STATE OF FLORIDA
DEPARTMENT OF CHILDREN AND FAMILIES
OFFICE OF APPEAL HEARINGS



[redacted]

APPEAL NO. 15F-07527

PETITIONER,

vs.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 05 Citrus
UNIT: AHCA

RESPONDENT.
_____/

## FINAL ORDER

Pursuant to notice and agreement, Hearing Officer Patricia Antonucci convened an administrative hearing in the above-referenced matter on three, separate occasions: October 20, 2015 at approximately 1:00 p.m., October 27, 2015 at approximately 9:00 a.m., and November 5, 2015 at approximately 9:00 a.m. All parties and witnesses appeared via teleconference.

## APPEARANCES

For the Petitioner: [redacted] Petitioner's mother

For the Respondent: Selwyn Gossett, Medical/Health Care Program Analyst, Agency for Health Care Administration

## STATEMENT OF ISSUE

At issue is a May 4, 2015 decision by Respondent, the Agency for Health Care Administration (AHCA or "the Agency"), through its contracted health plan, United Healthcare Community Plan (United), to deny Petitioner's request for the prescription

medication [redacted]. Petitioner bears the burden of providing, by a preponderance of the evidence, that Respondent's denial was improper.

## PRELIMINARY STATEMENT

The Agency for Health Care Administration is responsible for administering Florida's Medicaid Program. Following transition to a managed care system, AHCA now oversees provision of services through designated managed care organizations (MCOs)/Health Maintenance Organizations (HMOs). United is the MCO to which Petitioner belongs.

Prior to the action at issue, United authorized Petitioner to receive [redacted] for a one-year certification period, ending March 10, 2015. At hearing on November 5, 2015, United incorrectly testified to the end of this certification as March 6, 2015. Although testimony varied between hearing on October 20, 2015 and hearing on November 5, 2015, it appears that Petitioner's former prescribing physician (or a staff member from his practice) attempted to request re-authorization on or about March 6, 2015.

Per United, this request was denied, with notification sent to the physician and to Petitioner on or about March 7, 2015. This notice is not a part of the record, and Petitioner's mother does not recall receiving same. However, at hearing on October 20, 2015, Petitioner's mother clarified that Petitioner's former physician left his practice (All Children's Medical), and while Petitioner was transitioning between physicians, United encouraged her to contact another doctor at All Children's medical to file an updated request for [redacted] Petitioner was informed that this request to "bridge the gap" in coverage was received, but denied; however, because Petitioner had obtained an

appointment with a new treating physician, she decided to await that appointment and obtain a new [redacted] prescription from the new physician.

The record is unclear with regard to this alleged March denial, which is *not* the denial that forms the basis of Petitioner's instant appeal. As such, the undersigned makes no ruling with regard to any denial implemented on or about March 7, 2015. As a procedural matter, if Petitioner was not notified of his right to appeal a March denial, the undersigned notes that the time for her to do so may not have started to toll. Should Petitioner wish to pursue this matter, and/or to request review regarding potential/temporary reinstatement pending outcome of that appeal, Petitioner may do so by filing a separate request with the Office of Appeal Hearings. Said request would be reviewed under the same rules and regulations that govern the instant Final Order.

Multiple Hearings

This matter initially convened for hearing on October 20, 2015. Petitioner was represented by his mother, who presented two additional witnesses: [redacted], Petitioner's current prescribing physician, and [redacted] Case Manager with the Patient Advocate Foundation. Respondent was represented by Selwyn Gossett, AHCA Medical/Health Care Program Analyst, who presented the following witnesses from United: Susan Frishman, Senior Compliance Analyst; Holly Moreau, Pharmacy Account Manager; Charity Willis, Pharm.D, Clinical Pharmacist; and Miquel Fernandez, D.O., Chief Medical Officer.

Following substantial testimony, it was determined that after its initial denial, United also denied a request for a peer-to-peer conference between Petitioner's prescribing physician and a medical director with United. The parties agreed to

reschedule hearing/set a telephonic status conference for the following week to allow for facilitation of a peer-to-peer, in the event that same would resolve the issue.

When this matter reconvened, as scheduled, on October 29, 2015, [redacted] stated that she had completed a peer-to-peer with Dr. Fernandez, but that the parties did not reach a resolution. As the parties could not find a mutually agreeable date and time during which all witnesses could reconvene, it was agreed that [redacted] would provide testimony and be cross-examined by Respondent during the October 29, 2015 hearing, with the rest of the witnesses reconvening on November 5, 2015.

On November 5, 2015, all witnesses other than [redacted] appeared as scheduled, with the exception of Holly Moreau, who was not present on the conference line. Because Dr. Fernandez had to leave the proceeding early for a "heart stop," testimony was taken piece-meal to accommodate witness availability. Respondent's Exhibits 1 through 5, inclusive, and Petitioner's Exhibits 1 through 7, inclusive, were accepted into evidence.

## FINDINGS OF FACT

Based upon the oral and documentary evidence presented at the final hearing and on the entire proceeding, the following Findings of Fact are made:

1. Petitioner is an 11-year-old male, born [redacted] He has a confirmed diagnosis of [redacted] (history of [redacted] with [redacted]

2. Prior to the action at issue, Petitioner had been taking [redacted] on and off since approximately 2010. He was authorized to receive it in other states, and most recently, was authorized by United to receive [redacted] in Florida.

3. United explained that along with the request for [redacted] which was prior authorized for a one-year period, Petitioner's treating physician was required to submit updated prescriptions for the medication on a recurring basis.

4. At some point near the beginning of 2015, Petitioner's treating physician, Dr. Jeffrey Ewing, left his practice at All Children's Medical Hospital. While Petitioner attempted to find a new treating physician, Petitioner's prescription expired. As a result, while Petitioner twice attempted to refill the [redacted] (once around April 28, 2015 and once around May 1 of 2015), the last successful fill was dispensed on or about January 19, 2015. Petitioner has been off of [redacted] since finishing that bottle.

5. On April 21, 2015, Petitioner had his first appointment with his new/current treating physician, [redacted] Following that visit, on or about April 27, 2015, [redacted] submitted to United a request for [redacted]

6. Via Notice of Case Action (NOCA) dated May 4, 2015, United notified Petitioner's provider of its decision, noting, in pertinent part:

> UnitedHealthcare Community Plan has reviewed the request to approve the prescription for [redacted]. After a review: The request is denied based on the reason below:
>
> The requested medication is a drug used for people who are at least 16 years old. The facts given to us show the patient is less than 16 years old. The requested medicine is given for certain sleep disorders. The facts given to us do not show that you have any of these conditions. The facts given to us do not show that you have improved while taking this medication. This decision was made per the United Healthcare Florida Community Plan [redacted] medication guideline.
>
> The requested medication is provided for patients 6 years of age and older with a diagnosis of [redacted] excessive daytime sleepiness, and/or disrupted nocturnal sleep. The information reviewed does not show the patient is 6 years of age or

> older. The requested medication is provided for patients 16 years or age and older with a diagnosis of [redacted] excessive daytime sleepiness, and/or disrupted nocturnal sleep when prescribed by a sleep specialist or neurologist. The information reviewed does not show the patient is being treated for one of the above diagnosis with documentation Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results which was not submitted. The requested medication is continued if the patient has demonstrated a response to [redacted] as evidence by the EpworthSleepiness Scale (ESS) and/or the Maintenance of Wakefulness Test (MWT). The information reviewed does not show the patient has demonstrated a response to [redacted] as evidence by the EpworthSleepiness Scale (ESS) and/or the Maintenance Wakefulness Test (MWT). This decision was made per the United Healthcare Florida Community Plan [redacted] medication guideline.
>
> **The decision will take effect on: 05/04/2015.**
> (emphasis original)

The NOCA also noted that if the requesting physician wished to discuss denial with a medical director, he/she could do so within 7 working days, and if Petitioner wished to a file an appeal with United, said appeal must be filed within 30 calendar days.

7. Per [redacted] she attempted to contact United multiple times for a peer-to-peer review, but because she finally got through 10 days after the NOCA, United declined the peer-to-peer.

8. On June 19, 2015, the Patient Advocate Foundation (PAF), on behalf of Petitioner, filed with United a request to appeal the denial. PAF's cover letter points to the conflicting language of the NOCA, and requests United's review of documentation submitted along with the appeal, including Petitioner's sleep study reports, and copies of medical journal articles discussing the use of [redacted] in treatment of children.

9. United acknowledged receipt of this request via letter dated June 22, 2015, which stated they were reviewing the appeal. However, via letter dated June 29, 2015, United notified Petitioner:

> An initial letter was sent to you regarding your child on May 4, 2015. This letter said you need to file an appeal within thirty days from the date of the letter. We received this appeal June 19, 2015. This was longer than the time allowed. This is why we cannot review your child's appeal. Please contact your child's doctor if your child still needs this service. The doctor will need to send in a new request for the service.

10. After additional correspondence with United and attempts by [redacted] to submit additional prescriptions, United continued to uphold its denial.

11. On or about August 27, 2015, Petitioner filed an appeal with the Office of Appeal Hearings to challenge the denial of [redacted]

12. At hearing, [redacted] explained that although she has never treated Petitioner while he was taking [redacted] she has reviewed his clinical reports and medical history. Petitioner has tried multiple stimulant therapies, but when taking [redacted] in 2012, he was noted to be more functional, alert, energetic, and focused during the day. Per [redacted] review, the dosage of [redacted] had to be titrated but was eventually stabilized for about a year. When Petitioner stopped [redacted] and reverted back to high dose stimulates during the day, he began to experience side effects and to feel down, with increased hallucinations and vivid dreaming.

13. [redacted] has treated other pediatric patients with [redacted] when stimulants do not work, starting them at a low dose and titrating up to effect using the FDA adult dosing guidelines, and testing the patients on that dosage. She believes [redacted] would assist Petitioner by providing stage 3 sleep, helping to avoid seizure-type symptoms of

[redacted] during the day. It is [redacted] opinion that the stimulants are not optimizing Petitioner's treatment, and that [redacted] is currently the best medicine to treat him because of its good safety profile and past effectiveness when used by Petitioner. Without [redacted] she feels Petitioner's independence is limited as he must be closely monitored to avoid falls due to [redacted]

14. Under [redacted] Petitioner has been taking 36 mg of extended release [redacted] with booster doses of 5 mg (10mg pill cut in half) immediate release during the day, as needed. Petitioner's mother reports that she noticed some difference when Petitioner started this medication, but did not increase the booster dose to the full, 10 mg because she was expecting to restart [redacted] Petitioner also tried [redacted] to alleviate hallucinations, but did not respond well, so this was discontinued. [redacted] also prescribed [redacted] to treat nighttime symptoms; however, Petitioner's mother did not feel this worked, thought it might be increasing hallucinations, and did not refill the prescription after the first month's supply ran out. She now gives Petitioner [redacted] at night, and the [redacted] during the day.

15. Petitioner's mother is concerned that after years of testing, treatment changes, and finally finding something that works, Petitioner will now have to start over. She notes that Petitioner has started to hide knives under his bed to protect his family because he hallucinates that people are after them. He does not sleep during the night, is not doing well at school, and frequently naps during the day. His schedule and actions have upset the dynamic of the whole family. She does not understand why

[redacted] was approved before, but is now denied, and believes denial may be a cost-saving measure since [redacted] is an expensive medication.

16. United was unable to present a consistent timeline of events, and provided conflicting testimony regarding its denial decision. Dr. Fernandez clearly stated that, despite the generic language used in United's NOCA, he did not doubt either that Petitioner has an accurate diagnosis of [redacted] or that Petitioner did better while taking [redacted] however, it was Dr. Fernandez's opinion that United did not have sufficient information to approve [redacted] for an 11-year-old, in contravention to FDA protocol. United could not explain why it had authorized the medication in the past, but Dr. Fernandez did not want to "open a Pandora's Box" by making an exception and authorizing the medication, now. When asked how United determines whether to make an exception to FDA guidelines, Dr. Fernandez stated they review what they have, then go through the appeal process and leave the decision to the hearing officer. He also noted that [redacted] mentioned submitting copies of the international studies upon which she relies, but that he had not received same. Dr. Fernandez stated that if these studies and/or additional literature on the safety and efficacy of off-label use were submitted, he would review them to determine whether an exception is appropriate in Petitioner's case.[1]

17. Charity Willis, Pharm.D., testified that in her review, United's decision to deny was partly because Petitioner did not demonstrate an effective response to [redacted] While sleep studies from 2011 and 2013 were submitted, Dr. Willis felt that these were

[1] As Petitioner did not wish to further delay disposition of this appeal, United agreed to review any subsequently submitted literature as part of a new request, and issue a NOCA to Petitioner regarding its decisions related, thereto.

both too old to be reliable, and also noted that the dosages assessed during the studies might be different than what is currently requested.

18. Dr. Willis also testified that Petitioner is not taking the [redacted] at maximum dosages, may not be taking it at the proper time each day, and is only utilizing half of the 10mg booster dose. In conjunction with discontinuing the nighttime medication ([redacted] after one month, and not attempting higher dosages of [redacted] it was Dr. Willis' opinion that Petitioner has not attempted adjusting his current medications to maximum effectiveness. Dr. Willis feels that such adjustments should be attempted and ruled out before instituting a "very serious" medication, such as [redacted] which does not have FDA approval for children under 16 (Dr. Willis also noted that the reference to a minimum 6 years of age within the NOCA is a typo that has been brought to the author's attention).

## CONCLUSIONS OF LAW

19. The Department of Children and Families Office of Appeal Hearings has jurisdiction over the subject matter of this proceeding and the parties, pursuant to Section 120.80, Florida Statutes. The Office of Appeal Hearings provided the parties with adequate notice of the administrative hearing.

20. Florida Medicaid State Plan is authorized by Chapter 409, Florida Statutes, and Chapter 59G, Florida Administrative Code. The program is administered by the Agency.

21. This hearing was held as a *de novo* proceeding, pursuant to Florida Administrative Code R. 65-2.056.

22. As this matter involves a request for a prescription approval, the burden of proof

was assigned to the Petitioner, pursuant to Florida Administrative Code R. 65-2.060(1).

23. The standard of proof in an administrative hearing is preponderance of the evidence, as provided by Florida Administrative Code R. 65-2.060(1).

24. Section 409.912, Florida Statutes provides that AHCA shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care.

25. The Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook (July 2014) ("the Handbook") is promulgated into law by Florida Administrative Code R. 59G-4.250. Page 1-4 of the Handbook lists requirements for Health Maintenance Organizations (HMOs), as follows:

> Prescribed Drug Services
> HMO prescribed drug services are defined the same as for the Medicaid fee-for-service program and include all legend drug products covered by fee-for-service Medicaid as defined in Chapter 2 of this handbook, Legend Drugs. Medicaid's contract with HMOs states that Medicaid HMOs may use prior authorization and/or step therapy to encourage compliance with the preferred drug list.
>
> A Medicaid HMO is required to cover any product that is required to be covered under the fee-for-service Medicaid program as specified in section 1927 of Title XIX of the Social Security Act. If a product meets the definition of a covered service under that section there must be a provision to make it available through the HMO and through fee-for-service.

26. Page 2-2 of the Handbook notes:

> In order to be reimbursed by Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with Section 1927(k)(6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency. Notwithstanding this rule, the Agency may

> exclude or otherwise restrict coverage of a drug in accordance with Section 1927 of the Social Security Act.

27. At page 2-11, the Medicaid Handbook explains that:

> In order to be reimbursed by Medicaid, providers must obtain prior authorization before dispensing certain drugs.
>
> Prior authorization from Medicaid is required prior to reimbursement in the following situations:
> 1. The drug is not on the Preferred Drug List.
> 2. Clinical Prior Authorization is required for specific drugs a) For an indication not approved in labeling; b) To comply with certain clinical guidelines; or c) If the product has the potential for overuse, misuse, or abuse. The Agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. A current list of drugs for which clinical prior authorization is required, and clinical prior authorization forms, may be found on the webpage at www.ahca.myflorida.com/Medicaid/Prescribed_Drug .[2]
> 3. If a prescriber hand writes "brand medically necessary" on the face of a prescription when a generic is available with a state or federal pricing limit.

28. As [redacted] is not on the preferred drug list, it requires prior authorization, and must also meet criteria listed on page 41 of AHCA's Summary of Drug Limitations (updated November 30, 2015, see link in footnote 2, below), which notes:

> [redacted] Solution Minimum age = 16

29. Because Petitioner is only 11-years of age, he does not meet this criteria. As such, the medication cannot be considered medically necessary, per Fla. Admin. Code R. 59G-1.010, which defines medical necessity, as follows:

> "Medically necessary" or "medical necessity" means that the medical or allied care, goods, or services furnished or ordered must:

[2] As the cited link is not functional, for the parties' convenience, a better direct link for preferred drug list and prior authorization information is: http://ahca.myflorida.com/medicaid/Prescribed_Drug/preferred_drug.shtml (see "Preferred Drug List" and "Summary of Drug Limitations").

> (a) Meet the following conditions:
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
> 2. 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;
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
> 4. 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; and
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider. ...
> (c) 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.

30. As the petitioner is under the age of 21, a broader definition of medically necessary applies, to include the Early and Periodic Screening, Diagnosis, and Treatment Services (EPSDT) requirements. Both EPSDT and Medical Necessity requirements (both cited, above) have been considered in the development of this Order.

31. EPSDT augments the Medical Necessity definition contained in the Florida Administrative Code via the additional requirement that all services determined by the agency to be medically necessary for the *treatment, correction, or amelioration* of problems be addressed by the appropriate services.

32. United States Court of Appeals for the Eleventh Circuit clarified the states'

obligation for the provision of EPSDT services to Medicaid-eligible children in Moore v. Reese, 637 F.3d 1220, 1255 (11th Cir. 2011). The Court provided the following guiding principles in its opinion, (which involved a dispute over private duty nursing):

> (1) [A state] is required to provide private duty nursing services to [a child Medicaid recipient] who meets the EPSDT eligibility requirements, when such services are medically necessary to correct or ameliorate [his or her] illness and condition.
> (2) A state Medicaid plan must include "reasonable standards ... for determining eligibility for and the extent of medical assistance" ... and such standards must be "consistent with the objectives of" the Medicaid Act, specifically its EPSDT program.
> (3) A state may adopt a definition of medical necessity that places limits on a physician's discretion. A state may also limit required Medicaid services based upon its judgment of degree of medical necessity so long as such limitations do not discriminate on the basis of the kind of medical condition. Furthermore, "a state may establish standards for individual physicians to use in determining what services are appropriate in a particular case" and a treating physician is "required to operate within such reasonable limitations as the state may impose."
> (4) The treating physician assumes "the primary responsibility of determining what treatment should be made available to his patients." Both the treating physician and the state have roles to play, however, and "[a] private physician's word on medical necessity is not dispositive."
> (5) A state may establish the amount, duration, and scope of private duty nursing services provided under the required EPSDT benefit. The state is not required to provide medically unnecessary, albeit desirable, EPSDT services. However, a state's provision of a required EPSDT benefit, such as private duty nursing services, "must be sufficient in amount, duration, and scope to reasonably achieve its purpose."
> (6) A state "may place appropriate limits on a service based on such criteria as medical necessity." In so doing, a state "can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis" and my present its own evidence of medical necessity in disputes between the state and Medicaid patients (citations omitted).

33. In the instant case, [redacted] is requested to treat and ameliorate

Petitioner's [redacted]. As such, in a general sense, [redacted] is in keeping with Fla. Admin. Code R. 59G-1.010(166)(1). However, because [redacted] is not indicated for children under the age of 16, it is not consistent with generally accepted medical standards for use in 11-year olds, and may be considered experimental, per Fla. Admin. Code R. 59G-1.010(166)(3). Additionally, Fla. Admin. Code R. 59G-1.010(166)(2) and (4) also require that any authorized service not be in excess of a patient's needs, and that there be no "equally effective and more conservative or less costly treatment is available; statewide."

34. Although United was not consistent it its approach to explaining its decision to deny [redacted] Dr. Fernandez correctly pointed to the age limitation set forth for dispensing of the drug, and Dr. Willis correctly noted that adjustments to Petitioner's stimulant therapy might be attempted prior to reinstituting [redacted]

35. It should be noted that the undersigned does not condone the manner in which United handled Petitioner's case. In refusing to speak with the treating physician until after hearing convened, United delayed potential resolution of an issue and failed to provide adequate customer service. Had United wanted additional literature to support a possible exception, they could have requested same when the decision was first appealed in June of 2015.

36. Petitioner's case is sympathetic, and the undersigned acknowledges the toll this has taken on Petitioner and his family. However, when jointly considering the requirements of both ESPDT and Medical Necessity, along with a review of the totality of the evidence and legal authority, the undersigned concludes that she does not have sufficient evidence to overturn United's denial.

37. Petitioner is encouraged to continue working with [redacted] in conjunction with United and Dr. Fernandez. Should Petitioner wish to file a new request for [redacted] including the literature requested by Dr. Fernandez, United is strongly encouraged to review same in light of Petitioner's individualized, specific needs, and his total medical history, to determine whether, consistent with EPDST, approval is appropriate in this, particular case.

## DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, the Petitioner's appeal is hereby DENIED and Agency's action is AFFIRMED.

## NOTICE OF RIGHT TO APPEAL

This decision is final and binding on the part of the agency. If the petitioner disagrees with this decision, the petitioner may seek a judicial review. To begin the judicial review, the petitioner must file one copy of a "Notice of Appeal" with the Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Tallahassee, FL 32308-5403. The petitioner must also file another copy of the "Notice of Appeal" with the appropriate District Court of Appeal. The Notices must be filed within thirty (30) days of the date stamped on the first page of the final order. The petitioner must either pay the court fees required by law or seek an order of indigency to waive those fees. The petitioner is responsible for any financial obligations incurred as the agency has no funds to assist in this review.

DONE and ORDERED this 10 day of December, 2015,

in Tallahassee, Florida.

Patricia C. Antonucci
Hearing Officer
Building 5, Room 255
1317 Winewood Boulevard
Tallahassee, FL 32399-0700
Office: 850-488-1429
Fax: 850-487-0662
Email: appeal.hearings@myflfamilies.com

Copies Furnished To: [redacted] Petitioner
Debbie Stokes, Area 4, AHCA Field Office Manager