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Texas House of Representatives
Committee on Business & Industry

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December 23, 2010

The Honorable Greg Abbott
Attorney General of Texas
P.O. Box 12548
Austin, TX 78711-2548

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OPINION COMMITTEE

FILE # ML-46651-11
I.D. # 46651

RQ-0938-GA

Dear Mr. Attorney General,

As Chairman of the House Committee on Business and Industry, my fellow committee members and I have worked diligently to serve the people of our great state by promoting innovative solutions. It is in this spirit that I am writing you today.

It is the intent of this letter to seek your opinion on whether or not the analysis of quantitative information gathered by machine, the TEG5000, constitutes the practice of medicine. The ultimate goal is to determine whether the data analysis must be performed by a licensed medical professional.

Ngine is a company which is designed to and currently provides data analysis and consultation for the TEG5000, a whole blood coagulation monitor. This device is designed to assist doctors and other medical staff in assessing whether a patient is prone to blood clotting, excessive bleeding, diabetes, and other such ailments.

The issue in question is whether the receipt of the TEG5000 tracing results and providing assessment and data readings to the client hospitals will constitute the practice of medicine as defined by Section 151.002(13) of the Occupations Code.

Enclosed is additional information sheet. I look forward to working with you on this matter. If you require any additional information, please do not hesitate to contact me at the above listed numbers.

Sincerely,

Joe Deshotel
Chairman

House Committee on Business and Industry

Background information - Scope of monitoring service provided by Ngine

TEG5000 is a point-of-care whole blood coagulation monitor that is designed to indicate whether a patient will experience excessive bleeding or clotting. Specifically, the TEG5000 analyzer allows acquisition of continuous quantitative information on the developing clot, including the time it takes for the first fibrin to develop, the kinetics of clot development, and the strength and stability of the clot. TEG5000 will determine whether a bleed is due to surgical, coagulopathy, or residual anticoagulation therapy. If the patient has a coagulopathy, the TEG5000 results will identify the specific therapy to treat it, whether it is medications or blood products.

Ngine will contract with hospitals across the country to receive the TEG5000 data from individual patients via the Internet. The service to be provided by Ngine will be to read and assess the test results from the TEG5000.

1. Ngine will not be involved in direct patient care at the bedside.
2. Ngine will not have any direct communication with the patient.
3. Ngine will not use the information to provide any diagnosis or any recommended course of treatment for the patient.
4. Ngine personnel will not be collecting, obtaining, transporting or storing blood samples for analysis. These responsibilities will belong to the health care providers at the point of care where the test is being performed.
5. Ngine personnel will electronically receive and monitor the TEG5000 tracing results from a remote location, not at the point of care. Applied Critical Care Sciences (ACCS) personnel will apply algorithms to the tracing results and communicate the outcome to the ordering health care provider(s) at the point of care for clinical interpretation and application of results to the patient's care.
6. Ngine personnel will not perform clinical interpretation of the results.
7. Ngine will not provide any orders or recommendations regarding the course of treatment.

Issue to be determined – Does the service provided constitute the practice of medicine?

The issue to be determined is whether the receipt of the TEG5000 tracing results and providing assessment and readings to the client hospitals will constitute the practice of medicine as that term is defined by Section 151.002(13) of the Occupations Code. The Code defines the practice of medicine as follows:

13) "Practicing medicine" means the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions by a person who:

- (A) publicly professes to be a physician or surgeon; or
- (B) directly or indirectly charges money or other compensation for those services.