STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 334-9505

IN THE MATTER OF:

[redacted]
Appellant
_____/

Docket No. 2010-3943 PHR
[redacted]

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.*, upon the Appellant's request for a hearing.

After due notice, a hearing was held on [redacted]. The Appellant appeared without representation. She had no witnesses. [redacted], Phr manager, represented the Department. There were no other witnesses.

ISSUE

Did the Department properly deny Appellant's request for prior authorization of 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. The Appellant is a [redacted] Medicaid beneficiary.

2. The Appellant is afflicted with low back pain and opioid dependence. See Testimony.

3. The Appellant completed substance abuse treatment on [redacted]. Department's Exhibit A, p. 3.

4. The Appellant has a prior Suboxone PA from [redacted] through [redacted] including Suboxone paid claims of [redacted], through [redacted]. Department's Exhibit A, p. 3.

5. The Appellant is not currently in counseling. Department's Exhibit A, p. 3 and See Testimony.

6. On [redacted], the Appellant's physician, [redacted] a family practitioner, submitted a PA for Suboxone for the Appellant who he diagnosed as suffering from "Opioid dependence" for his patient. Department's Exhibit A, p. 1.

7. Owing to a lack of supporting documentation the first request was not approved by either [redacted] or then by [redacted]. Department's Exhibit A, pp. 1, 8-10.

8. Next, the request was resubmitted [on [redacted]] with the inclusion of a negative drug screen for the Appellant dating back to [redacted], Department's Exhibit A, p. 6.

9. On [redacted], the request was resubmitted and denied for lack of active counseling. Department's Exhibit A, p. 1.

10. The request was next forwarded to [redacted] for review and was denied again for lack of program compliance and failure to meet treatment criteria – particularly in light of the patient not receiving active counseling. Department's Exhibit A, p. 11 and See Testimony.

11. The Appellant's physican was notified of the needed clinical information for reconsideration. No additional information was submitted by the prescriber. Department's Exhibit A, p. 1.

12. The Appellant was notified of the denial and her further appeal rights, by Adequate Action Notice, on [redacted]. Department's Exhibit A, pp. 1, 12, 13.

13. The instant request for hearing was received by the State Office of Administrative Hearings and Rules for the Department of Community Health on [redacted]. Appellant's Exhibit #1.

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.

Social Security Act § 1927(d), [*42 USC 1396r-8(d)*]

LIMITATIONS ON COVERAGE OF DRUGS –

(d) (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.

(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).

(6) OTHER PERMISSIBLE RESTRICTIONS – A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances or fraud or abuse by individuals in any manner authorized under this Act.

Furthermore, the Medicaid Provider Manual (MPM) sets forth significant criteria for documentation of purported off-label uses and prior authorization requests:

DOCUMENTATION REQUIREMENTS

For all requests for PA, the following documentation is required:

- Pharmacy name and phone number;
- Beneficiary diagnosis and medical reason(s) why another covered drug cannot be used;
- Drug name, strength, and form;
- Other pharmaceutical products prescribed;
- Results of therapeutic alternative medications tried; and
- MedWatch Form or **other clinical information** may be required.

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PRIOR AUTHORIZATION DENIALS

PA denials are conveyed to the requester. PA is denied if:

- The medical necessity is not established.
- Alternative medications are not ruled out.
- Evidence-based research and compendia do not support it.
- It is contraindicated, inappropriate standard of care.
- **It does not fall within MDCH clinical review criteria.**
- **Documentation required was not provided**.[1]

MPM, Pharmacy §§8.4, 8.6, pages 15 and 16, January 1, 2010.

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The Department witness, [redacted] testified that the requested drug was designed to help treat addiction - it was not to be used as a pain medication. [redacted] added the claim was denied chiefly because of the non-current drug screen and evidence that the Appellant had "finished" counseling in [redacted] She said the Department requires concurrent [active] counseling and a drug screen of more recent origin "within a month or weeks of the service request." *See* Department's Exhibit A, p. 9.

The Appellant testified that she has been on Suboxone since [redacted] and has been through "the program" three times. She said that she goes to NA, but the meetings are confidential so records are unavailable. She added that she has been involved with Child Protective Services and that many current drug screens should be available for review.[2]

1 This edition of the MPM is substantially similar to the version in place at the time of appeal.
2 None were submitted by the Appellant for hearing.

On review, based on the Appellant's own testimony she has been on Suboxone for [redacted] [as of the date of hearing] and has attended three addiction programs without successful resolution.

The clinical judgment of the Department and its medical reviewers [redacted] was deft. First, Suboxone generally is not indicated for long term treatment. The medical literature shows that that the Appellant is already on the far-end of practical use having gone through the above referenced programs.

Suboxone treatment beyond 12-months merits further MDCH scrutiny such as the provision of detailed counseling plan(s) and detailed proof that the Appellant is not using illicit drugs [current testing]. Clearly, the Appellant's documentation, as well as the incomplete response from the Appellant's physican, missed the mark. *See* Department's Exhibit A at pp. 16-17.

I found the testimony of the Department's witness [redacted] to be credible. I found the testimony of the Appellant to be lacking in sufficient detail to allow PA of Suboxone. The Appellant has failed to preponderate her burden of proof.

The Department's decision to deny PA, based on the information submitted by [redacted] and the evidence in today's record was correct.

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 PA request for Suboxone.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

Dale Malewska
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 1/21/2010

***** NOTICE *****

The State Office of Administrative Hearings and Rules for the Department of Community Health 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 State Office of Administrative Hearings and Rules for the Department of Community Health 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 30 days of the receipt of the Decision and Order or, if a timely request for rehearing was made, within 30 days of the receipt of the rehearing decision.