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]

Docket No. 2011-15311 PHR
Case No. 36155951

Appellant
_____/

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. His witness was his [redacted]. [redacted], represented the Department. She had no witnesses.

ISSUE

Did the Department properly deny Appellant's request for prior authorization (PA) 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 [redacted] ABW beneficiary. (Appellant's Exhibit #1)

2. The Appellant is afflicted with opioid dependence. (Department's Exhibit A, p. 1)

3. On [redacted], the Appellant's physician, a family practitioner, submitted a PA for continuation therapy of Suboxone to treat the Appellant who he diagnosed as suffering from "opioid dependence." (Department's Exhibit A, p. 1)

4. The Appellant had been on Suboxone therapy for [redacted]. There was no evidence that tapering had begun. (Department's Exhibit A, p. 1)

5. Owing to contractual requirements between [redacted] and the Michigan Department of Community Health the request for continued Suboxone therapy was reviewed for clinical compliance by MSA physican, [redacted] – who denied the request for no evidence of tapering. (Department's Exhibit A, p. 12)

6. The Appellant and the prescriber were notified of the denial. (Department's Exhibit A, pp. 13, 14).

7. The Appellant was notified in writing of his further appeal rights via adequate action/denial of service on [redacted]. (Department's Exhibit A, p. 14)

8. The instant request for hearing was received by the State Office of Administrative Hearings and Rules (SOAHR) 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 --

(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).

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.
>
> ***
>
> **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.

(Emphasis supplied)

MPM, Pharmacy §§8.4, 8.6, pages 15 and 16, April 1, 2011.[1]

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The Department witness, [redacted] testified that while the requested drug was designed to help treat addiction – that approvals beyond 6-months require another prior authorization for a total of 12-consecutive months usage.

The Department's evidence clearly showed Suboxone is not endorsed by the MDCH for chronic, maintenance or lifetime use. *See* Testimony of [redacted].

She added that the MDCH program for approval of Suboxone requires an office supervised plan, counseling and a program of tapering – information that was never communicated to FHSC or the reviewing MDCH/MSA physician. *See* Department's Exhibit A – throughout and Testimony of [redacted].

The Appellant testified that he was an addict and that Suboxone was very helpful in keeping "clean." He said no one ever told him about the necessity to "taper." He requested another six months of Suboxone therapy to effectuate his taper.

The Appellant's witness testified that his [redacted] was "doing good on the medicine" and he hoped it would be continued.

In review, based on the clinical judgment of the state reviewing physician and the credible testimony of Department witness [redacted] I find that the Appellant has failed to preponderate his burden of proof. The necessary [but omitted], information concerned a tapering program which was never reported to MDCH. *See* Department's Exhibit A, at pages 1, 4, 12, and 13.

The Department's decision to deny PA, based on the information submitted by [redacted] and today's record was sufficient to justify denial of PA for Suboxone.

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 request for PA of continued Suboxone therapy.

[1] This edition of the MPM is identical to the version in place at the time of the Appellant's appeal.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

_____
Dale Malewska
Administrative Law Judge
for Olga Dazzo, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 4/15/2011

***** NOTICE *****

The State Office of Administrative Hearings and Rules 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 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.