

# RECORD IMPOUNDED

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SUPERIOR COURT OF NEW JERSEY  
APPELLATE DIVISION  
DOCKET NO. A-5603-18

A.O.,<sup>1</sup>

Appellant,

v.

CATASTROPHIC ILLNESS IN  
CHILDREN RELIEF FUND  
COMMISSION,

Respondent.

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Submitted February 1, 2021 – Decided February 25, 2021

Before Judges Currier and DeAlmeida.

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

A.O., appellant pro se.

Gurbir S. Grewal, Attorney General, attorney for  
respondent (Melissa H. Raksa, Assistant Attorney

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

General, of counsel; James A. McGhee, Deputy Attorney General, on the brief).

PER CURIAM

Plaintiff A.O. appeals from the July 9, 2019 final agency decision of defendant Catastrophic Illness in Children Relief Fund Commission (the Commission) denying reimbursement of his child's medical expenses for hyperbaric oxygen therapy (HBOT) incurred in 2016 and 2017. We affirm.

I.

A.O.'s child, P.O., suffers from a number of serious medical conditions related to Lyme disease. P.O.'s medical conditions qualify for expense reimbursement from the Catastrophic Illness in Children Relief Fund (Fund), provided his family meets certain financial requirements, and the expenses satisfy Commission regulations.

In 2016, A.O. applied to the Commission for reimbursement of \$33,296.59 in uncovered medical expenses incurred for P.O. in 2015, including expenses for HBOT. HBOT is not approved by the United States Food and Drug Administration (FDA) as a treatment for P.O.'s medical conditions or Lyme disease. The Commission determined A.O.'s family to be financially eligible for reimbursement and approved the application in its entirety.

In 2017, A.O. applied for reimbursement of \$24,310.77 in uncovered medical expenses incurred for P.O. in 2016, including expenses for HBOT. Although the Commission found the family to be financially eligible for relief, it determined that \$11,200 in HBOT expenses were ineligible for reimbursement because the FDA had not approved the therapy as a treatment for P.O.'s medical conditions. The Commission approved reimbursement of the remaining \$13,110.77 in expenses not associated with HBOT. The Commission denied A.O.'s internal appeal of its decision.

A.O. appealed the Commission's decision. On April 10, 2019, we remanded A.O.'s appeal, along with that of another parent who was denied reimbursement for his child's HBOT expenses, to permit the Commission to explain why it reimbursed A.O. for HBOT expenses incurred in 2015, but not in 2016. M.M. v. Catastrophic Illness in Children Relief Fund Comm'n, No. A-2298-17 (App. Div. Apr. 10, 2019).

At about the same time, A.O. submitted an application to the Commission for reimbursement of \$30,464.18 in HBOT expenses incurred for P.O. in 2017. The Commission denied that application. In a separate appeal from the denial of reimbursement of the 2017 expenses, we granted the Commission's motion

for a remand to permit it to explain why it reimbursed A.O. for HBOT expenses incurred in 2015, but not in 2017.

On July 9, 2019, the Commission issued a written decision addressing its denial of reimbursement of HBOT expenses incurred in both 2016 and 2017.

The Commission explained its decisions:

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-approved clinical trial (N.J.A.C. 10:155-1.14(a)(14)).<sup>2</sup> Moreover, such applications for experimental treatment or medication in connection with an FDA-approved clinical trial may require additional review by the Commission (Ibid.)

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.

In following these guidelines, the Commission has consistently not approved reimbursement for HBOT in cases where the child's diagnosis, such as Lyme disease, is not established by the FDA to benefit from

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<sup>2</sup> 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." Conducting Clinical Trials, U.S. Food and Drug Administration (last updated June 15, 2016).

HBOT. After careful review, the Commission acknowledges that the reimbursement of [P.O.'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.

Noting that each year's reimbursement application stands alone, the Commission concluded that no grounds existed to grant A.O.'s application for reimbursement of HBOT expenses incurred in 2016 and 2017.

This appeal followed. A.O. makes the following arguments.

#### POINT I

RESPONDENT'S EXPLANATION/DECISION THAT HBOT WAS INELIGIBLE DUE TO IT NOT BEING "FDA-APPROVED" MISINTERPRETED LAWS AND REGULATIONS THAT GOVERN FDA AND CATASTROPHIC ILLNESS IN CHILDREN RELIEF FUND AND THEREFORE WAS UNLAWFUL.

#### POINT II

RESPONDENT'S EXPLANATION THAT APPROVAL OF HBOT EXPENSES IN 2015 WAS IN ERROR IS NOT SUPPORTED BY EVIDENCE IN THIS CASE AND FOR THAT REASON ITS DECISION TO DENY HBOT EXPENSES IN 2016-2017 WAS UNFAIR AND ARBITRARY.

## II.

"Judicial review of agency determinations is limited." Allstars Auto Grp., Inc. v. N.J. Motor Vehicle Comm'n, 234 N.J. 150, 157 (2018). "An

administrative agency's final quasi-judicial decision will be sustained unless there is a clear showing that it is arbitrary, capricious, or unreasonable, or that it lacks fair support in the record." Ibid. (quoting Russo v. Bd. of Trs., Police & Firemen's Ret. Sys., 206 N.J. 14, 27 (2011)). In reviewing the agency's decision, we consider:

- (1) whether the agency's action violates express or implied legislative policies, that is, did the agency follow the law;
- (2) whether the record contains substantial evidence to support the findings on which the agency based its action; and
- (3) whether in applying the legislative policies to the facts, the agency clearly erred in reaching a conclusion that could not reasonably have been made on a showing of the relevant factors.

[Ibid. (quoting In re Stallworth, 208 N.J. 182, 194 (2011)).]

"A reviewing court 'must be mindful of, and deferential to, the agency's expertise and superior knowledge of a particular field.'" Id. at 158 (quoting Circus Liquors, Inc. v. Governing Body of Middletown Twp., 199 N.J. 1, 10 (2009)). "A reviewing court 'may not substitute its own judgment for the agency's, even though the court might have reached a different result.'" Stallworth, 208 N.J. at 194 (quoting In re Carter, 191 N.J. 474, 483 (2007)).

"Deference to an agency decision is particularly appropriate where interpretation of the [a]gency's own regulation is in issue." R.S. v. Div. of Med. Assistance & Health Servs., 434 N.J. Super. 250, 261 (App. Div. 2014) (quoting I.L. v. N.J. Dep't of Human Servs., Div. of Med. Assistance & Health Servs., 389 N.J. Super. 354, 364 (App. Div. 2006)). "However, a reviewing court is 'in no way bound by [an] agency's interpretation of a statute or its determination of a strictly legal issue.'" Allstars Auto Grp., 234 N.J. at 158 (alteration in original) (quoting Dep't of Children & Families, Div. of Youth & Family Servs. v. T.B., 207 N.J. 294, 302 (2011)).

The Fund is a State-run, non-lapsing fund created to provide financial assistance to any eligible family with a child who has a qualifying illness which could have a "potentially devastating financial consequence" for the family. N.J.S.A. 26:2-148(a). A catastrophic illness eligible for reimbursement under the Fund is "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" certain percentages of the family's income. N.J.S.A. 26:2-149(a). Those eligible for reimbursement include a child's "parent . . . who is legally responsible for the child's medical expenses." N.J.S.A. 26:2-149(d).

N.J.S.A. 26:2-154(b) authorizes the Commission to "[e]stablish procedures for . . . determining the eligibility for the payment or reimbursement of medical expenses for each child . . . ." Reimbursements for medical expenses are "subject to the rules and regulations established by the [C]ommission . . . ."

N.J.S.A. 26:2-156. According to N.J.A.C. 10:155-1.2, expenses eligible for reimbursement are those

not covered by any other source, including, but not limited to, other State or Federal agency programs, insurance contracts, trusts, proceeds from fundraising, or settlements . . . .

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 may 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).

HBOT has not been approved by the FDA as a treatment for Lyme disease. P.O.'s treatments were not part of an FDA-approved 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 within the Commission's discretion to deny reimbursement of HBOT expenses incurred in 2016 and 2017.

A.O. contends that because the Commission approved reimbursement for HBOT expenses incurred in 2015, it was bound to approve those incurred in later years. We disagree. The Commission has admitted it erred in approving reimbursement for P.O.'s 2015 HBOT treatment. That error, however, did not obligate the Commission to reimburse HBOT costs in future years. The Commission is not required by any legal principle to repeat its mistake.

Nor were there any promises made by the Commission on which A.O. could reasonably have relied for reimbursement of HBOT expenses in future

years. The law clearly provides that the Commission determines whether to reimburse medical expenses on a yearly basis and may deny otherwise qualified expenses for budgetary purposes. It would not be reasonable for any applicant to assume that the Commission will reimburse any expenses in a future year because the same category of expenses was approved in a prior year.

We have carefully considered A.O.'s arguments to the contrary and find no basis in them to reverse the Commission's decision. While the FDA may permit off-label uses of therapies and physicians may treat patients with HBOT, those facts are not determinative here. The Commission has the statutory and regulatory authority to decide which medical treatments will be eligible for reimbursement from the Fund. The Commission acted within the bounds of that authority when it determined that its limited recourses will be expended only on FDA-approved clinical trials of experimental treatments. While we recognize the difficult position A.O. is in, we cannot substitute our judgment for that of the Commission, which has expertise in this area, in the absence of an arbitrary, capricious, or factually unsupported exercise of the Commission's authority.

Affirmed.

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



CLERK OF THE APPELLATE DIVISION