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SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO. A-5660-18T3

M.M. and S.O.,1

Appellants,

v.

CATASTROPHIC ILLNESS IN CHILDREN RELIEF FUND COMMISSION,

Respondent.

Submitted November 9, 2020 – Decided January 27, 2021

Before Judges Sabatino and Currier.

On appeal from the New Jersey Catastrophic Illness in Children Relief Fund Commission.

M.M. and S.O., appellants pro se.

Gurbir S. Grewal, Attorney General, attorney for respondent (Melissa H. Raksa, Assistant Attorney General, of counsel; Francis X. Baker, Deputy Attorney General, on the brief).

¹ We use initials and pseudonyms to preserve the child's privacy. The matters are sealed. <u>R.</u> 1:38-11(b)(2).

PER CURIAM

This case returns to us after remand in which we required defendant, the Catastrophic Illness in Children Relief Fund Commission (the Commission), to explain why it reimbursed plaintiffs for their uncovered medical expenses incurred by their daughter's hyperbaric oxygen therapy (HBOT) in 2015 but not in 2016.

The Commission informed this court on the first appeal that HBOT treatments have not been approved by the Food and Drug Administration (FDA) for this child's condition. On remand, the Commission explained it erred in reimbursing the HBOT treatments in 2015. Therefore, it denied the reimbursement of costs for HBOT treatments incurred in 2016 and thereafter. Given the deference we grant an administrative agency, we affirm.

Plaintiffs' daughter Susan suffered severe brain injuries during her birth in 2010. Her diagnosis is hypoxic ischemic encephalopathy. Her parents describe Susan as being a "quad cerebral palsy" with "medication resistant seizures, visual impairments, respiratory insufficiencies, digestive problems, auditory impairments, and many developmental delays." After Susan was prescribed HBOT treatments by her physician, her parents reported seeing "remarkable results."

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In 2016, the Commission reimbursed plaintiffs for approximately \$50,000 in expenses incurred in 2015 for HBOT and other treatment. In 2017, plaintiffs again applied for reimbursement of expenses for 2016 HBOT treatments. The request was denied as an ineligible expense.

Plaintiffs appealed, contending HBOT treatments should be considered eligible expenses. We remanded to the Commission for an explanation as to why HBOT expenses were reimbursed in 2015 and not in 2016.

In a June 13, 2019 letter, the Commission advised plaintiffs:

For any experimental medical treatment or drug, such as HBOT, to qualify for reimbursement, the Commission requires, among other things, that the treatment or drug at issue be used in connection with an FDA^[2]-approved clinical trial (N.J.A.C. 10:155-1.14(a)(14)). . . . The Commission has an interest in ensuring that families seek high quality medical care. In that vein, the Commission discourages experimental treatment that is not based on scientific evidence and may not be safe and effective. With respect to HBOT treatment, the FDA specifically states that the safety and effectiveness of HBOT has not been established for a number of conditions, including, but not limited to, cerebral palsy.

(https://www.fda.gov/consumers/consumerupdates/hyperbaric-oxygen-therapy-dont-be-misled).

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² The FDA is tasked with regulating clinical trials of drugs and medical devices "in human volunteers to see whether they should be approved for wider use in the general population." <u>Conducting Clinical Trials</u>, U.S. Food and Drug Administration (last updated June 15, 2016).

In following these above guidelines, the Commission has consistently not approved reimbursement for HBOT in cases where the child's diagnosis, such as cerebral palsy, is not established by the FDA to benefit from HBOT. After careful review, the Commission acknowledges that the reimbursement of [Susan's] HBOT treatment in your 2016 application was an error because such treatment was experimental and not administered in connection with an FDA-approved clinical trial. In reviewing subsequent applications, the Commission has consistently denied reimbursement for HBOT treatment based on the fact that the FDA has neither approved this treatment for cerebral palsy nor provided it in connection with an FDA-approved clinical trial.

. . . .

Because the reimbursement of [Susan's] HBOT treatment in your 2016 application was in error, the Commission has not and will not seek to recover such funds that were paid in error. . . . All families should understand that the approval for reimbursement of services in one year in no way guarantee[s] that the same service will be reimbursed in the same manner or at all in subsequent years. Funding is limited and may vary from year to year. . . . For these reasons, the Commission again denies your 2017 application for reimbursement of [Susan's] HBOT expenses incurred between January 1, 2016 and December 31, 2016.

Plaintiffs appeal again, contending it is not fair for the Commission to deny their reimbursement requests for HBOT treatments in 2016 because the same treatments were reimbursed in 2015.

The scope of appellate review of an administrative decision is limited. Lewis v. Catastrophic Illness in Children Relief Fund Comm'n, 336 N.J. Super. 361, 369 (App. Div. 2001). In reviewing a final agency decision, we must defer to an agency's expertise and superior knowledge of its field. Dep't of Children & Families, Div. of Youth & Family Servs. v. T.B., 207 N.J. 294, 301 (2011); see also Campbell v. N.J. Racing Comm'n, 169 N.J. 579, 588 (2001) (granting deference to agency expertise on technical matters). This court "may not second-guess those judgments of an administrative agency which fall squarely within the agency's expertise." In re Stream Encroachment Permit, Permit No. 0200-04-0002.1 FHA, 402 N.J. Super. 587, 597 (App. Div. 2008).

"In order to reverse an agency's judgment, an appellate court must find the agency's decision to be 'arbitrary, capricious, or unreasonable, or . . . not supported by substantial credible evidence in the record as a whole.'" <u>In restablement</u> Stallworth, 208 N.J. 182, 194 (2011) (quoting Henry v. Rahway State Prison, 81 N.J. 571, 579-80 (1980)).

In 1987, the Legislature found "children have the highest average medical costs among the population as a whole[,]" and as a result, some families are "push[ed] . . . into bankruptcy and others toward seeking inferior medical care." N.J.S.A. 26:2-148(c), (b). In response, the Legislature enacted the Catastrophic

Illness in Children Relief Fund Act (the Act), which created a non-lapsing, revolving fund earmarked "to provide assistance to children and their families whose medical expenses [related to a catastrophic illness] extend beyond the families' available resources." N.J.S.A. 26:2-148(e); N.J.S.A. 26:2-151.

Under the Act, a "catastrophic illness" is defined as "any illness or condition the medical expenses of which are not covered by any other State or federal program or any insurance contract and exceed 10% of the first \$100,000 of annual income of a family plus 15% of the excess income over \$100,000." N.J.S.A. 26:2-149(a). "The moneys necessary to establish and meet the purposes of the [Act] are generated by a one dollar annual surcharge per employee for all employers who are subject to the New Jersey Unemployment Compensation Law." Lewis, 336 N.J. Super. at 365-66 (citing N.J.S.A. 26:2-157).

The Act statutorily creates the Commission to effectuate its purpose. N.J.S.A. 26:2-151. The Commission is tasked with administering the fund by establishing procedures to apply for reimbursement, determining eligibility, calculating the reimbursement amount, and processing the fund awards. N.J.S.A. 26:2-154(a) to (c).

A family seeking reimbursement must apply each year, listing costs already incurred from the prior twelve-month time period. N.J.A.C. 10:155-1.4; N.J.A.C. 10:155-1.5(d); N.J.A.C. 10:155-1.13; N.J.A.C. 10:155-1.12(a)(2) (mandating the Commission must meet and determine eligibility). Even after the Commission deems a recipient "eligible, . . . disbursements on behalf of a child shall be limited by the monies available[,]" giving the Commission discretion on whether to approve the award requested. N.J.A.C. 10:155-1.3(b); N.J.A.C. 10:155-1.7 (establishing caps per child). Further, the award is subject to the rules and regulations adopted by the Commission. N.J.S.A. 26:2-154(i); N.J.S.A. 26:2-156.

N.J.A.C. 10:155-1.14 provides a non-exhaustive list of eligible health services which the Commission <u>may</u> fund. N.J.A.C. 10:155-1.14(a)(14) allows reimbursement for "[e]xperimental medical treatment/experimental drugs in connection with an FDA-approved clinical trial, which are provided by licensed health care providers." The regulation further notes applications for these treatments "may require additional review[.]" N.J.A.C. 10:155-1.14(a)(14).

As stated, HBOT has not been approved by the FDA as a treatment for cerebral palsy or Lyme disease. Susan's HBOT treatments were not part of a clinical trial. Because HBOT treatment is not on the non-exhaustive list of

eligible health services in N.J.A.C. 10:155-1.14, it was well within the Commission's discretion to deny the 2016 HBOT costs.

Plaintiffs contend that because the Commission approved reimbursement for HBOT costs in 2015, it was bound to approve them in later years. We disagree. The Commission has admitted it erred in approving reimbursement for Susan's 2015 HBOT treatment. As we have stated, the Commission was within its wide discretion to deem the costs ineligible in 2015. But it did not.

That error, however, did not obligate the Commission to reimburse the HBOT costs in future years. Nor were there any promises made by the Commission on which plaintiffs could rely for future reimbursement. The award letter sent by the Commission to plaintiffs in 2016 for the 2015 expenses stated that the award was for expenses incurred in that calendar year. Reimbursement was made for qualifying expenses from the prior year. There were no promises for reimbursement of any future costs. There were no misrepresentations. Moreover, plaintiffs were familiar with the process as demonstrated by their annual applications and they knew each application was assessed on its merits each year.

Because the Commission's decision was not arbitrary, capricious, or unreasonable, we affirm.

Affirmed.

I hereby certify that the foregoing is a true copy of the original on file in my office. N_1/N

CLERK OF THE APPELLATE DIVISION