COMMONWEALTH OF PENNSYLVANIA
HOUSE OF REPRESENTATIVES

HEALTH COMMITTEE HEARING

STATE CAPITOL
HARRISBURG, PA

IRVIS OFFICE BUILDING
ROOM G-50

MONDAY, SEPTEMBER 17, 2012
1:00 P.M.

PRESENTATION ON HB 2290
CENTRAL SUPPLY TECHNICIAN
CERTIFICATION ACT

BEFORE:
HONORABLE MATTHEW E. BAKER, MAJORITY CHAIRMAN
HONORABLE RYAN P. AUMENT
HONORABLE BRYAN CUTLER
HONORABLE KEITH GILLESPIE
HONORABLE MAUREE GINGRICH
HONORABLE KURT A. MASSER
HONORABLE JERRY STERN
HONORABLE MARCY TOEPEL
HONORABLE JOHN MYERS, DEMOCRATIC CHAIRMAN
HONORABLE PAMELA A. DeLISSIO
HONORABLE JOHN P. SABATINA, JR.
HONORABLE KEN SMITH
HONORABLE RONALD G. WATERS

* * * * *

COMMITTEE STAFF PRESENT:

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1 P R O C E E D I N G S
2 * * *
3 MAJORITY CHAIRMAN BAKER: Good afternoon, everyone.
4 The hour of 1 o'clock having arrived, the Health
5 Committee will come to order.
6 If the Members would be so kind as to introduce
7 themselves, and we'll then proceed.
8 REPRESENTATIVE MASSER: Representative Kurt Masser,
9 107th District, Northumberland County.
10 REPRESENTATIVE TOEPEL: Marcy Toepel, 147th
11 Legislative District, Montgomery County.
12 REPRESENTATIVE STERN: Jerry Stern from the
13 80th District in Blair County.
14 REPRESENTATIVE SABATINA: John Sabatina, the 174th
15 District in Philadelphia.
16 REPRESENTATIVE DeLISSIO: Pam DeLissio, the 194th,
17 representing parts of Philadelphia and Montgomery Counties.
18 MINORITY CHAIRMAN MYERS: John Myers, Philadelphia
19 County, Democratic Chairman.
20 MAJORITY CHAIRMAN BAKER: Matt Baker, representing
21 Tioga and Bradford Counties, Majority Chairman.
22 To my left is Janelle Lynch, the Executive Director
23 of the Health Committee.
24 REPRESENTATIVE GINGRICH: Thank you, Mr. Chairman.
25 I know Janelle has a voice.

1 And I'm Representative Mauree Gingrich from Lebanon
2 County and the sponsor of the bill we're discussing today,
3 HB 2290. Thank you.
4 MAJORITY CHAIRMAN BAKER: And Representative
5 Gingrich, would you like to make some opening remarks on your
6 legislation?
7 REPRESENTATIVE GINGRICH: Thank you, Mr. Chairman.
8 In fact, thank you very much to both Chairmen for
9 scheduling this hearing. Thank you to the staff who are always
10 there for us -- Janelle for helping to arrange it, and Gina in
11 patience. Thank you, and thank you all for coming.
12 To talk a little bit more in depth about
13 HB 2290.
14 2290, as you can see from the language of the bill,
15 requires certification and continued education for central
16 supply technicians -- some people refer to them as "sterile
17 processing technicians" -- and those are the people who are
18 responsible for the sterile processing of all the durable
19 medical instrumentation in our health-care facilities.
20 And this bill is totally and completely about
21 patient protection. We feel that certification will lead to a
22 higher level of competency and patient care, and continuing
23 education, of course, will ensure that those high standards are
24 maintained. With the cost, the high cost of infections being
25 so high, prevention definitely is the key.

1 In the past decade, I think we've all recognized and
2 certainly awareness has been elevated for those of us that were
3 professionals or are professionals in the health-care field and
4 the public at large. The intricacy and the advancements that
5 have revolutionized surgery also come with it some more
6 elaborate processes necessary to maintain, clean, and sterilize
7 the equipment.
8 Strange things happen that as laypeople we probably
9 don't think about or recognize, but in the complicated,
10 sophisticated mechanisms that are used in surgery
11 instrumentation now, we're dealing with a term that I knew from
12 my college days, but never referred to it commonly, but is
13 "bioburden." To you and I, that's blood and tissue. And part
14 of the process and the responsibility of the individuals doing
15 this job is to make sure that the instrumentation, all this
16 instrumentation, is clean, sterile, and functioning before it
17 gets to the area, you know, where it's being used.
18 So it's a very complicated role that they play, much
19 more so now than it was in the past for sure, and our awareness
20 level has really risen according to some of the infection
21 rates, which I think in Pennsylvania we are doing a good job
22 with it.
23 But in talking about the demands on that personnel
24 and what kind of training should be in place and how we can
25 best deal with that, this is a good factfinding venture,

1 Mr. Chairman. I thank you. I'm looking forward to hearing
2 from our professional presenters with us today.
3 Thanks.
4 MAJORITY CHAIRMAN BAKER: Thank you, Representative
5 Gingrich, for your leadership and bringing this important
6 patient safety legislative initiative to our attention.
7 Our first testifier this afternoon is Anna Marie
8 Sossong.
9 DEPUTY SECRETARY SOSSONG: Very good.
10 MAJORITY CHAIRMAN BAKER: Thank you.
11 She is the Deputy Secretary for Quality Assurance
12 with the Pennsylvania Department of Health, and you may proceed
13 when you're ready.
14 DEPUTY SECRETARY SOSSONG: Thank you very much.
15 Good afternoon, Chairman Baker, Chairman Myers, and
16 Members of the Health Committee. I wanted to first thank you
17 for extending an opportunity to provide you testimony on the
18 bill, which, if enacted, will provide for certification of
19 central supply technicians who perform sterilization procedures
20 in health-care facilities.
21 The Department of Health has statutory authority and
22 contractual authority via CMS to oversee the compliance with
23 State law of various licensed health-care facilities in the
24 Commonwealth. As a point of information, we do not oversee or
25 inspect doctor's offices or urgent-care centers.

1 The Quality Assurance Deputate carries out the
2 statutory mandates of the Health Care Facilities Act and other
3 State laws that regulate the delivery of patient care in
4 hospitals, nursing homes, ambulatory surgical facilities,
5 abortion clinics, home health agencies, hospices, and cancer
6 treatment centers.
7 As part of our licensure, certification, and
8 enforcement functions, we survey health-care facilities to
9 ensure that they are in compliance with the State regulations
10 outlined in PA Code Section 28 and with the Conditions of
11 Participation established by the Federal Government's Centers
12 for Medicare & Medicaid Services, CMS, and I referred to them
13 earlier. Any facility that desires to accept Medicare or
14 Medicaid payments for patient care must comply with the CMS
15 Conditions of Participation.
16 The Department of Health's Quality Assurance
17 Deputate is responsible for inspecting the facilities and
18 reporting their compliance status to CMS. Regardless of
19 whether our inspections are done to ensure compliance with
20 State law or with the CMS Conditions of Participation, the
21 regulations and conditions are in place to promote the delivery
22 of quality, safe health care for Pennsylvania citizens.
23 In addition to collecting and reviewing our own
24 data, the department also reviews and publishes
25 healthcare-associated infections, known as HAI data, reported

1 by Pennsylvania hospitals as required by statute, Act 52 of
2 2007, which is known as the PA Health Care-Associated Infection
3 and Control Act.
4 Since the focus of HB 2290 is infection control, I
5 will limit my remarks to selected relevant aspects of the
6 Department of Health and, in particular, the Quality Assurance
7 Deputate's role and activities related to infection prevention
8 and control.
9 Our current regulations require facilities to have a
10 documented infection control plan and policies, including
11 identification of the nationally recognized guidelines the
12 facility chooses to follow for the establishment and conduct of
13 its infection control program. The department reviews
14 compliance with these regulatory obligations during our
15 licensure surveys and any other surveys we may conduct where
16 infection control is a potential issue.
17 The Centers for Disease Control 2008 Guideline for
18 Disinfection and Sterilization in Healthcare Facilities
19 presents evidence-based recommendations on the preferred
20 methods for cleaning, disinfection, and sterilization of
21 patient-care medical devices and for cleaning and disinfecting
22 the health-care environment. Health-care facilities are
23 expected to incorporate this guideline in their infection
24 control policies and practices, and the department surveyors
25 look for evidence of this compliance during our surveys.

1 Our staff also review facilities' infection control
2 policies and procedures, adherence to nationally accepted
3 evidence-based practices related to prevention of infection,
4 and procedures related to training of their personnel about
5 infection control standards and practices. The department
6 surveyors also observe personnel onsite in facilities as they
7 carry out their day-to-day patient-care activities and
8 carefully scrutinize the care environment.
9 Our current regulations require that the person in
10 charge of infection control has specialized infection control
11 training. However, we do not specify the content or teaching
12 methods for the education and training that facilities are
13 required to provide to personnel who hold any position directly
14 responsible for sterilizing instruments and devices used in
15 surgery or other procedures.
16 Our 2011-12 survey data reveal very few -- 11 --
17 deficiencies in hospitals related to infection control. All
18 11 deficiencies cited were due to behavior of personnel in the
19 patient-care setting and did not involve any instrument
20 sterilization process. We identified deficiencies such as the
21 failure to follow policies for handwashing, handling soiled
22 linens, and IV procedures; or we observed unsanitary conditions
23 in a nursing unit such as stains in a refrigerator, or failure
24 to label stored breast milk as a potential biohazard, and used
25 laryngoscope blades found in a sink.

1 Nursing homes reported slightly more deficiencies.
2 The bulk of these were violations of policies related to
3 handwashing and handling of linen, with a few related to the
4 storage of supplies, ice machine functioning, and screening of
5 patients and/or staff for tuberculosis. Again, violations in
6 nursing homes were not related principally to the sterilization
7 process.
8 Ambulatory surgical facilities were cited for
9 24 deficiencies related to infection control of the same
10 general nature as those for hospitals and nursing homes; for
11 example, failure to follow stated policies for hand hygiene and
12 disinfection of equipment, improper surgical attire, and lack
13 of awareness of infection control guidelines. There were a few
14 deficiencies cited related to sterile techniques in ASFs,
15 ambulatory surgical facilities, but those reflect actions by
16 clinic staff such as the failure to sterilize an IV tubing port
17 before injecting medication. These numbers were still small in
18 comparison to the universe of deficiencies or the totals of all
19 infection control deficiencies cited in ASFs.
20 Hospitals and nursing homes are subject to Federal
21 guidelines, regulations, and special programs focusing on
22 prevention of infection and reduction of rates of infection
23 that patients acquire from being in that facility. Many of the
24 facilities we regulate are accountable to other entities for
25 their patient-care outcomes, including infection rates.

1 The prevention of infection is one primary focus of
2 National Patient Safety Goals, CMS Conditions of Participation,
3 and standards established and enforced by accrediting bodies
4 such as the Joint Commission.
5 CMS mandates that nursing homes have a program to
6 "investigate, control and prevent infections." Many of the PA
7 nursing homes are involved in the nationwide "Advancing
8 Excellence in America's Nursing Homes" campaign, which has
9 "prevent and manage infections" as one of its goals.
10 Overall, Pennsylvania has experienced a decline in
11 healthcare-associated infections, and this decline has
12 continued every year since we started to measure these
13 outcomes.
14 If enacted, the Quality Assurance Deputate will bear
15 responsibility to ensure compliance with HB 2290 through
16 examination of the education and training records of all
17 facility personnel designated as "central supply technicians."
18 We will also ensure that the required continuing education is
19 maintained and documented by the facility. Individuals who
20 perform the same function as central supply technicians within
21 the scope of their current licensure but who are not designated
22 as "central supply technicians" by the facility will not be
23 reviewed by the department and are not currently covered by the
24 act.
25 HB 2290, if enacted, will have minimal impact on the

1 Quality Assurance Deputate's inspection and survey role with
2 the affected facilities. However, the department believes that
3 the existing laws and regulations enacted by this General
4 Assembly, coupled with private accrediting body rules and CMS
5 compliance standards, are addressing many of the policy points
6 HB 2290 intends to regulate.
7 That's the extent of my comments. If you have any
8 questions.
9 MAJORITY CHAIRMAN BAKER: Thank you very much for
10 your testimony on HB 2290.
11 I'm curious, with respect to the infections
12 themselves, what are the most common infections that you find
13 prevalent?
14 DEPUTY SECRETARY SOSSONG: Of the ones that we
15 track, the most common is the catheter, let's call it
16 catheter-acquired infections. That is also one that is a
17 priority track for CMS. It is a priority for the Joint
18 Commission. It is, as these things go, it is the number-one
19 issue of every organization that is reviewing
20 healthcare-acquired infections.
21 MAJORITY CHAIRMAN BAKER: And what does that result
22 in? What I'm looking for is the actual diagnosis.
23 DEPUTY SECRETARY SOSSONG: In most cases, it's going
24 to be a urinary tract infection.
25 MAJORITY CHAIRMAN BAKER: UTI.

1 DEPUTY SECRETARY SOSSONG: Yes; right.
2 MAJORITY CHAIRMAN BAKER: Okay.
3 DEPUTY SECRETARY SOSSONG: And the infection is not
4 -- I can't speak across the board, but generally the infection
5 is not related to a nonsterile piece of equipment. It's just
6 the nature of the thing. It's a UTI problem.
7 MAJORITY CHAIRMAN BAKER: So hospital-acquired
8 infections -- MRSA, staph infections, et cetera -- I'm just
9 trying to get a feeling for how prevalent that is in a medical
10 setting.
11 DEPUTY SECRETARY SOSSONG: In terms of?
12 MAJORITY CHAIRMAN BAKER: Of either human error,
13 equipment, sterilization issues.
14 DEPUTY SECRETARY SOSSONG: It's far less -- far, far
15 less prevalent than it was as recently as 4 or 5 years ago.
16 There has been a nationwide, not only in Pennsylvania, but a
17 nationwide move to attack the healthcare-acquired infection
18 problem because it increases the cost of health care; it
19 increases the payouts from insurance companies to the extent
20 that, at least in the nursing-home arena and the hospital arena
21 both, the CMS Conditions of Participation, soon CMS will be
22 imposing -- well, they're not going to pay if they decide that
23 a person is in the facility longer than they should be because
24 of a healthcare-acquired infection. They are not going to pay
25 for that care. They have told facilities that far enough in

1 advance that the knowledge that they will not be paid for this
2 has really put this right on front and center of everybody's
3 radar to make this problem go away.
4 MAJORITY CHAIRMAN BAKER: It's a new policy that
5 they---
6 DEPUTY SECRETARY SOSSONG: Well, not really new but
7 relatively. They haven't started it yet. I think it kicks in
8 next year.
9 MAJORITY CHAIRMAN BAKER: Okay.
10 DEPUTY SECRETARY SOSSONG: In other words, they gave
11 everybody---
12 MAJORITY CHAIRMAN BAKER: They're proposing it.
13 DEPUTY SECRETARY SOSSONG: Right. They told
14 everybody it's coming, and they've given everybody time to put
15 the ball in motion, so to speak.
16 MAJORITY CHAIRMAN BAKER: Thank you.
17 Chairman Myers.
18 MINORITY CHAIRMAN MYERS: Thank you, Mr. Chairman.
19 Thank you for your testimony.
20 DEPUTY SECRETARY SOSSONG: Sure.
21 MINORITY CHAIRMAN MYERS: I have a couple of
22 questions, but I guess I wanted to make a comment that, you
23 know, the need for this legislation just baffles me, that we
24 need this kind of legislation, you know? I mean, people know
25 when they go in the hospital they aren't supposed to come out

1 sick. People who work in the hospital know they aren't
2 supposed to make people sick. Everybody knows the way to wash
3 their hands. Folks know -- I mean, you know, this is like, I
4 don't know, like kindergarten or something, you know? People
5 that do this, I mean, they really know what they should be
6 doing, but now we've got to pay for them to, you know, be
7 re-educated about cleaning your hands and brush your teeth and
8 clean underneath your arm and wash your sneaks and socks. And,
9 you know, it just amazes me that we're even here at this point.
10 However, having said that, I guess in the context of
11 it being weird, I wanted to see how weird it really is: How
12 many cases have been reported?
13 DEPUTY SECRETARY SOSSONG: In terms of the actual
14 subject of this, which is specifically---
15 MINORITY CHAIRMAN MYERS: Infectious diseases.
16 DEPUTY SECRETARY SOSSONG: Well, the specific thing
17 here is the cleaning of medical equipment that has resulted in
18 some sort of a deficiency. It is extraordinarily rare. In our
19 deficiency citations, we found virtually none. I can't tell
20 you exactly how many, but I'm thinking it was less than
21 10 total last year that were specifically related to the topic
22 of this bill, which is machinery and equipment and medical
23 devices that require cleaning.
24 The context that we found, healthcare-acquired
25 infection or infection control prevention issues, were not the

1 matters that would be addressed by this bill. They were things
2 that you were speaking of earlier -- handwashing and cleaning
3 linens and things that have nothing to do with this bill.
4 Those are the more common and, quite honestly, more difficult
5 to control, because they're personal. You know, whether you
6 remember to wash your hands or I remember to wash my hands or
7 what happens -- did I drag the sheet on the floor before I put
8 it on the bed? -- those are different issues not covered by
9 this.
10 MINORITY CHAIRMAN MYERS: Okay. Well, then I guess
11 there is some reason why they're not covered, you know, in this
12 context. I mean, we decided to target a specific segment of
13 health care, those who actually have the responsibility of
14 moving mechanisms and instruments that are involved in the
15 health care. So that's specifically where this bill is, I
16 understand that.
17 I guess, like I said, part of my amazement was that
18 we had to deal with it. So I wanted to find out, in addition
19 to this specific area of concentration, if there was any
20 thought given to broadening our oversight of this so that it
21 covers a whole spectrum of "keep things clean".
22 DEPUTY SECRETARY SOSSONG: Well, we do have, you
23 know, the Health Care Facilities Act, which does include the
24 obligation to file the infection control plan and the
25 obligation for the facility to maintain the plan that, you

1 know, when the surveyors from the department go in, they survey
2 and make sure that there is compliance with that plan, and if
3 there is not compliance, we cite them for a deficiency and they
4 have to file corrections to do that. So there is some existing
5 regulatory authority for us to go in and make sure that they
6 are doing whatever they have devised as their plan now.
7 MINORITY CHAIRMAN MYERS: Let me ask you this
8 question here: How much does it cost? And on many occasions,
9 you know, I try not to be like so pressurized that when we
10 leave out of here we've got to go get an aspirin or something,
11 you know? So I'm not approaching this from that context.
12 DEPUTY SECRETARY SOSSONG: Okay.
13 MINORITY CHAIRMAN MYERS: But actually I was
14 thinking about -- I don't know why -- but I was thinking about
15 meat cutters, you know, people that slaughter meat. They know
16 they're supposed to keep the utensils clean, you know?
17 DEPUTY SECRETARY SOSSONG: Yes.
18 MINORITY CHAIRMAN MYERS: And I guess I'm trying,
19 the question I want to ask is, how much does it cost for us to
20 send these technicians back to school to tell them that, you
21 know, your knives have got to be clean before you can cut
22 somebody?
23 DEPUTY SECRETARY SOSSONG: I actually did look at
24 this, because this was a question I had been asked previously.
25 And there are a lot of different programs, but we just picked

1 one of the sort of national trade association, and the programs
2 are running just a shade around $500. There are some that are
3 more, there are a few that are very slightly less, but that's
4 about what it seems.
5 MINORITY CHAIRMAN MYERS: All right.
6 DEPUTY SECRETARY SOSSONG: You know, it could be any
7 one of anything, but that was one of my questions because we
8 were curious.
9 MINORITY CHAIRMAN MYERS: That's a ballpark. Okay.
10 Now, I have one question, one remaining question
11 about the meat cutter not cleaning his knife: Who does it get
12 reported to?
13 DEPUTY SECRETARY SOSSONG: The meat cutter? Who
14 knows?
15 MINORITY CHAIRMAN MYERS: Is it reported to you all?
16 DEPUTY SECRETARY SOSSONG: No; I'm thinking that's
17 the Department of Agriculture.
18 MINORITY CHAIRMAN MYERS: What?
19 DEPUTY SECRETARY SOSSONG: I'm thinking that's the
20 Department of Agriculture, because they do food.
21 MINORITY CHAIRMAN MYERS: No, no, no. I know.
22 DEPUTY SECRETARY SOSSONG: They do food. It's not
23 me.
24 MINORITY CHAIRMAN MYERS: Yes; I know. Okay. Well,
25 you know, in the realm of what we're talking about. I know you

1 can follow me on this here.

2 DEPUTY SECRETARY SOSSONG: Right.

3 MINORITY CHAIRMAN MYERS: If a health-care facility
4 fails to report, you know, that the equipment is not being
5 cared for properly, what's the consequence, or is there a
6 consequence?

7 DEPUTY SECRETARY SOSSONG: Certainly.

8 If we identify that they have -- now, they do have
9 an obligation to report what are known as infrastructure
10 failures under the reporting system, so they would have an
11 obligation to report that. Let's say an autoclave broke or
12 something and they would have an obligation to report that to
13 us, if they either did not report it or continued to use it
14 even though it was broken, we would cite them. If they didn't
15 fix it, ultimately that could end up, after some time that
16 could result in CMS pulling their participation in the Medicare
17 program, which means they're not going to be able to accept
18 Medicare patients. So there is a consequence.

19 And in the instance, using your meat-cutter analogy,
20 there are also, of course, real practical liability issues that
21 have nothing to do with the Department of Health or CMS, that
22 if they're not doing what they should be doing, presumably it
23 will come back to haunt them.

24 MINORITY CHAIRMAN MYERS: All right.

25 Representative Gingrich, I think this is a great

1 bill, and, you know, if we just keep tweaking it out, then
2 we're going to get it where it needs to go.
3 MAJORITY CHAIRMAN BAKER: Thank you, Chairman Myers.
4 Deputy Secretary, I'm just curious, my mother
5 currently is hospitalized in isolation. I have to wear latex
6 gloves and I have to put a gown on because of previous UTI and
7 MRSA issues associated with her underlying conditions. Is it
8 CMS, is it the hospital, is it the Department of Health, is it
9 a combination of all of them that governs the patient's safety
10 infection control protocols?
11 DEPUTY SECRETARY SOSSONG: The protocols themselves
12 are mostly driven by the hospital in how they choose. The
13 obligations to have those protocols are driven both by the
14 Department of Health and CMS.
15 MAJORITY CHAIRMAN BAKER: Okay. Thank you.
16 I would like to recognize the presence of
17 Representative Aument, Representative Cutler, Representative
18 Smith, and Representative Gillespie, who are here with us and
19 are also good Health Committee Members.
20 Representative Gingrich.
21 REPRESENTATIVE GINGRICH: Thank you, Mr. Chairman
22 and Chairman Myers.
23 No meat cleavers working on me, okay?
24 MINORITY CHAIRMAN MYERS: Okay.
25 REPRESENTATIVE GINGRICH: Thank you for your

1 questions on the bill.

2 Specific to your role, and there will be a lot of

3 questions and a lot of dialog, let us know when we're going out

4 of your realm of responsibility.

5 DEPUTY SECRETARY SOSSONG: I will.

6 REPRESENTATIVE GINGRICH: One of the things in my

7 search, because this is of great interest to me, that despite

8 all the modern infection control practices and so on, from what

9 I've read and read even in the Pennsylvania Safety Authority

10 reports, that SSIs, which is the surgical site, which I'm most

11 interested in, the surgical site infections have been estimated

12 to be the number one or at least the one or two leading cause

13 of infections. This data is really hard to break down, and

14 first of all I commend the Department of Health. I think

15 you're doing a great job, and I think the hospitals are doing a

16 great job also working with us on that. The data part of the

17 initial source of the infection is an obstacle here for us, so

18 therefore, I keep bringing this back to the ounce of prevention

19 on the front side of it so that we don't even risk having this

20 happen with surgical site infections.

21 How much would the Department of Health know -- I

22 guess this is all I would want to ask you. Out of that data,

23 how would you ever know, the Department of Health, if equipment

24 is coming through the sterilization process and literally not

25 being totally clean and sterile by virtue of, and I'm being

1 technical here, but the bioburden in the tiny little clog, the
2 tubing and robotic instruments that we're now using, they don't
3 function or they come through that way and of course are tossed
4 in the operating room, and screaming the surgeon has got the
5 patient on the table and the equipment is not functional, not
6 ready, it's literally carrying old, sterilized tissue and
7 blood. Would you know that, and how would you know that?
8 DEPUTY SECRETARY SOSSONG: It would be difficult for
9 us to know it at the time that it happens. We have had
10 instances where equipment was being used, the autoclave example
11 I gave earlier where we had autoclaves being used that were
12 actually not functioning. That we did know. We make people
13 turn the stuff on, and when it's clear it's not working right,
14 we cite them. But something that might have occurred at the
15 time of the event, the surgical or whatever, the odds of us
16 identifying that are pretty slim.
17 The only reason that we might know that is because
18 the people in, let's assume it's a surgery room, the people in
19 the room, somebody might report it. And don't underestimate
20 how many times that happens. That's probably our number-one
21 source of complaints to the department, is employees reporting
22 something that they believe is not acceptable to them or in
23 compliance with our State or CMS regs. So the odds are, in my
24 estimate, we would hear about that.
25 REPRESENTATIVE GINGRICH: Yeah; the diligence on the

1 part of the employees---

2 DEPUTY SECRETARY SOSSONG: Right.

3 REPRESENTATIVE GINGRICH: ---is the factor there.

4 One of the things we all need to recognize, and I
5 know that we do, is that with specialized instrumentation that
6 is no longer just steel and glass that you threw in an
7 autoclave when you used autoclaves -- that's almost like, not
8 antiquated, but autoclaves are not like autoclaves used to be,
9 and you can't clean them with a hot shot of steam and expect
10 them to be clean. So they're very intricate. And again, this
11 isn't for you, so I'm going to hold the questions for people
12 who do the job and how would you actually clean that, because
13 you know a lot---

14 DEPUTY SECRETARY SOSSONG: Yeah; I have no clue.

15 REPRESENTATIVE GINGRICH: ---but you probably don't
16 know that.

17 DEPUTY SECRETARY SOSSONG: That I don't know.

18 REPRESENTATIVE GINGRICH: Thank you. Thank you very
19 much.

20 DEPUTY SECRETARY SOSSONG: Sure.

21 MAJORITY CHAIRMAN BAKER: Representative DeLissio.

22 REPRESENTATIVE DeLISSIO: Thank you.

23 Deputy Secretary, I just want a point of
24 clarification. When you talked about the Department of Health
25 doing a record review, this legislation is requiring people to

1 carry a certification. I just want to clarify that you're
2 team, surveyor team, does not go in and review every HR record
3 first?
4 DEPUTY SECRETARY SOSSONG: For central supply
5 technicians we would, yes.
6 REPRESENTATIVE DeLISSIO: You would.
7 DEPUTY SECRETARY SOSSONG: Yes.
8 REPRESENTATIVE DeLISSIO: You would pull and review
9 every---
10 DEPUTY SECRETARY SOSSONG: Yes. If they were
11 carrying a position description that was "central supply
12 technician," as this bill is written, we would go to a facility
13 and we would ask to see the personnel records of every central
14 supply technician, or at least their educational records, not
15 their personnel records, you know, complete personnel record,
16 but their educational record and their CE, continuing
17 education, records. Yes, we would.
18 REPRESENTATIVE DeLISSIO: Do you do that for any
19 other type of certification that's required?
20 DEPUTY SECRETARY SOSSONG: If it's required as part
21 of a regulatory obligation, yes, we do.
22 REPRESENTATIVE DeLISSIO: Give me an example.
23 DEPUTY SECRETARY SOSSONG: So we do credentialing,
24 for example, physicians' credentialing. We review whether or
25 not a particular physician has been credentialed in accordance

1 with the requirements of the facility. They are required to
2 have a credentialing procedure. We look at the procedure, and
3 then we take a random sample of the physicians and make sure
4 that their credentialing meets the procedure that the facility
5 has put in place. Yes, we do.
6 REPRESENTATIVE DeLISSIO: So you take a random
7 sample for that.
8 DEPUTY SECRETARY SOSSONG: Well, in the case of
9 physicians, because their tend to be a lot of them. We
10 wouldn't look at every one. I suspect with central supply
11 technicians, there aren't going to be that many.
12 REPRESENTATIVE DeLISSIO: Okay. That was one of my
13 questions, at what point do you do a sampling and at what other
14 points do you look at---
15 DEPUTY SECRETARY SOSSONG: That's largely a function
16 of numbers, how many we may be looking at. But if there were
17 10, I would guess we would look at them all, and I would
18 suspect that that would be about right, 10, 15 people.
19 REPRESENTATIVE DeLISSIO: Do you happen to know if
20 other States, is this similar? Is this required by CMS at all?
21 DEPUTY SECRETARY SOSSONG: Personally, I haven't
22 looked at it. Now, Representative Gingrich has indicated to me
23 that there are other States that do credentialing of some sort.
24 Whether it's similar to this, I don't know, and I haven't
25 spoken to any of the other States to ask.

1 REPRESENTATIVE DeLISSIO: To do that.
2 Some of my other questions have been answered
3 through the dialog here.
4 Nothing more at the moment, Mr. Chair. Thank you.
5 MAJORITY CHAIRMAN BAKER: Thank you.
6 Representative Stern.
7 REPRESENTATIVE STERN: Thank you, Chairman Baker.
8 Good afternoon, Secretary.
9 A couple of questions that Representative Gingrich
10 was bringing up. With reporting, from hospitals especially,
11 most of it was all behavioral personnel, right?
12 DEPUTY SECRETARY SOSSONG: Most of what we saw, yes.
13 REPRESENTATIVE STERN: Okay. And nothing really
14 with instrument sterilization. So this was all like human
15 error, the 11 cases that you documented.
16 DEPUTY SECRETARY SOSSONG: Yes.
17 REPRESENTATIVE STERN: Also, the same thing with the
18 ambulatory surgical facilities, a few deficiencies cited. Is
19 that where you talked about maybe somebody was in an operating
20 room or someplace and may have reported something?
21 DEPUTY SECRETARY SOSSONG: Well, that could be
22 anywhere. I think that was in response to Representative
23 Gingrich's discussion. Yes.
24 REPRESENTATIVE STERN: Okay.
25 When you mentioned in your closing testimony that

1 you believe existing laws and regulations enacted already by
2 the General Assembly, coupled with private accrediting body
3 rules and CMS compliance standards, are already addressing many
4 of the policy points that this bill tends to regulate, is some
5 of that the Pennsylvania Health Care Cost Containment Council?
6 Would they be retrieving information from---
7 DEPUTY SECRETARY SOSSONG: They can.
8 REPRESENTATIVE STERN: Okay.
9 DEPUTY SECRETARY SOSSONG: Yeah. Now, they don't
10 regulate it. I mean, they're an after-the-fact reviewer of
11 information certainly. They will have the data; you know, they
12 will be able to identify that sort of.
13 REPRESENTATIVE STERN: I think that's our number-one
14 resource that we use as Legislators a lot of times, that we get
15 those reports from the Pennsylvania Health Care Cost
16 Containment Council. We get those reports on infections and so
17 forth. Would these same infections be reported to them as
18 well?
19 DEPUTY SECRETARY SOSSONG: Well, if the behavior
20 here results in an infection. I mean, what we're talking about
21 is central supply technician sterilization procedures.
22 Assuming that it results in an infection, it will be reported
23 first, well, as part of the PHC4 exit data, you know, their
24 discharge data reporting, yes. It would also, in this case, it
25 would also be reported as part of the PSA, either a serious

1 event, depending on how it goes. If it's an actual infection,
2 it would be reported as a serious event under that reporting
3 system. If the sterilization process failed but they have no
4 objective evidence that anybody was actually harmed by that
5 failure, they just picked up the fact that they didn't do
6 something right, they would report it as an infrastructure
7 failure. But the department would know in either instance,
8 yes. Very shortly after it occurred, PHC4 would know. Upon
9 discharge data, they would know.
10 REPRESENTATIVE STERN: Okay. Thank you. That
11 answered my question.
12 MAJORITY CHAIRMAN BAKER: I noticed that the highest
13 number of deficiencies existed within ASFs, ambulatory surgical
14 facilities. I believe we have approximately 200 in the
15 Commonwealth.
16 DEPUTY SECRETARY SOSSONG: A couple more than that;
17 yes.
18 MAJORITY CHAIRMAN BAKER: And one of the things that
19 was mentioned as an example, disinfection or lack of
20 disinfection of equipment, and that is very, very troubling,
21 because that can result in some very nasty infections. Could
22 you clarify what kinds of equipment?
23 DEPUTY SECRETARY SOSSONG: I don't know that they're
24 necessarily the sorts of things, though some of them might
25 certainly be the kinds of things that we'd be talking about

1 here. Other ones may be things like not cleaning the IV port
2 that's in a patient's, you know, that's already hooked up. So
3 that's not really a central supply technician issue. But, you
4 know, if I'm about ready to put some sort of medication in your
5 IV, there's a protocol that you swab it before you do that,
6 that sort of thing. Or, you know, the example that I had given
7 earlier is a patient on a gurney on their way into the
8 operating room and, you know how they strap you in, they
9 haven't strapped you in yet and the strap is dragging on the
10 floor as they're rolling you in. The strap, you know, now,
11 that's equipment. It's a problem.
12 MAJORITY CHAIRMAN BAKER: One of the things that I
13 personally noticed in both nursing homes and even in hospitals,
14 oxygen masks or the leads---
15 DEPUTY SECRETARY SOSSONG: Cannulas.
16 MAJORITY CHAIRMAN BAKER: Yes -- lying on the floor.
17 Would that also be classified as part of the equipment
18 category?
19 DEPUTY SECRETARY SOSSONG: I would guess. It's hard
20 for me to -- I don't really know.
21 MAJORITY CHAIRMAN BAKER: Okay.
22 DEPUTY SECRETARY SOSSONG: It would certainly not be
23 covered by this, because most of that equipment is prepackaged,
24 sterilized, you know, once-and-done use, not recleaned.
25 MAJORITY CHAIRMAN BAKER: Okay. So they don't---

1 DEPUTY SECRETARY SOSSONG: You know, there's an
2 enormous amount of what used to be cleaned and reused, you
3 know, when I was young, that is now plastic and prepackaged and
4 shrink-wrapped, and as soon as you open it, it's toast. You
5 know, there's an awful lot of that now.
6 MAJORITY CHAIRMAN BAKER: So if you were to see
7 something like that lying on the floor, and I don't want to get
8 anyone into trouble here, but let's say a nurse's aide picked
9 that up and put that on the patient.
10 DEPUTY SECRETARY SOSSONG: We'll cite them.
11 MAJORITY CHAIRMAN BAKER: That would be a cite.
12 DEPUTY SECRETARY SOSSONG: And that kind of thing we
13 may very well see, in response to the, you know,
14 would-I-catch-it question. Those sorts of things we
15 occasionally do see, because people just do it instinctively.
16 MAJORITY CHAIRMAN BAKER: Okay. Thank you. Thank
17 you very much.
18 Representative Gingrich, anything else?
19 I do not see any more questions at this point.
20 REPRESENTATIVE GINGRICH: Thank you very much.
21 DEPUTY SECRETARY SOSSONG: Thank you very much.
22 MAJORITY CHAIRMAN BAKER: Our next testifier is
23 Michele DeMeo, former central service technician, and Michele
24 has a very thought-provoking testimony to give us today.
25 Welcome.

1 MS. DeMEO: Thank you. Thank you very much. Can
2 you hear me okay? Wonderful.
3 I also managed sterile processing functions.
4 Mr. Chair, Members of the committee, good afternoon.
5 My name is Michele DeMeo. I started my career in sterile
6 processing as a teenager by applying at a local hospital and
7 was hired. No previous hospital experience was necessary.
8 I thought at the time that I would be issuing out
9 Band-Aids, supplies, general surgical instruments to the
10 nursing floors in a hospital. I was completely wrong. These
11 were complex instruments even then, 22 years ago. They needed
12 to be sterilized correctly in order to be used on patients.
13 For example, these are some of the issues that I faced as a new
14 technician that still hold true today, 22 years later:
15 • 1: Thousands, thousands of uniquely different
16 instruments all needing unique processing. I must stress
17 that.
18 • 2: Complex instrument setups that have to be
19 memorized and sometimes do not match what is required by
20 the manufacturer but rather physician preference.
21 • No structured training. I was trained by
22 different people with little or no educational
23 experience, all who learned from someone else with the
24 same or less experience. And believe me, these
25 techniques vary from facility to facility. I later

1 became a consultant and can speak to that.
2 • A lack of proper competency measures. Rather, any
3 means to improve competency in a consistent manner,
4 that's key. It's pivotal.
5 • A lack of continuing education. I took the
6 personal time and effort to research and learn on my own
7 because it was not offered where I worked. You learned
8 on the job -- if there was time, if the person knew what
9 they were doing, if someone wasn't screaming for
10 something fast.
11 While improvements have been made over the years --
12 there have been -- technicians need a foundation of knowledge
13 that will only come from certification. Poor techniques result
14 in poor quality outcomes. You cannot sterilize something that
15 is not properly cleaned. You cannot properly clean with just
16 any old detergent. You cannot sterilize everything by a
17 standardized manner or with the same method. You must follow
18 manufacturer's instructions. They must be understood. They
19 must be compared and contrasted to the machines, to the
20 devices, and to the method, period. That takes knowledge.
21 There are core cleaning, disinfection,
22 sterilization, and storage principles that must be taught,
23 understood, refreshed, and adhered to in order to produce
24 instruments for every surgical case that is as safe as possible
25 for every surgical patient. To accomplish this, certification

1 is necessary combined with continuing education so that a
2 trainee understands, retains, executes the correct information
3 that they are provided. It is a complex role with complex
4 organisms with serious, serious ramifications if a single
5 mistake is made.
6 I have worked hard to try to improve our profession
7 for 22 years, and I'm 38, and I have tried to lead by example,
8 all the while trying to elevate the role to a level it truly
9 is: meaningful education, competency, and proper
10 quality-assurance measures.
11 Certification provides the means to close a gaping
12 hole in our profession. Certification provides a means for
13 accurate course material -- accurate course material.
14 Extensive testing to measure competency. You have
15 to be able to measure it.
16 Required continuing education that matches technical
17 advances our patients deserve, our hospitals must have, to
18 reduce the potential for extremely costly infections or other
19 harm -- 97,000-plus a year surgical site infections in the U.S.
20 There was a question earlier about the types of
21 surgical site infections. Open abdominal, minimally invasive,
22 and total joints rank high. All require complex instruments,
23 not scissors and needle holders.
24 I believe in this so much that I am here while
25 actively dying. I missed my hospice appointment to be here.

1 It's that important. It's that important to me. It's
2 important to me that each of you, each of your friends, each of
3 your family members, are not only in the hands of a safe
4 operating room or operating room personnel or pre-op staff
5 members that are inserting IVs or post-op-care technicians that
6 are caring for IVs or putting on nasal cannulas or other
7 devices, but rather that those same trusted surgical hands hold
8 safe-to-use instruments.
9 I'd like to close on one thought, if I may. Just
10 because an item goes through a sterilizer and the tests for the
11 sterilizer show that it "sterilized" properly, it does not mean
12 the device was sterile. It means that the process by which it
13 was put through was capable for sterilization to have occurred,
14 not that it did. That's where proper technique and knowledge
15 is critical, because failures are often unnoticed through a
16 sterilization cycle. There's no way to see an error. The
17 printout on the sterilizer will say it got sterilized, the
18 biological will say it passed, but if that technician put it
19 2 inches too close to the next, you have deviated from one out
20 of hundreds of principles necessary to sterilize it properly,
21 and no one will have known.
22 Thank you.
23 MAJORITY CHAIRMAN BAKER: Thank you very much,
24 Michele, for your very compelling and relevant testimony.
25 Before we take questions of Michele, I'd like to go

1 to Anna Grayson, MS, RN, CRCST, Manager, Sterile Processing
2 Case Cart, Thomas Jefferson University Hospital, and then if
3 the Members don't mind, we'll then proceed with questions for
4 both.
5 You may proceed, Anna.
6 MS. GRAYSON: Mr. Chairman, Members of the
7 committee, my name is Anna Grayson, and I am a registered nurse
8 and have been in positions as a Manager and Director of sterile
9 processing departments for over 20 years in New Jersey,
10 New York, and Pennsylvania.
11 Currently I'm responsible for 72 technicians at
12 2 hospital sites, the daily operations of the departments as
13 well as providing education and training to technicians. Today
14 I'm testifying on behalf of myself in support of HB 2290, which
15 requires certification of central sterile supply technicians
16 and maintain continuing education credits.
17 Central sterile supply department professionals are
18 those responsible for ensuring that instrumentation and
19 equipment used in medical and surgical procedures is properly
20 cleaned, disinfected, inspected, and sterilized prior to
21 patient use. The central sterile supply department of a
22 health-care facility is the heart of all activity surrounding
23 supplies and equipment required for operating rooms, endoscopy
24 suites, ICUs, neonatal ICUs, birth centers, labor and delivery,
25 and other patient-care areas. Central sterile supply

1 technicians are responsible for first-line processes to prevent
2 patient infections.
3 The central sterile supply profession continues to
4 evolve at a rapid pace, with new surgical items being
5 introduced regularly. The processing of robotics, endoscopes,
6 joint replacement, and related instruments and equipment
7 requires advanced technical knowledge that only certification
8 will provide.
9 The Association for the Advancement of Medical
10 Instrumentation Standards recommends certification for
11 individuals responsible for sterilization activities as well as
12 those who manage central sterile supply processes. It is
13 paramount that the central sterile supply department
14 technicians receive ongoing, formal training, including
15 certification, in order to perform their daily duties safely,
16 effectively, and consistently. Certification will promote
17 health-care quality, reduce the risk of healthcare-associated
18 infections, and ensure successful patient care.
19 Currently, a person only has to have a GED or a
20 high school diploma to qualify for the job. However, the job
21 requires knowledge in the following subjects: microbiology,
22 medical terminology, anatomy and physiology, infection control,
23 decontamination, et cetera, and sterilization. Allowing
24 undertrained or inappropriately trained health-care
25 professionals to sterilize medical instruments used in surgical

1 procedures places the patient at risk of unintended
2 consequences that may include physical harm or even loss of
3 life.
4 I have seen how uncertified technicians view the job
5 as merely a paycheck. These technicians take shortcuts to get
6 the work done -- use the wrong detergents, place dirty or
7 broken instruments in surgical trays, overload sterilizers to
8 cause wet trays, and other types of unacceptable processes that
9 affect patient outcomes. Certification through education
10 changes behavior, attitude, and processes, and it also boosts
11 the morale of the individual. Continued education reinforces
12 these changes in behavior, attitude, and processes and is the
13 pathway for assuring better patient outcomes.
14 Surgical site infections are the most common type of
15 healthcare-associated infection. The Centers for Disease
16 Control and Prevention estimates that the direct costs
17 associated with healthcare-associated infections are as high as
18 $45 billion each year. In 2002, there were 1.7 million
19 healthcare-associated infections and 99,000 deaths. Surgical
20 site infections result in an estimated 290,485 infections per
21 year, 13,088 deaths per year, cost a hospital $25,546 per event
22 per year, and cost a hospital $7.4 million per year.
23 According to the "Healthcare-Associated Infections
24 in Pennsylvania 2010" report, surgical site infections were the
25 most common type at 26.8 percent. SSIs are linked to

1 significant health-care costs and frequent hospital
2 readmissions. The 2010 Pennsylvania report focuses on six
3 benchmark operations such as cardiac surgery, coronary artery
4 bypass graft with one incision, coronary artery bypass graft
5 with two incision sites, hip replacements, knee replacements,
6 and abdominal hysterectomies.
7 The Pennsylvania data indicates that in the last
8 half of 2008, there were a total of 44,640 operations performed
9 on these six benchmarks. There were a total of 608 SSIs
10 identified and reported from these procedures. This produced
11 an overall SSI rate of 1.36 infections per 100 procedures.
12 For 2009, there were a total of 94,179 benchmark
13 procedure operations, which produced a total of 1,269 SSIs.
14 This produced an overall SSI rate of 1.35 infections per
15 100 procedures.
16 Overall, hospital-acquired-infection data through
17 2010 indicates that SSIs increased in 2009 and 2010. The
18 Pennsylvania report concludes that "this supports the idea that
19 SSI rates are either not declining or are declining less
20 rapidly than other HAI categories. Thus, there are enough
21 signals in the available data to indicate that greater efforts
22 are needed to produce reductions in preventable SSIs."
23 This bill is about patient safety. Patients of
24 surgical services will benefit from a more qualified and
25 competent health-care workforce. The patient can pick the best

1 physician and the best health-care facility but does not pick
2 the central sterile supply technician that sterilizes his or
3 her medical instruments used for surgery. The education,
4 training, and assurance of competency of this vital member of
5 the surgical team will reduce the incidence of surgical site
6 infections, resulting in a reduction of readmissions and
7 surgical complications.
8 I urge you to support HB 2290. Thank you.
9 MAJORITY CHAIRMAN BAKER: Thank you very much,
10 Ms. Grayson, for your testimony.
11 We'll at this time take some questions.
12 I would just like to ask a couple of questions
13 first, and it goes back to your point, Michele, about
14 sterilization does not necessarily mean that it's totally clean
15 or sterile.
16 MS. DeMEO: Yes.
17 MAJORITY CHAIRMAN BAKER: And to most of us,
18 especially laypeople, this is a stunning revelation, because we
19 just assumed sterilization means it's sterile, it's clean, it's
20 good to go.
21 MS. DeMEO: Yes.
22 MAJORITY CHAIRMAN BAKER: What you're saying,
23 though, is if it's not properly cleaned in the first place,
24 it's not necessarily going to be sterile.
25 MS. DeMEO: One example out of many, yes.

1 MAJORITY CHAIRMAN BAKER: Okay. Would you like to
2 elaborate?
3 MS. DeMEO: I would love to. Thank you.
4 MAJORITY CHAIRMAN BAKER: Okay.
5 MS. DeMEO: I would like to first disclose, if it's
6 needed, I'm the only sterile processing expert on the FDA's
7 overarching committee for the Center for Devices and
8 Radiological Health. I'm being replaced due to my health, but
9 I'm listed as an expert for sterilization.
10 My comment was hospitals are required to test and do
11 biological monitoring of sterilizer functioning. So one would
12 assume that if a biological test tests the function of a
13 machine and it "passes," that anything that goes into the
14 machine would come out sterile. What it means is that the
15 machine was capable for sterilization to have occurred, not
16 that it did.
17 What could happen are the following things: There's
18 a continuum for processing an instrument. There's a start
19 point and an end point, and for the purposes of this
20 discussion, I'll just say the start point will be end of use
21 and cleaning it through to reuse. And anywhere along that
22 continuum, something can occur that breaks the chain required
23 to keep the link together to maintain sterility.
24 So one or two examples is that we can make an
25 assumption that we have the best technician cleaning an

1 instrument, the absolute finest. He cleans it impeccably. We
2 can make an assumption one day a different technician packages
3 that same instrument precisely as the manufacturer indicates.
4 They go to break. The next best tech covers for the break,
5 doesn't have enough knowledge, looks up at the clock and says,
6 oh, my break is in 15, 20 minutes; I've got to ram this stuff
7 in the sterilizer. They pack it too close together. The steam
8 has no way to penetrate the sterilization container or wrapper.
9 Hence, the item was not adequately exposed to the sterilant to
10 produce a quality product at the end of the cycle.
11 However, that tech goes on break now. The good
12 technician comes back. The sterilizer ends its cycle. The
13 printout from the cycle says it met all of its parameters.
14 Nothing looks out of the ordinary. It met its temperature, its
15 timing, and its exposure. He pulls it out. This technician
16 looks for visual clues. There is indicator tape on every
17 surgical basket or tray. Oh, it turned black or blue or
18 whatever the company might have. That visual clue says not
19 that it's sterile, but rather, I was exposed to a sterilant; I
20 was processed. The technician pulls it out, cools it
21 appropriately, sends it to the operating room, it's used.
22 Inside, they go to open it. There's an indicator,
23 yes. An indicator shows that it was or had gone through a
24 process. They aren't necessarily sensitive enough to say that
25 it went through the "appropriate" exposure to kill all of the

1 organisms on the instrumentation.
2 That's an example. No one would have any idea.
3 MS. GRAYSON: I could give an example that happened
4 to me in a facility at one time.
5 A technician, not certified, was running a prevacuum
6 sterilizer and went off to break, then came back, started doing
7 another sterilizer, and realized that the first sterilizer was
8 still in exhaust. Opened it up, finally got it to open up, and
9 left it to cool -- never said anything to anyone. Someone did
10 say to this technician, don't you think you should test the
11 sterilizer, run an air test, because the parameters of one type
12 of sterilization method include the exposure time, the
13 temperature, and the pressure of the chamber. That's vital to
14 the process. The technician didn't do it.
15 The next morning, the supervisor that came on
16 noticed the long exhaust time on the printout and recalled
17 every single tray that was on that load -- 23 trays. Some of
18 them were on case carts for surgery. Thank God none of them
19 were used. We managed to get them all back, we opened them up,
20 and sure enough the integrator on the inside on the majority of
21 them did not turn black, which meant they were not sterile. If
22 they had been opened in a rush and used, you can only imagine
23 what could have happened to that individual patient.
24 So that is another good example, I believe, of why
25 technicians need to be educated and certified and then the

1 education reinforced.

2 MAJORITY CHAIRMAN BAKER: Is there an accountability
3 component to that? Is there proper supervision to make sure
4 that these things are going on?

5 MS. GRAYSON: The supervisor that was on that shift
6 was busy trying to put, we call them fires, putting fires out,
7 and was told but never got back to it, and then the next
8 supervisor that came on caught it.

9 MAJORITY CHAIRMAN BAKER: You had proffered in your
10 testimony an amazing array of statistics: 10 years ago, almost
11 2 million healthcare-associated infections and nearly 100,000
12 deaths, which I presume are interconnected, related, there's a
13 nexus between the two. I guess I'm looking for a more specific
14 etiology in that was this because of the lack of sterilization
15 or is there a whole panoply of reasons and different causes of
16 infections here?

17 MS. GRAYSON: I would assume that that would be the
18 case, that there would be multiple reasons for the amount of
19 infections that were reported and the amount of deaths. I
20 don't think they're all related to surgical site infections.
21 But until now, we weren't really looking at data on a bioburden
22 of instruments and how to prevent it and what harm it can cause
23 a patient.

24 MAJORITY CHAIRMAN BAKER: Yes? Michele.

25 MS. DeMEO: May I add to that, Anna made a good

1 point up to this point. However, it is on the radar of major
2 organizations at the moment. I'm heavily involved with AAMI,
3 which stands for the Association for the Advancement of Medical
4 Instrumentation. The FDA, CDC, APIC, various other entities,
5 are voting members. I'm a voting member for
6 understerilization, soon to be replaced. My name may still be
7 on there.
8 They currently have a product that is in beta
9 testing in several hospitals. I helped to develop a tool that
10 they acquired to capture error rates associated with mistakes
11 with instrumentation. AAMI is looked to by the Joint
12 Commission, the FDA, the CDC, the World Health Organization,
13 countless other entities. They lead the way for medical
14 instrumentation and are highly regarded, as most of you know.
15 So while it's hard to decipher what exact causes are
16 related to instrumentation with SSIs, in the future and
17 currently, there are developments in the works and in beta
18 sites to be able to capture data, and in the future we will
19 have that because it is recognized that there is a link and we
20 need data to support it, and hence, a major organization is
21 working to help capture that.
22 MAJORITY CHAIRMAN BAKER: Thank you.
23 MS. DeMEO: You're welcome.
24 MAJORITY CHAIRMAN BAKER: Chairman Myers.
25 MINORITY CHAIRMAN MYERS: I really don't have any

1 questions, but I certainly can feel you, you know? And this
2 just further adds to my belief that this whole scope of
3 accountability around surgical instruments in nursing homes,
4 it's important that we address that. I'll certainly agree with
5 that.
6 MAJORITY CHAIRMAN BAKER: Representative Gingrich.
7 REPRESENTATIVE GINGRICH: Thank you, Mr. Chairman.
8 Thank you both for taking us into the "trenches" of
9 the actual role of a central supply technician, sterile
10 processing technician. Clearly it's a great opportunity if
11 somebody wants to get involved in that field, come in with no
12 experience and learn, but right now I need to get a better
13 understanding of really how we're doing that in any consistent
14 or standard method.
15 Also, before we get into that, I know that in my
16 discussions with people on this topic, Pennsylvania is not the
17 only State looking at this. I know New Jersey has actually
18 been able to move something forward and has that legislation in
19 place. I know New York has been looking at it. Have you all
20 been involved in other States, and is there a heightened
21 awareness as we definitely have here in Pennsylvania?
22 MS. GRAYSON: I was involved in New Jersey in the
23 beginning of their trek and New York.
24 REPRESENTATIVE GINGRICH: Both.
25 MS. GRAYSON: Yes; yes. And New York's just passed.

1 They're just waiting for the Governor to sign.
2 REPRESENTATIVE GINGRICH: Okay. So both our
3 neighbors then have dealt with this already.
4 MS. GRAYSON: Yes. Maryland and Connecticut are
5 moving forward.
6 REPRESENTATIVE GINGRICH: Okay.
7 MS. DeMEO: And as for heightened awareness, to this
8 day I know, even with ALS and cancer and brain tumors, I have
9 published over 200 articles for columns mostly centering on
10 both the technical aspects of sterilization but the management
11 and education and imperative nature of this.
12 If you were to Google "Michele DeMeo sterile
13 processing," you can read some of that work. Or I'm very
14 active, I volunteer my time to make sure people are aware and
15 provide a free means to learn on their own through trade
16 magazines for technicians and management. That's just a small
17 little piece that I personally do that is circulated nationally
18 and internationally in various trade magazines and journals, as
19 well as contributions in textbooks for IAHCSMM and various
20 other things.
21 REPRESENTATIVE GINGRICH: That's a good segue for
22 me, because part B to my question was what we are seeing done
23 in that education mechanism. As we heard stated by the
24 Department of Health and from both of you even testifying, it
25 appears to me that the training itself is up to the discretion,

1 the style, the determination of the facility in which this, say
2 I'm this individual applying for the job and I have no
3 background whatsoever, so I'm coming into this position as a
4 sterile processing technician. Who's going to train me, and is
5 there consistency in that? How long am I going to be trained?
6 Because people I've talked to, they'll say, well, there's like
7 a 6-week orientation, and I go, whoa, wait a minute. Other
8 ones say we have a 3-month program. Other hospitals say, we
9 have certification; we choose to have certification. Other
10 hospitals say, no, we don't have a certification; the process
11 is, we do our own in-house training and there's no structured
12 competency assessment.
13 So am I understanding that correctly, that I'm going
14 to be hired in a specific facility, health-care facility, and
15 they're going to train me in whatever design that meets the
16 Department of Health going in and checking and making sure of
17 whatever curriculum or information they're sharing? Because
18 this is a pretty complicated position now. This isn't that now
19 I'd be scared to stick something in an autoclave, not even
20 knowing they can't be that close together, of course. But what
21 happens over the board when you're being trained as a central
22 processing technician?
23 MS. GRAYSON: Well, you're right, it is very
24 inconsistent from hospital to hospital, probably even from
25 State to State. It depends, again, on the management of the

1 department or the administration of the hospital. Sometimes in
2 some facilities that I first went to, the new individual would
3 be trained by you today and by Janelle tomorrow and by someone
4 else the following day. There was no consistency. It was
5 whatever they did, you would watch and you would repeat,
6 without any type of theory behind what it is that they were
7 doing.
8 In some other facilities where the manager was
9 concerned about the education of the technicians, they would
10 have an orientation program outlined for the individual.
11 Hopefully they would partner them up with a certified
12 technician, or at least someone that they felt was able to
13 train an individual from decontamination all the way through to
14 the storage of sterile supplies.
15 And in some facilities, when I first got there, they
16 thought that training would only take 4 weeks, 6 weeks, some
17 thought 8 weeks. One did agree that it needed to be a minimum
18 of 3 months with follow-up thereafter, because there are so
19 many, so many complicated instruments, especially today, and
20 they need to follow device manufacturers' written instructions
21 for how to take them apart, how to clean them, whether to put
22 them in an ultrasonic, not put them in, how long to put them
23 in, the temperature of the water, the type of detergent. It's
24 a very complex process. It's not just taking a piece of metal,
25 wiping it down, and putting it in a machine to "cook" it, as

1 some places say.

2 MS. DeMEO: If I may add to Anna's comment, which is
3 so, so, so true, certification would complement the on-the-job
4 training that would have to still occur in a hospital. What it
5 does is it provides a standard method of delivering principles
6 and knowledge in a consistent manner. It would require
7 continuing education, an even playing field, and a foundation.

8 Any person in any new job needs training specific to
9 their facility. That would not change, but rather, this would
10 interlock the two. It closes that gap. Then our technicians
11 have the foundation of principles, and then they can get
12 trained specific to their facility.

13 REPRESENTATIVE GINGRICH: That's very helpful.

14 Yes? Anna.

15 MS. GRAYSON: One thing I'd like to bring up at this
16 point as far as training and education of individuals is how
17 important it is to train the people and educate and mentor the
18 individuals that are doing this process. It not only brings
19 the skills to the forefront and their knowledge, but it boosts
20 their morale. They seem to show more pride in doing what they
21 are doing when they know why they are doing it, and I've
22 noticed that.

23 REPRESENTATIVE GINGRICH: Yes; I can certainly
24 understand that.

25 Gone are the days when it should be looked at as a

1 housekeeping job or, you know, a factory job. It's more like a
2 laboratory process, a laboratory structure, to my mind.
3 MS. GRAYSON: Yes.
4 REPRESENTATIVE GINGRICH: Having to know, understand
5 chemicals, the microbiology of it all. So that foundation, I'm
6 really subscribing to that. Thank you.
7 MS. DeMEO: Well, I liken it -- and I wrote an
8 article at some point on it -- I liken it and I have strived
9 for this: The counterpart of a surgical technician in the
10 operating room, they are the clinical counterpart in the OR,
11 and the sterile processing technician is the technical
12 counterpart, period.
13 MAJORITY CHAIRMAN BAKER: I do have a couple of
14 follow-up questions, but the gentleman from Philadelphia,
15 Mr. Waters, is with us.
16 You know, I've got to say, I am still somewhat
17 stunned that this is such an important aspect of patient safety
18 and yet there is no real set-in-stone training requirements.
19 And, you know, you've testified $45 billion a year in
20 hospital-acquired infections; the potential for medical
21 malpractice, the potential for people's lives and disability
22 being impacted. I am still rather stunned that people with a
23 GED, with virtually no training whatsoever, it's very
24 disconcerting to me that there is no solid requirement that
25 proper training necessarily be in place.

1 Now, it seems to me that all of these health-care
2 facilities, it would be in their best interests to do this,
3 obviously, and hopefully they are doing this internally, some
4 probably better than others. But I just think you've made a
5 very compelling argument for certification for this very, very
6 important position, because we really don't stop and think how
7 a lot of patients' lives could be at stake here if it's not
8 done properly, this role. So thank you very much for your
9 testimony.
10 MS. DeMEO: Well, especially since more States
11 require dog-grooming licenses and manicure licenses that don't
12 invade the body.
13 MAJORITY CHAIRMAN BAKER: Good point.
14 MS. DeMEO: Thank you.
15 MAJORITY CHAIRMAN BAKER: Good point.
16 Representative DeLissio.
17 REPRESENTATIVE DeLISSIO: Thank you, Mr. Chairman.
18 A couple, a variety of questions here.
19 Ms. DeMeo, do you know how long this certification
20 takes? The legislation refers to two different certifying
21 bodies. Is this a course that somebody goes to full time? Is
22 it on line? Is it---
23 MS. GRAYSON: All of the above.
24 MS. DeMEO: It's actually all of the above. There
25 are several options for technicians -- I'm sorry for my voice.

1 There are several options for technicians: Purdue University;
2 IAHCSMM has a course; there's self-study. All are quantifiable
3 with exams, and Anna can speak in more depth also to that.
4 They all are founded on Spaulding principles and
5 Seymour S. Block's "Disinfection, Preservation, and
6 Sterilization," also a spinoff of Spaulding's work. But Anna
7 can talk about the options; there are numerous.
8 MS. GRAYSON: The options for training and education
9 are through the IAHCSMM, the international association and the
10 national association. Those are the two associations
11 nationwide that provide education and training. You can get it
12 on line. You can do self-study. Some IAHCSMM instructors are
13 now providing actual online courses for not only the technical
14 certification but the instrument-specialist certification and
15 the health-care-leader certification.
16 It can vary in time as far as how long a course
17 would take. Usually it's 16 weeks. It's like a semester of
18 college. I don't know offhand if colleges here in Pennsylvania
19 offer the program yet, but I'm sure they're going to be looking
20 into it. They do offer them in the other States. And again,
21 some of them are more extensive than just the technical
22 aspects, involve a course in anatomy and physiology and
23 microbiology. So it varies.
24 MS. DeMEO: And just to add to that, both of the
25 major two organizations that Anna spoke of do have content that

1 covers anatomy and physiology, instrumentation, sterilization,
2 disinfection, every element that---
3 MS. GRAYSON: Microbiology.
4 MS. DeMEO: Microbiology. ---every element
5 necessary for the gamut of potential tasks asked of an
6 individual in a health-care facility.
7 As far as the timing also, there are approved
8 instructors. You have to be approved. I'm an approved
9 international instructor. My course I based off of IAHCSMM's
10 course material. They have an instructor's guide, and I'm
11 required to use the instructor's guide. So there is a
12 consistent method of delivery for the course material. Every
13 instructor might have a slight nuance, but they are required to
14 use the instructor's guide issued by IAHCSMM.
15 REPRESENTATIVE DeLISSIO: Thank you.
16 These 12 hours of CEUs to maintain the
17 certification, is that a requirement of the certification or is
18 that a requirement of the legislation?
19 MS. GRAYSON: Certification.
20 REPRESENTATIVE DeLISSIO: It's a requirement of the
21 certification.
22 And who do you envision would be responsible for the
23 costs of this certification, initial and ongoing?
24 MS. DeMEO: Well, I believe it will vary from
25 facility to facility. Most already pay for continuing

1 education for technicians. Most are free.
2 My articles, many of my articles I put posttests in,
3 and I do the pre-work and submit them to the organizations for
4 continuing educational credits. So the technician reads the
5 information, takes the posttest, submits it, obtains credits
6 for free.
7 So the credits are rather easy to get. Companies
8 and manufacturers offer them to come to your facility for free
9 to give in-services and then do an actual test. You have to
10 pass the test to get the credit. So they're rather inexpensive
11 or free, and most facilities offer that. And if they don't,
12 there's enough out there to obtain them for free.
13 REPRESENTATIVE DeLISSIO: So that's the CEUs.
14 MS. DeMEO: Right.
15 REPRESENTATIVE DeLISSIO: But in terms of the
16 original certification, that would probably be on a
17 facility-by-facility basis.
18 MS. DeMEO: Correct; correct.
19 REPRESENTATIVE DeLISSIO: I get that, and if I
20 understand this correctly, this SSI data, it is not currently
21 tagged to how many of these infections actually are the result
22 of sterilization or equipment issues. I understood that
23 correctly, did I not?
24 MS. DeMEO: You did.
25 MS. GRAYSON: Yes.

1 REPRESENTATIVE DeLISSIO: Okay. And that's where
2 you said they're looking to focus in on that more perhaps to
3 produce some of that.
4 MS. DeMEO: Yes.
5 REPRESENTATIVE DeLISSIO: Hospitals by nature are
6 kind of risk averse and are always looking to minimize risk and
7 liability -- and always striving to do that. It's an evolving
8 thing. The more technology evolves, the more they have to
9 evolve in terms of the risk side of it.
10 Do you know if any -- we'll talk about hospitals. I
11 think there are about 270 of them licensed in the Commonwealth
12 of Pennsylvania. My guess is, most long-term-care facilities
13 don't have such a position in their facilities any longer,
14 probably haven't had for decades, so this is probably focused
15 on primarily hospitals and maybe ambulatory surgical facilities
16 as well. Do they currently require some type of certification
17 of their staff? Do we happen to know that piece of data?
18 MS. DeMEO: We don't have an exact number, but most
19 don't require it. And you are correct about the long-care
20 facilities. This would impact facilities that handle
21 semi-critical and critical devices, which would be anything
22 that goes into an oral cavity or a mucus-membrane cavity or
23 sterile cavity.
24 REPRESENTATIVE DeLISSIO: So, Michele, as I listened
25 to your testimony, I want to make sure I extrapolate this

1 accurately. There is always going to be human error. We're
2 human; there's always going to be error. I know like when you
3 administer meds, there is a med error rate. If it's too high
4 or too low, you know, there is an acceptable error rate type of
5 thing, and I think it's important that we know that that's out
6 there, unfortunately. So is it fair to say that this
7 certification addresses the concern that you and Anna have:
8 because the more training, and the training heightens the
9 awareness, the awareness will mitigate the risk?
10 MS. DeMEO: Yes. And if we talk about mitigating
11 risk, and I love that, because I love failure-mode analysis in
12 general in mitigating risks. If you were to look at the
13 continuum of types of risk, the purpose of any facility would
14 be to mitigate as many potential risks as possible. An
15 uncertified or improperly trained technician is a risk. So the
16 hope would be that a facility would identify as many potential
17 risks in the spectrum of a patient entering its building,
18 through its facility, through its discharge, and on that
19 continuum of a person's stay, a central sterile processing
20 technician currently is a risk. So if we can reduce one risk,
21 we're working our way through the chain of entering into the
22 facility and exit of a facility with less potential of
23 obtaining an issue or a problem or an infection.
24 REPRESENTATIVE DeLISSIO: And my final question.
25 I don't know if you were part of the drafting of the

1 legislation, but in Section 3, number (2) -- I might be reading
2 this incorrectly -- on page 2, lines 20 through 25, it talks
3 about, the upper paragraph, "...unless the person meets one of
4 the following:..." and the second following is, "provides
5 evidence that the person was employed or otherwise contracted
6 for the services as a central service technician in a health
7 care facility on or within the two-year period immediately
8 prior to the effective date of this section...." It sounds
9 like if somebody is already on the job, they're going to be
10 grandfathered in. Am I reading that correctly? And that may
11 be a question for either Representative Gingrich or somebody
12 who was more involved in drafting the legislation, but I am not
13 clear on what that means. To me, it looks like anybody on the
14 job would be grandfathered in, which could then, at some other
15 point I think I read where they had a 2-year window to get
16 certified. So I may not be reading this in proper sequence
17 or---
18 REPRESENTATIVE GINGRICH: Pam, the way I am
19 interpreting the language of the bill myself is that, yes, that
20 2-year window after hire, okay? I imagine what we meant here,
21 and I can doublecheck on that, is that as long as that is
22 within the 2-year window of working professionally and having
23 been through the education and continuing education process,
24 unless you're reading it the opposite.
25 REPRESENTATIVE DeLISSIO: To me, it almost looks as

1 if it's grandfathering anybody in who is currently on the job,
2 and I don't know if that was the intent. If that's not the
3 intent---
4 REPRESENTATIVE GINGRICH: That's not the intent.
5 REPRESENTATIVE DeLISSIO: That's not the intent, and
6 that's what I'm concerned with more now. Language can always
7 be tidied.
8 MS. DeMEO: I would not envision that, no.
9 REPRESENTATIVE DeLISSIO: That this 2 years is a
10 window for folks who are currently on the job to go get that
11 certification and be compliant going forward.
12 MS. DeMEO: Yes.
13 REPRESENTATIVE DeLISSIO: Okay. That was my last
14 question. Thank you, Mr. Chairman.
15 MAJORITY CHAIRMAN BAKER: Thank you.
16 Representative Toepel. Oh, very good. Thank you
17 very much.
18 Members, any other questions of our panelists?
19 Seeing none, we thank you very much for your testimony and
20 time.
21 MS. GRAYSON: Thank you.
22 MS. DeMEO: Thank you.
23 MAJORITY CHAIRMAN BAKER: And sorry you missed your
24 appointment today.
25 MS. DeMEO: Oh, that's okay. It's a pleasure.

1 Thank you for having us.
2 MS. GRAYSON: She's glad to be here.
3 MAJORITY CHAIRMAN BAKER: Thank you very much.
4 We're almost on time, just a few minutes late for
5 our last testifier: Lauren D. Lloyd, Director, Recruitment,
6 University of Pittsburgh Medical Center.
7 Welcome, Lauren.
8 MS. LLOYD: Thank you.
9 MAJORITY CHAIRMAN BAKER: And it looks like you have
10 some company with you.
11 MS. LLOYD: I do. I am the Director of Recruitment
12 for UPMC. And with me I also have Dawn Vocke, who is the Unit
13 Director at UPMC St. Margaret. She is responsible for the
14 operating rooms at that facility as well as sterile processing.
15 MS. MEBUS: And I'm Kathy Mebus from the Hospital
16 Association.
17 MAJORITY CHAIRMAN BAKER: It's nice to see you all
18 here.
19 MS. MEBUS: Mr. Chairman, if I may clarify a little
20 bit about surgical site infections.
21 MAJORITY CHAIRMAN BAKER: Yes.
22 MS. MEBUS: The report that Anna cited was the 2010
23 report that is actually 2009 data from the Department of
24 Health. It takes them awhile to get the information.
25 There are currently three areas that they look at

1 very carefully. One is central line infections, one is urinary
2 tract infections, and the third, which she mentioned, there are
3 six or seven categories of surgical site infections.
4 The first two infections, urinary tract and central
5 line infections, there is evidence that there has been a
6 40-percent decrease in those infection rates. The surgical
7 site infections is baseline data. Even though it says it went
8 from 1.36 to 1.35, we are still collecting baseline data. The
9 difference is that the other two infections are reported while
10 they are in the hospital. The surgical site infection gets
11 reported up to a year after they have been discharged from the
12 hospital.
13 So we control the environment for the first two
14 infections; we only semi-control the environment for the third
15 infection. And as I think Michele said, they are now looking
16 at how we can see which of those infections are actually from
17 the instrumentation and things like that.
18 But we do not currently have that data. So I just
19 want you to be aware that because of that lag of 1 year in
20 reporting, the data is different than the central line or the
21 urinary tract infections.
22 MAJORITY CHAIRMAN BAKER: Do you know if there is
23 any longitudinal data on this issue of surgical instrument
24 contamination, infections, patient illness?
25 MS. MEBUS: No, because even at the Federal level,

1 that's how this is required to be reported, that any infection
2 within a year gets reported as a surgical site infection.
3 MAJORITY CHAIRMAN BAKER: Okay.
4 MS. MEBUS: I just wanted to clarify that so that
5 you were looking at it not as apples and apples, because it's
6 really not.
7 MAJORITY CHAIRMAN BAKER: Okay. Thank you.
8 Lauren.
9 MS. LLOYD: Well, thank you again.
10 And just for background, UPMC is headquartered in
11 Pittsburgh, and we are Pennsylvania's largest employer with
12 over 55,000 employees. We're one of the leading nonprofit
13 health systems in the country and are comprised of more than
14 20 hospitals, over 400 clinical locations, including
15 long-term-care and senior-living facilities and a health plan
16 with over 1.8 million members.
17 Currently, UPMC employs approximately 200
18 staff-level central sterile supply technicians, and nearly
19 10 percent of those central sterile technicians maintain
20 certification through the International Association of Health
21 Care Central Service Material Management, aka IAHCSMM, or the
22 Certification Board for Sterile Processing and Distribution,
23 which is CBSPD.
24 UPMC appreciates the opportunity to provide comments
25 to the House Health Committee on behalf of The Hospital and

1 Healthsystem Association of Pennsylvania regarding the
2 development of HB 2290, which would provide for certification
3 of central supply technicians.
4 UPMC does not support the proposed requirement of
5 certification for central supply technicians. Our organization
6 provides quality patient care and goes to great measures to
7 ensure low rates of hospital-acquired infections.
8 While we share the Legislature's desire to eliminate
9 these infections, we do not believe that a central supply
10 technician certification requirement will decrease those
11 hospital-acquired infection rates. In fact, the national and
12 State infection rates are decreasing without widespread
13 certification requirements for those roles.
14 The 2010 Pennsylvania Department of Health report,
15 released in September of 2011, on the occurrence and patterns
16 of healthcare-associated infections, demonstrates a continued
17 decline in the overall incidence of HAIs in Pennsylvania. The
18 reports required under Act 52 are based on scientifically
19 demonstrated interventions to reduce those hospital-acquired
20 infections.
21 Both the Joint Commission and the Department of
22 Health provide regulatory oversight to hospitals. This
23 oversight requires organizations to report hospital-acquired
24 infections to the State regulatory agencies. In fact,
25 Pennsylvania is a leader in this reporting and has set the

1 standard for this level of oversight. Additionally, compliance
2 with policies and procedures as well as the physical space of
3 the central sterile supply department is inspected by these
4 agencies during onsite reviews. UPMC believes that the
5 proposed legislation is unnecessary given the current oversight
6 by the two regulatory agencies.
7 Given our commitment to excellence, quality, and
8 safety, UPMC places focus on processes, procedures, and
9 protocols in many areas. For example, our central sterile
10 supply processing employee training program is rigorous and
11 ensures staff competence to avoid risk to our patients. It is
12 our belief that hospital-acquired infection rates will continue
13 to decrease as organizations ensure compliance with these types
14 of processes. The oversight provided by the Joint Commission
15 and the Department of Health provides accountability for
16 hospitals to ensure compliance.
17 In the hospital setting, all employees are
18 responsible for infection control. UPMC has focused additional
19 training in areas that are at high risk of spreading
20 infections. Professional certification is not the standard for
21 many of these roles. Hospitals have developed training
22 programs for these positions to ensure competence in all
23 aspects of the role, and specific emphasis is placed on
24 infection control procedures. In many cases, these internal
25 training programs surpass the learning objectives of the

1 outside certification process.

2 UPMC believes that in many cases, internal training
3 programs for central sterile supply processing techs surpass
4 the education obtained through external certification programs
5 because they allow for hands-on experience with the exact
6 equipment that is used to sterilize those many instruments. If
7 hospitals were to rely on the certification process alone, the
8 opposite effect of the bill's intent may occur. For these
9 reasons, UPMC is unable to support HB 2290.

10 In addition to our overall concern for this
11 legislation, we would like to present our views about the
12 following specific topics within the bill:

13 • The definition of "student" or "intern" and their
14 certification requirements.

15 • Certification requirements of incumbent workers.

16 • Continuing education credits and the proposal to
17 have them submitted to the Department of Health.

18 • As well as the hospital's overall credentialing
19 process.

20 Specific to the student and intern certification
21 requirements, in Section 3(3), the proposed legislation states
22 that a student or intern may work under the direct supervision
23 of an appropriately licensed or certified health-care
24 practitioner and is functioning within the scope of the
25 student's training. "Student" and "intern" are not clearly

1 defined in the legislation, nor is a time restriction set for
2 the student or intern to work without certification. Neither
3 IAHCSMM nor the CBSPD require the completion of a formal
4 education program in order to obtain certification.
5 Due to a consistent shortage of candidates with
6 formal education in central sterile supply processing, UPMC
7 currently provides on-the-job training to develop and ensure
8 competency in these roles and responsibilities of central
9 supply technicians. This internal training program has been a
10 valuable recruitment tool for these hard-to-fill positions and
11 has provided inexperienced candidates with a gateway to
12 health-care careers and compensation during the training
13 window. These are entry-level positions that provide
14 family-sustaining wages and benefits. Certification may create
15 a barrier to those job opportunities that currently exist.
16 Immediately following hospital orientation, central
17 sterile supply processing technicians begin department-specific
18 orientation. The timeframe for completion of the orientation
19 period and competency checklists vary based on experience but
20 generally take 60 to 90 days. The training content includes
21 but is not limited to policies and procedures related to
22 sterile processing; workflow of the department; infection
23 control; decontamination processes and methods; preparation and
24 handling of instruments; sterilization cycles; documentation
25 standards; sterile storage; and inventory management. This

1 on-the-job training, shadowing, mentoring, and preceptorship
2 are facilitated by coworkers as well as senior staff and
3 departmental leadership.
4 The department manager or director is responsible
5 for ensuring competency in decontamination, sterilization, prep
6 and pack, case cart assembly, and daily operations before a new
7 staff member may work independently. Decontamination
8 competency includes usage of correct personal protective
9 equipment; manual cleaning requirements; automated washing
10 equipment, including an ultrasonic washer, usage; and cleaner
11 selection. Sterilization competency includes operation of
12 steam autoclaves, HvP Sterrad, ETO, and scope reprocessing
13 units for high-level disinfection; proper readout of all
14 quality assurance checks; and coinciding recordkeeping. Prep
15 and pack competency includes instrumentation familiarization;
16 quality assurance checks; tray assembly according to content
17 sheet; and assembly. Case cart assembly competency includes
18 case cart preparation; quality assurance checks; and case cart
19 delivery. Finally, competency in daily operations includes
20 organizational skills; time management and prioritization;
21 customer service; troubleshooting; departmental policies; and
22 safety guidelines. There is a validated written process that
23 outlines the key elements of this precepted new-hire
24 experience.
25 UPMC respectfully requests that the definition of a

1 "student" or "intern" include acknowledgement of internal
2 training programs and self-study preparation for the
3 certification in addition to formal education programs that are
4 offered through external educational institutions.
5 In Section 4(a) the proposed legislation states that
6 a new employee "...may be employed or contracted to practice as
7 a central" sterile "supply technician during the 12-month
8 period immediately following successful completion of
9 certification...but may not continue to be employed or under
10 such contract beyond that period without documentation that the
11 employee or contractor holds and maintains the certification
12 required...." The intention of this language is unclear to
13 UPMC.
14 If the intention is to allow an uncertified
15 individual a 12-month period to work preceding certification,
16 the language would only support certification through IAHCSMM.
17 For an inexperienced individual, IAHCSMM requires 400 hours of
18 related experience prior to testing for certification, whereas
19 the CBSPD requires a year of experience or completion of a
20 sterile processing training course prior to testing. Assuming
21 the intention of the legislation is to provide a timeframe for
22 individuals to work to become certified, this window does not
23 provide enough experience for the individual to be eligible for
24 and complete the CBSPD exam. UPMC respectfully requests that
25 this timeframe be revised to allow 2 years to complete

1 certification.

2 As it relates to certification requirements for

3 incumbent workers, in Section 4(b) the proposed legislation

4 states that "A person who is employed or contracted to practice

5 as a central supply technician on the effective date of this

6 section must be certified within two years of the effective

7 date of this section." The proposed legislation does not allow

8 for the exemption of current staff with significant years of

9 experience, as is allowed in other States.

10 Of our 200 staff in UPMC sterile processing, nearly

11 half have been working in the field for more than 10 years and

12 have been consistently deemed competent through annual

13 performance evaluations and through ongoing observations by our

14 sterile processing leadership teams. The proposed legislation

15 would require these staff members to successfully complete the

16 certification exam in order to keep their jobs. UPMC

17 respectfully requests the consideration of an incumbent

18 grandfathering clause in the legislation to ensure that

19 experienced staff are able to maintain their positions.

20 Relating to continuing education credits. In

21 Section 4(c) the proposed legislation states that "A person who

22 qualifies to function as a central supply technician in a

23 health care facility under section 3(1) and (2) shall annually

24 complete 12 hours of continuing education to maintain the

25 person's certification as a central sterile supply technician."

1 Section 4(d) goes on to state that "A health care
2 facility that employs or contracts with a central supply
3 technician shall verify to the department and maintain
4 documentation that the person is properly certified and meets
5 the continuing education requirements of this section."
6 Hospitals do not currently submit information
7 regarding continuing education credits achieved by its hospital
8 personnel to any other State agency. For example, a pharmacist
9 must independently provide evidence of continuing education
10 credits to the State Board of Pharmacy at the time of license
11 renewal. Organizations such as IAHCSMM that certify the
12 central sterile supply technicians set the criteria for
13 continuing education requirements, and each certifying body
14 sets different continuing education requirements. As a result,
15 these criteria may change according to the evolution of the
16 trade or profession. For example, IAHCSMM does require
17 12 hours annually of continuing education. However, the CBSPD
18 requires 60 hours over a 5-year period. So there are
19 inconsistencies in how those are reported. The intent of this
20 legislation, however, is to require that experts in sterile
21 supply provide certificates, and the State requires
22 certification as a requirement for employment.
23 Health-care practitioners who achieve certification
24 in the specialty area assume the responsibility for meeting
25 requirements for recertification on an ongoing basis. In

1 Pennsylvania, many of the licensed health-care occupations do
2 not require continuing educations to renew licensure.
3 Hospitals are required to verify the credentials of the
4 individual, such as the validated certificate or license, but
5 do not keep record of continuing education programs for all
6 practitioners. To impose that specificity would set a
7 precedent for future practitioners.
8 To expect that the hospital would require
9 certification is sufficient for the Department of Health
10 licensure process as well as the Joint Commission accreditation
11 process. Requirements beyond recertification would impose
12 administrative burdens on hospitals that would be inconsistent
13 with the typical recertification process. Because hospitals do
14 not submit information regarding continuing education credits
15 achieved by the hospital personnel to any other State agency,
16 UPMC respectfully requests that this requirement be
17 reconsidered.
18 And finally, regarding UPMC's process for verifying
19 credentials. Hospitals are required to verify the credentials
20 of staff on a regular basis. At UPMC, we verify license,
21 certification, and/or registration for more than 300 individual
22 job titles. This is a resource-intensive process that requires
23 numerous staff hours as well as access to hundreds of external
24 databases for primary-source verification of the credentials.
25 To ensure consistent compliance with licensing

1 policy, UPMC verifies the required credentials for newly hired
2 staff, tracks expiration dates of the credentials on at least a
3 monthly basis, ensures that staff members renew credentials,
4 verifies renewal, and updates tracking of expiration dates.
5 Failure on the part of the staff member to renew the license,
6 certification, or registration and then present the required
7 documents prior to expiration results in his or her immediate
8 suspension without pay. Employees who do not provide evidence
9 of licensure renewal during the suspension period are
10 terminated.
11 Credentials are primary-source verified with the
12 appropriate issuing board or registry to ensure that the
13 credential is in good standing. A printout of the verification
14 is maintained. This process requires navigation of various
15 State and issuing-board Web sites, which lack consistency in
16 information required and the level of verification detail that
17 is provided.
18 UPMC recently has automated verification with the
19 State of Pennsylvania for registered nurses, occupational
20 therapists, physical therapists, and pharmacy licenses, but
21 this is not available for many of our job titles, particularly
22 those with credentials that are not issued by the State.
23 Newly obtained sterile processing certifications are
24 currently verified by reviewing the document provided from the
25 issuing board or registry. Our sterile processing leaders

1 dedicate numerous hours to coordinating continuing education
2 opportunities, in-services, and providing documentation for
3 staff to submit to the issuing boards. After completion and
4 submission of the required continuing education credits, that
5 staff member is required to submit proof of recertification.
6 In order to facilitate tracking of the credential,
7 UPMC respectfully requests that the sterile processing
8 certifications be somehow added to an online verification
9 resource similar to the State of Pennsylvania's license Web
10 site. We're unable to easily operationalize the verification
11 of this credential because of the process used and the lack of
12 the standard.
13 So in conclusion, thank you for the opportunity to
14 share our perspective as it relates to this proposed
15 legislation, and I would be happy to answer any questions that
16 you may have.
17 MAJORITY CHAIRMAN BAKER: Thank you very much,
18 Lauren.
19 Before we go to questions, any other comments?
20 Would you like to make a statement or observations?
21 MS. VOCKE: I would like to make many statements,
22 but I'm going to wait.
23 MAJORITY CHAIRMAN BAKER: You're going to wait.
24 Okay; all right.
25 Members, questions?

1 Representative Gingrich.
2 REPRESENTATIVE GINGRICH: Thank you, Mr. Chairman.
3 Naturally I would have a question since this is a topic I'm
4 really enthusiastic about discussing.
5 Thank you so much for being here.
6 First off, I want to commend UPMC for the fine job
7 they're doing in this area. That, however, is no surprise to
8 me. As I mentioned to you earlier, I worked with the
9 university medical systems out in Pittsburgh many years ago.
10 So high quality has always been, you know, their cornerstone.
11 So this was no surprise to me, and what I want is for all of
12 our health-care facilities to be like UPMC. So I go back to
13 the consistency in the training. Your training, obviously, is
14 extremely effective, well monitored, tested for competency,
15 continued. Many hospitals are not able, do not, or for
16 whatever reason match your quality and the status of your
17 training.
18 So I'm looking at a combination of the type of
19 in-house training that is currently being done very well in
20 some areas, maybe not quite as well in other areas, bringing it
21 to a more consistent and a basic foundation of understanding
22 why you're doing what you're doing and then the how, how to do
23 it, because it really does vary according to the kinds of work
24 that goes on in your facility -- right? -- the equipment that
25 is used, the ever-changing equipment cycle that clearly most

1 recently I've recognized as not quite so easy to maintain --
2 keep clean, keep sterilized, keep functional. So what's the
3 real problem? If we're talking about the financial aspect --
4 which you can't get around. You know, we talked about risk
5 management. Well, some of that is finance as well. You look
6 at it as an investment, but there's really no measure, I think,
7 to the cost of pain and suffering on the part of a less than
8 high quality outcome, you know, surgical outcome.
9 So if more hospitals did what you did, wouldn't we
10 be looking potentially at some financial savings being realized
11 with the proper training, with certification, with a strong
12 base of the employee doing the central processing work? Never
13 mind, you know, decreased turnover rates and potentially less
14 infection and expensive readmissions, and not to mention saving
15 lives and decreasing mortality rates, all those good things.
16 I love what I hear you say, because you're doing it
17 right, but I'm only hearing you say that about UPMC. So you
18 understand where I'm coming from, at least me having worked on
19 the bill. So it's probably not as much a question as a wow,
20 pat you on the back, because you're doing a great job, and I'd
21 like to see that happening across the board in more facilities.
22 Kathy.
23 MS. MEBUS: Thank you, Representative Gingrich.
24 Because the Joint Commission, and because most of
25 our hospitals are Joint Commission accredited, has a higher

1 level of evidence-based outcomes, we believe that most of the
2 hospitals are doing some kind of a program. Whether that
3 program exactly meets the needs of the certification process is
4 another question.
5 What our fear is is that if you require
6 certification prior to them being hired, we have no way to
7 recruit except from other States, because they have to have
8 experience in order to get the certification to begin with. So
9 we were looking at at least 2 years' experience because that
10 then allows them to use the hospital in-service and the
11 hospital training programs in order to help them get that
12 certification.
13 We currently have hospitals that do require
14 certification, and we have hospitals that do not require
15 certification. As you can well imagine, the larger facilities
16 in some of our areas are requiring the certification.
17 The cost of certification may become a barrier to
18 some of the individuals, particularly those who have been
19 working for 10 and 20 years. They're questioning, why do we
20 need this now when the hospital has been educating us all
21 along?
22 The continuing education that Michele mentioned,
23 there are ample opportunities for continuing education. Every
24 manufacturer who brings in a new piece of equipment does
25 continuing education for our central sterile staff, and so I'm

1 not as concerned about the 12 hours as I am about the actual
2 certification process itself.
3 REPRESENTATIVE GINGRICH: Well, and I appreciate
4 that being brought up and the points that you make, legitimate
5 discussion on at least those four items that we'll be happy to
6 work with you on.
7 And again, I thank you very much, and bring back my
8 greetings to work well done at Pitt.
9 MAJORITY CHAIRMAN BAKER: If I may, is it your
10 opinion that most hospitals provide adequate training,
11 continuing education, some certification, some not?
12 MS. MEBUS: They're infection rates would be a lot
13 higher if they weren't doing something to curtail that.
14 MAJORITY CHAIRMAN BAKER: So they're doing something
15 but not necessarily is there evidence that there is a
16 consistent model or paradigm of training, whether it be on the
17 job or continuing education.
18 MS. MEBUS: No, it's facility based at this point.
19 MAJORITY CHAIRMAN BAKER: It's all facility based.
20 Okay.
21 I don't want to put you on the spot, but do you
22 think the hospitals are doing a better job of this than nursing
23 homes or ambulatory surgical centers? And you can take the
24 fifth, if you'd like.
25 MS. MEBUS: No; I think we do five-star work.

1 MAJORITY CHAIRMAN BAKER: Okay. That's quite an
2 answer there. Well done.
3 Members? Questions?
4 Representative DeLissio.
5 REPRESENTATIVE DeLISSIO: Just real quick and to
6 reiterate behind your comment there again, I think long-term
7 care is probably out of the discussion by nature of the service
8 delivery, so I can't speak to ambulatory surgical facilities.
9 Lauren, you had said about 10 percent of your
10 complement are currently certified. Is that a voluntary
11 certification?
12 MS. LLOYD: It is. We actually are in the process
13 right now of rolling out a new career ladder for central
14 sterile processing that would actually provide promotional
15 opportunity for someone who immediately obtains certification,
16 but it is completely voluntary at this point. And we're doing
17 that because we do believe that promoting certification is the
18 right thing to do, it's just that we don't believe that
19 requiring it is necessary.
20 REPRESENTATIVE DeLISSIO: And then my follow-up
21 question was, is there additional compensation as a result of
22 somebody achieving that certification either currently in place
23 or, as you're indicating, a career ladder to be rolled out?
24 MS. LLOYD: Yes, there will be next month when the
25 new career ladder is rolled out.

1 We actually did have a higher percentage of our
2 staff that were certified, but they have chosen not to
3 recertify because the cost is, in some cases, prohibitive and
4 there wasn't a financial incentive to maintain it.
5 REPRESENTATIVE DeLISSIO: I believe that.
6 Sort of let's turn this around a little bit the
7 other way. And given that there are some details in the
8 legislation that need to be sort of worked out and worked
9 through, would there be an adverse impact to this legislation
10 other than, you know, it's mandates; there are lots of mandates
11 already out there? Would there be an immediate adverse impact
12 that you think UPMC would have a concern about?
13 MS. LLOYD: I think it would drastically -- I think
14 it would depend on whether some of these details were worked
15 out. But as it's written currently, it would drastically
16 impact our ability to recruit staff. We do feel that our
17 training program is better than any of the local training
18 programs -- or actually, there aren't that many local training
19 programs, and they don't produce that many students, so we just
20 don't have a pool of candidates that are ready to take these
21 jobs.
22 And, you know, it does very much concern me that we
23 have over 100 staff members that have over 10 years of
24 experience and that they are not grandfathered in and they
25 would have to test for their jobs, and that's just very

1 concerning to our organization.
2 REPRESENTATIVE DeLISSIO: And is this position, I
3 guess in an organization as large as yours, is it 24/7? Are
4 they scheduled around the clock?
5 MS. LLOYD: It depends on the facility, but in some
6 facilities, yes, they are around the clock.
7 REPRESENTATIVE DeLISSIO: Thank you.
8 MAJORITY CHAIRMAN BAKER: Representative Waters had
9 a question, but he had to step out for a moment.
10 Any other Members?
11 I'm just curious about your comment with respect to
12 recruitment. What is the nature, what is the typical,
13 prototypical employee that works in this arena? Is it the
14 person with a high school diploma? a 2-year degree? a 4-year
15 degree? Could you describe that person that works in this
16 medical arena.
17 MS. LLOYD: Yes. Actually, I just went through the
18 exercise of looking at all of our staff's credentials and
19 educational background. So the typical candidate for
20 employment would have a minimum of 6 years of experience in a
21 health-care environment -- that could mean really anything in a
22 hospital or health-care environment -- and a high school
23 diploma. We do have staff that have associate's degrees as
24 well as bachelor's degrees in unrelated fields, but the vast
25 majority of our staff do have high school diplomas and at least

1 6 months of experience prior to starting this role.

2 MAJORITY CHAIRMAN BAKER: Within your organization;

3 okay.

4 MS. LLOYD: Within our organization; yes.

5 MAJORITY CHAIRMAN BAKER: Or is it across the field?

6 MS. LLOYD: That is within our organization.

7 Correct.

8 MAJORITY CHAIRMAN BAKER: Okay. Thank you.

9 Representative Waters.

10 REPRESENTATIVE WATERS: Thank you, Mr. Chairman.

11 Thank you, ladies, for being here.

12 The question I want to ask is dealing with maybe a

13 financial cost that may be associated with any hospital-borne

14 infections or diseases. In your opinion, do you think that

15 this could have any implications in terms of insurance rates

16 for hospitals or medical facilities that require this

17 certification as opposed to people who might make it optional?

18 You don't think it would? Because what happens if a person has

19 a longer stay in the hospital as a result of them getting sick

20 by being contaminated or infected by some kind of medical tools

21 or equipment?

22 MS. MEBUS: If you're talking about whether there's

23 a financial impact.

24 REPRESENTATIVE WATERS: Yes.

25 MS. MEBUS: Because the patient has to stay longer,

1 yes. In terms of insurance, right now if they get a
2 hospital-acquired infection, the insurer is not paying for it.
3 REPRESENTATIVE WATERS: Insurance---
4 MS. MEBUS: Will not pay the hospital.
5 REPRESENTATIVE WATERS: Who absorbs that cost?
6 MS. MEBUS: The hospital.
7 REPRESENTATIVE WATERS: The hospital absorbs the
8 cost.
9 MS. MEBUS: So our objective is to have a minimum
10 number of hospital-acquired infections.
11 REPRESENTATIVE WATERS: Right. Well, I guess that's
12 what this legislation is intending to do, too. So there will
13 be no insurance interest in this at all in terms of the people
14 who are here, if they have certifications or not.
15 MS. MEBUS: No. That's what I meant when I said no.
16 REPRESENTATIVE WATERS: Okay. All right. That's my
17 question.
18 Thank you, Mr. Chairman.
19 MAJORITY CHAIRMAN BAKER: Seeing no other questions,
20 the sponsor of the bill has a closing comment or remark.
21 Representative Gingrich.
22 REPRESENTATIVE GINGRICH: A big thank-you to my
23 fellow Members. It's so good to see you again, and thank you
24 for coming in for the hearing and from all those who
25 testified.

1 I did want to acknowledge quickly one of my
2 employees who is sitting out here now. Carissa Mellinger now
3 works in my district office. But Carissa was a member of our
4 Bipartisan Fellowship Program when she was in college at
5 Lebanon Valley College. And I was just beginning to work on
6 this topic at the time, and she did a tremendous amount of
7 background research on this issue, and I just want to commend
8 her also, because I don't like to ignore employees. Anne
9 Yanikov, who takes care of everything here in Harrisburg for
10 me, is sitting with us, too.
11 Thanks so much for talking about this. I was hoping
12 this would be a think tank, and it really was. It brought to
13 the table a lot of information we all need to know about.
14 There are issues to consider. The points you brought forth I
15 think we need to bring into play as we move forward dealing
16 with this particular issue.
17 There are a lot of medical professionals across
18 Pennsylvania that I have personally talked to who very strongly
19 support the concept, and these are the medical professionals
20 themselves from doctors to nurses to OR people to surgical
21 supply individuals. They want to see us do something here like
22 is being done in some of the other States for all those reasons
23 that we could interpret as obstacles. So we need to think
24 about that as we move forward.
25 But I do want to close with a quote that really

1 stuck with me as I was doing my research on this, and it's from
2 a Dr. Bertha Litsky, who was a specialist. I'm sure someone
3 like Michele knows her. Her famous quote was, "A nonsterile
4 instrument in the OR is like a loaded gun," and that has never
5 left me. And I know we all, every one of us, will think about
6 that and care about that and work together to put together the
7 best plan we can for the future of health care in Pennsylvania.
8 Thank you.
9 MAJORITY CHAIRMAN BAKER: I would like to thank all
10 the Members for their attendance. And also the panelists,
11 thank you very much for your testimony.
12 The Health hearing is now adjourned.
13
14 (The hearing concluded at 3:15 p.m.)
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1 I hereby certify that the foregoing proceedings are
2 a true and accurate transcription produced from audio on the
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