STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

MARIANNE FAHLE,	)	
	)	
Petitioner,	)	
	)	
vs.	)	Case No. 02-3116
	)	
DEPARTMENT OF MANAGEMENT SERVICES, DIVISION OF STATE GROUP INSURANCE,	)	
	)	
Respondent.	)	
	)	

RECOMMENDED ORDER

Pursuant to notice, a formal hearing was conducted in this case on October 18, 2002, in Tampa and Tallahassee, Florida, via video teleconference, before Lawrence P. Stevenson, a duly-designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Marianne Fahle, pro se
12205 North Marjory Avenue
Tampa, Florida 33612

For Respondent: Julia P. Forrester, Esquire
Department of Management Services
4050 Esplanade Way, Suite 260
Tallahassee, Florida 32399-0950

STATEMENT OF THE ISSUE

The issue presented for decision in this case is whether the Department of Management Services properly denied medical insurance reimbursement to Marianne Fahle for EDTA chelation therapy services provided to her husband, John Fahle.

PRELIMINARY STATEMENT

By letter dated July 17, 2002, the Department of Management Services, Division of State Group Insurance (the "Department") notified Petitioner, Marianne Fahle, that it concurred with a prior decision by its servicing agent, Blue Cross Blue Shield of Florida, to deny claims for EDTA chelation therapy for her husband, John Fahle. The Department's letter stated that the state group insurance plan denied coverage because EDTA chelation therapy is considered "experimental or investigational" as those terms are employed by the "State Employees' PPO Plan Group Health Insurance Plan Booklet and Benefit Document." By letter dated July 30, 2002, Petitioner requested a formal administrative hearing to contest the denial of benefits. On August 7, 2002, the Department forwarded the case to the Division of Administrative Hearings for assignment of an Administrative Law Judge and the conduct of a formal administrative hearing. The case was scheduled for hearing via video teleconference on October 18, 2002. The hearing was held on that date.

At the formal hearing, Petitioner testified on her own behalf and presented the testimony of Dr. Carol Roberts. Petitioner's Exhibits 1 through 12 were admitted into evidence. The Department presented the testimony of Dr. William Wood, an expert in the practice of medicine and the evaluation of emerging medical technologies. The Department's Exhibits A through E were admitted into evidence.

No transcript was provided. Both parties timely filed proposed recommended orders.

FINDINGS OF FACT

Based on the oral and documentary evidence adduced at the final hearing, and the entire record in this proceeding, the following findings of fact are made:

1. Marianne Fahle is a retired employee of the State of Florida. At all times pertinent to this case, Marianne Fahle was a participant in the State of Florida group health insurance plan. Her husband, John Fahle, is a covered dependent.

2. The state group insurance program is a self-insured health insurance plan administered for the State of Florida for its employees by Blue Cross Blue Shield of Florida ("BCBSF").

3. In August 2000, John Fahle was hospitalized after he collapsed at his home. Medical tests revealed that Mr. Fahle suffered from arteriosclerosis with an estimated 60-80% stenosis, or blockage, of his carotid artery.

4. Rather than undergo surgery to relieve the blockage, Mr. Fahle chose a course of treatment commonly called EDTA chelation therapy. Chelation therapy involves the intravenous injection of ethylene-diamine-tetra acetic acid (edetic acid or EDTA) accompanied by nutritional supplements.

5. After undergoing chelation therapy, Mr. Fahle's diagnostic tests were repeated, with reported results indicating some reduction of the blockage in his coronary artery and a reduction of the carotid artery blockage to 40-60 percent. The actual tests, as opposed to the physicians' reports of their results, were not offered as evidence. The weight of the evidence established that the reported improvement in Mr. Fahle's carotid artery blockage, from a 60-80 percent blockage to a 40-60 percent blockage, could be attributed to the subjectivity involved in reading the results of the diagnostic tests. In any event, the reported improvement was of little medical significance.

6. Chelation therapy is generally accepted in the medical community as a safe and efficacious treatment for heavy metal toxicity, e.g., lead poisoning. The United States Food and Drug Administration ("FDA") approved EDTA as a lawfully marketed drug in 1953. The FDA cannot limit the manner in which a licensed physician may prescribe an approved drug, though it can place limits on the marketing representations that may be made as to

the efficaciousness of a drug for certain uses. The FDA has approved the marketing of EDTA as a treatment for heavy metal poisoning. The FDA prohibits any person from representing that chelation therapy is a safe and efficacious treatment for arteriosclerosis, though a physician may lawfully treat arteriosclerosis with chelation therapy.

7. Petitioner submitted several articles attesting to the value of chelation therapy in treating arteriosclerosis. A significant minority of physicians in the United States employs chelation therapy as an option in the treatment of arteriosclerosis. However, reliable, formal clinical trials have yet to establish the efficacy of chelation therapy as a standard treatment for arteriosclerosis. The strength of the anecdotal evidence and the persistent advocacy of physicians have led the National Institute of Health to begin clinical trials on the use of chelation therapy in the treatment of arteriosclerosis, but the results of these trials will not be available for five years.

8. In any event, Mr. Fahle's coverage is determined by the terms of Ms. Fahle's insurance policy. The terms of coverage for the state group health insurance plan are set forth in a document titled, "State Employees' PPO Plan Group Health Insurance Plan Booklet and Benefit Document." The benefit document states, in pertinent part:

> Services Not Covered By The Plan
>
> The following services and supplies are excluded from coverage under this health insurance plan unless a specific exception is noted. Exceptions may be subject to certain coverage limitations.
>
> * * *
>
> 47. Services and procedures considered by BCBSF to be experimental or investigational, or services and procedures not in accordance with generally accepted professional medical standards, including complications resulting from these non-covered services.

9. The benefit document defines "experimental or investigational services" as follows:

> [A]ny evaluation, treatment, therapy or device that:
>
> * cannot be lawfully marketed without approval of the US Food and Drug Administration or the Florida Department of Health if approval for marketing has not been given at the time the service has been provided to the covered person
>
> * is the subject of ongoing Phase I or II clinical investigation, or the experimental or research arm of Phase III clinical investigation-- or is under study to determine the maximum dosage, toxicity, safety or efficacy, or to determine the efficacy compared to standard treatment for the condition
>
> * is generally regarded by experts as requiring more study to determine maximum dosage, toxicity, safety or efficacy, or to determine the efficacy compared to standard treatment for the condition

> * has not been proven safe and effective for treatment of the condition based on the most recently published medical literature of the US, Canada or Great Britain using generally accepted scientific, medical or public health methodologies or statistical practices
>
> * is not accepted in consensus by practicing doctors as safe and effective for the condition
>
> * is not regularly used by practicing doctors to treat patients with the same or similar condition
>
> BCBSF and [the Department] determine whether a service or supply is experimental or investigational.

10. The benefit document is not explicit as to whether the elements of the quoted definition are to be considered in the disjunctive, but the plain sense of the document leads to the reading that if any one of the definitional elements applies, then the service or supply must be considered experimental or investigational. Dr. William Wood, BCBSF's medical director, confirmed that if any single element of the definition applies to a service or supply, then it is considered experimental or investigational.

11. Chelation therapy would fall under every element of the definition except, arguably, the last element dealing with regular use by practicing physicians. The FDA does not allow chelation therapy to be marketed as a treatment for

arteriosclerosis, chelation therapy is currently the subject of clinical trials, and it is not accepted "in consensus" by practicing physicians as a treatment for arteriosclerosis.

CONCLUSIONS OF LAW

12. The Division of Administrative Hearings has jurisdiction over the parties and subject matter of this proceeding pursuant to Section 120.57(1), Florida Statutes.

13. Exclusions from coverage in insurance policies are to be strictly construed against the insurer. Comprehensive Health Association v. Carmichael, 706 So. 2d 319, 320 (Fla. 4th DCA 1997).

14. In this case, the policy exclusion is plainly written and clearly applies to chelation therapy. The Department correctly upheld the determination by BCBSF that chelation therapy is an experimental or investigational service and is thus not reimbursable under the state group health insurance plan.

RECOMMENDATION

Upon the foregoing findings of fact and conclusions of law, it is recommended that the Department of Management Services enter a Final Order dismissing the petition of Marianne Fahle.

DONE AND ENTERED this 2nd day of December, 2002, in Tallahassee, Leon County, Florida.

LAWRENCE P. STEVENSON
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 2nd day of December, 2002.

COPIES FURNISHED:

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this recommended order. Any exceptions to this recommended order should be filed with the agency that will issue the final order in this case.