

HOUSE PROFESSIONAL LICENSURE COMMITTEE PUBLIC HEARING

Wednesday, March 19, 2008 - - 10:00 a.m. to 12:00 p.m.
418 Main Capital Building

HOUSE BILL 2015 PN 2844 and Amendment
(Orthotics, Prosthetics and Pedorthics Licensure)

REMARKS BY REP. MARIO SCAVELLO - PRIME SPONSOR OF HOUSE BILL 2015

First, I wish to thank the House Professional Licensure Committee, especially Chairman Sturla and his excellent staff, for holding this hearing and for their diligent work to further improve House Bill 2015 by drafting the amendment which is also before the members today, and those testifying on the bill.

I introduced this legislation because constituents shared their difficult experiences with me. They told me how an improperly fitted prosthesis or other custom-fitted device can impair their ability to function optimally. Many times, the pain experienced from not being fitted appropriately creates a situation where, because the device cannot be refitted properly or affordably replaced, the individual ends up having to live without the necessary device.

I learned Pennsylvania does not have any licensing requirements for those who evaluate, measure, design, fabricate, assemble, fit, adjust or service a custom-fabricated or custom-fitted brace or support known as an orthosis, or for a prosthesis, which is a custom-fitted or custom-modified device to replace an absent external limb, nor for pedorthic devices, such as therapeutic footwear and lower limb orthosis. I also learned several other states do license these individuals as orthotists, prothetists, orthotic fitters and pedorthists. In fact, New Jersey Licensing sent us an email confirming they license all these individuals and there is no licensing exemption for anyone who does hands-on patient fitting.

Last session I introduced House Bill 401 which was language taken from Illinois' licensing statute. During that time, the House Professional Licensure Committee staff worked with me to draft an amendment to HB401 to bring the bill's provisions more in line with Pennsylvania's licensure requirements for professions and occupations licensed by the Department of State. Subsequently, the House Professional Licensure Committee from last session held a hearing on House Bill 401 and the amendment. This sessions' bill, House Bill 2015, is drafted with further improvements, as obtained through testimony received at that public hearing.

We live in a wonderful, high-tech time. Last session I shared with the committee members a copy of a Harrisburg Patriot News Article by the Associated Press that showed just how far we have come in the development of prosthetics. Because there are new members serving on the committee, I am again sharing this same article with the standing committee. Here, Jesse Sullivan, has been fitted with a bionic arm. It is a high-tech prosthetic arm that enables him to control his left arm in a coordinated and smooth way by his thoughts. There is no perceivable delay in the motions of his arm. This prosthesis recreates the subtle and complex motions of a human arm so that Jesse can use a weed-whacker, hug his grandchildren, and even do something many of us take for granted, hold a bottle of water and take a drink.

Productivity is enhanced by this new high-tech device. We need to be sure that there are qualified and competent people providing the proper services to those in need so they can reach their fullest potential.

The federal government recently published in the Federal Register / Volume 73, No. 17 dated Friday, January 25, 2008, proposed rules to clarify and revise existing Durable Medical Equipment Standards for suppliers of Prosthetics, Orthotics Supplies in regards to licensure. This is being done to ensure these specific suppliers understand how the Centers for Medicare and Medicaid Services (CMS) interpret the current supplier standards. In addition the CMS is proposing several new Durable Medical Equipment , Prosthetics, Orthotics, and Supplies standards, also known as “demeepaz” standards, as CMS wants to ensure that legitimate DMEPOS suppliers are furnishing these items to Medicare beneficiaries.

The proposed rule clarifies the supplier standard that the owner must operate its business and furnish Medicare covered items in compliance with all applicable Federal and State licensure and regulatory requirements. The purpose of this standard is to ensure that DMEPOS suppliers obtain and maintain the necessary State license required to furnish the services provided to Medicare beneficiaries.

In addition, Medicare believes each supplier is responsible for determining what licenses are required to operate a DMEPOS supplier’s business. While the National Suppliers Clearing House maintains information regarding State licensure laws, CMS (Medicare) does not believe that the Clearing House is responsible for

notifying any supplier of what licenses are required or that any changes have occurred in the State licensing requirements. Further, CMS does not believe there are any exceptions to State licensing requirements, unless the State in which the DMEPOS supplier furnishes services provides for such an exemption. If a State requires a specific license to furnish certain services, Medicare believes a DMEPOS supplier cannot contract with an individual or other entity to provide these licensed services, but rather, the supplier would have to hire the individual as a W-2 employee. The owner of the supplier, or full time W-2 employee, must obtain and maintain licensing. Thus, the proposed rule clarifies that a DMEPOS supplier must be licensed to provide a licensed service and cannot contract with an individual or entity to provide the licensed service. CMS wants to be clear that Medicare enrolls only DMEPOS suppliers, not third-party agents that subcontract their operations to suppliers that are not enrolled or cannot enroll in the Medicare program. CMS believes DMEPOS suppliers must be licensed to provide licensed service(s) and cannot contract with an individual or entity to provide the licensed service(s).

What this demonstrates is the federal government is working to ensure only qualified suppliers are enrolled in the Medicare program so proper services are received by Medicare beneficiaries. Similarly, just as Medicare is striving for proper care, we are working towards the same objective through House Bill 2015, which is, that Pennsylvania residents needing orthotics, prosthetics or pedorthics services receive the proper care.

It is my hope we will learn even more today about the need for this legislation and acquire additional suggestions to improve it so that Pennsylvania, in the near future, has a licensure statute that helps protect our constituents from unnecessary and undue hardship.

Thank you.

Amputee reaches out and embraces life

His brain controls artificial arm via re-routed nerves

BY BILL POOVEY
Of The Associated Press

DAYTON, Tenn. • Jesse Sullivan has two prosthetic arms, but he can climb a ladder at his house and roll on a fresh coat of paint.

He's also good with a weed-whacker, bending his elbow and rotating his forearm to guide the machine. He's even mastered a more sensitive maneuver — hugging his grandchildren.

The motions are coordinated and smooth because his left arm is a bionic device



Rehabilitation Institute of Chicago

Jesse Sullivan uses his high-tech prosthetic arm to hold a bottle of water at the Rehabilitation Institute of Chicago.

the bionic arm work. A procedure called "muscle reinnervation," developed by Kuiken and used on five additional patients so far, is the key.

For Sullivan, it involved grafting shoulder nerves, which used to go to his arms, to his pectoral muscle. The grafts receive thought-generated impulses, and the muscle activity is picked up by electrodes; these relay the signals to the arm's computer, which causes motors to move the elbow and hand, mimicking a normal arm.

"The nerves grow into the chest muscles, so when the patient thinks 'close hand,' a portion of the chest muscle contracts," according to an institute fact sheet.

Kuiken added: "Basically, it is connecting the dots. Finding the nerves. We have to free the nerves and see how far they reach" and connect to muscles.

About three months after the surgery, Sullivan first noticed voluntary twitches in his pectoral muscle when he tried to bend his missing elbow, the institute said. By five months, he could activate four areas of his major pectoral muscle.

Trying to flex his missing elbow would cause a strong contraction of the muscle area just beneath the clavicle. When he mentally closed his missing hand, a signal could be detected on the pectoral region below the clavicle, and when he tried to open his hand there was a separate signal.

Sullivan said his bionic arm allows him to rotate his upper arm, bend his elbow, rotate his wrist, and open and close his hand — in some instances simultaneously.

controlled by his brain. He thinks, "Close hand," and electrical signals sent through surgically re-routed nerves make it happen.

Doctors describe Sullivan as the first amputee with a thought-controlled artificial arm.

Researchers encouraged Sullivan, 59, who became an amputee because of an industrial accident in 2001, not to go easy on his experimental limb. At times, he has been so rough with the bionic arm that it has broken, including once when he pulled the end off starting a lawnmower.

That prompted researchers to make improvements, part of a U.S. government initiative to refine artificial limbs that connect body and mind. The National Institutes of Health has supported the research, joined more recently by the military's research-and-development wing, the Defense Advanced Research Projects Agency. Some 411 U.S. troops in Iraq and 37 in Afghanistan have had wounds that cost them at least one limb, the Army Medical Command said.

Although work that created

Sullivan's arm preceded the research by DARPA, Sullivan said he's proud to test a type of bionic arm that soldiers could someday use. "Those guys are heroes in my book, and they should have the best there is," he said.

"We're excited about collaborating with the military," said the developer of Sullivan's arm, Dr. Todd Kuiken, director of neuroengineering at the Center for Artificial Limbs at the Rehabilitation Institute of Chicago, one of 35 partners in a DARPA project to develop a state-of-the-art arm.

Sullivan's bionic arm represents an advance over typical artificial arms, such as the right-arm prosthesis he uses, which has a hook and operates with sequential motions. There is no perceivable delay in the motions of Sullivan's flesh-colored, plasticlike left arm. Until now, it has been nearly impossible to recreate the subtle and complex motion of a human arm.

"It is not as smooth as a normal arm, but it works much smoother than a normal prosthesis," Kuiken said.

High-tech science makes

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