STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION
OFFICE OF FAIR HEARINGS

FILED
Sep 30, 2024, 3:49 pm
OFFICE OF FAIR HEARINGS

[redacted],

PETITIONER, **AHCA Case No.: 24-FH1462**

vs.

AGENCY FOR HEALTH CARE ADMINISTRATION,

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing on June 27, 2024, at 1:00 p.m. Eastern Standard Time ("EST").

APPEARANCES

For the Petitioner: [redacted]
Petitioner's Authorized Representative

For the Respondent: Marielisa Amador
Medical Health Care Program Analyst
Agency for Health Care Administration

STATEMENT OF ISSUE

The issue is whether Respondent proved by a preponderance of the evidence that Respondent's denial of medical equipment (AIRVO2 device) was incorrect.

PRELIMINARY STATEMENT

All parties and witnesses appeared telephonically. [redacted] ("[redacted]"), Nurse Practitioner and Petitioner's Authorized Representative, appeared for the hearing and offered

testimony on behalf of Petitioner. [redacted] ("[redacted]"), Petitioner's pediatric pulmonologist, provided testimony for Petitioner.

Marielisa Amador, Medical Health Care Program Analyst for the Agency for Health Care Administration ("Agency" or "AHCA") represented Respondent. Dr. Rakesh Mittal ("Dr. Mittal"), physician consultant for eQHealth Solutions of Florida ("eQHealth") appeared as a witness for Respondent.

Prior to the hearing, Respondent sent to the Office of Fair Hearings and Petitioner a four hundred and eighty (480)-page evidence packet. The packet appears in the Office of Fair Hearings' case management system as "[redacted] FH 06.27.2024 1-71.pdf," "[redacted] FH 06.27.2024 72-98.pdf," "[redacted] FH 06.27.2024 99-124.pdf," "[redacted] FH 06.27.2024 125-149.pdf," "[redacted] FH 06.27.2024 150-172.pdf," "[redacted] FH 06.27.2024 173-197.pdf," "[redacted] FH 06.27.2024 198-214.pdf," "[redacted] FH 06.27.2024 215-233.pdf," "[redacted] FH 06.27.2024 234-331.pdf," "[redacted] FH 06.27.2024 332-366.pdf," and "[redacted] FH 06.27.2024 367-480.pdf." Absent an objection from Petitioner, the undersigned admitted Respondent's evidence packet into evidence as Respondent's Composite Exhibit 1.

Prior to the hearing, Respondent sent to the Office of Fair Hearings and Petitioner a seventy-six (76)-page evidence packet. The packet appears in the Office of Fair Hearings' case management system as "24-FH1462 AHCA Evidence (Pages 1-76 of 76).pdf." Absent an objection from Petitioner, the undersigned admitted Respondent's evidence packet into evidence as Respondent's Composite Exhibit 2.

FINDINGS OF FACT

1. Petitioner receives Medicaid services on a fee-for-service basis from the Agency. *See* Respondent's Composite Exhibit 1 at page 16. eQHealth is a Quality Improvement Organization contracted by the Agency to review prior authorization requests for services. *See* Respondent's Composite Exhibit 2 at page 2.

2. As of the date of the hearing, Petitioner is a [redacted] with diagnoses that include [redacted] *See* Respondent's Composite Exhibit 1 at page 16.

3. Petitioner requested a code E1399 – AIRVO2 device ("AIRVO system"). *Id*. at 17. Petitioner's physician, [redacted], provided a letter of medical necessity dated April 12, 2024, which states in pertinent part:

[redacted]

Id. at 333.

4. On April 11, 2024, Respondent issued a Notice of Outcome ("NOO") denying Petitioner's request for Code E1399 Specialized medical Equipment/Supplies or AIRVO system. *Id.* at 22. The NOO stated the reason for Respondent's determination as follows:

> The request for services is denied in whole or in part because they are not medically necessary as defined in Rule 59G-1.010, Florida Administrative Code. Specifically, The requested services are not medically necessary under the following standard (s):
>
> Individualized, specific, consistent with symptoms or diagnosis of illness or injury and not be in excess of the patient's needs.
>
> . . .
>
> PR Principal Reason – Denial:
> The clinical information provided does not support Medicaid's medical necessity definition.
>
> Clinical Rationale for Decision: [redacted]

Id. at 21 - 22.

5. On April 8, 2024, Petitioner requested reconsideration. *Id*. at 33. On April 17, 2024, respondent issued a Notice of Reconsideration Determination ("NRD") upholding its decision. *Id*. at 33-34. The NRD states, in pertinent part:

> PR Recon Determination: [redacted].

Id. at 34.

6. On April 30, 2024, Petitioner requested a Fair Hearing due to the denial of the Airvo system. The undersigned scheduled the Fair Hearing for June 27, 2024 at 1:00 p.m. EST, and all parties were duly notified.

7. [redacted] testified that [redacted] can negatively affect Petitioner's behavior and learning. [redacted] also asserted that Petitioner [redacted]

8. Dr. Mittal testified that Petitioner's chart does not include a diagnoses of [redacted] Dr. Mittal established that Petitioner's provider submitted a letter of medical necessity. *Id*. at 243 – 244. [redacted] also submitted office notes for a follow-up office visits related to [redacted]. *Id*. at

251, 256. Petitioner's height and weight were reported in the notes but no vital signs were recorded and no physical exam was conducted. *Id*. at 253, 258. Dr. Mittal asserted that notes for a total of [redacted] visits to the pulmonologist were submitted and Petitioner has never had a physical exam or vitals taken such as blood pressure, heart rate, etc. *Id*. at 261, 263, 291, 292, 296, 297, 300 - 302. Dr. Mittal asserted that, although [redacted] did not physically examine or collect vitals for Petitioner, [redacted] ordered a [redacted] *Id*. at 326. Dr. Mittal further argued that the research studies provided by [redacted] in support of the use of AIRVO system are limited studies, involving a few patients, that are not peer reviewed. Dr. Mittal concluded that the AIRVO system is not indicated for Petitioner due to the need for close monitoring by trained professionals. Dr. Mittal testified that the AIRVO system is a dangerous machine, used in a hospital setting, and monitored by skilled and highly trained professionals. Dr. Mittal pointed out that [redacted] is the only physician [redacted] is aware of who would prescribe and AIRVO machine on an outpatient basis. The machine is FDA approved for use in hospital ICU settings by trained pediatric and ICU nurses.

CONCLUSIONS OF LAW

9. The Agency's Office of Fair Hearings has jurisdiction over the subject matter of this proceeding and the parties pursuant to section 409.285(2), Florida Statutes. This order is the final administrative decision of AHCA under section 409.285(2)(a).

10. This hearing was held as a *de novo* proceeding pursuant to Florida Administrative Code ("Fla. Admin. Code R.") 59G-1.100(17)(b).

11. The burden of proof in this proceeding is governed by Fla. Admin. Code R. 59G-1.100(17)(g), which provides as follows:

> The burden of proof is on the party asserting the affirmative of an issue, except as otherwise required by statute. The burden of proof is on the Agency or plan, whichever is applicable, when the issue presented is the suspension, reduction, or termination of a previously authorized service. The burden of proof is on the recipient or enrollee, when the issue presented is the denial or a limited authorization of a service. The party with the burden of proof shall establish its position to the satisfaction of the Hearing Officer by a preponderance of the evidence.

12. Because Petitioner is requesting a new service, Fla. Admin. Code R. 59G-1.100(17)(g) assigns the burden of proof to Petitioner. The standard of proof in an administrative hearing is a preponderance of the evidence. The preponderance of the evidence standard requires proof by "the greater weight of the evidence" (Black's Law Dictionary at 1201, 7th Ed.).

13. The Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage Policy: Respiratory (December 2023) ("Respiratory DME Policy"), incorporated by reference in Fla. Admin. Code R. 59G-4.070, governs requested for Respiratory DME services available under Florida Medicaid. The Respiratory DME Policy provides the following:

> **1.4 Definitions**
> . . .
> **1.4.5 Medically Necessary/Medical Necessity**
> As defined in Rule 59G-1.010, F.A.C.
> . . .
> **4.0 Coverage Information**
> **4.1 General Criteria**
> Florida Medicaid covers services that meet all the following:
> - Are determined medically necessary
> - Do not duplicate another service
> - Meet the criteria as specified in this policy
>
> **4.2 Specific Criteria**
> Florida Medicaid covers respiratory DME services in accordance with the American Medical Association's Current Procedural Terminology (CPT) and

Healthcare Common Procedure Coding System (HCPCS), and the applicable Florida Medicaid fee schedule(s), or as specified in this policy.

Florida Medicaid covers custom and specialized equipment when a less costly alternative is not available to fulfill the recipient's need.

Florida Medicaid-covered DME must include a manufacturer's or one-year warranty, whichever is greater.

. . .

4.2.2 Ventilators and Respiratory-Assist Devices

4.2.2.1 Continuous Positive Airway Pressure Devices (CPAP) and Bi-Level Positive Airway Pressure Devices (BIPAP)

Florida Medicaid covers CPAP and BIPAP devices for recipients who have completed a sleep study, within 30 days of the prescription of the device.

- A recipient must first have unsuccessful results from use of a CPAP before becoming eligible to receive a BIPAP device.
- Heated or non-heated humidifiers prescribed for use with the covered CPAP or BIPAP device are not included in the device's monthly rental fee and may be reimbursed separately if the humidifier is not integral to the CPAP or BIPAP device itself.

4.2.2.2 Ventilators

Florida Medicaid covers the following types of ventilators that include back-up ventilators:

- Alternating positive airway pressure
  - Reimbursement includes all connectors, pressure measuring and alarm devices, breathing circuits, in-line thermometers, water traps, adapters, and training by licensed professionals.
- Intermittent positive pressure breathing machines (IPPB)

4.2.2.3 Apnea Monitors

Florida Medicaid covers apnea monitors with or without recording features for recipients under the age of 21 years.

The provider must ensure that the following equipment is available at the time of delivery and set-up:

- Battery pack, case, and emergency battery
- Two sets of electrodes
  - If disposable electrodes are necessary, at least ninety per month
- Two sets of modified safety lead wires.
- Two electrode belts
- Operator's manual
  - If necessary, a copy of the infant monitoring handbook.
- Remote alarm, if prescribed

4.2.2.4 Nebulizers

Florida Medicaid covers nebulizers that include administration kits that include the following:

- Hand-held mouthpiece

- Lid, jar, and baffles
- Tubing
- T-piece

Providers may store nebulizers at physicians' offices for distribution, in accordance with section 409.912, F.S.

4.2.3 Respiratory Equipment

Florida Medicaid covers the following respiratory equipment:

- Compressors
  - Medicaid covers an air powered source compressor when it is:
    - Used to support medical equipment that is not self-contained
    - Used with a nebulizer that provides at least 50 pounds per square inch (psi)
- Peak flow meters
  - Providers must train the recipient and caregiver in the proper use of the device at time of pick-up or delivery.
- Pulse oximeters
  - At a minimum, a quarterly visit must be made by a qualified technician to ensure the device is functioning properly and being used appropriately
- Resuscitator bags for recipient-owned ventilators
- Tracheostomy supplies

. . .

4.3 Early and Periodic Screening, Diagnosis, and Treatment

As required by federal law, Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the SSA, codified in Title 42 of the United States Code 1396d(a). As such, services for recipients under the age of 21 years exceeding the coverage described within this policy or the associated fee schedule may be approved, if medically necessary. For more information, please refer to Florida Medicaid's Authorization Requirements Policy.

. . .

7.0 Authorization

. . .

7.2 Specific Criteria

Providers must obtain authorization from the quality improvement organization (QIO) as
follows:

- For miscellaneous procedure codes
- When indicated on the applicable Florida Medicaid fee schedule(s)

. . .

Code 1399 . . . Limit: Medical Necessity

Respondent's Composite Exhibit 2 at pages 49 - 76.

14. States must provide Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") services to Medicaid-eligible children under age 21 when requested under the Medicaid state plan. See 42 U.S.C. § 1396a(a)(43); 42 U.S.C. § 1396d(a)(4). According to 42 U.S.C. § 1396d(r)(5), EPSDT services mean, in relevant part, the following items and services:

> Such other necessary health care, diagnostic services, treatment, and other measures described in subsection (a) of this section to correct or ameliorate defects and physical and mental illness and conditions discovered by the screen services, whether or not such services are covered under the state plan.

15. Petitioner is under age 21, and therefore eligible for EPSDT services. However, a state may place medical necessity limitations on EPSDT services. See 42 C.F.R. §§ 440.230(a), (b), (d). Section 409.905(2), Florida Statutes, limits EPSDT services with a medical necessity standard:

> The [Agency] shall pay for early and periodic screening and diagnosis of a recipient under age 21 to ascertain physical and mental problems and conditions and all services determined by the agency to be medically necessary for the treatment, correction, or amelioration of these problems and conditions, including personal care, private duty nursing, durable medical equipment, physical therapy, occupational therapy, speech therapy, respiratory therapy, and immunizations.

16. The Florida Medicaid Definitions Policy (August 2017) ("Definitions Policy"), which is incorporated by reference in Fla. Admin. Code R. 59G-1.010, defines "medically necessary" or "medical necessity" as follows:

> **2.83 Medically Necessary or Medical Necessity**
> The medical or allied care, goods, or services furnished or ordered must meet the following conditions:
> - Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain
> - Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs

- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational
- Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide
- Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider

The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

17. In the instant case, Petitioner requested a AIRVO system. *See* supra ¶ 3. As established on the record by the evidence and testimony, Respondent denied Petitioner's request because the documentation submitted in support of Petitioner's request failed to establish that the requested AIRVO system is medically necessary. *See* supra ¶ 4.

18. The Respiratory DME Policy provides that Florida Medicaid reimburses for services that do not duplicate another provider's service and are determined to be medically necessary. *See supra* ¶ 13. Pursuant to section 2.83 of the Definitions Policy, the five (5) conditions of medical necessity must be met in order for "medical or allied care, goods, or services furnished or ordered" to be determined medically necessary. *See* supra ¶ 16. Accordingly, all five (5) of the conditions must be met in order for Respondent to approve requested DME services.

19. The evidence presented in this case reflects that Respondent correctly denied Petitioner's request for the AIRVO system. Specifically, Petitioner's request for the device failed to meet the second criteria of medical necessity, which mandates that "[t]he medical or allied care, goods, or services furnished or ordered must . . . [b]e individualized, specific, and consistent with symptoms

or confirmed diagnosis of the illness under treatment, and not in excess of the patient's needs." *See* supra ¶ 13.

20. Dr. Mittal testified credibly and persuasively that outpatient use of the AIRVO system carries with it a heightened risk of serious injury and death. *See* supra ¶ 8. Dr. Mittal established that the FDA approved the AIRVO system for hospital use by highly trained medical professionals. *See* supra ¶ 8. Thus, use of the AIRVO system on an outpatient basis, as prescribed by [redacted], is not indicated for Petitioner, and is not "individualized and specific to Petitioner's needs," because it would not be closely monitored by highly trained professionals. *See* supra ¶ 8. In this case, the testimony and documentation provided by Petitioner lack credibility. As Dr. Mittal testified, [redacted] is the only physician [redacted] is aware of in Florida who has prescribed an AIRVO system for use on an outpatient basis. *See* supra ¶ 8. Further, although [redacted] testified that the AIRVO system would help with Petitioner's [redacted] these diagnoses were not found in Petitioner's chart and no cardiology notes were provided to support the use of an AIRVO system on an outpatient basis to treat such diagnoses. *See* supra ¶ 8. The physician notes that were provided in this case showed that Petitioner visited [redacted] times without a physical exam or vitals taken. *See* supra ¶ 8. [redacted] proceeded to order a sleep study that was conducted at [redacted], which has the same address as [redacted]'s office, which calls into question the credibility of the study. Based on the aforementioned facts, Petitioner's request does not meet medical necessity requirements, as the requested outpatient AIRVO system was not shown to be "individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness under treatment."

21. In this case, Petitioner's physician recommended a AIRVO system for use on an outpatient basis. *See* supra ¶ 3. However, Section 2.83 of the Definitions Policy mandates that "[t]he fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service." *See* supra ¶ 16.

22. In light of the both parties' testimony, Respondent's Composite Exhibit 1, Respondent's Composite Exhibit 2, the Respiratory DME Policy, and the Definitions Policy, the undersigned Hearing Officer finds that Petitioner did not prove by a preponderance of the evidence that Respondent's denial of the requested AIRVO system was incorrect.

DECISION

Respondent's denial of Petitioner's request for medical equipment (AIRVO system) is **AFFIRMED**. Petitioner's appeal based on Respondent's denial in this matter is **DENIED.**

DONE AND ORDERED this 30th day of September 2024, in Tallahassee, Leon County, Florida.

Digitally signed by Laura Gallagher
Reason: 24-FH1462
Date: 2024.09.30 07:45:40 -04'00'

LAURA GALLAGHER, Hearing Officer
Agency for Health Care Administration
Office of Fair Hearings
2727 Mahan Drive, Mail Stop # 11
Tallahassee, FL 32308-5407

NOTICE OF A RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW, WHICH SHALL BE INSTITUTED BY FILING THE ORIGINAL NOTICE OF APPEAL WITH THE

AGENCY CLERK OF AHCA, AND A COPY, ALONG WITH THE FILING FEE PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE AGENCY MAINTAINS ITS HEADQUARTERS OR WHERE A PARTY RESIDES. REVIEW PROCEEDINGS SHALL BE CONDUCTED IN ACCORDANCE WITH THE FLORIDA APPELLATE RULES. THE NOTICE OF APPEAL MUST BE FILED WITHIN 30 DAYS OF THE RENDITION OF THE ORDER TO BE REVIEWED.

COPIES FURNISHED TO:

[redacted]

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