acceptable readings on the same day. He opined that the recordation of the minimum/maximum numbers was plain error and there was no correlation with the correct twice daily readings. In response to Wetstein's report, Sless

retrained her staff with respect to accurately recording the temperatures of the units storing vaccines.

DOH subsequently issued Sless a notice of non-compliance and demand for corrective action. The agency informed her of its determination that she had:

> (1) Failed to undertake appropriate steps to ensure that the VFC vaccine refrigeration units operated and would continue to operate within required minimum and maximum temperature ranges;
>
> (2) Failed to quarantine VFC vaccines that had been potentially exposed to out-of-range temperatures;
>
> (3) Failed to notify vaccine manufacturers that VFC vaccines might have been exposed to out-of-range temperatures and failed to obtain the manufacturers' assessments of the viability of those vaccines;
>
> (4) Failed to notify VFC that vaccines might have been exposed to out-of-range temperatures;
>
> (5) Caused DOH, in reliance on the data she reported to continue to fill her VFC vaccine orders, over a period of at least ten months; and
>
> (6) Administered potentially compromised and/or nonviable VFC vaccines to children over a period of at least ten months.

The agency stated that while it acknowledged the corrective actions taken by Sless, it was concerned that her staff had "previously lacked a fundamental understanding of the very basics of temperature monitoring and that [Sless]

failed to appropriately supervise her staff in their vaccine management responsibilities." The agency found that because it had no confidence the vaccines had been maintained at recommended temperatures from January 1, 2017 through October 2017, the quarantined vaccines were waste.

DOH directed Sless to: (1) replace the wasted vaccines at her expense; (2) notify patients who had received vaccines during the relevant period that they had received potentially compromised vaccines; and (3) provide revaccination and counseling to those patients at her expense. The agency excluded Sless from the VFC program until the corrective action was taken.

On March 10, 2018, Sless appealed the notice and demand for corrective action to the DOH, arguing she had strictly complied with all requirements of the VFC and there had been no temperature excursions at her offices. Sless requested a hearing at the Office of Administrative Law (OAL) and a stay of all corrective actions. DOH denied her request for a hearing and a stay.

On April 13, 2018, Sless filed a complaint in the Law Division for a declaratory judgment and for temporary restraints pending the grant of a hearing. Ultimately, the corrective action directive was stayed, the complaint dismissed, and the matter transferred to the DOH for resolution. The agency subsequently transmitted the matter to the OAL for a hearing.

At a three-day hearing, Sless, Braddock, Barbara Montana, the DOH Medical Director, Susan Morton, a registered nurse employed by Sless, and Wetstein testified. Administrative Law Judge (ALJ) Elaine B. Frick thereafter issued an initial decision and recommendation.

She found as fact that the VFC required a twice daily recordation of the temperature of the vaccine storage units and recommended the recordation of the minimum/maximum temperatures of those units. She found the Fisher thermometers used by Sless were acceptable for use in the VFC program at that time, and that Sless's staff accurately recorded the twice daily current temperature of the vaccine storage units. Those temperatures were within the acceptable range.

ALJ Frick found Wetstein's testimony, which was consistent with his report, to be credible and persuasive. Based on his testimony, the ALJ found that Sless's staff recorded erroneous minimum/maximum temperatures for those units. The judge concluded that the majority of those recordings reflected the default alarm settings on the thermometer. ALJ Frick found that the erroneous minimum/maximum recordings did not affect the accuracy of the actual temperature recordings noted by the staff. In addition, the ALJ found that it would not be possible for the refrigeration units to swing from the

minimum/maximum temperatures recorded by staff to actual temperatures recorded by staff in a single day. In light of these findings, the ALJ concluded that the vaccines were not exposed to temperatures outside of the acceptable range at Sless's offices.

The ALJ found, however, that Sless's "staff did not appreciate or understand what the minimum/maximum temperatures" they recorded reflected and "blindly recorded numbers from the device, as they were trained to do." The minimum/maximum temperatures Sless's staff reported, the ALJ found, even if inaccurate, were outside of acceptable ranges, which should have been apparent to staff. However, the ALJ concluded, although the temperature logs used in 2017 contained instructions for reporting excursions from the acceptable temperatures for current temperature readings, it contained no instructions with respect to reporting excursions from the acceptable temperature ranges for minimum/maximum temperature readings. Thus, the ALJ concluded, Sless was not required to report the excursions from minimum/maximum temperature ranges. As a result, the ALJ concluded, Sless did not violate the terms of the VFC or the PEA.

The ALJ found it was reasonable and appropriate for Braddock to quarantine the vaccines based on the temperature information reported by Sless's

staff and for the DOH to waste those vaccines out of an abundance of caution. However, the ALJ found that the vaccines had not actually been compromised. Thus, the ALJ concluded that DOH was not entitled to reimbursement for the cost of the wasted vaccines and its directive for Sless to take corrective action in the form of written notification to her clients and vaccinations and counseling at her expense was not warranted. The ALJ recommended Sless be readmitted as a medical provider under the VFC program. DOH filed exceptions to the ALJ's initial decision.

On November 22, 2021, the Commissioner issued a final decision adopting the ALJ initial decision in part and modifying the initial decision in part. The Commissioner adopted the ALJ's findings of fact and found it was more probable than not Sless's vaccine storage units had maintained the vaccines at appropriate temperatures during the relevant period. In addition, the Commissioner accepted the finding that the minimum/maximum recorded temperatures were erroneous due to Sless's staff not understanding how to operate the Fisher thermometer.

The Commissioner, however, rejected the ALJ's conclusion that Sless did not violate the terms of the VFC and PEA. She reasoned that Sless was responsible for ensuring the vaccine storage units were operating properly and

that her staff was complying with the monitoring processes required by the VFC. The Commissioner found that Sless failed to meet that requirement when her staff recorded "wildly out-of-range" minimum/maximum temperatures and then failed to contact the VFC and the vaccine manufacturer as required by the PEA. The Commissioner disagreed with Sless's argument that she only needed to contact the VFC if the twice daily current temperature readings were excursions, finding that it "defies logic that a provider would record out-of-range minimum/maximum temperatures and not take action on those excursions. Such a practice would render the recordings as nothing more than a writing exercise." In addition, the Commissioner noted that the temperature log forms indicate that "any" out-of-range temperature recorded must be reported to VFC.

The Commissioner found "the voluntary nature of the minimum/maximum recordings does not grant [Sless] permission to ignore the excursions when they were recorded by her staff" and she was obligated to act because her office had recorded excursions. In addition, the Commissioner found that Sless should have ensured her staff was properly trained in recognizing and responding to recorded excursions. The Commissioner found "this entire matter would have been avoided if [Sless] simply ensured that her staff was properly trained on the

use of the Fisher thermometers and the actions that were required for temperature excursions, as required by the PEA."

The Commissioner agreed that Sless was not required to replace the wasted vaccines or notify patients the vaccines they received may have been compromised. However, the Commissioner found that the DOH had established that Sless violated the terms of the PEA. She concluded that Sless's remedial actions, including installation of electronic data logger thermometers, ensuring her storage units were properly working, and the length of time she was excluded from the VFC were sufficient sanctions. The Commissioner ordered Sless reinstated to the VFC.

This appeal followed. Sless argues that: (1) the Commissioner's decision was arbitrary, capricious and unreasonable and not supported by substantial credible evidence in the record; and (2) that she complied with all terms of the VFC and the PEA.

II.

An appellate court's review of an administrative agency's final decision is limited. CWA, AFL-CIO v. N.J. Civ. Serv. Comm'n, 234 N.J. 483, 515 (2018). An agency's decision will not be reversed unless "(1) it was arbitrary, capricious, or unreasonable; (2) it violated express or implied legislative policies; (3) it

offended the State or Federal Constitution; or (4) the findings on which it was based were not supported by substantial, credible evidence in the record." Univ. Cottage Club of Princeton N.J. Corp. v. N.J. Dep't of Env't Prot., 191 N.J. 38, 48 (2007) (citing In re Taylor, 158 N.J. 644, 656 (1999)). Moreover, courts generally afford substantial deference to an agency's interpretation of a statute that it is charged with enforcing, but an appellate court is not "bound by the agency's interpretation of a statute or its determination of a strictly legal issue." Ibid. (quoting Taylor, 158 N.J. at 658). "[I]f substantial credible evidence supports an agency's conclusion, a court may not substitute its own judgment for the agency's even though the court might have reached a different result." Greenwood v. State Police Training Ctr., 127 N.J. 500, 513 (1992).

Having carefully reviewed Sless's arguments in light of the record and applicable legal principles, we affirm the November 22, 2021 final agency decision for the reasons stated by the DOH Commissioner. We add only the following comments. We see no error in the Commissioner's conclusion that although the minimum/maximum temperatures recordings were not required, once Sless elected to have her staff make those recordings, it was incumbent on her to ensure that her staff was properly trained to report to VFC any out-of-range temperatures they recorded. The Commissioner's finding that it is more

likely than not that there were no temperature excursions in the units during the relevant period, does not negate Sless's failure to properly train her staff, monitor the temperatures they recorded, and report the recorded excursions to the VFC. We cannot find that the Commissioner acted in an arbitrary or capricious fashion by concluding that Sless violated the terms of the VFC and PEA, while also dissolving the agency's directive that Sless take corrective measures at her own expense to cure the reasonable decision to waste vaccine because of the inaccurate records produced by Sless's staff.

To the extent we have not specifically addressed any of Sless's remaining contentions, we conclude they lack sufficient merit to warrant discussion in a written opinion. R. 2:11-3(e)(1)(E).

Affirmed.