STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 373-4147

IN THE MATTER OF:

Docket No. 2014-33315 PHR

[redacted] [redacted] [redacted]

Appellant
_____/

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and MCL 400.37, and upon the Appellant's request for a hearing.

After due notice, a hearing was held [redacted] Appellant appeared and testified on her own behalf. [redacted], a Clinical Pharmacist with the [redacted] represented the Michigan Department of Community Health ("MDCH" or "Department").

ISSUE

Did the Department properly deny Appellant's prior authorization request for the drug Suboxone?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material and substantial evidence on the whole record, finds as material fact:

1. Appellant is a [redacted] year-old Medicaid beneficiary who has been diagnosed with opioid dependence. (Respondent's Exhibit A, page 3).

2. Appellant has been receiving Suboxone through the Department since [redacted]. (Respondent's Exhibit A, page 14; Testimony of Appellant).

3. On [redacted] submitted a prior authorization request for Suboxone on behalf of Appellant to [redacted]. (Testimony of [redacted].

4. [redacted] contracts with the Department to review drug prior authorization requests. (Testimony of [redacted].

5. After noting that Appellant had already been on Suboxone for [redacted] months, requesting additional information from [redacted] regarding a missing taper plan, extenuating circumstances justifying the length of treatment, and any referral for chronic intervention. (Respondent's Exhibit A, page 12; Testimony of [redacted]

6. On [redacted] submitted a taper plan. (Testimony of [redacted]

7. In an updated prior authorization request, [redacted] also indicated that Appellant has been attending Alcoholics Anonymous (AA) meetings regularly with her sponsor. (Respondent's Exhibit A, pages 5).

8. [redacted] further indicated that Appellant has attended all of her scheduled appointments and that her drug screens demonstrate that she has been compliant. (Respondent's Exhibit A, page 5).

9. [redacted] also wrote that Appellant is stable on her current dosage and not ready to wean, but that she also agrees to begin preparing to wean. (Respondent's Exhibit A, page 5).

10. In a subsequent documentation, [redacted] responded to a question asking if Appellant had been referred for chronic intervention and, if so, what are the details of that intervention, by proving a name and address. (Respondent's Exhibit A, page 13).

11. [redacted] then forwarded Appellant's prior authorization request to the Department for a physician review. (Respondent's Exhibit A, page 15; Testimony of [redacted]

12. Following that review, the physician for the Department found that the request should be denied as Appellant had previously been given [redacted] months to wean; the weaning has not begun; there were no extenuating circumstances as to why the weaning has not begun; and there was no useful explanation regarding any chronic intervention. (Respondent's Exhibit A, page 15).

13. On [redacted], the Department sent Appellant's physician written notice that the prior authorization request was being denied. The notice also identified the reasons given by the Department's physician. (Respondent's Exhibit A, page 16).

14. On [redacted], the Department sent Appellant written notice that the prior authorization request was being denied on the basis that the request did not meet criteria. (Respondent's Exhibit A, page 16).

15. On [redacted], the Michigan Administrative Hearing System (MAHS) received the request for hearing in this matter. (Respondent's Exhibit A, page 2).

CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statute, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

The Social Security Act § 1927(d), 42 USC 1396r-8(d), also provides as follows:

> Limitations on Coverage of Drugs –
>
> (1) Permissible Restrictions –
>
> (A) A state may subject to Prior Authorization any covered outpatient drug. Any such Prior Authorization program shall comply with the requirements of paragraph (5).
>
> (B) A state may exclude or otherwise restrict coverage of a covered outpatient drug if –
>
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6);
>
> (ii) the drug is contained in the list referred to in paragraph (2);
>
> (iii) the drug is subject to such restriction pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or
>
> (iv) the State has excluded coverage of the drug from its formulary in accordance with paragraph 4.

(2) List of drugs subject to restriction–The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs, which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

* * *

(4) Requirements for formularies — A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer, which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The state plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a Prior Authorization program that is consistent with paragraph (5),

> (E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.
>
> A Prior Authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.
>
> (5) Requirements of Prior Authorization programs—A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval –
>
> (A) Provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
>
> (B) Except with respect to the drugs referred to in paragraph (2) provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

The Department is therefore authorized by federal law to develop a formulary of approved prescriptions and a Prior Authorization process.

Here, the Michigan Medicaid Clinical and PDL Criteria developed and used by the Department only support use of Suboxone for a maximum period of [redacted] months, including weaning, and does not support long-term use of Suboxone for chronic or maintenance intervention. (Respondent's Exhibit A, page 18; Testimony of [redacted].

However, the Department's witness testified that extensions beyond [redacted] months can be granted at the Department's discretion. (Respondent's Exhibit A, page 22; Testimony of [redacted] The Department requires that the prescriber provide the following information in order to consider an extension:

- The information requested for initial approval.
- Information on compliance/non-compliance with counseling sessions.

- Information on compliance/non-compliance with the prescribing physician,
- The plan for continued therapy to include a tapering schedule.
- Documentation that the patient is not using illicit drugs; including a copy of the drug screen no more than one month old.
- Details regarding extenuating circumstances warranting continued coverage,
- Result of the referral to the substance abuse treatment center for chronic intervention (see details under section marked "General MDCH information about coverage"
- A screen-print of paid claims through POS claims history.

Respondent's Exhibit A, page 22

The Department reviewed the prior-authorization requests against the criteria set forth above. It was determined that the information did not support an extension in this case.

The Department's clinical pharmacist testified that in [redacted] Appellant sought prior authorization for treatment with Suboxone, but Appellant's claim history shows paid claims for Suboxone for the prior [redacted] months. She also testified that additional information was requested from the prescribing physician describing and documenting extenuating circumstances that may allow for therapy exceeding [redacted] months, in addition to information related to a detailed taper plan and the result of the referral to the substance abuse treatment center for chronic intervention. The Department's clinical pharmacist indicated, however, that when additional information was received from Appellant's doctor, he failed to describe any extenuating circumstances warranting continued coverage or details of the referral to chronic intervention, as required. The Department's clinical pharmacist further testified that the requests and supporting information were forwarded to a physician reviewer at MDCH, but the physician reviewer denied the request because Appellant had previously been given six months to wean; the weaning has not begun; there were no extenuating circumstances as to why the weaning has not begun; and there was no useful explanation regarding any chronic intervention

In response, Appellant testified that she became addicted to drugs following [redacted] horrific accidents and that, given the severity of her injuries and addiction, [redacted] year on Suboxone would not have done anything for her. She also testified that this case is a matter of life-and-death and that, if the prior authorization request is denied, she will have to go back to heroin.

This Administrative Law Judge has reviewed the evidence of record and, while Appellant's position is understandable, she has been receiving Suboxone for [redacted] months and has already be permitted to exceed the tapering within the [redacted] months of continuous

therapy supported by the Department. Moreover, the prescribing physician did not submit the additional information or details required for therapy exceeding [redacted] months in this case. Instead, he merely made broad, unsupported statements regarding Appellant's need to continue with the Suboxone and her referral for chronic intervention.

To the extent Appellant has new or updated information to provide, she and her doctor can submit a new prior authorization request. With respect to the previous denial at issue in this case, however, the undersigned Administrative Law Judge finds that the Department's denial is proper based on the submitted information.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the Department properly denied the Appellant's prior authorization request.

IT IS THEREFORE ORDERED that:

The Department's decision is **AFFIRMED**.

Steven Kibit

Steven Kibit
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

Date Signed: [redacted]

Date Mailed: [redacted]

SK/db

cc: [redacted]

***** NOTICE *****

The Michigan Administrative Hearing System may order a rehearing on either its own motion or at the request of a party within 30 days of the mailing date of this Decision and Order. The Michigan Administrative Hearing System will not order a rehearing on the Department's motion where the final decision or rehearing cannot be implemented within 90 days of the filing of the original request. The Appellant may appeal the Decision and Order to Circuit Court within 60 days of the mailing date of the Decision and Order or, if a timely request for rehearing was made, within 60 days of the mailing date of the rehearing decision.