HOUSE OF REPRESENTATIVES
COMMONWEALTH OF PENNSYLVANIA

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House Bill 2015

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House Professional Licensure Committee

Main Capitol Building
Room 140, Minority Caucus Room
Harrisburg, Pennsylvania

Wednesday, March 19, 2008 - 10:00 a.m.

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BEFORE:

Honorable P. Michael Sturla, Majority Chairman
Honorable Neal Goodman
Honorable Nick Kotik
Honorable Harry Readshaw
Honorable John Sabatina, Jr.
Honorable Timothy Solobay
Honorable James Wansacz
Honorable Ronald Waters
Honorable John Yudichak
Honorable William Adolph, Minority Chairman
Honorable Susan Helm
Honorable Thomas Killion
Honorable Mark Mustio
Honorable Bernie O'Neill
Honorable Richard Stevenson

IN ATTENDANCE:

Honorable Mario Scavello

KEY REPORTERS 717-764-7801

ALSO PRESENT:

Marlene Tremmel
Majority Executive Director

Antoinette Florn-Mihalic, Esquire
Majority Legal Counsel

Jim Dawes
Majority Communications Director

Wayne Crawford
Minority Executive Director

Christine Line, Esquire
Minority Legal Counsel

Sharon Engdhal
Minority Staff

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ACTING CHAIRMAN ADOLPH: Good morning. The hour of 10 o'clock having arrived, I'd like to call to order the public hearing on House Bill 2015. Chairman Sturla is on his way in from Lancaster. He'll be here in a few minutes, but we've been advised to get the meeting started because many members have a long road trip today, and I know some of the testifiers would like to get on the road as well.

My name is Bill Adolph. I'm the Republican Chair of the Professional Licensure. And I think the first order of business will be the members of the committee identifying themselves. I'd like to start way down there to my right and we'll come towards the center.

REPRESENTATIVE MUSTIO: Representative Mark Mustio from Allegheny County.

REPRESENTATIVE O'NEILL: Good morning. Representative Bernie O'Neill from Bucks County.

REPRESENTATIVE HELM: Representative Sue Helm, Dauphin County.

REPRESENTATIVE KILLION: Tom

Killion, Delaware County.

REPRESENTATIVE KOTIK: Nick Kotik, Allegheny County.

REPRESENTATIVE SOLOBAY: Tim Solobay, Washington County.

REPRESENTATIVE READSHAW: Representative Harry Readshaw, Allegheny County.

REPRESENTATIVE STEVENSON: Representative Dick Stevenson, Mercer and Butler counties.

(Representative Sturla entered the hearing room.)

ACTING CHAIRMAN ADOLPH: Thank you. The first testifier today is actually the prime sponsor of the bill, state Representative Mario Scavello from the 176th Legislative District in Monroe County. Good morning, Representative.

REPRESENTATIVE SCAVELLO: Good morning.

Good morning, Chairman Adolph and Chairman Sturla, and members of the House Professional Licensure Committee. I want to thank Chairman Sturla especially and his staff for holding this hearing, 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 just want to stop here for a moment and explain. I witnessed it with a young man about 12 years old who had a prosthe -- a leg. He took it off and he started jumping on the other side. So as he was doing that, you know, he's really ruining the rest of his body. And I approached him, why aren't you wearing your piece? And he said to me, his bionic leg, he says, it's uncomfortable, it doesn't fit right. You know, just think about how many of those situations are out there in this Commonwealth.

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 orthosis, or prosthesis, which is a custom-fitted or custom-modified device to replace an absent external limb, nor for pedorthic services, such as therapeutic footwear or lower limb orthosis.

I also learned several other states do license these individuals as orthotists, prothestists and orthotic fitters and pedorthists. In fact, New Jersey Licensing sent us an e-mail confirming that 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 the Illinois licensing statute. During that time the House Professional Licensure Committee staff worked with me to draft an amendment to House Bill 401 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 session's bill, House Bill 2015, is drafted with further improvements, as obtained through testimony received at the 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've come in the development of prosthetics. Because there are new members serving on this committee, I'm again sharing this same article with the standing committee.

Have you received the article?

MS. ENGDHAL: It's on the back of the comments.

REPRESENTATIVE SCAVELLO: Okay. It's on the back of the comments. 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's 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 that they can reach their fullest potential.

The federal government recently published the Federal Register, Volume 73, Number 17 dated Friday, January 25th, 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 known as the DMEPOS standards, as CMS wants to ensure that the legitimate DMEPOS suppliers are furnishing these items to Medicare beneficiaries.

The proposed rule clarifies that 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 Clearinghouse maintains information regarding state licensure laws, CMS (Medicare) does not believe that the clearinghouse 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 that

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 that DMEPOS suppliers must be licensed to provide licensed services and cannot contract with an individual or an entity to provide the

licensed services.

What this demonstrates is that 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 that 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 with unnecessary and undue hardship. Thank you, Mr. Chairman.

CHAIRMAN STURLA: Thank you. Questions from members?

(No response.)

CHAIRMAN STURLA: Okay, thank you.

REPRESENTATIVE SCAVELLO: Thank you very much.

CHAIRMAN STURLA: I'll call up the next panel, which is Eileen Levis, President and CEO of Pennsylvania Orthotics and Prosthetics Society; Thomas Been, a member of that same society; Randy Stevens, another member; and Chauncey Ace Plyley, a patient.

While they're coming up, I'd also like to point out that we have a letter to enter into the record that is from the Pennsylvania Physical Therapy Association.

And I'll note that we have been joined by Representatives Wansacz and Sabatina.

MS. LEVIS: Good morning, Chairman Sturla, and members of the committee. My name is Eileen Levis and I am President of the Pennsylvania Orthotic and Prosthetic Society and currently serve as managing partner and President of Orthologix, a Philadelphia-based orthotics and prosthetics practice.

With over 25 years working in the orthotics and prosthetics industry here in Pennsylvania, my own experience ranges from regulatory and fiscal affairs to process development and implementation. I sit on the Medicare Provider Outreach and Education

Advisory Board and have successfully managed the reorganization of the Milton S. Hershey Medical Center Orthotics and Prosthetics Department.

I would like to thank you for allowing me and my colleagues to present our opinions on House Bill 2015 and on the issues of licensure for orthotists, prosthetists and pedorthists practicing in the State of Pennsylvania. I will be brief in my comments today, but this issue regarding licensure of orthotists, prosthetists and pedorthists is extremely important to the citizens of this state who require our expert care.

Across the country, licensure for providers of orthotics, prosthetics and pedorthics has been progressing over the past few years. Currently, the states of Alabama, Florida, Georgia, Illinois, New Jersey, Ohio, Oklahoma, Rhode Island, Tennessee, Texas and Washington have all established licensure, with other states currently in the process.

Licensure establishes a level of qualifying for those who are providing health care services. The outcome of unregulated

health care services such as these may be starkly evident, but many times may not be directly apparent. Over time inappropriate components or a lack of knowledge of a patient's all-over health status can result in added medical expenses, poor outcomes, health complications, and even death. Essentially at present, in the State of Pennsylvania you are more accountable if you are a hairdresser than a health care professional providing orthotic, prosthetic, pedorthic services.

Organizations throughout the health care community strongly support licensure for orthotists and prosthetists and pedorthists, and that includes the American Academy of Orthotists and Prosthetists, as well as the Amputee Coalition of America.

At this time I'd just like to interject something from my own personal practice. We provide service to Children's Hospital in Philadelphia. We are the only health care specialty providing service to children from across the world, across the nation that are not licensed.

In closing, I would just like to say

that licensure is for the protection of the people, the very people who work here in the Commonwealth. One day that need may be yours, a family member or a friend. Are you comfortable with the knowledge that you might get a better haircut than a prosthesis? I leave you with that thought as you'll hear testimony today from my colleagues who will cover all areas of this issue.

You'll hear how orthotic and prosthetic services and technology have advanced in the past 30 years; how this technology is enabling our servicemen and women to regain their lives; how other states have managed to license O and P providers; how detailed and advanced O and P education has become; evidence of incidents of fraud and abuse, which will demonstrate how licensure will help protect Pennsylvanians in your district and give them the quality, professional care they deserve.

Thank you, Mr. Chairman, and I turn the next part over to Mr. Thomas Been, who is CEO and President of Central Orthotics and Prosthetics.

MR. BEEN: Good morning, Mr. Chairman. I want to thank you for allowing us to come in here and try to get this bill passed. My name is Tom Been. I'm the owner of Central Orthotic and Prosthetic Company in Johnstown, Pennsylvania. I have been implementing orthotic and prosthetic treatment for over 36 years. Between my four offices we see approximately 30 patients on average per day.

With my manufacturing lab in Johnstown -- At the Johnstown location we're able to manufacture custom items in as short as five to eight hours depending on the complexity of the device. The majority of the areas which my office covers are rural, which means many of my patients are farmers, steel mill workers and miners.

My company also has a Veteran Administrative (sic) contract. We attend a Veteran Administrative clinic every other Friday at the VA Hospital in Altoona. We see approximately sevens veterans a week between our four offices.

The reason I am here today to present

testimony to this committee is because of my strong belief in the need for licensure for the professions of orthotics, prosthetics and pedorthics, and a future pledge of my support for the bill, 2015.

Mr. Chairman, and members of the committee, I've seen many changes in my 36 years in this profession. The advancement of components over time in both orthotics and prosthetics has been dramatic. When I began in 1972, most orthotic components were handmade before the advance technology of prefabricated components, which make it unnecessary to fabricate most joints at this time.

However, these parts have been (sic) more complicated and require greater knowledge and skill to properly fit patients with devices.

Prosthetics have changed too. Older prosthetics normally consisted of wood components with steel knee construction. These prostheses weighed approximately 15 pounds. And with the advancement of the endo-skeletal components and the advancement of technology, a prosthesis can now be lighter weight. In the

same regard with the advancement in technology, these devices have become more complicated and require more precise fittings.

Now, Mr. Chairman, and members of this committee, the reasons I have given you information in regards to the components of a prosthesis and detailed advancement of prosthetics and orthotics is because of my strong belief in the need for licensure. The reasons I feel we should have a licensure, and thus, pass bill, H.B. 2015, began with the fact that orthotics and prosthetics fall under DME, and that's durable medical equipment.

As it now stands, Mr. Chairman, anyone in Pennsylvania can engage in the profession of prosthetics and orthotics without any set guidelines, proper rules for evaluation and measurements of qualification. It's not right, in my opinion, for people of Pennsylvania and the citizens of your districts to be subjected to receive inadequate care or sold devices without proper fitting.

Without a state law to protect patients from going to someone inadequately trained, fraud and abuse could become more

rampant and widespread. Simply put, Mr. Chairman, orthotics and prosthetics have evolved in Pennsylvania to warrant licensure. We need state licensure so we would have required guidelines to be able to treat patients for orthotic and prosthetic services in your districts.

With the passage of House Bill 2015, patients will receive proper evaluations and be fitted with the proper orthotic or prosthetic components needed to enable them to ambulate, work and go about with daily activities.

Now, Mr. Chairman, and members of this committee, this story could happen to any amputee in your district, whether they are soldiers from Iraq or Afghanistan, or simply members of society. It is my belief that these Pennsylvanians need not only quality care, but to be assured that the people they entrust with their prosthetic care are qualified and prepared to deal with the situations that may occur. The only way to ensure that is to ensure that those delivering care are properly trained, certified and licensed.

Mr. Chairman, this is most

importantly a quality-of-care issue. We owe it to our patients to make sure they are active members of this state and protect them from medical fraud that is too prevalent. This is why we need to pass House Bill 2015 to create licensure for the professions of orthotics, prosthetics and pedorthics.

I'd like to add a note here. What I did too is, I brought copies of newsletters that we send out. What these have in here is pretty much advancements that happen almost daily in orthotics and prosthetics. What I'm going to do is, I'll leave these on the table over there. If you're interested in reading these and try to better understand orthotics and prosthetics, these will probably give you a little bit of input on that.

With that, I'm going to conclude my little talk here and thank everyone.

MR. STEVENS: Good morning, Chairman Sturla, and members of the committee. My name is Randy Stevens and I'm the sole proprietor of Randy Stevens Family Footcare here in Pennsylvania in Harrisburg. I'm certified through the American Board for Certification in

Orthotics, Prosthetics and Pedorthics, which is ABC, as a certified pedorthist, C.Ped., also credentialed through the Board for Orthotist/ Prosthetist Certification, BOC, as a BOC pedorthist.

I'm also credentialed through the American Board for Certification in Orthotics, Prosthetics and Pedorthics, ABC, as a certified fitter of orthotics, CFO, and I am a member of POPS.

Additionally, I'm a member of the Pedorthic Footware Association, in which I serve as President, and also the Chairman of the Government Relations Committee and I'm the Chairman of PFA's Coding/Insurance and Third-Party Payers Committee. As Chairman of PFA's Government Relations Committee, I'm active in participating in legislative and regulatory issues at the federal and state levels.

Today, I am here to speak to gain your support regarding the licensure of orthotics, prosthetics, orthotic fitters and pedorthics in this state.

One thing I would like to reiterate and I'd like to let this committee know that

the -- this would not be a new stand-alone licensing board; that this board would actually fall underneath the State Board for Licensing of the Podiatrists. Also, in no way does this act prohibit anybody that's currently practicing in this state from moving forward and treating and providing the continued quality patient care that they currently do.

First off, though, I'd like to say here also, I am in support and in agreement with H.B. 2015 and the amendments that were made to H.B. 2015. In order to fully explain and understand the issue, I am going to talk about some national efforts regarding licensure and some reasoning behind my strong beliefs in the need for licensure for the O, P and P professions.

To help in my explanation regarding the national efforts, currently there are 11 states that have some sort of licensure in regards to prosthetics, orthotics or pedorthics. There are also currently four other states that are actively pursuing licensure of prosthetics, orthotics and/or pedorthics. The National Suppliers

Clearinghouse, NSC, also recognizes licensure in C.R. 3959, which was implemented in October of 2005, and in the proposed enrollment requirements for durable medical equipment and prosthetics, orthotics and supplies, which is DMEPOS.

Mr. Chairman, and members of the committee, licensure is important not only to the people living throughout Pennsylvania and in your representative districts, but also to our patients that we see on an everyday basis.

Mr. Chairman, and members of this committee, it is being heard by my patients that my profession is the only non-M.D. medical profession which is currently not licensed in Pennsylvania and providing services to Medicaid, Medicare, third-party payers and private-pay beneficiaries/patients. Again, the profession of orthotics, prosthetics, orthotic fitters and pedorthics is the only non-M.D. medical profession which is currently not licensed in Pennsylvania.

To further illustrate, Mr. Chairman, I would like to say in the current practice settings in Pennsylvania today, I have

experienced those being hired having no patient care or clinical experiences signing onto companies that would guarantee them employment if they would become certified within two years.

I've worked with an individual who was a ski instructor and fit ski boots in the Scranton/Wilkes-Barre area, had no experience, and was paired with an orthotist to see patients in the office, taken into hospitals, rehab centers and nursing homes in the Harrisburg area and given on-the-job training. The patient care population should not be used to gain knowledge so that one can become certified, but should be obtained through competencies and education so one can treat the patient care population here in Pennsylvania.

Licensure ensures that the beneficiaries of orthotic, prosthetic, orthotic fitter and pedorthic services here in Pennsylvania will have the appropriate education and training to provide treatment to those beneficiaries that receive patient care treatment with the use of orthotic, prosthetic, and pedorthic modalities.

By initiating licensure here in Pennsylvania, it would make the practitioners obtain the necessary education and training to treat the patients here in Pennsylvania rather than using the patient or the individual that one is treating as one's education in order to provide treatment to those patients here today. The beneficiaries and residents of the State of PA that receive treatment from an O, P and P provider deserve to know that because of through licensure, the practitioner that is treating them had appropriate education and training prior to treating them.

In conclusion, I would like to thank you, Chairman Sturla, and members of the committee for giving the members of POPS the opportunity to speak here today. Please remember one thing before we take questions. You know, this is all about providing quality patient care and the protection of those patients who receive prosthetic, orthotic, orthotic fitter and pedorthic coverage.

Pennsylvanians deserve the best care that we can give them, and House Bill 2015 would accomplish this. I would ask you to vote

yes for the passage of H.B. 2015 and give Pennsylvanians who have O, P and P disabilities the assurances they need to have a successful future.

Thank you. My fellow POPS members and I will be willing to answer any questions at this time.

MR. PLYLEY: Good morning, Chairman Sturla, and members of the committee. My name is Ace Plyley, and I'm pleased and honored to have been invited by Randy Stevens to testify at this Professional Licensure meeting in the House of Representatives.

I am not diabetic, but I inherited a neuropathy called Charcot Marie Tooth Disease. This caused me to develop a pressure ulcer on the bottom of my right foot in 1991. In the past 17 years, I have been hospitalized with infections and osteomylitis several times. I've had three surgeries on this foot.

When living in New Jersey, I spent one full year driving over an hour to a wound center every week. Every treatment they knew was tried to heal my wound, but to no avail. Several doctors had even told me that I

might -- could possibly lose my foot.

In 1999, we moved to Pennsylvania. The same week as we moved, my foot became infected and the leg swollen. I was seen by Mark Pinker, DPM in Carlisle, who immediately sent me to the hospital. I was operated on and spent six weeks in Manor Care, given IV six times a day.

In March 2001, Mark Pinker, DMP performed Bilaminate Skin Graft on my foot. I had temporary success in resolving the ulcer. I was prescribed my first pair of custom-molded shoes with a brace to avoid pressure on the ulcer. Randy Stevens measured me for the footwear. Until the new shoes, I was always on crutches, my only means of being mobile. As much as these shoes helped, the wound at times would be large, become infected, and I was constantly using antibiotics, and sometimes being hospitalized.

Randy opened his own business. In June 2006, he introduced me to Arizona AFO, Inc. and had the company make a custom-molded Neurowalker that I have been wearing for the last 20 months. Randy customized the boot just

for me. The ulcer is healed because of his professionalism, his caring and his expertise of knowing just what to do.

Because of Randy, and I say this sincerely, I do not have to rely on crutches. I can walk on my own. I love my freedom to walk with my wife. I can exercise and bend over without falling over. Randy has helped me lead an active life. Because of Randy, my wound has healed; there have been no infections and no hospital stays. I credit his professional manner, his expertise, his caring and can't thank him enough for all the blessings he has given me.

Being from the State of New Jersey-- Please don't hold that against me--there is state licensure and thorough licensing that lets the public and myself know if one is qualified to provide the services for which I needed. But here in Pennsylvania it's been by trial and error. Because of the lack of licensure, it has made it difficult to know who is qualified and who is not until you see the individual and then it is a hit-or-miss situation. To ensure quality of care and to

protect myself and the public here in Pennsylvania, I believe that licensure needs to and should be enacted within this state

Therefore, I request the licensure act, House Bill 2015, and its amendments be passed and made a state law. Thank you for letting me come in.

CHAIRMAN STURLA: Thank you. Questions from members? Representative Wansacz.

REPRESENTATIVE WANSACZ: Thank you, Chairman Sturla. I have a couple questions and anyone can answer these; just trying to figure this out a little bit better.

Do people -- When you go into this business to become a practitioner, obviously, when do you have to become certified? Is there a certain point that you have time -- I believe in one testimony somebody said it was two years that you had to wait.

MR. BEEN: Right now, no.

REPRESENTATIVE WANSACZ: Or do you not have to become certified at all?

MR. STEVENS: In order to be recognized through Medicare or Medicaid you

need to be licensed or certified. C.R. 3959, which recognizes certified practitioners or licensed practitioners, so prior to dispensing or billing that individual would need to be certified or licensed within the state and that they recognize, you know, all credentialing and licensing bodies in order to submit and bill for devices that are provided to the patient.

REPRESENTATIVE WANSACZ: So, what is the training then to become a practitioner? For example, can I just turn around tomorrow and decide I want to be a practitioner even though I have no idea what I'm doing?

MR. STEVENS: There are multiple different pathways. There is competency and education-based combination. You know, so there's actually within both organizations two different -- within both our credentialing bodies there are two different pathways that can be achieved -- in order to achieve certification. But in order to achieve licensure within the other states also, the individuals must pass testing, you know, and achieve certification through either one of those two bodies that are currently recognized

by CMS.

REPRESENTATIVE WANSACZ: I'm talking specifically here about Pennsylvania. For example, what training do you need just to be able to come in today and practice in Pennsylvania? I read in -- I believe it was your testimony that said a ski boot instructor -- a ski instructor in Scranton/ Wilkes Barre, where I'm from, just decided, hey, this is what I'm going to do.

MR. STEVENS: Right. It can be a combination of schooling plus competency-based education. Like, Temple currently in Pennsylvania has 101 courses where individuals are actually -- you know, their -- They could have a degree. You know, they could be a physical therapist, they could be a podiatrist, and they could take the appropriate course work to become a pedorthist.

I know also out at the University of Pittsburgh right now they've entered into a two-year program that, you know, a master program for orthotics and prosthetics. So we do have those two educational arts in there. But it is both competency based and education

based and usually those working side by side, you know, with an orthotist on a similar thing, or prosthetist or pedorthist within their practices.

REPRESENTATIVE WANSACZ: So does that mean -- I'm trying to clarify this a little bit better.

MR. STEVENS: Right.

REPRESENTATIVE WANSACZ: Does that mean that you need a health care background currently now and go to -- whether you said two-year school or can -- Again, I'm asking, can I turn around tomorrow and decide this is what I want to do with no education --

MS. LEVIS: Yes.

REPRESENTATIVE WANSACZ: -- or training to be a --

MS. LEVIS: Yes, you could. Yes. Currently, in the State of Pennsylvania -- What Randy was enforcing is what the pathways are to become a certified practitioner nationwide. In the State of Pennsylvania there is no requirement to open the door, put a shingle outside that says you're an orthotist. There is nothing to prohibit you from doing that.

REPRESENTATIVE WANSACZ: And you can still be reimbursed for this --

MS. LEVIS: You could charge patients.

REPRESENTATIVE WANSACZ: -- to be certified.

MS. LEVIS: There are some insurance companies that may reimburse you. You will not get reimbursed from Medicare, no.

REPRESENTATIVE WANSACZ: And you would have to become certified to be reimbursed for Medicare?

MS. LEVIS: You would have to become certified and meet the many standards that CMS has to become a DMEPOS supplier.

REPRESENTATIVE WANSACZ: And at that point then, I'm assuming you would have to pass a state exam nationally?

MS. LEVIS: Well, most providers, orthotists, prosthetists, pedorthists, have formal education, in most cases college degree. They study a specialty. There are a few colleges in the country, maybe five, that offer the orthotic and prosthetic courses that people attend.

There's a residency program that you must be part of once you finish your schooling, and there's a one-year residency in each discipline. You need to work for a certified practice in order for yourself to become certified at the national level through one of the certifying agencies.

So to become a certified practitioner in one of the three disciplines, it requires a lot of training and education.

Many of the technical components, prosthetic components and prosthetic technologies require additional training and certifications in order to be able to provide those. C-Legs, the Touch Bionic hand, M.A.S. socket design, you need to get further education to be able to do those.

But, in Pennsylvania, if you have a patient who's willing to pay you cash, that patient can come to any one of you for that service because we are not regulated in any way here in the state.

REPRESENTATIVE WANSACZ: Okay. No further questions at this time. Thank you.

CHAIRMAN STURLA: Chairman Adolph.

REPRESENTATIVE ADOLPH: Thank you, Chairman Sturla. Good morning, ladies and gentlemen, thanks for testifying.

I was reading the amendment that will be offered a little later on if we ever vote on this piece of legislation. But I guess I have some questions.

I'm sure all three of you are certified and have gone through the examinations, and so forth and so on. I'll try to get to the point without pronouncing all these professionals here. The members of POPS, how many members are certified in Pennsylvania in your organization?

MS. LEVIS: All members of POPS are certified practitioners, and all of the facilities are ABC, BOC-certified facilities.

REPRESENTATIVE ADOLPH: Okay. All right. Under the prosthetics, how many are out there?

MS. LEVIS: How many in numbers?

REPRESENTATIVE ADOLPH: Yes.

MS. LEVIS: There are almost 300 individual practitioners within the State of Pennsylvania.

REPRESENTATIVE ADOLPH: Three hundred, okay. And orthotics fitters, how many are certified in Pennsylvania, orthotic fitters?

MS. LEVIS: There are orthotic fitters who are certified, there are orthotic fitters who are trained. Orthotic fitters under the 300 --

MR. STEVENS: It's probably around 300 between BOC and ABC.

MS. LEVIS: Yeah.

MR. STEVENS: I think it's a higher percentage when I was looking. It's 300 plus, so I mean, it's really --

REPRESENTATIVE ADOLPH: So, we're talking about 300 total in Pennsylvania?

MR. STEVENS: If you would throw in -- Yeah. The total you would be looking at is, your direct question, orthotists, prosthetists and pedorthists, combination is right around 300. The orthotic fitters with that, that would put that, I would look at it well over 600 practitioners.

REPRESENTATIVE ADOLPH: Fine. So we have 300 of what you would consider qualified

professionals out there. How many right now in the State of Pennsylvania do you think are operating a business or practicing this profession without being certified?

MR. STEVENS: I would say in today's world, and if you're working in quality patient care and you're providing, you know, to the patient, it's prescription-based, so I think it's difficult, but yet it's not -- especially in pedorthics where I'm at because you can have individuals that can be doing modifications and stuff like that pedorthically that could affect an individual like Ace here that has Charcot Marie Tooth Syndrome and has a Charcot deformity, and someone could be modifying and taking care of his custom-molded footwear that's attached to a brace, that's a component of a brace and, in effect, could be detrimental to an individual like Ace.

I want to reiterate also, it's just not the numbers here in Pennsylvania because Philadelphia and Pittsburgh are so close to Ohio and New Jersey. There's New Jersey licensure and there's Ohio licensure. So oftentimes, even in West Virginia, which does

not have licensure, you'll see practitioners where -- might travel back and forth across state lines.

So you'd have to take -- especially Philadelphia, the population being that close to New Jersey, patients, practitioners travel both sides; likewise, the same way in Pittsburgh. They go back and forth, you know, between Ohio for services from Ohio to Pittsburgh. In Ohio they mandate licensure, you know, in order to take care of their patients also for orthotics, prosthetics and pedorthics.

REPRESENTATIVE ADOLPH: Okay. I'm not quite sure if you answered my question. But maybe it was more difficult than I thought.

You gave testimony that there was a ski instructor.

MR. STEVENS: Yeah.

REPRESENTATIVE ADOLPH: How many ski instructors are out there fitting folks? I mean, we're talking about patient care here.

MS. LEVIS: I think it goes beyond that because, patients are victimized, if you will, from a variety of sources, mail order,

Internet. They're obtaining services not just from knocking at the door, one of, you know, a shady operation down the street. There's a variety of sources. There are people coming over and providing service from other states.

So, to pinpoint a number you have to look at a lot. There are retail shoe stores that are providing some pedorthic services they're not qualified to do. So, it extends over a vast --

REPRESENTATIVE ADOLPH: So we may not have a number?

MR. STEVENS: Yeah. One of the other things is because of direct marketing also. I'd like to reiterate, I had a patient yesterday, they received two postcards from a company out of New York soliciting their business, saying it is time for them to replace their current diabetic shoes and inserts. And I told them, you know, that's something CMS frowns very much upon.

First off, we can't send out reminder cards. Second off, they're being solicited, you know, replace their shoes and inserts and it's being done by mail order. Now, if we have

licensure within that state, it would take away from those attacks that are being proposed and imposed upon our current patients here in this population to ensure the quality care. And in those types of individuals it would also -- they're at risk for amputation because of their condition.

So, it helps to further ensure their quality of life to make sure that they're being provided services through a licensed individual instead of somebody sending out a postcard and mailing them one pair of diabetic shoes and three pair of inserts for in the shoes.

REPRESENTATIVE ADOLPH: Are we talking about four different licensing for your group?

MR. STEVENS: Yeah. The field of orthotics, prosthetics and pedorthics, we all -- is comprised of orthotists, prosthetists, pedorthists and certified orthotic fitters. So we're looking at licensing all three of those, yeah. And it all falls underneath O, P and P, orthotics, prosthetics and pedorthics, which we have a very close tie to.

REPRESENTATIVE ADOLPH: Do you think there's people out there -- Representative Scavello talked about, in his testimony, a constituent of his who was having difficulty with an artificial leg. Do you think there's individuals out there in Pennsylvania that are fitting patients for artificial legs that are not certified?

MS. LEVIS: I believe there are people who are fitting patients who are not qualified. They may be borderline certified, they may be board eligible and they shouldn't be actually moving to that next stage of practice because there's no regulation within the scope of practice.

Yeah, I do believe that there are people that are getting sub-par treatment, the same in any health care specialty, but at least some of the others are licensed and regulated. So, people are getting sub-par treatment, and there are complications as a result of it.

REPRESENTATIVE ADOLPH: Thank you.

CHAIRMAN STURLA: I'd like to point out that we've been joined by Representative Yudichak and Representative Waters.

Representative Kotik has a question.

REPRESENTATIVE KOTIK: Thank you, Mr. Chairman. Thank you members of the panel. My question goes to the training that's being offered in a number of our vocational schools and possibly junior colleges. What criteria --

Is there any evaluation of the programs that are offered in these different institutions of learning to see whether they're really offering the kind of education that would qualify someone to go on and become certified?

MR. STEVENS: As far as the education pathways, the certifying bodies recognize, you know, specific schools oftentimes in their programs within their -- in order to achieve certification through their organizations, whether it's ABC or BOC. So, there -- You know, there are lists of schools out there currently.

I think if I recall last session Representative Sturla was concerned about, is there anything in this state. I'm very happy to say we do have two colleges in this state. University of Temple and now University of

Pittsburgh are now offering educational programming to support, you know, not just pedorthics, but orthotics and prosthetics.

REPRESENTATIVE KOTIK: I know there are a number of vocational tech schools, for lack of a better word, that are offering--

MR. STEVENS: Yeah.

REPRESENTATIVE KOTIK: -- a year and a half of training. I'm just wondering how qualified they are to offer these kind of instructions; whether they are really offering the students what they need to move on and become credentialed and certified.

MR. STEVENS: Yeah, I mean, virtually, a lot of them have universities. The majority of them all have ties to universities as far as their training and everything else. So, most of them are tied to universities of some sort or another.

REPRESENTATIVE KOTIK: Okay, thank you.

CHAIRMAN STURLA: Representative Mustio.

REPRESENTATIVE MUSTIO: Thank you, Mr. Chairman.

Eileen, could you go over with me a little bit how this two-year transition period will work? Basically, it sounds like it's a grandfathering clause.

MS. LEVIS: The grandfathering clause? I think, actually, Randy would be better, if I could defer to him, on that particular aspect.

REPRESENTATIVE MUSTIO: Okay.

MR. STEVENS: The grandfathering clause would be sort of like maybe Eileen addressed earlier. You know, you have some of those individuals that might not be certified currently, recognized, but there's a pathway for them so that their abilities can be tested and reviewed by, I guess it would be the board of directors of the licensing board and could actually qualify to be licensed.

So, if there is a group of individuals out there that are currently not certified, but, you know -- you know, it would give them that opportunity to achieve licensure even though they did not achieve certification at this point through a testing process.

REPRESENTATIVE MUSTIO: And you're

comfortable with that? Why not establish -- (inaudible words; voice trails off).

MR. STEVENS: It seems to be common ground pretty much because of -- especially I guess, how would you say it, in more rural areas where there might be an access issue and you could have somebody currently practicing within that setting. More than likely that individual would be a cash-pay basis because most insurances would not recognize the individual because they wouldn't be credentialed.

But, I would imagine in more rural areas there are probably individuals, you know, that -- especially pedorthically I'd think more so than orthotically and prosthetically, you know, that you would see maybe patients being treated with pedorthic modalities that are not certified.

REPRESENTATIVE MUSTIO: How do you see this individual providing verification to the board of their experience? What would they include in that resume?

MR. STEVENS: The resume would -- You know, currently I can't speak for a

committee -- or a board that has not been currently established at this time. But the board would, you know, have to regulate and promulgate those regulations, you know, that would pertain to those individuals. You know, basically, it would be like, I guess, what, an interview process and application process for them to submit to be licensed through the State of Pennsylvania.

REPRESENTATIVE MUSTIO: As a professional you're comfortable with that?

MR. STEVENS: I feel there has to be that two-year clause. Seeing that -- Like I said, because in some of those more rural areas, especially pedorthically, probably not as -- I'll reiterate, not so much orthotically and prosthetically, but to give those individuals that maybe might have been practicing for quite a few years but not as pedorthists, but providing these types of medical devices--And that's what they are, they're medical devices, you know--would be able to achieve licensure so that way those individuals in their area in which they reside could be guaranteed that those individuals are

qualified in treating them so no undue harm is brought to them.

MS. LEVIS: And those individuals would be licensed within the scope of the licensure practice as an orthotic fitter, as an orthotist, a prosthetist or pedorthist. So that if you are not qualified to fit prosthetics, you won't be licensed as a prosthetist. You would be licensed under the licensing within the scope of your expertise and your experience.

REPRESENTATIVE MUSTIO: As you were saying all those words, it just came across my mind whether you actually have to take some sort of speech class to qualify.

MS. LEVIS: Yes.

REPRESENTATIVE MUSTIO: I can't even say it. Thank you, Mr. Chairman.

CHAIRMAN STURLA: Thank you. Representative Helm.

REPRESENTATIVE HELM: Thank you, Chairman Sturla.

My question has to do with continuing education. The statement was made about how these devices have progressed and changed

through the years. I just wonder, say somebody gets licensed in the future, next month, whenever we approve the bill, and they become complacent. What requirements are there that they have to keep up on what's going on in continuing education?

MR. STEVENS: Currently, both certifying bodies I believe go on a five-year cycle for C.P.'s. And I understand the state's norm is a three-year cycle. So the board would adopt the -- or two-year cycle--I'm sorry, correction there--would go on a two-year cycle and then whatever, you know, would be orchestrated, you know, to sort of parallel what would be mandated.

Whatever percentage would be required within that five-year period would be reduced within that two-year period. So, it would follow the current set standards for what C.P.'s are out there.

CHAIRMAN STURLA: Questions from other members? Representative Waters.

REPRESENTATIVE WATERS: Thank you, Mr. Chairman. Thank you for being here today with your testimony and thanks to my colleague

Mario.

This practice -- I just want to ask you, during wartime, and we are unfortunately losing -- soldiers losing legs because of the war, does this -- Are there more and more of a demand for people, and are they being used abroad to practice this?

MS. LEVIS: There is more of a demand. There are more amputees coming back from the war. And typically what happens, they'll come in through the central V.A. and they'll be treated there, their prosthesis may be ordered there, and then they are dispensed to be followed by local V.A.'s.

But then once they leave there, you don't know where they're going to go; you don't know where they're going to have their follow-up work. You know, we like to stay with our patients when we get them, but sometimes if they live in rural parts of the nation, you don't know where some of those veterans are going to wind up getting their treatment.

REPRESENTATIVE WATERS: I see. Right now the certification is a national certification that currently governs this

practice. And I do see cases where there are children because of an accident or some other reason lose their limbs too. What is the standard for a background check for people who practice this? What is the standard on a background check?

MS. LEVIS: In our practice all practitioners are required to have a background check done; state background check, a check of their credentials with the certifying agencies. That check is updated every year. That's pretty much the standard in the certified orthotics and prosthetic practices.

REPRESENTATIVE WATERS: Yeah, but there are some people who are practicing that are not certified.

MS. LEVIS: Exactly.

REPRESENTATIVE WATERS: So it is important that there are standards, first of all, that people must enter and cross in order for them to show that they are okay in order to practice this.

MS. LEVIS: So, in the State of Pennsylvania if you find yourself at a Pennsylvania Children's Hospital or at a

Pennsylvania Veterans Administration, there's no regulation. If you're in another state, you may get a higher quality of care.

REPRESENTATIVE WATERS: Okay. So you're -- I'm assuming you don't oppose this. So you're saying that it would definitely be the standard to make sure that these background clearances are --

MS. LEVIS: Yes.

REPRESENTATIVE WATERS: -- done routinely and updated, I guess periodically to make sure that there are no changes in a person's status?

MS. LEVIS: Um-hm.

REPRESENTATIVE WATERS: Am I correct to assume that?

MS. LEVIS: Yes.

REPRESENTATIVE WATERS: Okay. Thank you, Mr. Chairman.

MR. STEVENS: Also, if I can make an addition. If nobody -- If anybody doesn't understand, really in all reality, in our types of facilities, the majority of us all operate more or less like a physician's office; by appointment. There are certain documentation,

that we keep patient records, we have to chart notes, we have to -- just as a physician would have to do.

So, you know, oftentimes, you know, you walk into a place like mine or any other members of POPS, you're walking into a very professional-type setting, so it's really -- You know, we have to maintain the same types of records that physicians maintain on our patients that we treat.

CHAIRMAN STURLA: Any final questions from members?

(No response)

CHAIRMAN STURLA: Thank you. Next on the agenda is Steve Fletcher, Immediate Past President of the Board of Directors of the American Board for Certification in Orthotics, Prosthetics and Pedorthics.

MR. FLETCHER: Thank you, Mr. Chairman. I will apologize up front for my voice. I'm not going to read through my entire testimony because I don't think my voice would last that long. And I realize that we're a little over on time according to the agenda, so I will try to keep my comments as brief as

possible.

My name is Steve Fletcher. I am currently the Immediate Past President of ABC, which is the American Board for Certification in Orthotics, Prosthetics and Pedorthics. I'm currently on the board of directors. I am a licensed prosthetist/orthotist from Florida. Actually, it's not in my testimony, but I was on the original licensing board in Florida when the licensure law was initiated there as well.

I'm representing ABC and NCOPE as well. NCOPE is the National Commission on Orthotic and Prosthetic Education. There is a lot, sort of background material in the first couple pages of my testimony that you have in front of you, I hope. And I think probably due to the nature of our time and since we're running a little bit behind, I'm going to just comment on some suggested amendments that we would respectfully hand to the committee. That's on page 3 of my testimony if you want to refer to that.

I think just a brief comment before I get into our suggested amendments, we really applaud this initiative. ABC and NCOPE support

licensure. We think this is appropriate. It's a protection for patients that we serve. We think that it is the right way to go.

ABC is a national certifying and accrediting organization. It's volunteer. It has been in existence for many, many years. Licensure is a more recent development in our profession, and as our profession has matured over the years, it's the appropriate thing to do. So we are in support of licensure.

Having said that, we do have some -- respectfully, some edits that we would suggest to the way the current amended statute reads. And I'm just going to go through these briefly and quickly. Please interrupt me if I'm not making any sense because there is language and terminology I understand that's foreign to many of you.

The thing that I just want to make sure all the committee members understand is, there is different levels of care. There's orthotics, prosthetics and pedorthics. The four different titles that you see listed, orthotist, prosthetist, pedorthist, and orthotic fitter, all represent a certain level

of care. And so, some of our comments are going to speak to that.

The first comment I would make would be, that in the definitions section of the statute under orthotic fitter there is a reference in there to custom-molded therapeutic footwear and custom-molded foot orthotics. That seems to be a foreign thing to us as far as existing standard and scope of practice of an orthotic fitter. We believe that that seems to be out of place. Those are custom-molded, custom-fabricated devices; whereas, the scope of practice of an orthotic fitter, the domain of where they interface with patients is in the prefabricated device realm.

So, we just believe that those two instances there seem to be out of place. We would respectfully suggest that those two references be removed from the definition of an orthotic fitter.

The bulk of my comments are going to be in Section 3(b), in the qualification section for currently listed orthotist, prosthetist, orthotic fitter and pedorthist.

As I mentioned earlier, we see a

significant difference in the level of care that's provided by each of those different types of professionals. We think that the science and art, if you will, of orthotics and prosthetics has changed dramatically over the last 20 years.

The complex nature of the interactions that we have with patients is a much higher and more sophisticated level. Twenty-five to 30 years ago we were brace fitters and device manufacturers; whereas, now we're an allied health care profession, and that's probably the best way of putting it.

We have to make qualitative decisions about what type of care. I'm going to speak to the orthotist and prosthetist license first. It is very common that a physician will rely on the orthotist or prosthetist to come up with the prescription criteria, what that patient needs. Because of that, we really feel strongly that the education and training that is behind that orthotist and prosthetist certification from ABC, but will be licensure if you pass this, is critical that they have a formal education in orthotics and prosthetics.

I think it's critical.

Orthotists and prosthetists and the combination, prosthetists/orthotists, those are folks who do comprehensive orthotics and prosthetics and pedorthics. They do the full realm of it from the lowest-end type of device to the most complex type of device with a high risk factor. We believe the requirements for them should be higher than for an orthotic fitter who has a domain of prefabricated devices.

As you can see on page 4 of my testimony, we have suggested this addition to Section 3(b) to the statute. To qualify for licensure to practice as a prosthetist, orthotist or prosthetist/orthotist an individual shall; 1, possess a minimum of a bachelor's degree in orthotics and prosthetics from a college or university, or a baccalaureate degree and a certificate in orthotics and/or prosthetics, as appropriate, from a program recognized by the Commission on the Accreditation of Allied Health Education Programs (CAAHEP) or an equivalent accrediting organization, as determined by the board.

And 2, complete an appropriate internship of one year of qualified experience as determined by the board, or a residency program recognized by the board.

What our suggestive edits would do would be remove numbers 1, 2, 3 and 5 from the existing statute, but number 4 would remain because there needs to be an examination requirement as well. To become a certified orthotist or prosthetist from ABC you have to have a bachelor's degree; you have to have done a residency; an NCOPE residency for one year in each discipline and then pass a series of three exams. We think that that is the optimum standard for patient care providers for orthotists and prosthetists.

I am going to keep moving because I know my time is short. The existing statute I believe would be appropriate for the orthotic fitter and the pedorthist statute; and so, our suggestions would be that the language would be similar to what it is, but that you would define each of these different professionals separately.

The next would be to qualify for

licensure to practice as a pedorthist, an individual shall, and then the existing 1, 2, 3 and 4 would be appropriate. I think removing the term prosthetic and orthotic would just clean up the language and it would make it defined specifically for a pedorthist.

Number 5 you'll see we have suggested to remove. We think it's just a redundant to number 2. We don't see a reason for it being there.

And for the orthotic fitter, it would be very similar where the existing 1, 2, 3 and 4 are still there, but the words prosthetic and pedorthic would be removed.

Just a couple other very brief edits that we would suggest, and just some questions maybe in Section 3(d) of the existing statute. The word certain in the title is just unclear to us. We're not sure if this denotes different types of prosthetists, orthotists, pedorthists and orthotic fitters. So we were unclear about what that exactly meant and, perhaps, that could be clarified or just removed.

Another one is in 3(d) Sections 2 and

3. There's reference there to a medical diagnostic examination, and we feel like that's another unclear term that we would just point out. And I think either the statute needs to define what that is, or perhaps, remove 2 and 3 from that section, especially if they're talking about the physicians. And if you all understand, we don't see anything other than by a physician's prescription. We don't see patients independently. They have to have a prescription to come to us.

If that reference to medical diagnostic exam means that it's an exam that the physician is doing that we have to do these things, then I think it's impractical because we don't have access to that. So that's just another question that we see in that.

The last edit I will just mention is in Section 10, number 3. What we would suggest you do, and I have some experience this way being on the floor of the licensing board in the past, that at the end of the sentence of number 10.3 that you would add, whose licensure requirements are equal to or higher than those required for licensure in this Commonwealth, as

determined by the board.

The reason for that suggestion is that you don't know what another state is going to do. You don't know what the level of requirement for their licensure is. And if you just openly say you will accept any, then the state of, you pick one, can create a licensure law that has very low, very poor standards, and if you have license in that state you can cross over by the way it's written now. We think if the goal of the statute is to protect the citizens of Pennsylvania, then you should add that, perhaps.

Again, I apologize for my voice. And I know I ran through those pretty quickly because I know we're a little behind, but I'll be glad to answer any questions.

CHAIRMAN STURLA: Thank you. Questions from members? Representative Solobay.

REPRESENTATIVE SOLOBAY: Thank you, Mr. Chairman. Thank you for your input.

Is this something that could -- maybe look at it and see a national-type certification registry across the board with

even the specifics on fitting the device, development, the whole works as opposed to doing it state by state?

MR. FLETCHER: That's an excellent question. It's a daunting one, though. Medicare currently is working really hard on trying to establish some quality standards and what they call supplier standards, because in the eyes of Medicare we're suppliers of DEMEPOS, durable medical equipment, prosthetic, orthotic supplies. We fall under that.

They are promulgating those rules today for quality standards to try to get a hold of this. To be perfectly honest, they're regulating the businesses, the facilities that provide this; not the individuals who are employed by those facilities.

And one other point, just based on some of the conversations and questions earlier. One of the challenging things that Medicare has done in 2006 is, when they created this system they invited accrediting organizations to become deemed authorities to accredit prosthetic/orthotic suppliers.

Well, they approved everyone that

applied. They didn't, in our opinion, use a lot of discretion to say that only those who have some experience in that area should be deemed as an authority. Eleven organizations applied, 11 got accepted. That's down to 10 now. It's changed.

But, we feel there are organizations that were deemed by Medicare, just basically filled an application out, to be honest. That's to accredit the organization, the business, if you will, to provide these services to a Medicare beneficiary.

What the licensure law does is come alongside that and says, no, but the person who is touching the patient has to have some qualifications. The challenge is that some of those deemed authorities in the accrediting organizations that Medicare said were okay, they may have very low standards and that's okay. And they may be within your state; and so, the control system is not good still.

Your question is excellent and we would love that, but I think it's a tough battle across -- Every state has its own issues, so it's a tough one.

REPRESENTATIVE SOLOBAY: Is there a national organization of the individuals that are certified?

MR. FLETCHER: There are several national organizations. There are two credentialing organizations: American Board for Certification, ABC, and BOC, the Board for Orthotic Certification. Those are the two that certify individuals and accredit facilities. There are also national organizations. The American Academy of Orthotists and Prosthetists is one, it's a scientific. And there's a trade association -- there's two, AOPA and PFA. And those are just a lot of alphabet soup, but there are national organizations.

REPRESENTATIVE SOLOBAY: And with all that, do they do a continuing-education process?

MR. FLETCHER: Absolutely. Academy sponsors it, PFA sponsors them, AOPA. The ABC and BOC are the ones who keep track, if you will, and make sure that if you're certified by us, that you have a certain type and certain amount of continuing-education credits.

REPRESENTATIVE SOLOBAY: It just

seems as we battle the high cost of health care, and this ties right in directly to that, that this would be something that we look at because, obviously, these devices can be very expensive as well as -- especially if it's fitted wrong or done wrong and have to be repeated. The situation just --

MR. FLETCHER: Absolutely. And, actually, it's been anecdotal, but in Florida when the licensure initiative was going, that was a huge issue that, you know, insurance companies are difficult to deal with. And once you've had a prosthesis or an orthosis paid for and it was inappropriate, you're kind of out of luck, even if it was terrible care and it was off -- They paid for it. You know, it would have to be extreme and they could possibly go back on that person, but yeah, that's an issue.

REPRESENTATIVE SOLOBAY: Correlation then, obviously, between those folks that are certified in a stronger sense of an educational background and the certifications versus those that are not, is there a big differential between the success of the device provided for a patient?

MR. FLETCHER: I might answer a little different than you're asking, but I think it might get to a little bit of what you're asking, because I think somewhat you're asking fairly subjective and hard to quantify.

A good example of the risk here is the recent issue in Florida a few years back where there was huge Medicare fraud, millions of dollars of patients being billed for prostheses and they weren't amputees.

Once that was all uncovered, it was discovered that none of the people who were perpetrating that were certified. These were all just out there; sort of durable medical equipment suppliers, if you will, and not to put a bad light on that title, but that's where the fraud was occurring. It wasn't within the certified realm. So there's a distinct, and Medicare recognizes that I think very clearly now.

But, quality is a hard one to be perfectly honest. This is an art as much as a science. We are fitting a human live, flesh person with a device.

REPRESENTATIVE SOLOBAY: And their

physical condition can change with the healing process and everything else how it fits.

MR. FLETCHER: Absolutely.

REPRESENTATIVE SOLOBAY: Thank you.

MR. FLETCHER: Yes.

CHAIRMAN STURLA: Chairman Adolph.

REPRESENTATIVE ADOLPH: Thank you. Thank you, Mr. Fletcher, for your testimony. You suggest some amendments. I have an amendment in front of me, and I think the biggest difference between your recommendations and the amendment that I have in front of me is, one says possess a high school diploma or its equivalent. And your suggestion is, possess a minimum of a baccalaureate degree in orthotics or prosthetics from a college or university. Would you comment on why you think a college degree is necessary to be licensed?

MR. FLETCHER: Absolutely. And I will go back a little bit to my testimony. For sake of time I didn't read through this, but I may refer back to that just so that there's a little more of a description of what we -- how we feel, ABC and NCOPE, toward this subject.

Let me read page 2. I'm sorry to

read this to you. The principal focus of ABC and NCOPE activities is to assure that qualified practitioners are the fundamental source for orthotic, prosthetic and pedorthic care. Indeed, the ABC and NCOPE standards address rigorous educational, training and experiential requirements, which are the essential building blocks for the competent care of patients.

I'm going to skip down to the next paragraph. Orthotics, prosthetics and pedorthics have grown from craft and manufacturing trades of the late 1800's and early 1900's to clinically-based allied health professions. ABC certified orthotists and prosthetists require a minimum of a four-year bachelor's degree and a clinical residency of one year. The profession has mandated an entry-level master's degree by the year 2012, so it's actually moving up to a master's level for orthotists and prosthetists.

Today, as a health care sciences clinician, an orthotist and prosthetist cares for patients with complex orthopedic disabilities, congenital anomalies or traumatic

injuries that are often -- that are also often affected by other complicated disease processes. As a clinical health care provider, he or she is involved with the custom fabrication of devices and the use of sophisticated technology that were unknown 25 years ago.

Parenthetically, as in medicine, advances in the art, science and technology of orthotics and prosthetics will also continue, probably at an exponential rate. By necessity, then, the orthotist and prosthetist must have advanced educational and training in biomechanics, anatomy, kinesiology, pathology and other medical and engineering sciences.

There is no better evidence than to look at the newspaper, magazines and television reports of how our soldiers are being helped after losing a limb or sustaining a spinal cord injury while fighting for our country in Iraq and Afghanistan.

The body of knowledge has grown and the sophistication of what we are doing has grown. And I think the change of health care where the physicians, the referral source, are

relying on the orthotist and prosthetist to make those tough decisions about what type of device is appropriate and when that device is appropriate, I think it is hard to argue against not having some formal education to be that level of care provider.

REPRESENTATIVE ADOLPH: Thank you.

CHAIRMAN STURLA: Representative Readshaw.

REPRESENTATIVE READSHAW: Thank you, Mr. Chairman. Thank you, Mr. Fletcher, for being here today.

I'd just like to ask what the state of Florida's position may or may not have been in consideration of the grandfather clause.

MR. FLETCHER: I'm glad you asked that. I would have forgot to mention it. There was a grandfather clause in that statute. One thing that we determined early on -- And to be honest, part of this was all promulgated by the rules of the board; not necessarily stated all specifically in statute, although a lot of it was.

We determined that you would have to have passed a test if you were not certified at

all and had no evidence that you could -- that you could show us that you were competent at some level. Even if you had already been practicing, then we required that you take a test and the board in Florida determined what that test was.

They did some analysis and determined which test would be the appropriate, what they called the licensure exam; different than a certification exam, if you understand. The certification exam is a series of exams. But the Florida board picked one of those exams for the candidate to take. If they could pass that and they could prove they had been practicing for five years in the state, five years in the state--And that was a bit of an issue, I'll be honest--then they could get their license. They didn't have to become certified. They just had to show by passing the test.

REPRESENTATIVE READSHAW: Thank you very much for your response.

MR. FLETCHER: Yes.

CHAIRMAN STURLA: Representative Wansacz.

REPRESENTATIVE WANSACZ: Thank you,

Chairman Sturla.

Representative Readshaw hit on some of the stuff we've been discussing down here considering the grandfathering and exactly how they do things in Florida. So, one thing, when they licensed practitioners in Florida, they said you have practiced for five years and then pass a licensing exam that the State of Florida came up with. Is there a -- and I believe there is. There's currently a national licensing certification exam. Is that what it is now?

MR. FLETCHER: There are two different ones. ABC has theirs and BOC has theirs.

REPRESENTATIVE WANSACZ: Okay. So what I'm hearing from you and what we heard from maybe some of the earlier testifiers is, as we discussed maybe in the example of a rural area of saying, you know, should we not license them or just say here's a license, they don't have to pass a certification, that draws a red flag up automatically saying what those people in the rural areas don't deserve as much as somebody in an urban area, make sure they have

the same qualification. And that's a concern of mine.

So, I'm wondering in Florida, it's pretty much no matter where you're from, I don't care if you're from Tallahassee, West Palm, or whatever part of Florida, you all have to be licensed to show what you're doing, correct?

MR. FLETCHER: That's correct.

REPRESENTATIVE WANSACZ: So I appreciate that. Thank you. I just want to compliment the sponsor of the bill. Obviously, he's taking on an issue here that has raised a lot of concerns and showing that we need to be taking a look at this. Thank you, Chairman Sturla.

CHAIRMAN STURLA: Any other questions from members?

(No response).

CHAIRMAN STURLA: All right. Thank you.

MR. FLETCHER: Thank you very much.

CHAIRMAN STURLA: Next is Donald Fedder, President Emeritus, Board of Orthotist/Prosthetist Certification.

DOCTOR FEDDER: Mr. Chairman, members of the committee, thank you very much for the opportunity to discuss this bill. My name is Don Fedder. I'm President Emeritus of the Board for Orthotist/Prosthetist Certification. We had to do a promo some time ago and it took a skilled actress about a day to be able to say that well on the promo. So I understand it's difficult.

Just for the record, I hold a bachelor degree of pharmacy from the University of Maryland and a master's and doctor of public health degrees from Johns Hopkins Bloomberg School of Public Health. And I'm currently professor of pharmacy and medicine at the University of Maryland, Baltimore, where I have served on the faculty since 1974.

I speak in support of House Bill 2015 and the proposed amendment. I especially wish to compliment the sponsors of this bill for recognizing, as the U.S. Congress, the Department of Health and Human Services, and its administrative arm, the Centers for Medicare/Medicaid Standards has, the validity of the standard and credentialing procedures

developed by the National Commission for Certifying Agencies, and its parent, the National Organization for Competency Assurance. These credentialing standards make it possible for even the smallest states to establish licensing to assure the availability of a competent and disciplined work force to serve its citizens.

Without nationally developed and credentialed procedures, it would be extremely difficult and prohibitively expensive for even a state the size of Pennsylvania to develop the range of exams necessary to assure their constituents of the competence of their licensees.

As Steve has testified before, some of the states have used just one part of the examination as some kind of a licensing examination, and it's problematic. What NCCA has done is laid out a procedure and both ABC and BOC have followed those procedures and have had their procedures accredited by NCCA--It's extremely important to understand that--so that you have national standards, and that's important.

I had the privilege to be involved in the '70's in the early development of NCCA--I'm an old guy, I've been around here a long time--so I've seen the development of all this. You need to understand that following World War II, HEW, and now HSS, saw the need to look at this problem of small professions that were not large enough to be able to have statewide state licensing, because they couldn't get a body big enough to put this all together.

So, what they did is, they convened a series of meeting and over time developed the National Commission for Certified Agencies. And that process requires that we establish a set of competencies necessary to perform the tasks that one needs to have to be able to perform; to do, whether we're an orthotist, a prosthetist, a fitter, or a pedorthist. Each of these things have a different set of competencies.

The competencies are developed by national surveys; not just in Pennsylvania, but across the country. So we look across the entire United States and do a national survey. And when we get those back, we were able to

look at the competencies, what are people doing first? What is the practice out there? And it varies a little bit, but it's pretty much the same.

What is being done out there is not all bad. I mean, some of the things you're hearing is that there's a tragedy out there. It's not really. There are things that are going on and there are some nasty stuff going on and there's some crooks. But for the most part, you have a group of people out there taking care of patients across the country.

And based upon what that is, we then bring together small committees and branch out to larger committees to be able to define what are the competencies. What are the things that one needs to do and what knowledge and skills and ability one has to have in order to perform those.

And then you bring together large groups of people to develop examinations. And those examinations are upgraded every year, and we have what is called a psychometric company. We use Applied Measurement Professionals, but there are a number of psychometric companies

who supervise this whole process and by statistics, and so forth, evaluate every single question that goes into that examination. So that, we end up with an examination which is valid, and those are technical statistical words, but it means that it is measuring what we say it's measuring. And both ABC and BOC follow the same procedures.

Several year ago we sat down together to explore some kind of merger, and we opened up each other's examination and we exposed them and looked at them. They weren't identical, of course not, because different committees did it. But they basically were the same. Both organizations were pleased that we were doing a good job.

As a matter of fact, we both opened up our roles to each other's certificate so that ABC said if you're BOC, we'll certify you. And BOC said if you're ABC, we will certify you as BOC. They won the battle, they got more people than we did.

But, in any event, what this says is that there -- this is a demonstration of the equivalency of the two examinations, the two

processes. When I say Congress has passed a bill, Congress did pass a bill in 2000 called BIPA 2000 and mandated that one had to be either ABC or BOC certified in order to be able to bill, to provide services for certain activities. It's not the entire growth of practice, but it was for certain activ -- certain services, and that the facility had to be accredited. Both ABC and BOC are in that law.

So the thing that I want to assure you is that this process is very, very good. As a single state it would be very difficult for you to duplicate this kind of process. You don't have enough people. You've got about 300 people serving in the state, or maybe 500 at the outset. In the entire country there are probably less than 20,000 people practicing across this whole board.

So, when you have these very small bodies you have difficulty dividing them up, 50 states to do this, that's why this bill is relying on NCCA for credentialing. And I would strongly advise that your board look to those certifications as a way to measure someone's

competency; that you can't replicate that process; the state can't actually replicate that process. It's very difficult to do.

The bill is not perfect. But I think as my mom taught me, perfect is the enemy of good. And I thank you for your attention. I'll be happy to answer any questions you might have.

CHAIRMAN STURLA: Representative Goodman.

REPRESENTATIVE GOODMAN: Thank you, Mr. Chairman. I absolutely love that line. It applies to the General Assembly on many levels.

You bring up a very good point, and a point that Timmy and I were talking about. My daughter is nurse at IEP, and my wife is a nurse. They only take a handful of nurses at IEP every year because, when I served on the PAR (phonetic) task force, we went all around the state during medical malpractice and all the issues that were going on, and we discovered that --

One of the questions I asked when we were at Saint Joe's was, I have constituents coming into my office who want to be nurses.

We have a nursing shortage, not only in Pennsylvania but nationwide. How is it that I have all these students who want to be nurses and they can't get into nursing school? They told me it's because we've raised the level of expertise so highly.

My wife is a nurse and she struggled to get her master's degree. When you come out of nursing school -- I'm taking a long way around the barn, Mr. Chairman. When she came out of nursing school, like a typical nurse, she wanted to get married, she wanted to start a family. She wanted to start working in her profession, and they told her you have to have a master's degree in order to teach. She went away from teaching. She's now the head of ICCU.

But when I asked that question, why do I have so many students who can't get into nursing school, they told me because we've made the pyramid so pointed, that in order to become a teacher of nursing you now have to have your doctorate degree.

I worry about this throughout the medical profession as a whole. We are becoming

so specialized that we are cutting people below them, saying that, you know, we have people in this profession right now who in your opinion are very well trained at this. As we keep raising the bar, though, we drop a lot of people out. In a field where it's difficult to get an awful lot of professionals, should we be doing that?

It's a word of caution I'm putting out there that we seem to be raising the bar so high. Now, granted, you know, this is not -- This is serious stuff. I mean, if someone has a prosthetic, they want a prosthetic that fits. They want it done by a professional, they want it done by somebody who knows what they're doing and someone who's going to be around for quite some time so if there's a problem it can be fixed.

But I'm worried that as we become more and more demanding on these different lines of professions, that we are cutting people out and making it almost -- extremely difficult for any other business to get into these businesses and soon we'll have nothing more than two or three that can do it.

It's more of a statement than, I guess, a question. But am I on the right path here?

DOCTOR FEDDER: If I may. It's not a question, but I think that I will tell you from my experience as far as pharmacy is concerned, my experience in orthotics is concerned; and if you'll look at physical therapy, physical therapy is now looking for a doctorate, somebody who fits -- who does the ear analysis for my hearing aids now has a doctorate in otolaryngology, this is the trend. The trend is -- Part of that trend is because people in the field like to be -- like good titles. This is why the basis that we have for certification of BOC is to look at the competencies and measure those competencies, and we don't have a pathway to get there.

The major problem in this field is that we don't have enough schools around here. If we talk about this education process, what you have in Pennsylvania are short-term courses, and there are very few straight college courses like you have in the larger professions. The reason for that is because we

were much late in coming into the field.

After World War II there was funding for all kinds of health care education, and this super structure developed. It's natural for people to want to get a higher and higher and higher degree. A lot of it is the guild mentality, which is to -- an area for me and keep the rest of the bastards out, pardon my language.

This is part of what does happen in professions, it really does. There's no question that there is a strong scientific and engineering underpinning of this field and you need competent people. But the process by which you get competent people is so diffused right now that it's very hard. The schools throughout the NCOPE process, the last I looked at the data, turn out about 190 people in the entire country a year. Now, that's a pittance of what we need.

So what happens is that, in practices all over the country, particularly in the chains, they train their own people. And they like to get them and they will probably send them through to become a certified fitter. But

then they send them to the hospital to take measurements, and then they set up a process by which they have confidence that the person can perform these certain things so they let them do the next thing and the next thing, working under their certification.

So, it's because you have this shortage of a process to be able to develop these folks, you end up with that kind of process.

One of the things that BOC established was that if anybody is performing the task of an orthotist or prosthetist or a fitter for two years or more, they are -- not only should be able to take the examination for certification at the level in which they are, they should be required to do that before they go forward with touching another patient. They shouldn't be allowed to practice under somebody else's certification for years, and they do. In a lot of these places they go for 10 years.

So it's one of those things that it's difficult, but what you have in this bill with the National Commission for Certifying Agency Standards is some assurance that your licensees

are going to be competent because they have to pass that series of examinations, and it's based upon national standards. And it's very difficult for each state, as I'm repeating myself -- But it is very difficult for each state to try to duplicate that. I don't think you can.

So, I would caution your board when they sit down to this thing not to try to micro manage that process because I don't think you'll be successful. And you'll have people coming to you to tell you, my goodness, you're letting people come in here and they don't have a bachelor's degree. Well, they're out there practicing without it, and you don't want them that way. They must have passed a certification examination. And I don't see how --

And as I said, I've been doing this thing for a long, long time. I'm an educator that's been in the field for a long, long time. And I can assure you that there are different pathways to get there, but the only way that you can assure your patient population and your citizens of something is that they've passed

these competency-based examinations.

I don't care how they got there. If they're out there in a practice site, they should be required to take a national accrediting examination. It is certainly comprehensive. But we try to keep it so that you don't have artificial barriers to be able to take that examination.

And what I see happening a lot of times is -- And I see this in my field in pharmacy. Now everybody has to have a doctor of pharmacy. When I graduated I had a bachelor of pharmacy. When I went on the faculty I had a bachelor of pharmacy. I found out that bachelor of pharmacy wouldn't work because they now have Pharm.D., doctor of pharmacy.

So that's when I went over to Hopkins and did a master's and doctorate in public health starting at age 50. I was nuts, but it was a good thing for me to do.

But in any event, this is what happens. Professionals want to raise the standards, raise the standards, but it's so much of what the guild did. I think that you need to take that into consideration. What

your responsibility is to your state, to your citizens is to try the best you can to ensure that the persons operating on your citizenry have competencies. National standards are the best you can do. It's very hard otherwise. Thank you.

CHAIRMAN STURLA: Questions from other members?

(No response.)

CHAIRMAN STURLA: One final comment I'll make. Here in the House Professional Licensure Committee in Pennsylvania we like to think that good and perfect are not mutually exclusive and we always try to be perfect as well as good. If you have comments that you can make this bill perfect, we're all for it today.

DOCTOR FEDDER: Well, the comments I would say, I don't really want to disturb the whole process because it's difficult. I don't want to see this go back to the next year.

The thing that I'm concerned about is the ability for the board -- It seems like it's setting up the potential for being able to write its own examination, and that's the thing

that I would caution you. And I think it's Section 3 of -- I've forgotten now what it is. I had been asked not to get into that.

I think that that's the problem that I would caution you, to make sure that the board understands that it can't set -- I mean, you can end up with a board that's only five members or something like that, it's a relatively small board. And I don't think they can substitute their judgment for this national standard kind of thing. That's the caution.

CHAIRMAN STURLA: Okay.

DOCTOR FEDDER: There's one other little thing that I think the ladies here will understand, if I can find it. I was told not to worry with this thing. Someplace it talks about exclusions under prosthetist, and it says to the words, cosmetic devices such as breast prosthesis or breast forms.

Breast forms are not cosmetic devices. I would take that cosmetic devices and put it after breast forms because they're not included for a prosthetist, but they are therapeutic devices. I will tell you the people that I know who fit mastectomy patients,

those are not cosmetic devices. Those are therapeutic devices. They shouldn't be on your bill calling them cosmetic devices.

CHAIRMAN STURLA: Thank you.

DOCTOR FEDDER: Thank you, sir. Thank you members of the committee.

CHAIRMAN STURLA: All right. Thank you. Next on the agenda is Mike Davis, Executive Director of the Pennsylvania Podiatric Medical Association.

MR. DAVIS: Good morning. Chairman Sturla and Representative Adolph and members of the committee, my name is Michael Davis. I'm Executive Director of the Pennsylvania Podiatric Medical Association. We count as our members over 85 percent of the doctors of podiatric medicine licensed in the State of Pennsylvania.

I'm appearing here today in order to support the licensure of pedorthists, orthotists and prosthetists under the terms of House Bill 2015.

The profession of podiatry enjoys a virtually unlimited scope of practice within a limited part of the anatomy. That scope,

focusing on the foot and ankle, is an area in which the podiatric physician often sees the first symptoms of diabetes. The lower extremity exhibits the results of the vascular compromise that often accompanies diabetes.

That disease, as well as other degenerative conditions, often results in wounds, structural failure and can lead to amputation. In these areas our association members work closely with the pedorthists, orthotists and prosthetists who would be covered by this legislation.

It is important to our profession, as well as to the patients that we serve, that the professionalism of pedorthist, orthotist and prosthetist be codified by licensure and receive the safety and transparency that licensure provides. One of the issues that licensure will provide is a type of quality assurance. Quality assurance is a current demand of both the health care system and the public.

We cannot overemphasize the importance of quality and patient safety. The areas in which pedorthists, orthotists and

prosthetists work relates directly to continued mobility, continued productivity and an elevated quality of life. These are not tangential subjects. Every statistical analysis relating to ambulation demonstrates that the ability to maintain ambulation is a key element in limb salvage, limb retention, delayed morbidity and delayed mortality.

Accelerated morbidity adds costs to the medical system at an almost logarithmic rate. Limb compromise and loss requires the services of these professionals. Without them, limb compromise and loss leads to loss of ambulation and accelerated mortality with its attendant end-of-life cost. Although the prosthetist works in all areas of the body, a substantial percentage of the work of all pedorthists, orthotists and prosthetists relates to the foot and ankle. This is one of the reasons that we welcome this legislation.

The profession of podiatry rests on the degree of doctor of podiatric medicine, which is granted after a four-year postgraduate education offered through eight schools around the country. One of the premier schools is the

Temple University School of Podiatric Medicine located in Philadelphia. I speak to this because the Temple school curriculum includes orthotics and pedorthics, which are required subjects for each medical student.

Additionally, Temple offers review courses in orthotics and pedorthy to orthotists and pedorthists who are preparing for certification by the orthotics and pedorthy certifying boards. The school also offers courses to orthotists and pedorthists who are already certified and who must maintain continuing education in their field.

However, while offering our support, we do have a technical insertion that we would like to see in order to avoid issues that could arise through a strict construction of Section 6 of the language of the proposed bill. Section 3(h) of the proposed legislation states that nothing in the legislation prevents a podiatrist from engaging in the, quote, practice in which the podiatrist is licensed.

Later in Section 6 the legislation provides that it shall be unlawful for any person who is not a licensed pedorthist,

orthotist and prosthetist from practicing orthotics, pedorthics or as a prosthetist, except as provide in Section 3(e). If you look back to Section 3(e), that relates to training.

We need to have words and Section 3(h) inserted in Section 6 directly after the words 3(e).

The doctor of podiatric medicine, upon conferral of the degree, has the education, training and ability to practice as an orthotist as that profession relates to the foot and ankle. We also practice as a pedorthist without additional certification or license.

We feel that the suggested additional language would eliminate restrictive interpretations and avoid issues that could cause confusion. This proposed licensing should apply to those who do not have a degree of doctor of podiatric medicine.

In conclusion, our association has worked with the members of POPS in trying to craft a pragmatic structure under which these professionals can become licensed and regulated. Our profession works with

pedorthist, orthotists and prosthetists on a regular basis, and will continue to work with their association in the promotion of their profession. Thank you.

CHAIRMAN STURLA: Questions from members?

(No response.)

CHAIRMAN STURLA: That's what happens when you get late.

MR. DAVIS: Fine by me.

CHAIRMAN STURLA: Thank you. Next is Brian Lagana, Executive Director of Pedorthic Footwear Association.

MR. LAGANA: Thank you, Chairman Sturla, and the members of the committee on Professional Licensure. I'm Brian Lagana, the Executive Director of the Pedorthic Footwear Association.

PFA appreciates the opportunity to speak here today in support of House Bill 2015 and its amendments which will provide licensure for orthotists, prosthetists and pedorthists here in the Commonwealth.

Before I go on, I just want to hopefully answer a bit better the question that

Representative Adolph had posed earlier. I went back through PFA's membership records yesterday. While these numbers -- I would not stake my life on the hundred percent accuracy of these numbers, they'll give you a pretty good representation of the percentage of credentialed orthotists to pedorthists here in the Commonwealth.

PFA has about 115 members that fall into two membership categories, regular individual member and regular company member. Those are the categories that, traditionally, a pedorthist and most certainly a credentialed pedorthist would fall under.

I calculate that out of about 115 members, there are about 65 of those that are credentialed either by -- mainly by ABC and BOC. The number that I quote, and this might be -- give or take a couple, there are about 98 credentialed ABC pedorthists here in the state. Add on top of that X number from BOC, and that will give you a relative percentage of credentialed versus noncredentialed practitioners.

Going back to PFA, PFA is one of only

three associations in the world that is solely dedicated to represent pedorthists and the pedorthic profession. Right not PFA has about 2,000 members in the U.S. and overseas. I was just going to reference that to you that I just provided you, so I'll skip that.

As you know, pedorthics is the design, manufacture, modification and fit of shoes and foot orthoses to alleviate problems caused by disease, congenital condition, overuse or injury. Through PFA's efforts over the past 50 years, the practice of pedorthics has become a well-established and recognized allied health profession with standards established by ABC and BOC.

Unlike many interest groups that seek to limit the attention from federal and state governing bodies and regulators, and work toward lessening regulations imposed on their constituents, PFA and its members have worked for years to increase the recognition of pedorthics at the federal and state level with the goal of achieving federal and state oversight of the practice.

The increase in population of elderly

and physically-challenged individuals who require pedorthic services indicates that the pedorthic profession be regulated to ensure the provision of high-quality services, footwear and orthotics. At-risk patients deserve the best care available, and will benefit from the assurance of initial and ongoing professional competence of credentialed and/or state-licensed pedorthists practicing in each of the 50 states.

The practice of pedorthics serves to improve and enhance the lives of individuals with disabilities by enabling them to resume productive lives following serious illness, injury, or trauma. Unregulated dispensing of pedorthic care does not adequately meet the needs or serve the interests of the public.

In keeping with the reasoning behind state requirements imposed on similar health care disciplines, licensure of the pedorthic profession will ensure -- help to ensure the health and safety of consumers, as well as maximize their functional abilities and productivity levels.

After a lot of effort on the part of

PFA, and the then Board for Certification in Pedorthics, now ABC, and other organizations representing Medicare suppliers, regulatory recognition has been achieved at the federal level. As mentioned earlier, CMS has proposed regulations that will require all providers of DMEPOS, pedorthists, orthotists and prosthetists in this case, to be credentialed by CMS recognized credentialing organizations. Again for pedorthists, those organizations are primarily ABC and BOC.

The CMS regulation is a tremendous step forward at the national level in ensuring quality and safe patient care through qualified practitioners, and maintaining the integrity of the Medicare program in general and, more specifically for pedorthists, at least the Medicare's Therapeutic Shoes for Persons with Diabetes benefit with TSD.

This benefit has been in place since 1993 with the goal of reducing the instances of lower-extremity amputations on diabetic patients using conservative therapeutic and protective shoes and orthotics. Diabetics are certainly a high-risk population, and one

deserving the best of care to prevent traumatic and life-altering amputations.

However, not all practitioners treat diabetic patients or accept Medicare assignment, leaving a population of practitioners outside the jurisdiction of Medicare's oversight and its qualified provider requirements. That gap has been addressed in eight states so far and, hopefully, will be addressed in Pennsylvania as well. State licensure requirements in all states for pedorthists and other DMEPOS suppliers is critical.

PFA has long encouraged the passage of legislation implementing professional licensure requirements for pedorthic practitioners at the state level. Licensure is currently required in seven states; Florida, Ohio, Illinois, Oklahoma, Tennessee, Arkansas and Alabama. New Jersey provides for optional pedorthic licensure within broader mandatory requirements for orthotic and prosthetic licensure. In addition to Pennsylvania, licensure legislation is currently under consideration in New York, and as what would

have it today in Kentucky.

State licensure ensures that all pedorthists, whether they accept Medicare assignment or not, are regulated. This, in turn, ensures that all patients receive uniform, safe and high-quality care; that state Medicaid programs and third-party payers are reimbursing only to qualified practitioners, again, thereby maintaining the integrity of the benefit. And that patient access is expanded since credentialed practitioners are recognized more often than noncredentialed practitioners by third-party payers.

PFA applauds the Commonwealth and Representative Scavello for its leadership in assuring quality health care by introducing H.B. 2015 and its amendments.

States license dentists, members of the clergy, lawyers, fortune tellers in Maryland, and frog catchers in South Carolina. It makes good public policy to require health care practitioners who have a significant impact on the quality of living of at-risk diabetic patients, and others with chronic foot problems or foot injuries, to be held to a

higher, regulated standard. Again, PFA strongly supports the passage of H.B. 2015 and its amendments. Thank you for your time.

CHAIRMAN STURLA: Thank you. Questions from members?

(No response.)

CHAIRMAN STURLA: All right. Thank you very much.

MR. LAGANA: Thank you.

CHAIRMAN STURLA: Next we have Richard Rafferty, a member of the National Orthotic Manufacturers Association.

MR. RAFFERTY: It's almost good afternoon. Good morning, thank you for the opportunity to let us speak in front of this board.

I have prepared testimony which everyone has. I'd also like to stray from that a little bit with several remarks. I will start with my testimony, though.

My name is Richard Rafferty. I'm the Group Product Manager for EPI, LP, doing business as Biomet, Incorporated. We're a manufacturer of orthotic and orthopedic devices headquartered in Parsippany, New Jersey. We

have over 1100 employees, many of whom are Pennsylvania residents. As a matter of fact, we have approximately 50 to 60 employees who live in the State of Pennsylvania, and our group, the NOMA group, has over 200 employees in the State of Pennsylvania.

I'd like to begin by thanking the committee for the opportunity to discuss House Bill 2015. My focus today is, actually, very narrow, and it is on the importance of providing an exemption under the licensing regime for representatives of orthotics manufacturers to measure and fit these devices under the supervision of a physician or other licensed health care professional. The bill currently does not contain such an exemption.

NOMA is a national trade association of FDA-regulated manufacturers of orthotic devices. Our members manufacture and sell thousands of devices in the Commonwealth, and we work alongside physicians and other health care professionals to provide orthotic devices to Pennsylvanians.

NOMA's member companies produce a wide range of technologically advanced orthotic

devices, and each of our members take great pride in the high quality of its products. Our members make both custom fitted; that is, adapted from components that are adjusted to the needs of the patient, or custom-fabricated products, which means that the device was built specifically for that particular patient.

Ultimately, our members' products benefit patients in Pennsylvania and the rest of the United States by providing a major therapeutic approach to a wide variety of diseases and disabilities.

My comments today are limited to the provisions of House Bill 2015 with respect to the practice of orthotics. Many of the testifiers up here have discussed prosthetics, have discussed pedorthics. We're talking about orthotics and, in general, we're talking about knee and spinal orthotics.

NOMA has no position regarding the bill's applicability to prosthetics and pedorthics. NOMA opposes H.B. 2015 in its current form for two reasons. First, we would respectfully point out that the vast majority of states do not have license requirements for

orthotists. And as been stated here, it is --

Thirteen states have licensing requirements, and I would point out that in every one of those states either by direct, a line in the bill, or by interpretation, there are exemptions for manufacturers' representatives in every one of those states.

It is doubtful that patients benefit from the licensing requirements that are in effect in a few states. These licensing requirements tend to limit competition, reduce treatment options for physicians and drive up costs.

Second, even if the state decides to adopt a licensing requirement, it should not apply to the kinds of activities in which NOMA manufacturers' representatives are engaged.

In particular, we urge the legislature to add an amendment that allows manufacturers' representatives to measure, fit and adjust orthotics under the supervision of a physician or other licensed health care professional. This amendment would allow NOMA's representatives to provide significant benefits to physicians and patients.

The states that have adopted the licensing requirements over the last few years, including Alabama, Oklahoma, Georgia, Tennessee, and Arkansas, have included such exemptions in their statutes. And I believe those exemptions are written into the New York State law and the Kentucky law that are both pending.

Today, physicians in Pennsylvania must prescribe an orthotic device in order for the patient to have access to one. In other words, we have to do this by prescription. Although the physician is the only professional qualified to prescribe such a device, the patient has to be measured and fitted for the device as well.

In order to measure and fit the device, physicians now have the option to refer the patient to an independent orthotist, to rely upon their own staff, or to rely upon a manufacturer's representative to measure and fit the patient for orthotic devices in the physician's office, usually during the same visit; thus, the choice for fitting the device currently rests with the physician. H.B. 2015

would take this choice away from physicians.

Allowing the patient to be measured and fitted in the physician's office can avoid a great deal of inconvenience and cost for the patient, particularly an elderly or disabled person, who might find it exceedingly difficult to travel from his or her physician's office to an orthotist's office, which might be located in another city.

In deciding who should measure and fit a device, the physician plays the role as gatekeeper. If he feels that an orthotist needs to see the patient, he has the option to refer the patient to one. If she feels that the patient can have the device measured and fitted in the doctor's office, he has that option. Thus, the interests of the patient are protected under our proposed amendment.

NOMA members' representatives have completed extensive specialized training, testing and quality assurance programs. They are required to develop expertise in their products and to understand the safest and most effective ways to use them. However, they do not make clinical or medical decisions.

Instead, they work under the supervision of a licensed physician or health care professional to provide the devices requested.

It's important to recognize that an orthotist's scope of practice under the current bill would be much broader than the activities of a manufacturer's representative contemplated by our proposed amendment. Under our proposed amendment, manufacturers' representatives would be limited to measuring, fitting and adjusting orthotics under the supervision of a licensed physician or other health care professional.

On the other hand, a licensed orthotist could evaluate, design, fabricate, assemble, and service orthotics, and such actions need not be supervised by anyone.

It is also important to keep in mind that there will not be a licensed orthotist in every community in Pennsylvania. Based on information we have regarding certified orthotists, many communities, particularly in rural areas, have no certified orthotists. Thus, patients would have to travel to another city to find one.

If the legislature imposes a

licensing requirement on NOMA's manufacturing representatives, the overall effect will be to prevent them from providing services that now benefit physicians and patients. Some of them may not be able to obtain a license because of education requirements, and even those who have the necessary educational requirements would be forced out of the marketplace for a significant period in order to comply with unnecessary and pointless licensing requirements.

We hope the committee will include an exemption to the proposed orthotic licensing requirement that allows manufacturers' representatives to measure, fit and adjust orthotics under the supervision of a licensed physician or other health care professional. Such an exemption would benefit patients and physicians in the Commonwealth, because it would allow our members to provide the low-cost and high-quality products and services that patients and health care providers have come to depend on.

Thank you for the opportunity for allowing me to give this testimony. I would welcome any questions from the committee.

CHAIRMAN STURLA: Questions? Representative Mustio.

REPRESENTATIVE MUSTIO: I just have a comment, Mr. Chairman. In the interest of time, if we could maybe have staff follow up with the previous testifiers getting their input on the exemption, or the exception, I think that would help.

CHAIRMAN STURLA: I appreciate that. Questions from other members?

(No response.)

CHAIRMAN STURLA: I have one question for you. When you talk about supervision of a physician or other licensed health care professional, I'm assuming that by other licensed health care professionals you mean those that have exemptions under 3(h) on the proposed amendment, so we're not having dental hygienist supervise --

MR. RAFFERTY: No.

CHAIRMAN STURLA: Okay. I think what we'll do is probably get -- Would you still believe that those employees should be certified if not licensed?

MR. RAFFERTY: Certified by the

state?

CHAIRMAN STURLA: Certified with the national certification for that.

MR. RAFFERTY: No, because we believe that they have the training applicable to allow them to fit those devices that are within the scope of our companies. They are certified by us in order to do those devices.

And again, they're working under the supervision of a physician who works as the gatekeeper to say, yes, that patient needs this device; no, they don't need this device. This is what we want, this is what I'd like this patient to have. And under the supervision of that physician, again, who is the gatekeeper there and who is making the medical decision on the care of that patient, that's the way our representatives work.

CHAIRMAN STURLA: Okay. Judging from some of the eyebrows I saw raised in the audience --

MR. RAFFERTY: I knew there would be. I felt them all raising up out there.

CHAIRMAN STURLA: Questions from other members?

(No response.)

CHAIRMAN STURLA: I think we will continue this discussion as we continue to develop this bill. Thank you.

MR. RAFFERTY: Thank you.

CHAIRMAN STURLA: Just for the information of members, we will continue to work on this and try to get input from those people who testified, as well as others to try and get this -- perhaps not a perfect bill, but a pretty darn good one. Thank you. Meeting adjourned.

(At or about 12 o'clock noon the hearing was concluded.)

* * * *

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