TESTIMONY ON HB 1570

Presented to The Pennsylvania House of Representatives Health Committee

October 20, 2011

By

JOSEPH F. TALARICO, DO

Past-President, Pennsylvania Society of Anesthesiologists

Good morning, Mr. Chairman and distinguished members of the House Health Committee. My name is Dr. Joseph Talarico. I was until last week President of the Pennsylvania Society of Anesthesiologists. I am a board-certified, practicing anesthesiologist at the University of Pittsburgh Medical Center, a tertiary care hospital that is part of a large health care system in Pittsburgh. I teach and train medical students, residents and fellows in anesthesiology as well as directly supervise nurse anesthetists (CRNAs) and instruct student nurse anesthetists. I also provide direct hands-on anesthesia care. Thank you for allowing PSA to present its views on HB 1570 and to raise concerns about its impact on medical care and our primary concern, patient safety.

PSA is the professional association for anesthesiologists in Pennsylvania, with almost 2,000 members. Anesthesiologists are physicians who, after medical school, have completed a four year residency program in anesthesiology; the residency program includes advanced training in internal medicine, surgery, pediatrics, and a number of other medical specialties necessary to perform their role in surgery: "protecting patients." While surgeons are busy performing surgery, anesthesiologists provide the patient with critical care medical management, free from pain and medically stable. I cannot overemphasize the importance of the latter (keeping patients medically stable): unexpected events that compromise patient safety occur routinely in surgery and addressing them properly is central to a good patient outcome.

Our comments address some issues related directly to the practice of anesthesia and others that affect medical care more generally.

First, we oppose allowing facility licensure based on satisfaction of standards of either a national accrediting organization, such as the Joint Commission, or of CMS, in lieu of complying with Pennsylvania standards developed by the Department of Health with legislative oversight. Doing so would cede important decisions and legislative authority about health care provided in Pennsylvania hospitals and ASFs to those organizations or, in the case of CMS, to the federal government. By doing so, Pennsylvania would be adopting all of the current standards of these organizations, regardless of whether they comport with Pennsylvania's rules. There are many places where, for example, the Joint Commission's rules differ from the Department's.

Even more importantly, Pennsylvania would be adopting those entities' rules, however they may change, for years to come. It is a certainty that the standards will change. How the standards will change, when they change, and what the process is or will be for changing them cannot be known now and will be entirely outside of Pennsylvania's control. There will be no opportunity for the regulated community or health care consumers to submit comments, no involvement of IRRC, no publication in the Pennsylvania Bulletin, no review by legislative committees, no certification by the Attorney General as to form and legality. The Joint Commission's changes will be a *fait accompli*; licensing standards will change without Pennsylvania's legislature or executive ever considering whether the change is desirable.

Because these accrediting agencies are generally private entities, they are quite protective of their work product. What this means is that these standards are not readily available, free and on line,

in the same way that DOH and other governmental licensing standards are. That, in turn, impedes the ability of many, including the public at large to access, evaluate, and work with and in compliance with the standards.

Finally on this issue, PSA understands that serious state constitutional issues are raised when the Legislature incorporates standards to be developed by private entities. We rely on others to press that point. PSA simply notes that doing so is a bad idea as a matter of policy.

Second, we have several comments about the provisions on ambulatory surgical facilities. Section 806(a.1) references three classes of ASFs – A, B, and C – but never establishes any rules as to what those classifications mean, *i.e.*, what makes something a Class B instead of a Class C. DOH regulations currently do so, relying primarily on a matrix that includes the procedure, the patient's physical status and the anesthesia to be used. For example, the regulations discuss the widely used patient "physical status classification" system developed by the American Society of Anesthesiologists and relates that system to which patients can be treated in what class ASF. The Bill includes none of this information. This may be simply a drafting oversight, but it needs to be fixed.

Section 806(a.1) also contains certain of the provisions now in the DOH ASF regulations. We do not understand why some of those standards, but not others, have been included in the Bill. More generally, PSA thinks that in health care facility licensing, it makes sense to provide the general standards via legislation and leave the details to the Health Department. The Bill contains too many details, yet omits others that are of equal or greater importance to patient safety, including as to anesthesia care in ASFs for non-pediatric patients.

This leads directly to PSA's major concern – Section 806(a.2)(3) on anesthesia for pediatric patients in ASFs. Some pediatric patients raise unique anesthesia concerns, arising primarily from their prematurity, low birth weight, co-existing disease, and unique physiology. Prematurely born babies can present with both low weight and medical issues associated with their premature birth. The increased risk in pediatric surgery, particularly at ASFs, is more directed to the anesthesia than the surgery *per se* (*e.g.*, common surgeries at ASFs are hernia repairs, insertion of ear tubes). Younger pediatric patients almost always need general anesthesia, even in situations in which adults would more likely have regional anesthesia or even sedation. This, in turn, requires pediatric surgery take place in a Class C ASF under current rules. While you might expect surgery on these preemies to take place in a hospital rather than an ASF, nothing in the current DOH regulations or Section 806(a.2)(3) requires that be done.

All anesthesiologists, as part of their residency, receive training in pediatric anesthesia. Some, but not many, anesthesiologists complete additional fellowship training in pediatric anesthesia. The extent to which anesthesia for pediatric patients should be provided only by pediatric anesthesiologists is difficult to establish for the wide variety of medical situations, including the nature of the procedure and the patient's condition ,which may occur across the breadth of Pennsylvania. There are some pediatric surgeries, for example operations on premature newborns with very low weight, or children with complex medical histories, in which the involvement of an anesthesiologist with extra training or experience in pediatric cases would seem warranted. Fellowship-trained pediatric anesthesiologists practice almost exclusively in

larger cities and in dedicated children's hospitals. Therefore, individual health care facilities have appropriately addressed this issue in their credentialing and privileging standards and decisions that take into account local needs and resources.

Before any statutory rules are enacted on these issues, PSA suggests that additional research and review be conducted. PSA would be pleased to assist the Committee if it decides to move forward on that issue.

Among the issues to consider are:

- Should CRNAs be permitted to provide anesthesia to pediatric patients, or to a subset of pediatric patients in an ASF unless they are medically supervised by an anesthesiologist? As written, it appears that CRNAs could provide anesthetic services at an ASF to seriously ill pediatric patients as young as 6 months of age without the supervision of an anesthesiologist. PSA certainly respects the ability of CRNAs to provide anesthesia care as part of the anesthesia care team, under the supervision of an anesthesiologist. We have concerns if CRNAs are caring for pediatric patients in ASFs without that supervision.
- Should the rules on anesthesia care for pediatric patients vary depending on physical status classification, age (including an adjusted age for premature babies), weight, procedure and similar factors so that the cases presenting the most difficulties and risks are handled by anesthesia providers with the greatest amounts of education and training, *i.e.*, anesthesiologists? For example, current DOH rules allow patients, including pediatric patients, with Physical Status I-III to be treated in ASFs. We would be quite concerned if Physical Status III pediatric patients had surgery in an ASF without an anesthesiologist's close involvement.

Our final area of commentary concerns the introduction of the concept of "specialized health care services" as a new licensing requirement. The definition – "certain diagnostic, treatment or rehabilitative services which involve highly technical medical procedures and require extraordinary expertise and resources to be effective and safe as determined by the Department of Health" – leaves PSA entirely in the dark as to what services would be included. We cannot comment on whether it is a good or bad idea until we know. Additionally, licensure for this category is, as written, issued to a provider, not a facility, which is quite contrary to DOH's historic role in licensing. We urge the Committee to flesh out the intended application of this provision if it determines to proceed with this concept.

Thank you again for the opportunity to present our views.