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:

[redacted],

Docket No. 2013-13546 PHR
Case No. [redacted]

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. She had no witnesses. The Department was represented by [redacted], clinical pharmacist manager. She had no witnesses.

ISSUE

Did the Department properly deny Appellant's request for prior authorization (PA) of Suboxone?

FINDINGS OF FACT

1. The Appellant is a [redacted]-year-old female Medicaid beneficiary. (Appellant's Exhibit #1)

2. The Appellant is afflicted with opioid dependence. (Appellant's Exhibit #1 and Department's Exhibit A – summary)

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

4. Owing to the extended use request beyond 12-months/extenuating circumstances. The PA was submitted for MSA physician review by [redacted], who denied the request without comment. (Department's Exhibit A, page 15)

5. The Appellant's physician was notified of the denial by "E-mail detailing the reasons for denial by [redacted]" (*See* Testimony of [redacted] and Department's Exhibit A, pp 15, 16). 1)

6. The Appellant was notified of the denial, in writing, on [redacted]. Her further appeal rights were contained therein. (Department's Exhibit A, p. 17)

7. The instant request for hearing was received by the Michigan Administrative Hearing System (MAHS) for the Department of Community Health on [redacted].

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)*, 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).
>
> 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).

42 USC 1396r-8(k)(6) MEDICALLY ACCEPTED INDICATION -

The term “medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

The Medicaid Provider Manual addresses prior-authorization requirements as follows:

8.2 PRIOR AUTHORIZATION REQUIREMENTS

PA is required for:

- Products as specified in the MPPL. Pharmacies should review the information in the Remarks as certain drugs may have PA only for selected age groups, gender, etc. (e.g., over 17 years).

- Payment above the Maximum Allowable Cost (MAC) rate.

- Prescriptions that exceed MDCH quantity or dosage limits.

- Medical exception for drugs not listed in the MPPL.

- Medical exception for noncovered drug categories.

- Acute dosage prescriptions beyond MDCH coverage limits for H2 Antagonists and Proton Pump Inhibitor medications.

- Dispensing a 100-day supply of maintenance medications that are beneficiary-specific and not on the maintenance list.

- Pharmaceutical products included in selected therapeutic classes. These classes include those with products that have minimal clinical differences, the same or similar therapeutic actions, the same or similar outcomes, or have multiple effective generics available.

* * *

8.4 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.

* * *

8.6 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.

Medicaid Provider Manual; Pharmacy §§8.1 – 8.6, October 1, 2012, pp. 14-16

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The Department reviewed the PA request and evidence submitted on the request for continued Suboxone therapy/extenuating circumstances and denied the request without further explanation. The Department's witness in her testimony testified that the screen print out for MAP was over 30 days old as evaluated by the Department. However, no date appears on the exemplars submitted as evidence.

Furthermore, all of the remaining criteria required under the relevant standard: RENEWAL REQUESTS BEYOUND 12-CONSECUTIVE MONTHS was provided and was timely submitted where required under the applicable standard. *See* Department's Exhibit A – throughout.

If the medical reviewer had objections with the sufficiency of the request her "detailed E-mail in response…" to the prior authorization seeking physican was puzzling. On review of that evidence as submitted by the Department – there was no communication to that physican at this review – other than to note – "DENIAL." [*See* Department's Exhibit A, at pages 15 and 16]

On review – in the absence of some proof that the MAPS request was late [there was none] and the lack of a "detailed response" by the reviewing physican - as alleged in the testimony the Department's witness the Department's case fails for lack of proof.

Furthermore, the written denial to the Appellant contained none of the lacking issues alluded to at hearing – but rather simply concluded that the request "does not meet criteria." The Department referenced 42CFR230d as the legal basis for their action. While persuasive in most circumstances the federal regulation does require some modicum of verifiable proof to avoid the appearance of reaching an arbitrary conclusion as cautioned in the controlling standard as well. *See* 42 CFR 240c.[1]

[1] 440.230 Sufficiency of amount, duration, and scope.(a) The plan must specify the amount, duration, and scope of each service that it provides for—(1) The categorically needy; and(2) Each covered group of medically needy.(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve

For purposes of preparing her appeal, preparing for fair hearing or understanding the underpinnings of her denial this action notice was inadequate.

When the Department's proofs fail there is little the Appellant need do to preponderate her burden of proof. Her credible testimony showed that she was following doctor's and counselor's orders [as did the records contained in the Department's exhibit]. She was successfully tapering and looking to an end date for the use of Suboxone in the near future. Her concern to avoid an abrupt discontinuation of what has been a successful medication necessary for her extenuating circumstances was understandable.

This Administrative Law Judge has reviewed the evidence. In the information submitted to the Department by the Appellant's physician – as a lay reviewer - I found it complete and timely [with the caveats noted above].

If the Department had other issues - presumably they would have communicated them to the requesting physican in the "detailed E-mail". They did not. [*See* Department's Exhibit A, at pp. 15 and 16][2].

The Appellant has preponderated her burden of proof. The Appellant requires Suboxone for the extenuating circumstances referenced in the PA at Department's Exhibit A, pages 9 through 14.

The Department improperly denied the Appellant's request for PA of Suboxone.

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its purpose.(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures. (Emphasis supplied)

[2] *See* record: [question by ALJ]

…Please turn to page 15
Ms [redacted], OK
Was that the extent of the doctor's comment - the word "denied"?
Ms. [redacted]: ah, yes…

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, finds that the Department improperly denied the Appellant's request for Suboxone.

IT IS THEREFORE ORDERED that:

The Department's decision is REVERSED.

\s\
Dale Malewska
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 2/1/2013

***** 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 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.