



AMERICAN SOCIETY OF EXTRACORPOREAL TECHNOLOGY

AmSECT Today March-April 2011

The Licensing Role In Perfusion Responsibilities

Mike Troike, LP, CCP, Chairman

Government Relations Committee

Lee Bechtel, Director of Government Relations

It is universally accepted that two forms of state legal credentialing - Certification and Licensure - of a medical profession are the only ways to ensure that the practice of a profession can be protected from actions that gradually or stealthily take away clinical practice responsibilities. Among these, Licensure is the most secure level to guarantee that a perfusionist's clinical responsibilities are not reassigned to a non-perfusion professional, other than a surgeon. Why is this, and what are circumstances under which a perfusionist's clinical responsibilities can be open to interpretation and reassignment via internal hospital protocols?

State certification is different from ABCP certification. State certification requires a state agency to grant professional status to persons meeting specific minimum entry to practice standards. These may include, for example, being a graduate of an accredited training program, passing a professional certification examination, and doing continuing education. State certified persons can use the professional title, e.g. Perfusionist. Non-certified persons are not restricted from performing the certified medical services but they cannot legally hold themselves out as being a certified practitioner. The Certification legal credential allows for enforcement of the law and grants some professional practice protection, but generally does not specify specific medical responsibilities as being practice protected.

Licensure is the best method to guarantee that a perfusionist's clinical responsibilities are not gradually or stealthily taken away in the hospital setting, especially when it comes to services outside of the operating room. Extensive AmSECT membership survey data has found that perfusionists ranked protecting their scope of practice responsibilities as the most important or very important concern to them. The model AmSECT perfusionist licensing legislative language and model regulation language includes a perfusionist medical scope of practice, as developed and revised by the Government Relations Committee over the past fifteen years. All medical professions licensure laws have scopes of practice specifying what a practitioner of a profession can do and, in turn, what cannot be done by others without a license for a profession. Some practice acts and responsibilities are more broadly defined than others, such as nursing and physicians and surgeons. These responsibilities are specified in statutory law and in state administrative/regulatory laws. When two licensed professions have overlapping responsibilities, it is not a violation of law for one to perform responsibilities of the other licensed profession. It is a violation to do the responsibilities of a licensed professional when a person is not licensed in that profession, or is licensed but has no specialized education, training, nor experience in the other licensed profession. It is a

punishable offense to engage in the practice of medicine without a license, or to engage in licensed functions and tasks that are beyond the scope of practice for which a license has been granted by a state.

Hospitals are licensed and regulated by states. As such, hospital staff protocols and assignment of responsibilities must be in compliance with other applicable state laws. In other words, they must hire a licensed surgeon to do surgery, whether it is general surgery or a specialized form of surgery. Without state licensing, there is no state sanctioned and recognized scope of practice protection for a perfusionist's clinical responsibilities, inside or outside of the operating room. ABCP certification is recognized by internal hospital credentialing, but it is more important for establishing a state mandated minimum entry to practice perfusion requirement. Non-certified perfusionists cannot legally obtain a license granting practice privileges in a state. There are "grandfathering" exceptions that apply when licensing is first implemented in a state. And, a license granted in one state can be transferred to another licensed state. Transferring a license to a state that does not license perfusionists cannot be done since no state authority exists to recognize the licensed status of a perfusionist in the non-licensed state. Listing it in the internal hospital credentialing form looks good, but it carries no practice responsibility protection in the state.

In licensed states, hospital clinical responsibilities are supposed to follow what is specified in a perfusion practice act. If not, perfusionists have the ability to challenge the right of hospital administrative personnel to reassign perfusion responsibilities to a different licensed profession, nurses for example, or to another allied health profession that is non-credentialed to perform perfusion services. There are exceptions, but at least a perfusionist has a say in the decision making process. The situation is reversed in non-licensed perfusionist states. Without state recognition, a hospital has no legal requirement to comply with a perfusion practice act. In non-licensed perfusion states, hospital administration and operating room supervisors are free to do whatever they want with regard to the non-licensed allied health professionals under their employment, as long as they have appropriate training. There is generally no question about who will run the pump in the operating room, but there are other associated perfusion responsibilities that can apply and are not protected in non-licensed states. In non-licensed states, a perfusionist has no state recognized standing upon which to challenge any decisions that are made.

The cardiovascular surgical field of medicine has and will continue to evolve to keep abreast of new medical practice procedures, and technological changes in perfusion medical devices. These are forces driven by research and the medical device marketplace. On the other hand, according to studies done by the National Council of State Legislatures, the non-physician allied health care providers of nurses, physician assistants, respiratory care, and medical technologists, among others, have all sought to convince state legislators to expand their respective medical scope of practice privileges. All three of these health care system delivery influences exist and will continue to come into play for years to come.

In the medical device marketplace, to use one example, miniaturized integrated pump oxygenators, or “portable extracorporeal blood oxygenation devices” for cardiac and/or pulmonary support, are not new as a bridge for corrective surgery. There are both short and longer-term use applications that have provided life saving support for millions of people. Bridge treatment for respiratory failure includes mechanical ventilation and extracorporeal membrane oxygenation (ECMO). Integrated pump-lung devices that combine the pumping and oxygenation functions into one single unit are attractive. Designs have had problems with insufficient gas transfer and device-induced hemolysis, even when fiber membranes with a large surface area have been used. As for direct clinical use implications, for perfusionists, there is the question of who is best trained to operate the device under the supervision of a physician, especially in emergency situations. Should manufacturer-trained OJT medical personnel without specialized knowledge, professional certification, and licensing status be permitted to safely operate these devices. Related to this is the decision of hospital administration when balancing staff cost vs. patient safety.

If and when manufacturer representatives market such devices and claim that manufacturer-trained OJT medical personnel can safely operate the device, they may be correct. However, depending on the state, this may or may not be a permissible practice for the hospital as a matter of law. Perfusionists in licensed states, in such situations, have an advantage over perfusionists in non-licensed states. In a licensed state, unless the selected manufacturer-trained OJT medical personnel is a licensed perfusionist, a licensed respiratory therapist, or a licensed nurse with ELSO certification, the person would be engaged in a practicing medicine without a license granting them the state sanctioned authority to operate the device. In non-licensed perfusionist states, this avenue is not available. Professional licensing establishes minimum entry to practice requirements to protect patient safety. It also grants to the practitioners of a profession the right to challenge hospital-staffing decisions that gradually or stealthily take away medical practice responsibilities. Decisions like this are occurring now every day in hospitals across the country.

Another current example on the value of perfusionist licensing comes from the state hospital regulatory front in the Sunshine state. Recently published regulations could negatively impact the responsibilities of perfusionists in performing alternative-site testing in the operating room. In this case, the non-licensed status of perfusionists raises problems with the performance of testing, the complexity of the tests allowed to be performed by the perfusionist, and if the supervisor should be perfusionist to ensure the quality assurance of testing procedures during CV surgeries. On a different perfusion responsibility, blood management is another area of perfusion responsibility and management that is likely to surface in the coming years.

There will be more types of these perfusion responsibilities versus cost management and hospital staffing protocol situations in our evolving health care system. Perfusionists at least risk for having their responsibilities being gradually and stealthily take away are those who are licensed. Those at most risk are the non-licensed practitioners of perfusion.