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BOARD OF REGISTRATION IN MEDICINE

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BOARD OF REGISTRATION IN MEDICINE

200 Harvard Mill Square, Suite 330

Wakefield, Massachusetts

Reporter: Marianne R. Wharram, CSR/RPR/CRR

A P P E A R A N C E S

BOARD OF REGISTRATION IN MEDICINE
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Panel:
CANDACE LAPIDUS SLOANE, MD, Chair
GEORGE W. ABRAHAM, MD, MPH FACP
SUSAN P. GIORDANO, ESQ.
GEORGE ZACHOS, ESQ.

Also Present:
MARGARET COOKE, ESQ., DPH

P R O C E E D I N G S

DR. SLOANE: All right. Can we announce that we're in public session, please? Welcome. Everyone come in. Good afternoon.

ALL: Good afternoon.

DR. SLOANE: Thank you. I want to thank everyone for coming, for helping contribute to the regulations, for providing your guidance so that we can improve patient safety while supporting the medical profession. So now I'm going to read the script that I must.

This is a public hearing of the Board of Registration in Medicine on proposed changes to its regulations at 243 Code of Massachusetts Regulations 1 and 3 through 5. The Board is holding this public hearing in accordance with Massachusetts General Laws Chapter 13, Section 10; Chapter 38, Section 2; and Chapter 112, Sections 2 and 5.

In accordance with state law, notice of this hearing was published in the Massachusetts Register, in a newspaper of general circulation, and on the Board's website. We also sent a notice of this hearing by first class mail to the over 100

individuals and agencies that identified themselves to the Board as interested parties.

I would like to introduce myself. I am Candace Sloane, member of the Board, and I'm joined by my colleague --

DR. ABRAHAM: George Abraham, member of the Board.

DR. SLOANE: And now I'm going to -- before I go around and introduce everyone who is up here, I want to thank Attorney Cooke for coming. She is our general counsel for DPH and has come to join, so welcome.

MS. COOKE: Thank you.

DR. SLOANE: And now I'll start with Attorney Giordano introducing herself.

MS. GIORDANO: Susan Giordano, acting general counsel.

MR. ZACHOS: Good afternoon. George Zachos, executive director.

MS. PREBENSEN: Eileen Prebensen, senior policy counsel.

DR. SLOANE: And now I'm going to turn this over to Attorney Giordano, who is going to sort of go over the procedure of a hearing, please.

MS. GIORDANO: The following rules will apply during the public hearing today. This hearing is for the purpose of receiving testimony. There will not be any question or answer period. There will not be a public dialog among the participants today. Testimony will be heard in the order in which people signed in at the registration desk.

We encourage all of those testifying today to limit their remarks to five minutes. This should give everyone a chance to speak. We ask that groups limit their remarks to ten minutes for the group. A panel should be no more than five persons. A panel should decide how to allocate the ten minutes amongst themselves.

Please set your cell phones and pagers to vibrate or shut them off while you are in the hearing room. When you are called to testify, please identify yourself and your organization, if any, for the stenographer.

The public comment period on these regulations continues until Friday, March 3rd, 2017, at 5:00 p.m. If you would like to submit written comments, you have until Friday to do so.

We ask that everyone submitting comments to do so using Word format. This will enable us to post the comments on our website. Information on how to submit comments and copies of the draft regulations are available at the sign-in desk. Thank you.

SPEAKER: Thank you.

DR. SLOANE: So the first individual to join us is Debra Grossbaum, please. Welcome.

MS. GROSSBAUM: Thank you. Thank you for having us. So --

DR. SLOANE: Can you just introduce yourselves and say where you are from?

MS. GROSSBAUM: Yes. I'm Debbie Grossbaum. I'm general counsel for Physician Health Services.

DR. ADELMAN: And I'm Steve Adelman. I'm the director of Physician Health Services.

MS. GROSSBAUM: We are here -- Physician Health Services is a subsidiary of the Medical Society that works with physicians who have a variety of health issues, so we're going to comment on Section 1, the disciplinary proceedings, from the perspective of those physicians that we tend to work with in our organization. We

appreciate the opportunity to present testimony to you today.

I have five or six quick points with respect to 243 CMR 1.0, and the first one is in the section under definitions, which is 1.01, sub 2, and the first has to do with the definition of a complaint.

The Board has expanded the definition of a complaint to include good and accepted medical practice, and good and accepted medical practice is basically a tort definition. Typically, the Board has had jurisdiction to discipline physicians who engaged in misconduct or malfeasance of some kind, not mere negligence. When you add a good and accepted medical standard, so basically, a tort standard, someone who makes a mistake could be included as having engaged in some kind of action worthy of a complaint and disciplinary action, and that's not really the intent of the Board, or what we think the Board is -- intends to include in its jurisdiction.

Complaints should encompass actions that knowingly violate tenets of practice, not simply actions that might involve some kind of

error. It's mentioned a second time under grounds for complaint, the good and accepted medical practice. Same thing again, where --

DR. SLOANE: Can you direct us to where --

MS. GROSSBAUM: And the second time it's mentioned is under 1.03, sub I, grounds for complaint, sub A, specific grounds for complaints against physicians. Again, in that case, it talks about violation of law or regulations or good and accepted medical practice.

So again, good and accepted medical practice is -- really should be something that falls within the tort civil actions, not something that the Board should discipline a physician for, because people can make errors.

If the Board is going to suggest that, well, we have this discretion; we're not going to discipline somebody just because they made a mere error, then you shouldn't have it in here, because if sometimes you can do that and sometimes you decide you're going to use your discretion not to, that really puts you in a position of applying the regulations in a way that has too much discretion

to be decided equally, and that creates its own set of risks.

The second issue I want to address, also under 243 CMR 1.0, 1.01, sub 2, Definitions, is disciplinary action, and this is probably the most emphatic point I'd like to make today. You've added two provisions for grounds for disciplinary action. One is remediation and one is probation, including academic probation, and that's under number 15 and 16 of that section.

PHS works with physicians to try to remediate their health problems. We hope they're going to come to us early. We hope they're going to come to us often. And we hope they're going to take advantage of that remediation, but if doing remediation is a grounds for discipline, we'll close our doors. We're not a resource any more, because who is going to come to us voluntarily and say I have a health issue, I have a problem, I'm struggling with this or that, let me remediate that problem; oh, but then the Board is going to find out about it and I'm going to lose my license, so I'm not going to do that? It's going to drive people underground. It's going to risk the

public's health in the long run, and that's completely antithetical to I think what the Board wants to do and certainly what we want to do. So that's the -- probably the biggest takeaway, if you take anything away from our testimony today, is that piece.

Very similarly, the probation, including academic probation, we want to encourage facilities, particularly training facilities, to have the ability to work with their potential physicians, young physicians, new physicians to remediate and to train and to give them that little extra they need to become good, strong physicians, so if it means they're going to put them on an academic probation to allow them extra classes, extra assistance, extra guidance, that's all a good thing and it shouldn't be a grounds for somebody to be disciplined. If you have it on the books as a grounds for discipline, rather than allowing the Board some discretion to decide when to apply it, what's going to happen is people won't do it. They'll say I'm not going to do an extra course, or I'm not going to say I'm having difficulty, because that's going to create liability for them.

The next point is under Section 1.03(5)8.

DR. SLOANE: I'm sorry. I didn't hear you.

MS. GROSSMAN: 1.03, and I believe it's parentheses five, and then number eight, practicing medicine deceitfully or engaging in conduct which has the capacity to deceive or defraud. That's been there and that's fine.

MS. GIORDANO: Pardon me. We're at five minutes, so you might want to summarize your final points.

MS. GROSSMAN: I'll grab this last one, and then you'll read the rest in the written, but this is conduct which is in violation of ethical standards of the profession. Okay. It's five minutes.

DR. SLOANE: Excuse me, Attorney Giordano. I'd like them to do this one and then just have a chance to direct us to the last. You only --

MS. GIORDANO: Certainly.

MS. GROSSMAN: I only have one more after this. Well, one and a half.

The ethical standards of the profession, violation of the ethical standards of the profession, while it seems like a nice, appropriate way of protecting the public, there's no real way of defining that based on what's in the regulations now. There are no parameters for defining what are the ethical parameters, and as we all know, what's ethical to one group of people might not be ethical to another, or one sitting board member on a particular day may not be the same as another sitting board member on another day, and without some parameters, that can be a very concerning provision.

And given the limited time, I'm going to jump down to the very last one, which is the ability of a licensee to review a complaint. This is not in the regulations.

DR. SLOANE: Okay.

MS. GROSSMAN: What's in the regulations is a right of the Board to investigation, inquiry, and conference, but there isn't a concurrent right of the individual to see the complaint that's been lodged against them so they can respond to the investigation, inquiry, or

conference. So what happens is people come in before the Board and they're told, well, there's been a complaint against you and here is a little summary of what the concern is. And naturally, they'll want to say, well, I need more context. Who was it who complained and what was the situation, and maybe I can explain it better. And often, they're not given that information, because you know, they're told it's part of the investigation and so forth. So we would encourage the Board to have a transparent disclosure opportunity for the person who is defending against something like that. It should be in the regulatory structure and it should be clear so that people know what these complaints are against them to be able to respond.

DR. ADELMAN: I get a few minutes, right? Okay.

I just want to circle back to the piece on remediation, which is 1.01(2)(c)15.

DR. SLOANE: Wait, wait, wait. So I'm going to ask, today, when we direct, give us a second to get to the exact place so we can see it. Second of all, everyone should feel free to sit.

In medicine, we sit when we talk. In law, we don't. It's up to all of you however you're comfortable.

We might also -- just to let you know one other thing. We may be looking at our computers. It's not because we're reading e-mails. It's because our regs and everything are on there and notes from our regs are on there, just so you know. But please, so where are we going now?

DR. ADELMAN: Back to the notion of remediation as being viewed as discipline, or meaning discipline, 1.01(2)(c)15, I think. Do I have that right?

MS. GROSSMAN: Yes.

DR. ADELMAN: Okay. So it was a little bit more than a couple of years ago that we came here and presented to the Board a program on occupational health monitoring where we recommend coaching interventions as a form of remediation to physicians, and we actually presented this as this is not a disciplinary thing and this is a program. This is an agreement we have with physicians. It's not like a monitoring contract. It's a monitoring agreement. Violation of the monitoring agreement

doesn't lead to a Board report. And the Board agreed that that was in fact the case.

I'm pleased to say that we've launched that program. We've had 20 or 30 physicians move through it. The results have been spectacular. We're presenting on it at national meetings, and it would be really -- as Debbie said, it would sort of close the door to a successful program.

And I'll just close by saying the thing that I'm most excited about is that we're getting referrals for coaching to this program from residency programs. We're seeing early-career physicians who are -- get -- learning to get out of their own way at the front end of their career as opposed to the old culture, which was to kind of go -- you know, look the other way and not attend to the matter at hand. And I will tell you, it's much, much easier to deal with shaping someone early on, so we really would hate to see regulations introduced that are going to put the kibosh on a very successful program.

DR. SLOANE: Thank you very much. Thank you for your comments.

Excuse me for one second.

(Pause.)

DR. SLOANE: All right. Joining us next is Ken Kohlberg.

MS. PREBENSEN: I believe this is a panel.

MR. HYAMS: We have a panel of four. Can we go up with Ken?

DR. SLOANE: Okay. Absolutely. So we have Ken Kohlberg, Joel Rosen, Ellen Epstein Cohen, Scott Liebert, and Andy Hyams.

MR. HYAMS: Right.

DR. SLOANE: And Andy Hyams is going to speak for us.

MR. HYAMS: Right. I'll just introduce everybody first. Unfortunately, Scott is not here.

So we have testimony on behalf of 19 attorneys who regularly represent physicians at the Board of Registration in Medicine. We did a quick calculation, and 19 of us in the aggregate have practiced before the Board for 430 years.

DR. SLOANE: Wow.

MR. HYAMS: Longer than the Board exists. So the first speaker will be Ken Kohlberg, and he's going to talk about the summary suspension

regulation.

MR. KOHLBERG: Dr. Sloane and members of the panel, thank you very much for having me and giving me the opportunity to speak today. Again, my name is Ken Kohlberg. I'm an attorney in private practice. My law office is in Concord. I've been practicing law in Massachusetts since 1990, and as you can see, I'm the new guy in this group. I have, however, been representing physicians and licensed health care professionals in civil and administrative litigation since around the mid-1990's. I'm a graduate of the Harvard School of Public Health and I've actually tried jury cases on behalf of both physicians, which is the bulk of it, but also on behalf of patients as well.

Like all of us here, I believe, in this room, I support the Board's mission, which is to protect the public, but we believe that this -- this -- any alleged danger to the public interest needs to be balanced against constitutional rights. And just recently, I litigated a case in a slightly different context involving constitutional due process requirements in administrative regulation.

That experience caused me to canvass my colleagues and to see what their experience has been recently with respect to some Board matters, and so we have identified a flaw, a fundamental flaw in the regulations that gives us bad news and good news.

The bad news is that your regulation is unconstitutional, and I'll explain in a moment very succinctly why. The good news is that you can fix it very simply, and that's what we're really asking you to do with respect to this regulation that deals with summary suspension.

So 243 CMR 1.03(11) is what we're talking about here. It's a regulation that simply provides that the Board has to provide a hearing on the necessity for summary suspension within seven days. The proposed new regulations just seem to reenact that provision without any change whatsoever, and as I mentioned, the provision is unconstitutional. The reason why it's unconstitutional, there's a United States Supreme Court case from 1979 called Barry versus Barchi. Anyone who likes law or constitutional law should download it and read it. It's a very interesting, very fun, very short decision, but it's the reason

why this regulation needs to be fixed.

The New York Racing Board had summarily suspended a horse trainer's license when the horse trainer was suspected of drugging the horse. The statute which provided for the suspension said it didn't specify the time that the hearing, the deprivation hearing, needed to be held and it gave the Racing Board I think 30 days after the decision or after the hearing to issue its decision.

The United States Supreme Court said that's unconstitutional for two reasons. First, it didn't provide a prompt hearing, but more importantly for our purposes today, it didn't provide a prompt disposition of the outstanding issues. That's a direct quote, page 66. And so the Barry court gave two beautiful -- right out of the decision, two -- reasoning for why that was unconstitutional. It said -- it gave even the brief suspension would give no opportunity to put the state to its proof until the licensee had suffered the full penalty imposed. That, we have from our summary suspension provision here. And then, once suspension has been imposed, the trainer's interest in a speedy resolution of the

controversy becomes paramount. And that's -- that's sort of the reasoning here.

Here, the Board's summary suspension regulation provides for a hearing within seven days, which is a good thing. That's constitutional, in our view. But the Board has no time requirement for any disposition at all, and that's the problem. There's no time requirement, much less a prompt disposition requirement, which is required by the lang-- by constitutional law, by the language in the Barry decision. So there is no mention in your regulation about how soon a decision has to issue and that's what renders it unconstitutional.

Now, just to sum up and to tell you why this is important and why --

MR. HYAMS: We're going to run out of time, because --

MR. KOHLBERG: Okay. I'm just going to point to 65(b). Very, very, very simple. Okay. Very simple. You understand the consequences of this. The physician is out of practice during this position -- during this period while he is waiting for a decision, while he or she is waiting for a

decision. So what can and should be done?

We have a legislative provision, Mass. General Laws, Chapter 112, Section 65(b), which is through the Office of Consumer Affairs and Regulation. It applies to psychologists, social workers, all -- a bunch of Allied Health professionals, other licensed professions. And it says that you get a hearing within ten days and there's going to be a preliminary written decision within ten days of the hearing. That, we consider prompt, and what we're finding in the experiences of some of the physicians who face summary suspension hearings is they can wait months and in some cases years before there's a decision, and that's the violation and that's why 243 CMR 1.03 is unconstitutional.

So what we're asking is that simply that the Board bring its summary suspension provision into compliance with the constitutional law as stated in Barry, follow the lead of the 28 other professional boards that have a seven-day or a -- excuse me; a time requirement for a written decision, and not leave it open-ended. I guess we believe that ten days from the date of the hearing

is reasonable. It's codified in Massachusetts General Laws. And I thank you very much.

MR. HYAMS: All right, Joel, you're up.

DR. SLOANE: Thank you very much.

MR. ROSEN: Good afternoon. My name is Joel Rosen. I'm in private practice in Andover. I've had many years representing doctors and dentists and other professionals in front of licensing boards. I have argued in front of the Supreme Judicial Court many times on due process issues.

I'm going to be very brief, because Deb Grossbaum did a very -- made a very articulate presentation of this issue. I just want to direct your attention to Section 1.03, 3 and 4.

DR. SLOANE: Say that again, please.

MR. ROSEN: Section 1.03.

DR. SLOANE: Okay.

MR. ROSEN: Subparagraphs 3 and 4.

Basically, we're not objecting to a change in the regulations. All we are doing is asking you, like -- sort of like my colleague just did, to put something new in the regulation which would provide that a doctor has the right to see

the complaint and the investigative file at any time. The way it is now, as Debra explained, the doctor -- the doctor gets called to a meeting with the prosecutor or to a -- to a conference under subsection four, and the doctor doesn't know yet what's being alleged or even who is alleging it, necessarily. So we think that that is contrary to Chapter 112, Section 5, which provides that the -- the doctor has the right to the investigative file at any time. It's been the practice of the Board not to provide it, though, and that has -- we think that's an absolute due process violation. We argued it in the Randall case at the SJC. We prevailed in the Randall case, but not on those grounds. They never reached that issue, but it will come up again and this is a great time to fix it. Thank you.

DR. SLOANE: Thank you.

MS. COHEN: Good afternoon. I'm Ellen Cohen from Adler Cohen in Boston. It's my pleasure to have an opportunity to share my thoughts on one particular issue, and that's with regard to the proposal to add remediation to the definition of discipline. And so I'm going to be brief, but that

doesn't mean that I don't think this is really important.

There are two reasons why I want to comment on this particular issue. One of them has to do with the fact that the proposed regulation would, I think, contravene the existing law that the legislature has enacted, and the second reason is more of a public policy, sort of practice of medicine type of issue.

So just to give you the reference, it's Massachusetts General Laws, Chapter 112, Section 5, which specifies that the Board is authorized and directed by the legislature to develop and implement a remediation program designed specifically to improve physicians' clinical and communication skills. And the Board was ordered by the legislation to promulgate rules and regulations for a remediation program, and the very first thing it says in the law about the provisions that must be included are that the Board shall offer a remediation program to physicians on a voluntary basis as an alternative to disciplinary action.

MS. GIORDANO: Pardon me for a moment. I just want to let you know we're at ten minutes.

MS. COHEN: Okay. I'll be really fast.

So the first argument, because you can read the law yourself, is that proposing to make remediation disciplinary totally contravenes what the legislature has defined as a remediation program. And the second issue that I would ask you to give serious consideration to is the chilling effect that doing that would have on the practice of offering remediation, particularly to doctors in training programs and people who could use some additional help with communication and clinical skills, and yet if it were to be defined as disciplinary, then it's either not going to be recommended when it should, or it's going to be vigorously opposed, when otherwise, it would likely be voluntarily agreed to.

And so I think what was proposed to be a simple and easily available self-corrective measure for the medical community to use in teaching and training and monitoring the quality of practice and communication skills, if you turn that into discipline, it's just not going to happen any more, and I think we will lose much more than you would gain, so I thank you very much.

DR. SLOANE: Thank you.

MR. HYAMS: So on the rest of the points that we have, the extension of the definition of disciplinary action into academic probation would have a similarly corrupting effect.

DR. SLOANE: Can you tell me exactly where you're at, please?

MS. PREBENSEN: We don't have your written testimony. Do you have a copy of your written testimony?

MR. HYAMS: Yes. Would you like it now?

MS. PREBENSEN: Yes. Do you have copies for the chair?

MR. HYAMS: Yeah, there are three.

MS. PREBENSEN: Thank you.

MR. HYAMS: So I'm on page -- if you want to follow, but I'm on page --

DR. SLOANE: Yeah. What page?

MR. HYAMS: On page 5. A lot of that is appended, so don't worry. So the -- I'm on page 5 and onto page 6, the adding academic probations in the same category as remediation in the academic atmosphere, it's going to -- it's

going to be corrupted, just as remediation would be, and there are others who can speak to that better than I can.

The next point is the addition to the definition of -- the addition of the grounds for complaint of conduct which is in violation of the ethical standards of the profession. Now, the one thing I did not get into the written testimony was that this -- a similar proposal was made in 2008. We were here. It's like Groundhog Day.

At that time -- I've got -- in fact, I'll hand this up. I have the testimony of Dr. Tozzi from UMass Memorial Health Care and Dr. Flotte. I don't know if I'm pronouncing it correctly. He was the dean of UMass Medical.

DR. SLOANE: What page are you on?

MR. HYAMS: I'm -- that's not in my testimony.

DR. SLOANE: Okay.

MR. HYAMS: But I will give you their -- I will give you their testimony from 2008 in which they made the same point about adding -- adding conduct which is in violation of the ethical standards of the profession.

At that time, the Board was trying to add failing to comply with recognized ethical standards of the profession, specialty and subspecialty, and they -- you know, they made the exact same points that we're making today that the Board seemed to have aborted eight years ago. Understood. Enacting as grounds for discipline ethical standards that are aspirational is no way to provide physicians with prior notice of what they -- what is ethical and what is unethical, what is legal and what's not legal. There are plenty of -- there are plenty of private professional societies and organizations that disagree. They're not in lockstep. You know, they're -- maybe there would be a private professional organization that would agree with the Florida legislature on the gun -- the gun information gag rule. Maybe some wouldn't. Not every professional organization agrees about end of life issues. And you know, to try to graft that -- a fuzzy standard like that into regulations that are supposed to give physicians some kind of prior -- some reasonable prior notice of what they can and can't do is not the way to go.

MS. GIORDANO: Pardon me. We're at 15 minutes and we have the testimony.

MR. HYAMS: All right, so --

DR. SLOANE: Do you have anything else that hasn't been addressed?

MR. HYAMS: Yes. The --

DR. SLOANE: That no one has addressed to date?

MR. HYAMS: Correct. I do. Yes.

DR. SLOANE: Okay.

MR. HYAMS: I'll be -- I'll be quick.

The new definition of complaint that removes the requirement that a complaint be filed, the new definition is a communication or document from any source which alleges physician misconduct, malfeasance, or any violation of law or regulation pertaining to the practice of medicine or good and best accepted medical practice. This is a disruptive definition, because anything --

DR. SLOANE: Where exactly are you looking?

MR. HYAMS: All right. The new definition complaint is -- I start on page 6.

DR. SLOANE: Okay.

MR. HYAMS: I'm sorry. I'm sorry. Page 7, right in the middle there.

DR. SLOANE: Page 7 in the rules.

MR. HYAMS: Anything can be a complaint -- a Facebook post, fake news -- because that's what you're proposing. There's no -- there's no requirement that anything be filed. On anybody's whim, something can be a complaint. And you have to look down the road, because a closed complaint is a public record, and if you're not careful in some minimal way about what constitutes a complaint, then everything that -- everything that becomes a complaint is a closed complaint and is a public record.

MR. ZACHOS: Thank you.

MR. HYAMS: The last -- all right. One last point that I think you might --

MR. ZACHOS: Has it been submitted in your written response?

MR. HYAMS: Yes.

MR. ZACHOS: Yes? Then we appreciate it.

MR. HYAMS: Okay.

MR. ZACHOS: Thank you very much.

MR. HYAMS: All right. Thank you for your time.

MS. COHEN: Thank you.

MR. ROSEN: Thank you.

DR. SLOANE: Deborah Levine. Welcome.

DR. LEVINE: Thank you. Hello. My name is Deborah Levine and I'm a radiologist and president of the Massachusetts Radiological Society, as well as vice chair of academic affairs in the Department of Radiology at Beth Israel Deaconess Medical Center. I'm submitting these comments on behalf of the MRS, which represents over a thousand member radiologists, radiation oncologists, and radiation physicists who practice in the Commonwealth.

The MRS is a state chapter of the American College of Radiology. For over three-quarters of a century, the ACR and its constituent chapters have devoted their resources to making imaging safe, effective, and accessible to the members of the public who need it.

I would like to focus my comments on the provisions of the proposed regulations governing informed consent within the act being

discussed. While the MRS is a strong proponent of engaging patients in informed decision-making regarding a patient's decision to undergo diagnostic imaging tests, we have serious concerns about the required informed consent provisions proposed in the regulations that are overly broad and vague, deviate from accepted medical standards, and sweep in tests that ordinarily do not require written informed consent and in doing so would greatly impede patient access to routine imaging tests.

So starting in Section 3.10, paragraph 1 --

DR. SLOANE: Okay. Give us one second. We're not as fast.

DR. LEVINE: Thank you. Our primary concern is predicated on the word removal of the word major from the current regulations governing the therapeutic and diagnostic procedures where informed consent should be obtained. The proposed regulations state that a physician has the obligation to obtain and record a patient's written informed consent before diagnostic, therapeutic and/or invasive procedures, medical interventions,

or treatments. By removing the word major from the regulations and inserting the words, the term has the obligation to obtain, the proposed regulations could be interpreted to require written informed consent for all diagnostic, therapeutic, or invasive procedures, medical interventions, or treatments.

Without the word major, diagnostic procedures subject to mandatory written informed consent could be interpreted to include such minor routine tests as blood draws and imaging procedures such as x-ray, ultrasound, CT, and MRI. These are commonly performed procedures with minimal risk. The MRS believes that information should be available to patients regarding these diagnostic consents before they're performed, but that written informed consent and the process for obtaining such consent as required under the proposed regulations is not needed for such tests and requiring this would constitute a major deviation from nationwide standards and practices.

For many imaging tests, such as x-ray, CT, and MRI, the performance of the test is done by a radiologic technologist under general supervision by the interpreting physician without direct

interaction between the radiologist and the patient, since the images are obtained separate from the performance of the imaging study. We do not dispute that major interventional procedures involving imaging should be subject to written informed consent as would any interventional or surgical procedure involving meaningful risk.

Next comment is regarding Section 3.10, paragraph 1, parts A and D. Both of these sections require the attending physician or primary operator to be responsible for discussing the risks and benefits of the procedure, intervention, or treatment and obtaining the patient's written informed consent. A resident or fellow in teaching hospitals are considered a physician extender under the proposed regulations, which imply that the primary operator cannot be a resident or fellow. However, residents and fellows commonly obtain patient consent for procedures at an appropriate level to their training and under the supervision of an attending. As written, the proposed regulations unnecessarily disrupt the commonly accepted practice of obtaining informed consent for procedures in academic medical centers. The

inclusion of the word major in describing the procedures that require written informed consent as previously mentioned in my comments would minimize the concern that residents and fellows cannot obtain consent for routine procedures under the supervision of an attending at a level appropriate to their training.

My next comment is on Section 3.10, part C, when informed consent is required. The proposed section states, written informed consent should be obtained before all diagnostic, therapeutic, or basic procedures, medical interventions, or treatments where disclosure of significant medical information, including risks involved, would assist the patient in making an intelligent decision whether to undergo the proposed procedure, medical intervention, or treatment.

The MRS is concerned about the word all and its implications as to whether it would include minor diagnostic tests or procedures as discussed previously. We recognize that the requirement is somewhat limited by the term significant medical information; however, the broadness of the word all is concerning. Hereto, MRS would propose that the

word major be substituted for the word all.

MS. GIORDANO: We are at five minutes, so you might want to summarize and finalize your remarks.

DR. LEVINE: Okay. I'd like to -- I have two other comments. One is Section 3.10(f), major -- patient's medical record must reflect who will participate. Our concern there is that due to duty hours and shift changes, there can be changes in personnel, and we want to make sure that the regulations allow for changes in personnel that are mandated by requirements for shift hours and duty hours, and in addition, sometimes there are emergencies that occur during procedures and you need to allow for physicians to be added in should emergencies happen.

The last one is on the sterile technique at all times, which is under the informed consent portion in 3.10(h), and that really has nothing to do with informed consent. And the way that it's written is saying that you need to have sterile technique at all times during the practice of medicine, and there are many times when we practice medicine when we don't use sterile

technique; for example, when talking to a patient or when examining a patient. But obviously, during major interventional procedures, you do need sterile technique, but the way this is written is that you would need to be sterile the entire time you're doing anything, which means you -- you just can't walk from one operating room to the other. We know that, but you actually break sterile technique in order to do that.

So I appreciate your time and I'm sorry I ran over. We will submit this.

DR. SLOANE: Thank you. Thank you very much.

John Erwin, please.

MR. ERWIN: That's my name. I was just going to say, John Erwin with COBTH.

DR. SLOANE: You have a new name now. Thank you.

MR. ERWIN: So my name is John Erwin. I'm with the Conference of Boston Teaching Hospitals, or COBTH, which is a group of 13 Boston area teaching hospitals that work together on issues related to their missions of medical education, medical research, and providing

specialized care.

Thank you for the opportunity to provide testimony on these regulations. I will be submitting to Eileen our full written comments by the deadline on Friday, but so I just want to highlight some of the concerns that we have, and a lot of them are of concern particularly to teaching hospitals, and some of them are mentioned, so I will just touch on those.

The first area is the area of definitions and the inclusion of remediation and academic probation in the definition of disciplinary action. As Dr. Adelman from PHS and Ellen Cohen have pointed out, that this could have a chilling effect on people coming forward and identifying issues that could be remediated and fixed before they actually become disciplinary problems. So we would recommend that both academic probation and remediation be stricken from that new definition section.

Turning to 243 CMR 3, we have concerns made to the changes in credentialing, so this is 3.05.3, Subsection I. Currently, when credentialing a physician, a health care facility

has -- must make an inquiry to other entities where the licensee has been employed for up -- for the past ten years. The proposal actually removes that ten-year time frame and basically makes it unlimited and would require inquiries to be made to all facilities where a physician was affiliated over his or her entire career, possibly as long as 20 years previously.

The current process itself, with that ten-year limit, is already pretty demanding administratively and seldom identifies an issue that has not already been identified through other sources. We feel that the extension of the time frame from ten years to unlimited would impose an undue administrative burden and in our opinion would yield very little information that, again, is not already available through other sources, so we recommend that the time frame, the ten-year time frame, be retained.

We appreciate that the Board has included a provision on telemedicine credentialing. We, the Conference of Boston Teaching Hospitals, as well as a number of providers and specialty groups in the state are part of the Mass. Telemedicine

Coalition, and we will be recommending language that we think is consistent with the intent of the Board's revision and reflects the most recent CMS guidance and regulations on telemedicine credentialing. So again, we appreciate the recognition of the role that telemedicine can have in -- in addressing work force shortages and improving access for people across the state, and we will have language there.

We also appreciate the Board in 3.07, Subsection 2, is eliminating some duplicative reporting by requiring reporting to the Board only those events that have not already been reported to DPH, so we appreciate this effort to streamline that, that process.

Last, but certainly not least, is our real concerns with Section 3.10. This is the informed consent. And a lot of the issues were identified by Dr. Levine. There are currently requirements and guidance on best practices, both from CMS, from the American College of Surgeons, and from the Board of Registration itself. We believe that they are clear and highly effective in ensuring that patients are provided with all the

relevant information prior to deciding on a clinical course.

Among the concerns we have is that -- and this was raised by Dr. Levine as well -- is that the application is overly broad to include, quote, any diagnostic, therapeutic, or invasive procedure, medical intervention, or treatment. That could basically mean any patient/physician interaction that you could imagine.

The proposal also requires information that may not be known at the time of consent. For example, a patient must be informed ahead of time who will be participating in the procedure, intervention, or treatment. While a physician may know that residents, fellows, physician assistants or others will be present during the procedure, in a teaching hospital with a large number of residents and complex trainee schedules, the physician may not and most likely won't be aware of what particular trainees will be in until shortly before the procedure. We don't believe that the proposed amendments to Section 3.10 should be adopted. Instead, we recommend that the language be add-- that language be added to the existing

Board regulation requiring indication of if other professionals other than the attending will be participating in the procedure, and we have language that we would be suggesting be added to that current Board regulation.

So thank you for your consideration of these. Again, a lot of these, I think, have been raised or will be raised that are particularly of concern to teaching hospitals and their role in medical education. Thank you.

DR. SLOANE: Thank you very much.

MR. ZACHOS: Thank you.

DR. SLOANE: I'm sorry. Forgive me if I -- Sarah Amholz?

MS. PREBENSEN: Arnholz.

MS. ARNHOLZ: Sarah Arnholz from Partners Health Care. I'm actually not testifying today. Thank you.

DR. SLOANE: Okay. I'm sorry. Linda Robinson, and I couldn't lead the last.

MS. ROBINSON-HIDUS: Hidus. Robinson-Hidus.

DR. SLOANE: Welcome.

MS. ROBINSON-HIDUS: Hello. I'm Linda

Robinson-Hidus. I'm the board of -- the president of the Board of Directors of the Acupuncture Society of Massachusetts. We have recently changed our name from the Acupuncture and Oriental Medicine Society of Massachusetts. And I'm here to speak with you about 243 CMR, Point 5. Thank you very much for some of the wonderful modernization and revisions of the language, but I would like to speak with you about the term Oriental. I think that it should be removed and substituted with East Asian to stay in keeping with the national move to remove pejorative language. Thank you.

DR. SLOANE: Thank you. Mass. Medical Society, just bring them all up and let them introduce, please. Welcome.

DR. ABEL: So in an attempt to make your lives a little bit easier and not have to flip so much, I have pulled out the sections that we will be discussing --

DR. SLOANE: Great.

DR. ABEL: -- and tried to highlight the language that we will discuss.

DR. SLOANE: Thank you. This is great. Can you also introduce yourselves for everyone,

please?

DR. ABEL: I'd be most happy to. My name is Brendan Abel from the Mass. Medical Society.

DR. GLOVER: McKinley, Dr. McKinley Glover. I'm a fellow at Mass. General Hospital.

DR. BOYER: And I'm Dr. Debra Boyer. I'm a pediatric pulmonologist at Boston Children's Hospital.

DR. ABEL: So thank you so much for the opportunity to provide comment today. I'm delighted to be joined by Dr. Glover and Dr. Boyer, who will provide their clinical perspective on the proposed regulatory changes, but I did want to go through a couple sections that we have some concern about and which we will be submitting extensive written comment about.

Before I dive in, I want to make two kind of high level points. The first is a reminder that these regulations are being undertaken pursuant to the governor's executive order to review these regulations through the lens of streamlining and reducing administrative burdens. We feel that many of these proposals are quite contrary to that charge, and so we urge a

reevaluation of the regulations through the lens of that executive order. But second, I do want to reiterate the Medical Society's strong support of the value of a fair adjudicatory process and a robust Patient Care Assessment Program as two key drivers of quality of care and patient safety in Massachusetts. We look forward to working with the Board and the staff to find solutions that are consistent with these two points.

But let's dive in very quickly to a couple of the concerns. So first, on the first page, number one, we have already discussed it quite a bit, and both Drs. Glover and Boyer will highlight it from their clinical perspectives, but we continue to have strong concern about the addition of the terms remediation and probation and we would urge their striking.

We also think that a lot of the disciplinary actions that are enumerated above actually do kind of sweep in a lot of the issues that may have kind of been targeted with the addition of this language, so we hope that striking them will still provide thoughtful grounds for disciplinary complaints.

Second, as also discussed before, the -- on the next page, Section 103-5, the striking of gross from negligence is quite concerning. Especially when added with the changes to some sections earlier, we feel as though this is sort of conflating, as some colleagues have already highlighted earlier, the kind of civil arena, which takes care of single instances of simple negligence, versus the Board of Registration in Medicine, and we have concern about that.

Again, number three on that same page, the addition of violation of ethical standards is also concerning. We at the Board -- at the Medical Society in dealing with issues of concerning ethical practice work with the AMA. At present, their code of ethics is over 500 pages long and it is consistently and constantly evolving, so you know, the idea of providing physicians with some sort of standard and basis is important, but it's also very challenging, and so we have significant concerns about just having that language in there without any further reference or definition.

On the next page, this will be 103, the number four on the following page, the suspension

of prior hearings, again, as we already discussed, we do have some concern, some serious concern, about the lack of a timeline put in there and we urge reconsideration with a timeline for a decision.

Going to the next page, we're onto number five, this has not been raised and I want to take a minute to go over it. The striking of entity and replacing with hospital in terms of the types of entities that are swept into the Patient Care Assessment Program is very important, because this change means that licensed clinics no longer have the important protection that the Patient Care Assessment Program provides to them, including many peer-review protections. We are committed to working with the Board to find alternative solutions. We have already started to have discussions as to what are some alternative pieces of language that we could use to clarify so that the types of clinics that have the infrastructure to fully comply with a patient care assessment program and all of its reporting requirements would be able to be included and those that perhaps do not would be excluded. We'd be happy to work with

you and we will include that language in our written comments for your review.

On the next page, number six, we have spent a great deal of time at the Medical Society talking about the credentialing process, and it has really become a significant burden to recruiting physicians from out of state. From board licensure to DPH, MCSR, all the way to the hospital credentialing process, adding additional burdens to the credentialing process with as far as we know no real justification for adding the additional requirements is concerning, especially when you're talking about reviewing and trying to contact every employer over the course of the entire physician's career, including those that he was just credentialed -- he or she was just credentialed to provide clinical care at, not even employed at. We urge the retention of the ten-year limit on that. We think that's very important.

And lastly would be the -- one more. Number seven includes increased reporting requirements under the PCA program. That is detailed in our written comments, and lastly, the informed consent provision.

DR. SLOANE: I'm sorry. Say what you just -- you're going so fast.

DR. ABEL: No problem at all. I want to provide my colleagues with an opportunity to provide their perspective. Number seven in my handout talks about increased reporting requirements for participants of the PCA program. The requirements now add unanticipated as opposed to unexpected and a broader definition of serious injury. Our concern is that this will significantly expand the reporting requirements put upon participants of the PCA program, and we're kind of unsure as to the justification for that expansion, especially knowing that there are additional reporting requirements that come from the DPH, from the Joint Commission, and from other entities.

And lastly, the informed consent provisions are also quite problematic from our perspective as well for all of the reasons that have been detailed so far. They're also detailed in the written comments that I will provide.

But most importantly, I am so happy to introduce Dr. McKinley Glover and Dr. Deb Boyer.

Dr. McKinley Glover the Fourth is a clinical fellow in neuroradiology at MGH and a fellow in their health policy management section as well. He graduated from Duke University and received a master's from Johns Hopkins School of Public Health and served on the Board of Trustees at the Medical Society. Dr. Boyer is a pediatric pulmonologist at Children's Hospital where she directs the pediatric pulmonology fellowship program and is a cochair of their GME committee.

Dr. Glover?

DR. GLOVER: Thank you. So as Brendan said, I am a fellow at Mass. General Hospital, and thank you for the opportunity to provide some comments here today and to give some perspective. I also serve on the National Governing Council for the American Medical Association resident fellow section, so I interface with residents and fellows throughout the country.

I want to speak specifically about item number one on the handout, which is talking about expanding the proposed regulations for disciplinary actions to include both academic probation and remediation.

So fundamentally, I believe that the proposed changes are really antithetical to the art and science of medicine and medical education. Having been a medical student recently, a resident, fellow, and actually supervising residents now, on a daily basis, there are opportunities for remediation, either written and/or oral. In fact, I believe that these processes are necessary to making good doctors and for safe patient care. Further, the inclusion of academic probation is a bit misguided. Probation in the medical school setting, as well as residency, is often a term used to signal that special attention is needed, that potentially additional coaching or training to bring someone up to speed on an area where they may be deficient. And we should be promoting that culture of transparency in education, and these proposed regulations would possibly have the opposite effect, which would ultimately be a negative consequence for students, for trainees, and the patients of the Commonwealth. Thank you.

DR. BOYER: Thank you for the opportunity. So I am Debra Boyer. I am the pediatric pulmonary fellowship director at Boston

Children's Hospital, and as stated, I work -- I cochair the GME committee. And I think as McKinley said, too, I also work nationally in medical education with various organizations such as the Council of Pediatric Subspecialties, the Association of Pediatric Program Directors, and the American Board of Pediatrics, so I feel like I do have my finger on the pulse of medical education, and then clinically, I do some work there, too. So I am the associate chief in pulmonary, but I am also the associate medical director of the lung transplant program, so I have a sense of how these regulations could impact folks clinically as well.

I wanted to speak just briefly on two topics, the first, again, being the disciplinary proceedings for physicians, and in particular, again, the requirements about reporting all types of remediation and academic probation to the Board.

I would say that it's so important, as all the other speakers have mentioned, that remediation is truly a key component of graduate medical education, and the majority of the time, it is not at all a disciplinary action, but actually, it's a way to improve the trainee. I think we all

understand that training is really supervised practice, where trainings are moving along a developmental continuum and will often need help at particular spots along the way. This extra help or focus is key to help them improve, and again, I can't emphasize how frequently, I think as McKinley said, on a daily basis, we remediate our trainees. I might work with a trainee to improve areas of medical knowledge, clinical decision-making, interpersonal interactions. All of those are what we would say would be key to be a truly stellar physician. And so as a program director, I can say that I have to feel that I have an opportunity to comfortably and safely work on improving my trainees to make them the best that they can be, and if I can't do that, it's going to be really hard to improve them, and ultimately, then, patient care will suffer, because these trainees will graduate and will not be able to really truly independently practice as they really won't have reached their true potential. So I think it's really key that we have that, that provision.

MS. GIORDANO: We're at ten minutes.

DR. BOYER: I have just three brief

points.

DR. SLOANE: Go ahead.

DR. BOYER: The second issue that I wanted to address was things that had been briefly addressed on informed consent issues, but I wanted to just again place them in maybe a bit of a clinical context in terms of my practice.

Again, folks have commented on the language requiring informed consent prior to all diagnostic, therapeutic, or invasive procedures, interventions or treatments, and this just covers a vast array. Again, in my practice, this could be getting a blood draw or a chest x-ray, or it could be me doing airway dilation on a sick lung transplant patient, and those are not the same and I don't think it's fair to require the same informed consent practice for those things.

Secondly, in terms of who obtains informed consent, it's been addressed by other speakers whether it's truly necessary that only the attending physician can obtain informed consent. It's been mentioned that it's not practical, but I would actually advocate that it's dangerous for the education of the trainees. Certainly, patients and

families need to have the opportunity to give informed consent and ask all of their questions, but it's critical that a trainee learn how to obtain informed consent, because that's safe, effective patient care, and if our fellow -- if my fellows don't have the opportunity to do this, I'm going to graduate fellows who don't know how to do it and one day are attendings who have never had to get their own informed consent, so I think it's key that they be allowed to do that.

And then lastly, as has been mentioned, is the requirement that all physician extenders be included in the informed consent. It's not practical, and I would advocate that it actually can result in harm to the patient. Clearly, the patients need -- and the families need to know who is the attending, who is the physician in charge of the procedure and any possible assistants that I know that may be working with me, but I can't necessarily know all fellows that might be in a procedure with me, and I'll give you one brief example and then I'll be done.

When I'm performing a bronchoscopy, my fellow might be called to an emergency, say, on the

floor, on the inpatient unit to take care of a patient. I would either then have to make a decision. I could continue to do the case without another trainee, since I didn't bring that up with the family, in which case I'm probably compromising care if I'm only going to have two hands instead of the four that I should have, or I might have to step out and go talk to the family, say I'm bringing in a new trainee, which is going to allow the patient to remain under anesthesia for a longer period of time than they need to be, and that's surely not in the best interest of the patient, so I would argue that -- that having to list all trainees is not in the best interest of the patient. Thank you.

DR. SLOANE: Thank you very much.

DR. ABEL: Thank you.

DR. SLOANE: Jeff Schneider. Welcome.

DR. SCHNEIDER: Thank you very much for the opportunity to allow me to speak before you today. My name is Jeff Schneider. I'm a practicing emergency medicine physician at Boston Medical Center. I currently serve as the chair of our GMEC committee as the designated institutional

official for ACGME, and I'm the assistant dean for graduate medical education at the Boston University School of Medicine. I want to provide, if I can, over the next few minutes a little bit of personal insight into how some of these regulations may change what we do.

I come before you today as a teacher and as an educator and as an individual who has made medical education the framework on which I have built my career. It is from this perspective that I am particularly concerned about the Board's proposal to define remediation and academic probation as disciplinary actions. While both I personally and Boston Medical Center as an institution are humbled by the great and enormous responsibility of training the next generation of leaders in health care, we are quite worried that the proposed alterations in language would actually have a significant and quite detrimental effect on the ability of physician educators to reach the very small number of learners who may require additional intensive and focused training to reach the level of knowledge necessary to provide outstanding care and practice independently at the

conclusion of their training.

As the preeminent teaching institution in one of the most sought-after training environments in the nation, Boston Medical Center and its sister teaching hospital -- and our sister teaching hospitals provide world class care in concert with world class education. We are home to innumerable expert educators who work tirelessly to help each resident and each fellow reach his or her potential. Residency program directors and faculty diligently access and evaluate each trainee and in doing so occasionally identify a resident or fellow who would benefit from additional attention in a particular area or to address a certain competency. Remediation plans are precisely designed to characterize a weakness while implementing specific focus and detailed plans to address any gaps.

Fortunately, the majority of these residents do reach the necessary level of competency or understanding and then successfully complete training. It's explicitly identifying remediation as not disciplinary in nature facilitates an important partnership between teacher and learner that is crucial for success and

for successful remediation.

In recent weeks, the conversations I've had with numerous program directors and faculty made it very clear that faculty would be incredibly reluctant to identify struggling learners and provide them with the necessary remediation plans if in doing so we would be mandated to report it to the Board as a disciplinary action. Rather than focusing and fostering an environment in which trainees and faculty work collaborative to identify and remove any weaknesses, this proposed change in regulation would clearly discourage faculty from performing a critically important function and aspect of education.

Our medical educators take great pride in the work that we do, both in the clinical care that we deliver and the education that we provide for our trainees. I, along with many of the educators at Boston Medical Center, remain quite concerned that the proposed language will have a substantial and damaging impact on our ability to provide outstanding training in the Commonwealth.

The Board and our faculty at our teaching institutions are very much aligned in

their desire to train outstanding physicians. I am fearful that the definitions proposed, including remediation and disciplinary ac-- as a disciplinary action would likely create unnecessary, substantial, and perhaps unintended obstacles. At its most basic level, providing for a learning environment in which residents and staff can accurately and comfortably partner together to identify gaps in knowledge should not and cannot be disciplinary in nature. It's for these reasons that Boston Medical Center proposes to strike academic probation and remediation from the definition of disciplinary action.

Thank you, and I'm very appreciative of the opportunity to present before the Board.

DR. SLOANE: Thank you very much.

Sue Gorman.

DR. GORMAN: Hi. I'm not testifying.

DR. SLOANE: Thank you. Steve Cina.

MR. CINA: Yes. Hi. My name is Steve Cina. I am an assistant professor at the New England School of Acupuncture at Mass. College of Pharmacy and Health Science University, and I'll be talking today about 243 CMR 5.01, Section 2,

under the definition of the practice of acupuncture. I'll be reiterating what my colleague has reiterated, that the removal of Oriental be made with either another term like East Asian or Asian medicine.

The next section I'll be talking about would be 5.012(A), which is not so much a change, but to commend the Board on the changes they have made, which is that going from the stimulation to acupuncture points and channels by use of any of the following was changed to anatomical locations on the body. I think that's a very important piece to add to our regulation as the illegal practice of acupuncture is being done in Massachusetts now under the term dry needling, so that was a nice change that you made.

The next would be Section 5.012(b), under acupuncture diagnostic techniques shall be included, but not limited to, I'm requesting that the term technique be changed to either approach or method. That way, it would sort of clarify that the diagnostic approaches are far more complex than a simple technique.

And then lastly, 5.08, Section 5, under

informed consent, the wording is a little bit confusing. It sort of speaks that the -- possibly that the consent to treatment would be needed for each individual treatment, and if the wording was changed to something that was to read consent to treatment should be obtained where disclosure of significant information, et cetera, clearing up the terminology would help us understand that consent to treatmeant wouldn't be required for each individual treatment, but rather only at the beginning of the cycle of treatment.

Thank you for your time.

DR. SLOANE: Thank you. Amy Mager.

MS. MAGER: Mager. Excellent. Thank you. Thank you for the opportunity to speak with you. My name is Amy Mager. I've been practicing acupuncture in the Commonwealth of Massachusetts since 1990. I sit on the Acupuncture Society of Massachusetts Board and I am its dry needling chair. I also sit on the Acu-- on the American Society of Acupuncturists Board, which represents 4,000 acupuncturists around the country, and I am also on that dry needling committee.

I want to thank the Board. In

Section -- we're going to be looking at Section CMR 5.0.1. I want to thank and appreciate the Board for the thoughtful changes you have made in Section A, and I want to respectfully request that -- to support those changes and to keep acupuncture practice only by people who are licensed and evaluated and who have shown competency and the ability to not do harm and who have been through a clean needle technique class to be practicing acupuncture in the Commonwealth of Massachusetts.

Under Section 2, after Section 2C, I would like to follow it with a Section 3. You have this language in writing. The insertion of acupuncture needles for the purpose of therapeutic release constitutes the practice of acupuncture, whether it is called acupuncture, dry needling, intramuscular manual stimulation, neurologic dry needling, or by any other name. We feel that this is so important, because the unlicensed practice of acupuncture is going on and patients do not know that their practitioner is not licensed to do it.

At a legislative hearing last year, I heard with my ears someone say, oh, I'm certified. When someone is certified by the National

Commission -- National Council Commission of Certification of Acupuncture and Oriental Medicine, they have taken over 2,000 clinical hours -- 2,000 didactic hours, of which 1,305 are acupuncture-specific. They have over 630 clinical hours and they have passed five exams, one of which is acupuncture-specific. These exams are expensive and they take a long time to study for and be able to sit for them.

Currently, people are practicing acupuncture under the pseudonym dry needling with 24 to 48 hours and taking an exam that is given by the person that taught them the class at the end of that time and referring to that as certification. We believe this is dangerous and there are -- there is documentation that has been sent, and I will forward a letter from Dr. Arya Nielsen, who sent it to the Board of Allied Health. We brought a petition to them asking them to rule that dry needling was out of scope of practice until such time as there were standards. And it was painful for me to hear them in another part of the meeting discuss that their charge was patient safety and consumer protection and refuse to address our

petition at all and refuse to let me speak at all.

So I thank you for your help, time, and I urge you to incorporate this language in our -- in our scope of practice to make sure that everyone who uses an acupuncture needle is either a medical physician who under our scope has permission and license to practice acupuncture, or a licensed acupuncturist who has been evaluated and assessed through the NCCAOM and the Board of Registration in Medicine in Massachusetts. Thank you so much.

DR. SLOANE: Thank you. We're going to just take a five-minute recess.

(Off the record.)

(Recess taken from 5:10 to 5:19.)

DR. SLOANE: All right. We're ready to get back in session. Can we announce, please, that we're back in public session?

SPEAKER: The Board is now in public session.

DR. SLOANE: We're going to ask Joel Rosen to join us, please.

MR. HYAMS: Joel was part of the panel.

DR. SLOANE: Okay. Thank you. And Bill Ryder.

MR. RYDER: Dr. Sloane, how are you?

DR. SLOANE: Welcome. I hope you're well.

MR. RYDER: I am. Thank you.

Dr. Abraham, how are you?

I am Bill Ryder. I'm the executive director of the Professional Liability Foundation. This foundation is a state-wide organization, a membership organization that includes Harvard Risk Management, Coverys, Bay State, UMass. We have -- we provide insurance. Our members provide insurance, medical malpractice insurance, for the vast majority of physicians in the state. We get involved in legislative, regulatory, and court issues, so we do a lot of work on court cases.

I'm going to raise a couple of procedural issues that haven't been brought first, and the first one is that what you are doing in the proposed regulations is you are putting forward a lot of things that will change the standard of care, and there is definitely -- that may establish per se negligence in some areas such as informed consent. Because of that, we think there is -- there is a direct conflict of interest with one of

your board members in any participation whatsoever, and we would ask for the recusal of Kathleen Meyer on any involvement in these regulations. We would ask you to go back and look at any involvement that she's had in the development of these regulations, because -- and our written testimony is more specific, but there are clear areas where -- where people will benefit. Her background as a medical malpractice lawyer, is married to a named partner in the largest medical malpractice firm in the state, it's a clear conflict of interest and it's a concern to the medical community and to -- a very significant concern to the Foundation.

The second procedural question is on the governor's directive on reviewing regulations. One of the things is a directive about how to establish appropriate operational standards and that you should always be very hesitant in any regulation that sets specific operational standards for any industry. And I think that in the area of informed consent, you're establishing very, very, very detailed operational standards, which is inconsistent with what the governor has directed and it's inconsistent with how the practice of

medicine works in terms of how standards for care evolve, so I think you should very much look at -- at eliminating that entire section on informed consent. Clearly, the Board has the ability in its other parameters when there's a complaint, where there's an issue on informed consent, you have the authority to go in and see whether that violation was broad or something like that, but the specifics here are a major issue.

The third is -- procedural question is in your own statement on the regulations, you state that the reduction or stabilization of the frequency, amount, and cost of claims against physicians and institutions is among the goals of the legislature and of the goals in establishing these relations -- regulations, and I think that there is a couple of areas that -- where -- that are inconsistent with that, that you would drive up the cost of defense; you would drive up the cost of claims based on these.

A couple of things that have been mentioned is the definition of a medical peer-review committee. Adverse events, again in Section 3.01 on definitions, that would --

potential harm and close calls as an adverse event, potential harm, you really don't want to hear everything about every potential harm that ever happened. You don't have the capacity to deal with those. So again, as was mentioned in previous testimony, if you ask for something that's extremely broad, you put yourself at risk of being arbitrary and capricious and okay, well, we're going to get it from this person, but we're not getting it from that one. So I think the potential harm in close calls, while it's a goal of the patient safety movement and it's certainly something that's done in peer review, I don't think the Board really wants to do that.

You also add utilization review and credentialing. From a perspective of professional liability, credentialing is an area where a lot of firms are looking to go forward and increase areas of liability, increase the areas of claims, increase the success for plaintiffs in going at credentialing issues. Also, you can go after the institutions, and in some instances, you are going after nonprofit institutions which don't have a cap, so credentialing is a big -- is a big ticket

item, so I think you should be very careful about adding specific things about credentialing.

MS. GIORDANO: Pardon me for one moment. We're at five minutes, so if you could finalize your comments?

MR. RYDER: Okay. Well, I'll let you read them.

DR. SLOANE: No, you can give me the -- give anything that hasn't been mentioned to this point by someone else, please.

MR. RYDER: I think that when you're looking, again, from the perspective of peer review, you say may designate peer review as confidential. I think the Board should be supportive of peer review and you should say shall designate it, and if there's a reason for it not to be, let people go.

Record-keeping requirements, three years to ten, again, from a liability perspective, what's the -- the goal there? I think the informed consent issue, I go into some detail on that, and it's been mentioned by others, but you can't have a situation where it's per se negligence that you didn't list the cardiologist as being involved in

the procedure when somebody codes. You know, if the cardiologist has to come in, you know, that can't be a violation per se, that you didn't list, of informed consent, because you didn't anticipate the necessity.

So I think the sterility one has been mentioned as there's question about that. I think questions on discipline, on malfeasance, and on remediation of probation, again, I think that those are -- have been mentioned, and negligence and the ethical standards. So with that, I'm done.

DR. SLOANE: Thank you very much.

MR. RYDER: You're welcome.

DR. SLOANE: Anuj Goel.

MR. GOEL: Thank you very much for the opportunity to come in and testify today. My name is Anuj Goel. I'm with the Massachusetts Health and Hospital Association. I've already submitted detailed comments, so I just wanted to briefly highlight three major issues from the MHA perspective that we would ask you to take serious consideration of.

First and foremost in the regulations, really looking at part three, the department -- or

the Board is really starting to develop a broad-based set of terms, adverse event, close call, serious injury, which are very vague and very general, and we're very concerned by the fact that how vague and general it is, you're going to have a plethora, an increased number of reporting, inappropriate reporting.

And I'm sure the DPH General Counsel will be shocked to hear me praise the department, but they have actually developed very specific clinical standards and operational guidelines that help in understanding when reporting is appropriate and not appropriate, and it's something we would ask the Board to consider.

Secondly is in the term of telemedicine. As you've heard, while we do appreciate the fact that you've added a provision related to telemedicine, the big problem here is you only limit it to the area that telemedicine uses between hospitals and nursing homes. As we've been looking at the area of telemedicine and the advance of this technology, it could really expand the access to care, behavioral health services and others in the community in other locations, and as

the Board has developed, it is so limiting that we ask you to consider the longer, broader language that we are proposing in our comment letter to ensure full access of this planned-for technology.

Last, but not least, is 3.10, the informed consent requirements. You've heard a lot of comments back and forth today about the problems in 3.10. Really, from a perspective, a provider perspective, this is totally in contradiction to the governor's regula-- or executive order. The amount of time, effort, resources that that one provision is going to require, detailed patient consent for every single procedure, really goes against that broad perspective.

What we would ask the Board to consider is to revoke or remove 3.10, pull together a stakeholder group. We understand the goals and the importance of having the informed consent process, but pull a stakeholder group to sit down and sift through how we can develop more appropriate informed consent requirements that fit the broader perspective of what the Board regulates and monitors. As developed right now, the daunting process that it would require will delay medical

care throughout the state, so we would ask you to take that into consideration as well.

So those are the three major highlights. There's obviously a lot more detail in our comment letter, but we appreciate the opportunity to come here and testify, and thank you very much.

DR. SLOANE: Thank you very much.

Ellen Cohen.

MR. HYAMS: Oh, she was part of the panel also.

DR. SLOANE: Oh, yeah. Jordan Maynard. Oh, doesn't want to. Maureen Connelly.

MS. CONNELLY: Thank you.

DR. SLOANE: Welcome.

MS. CONNELLY: My name is Maureen Connelly. I'm from Winthrop, Massachusetts, and I am a private citizen. I have been a nurse for 40 years and a health care consumer. I am here today to voice my support for the amendments as -- specifically as they relate to informed consent.

I consider informed consent a fundamental principle of health care. The first time that I heard some surgeons were scheduling two

or more procedures simultaneously without patients being aware, I dismissed it as a rumor. After finding out more through an article in The Globe, I could no longer ignore this fact.

Included in the Massachusetts Bill of Rights is the right to receive timely, complete, and accurate information. Know the names and specialty of those providing care. These rights can only be achieved when a patient is fully informed. Omitting important information such as who their physician extenders are, their level of training, and the role they will play during the procedure is not truthful and jeopardizes the relationship between patients and all health care providers.

Equally important for complete and accurate patient records is having written documentation of the attending physician's presence or absence during the procedure, intervention, or treatment. Providing truthful and complete information lies at the core of being an ethical and moral caregiver.

As a health care provider for more than 40 years, I do not see those proposed amendments as

adversarial or cumbersome. I see the amendments for informed consent as an important tool in strengthening the patient/physician relationship, improving health literacy, and acknowledging the patient as an equal partner in his or her health care team. I applaud the Massachusetts Board of Registration in Medicine for recognizing the need to strengthen accountability to the patient and proposing the amendments to the Patient Care Assessment Program. I trust these changes will produce a more deliberate decision-making process. Thank you.

DR. SLOANE: Thank you very much. We have one more, and before -- we have Scott Liebert before. Please come join us, Scott. Welcome.

MR. LIEBERT: Thank you.

DR. SLOANE: Before Scott -- in case anyone is going to leave, just please make sure everything we've heard, you can submit written statements, so that we have them. Okay.

MR. LIEBERT: Thank you very much. I was supposed to --

DR. SLOANE: Welcome.

MR. LIEBERT: -- be a part of the panel

earlier and couldn't make it at that time, so thank you for giving me an opportunity now.

Virtually everything that I was going to say with regard to the proposal to add probation as a basis for discipline has been said and said in a more articulate and complete manner than I could and by people who deal with that issue, obviously, at the hospital, the teaching hospital level.

What I'd like to do, then, is offer you a little bit more of a personal statement in response to the proposal to add additional authority and basis for reporting and offer some suggestions, if I may.

Let me start with just a little bit of an introduction, and I hope that it's relevant here. I've been an attorney for almost 34 years, and the majority of my work over the past 25 years has been with this Board. I was the chief of litigation here for three years, and in the years since, I've been in private practice, and my practice has probably been about 90 percent working with doctors and with this Board. I think that my name is on more pleadings before this Board and consent orders than any other attorney. Paul Cirel

might be in the same ballpark, but I think there's a lot of doctors that I've represented and a lot of work that I've done over the years with this Board.

To the extent that I leave a legacy in my legal work, my legacy is really tied to this Board. I care very much about the work that the Board does and I care about the relationship that I have with the Board, with the board members, and with the board staff. It's -- this work has been the basis for my professional relationships, with my colleagues in practice, both the defense bar and the many talented and very hardworking staff at the Board. My wife is a health care attorney and I met her doing this work. I tell you this to provide some context for the comments that follow regarding the proposed changes to the Board's regulations.

The Board in its functioning and in its ability to ensure quality of medicine for all of us has to be able to operate in a way in which there is an orderly flow, there is an efficient flow of what comes in, how you handle it, and how you resolve it. I have become and my colleagues have become increasingly concerned about the challenges that the Board faces in doing that, the amount of

work that you have coming in, and that was one of the main reactions that I had when I saw that you were looking, as a number of speakers had mentioned, to add potentially significantly to the reports coming in and the work that you have to do.

First and broadly, I'm concerned about the Board expanding its workload when there is such a challenge on the part of the board members and the board staff to be able to stay up with the workload that exists now.

I last testified before this Board regarding proposed regulatory revisions in 2008, and at that time, the Board was also seeking to broaden its authority and the basis for imposing discipline. Some of the same changes that were proposed then are proposed now.

There was also then a very significant push-back by the medical community and -- with regard to those proposed changes, and with regard to the disciplinary regulations, those regulations ended up being withdrawn. They were not enacted. I don't know how much of that history may have been lost since 2008 in terms of people not having that perspective when considering some of the changes

now.

My opinion and that of many of my colleagues is that this Board has moved in the direction over the past five years where it has become overextended in its ability to perform its essential functions in a timely manner, in a reasonable manner, and in too many instances, in a manner that ends up feeling disrespectful to the doctors that come before it. I know very well that that is not what this Board intends, that not one board member intends a doctor to walk away from here feeling that they have not been treated respectfully, but unfortunately, inevitably, I think some of the burden of the work ends up resulting in that.

Over the last five years, the function of the agency has been seriously impaired by the inability to have consistent senior staff, and I think that that's then put much greater pressure on the board members.

MR. ZACHOS: Attorney Liebert --

MR. LIEBERT: Yes?

MR. ZACHOS: -- can you limit your discussions relevant to the regulations that are

before us?

MR. LIEBERT: My intent is that they are specifically with regard to the proposal to add bases for additional reporting to this Board.

MR. ZACHOS: I just didn't understand the nexus to senior staff.

MR. LIEBERT: That is the nexus.

It has become routine for doctors and their counsel, if they have them, to wait three, four, five hours when they come in for a board meeting before they can be heard. Nobody is happy about that. I know that it puts a burden on the board members, but it creates a situation where by the time somebody comes in before the Board and in the events that follow, there is a tension there that wasn't intended, but works, again, counter to the mission of this Board.

Before the Board adopts new regulations, to just give you a specific example, the Board needs to follow through on the promise that was made on April 30th of 2014, when the 1994 Physician Health and Compliance Policy was rescinded. The promise was that it would be replaced with a better policy with regard to

dealing with physician health matters.

MS. GIORDANO: Pardon me for one moment. I'm sorry. We're at five minutes.

MR. LIEBERT: All right. If I may finish very quickly?

DR. SLOANE: Could you keep it to something, you know, specifically to the regs, please, and specifically how you would like us to change them, please?

MR. LIEBERT: Yes. Let me finish by making a suggestion, and that suggestion is that in terms of moving forward for this Board, this Board accomplishing its goal of protecting the public, which I hope the board members know everybody in this room is equally committed to, that the Board would establish some policy, which has already been suggested by some of the other parties, for some ongoing dialog, for some ongoing conversation. There's an enormous amount of expertise in this room on the part of the interested parties with what the Board does, and that added expertise, that experience could be an enormous benefit to the Board accomplishing its goal of protecting the public.

MR. ZACHOS: Thank you.
MR. LIEBERT: Thank you very much.
DR. SLOANE: Thank you, Attorney Liebert. Thank you very much.
MR. LIEBERT: I appreciate the opportunity.
DR. SLOANE: Thank you very much. Is there anyone else? Is there anyone else here who would like to give oral testimony who has not given the oral testimony? I think we're -- oh, I'm sorry. Thank you.
First of all, I would like to thank everyone for taking the time to come here from their day, to submit written comments, to give their opinions that will help us as we try to make these regulations the best that they can be to protect the public and support the physicians. I am very grateful for that.
We encourage, again, the submit -- the written comment, too. And it will be posted on our website, correct?
MS. PREBENSEN: Yes.
DR. SLOANE: And the written period will be over Friday, March 3rd, at 5:00 p.m. I

want to thank everyone for coming.

ALL: Thank you.

DR. SLOANE: And we are adjourned.

(Off the record.)

(Whereupon the proceedings were adjourned at 5:41 p.m.)

C E R T I F I C A T E

I, Marianne R. Wharram, Certified Shorthand Reporter, Registered Professional Reporter, Certified Realtime Reporter, and Notary Public, do hereby certify that the foregoing transcript, Volume I, Pages 1-85, is a true and accurate transcription of my stenographic notes taken on Wednesday, March 1, 2017, in Wakefield, Massachusetts.

Dated this tenth day of March, 2017.

Marianne R. Wharram
Certified Shorthand Reporter
CSR No. 1426S96
Registered Professional Reporter
Certified Realtime Reporter
Notary Public
My Commission Expires:
July 20, 2023