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. 2009-23209 CMH
Case No. [redacted]

DECISION AND ORDER

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

After due notice, a hearing was held on [redacted]. [redacted] appeared as Authorized Representative for [redacted] (Appellant). Also appearing as witnesses for the Appellant were [redacted].

[redacted], appeared on behalf of [redacted], which is directly and/or indirectly an agency contracted with the Michigan Department of Community Health to provide Medicaid-funded community mental health supports and services (hereafter, 'Department'). Also appearing as witnesses for the Department were [redacted] and [redacted].

ISSUE

Has the Department appropriately applied Enhanced Pharmacy Benefit policy in terminating coverage of the Appellant's ongoing physician-ordered prescription for compounded vitamins and minerals?

FINDINGS OF FACT

Based upon the competent, material, and substantial evidence presented, I find, as material fact:

1. The Appellant is an [redacted] who is diagnosed with Joubert Syndrome, Pervasive Developmental Disorder and Anxiety Disorder NOS. *(Exhibit 2; p. 3)* She is a Medicaid beneficiary, currently receiving Enhanced Pharmacy Services through Northcare Network PIHP and its contracted agency, Pathways Community Mental Health Services Program. She resides with her mother in the family home.

2. On [redacted], the PIHP notified the Appellant that it planned to reduce the Enhanced Pharmacy Services identified in her Individual Plan of Service. Specifically, the PIHP terminated coverage of the Appellant's ongoing physician-ordered prescription for compounded vitamins and minerals solely on the basis of its belief that compounded vitamins and/or minerals are not a Medicaid-covered service for the purpose the Appellant's physician has prescribed.

3. The Appellant currently receives treatment through [redacted], [redacted]. She is prescribed both an AM Compound and a PM Compound. The AM Compound consists of the following vitamins and/or minerals: *500 mg Vitamin C (corn-free); 250 mg B-6; 200 mg P5P; 600 mcg Biotin; 1000 mcg Vitamin B12 methylcobalamin; 200 mcg Chromium Polynicotinate; 400 mg Methionine; 100 mg Magnesium as glycinate; 3750 IU Vitamin A; and 125 mcg Molybedenum.* The PM Compound consists of the following vitamins and/or minerals: *500 mg Vitamin C (corn-free); 80 mg Zinc as picolinate; 10 mg Manganese as gluconate; 200 IU Vitamin E; 600 mcg Biotin; 200 mcg Chromium Polynicotinate; 400 mg Methionine; 125 mcg Molybdenum; 100 mcg Selenium as selenomethlonine. (Exhibit 1; p. 4)*

4. A [redacted], letter from [redacted], [redacted], contains the following pertinent comments, all of which are hereby specifically adopted as Finding of Fact #4:

> *[redacted] is an [redacted] young lady with Joubert Syndrome, who is well known to me, who because of the limited knowledge of her syndrome had multiple approaches used to address her behavior and her comfort level. Her multifaceted approaches include traditional medicines, chiropractic, dietary supplements and nutritional approaches. What we have seen is supplementation in the form of specific proteins and other nutrients is marked improvement in her behavior beyond what would be expected from a placebo effect. These include: Nordic Naturals ProOmega 1 capsule in the morning, GABA 500 mg twice daily, L-Carnitine 500 mg 2 caplets 3 times daily, Bio-D Mulsion Forte, which is equivalent to 4,000 units of Vitamin D, once daily and a Primer IV caplet at noontime. She also takes inositol 650 mg tablet at bedtime but can take up to 3 pills. She is also on Vitamin C 500 mg twice daily, Vitamin B6 250 mg in the morning, biotin 600 mcg twice daily, Vitamin B12 100 mcg daily, 200 mcg of chromium polynicotinate twice daily, methlonine 400 mg twice daily, magnesium glycinate 100 mg once daily, Vitamin A 3750 international units once daily, molybdenum 125 mcg twice daily, zinc 60 mg daily, manganese glycinate 10 mg daily and selenium 100 mcg daily.*
>
> *What we have found is with adjusting these nutrients and vitamins*

and nutritional supplements we have seen a marked improvement in [redacted] comfort level and improvements. My fear is that having found this balance not having the resources to continue her on her present regimen will result in a worsening of her condition." "…"

(Exhibit 2; p. 2)

5. A [redacted], letter from [redacted], contains the following pertinent comments, all of which are specifically adopted as Finding of Fact #5:

"At the time of presentation, the patient had a diagnosis of Joubert Syndrome, Pervasive Developmental Disorder and Anxiety Disorder, NOS. In discussion with the patient's mother, it was apparent that the patient had not tolerated a variety of anti-depressant medications. We attempted a variety of treatments for her anxiety including Inderal, Abilify, Lamictal and Ativan. The patient did not tolerate the medications that were attempted during her course of treatment. (Emphasis supplied by ALJ)

Also, at the same time, the patient was on a course of nutrient therapy of unclear benefit at that time. Currently, the patient's mother indicates that she has continued to take these and that she feels they have been beneficial." "…"

(Exhibit 2; p. 3)

6. The [redacted]) is a specialty clinic that treats biologically-based illness. The Center focuses on the identification of biologically-based, dysfunctional body chemistry that may be underlying physical and behavioral abnormalities. *(Exhibit 2; p. 4)*

7. The Appellant initially received treatment from [redacted] for biologically-based illness on [redacted], at which time she presented with a history of Joubert Syndrome, with symptoms including fatigue-aggression, sensory sensitivity, stomach aches, headaches, focus and sleep difficulties. She also presented with an inability to tolerate traditional medication as reported by her mother. *(Exhibit 2; p. 4)*

8. Based on a comprehensive health history, physical examination and diagnostic testing, [redacted] diagnosed the Appellant with a mineral metabolism disorder and undermethylation. *(Exhibit 2; p. 4)*

9. The Appellant underwent diagnostic testing by [redacted] on [redacted]. The results are as follows, and are hereby specifically adopted as Finding of Fact #9:

> *"Serum Zinc, Copper and Lead Levels – These levels are frequently out of balance in people who suffer from skin disorders, anxiety and/or stress disorders and behavior problems.*
>
> *Ceruloplasmin – levels of this copper-binding protein are used to calculate the level of free (unbound) copper in the blood stream. Elevated Cu can interfere with glycolysis (Lai and Blass 1984) and causes CNS overstimulation. Elevated copper is also associated with PMS, dyslexia, learning disorders, temper, depression, skin sensitivities, insomnia and hyperactivity.*
>
> *Comprehensive Blood Chemistries*
>
> *Ferritin – Used to determine levels of storage iron that may impact learning and general health.*
>
> *Histamine – Whole blood levels have a major impact on immune function, allergies, behavior and neurotransmitter levels.*
>
> *Kryptopyrrole Urinalysis (84120) Used to test for overproduction of urinary kryptopyrroles or hemepyrroles, due to a vitamin B-6 related abnormality in hemoglobin synthesis. These are often elevated in stress and behavior disorders.*
>
> ***Improvements: [redacted] is overall calmer and brighter, sleeps better and is less aggressive. She no longer seems to be in pain with her stomach and headaches.***
>
> *Comprehensive and clinical laboratory assessments are used to prescribe an individualized program of treatment to balance the patient's specific body chemistry. It must be compounded through a pharmacy. This program is medically necessary to correct those imbalances, and compliance with the prescribed treatment program is considered essential to progress."*
>
> *(Exhibit 2; p. 4)*

10. On [redacted], the Appellant filed her Request for Hearing with the State Office of Administrative Hearings and Rules for the Department of Community Health.

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.

> Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services.
>
> *42 CFR 430.0*

> The State plan is a comprehensive written statement submitted by the agency describing the nature and scope of its Medicaid program and giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances of the Department. The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.
>
> *42 CFR 430.10*

Section 1915(b) of the Social Security Act provides:

> The Secretary, to the extent he finds it to be cost-effective and efficient and not inconsistent with the purposes of this subchapter, may waive such requirements of section 1396a of this title (other than subsection (s) of this section) (other than sections 1396a(a)(15), 1396a(bb), and 1396a(a)(10)(A) of this title insofar as it requires provision of the care and services described in section 1396d(a)(2)(C) of this title) as may be necessary for a State…

The State of Michigan has opted to simultaneously utilize the authorities of the 1915(b) and 1915(c) programs to provide a continuum of services to disabled and/or elderly populations. Under approval from the Centers for Medicare and Medicaid Services (CMS), the Department operates a section 1915(b) Medicaid Managed Specialty Services and Support program waiver

in conjunction with a section 1915(c) Habilitation and Supports Waiver. [redacted] contracts with the Michigan Department of Community Health to provide Medicaid State Plan Specialty Supports and Services.

My jurisdiction in this case is restricted to a determination of whether the Department has appropriately reduced the Appellant's Enhanced Pharmacy Services by eliminating compounded vitamins and/or minerals from coverage.

Enhanced Pharmacy Services is listed in the Medicaid Provider Manual (MPM) as a separate and distinct "B3" service under the Mental Health/Substance Abuse Chapter. Coverage for compounded vitamins and/or minerals is also addressed under the Pharmacy Chapter of the MPM.

Compounded vitamins and/or minerals are a covered service under the MPM if used for certain conditions. The MPM, Pharmacy Benefits Chapter, provides, in pertinent part, as follows:

> **SECTION 6 – GENERAL NONCOVERED SERVICES**
>
> This section specifies general coverage restrictions. However, drugs in other classes may not be covered. Pharmacies should review the MPPL for specific coverage. When possible, pharmacies are encouraged to suggest alternative covered therapy to the prescriber if a product is not covered.
>
> The following drug categories are **not covered** as a benefit:
>
> - Agents used for anorexia or weight loss.
> - Agents used for weight gain.
> - Agents used for cosmetic purposes or hair growth.
> - Agents used for symptomatic relief of cough and colds.
> - Experimental or investigational drugs.
> - Agents used to promote fertility.
> - Agents used to promote smoking cessation not on the MPPL.
> - *Vitamin/Mineral combinations not for prenatal care, end stage renal disease or pediatric fluoride supplementation. (Emphasis supplied by ALJ)*
> - Covered outpatient drugs that the Labeler seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the Labeler or their designee.
> - Covered outpatient drugs where the Labeler limits distribution.
> - Proposed less-than-effective (LTE) drugs identified by the Drug Efficacy Study Implementation (DESI) program.
> - Over-the-counter drugs not on the MPPL.
> - Drugs of Labelers not participating in the Rebate Program.
> - Drugs prescribed for "off label" use if there is no generally accepted medical indication in peer reviewed medical literature (Index Medicus), or listing of such use in standard pharmaceutical references such as Drug Facts and

Comparisons, AMA Drug Evaluations, American Hospital Formulary Service Drug Information, or DRUGDEX Information Systems.
- Drugs prescribed specifically for medical studies.
- Drugs recalled by Labelers.
- Drugs past CMS termination dates.
- Lifestyle agents.
- Standard Infant Formulas.
- Drugs used to treat gender identity conditions, such as hormone replacement.
- Drugs covered by the Medicare Part D benefit.
- Drugs not FDA approved or licensed for use in the United States.
- Agents used for treatment of sexual or erectile dysfunction.

Michigan Department of Community Health
Medicaid Provider Manual; Pharmacy
Version Date: July 1, 2009; p. 12

(Policy in force at time of action substantively identical to the above-cited policy)

The Appellant's B3 Enhanced Pharmacy Benefit provides coverage for vitamins and minerals under certain circumstances. It is important to note that the policy does neither specifically excludes, nor addresses, compounded vitamins and minerals.

Enhanced Pharmacy Policy provides, in pertinent part, as follows:

17.3.C. ENHANCED PHARMACY

Enhanced pharmacy items are physician-ordered, nonprescription "medicine chest" items as specified in the individual's plan of service. *There must be documented evidence that the item is not available through Medicaid or other insurances, and is the most cost effective alternative to meet the beneficiary's need. (Emphasis supplied by ALJ)*

The following items are covered only for adult beneficiaries living in independent settings (i.e., own home, apartment where deed or lease is signed by the beneficiary):

- Cough, cold, pain, headache, allergy, and/or gastrointestinal distress remedies
- First aid supplies (e.g., band-aids, iodine, rubbing alcohol, cotton swabs, gauze, antiseptic cleansing pads)

The following items are covered for beneficiaries living in independent settings, with family, or in licensed dependent care settings:

- Special oral care products to treat specific oral conditions beyond routine mouth care (e.g., special toothpaste, tooth brushes, anti-plaque rinses, antiseptic mouthwashes)
- *Vitamins and minerals (Emphasis supplied by ALJ)*
- Special dietary juices and foods that augment, but do not replace, a regular Diet
- Thickening agents for safe swallowing when the beneficiary has a diagnosis of dysphagia and either:
  --A history of aspiration pneumonia, or
  --Documentation that the beneficiary is at risk of insertion of a feeding tube without the thickening agents for safe swallowing.

Coverage excludes:

- Routine cosmetic products (e.g., make-up base, aftershave, mascara, and similar products)

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Page 101

(Policy in force at time of action substantively identical to the above-cited policy)

A Medicaid beneficiary bears the burden of proving he or she was denied a medically necessary and appropriate service. See, e.g., *J.K By and Through R.K. v Dillenberg*, 836 F Supp 694, 700 (Ariz, 1993). Whether the Appellant satisfied that burden here must be determined in accord with the preponderance of the evidence standard. See, e.g., *Aquilina v General Motors Corp*, 403 Mich 206, 210; 267 NW2d 923 (1978).

Regarding an appeal filed with the State Office of Administrative Hearing and Rules for the Department of Community Health, the Administrative Law Judge is given ultimate discretion to determine the weight and credibility of the evidence presented. *Wiley v Henry Ford Cottage Hosp*, 257 Mich App 488, 491; 668 NW2d 402 (2003); *Zeeland Farm Services, Inc v JBL Enterprises, Inc*, 219 Mich App 190, 195; 555 NW2d 733 (1996) (the fact finder is provided with the unique opportunity to observe or listen to witnesses; and, it is the fact finder's responsibility to determine the credibility and weight of the testimony and other evidence provided).

Enhanced Pharmacy policy specifically covers vitamins and minerals when a beneficiary establishes that; (1) it is physician-ordered; (2) there is documented evidence the coverage is not available through Medicaid or other insurances; and (3) it is the most cost-effective alternative to meet the beneficiary's need.

A review of both policies leads me to conclude that the Appellant is entitled to coverage for the

vitamins and minerals that comprise her AM and PM compounded physician-ordered prescription dosages under the Enhanced Pharmacy policy. It is noteworthy that Enhanced Pharmacy policy language does not specifically exclude from coverage those vitamins and minerals that may be compounded; it simply covers vitamins and minerals, assuming all other conditions have been satisfied.

Enhanced Pharmacy policy specifically provides for coverage when there is documented evidence that vitamins and minerals are not otherwise available through State Plan Medicaid coverage. As the Appellant is not using the compounded vitamins for one of several listed purposes, she is not entitled to coverage under State Plan policy.

Here, the documented evidence of non-availability is the Medicaid Provider Manual itself, which rather clearly conditions coverage upon certain specific medical criterion, none of which the Appellant can satisfy.

Next, the Appellant's mother very credibly testified she is familiar with all of the articulated substances that comprise the Appellant's AM and PM vitamin/mineral regimen, and that they are all either vitamins and/or minerals or both. When questioned about how she acquired such knowledge, the Appellant's mother responded by asserting she has read a significant volume of material related to the Appellant's condition, and has become familiar with all of the medications, vitamins and minerals the Appellant is consuming.

The Appellant's mother also credibly testified that the Appellant has neither tolerated nor benefited from traditional medications. Evidence of the failure of traditional medications to help the Appellant was also echoed by her [redacted] physician. *(Exhibit 2)* Regarding cost-effectiveness, the Appellant's mother claims that vitamins and minerals should be covered, because they have been both effective in treating the Appellant's condition(s), and are less expensive than traditional medications that have been tried and failed.

The Department's witness(es) testified that compounded vitamins and minerals are not covered under the Pharmacy chapter of the MPM, because they are not being used for prenatal care, end stage renal disease or pediatric fluoride supplementation.

When I questioned the Department about why the vitamins and minerals that comprise the Appellant's AM and PM prescription appeared to be covered under Enhanced Pharmacy policy, the Department's witness(es) asserted that there was no "documented evidence" that the compounded vitamins and minerals were unavailable under Medicaid or other third party coverage.

Yet, when I highlighted that portion of the MPM limiting coverage of compounded vitamins and minerals for only certain uses, the Department insisted the MPM was not documented evidence. When asked to explain, the Department witness(es) asserted that policy requires "documented medical evidence" that coverage is unavailable through either Medicaid or other third party carriers.

Following clearly established Michigan precedent, I decline to read into this particular policy an intent that is otherwise unambiguous on its face. The primary goal of statutory interpretation is to

ascertain and give effect to the Legislature's intent as expressed by the language of the statute. *Neal v Wilkes*, 470 Mich 661, 665; 685 NW2d 648 (2004). Courts must give effect to every word, phrase, or clause in a statute and avoid an interpretation that renders nugatory or surplusage any part of a statute. *Koontz v Ameritech Services, Inc*, 466 Mich 304, 312; 645 NW2d 34 (2002). Provisions must be read in the context of the entire statute so as to produce a harmonious result. *People v Couzens*, 480 Mich 240, 249; 747 NW2d 849 (2008).

The Michigan Court of Appeals has recently held that a court may not read anything into clear statutory language that is not within the manifest intent of the Legislature as derived from the words of the statute itself. In *Georgette Mericka v Department of Community Health, et al*, 283 Mich App 29 (March 2009), the Michigan Court of Appeals, in reversing a lower court's affirmation of erroneous agency interpretation, held, in pertinent part, as follows:

> *"In affirming ALJ Snider's determination that petitioner possessed the "capacity for independent living" notwithstanding her physical inability to live independently, the trial court essentially imposed a limitation or restriction on the phrase "capacity for independent living" that is not included in the statute itself. The circuit court's and ALJ Snider's interpretation of the phrase "capacity for independent living" in § (21)(a)(iv)(F) precludes an individual who is mentally, but not physically, able to live independently from possessing a substantial functional limitation in the "capacity for independent living" area of major life activity. The error in such a construction is that the Legislature did not so limit the phrase "capacity for independent living."*
>
> *The word "mental" or "intellectual" does not appear before the provision "capacity for independent living." The Legislature could have imposed such a limitation, but it did not do so. In construing a statute, this Court will not read anything into clear statutory language that is not within the manifest intent of the Legislature as derived from the words of the statute itself. City of Warren v Detroit, 261 Mich App 165, 169; 680 NW2d 57 (2004).*
>
> *If the Legislature had intended to preclude an individual who is physically, but not mentally, incapable of living independently, from being considered as having a substantial functional limitation on his or her "capacity for independent living," it would have explicitly so indicated by including the term "mental" or "intellectual" before the phrase "capacity for independent living." We decline to read such a limitation into the statute when the Legislature did not include it in the statute itself."*
> 283 Mich App 29 (2009), at p. 38

Here, Enhanced Pharmacy policy requires only that there be documented evidence that vitamins and minerals are non-covered by Medicaid or other third party payors. Policy neither specifies the nature of documented evidence, nor does it specifically constrain the contents of any such documentation to a medical nature. I am not at liberty to ignore the clear meaning and import of unambiguous policy. *Mericka v DCH et al, supra.*

I conclude that the Appellant's B3 Enhanced Pharmacy benefit provides coverage for vitamins and minerals, regardless of whether they are compounded, when there is documented evidence that compounded vitamins and minerals would not otherwise be covered under the State Plan.

Here, compounded vitamins and minerals are unavailable to this beneficiary under the State Plan, because she is not using them for the indicated purposes. Thus, the record contains documented evidence of this fact.

The Appellant's mother credibly established that the Appellant's AM and PM prescription are compounded vitamins and/or minerals. Under the B3 Enhanced Pharmacy service, vitamins and minerals are covered, when, as here, they are otherwise unavailable under the State Plan, and the Appellant resides with family.

Department witnesses attempted to assert that the Appellant's vitamin and mineral combinations are not FDA-approved, and therefore not covered. While this may or may not be an accurate observation, this claim nonetheless cannot be accorded serious consideration for two basic reasons.

First, the Department articulated this theory at the time of hearing; it is not the basis under which the Department's action is based. Thus, it cannot be a proper basis upon which to affirm Department action. To do so would exact a violation of the Appellant's due process rights to notice and hearing.

Second, the Department produced no documented evidence the subject vitamins and minerals were not FDA-approved. Additionally, both State Plan and Enhanced Pharmacy policy covers "vitamins and minerals". The Department's claim that the Appellant's compounded vitamins and minerals are not FDA-approved is therefore disingenuous, and unsupported by substantial evidence.

The record contains no evidence of whether traditional medications are more or less expensive than vitamins and/or minerals. However, the Appellant's mother presented evidence that traditional medications have failed, and that vitamins and/or minerals, when compounded, may be less expensive than traditional medications and therefore more cost-effective. The Department's witnesses failed to challenge this assertion whatsoever. Nor could the Department respond to questions regarding what alternative treatments may be more or less cost-effective in treating the Appellant's disability.

Based on a preponderance of the evidence presented, I conclude the Appellant has demonstrated entitlement to coverage for compounded vitamins and/or minerals under her B3 Enhanced Pharmacy benefit. Accordingly, the Department's removal of compounded vitamins and minerals is in error.

DECISION AND ORDER

Based on the above findings of fact and conclusions of law, I decide that the Department's reduction in Enhanced Pharmacy service to reflect removal of compounded vitamins and minerals is inappropriate, as in violation of Enhanced Pharmacy policy.

IT IS THEREFORE ORDERED that:

The Department's decision is REVERSED.

[redacted]
Docket No. 2009-23209 CMH
Decision and Order

Stephen B. Goldstein
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 7/23/2009

***** 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.