

From: [Sunset Advisory Commission](#)
To: [Janet Wood](#)
Subject: FW: Form submission from: Public Input Form for Agencies Under Review (Public/After Publication)
Date: Monday, June 23, 2014 3:10:40 PM

-----Original Message-----

From: sundrupal@capitol.local [<mailto:sundrupal@capitol.local>]
Sent: Monday, June 23, 2014 1:45 PM
To: Sunset Advisory Commission
Subject: Form submission from: Public Input Form for Agencies Under Review (Public/After Publication)

Submitted on Monday, June 23, 2014 - 13:45

Agency: DEPARTMENT STATE HEALTH SERVICES DSHS

First Name: Dennis

Last Name: Biggan

Title: Perfusionist

Organization you are affiliated with: Licensed Perfusionist

City: Austin

State: Texas

Your Comments About the Staff Report, Including Recommendations Supported or Opposed:

To: Sunset Advisory Committee for The State of Texas

Re: De- Regulation of Perfusionist Licensure

Madams/Sirs:

I am currently a licensed perfusionist in the State of Texas, with thirty-three years of clinical experience. During that time I have worked in five major metropolitan areas within the state of Texas, and currently help manage a contract perfusion company servicing most of the hospitals in the Austin metropolitan area.

It has come to my attention that the committee wishes to do away with regulation and licensure for perfusionists. This decision comes as a surprise. I can only ascertain that its members clearly do not understand the hands-on skills and the need for split second decision-making abilities required of a clinical perfusionist. There are approximately three-hundred-sixty of us in the state. Whereas we represent a small constituency of the total number of allied health care professionals, our job is extremely important. Failure to license and regulate those individuals who work in this field could result in potential patient safety issues.

A perfusionists primary job is the operation of the heart-lung machine used in open heart surgery. The heart-lung machine is a complex device that is used when patients require their heart to be stopped in order to be repaired (ie. coronary bypass surgery, valve surgery...). In that state, the anesthesiologist is unable to breath for the patient. The patients circulation is re-routed to the heart-lung machine prior to entry to the heart, where it is oxygenated and

carbon dioxide is removed from the blood.

The blood is also cooled and warmed as required for the particular procedure in order to maintain a specific body temperature. That blood is then returned to the on the other side of the heart and pumped to the body. Hence the term cardiopulmonary bypass, where blood bypasses the heart and lungs. Consider the requirement for a heart transplant or heart-lung transplant, where those organs are completely removed from the body prior to their replacement by donor organs. Without some controlled mechanism to sustain the circulatory system, one would die.

Many times services are needed in an emergent situation. Take the example of a patient undergoing CPR in a cardiac cath lab. A cardiac surgeon and a perfusionist may be called to emergently initiate cardiopulmonary bypass.

There are many things that have to happen in a timely and specific order.

During that time period, whereas the perfusionist is under the supervision of a physician, he or she must make independent decisions in order to make that maneuver happen. Without a skilled perfusionist, that life saving event may not occur. Yet, within the last year, I heard a cardiologist in a cath lab say, "I didn't know we could do this", after we had just placed his patient emergently on bypass. His patient successfully left the hospital.

With respect to other licensed individuals, being a perfusionist is not cutting hair or rubbing sore muscles. The proper or improper use of our skills, knowledge base, or lack of, may result in life or death.

In addition to the operation of the heart-lung machine, perfusionists operate autotransfusion equipment for the salvage and return of a patient's own blood in open-heart, trauma and other surgeries involving significant blood loss. Many perfusionists are involved in the operation of an increasing number of ventricular assist devices and are recognized as the clinical expert in extra-corporeal membrane oxygenation (ECMO).

The Sunset Committee suggests several points for the deregulation of perfusionist licensure.

- "Would deregulation have little impact on patient safety?" This was the whole purpose for perfusionist licensure. Whereas, there is a national certification for perfusionists, there is no vehicle in place to require a hospital to use a certified perfusionist. There are some very skilled perfusionists in the state who have practiced for many years, that were trained "on the job" many years ago, who are unable to receive national certification. Whereas on-the-job may have been more common thirty to forty years ago, it is not the standard in perfusion today. Prior to licensure, non-certified perfusionists had no requirement to maintain satisfactory clinical activity as well as continuing education. Perfusionist licensure requires all perfusionists in the State of Texas to maintain clinical skills and competency by performing a specific number of cases and maintaining continuing education credits. Rescission of the licensure law would negate that requirement and could enable "on-the-job" training of perfusionists.
- "Do Practitioners operate in a highly regulated environment?" For the most part, perfusionists work under the direct supervision of the cardiac surgeon and anesthesiologist in the operating room. That said, in many emergent and non/emergent situations, perfusionists are required to make independent decisions and perform tasks while the surgeon and the anesthesiologist are taking care of their aspect of patient care. There are new and evolving arenas where perfusionists are becoming involved both in and out of the operating room (such as ECMO and operation of various ventricular assist devices, where judgment, expertise and clinical knowledge of a perfusionist may work to enhance the particular knowledge base of the physician involved. Within the last year or so, I had a physician working in the intensive care unit tell me that his patient would have died, had our perfusionist not been standing their to act appropriately during an equipment malfunction. An experienced cardiac surgeon and/or a cardiac anesthesiologist would vouch for the requirement with regard to judgment and experience of a sound perfusionist.
- "Is regulation also provided by another state or local regulatory program, or private sector accreditation?" There is no other state or local regulatory program accrediting perfusionists. The body is the American Board of Cardiovascular Perfusion. There is a national certification granted after graduation from an accredited perfusion program, clinical practice following training and a two-part exam specific to didactic and clinical information and practice. However, there is no requirement for a facility to require certification of a perfusionist.
- "Does the program generate little regulatory activity?" To the best of my knowledge, the original "Board of Perfusion Examiners" defined with the creation of perfusion licensure for the State of Texas in 1995 did have some regulatory activity with regard to the revocation of at least one license for a perfusionist working outside of the defined scope of practice.

In 2005 the Sunset Committee made a change to the Board to an Advisory Board consisting of two perfusionists and a cardiac surgeon. I personally acted on that board. During my six year tenure, several situations regarding the interpretation of perfusionist scope of practice were sent our way for discussion. The fact that perfusionists are not having problems should not be considered an issue. It may actually be a result of more defined practice standards as described in and required by the Licensed Perfusionist Act.

- “Can consumers access enough information to make informed choices regarding this industry or field?” In reality, there are less than four thousand perfusionists in the United States and Canada. Texas is the most populous state for perfusionists, with approximately 365 licensed. There is a National Certification Body (The American Board of Cardiovascular Perfusion which is responsible for provision of a two part certification exam), several national professional organizations (The American Society of Extra-Corporeal Technology and the American Academy of Perfusion Technology which are partially responsible for meetings and continuing education) as well as a number of state and regional perfusion organizations, and several clinical publications. Public information outside of those references is limited. It should be noted that Society of Thoracic Surgeons receives and adheres to recommendations regarding perfusion practice suggested by the afore mentioned organizations. There are instances where perfusion practice does come into the public eye. During the flu epidemic here in Austin last fall, there was quite a bit of information disseminated in the press regarding the H1N1 virus and its treatment with ECMO utilizing perfusionists.

Multiple patients were successfully transported to and from facilities while on bypass over a four month period, enabling 24/7 support and treatment. It was perfusionists who were responsible for the procurement, operation and maintenance of those machines. During that time period, many clinical decisions were made with the advice of the perfusionists involved. This demonstrates just one small area of which perfusionists are involved in clinical practice.

Considering the nature and importance of our profession, it is not uncommon for most of the personnel in a hospital, to include physicians and registered nurses to have even heard of a perfusionist, much less understand the importance, value and clinical significance of one. Due to the nature of our work, we are required to carry much higher levels of liability insurance than most other allied health care professionals, to include registered nurses. Our attention to detail for evolving procedures and operation of multiple pieces of complex equipment requires an increasing level of education and clinical expertise. With less than 20 accredited perfusion education programs in the United States, half of them have developed into Masters Prepared Programs. The trend for perfusion education is in that direction.

The State of Texas was the first state to license a perfusionist with approximately 18 other states having licensure and several others moving in that direction. The purpose of that process was to protect the public from unqualified personnel through the requirements specific to education, clinical practice and continuing education. I believe the proposal to de-regulate perfusionists by rescission of perfusionist licensure has been made without understanding the facts and complexities of this vital profession. The procurement of more information is paramount to the understanding of the need for licensure as a standard for patient safety. I would advise the committee to seek information from perfusionists, cardiac surgeons and cardiac anesthesiologists before making decisions that could affect patient safety in open-heart surgery and related practices in this state. I would be happy to provide a much more detailed picture of what a perfusionist actually does. Please feel free to contact me.

Please note, as stated previously, we as a group are in small numbers. Many cities have as few as two to three perfusionists, if any, in their city to perform their duties. With regard to the public hearings on June 24 and 25, our representation may be limited, as we do not always have the luxury to abandon patients in order to attend public forums. As stated above, I (we) would be glad to entertain any questions regarding our profession.

Sincerely,

Dennis P. Biggan LP, CCP
President
Capital Area Perfusionists, Inc.

Any Alternative or New Recommendations on This Agency: It is imperative as a public safety issue that perfusionist

licensure must be upheld

My Comment Will Be Made Public: I agree