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

[redacted]

PETITIONER,

APPEAL NO. 14F-02227

Vs.

CASE NO.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 17 Broward
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned hearing officer convened an administrative hearing telephonically in the above-referenced matter on April 25, 2014, at 10:40 a.m. The hearing was convened in Fort Lauderdale, Florida. The hearing was reconvened telephonically on July 7, 2014, at 10:53 a.m.

APPEARANCES

For the Petitioner: [redacted]
Petitioner

For the Respondent: Ken Hamblin
Agency for Health Care Administration

STATEMENT OF ISSUE

The issue is the denial by the Agency for Health Care Administration (sometimes hereinafter referred to as "respondent", "AHCA" or the "Agency") of petitioner's request for Suboxone along with the denial by the Agency to reimburse the petitioner for his out-of-pocket costs associated with independently purchasing the medication.

PRELIMINARY STATEMENT

[redacted] the petitioner ("petitioner"), appeared on his own behalf. [redacted] appeared as a witness on behalf of the petitioner at the first portion of the hearing.

Ken Hamblin, Field Office 10 Medicaid Fair Hearing Coordinator for the Agency for Health Care Administration, appeared on behalf of the Agency for Health Care Administration. The following appeared as witnesses on behalf of the Agency: David Gilchrist, D.O., Medical Director of Sunshine Health; Donna Laber, R.N., Manager of Grievances and Appeals for Sunshine Health; Carolyn Janvier, Grievance and Appeals Coordinator for Sunshine Health; India Smith, Grievance and Appeals Coordinator for Sunshine Health; and Patricia Helmlinger, R.N., Case Manager for Sunshine Health. Miguel Venereo, M.D., Medical Director for Sunshine Health, was present solely for the purpose of observation at the first portion of the hearing. Antonio Mercado, R.N., and Fulani Sutherland, M.S., both with the Agency for Health Care Administration, were present solely for the purpose of observation during the second portion of the hearing.

The petitioner introduced petitioner's Exhibits "1" through "5", inclusive, at the hearing, which were accepted into evidence and marked accordingly. The respondent introduced Exhibits "1" through "8", inclusive, at the hearing, which were also accepted into evidence and marked accordingly. The hearing record in this matter was left open until the close of business on May 2, 2014 for the Agency to provide both the Agency and Sunshine Health policies regarding the approval of Suboxone. Once received, this information was accepted into evidence and marked as respondent's Exhibit "9". When the hearing was reconvened on July 7, 2013, the respondent introduced Exhibits "10"

through "13", inclusive, which were also accepted into evidence and marked appropriately.

FINDINGS OF FACT

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

1. The petitioner is an adult male. The petitioner resides in Broward County.

2. The petitioner was eligible to receive Medicaid at all times relevant to this proceeding.

3. The petitioner is enrolled in Sunshine Health. Sunshine Health is a Health Maintenance Organization ("HMO") which is contracted by the Agency for Health Care Administration, the respondent, to provide services to certain Medicaid eligible persons in the State of Florida.

4. Petitioner has a long-standing history of opioid abuse. He is a recovering drug addict.

5. The petitioner underwent a fusion of the right hip on November 14, 2013. This surgery was the result of a failed total hip arthroplasty on his right side. The failed surgery several years earlier caused the petitioner's right leg to be shorter than his left and is a source of chronic pain for the petitioner.

6. While in the hospital in November 2013, petitioner was placed on opioid-based medications for pain management. Petitioner continued to be in pain after his discharge from the hospital.

7. When the petitioner began to feel he was abusing these medications, he requested that Sunshine Health approve him for the receipt of Suboxone.

8. Suboxone is a prescribed medication that assists with the treatment of opioid dependence. Suboxone may not be prescribed concurrently with any opioid medications and may only be approved in conjunction with a comprehensive treatment plan which includes a request from the patient's doctor, including the patient's drug use and social histories, consistent regular drug screenings, a referral to substance abuse counseling and/or a support group, and possibly a taper plan.

9. The petitioner testified at the hearing that Suboxone may be used for pain management and provided copies of internet articles discussing the use of Suboxone for this purpose. The respondent's witness testified that Sunshine Health does not recognize Suboxone as an approved pain management medication. He explained he has not seen Suboxone used for pain management in the medical community and explained that the Suboxone and Food and Drug Administration websites do not list Suboxone as an approved pain management medication. The respondent provided the Sunshine Health approval criteria for Suboxone which state Suboxone is not approvable for pain management.

10. The hearing officer finds that Suboxone is a medication approved to assist with opioid dependence and is not a pain management medication.

11. Sunshine Health policy indicates that Suboxone may only be approved for a limited amount of time with the expectation that the patient be weaned off any opioids as well as the Suboxone itself during that time.

12. The petitioner made multiple requests for Suboxone to Sunshine Health. These requests were made on January 10, 2014, January 31, 2014, February 3, 2014, February 7, 2013, and February 20, 2014. These requests for Suboxone were denied.

13. On February 19, 2014, Sunshine Health's Appeals and Grievance Department received an appeal from the petitioner requesting coverage for Suboxone. In the member's complaint, it explains that he had a hip arthrodesis in November 2013 and that he used Suboxone for treatment of chronic pain and management of his opioid addiction prior to this surgery.

14. The February 24, 2014 denial letter from Sunshine Health to the petitioner states as follows

> We have looked at your appeal regarding the denial of Suboxone MIS 8-2mg.
>
> As of 2/21/2014, the medication Suboxone is: Denied.
>
> The case was reviewed by Sunshine Health's Medical Director who is an MD and is Board Certified and Specializes in Emergency Medicine. Based on the additional medical documentation received for review, clinical judgment, standards of practice and Sunshine Health Medical Necessity Guideline (CP.PMN.23) if there are narcotic medication claims in member's claim history within past 30 days of a current Suboxone claim, the Suboxone claim will be rejected. In addition, the patient has admitted to using recreational drugs. Therefore, the request for Suboxone is denied.

15. The petitioner's requests for Suboxone did not include a letter from his physician documenting the medical necessity for the use of this medication and setting forth a treatment plan. Sunshine Health representatives attempted to contact the petitioner's physician for a peer-to-peer consultation but were unsuccessful.

16. Sunshine Health's Appeals and Grievance Department received a request for a second level appeal from the petitioner again requesting coverage for Suboxone on March 19, 2014.

17. The petitioner's request for a second level appeal included a letter from his physician dated February 25, 2014 documenting the medical necessity of Suboxone for the petitioner. As a result of this letter, Sunshine Health approved Suboxone for a four month period on March 25, 2014. The purpose of the approval was to assist the petitioner in addressing his drug dependency.

18. The letter from Sunshine Health to the petitioner approving the Suboxone is dated March 25, 2014. The letter explains that the medication was approved for four months, for the period March 25, 2014 through July 25, 2014.

19. The respondent's witness testified that Suboxone is initially approved for a 30-day period so that its effectiveness on a patient can be evaluated. Once a patient is evaluated after the 30-days and it is determined that the Suboxone is having the desired effects, an additional three month supply of the medication is approved.

20. The respondent's witness testified that, in this case, the Suboxone was initially approved for four months instead of 30-days because the petitioner had already taken the Suboxone for 30-days.

21. Sunshine Health's Medical Director testified that, when it approved the Suboxone for the petitioner on March 25, 2014, it was not the intent of Sunshine Health to reimburse the petitioner for his out-of-pocket costs associated with purchasing the medication independently prior to March 25.

22. Sunshine Health's Medical Director testified the petitioner is not entitled to reimbursement of his out-of-pocket costs associated with purchasing Suboxone directly because of the following reasons: petitioner was going to an out-of-network physician at that time; petitioner refused to see an in-network physician which could facilitate his

care; petitioner was non-compliant with his care plans; and petitioner was not providing drug screens. The Medical Director testified that all of the above reasons are in violation of Sunshine Health policy.

23. Petitioner's drug screens were positive for the use of Benzodiazepines for the period January 2013 through August 2013, with only July showing a negative result. Petitioner did not provide Sunshine Health with drug screen results for the period during which he was paying for Suboxone directly.

24. The petitioner did not provide consistent negative drug screen results to Sunshine Health.

25. Sunshine Health received the petitioner's second level appeal on March 19, 2014 and approved the Suboxone seven days later, on March 25, 2014.

26. The petitioner paid for the Suboxone out-of-pocket for the period January 14, 2014 through March 13, 2014 and is seeking reimbursement for that cost.

27. The petitioner's out-of-pocket costs for purchasing the Suboxone from the period of time he initially requested the medication on January 10, 2014 until the time it was approved by Sunshine Health on March 25, 2014 were $1,256.69.

CONCLUSIONS OF LAW

28. By agreement between the Agency for Health Care Administration and the Department of Children and Families, AHCA has conveyed jurisdiction to the Office of Appeal Hearings to conduct this hearing pursuant to § 120.80, Fla. Stat.

29. This is a final order pursuant to § 120.569 and § 120.57, Fla. Stat.

30. This hearing was held as a *de novo* proceeding pursuant to Fla. Admin. Code R. 65-2.056.

31. Petitioner in the present case is requesting a change in his prescription coverage. Therefore, in accordance with Fla. Admin. Code R. 65-2.060 (1), the burden of proof is assigned to the petitioner.

32. The standard of proof in an administrative hearing is by a preponderance of the evidence. (See Fla. Admin. Code R. 65-2060(1).) The preponderance of the evidence standard requires proof by "the greater weight of the evidence," (Black's Law Dictionary at 1201, 7th Ed.

33. The Florida Medicaid program is authorized by Fla. Stat. ch 409 and Fla. Admin. Code R. 59G. The Medicaid program is administered by the respondent.

34. Section 409.912, Fla. Stat. states, in relevant parts:

> **Cost-effective purchasing of health care.**—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care ...
>
> (3) The agency may contract with health maintenance organizations certified pursuant to part I of chapter 641 for the provision of services to recipients. This subsection expires October 1, 2014.

35. The Florida Medicaid Provider General Handbook – July 2012 is incorporated by reference in the Medicaid Services Rules found in Fla. Admin. Code Chapter 59G-4. In accordance with the above Statute, the Handbook states on page 1-27

> Medicaid contracts with Health Maintenance Organizations (HMOs) to provide prepaid, comprehensive, cost-effective medical services to enrolled Medicaid recipients.
>
> Medicaid pays each HMO a monthly capitation fee for managing and providing care to each enrolled recipient. In accordance with certain contractual agreements with Medicaid, the HMO provides a specified, comprehensive package of medical services for this monthly Medicaid fee.

> Medicaid HMOs are also required to provide quality and benefit enhancements and can provide other expanded benefits as described in this section.

36. Pages 1-28 of the Florida Medicaid Provider General Handbook provide a list of HMO covered services. These services include prescribed drug services.

37. Page 1-30 of the Florida Medicaid Provider General Handbook states: "An HMO's services cannot be more restrictive than those provided under Medicaid fee-for-service."

38. Fla. Admin. Code R. 59G-1.010(166) explains that medical or allied care, goods, or services furnished or ordered must meet the definition of medically necessary or medical necessity, and defines medical necessity as:

> (a) "Medical necessary" or "medical necessity" means that medical or allied care, goods or services furnished or ordered must 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 patent's needs;
> 3. Be consistent with generally accepted professional medical standards as defined by the Medicaid program and not be experimental or investigational;
> 4. Be reflective of the level of service that can safely be furnished, 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.

39. Section 409.912 (37)(a), Fla. Stat. states, in relevant parts:

14. The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize the use of a product:
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....

40. Fla. Admin. Code R. 59G-4.250 Prescribed Drug Services incorporates by reference the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook, updated June 2012.

41. The Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook defines the Preferred Drug List on Page 3-xv as follows

The Preferred Drug List (PDL) is a listing of efficacious, safe, and cost effective choices for practitioners in all outpatient settings to reference when prescribing for Medicaid patients. Reimbursement for these products usually does not require prior authorization, and the PDL pertains to all provider locations where these drugs are prescribed, dispensed or administered. (Note: Prior authorization may be required to ascertain specific clinical factors related to the use of some drugs.)

42. Suboxone is not on the Agency's Preferred Drug List.

43. The Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook, on Page 3-xv, states: "In order to be reimbursed by Medicaid, providers must obtain prior authorization before dispensing certain drugs."

44. In discussing the prior authorization requirements, the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook, also on Page 3-xv, states as follows

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.
> 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.

45. Prior authorization is required from Medicaid prior to reimbursement for Suboxone.

46. The Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook, on Page 3-xvi, explains

> When requesting prior authorization to obtain a non-PDL drug, the prescriber must provide the following information:
> 1. Recipient data – recipient's name, ten-digit Medicaid identification number, and date of birth;
> 2. Prescriber data – prescriber's name; mailing address; telephone and fax numbers and professional license number;
> 3. Drug data – drug name, strength, dosage form, and quantity needed;
> 4. Documentation of the reason for drug selection (i.e., physical or progress notes; hospital discharge summary; or other information pertinent pertaining to the specific need for the non-PDL drug); and
> 5. A copy of the prescription.

47. Following the link in Paragraph 35 above takes the user to the Florida Medicaid Prior Authorization [Form for] Suboxone/Subutex. Page 2 of this Form sets forth the Prior Authorization Standards for Review and states as follows

> Medicaid prior authorization review is intended for office-based treatment of opioid dependency for individuals who meet the following criteria:
> - with an adequate amount of psychosocial support; family/peers
> - with a readiness for change and a personal commitment to live a drug-free lifestyle
> - with a willingness to comply with all elements of the treatment plan, including pharmacologic and non-pharmacologic aspects of the established protocol

- with consistent regular drug screens that are negative for opiates
- with a willingness to abstain from illicit drugs

48. The Sunshine Health criteria for approval of Suboxone are as follows

A. Treatment for opioid dependence (not approvable for pain management).
B. Prescriber has been certified to prescribe Subutex and Suboxone and manage opioid dependence.
C. Patient will be followed in a drug abuse counseling program and will undergo random monthly drug screenings for the duration of treatment.
D. Subutex may be approved for the induction phase for a period not to exceed 2 days (see pregnancy exception below).
E. After initiation of Suboxone therapy the patient's prescription history will be electronically monitored. If there are narcotic medication claims in member's claim history with past 30 days of a current Suboxone claim, the Suboxone claim will be rejected.
F. Requests for Suboxone maintenance therapy will be authorized for the film formulation only unless a clinical contraindication exists that precludes the use of the film formulation.
G. Request for Subutex for maintenance therapy will only be approved in cases of naloxone allergy, pregnancy or if a genuine clinical contraindication is provided that precludes use of Suboxone.

49. The Florida Medicaid Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook directs that clinical prior authorization is required for specific drugs if the product has the potential for overuse, misuse, or abuse. As part of the prior authorization process, the Agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. Prior authorization is required for Suboxone. In the present case, the petitioner did not provide a letter to Sunshine Health from his doctor substantiating his need for Suboxone at the time he initially requested the medication. Sunshine Health did not receive such a letter until the time of its receipt of the petitioner's request for second level review on March 19, 2014. Furthermore, petitioner did not provide Sunshine Health with current negative drug screen results with his request for Suboxone.

50. Based on the above, the respondent correctly denied petitioner's request for Suboxone.

51. Accordingly, petitioner has not met his burden of proof that he is entitled to reimbursement of his out-of-pocket costs for the purchase of Suboxone during the period January 10, 2014 through March 25, 2014.

DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, the appeal is DENIED.

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 28th day of August, 2014, in Tallahassee, Florida.

Peter J. Tsamis

Peter J. Tsamis
Hearing Officer
Building 5, Room 255
1317 Winewood Boulevard
Tallahassee, FL 32399-0700
Office: 850-488-1429
Fax: 850-487-0662
Email: Appeal_Hearings@dcf.state.fl.us

Copies Furnished To: [redacted]Petitioner
Ken Hamblin, Area 10, AHCA Program Operations Adminstrator
Beverly Smith, Esq.
Bureau of Managed Health Care AHCA