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January 27, 2005

David Marcarian
2801 First Avenue
Suite 1211
Seattle, Washington, 98121

Re: Richard W. Merritt, D.C. vs.
State of Florida, Department of Health
64B-3.004 Rule Challenge

Dear David:

Pursuant to your request, the following is a synopsis of the above referenced case:

During the 2003 legislative session, the Florida Legislature enacted Section 627.736(5)(b)6., Florida Statutes. Section 627.736, F.S. is part of the "Florida Motor Vehicle No-Fault Law," and includes PIP coverage. PIP is "personal injury protection" insurance which must be carried by every motorist in Florida as no-fault insurance in the amount of \$10,000, and is, by law, "personal injury protection to the named insured, relatives residing in the same household, persons operating the insured motor vehicle, passengers in such motor vehicle, and other persons struck by such motor vehicle and suffering bodily injury while not an occupant of a self-propelled vehicle . . . , to a limit of \$10,000 for loss sustained by any such person as a result of bodily injury, sickness, disease, or death arising out of the ownership, maintenance, or use of a motor vehicle" The 2003 enactment of Section 627.736(5)(b)6. was ostensibly designed to combat fraud and abuse in the PIP insurance program, and provides, in its entirety, that:

The Department of Health, in consultation with the appropriate professional licensing boards, shall adopt, by rule, **a list of diagnostic tests deemed not to be medically necessary for use in the treatment of persons sustaining bodily injury covered by personal injury protection benefits** under this section. The initial list shall be adopted by January 1, 2004, and shall be revised from time to time as determined by the Department of Health, in consultation with the respective professional licensing boards. **Inclusion of a test on the list of invalid diagnostic tests shall be based on lack of demonstrated medical value and a level of general acceptance by the relevant provider community and shall**

not be dependent for results entirely upon subjective patient response. Notwithstanding its inclusion on a fee schedule in this subsection, an insurer or insured is not required to pay any charges or reimburse claims for any invalid diagnostic test as determined by the Department of Health. (e.s.)

In order to implement the statute, the DOH approached the insurance industry for a list of tests that it believed to have no medical value. The first list did not include SEMG, but did include Nerve Conduction Velocity (NCV) Studies. After a public workshop, SEMG was added and NCV was removed from the list, and the rule went forward. The rule was adopted effective January 7, 2004 as Rule 64B-3.004, Florida Administrative Code, and provided, in its entirety, that:

64B-3.004 Diagnostic Testing.

For the purposes of Section 627.736(5)(b)6., F.S. (2003), the Department of Health, in consultation with the appropriate licensing boards, hereby adopts the following list of diagnostic tests based on their demonstrated medical value and level of general acceptance by the provider community:

(1) Spinal ultrasound, also known as sonography, ultrasonography, and echography, is deemed not to be medically necessary for use in the diagnosis and treatment of persons sustaining bodily injury covered by personal injury protection benefits.

(2) Surface EMG is deemed not to be medically necessary for use in the diagnosis of persons sustaining bodily injury covered by personal injury protection benefits.

(3) Somatosensory Evoked Potential is deemed not to be medically necessary for use in the diagnosis of radiculopathy or distal nerve entrapment when treating persons sustaining bodily injury covered by personal injury protection benefits.

(4) Dermatomal Evoked Potential is deemed not to be medically necessary for use in the diagnosis and treatment of persons sustaining bodily injury covered by personal injury protection benefits.

Specific Authority 627.736(5) FS. Law Implemented 627.736(5) FS. History - New 1-7-04.

On April 2, 2004, a petition to challenge the rule was filed with the Florida Division of Administrative Hearings on Dr. Merritt's behalf by Bill Furlow and Jim DuRant of the Akerman Senterfitt lawfirm in Tallahassee, Florida. The Division of Administrative Hearings is an autonomous entity of state government that is charged with handling appeals and challenges to all

forms of agency action statewide. The DOAH consists of 36 Administrative Law Judges, each of whom have the same degree of qualification as a circuit court judge.

The petition challenged the inclusion of all four tests on the list. The case was assigned to Administrative Law Judge Diane Cleavinger. Judge Cleavinger is one of the more experienced ALJs at the Division. The Department of Health filed its appearance in the case, counsel for the DOH being Thomas D. Koch (pronounced "cook") and Lucy Schneider. The case was set for hearing on April 26 and 27, 2004.

On April 14, 2004, the DOH requested that the hearing be continued. The basis for the motion was the pending intervention into the case by various members of the insurance industry who believed that they were affected by the rule. The continuance was granted, and the hearing was rescheduled for July 19 and 20, 2004.

On April 29, 2004, the following groups and companies filed their petition to intervene in the case on the side of the DOH:

The Florida Insurance Council, Inc.
The Property Casualty Insurers Association of America
The American Insurance Association
The National Association of Mutual Insurance Companies
The Florida Automobile Joint Underwriting Association
State Farm Mutual Automobile Insurance Company
Allstate Insurance Company
Government Employees Insurance Company
The Florida Farm Bureau Insurance Companies
Liberty Mutual Insurance Group
First Floridian Auto and Home Insurance Company
United Services Automobile Association

The insurance industry was represented by Cynthia S. Tunnicliff and Brian A. Newman of the Tallahassee law firm of Pennington, Moore, Wilkinson, Bell & Dunbar, P.A. and Fernando L. Roig of the Deerfield Beach law firm Roig, Kasperovich & Tutan. Ms. Tunnicliff is well regarded as an administrative practitioner, while Mr. Roig's practice focuses on insurance defense.

Dr. Merritt's counsel at the time, the Akerman Senterfitt law firm, represents a number of insurers in Florida. When the insurance interests intervened, the Akerman firm discovered that there was a conflict that prevented its further representation of Dr. Merritt. Therefore, Bill Furlow and Jim DuRant were compelled to withdraw as counsel for Dr. Merritt. The notice of withdrawal was filed on April 10, 2004, and granted by the Administrative Law Judge on April 14, 2004. My firm was

approached to represent Dr. Merritt, and after reviewing the file and discussing the matter with Dr. Merritt, Tico Gimbel and I joined the fray on April 21, 2004.

After a good bit of discovery, and numerous discussions with Dr. Merritt, we decided that it would be best to focus attention on the provision of the rule that listed SEMG as not medically necessary, and to forego challenging the other three tests. Dr. Merritt did not use the other tests, and there was no reason to confuse the real issue of interest to Dr. Merritt. Therefore, on June 7, 2004, the rule challenge petition was amended to challenge only the inclusion of SEMG on the list.

The basis for the challenge to the rule (as is the case with any challenge to a rule) was that the rule was an "invalid exercise of delegated legislative authority." To show that a rule is an "invalid exercise of delegated legislative authority," a challenger must show that the rule meets one of the elements in the statutory definition of the term. The term is defined in Section 120.52, Florida Statutes, as follows:

(8) "Invalid exercise of delegated legislative authority" means action which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:

(a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;

(b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;

(c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

(d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;

(e) The rule is arbitrary or capricious;

(f) The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the same statute.

Our approach to the challenge was to attack it on the basis that the rule was facially contrary to the statute and on the basis that SEMG was, as a factual matter, medically necessary as defined by the statute. Thus, our focus was on subsection (b) (the DOH exceeded its grant of rulemaking authority), subsection (c) (the rule enlarged, modified, or contravened the specific provisions of law implemented), and subsection (e) (the rule was arbitrary or capricious).

Testifying at the hearing in opposition to the rule were Dr. Mark Rubenstein (qualified as an expert witness in electrodiagnostic medicine, physical medicine and rehabilitative medicine, pain management, pain medicine and surface electromyography), a physiatrist practicing in West Palm Beach, and Dr. Gene Jenkins (qualified as an expert witness in chiropractic medicine including treatment of persons bodily injured in automobile accidents) a Tallahassee chiropractor who is on the board of the Florida Board of Chiropractic Medicine, who both testified that SEMG was not medically necessary and had little value in diagnosing injury of the type caused by vehicular accidents. Dr. Jenkins also testified that SEMG was not widely accepted in the chiropractic community. In addition, Larry MacPherson, an attorney who currently serves as the Executive Director of the DOH Board of Medicine, was called to testify as to the rulemaking process. Each of those three witnesses were called by the Department of Health. The Interveners called Vince Rio, counsel for Florida for State Farm Insurance Companies, who testified as to the history of the PIP program, and the legislative intent of the enactment of Section 627.736(5)(b)6., Florida Statutes.

Testifying in support of the rule were David Marcarian (qualified as an expert witness in the principles of SEMG), and Dr. Richard Merritt (qualified as an expert witness in chiropractic medicine and surface electromyography). Both Mr. Marcarian and Dr. Merritt testified as to the principles of SEMG, how it works, its usage in identifying and diagnosing injury commonly encountered in vehicular accidents, and its use in the chiropractic field.

As to the legal argument, Section 627.736(5)(b)6., Florida Statutes, authorized the DOH to develop “a list of diagnostic tests deemed not to be medically necessary for use in the treatment of persons sustaining bodily injury covered by personal injury protection benefits.” However, SEMG was included in the Rule because it was “deemed not to be medically necessary for use in the diagnosis of persons sustaining bodily injury covered by personal injury protection benefits.” We argued that since treatment and diagnosis describe different things, and since the DOH admitted that SEMG had some medical value when used for treatment, the rule was, on its face, invalid. Judge Cleavinger disagreed, ruling that treatment could include some elements of diagnosis. However, given her rulings on the factual issues, it was in Dr. Merritt’s long term benefit that she didn’t find the legal question to be determinative.

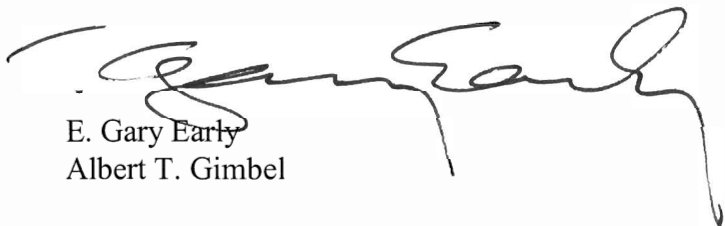
As to the factual arguments, Judge Cleavinger found that SEMG had demonstrated medical value, a level of general acceptance by the relevant provider community, and was not dependent for results entirely upon subjective patient response. Thus, it was error for the DOH to include SEMG in the rule. Her findings were based primarily on published studies and journal articles, the Chiropractic Practice Guidelines and Parameters for the State of Florida, and the inclusion of SEMG in the CPT codes.

As a result of the foregoing, Judge Cleavinger entered a Final Order on January 25, 2005 in which she struck down the rule as an invalid exercise of the DOH’s delegated legislative authority. Although the DOH can, within 30 days of the entry of the Final Order, appeal the order to the Florida District Court of Appeal, I would be surprised, given the extent of her factual findings, if any party chooses to do so.

The effect of the invalidation of Rule 64B-3.004, Florida Administrative Code is that PIP insurers can no longer use the rule as a basis for denying reimbursement of charges for SEMG. It does not affect other bases for denial of a claim, e.g., overutilization.

We hope this has provided you with an overview of the history of the litigation regarding Rule 64B-3.004, Florida Administrative Code as it relates to surface electromyography. Please let us know if you need additional information.

Sincerely,



E. Gary Early
Albert T. Gimbel