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COMMONWEALTH OF MASSACHUSETTS

BOARD OF REGISTRATION IN MEDICINE

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PUBLIC HEARING

In the Matter of Licensing and the Practice of Medicine, Proposed Regulations 243 CMR 2.00

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BOARD OF REGISTRATION IN MEDICINE

200 Harvard Mills Square, Room 330

Wakefield, Massachusetts

May 18, 2017

4:00 P.M - 5:25 P.M.

Reporter: Donna J. Whitcomb, RMR

APPEARANCES:

BOARD CHAIRPERSON: Candace Lapidus Sloane, M.D.

BOARD MEMBERS:

George M. Abraham, M.D.

Susan Giordano, Acting General Counsel

George Zachos, Esquire, Executive Director

Eileen Prebensen, Senior Policy Counsel

ALSO PRESENT:

Marian Ryan, District Attorney

Henry Dorkin, M.D., Mass. Medical Society

Brendan Abel, Mass. Medical Society

John Erwin, COBTH

Bill Ryder, Professional Liability Foundation

Andy Hyams, Esquire

Ken Kohlberg, Esquire

Scott Liebert, Esquire

Steve Adelman, M.D.

Deb Grossbaum, Esquire

Celeste Williams, Esquire

Omar Eton, MSCO

Ed Brennan, MSCO

I N D E X

P R O C E E D I N G S

DOCTOR SLOANE: All right, we're going to start with introductions. Can you please announce we're going into public session.

MS. PREBENSEN: Molly's going to do that for us.

DOCTOR SLOANE: Good afternoon. This is a public hearing of the Board of Registration In Medicine on proposed changes to its regulations at 243 Code of Massachusetts Regulations No. 2. The Board is holding this public hearing in accordance with Massachusetts General Laws Chapter 13, Section 10, Chapter 30A, 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 over a hundred individuals and agencies that identified themselves to the Board as interested parties.

I would like to introduce myself and the members of the Board that will be here and the staff members at the Board. And I'll start with

myself, Candace Lapidus Sloane, I'm chair of the Board, and we'll be joined by George Abraham, another board member, and I'm going to turn it over to our executive director.

MR. ZACHOS: My name is George Zachos, I'm executive director with the Board.

MS. GIORDANO: Susan Giordano, acting general counsel.

MS. PREBENSEN: Eileen Prebensen, senior policy counsel.

MS. GIORDANO: Okay, good afternoon. I'd like to take a moment to go over the rules that will apply during this public hearing today. This hearing is for the purpose of receiving testimony. There will not be any question and answer period and there will not be a public dialogue among the participants today.

Testimony will be heard in the order in which people signed in at the registration desk, testimony will be heard on a first-come-first-serve basis. We encourage all those testifying today to limit their remarks to five minutes, this should give everyone a chance to speak. If you will be testifying as a group, we ask that you limit your

remarks to ten minutes per panel. Panels 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, May 19th, 2017 at 5 p.m. If you would like to submit written comments, you have until Friday to do so. We ask 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 is available at the sign-in desk, thanks.

DOCTOR SLOANE: Thank you, Attorney Giordano. We're just going to wait another ten minutes and Doctor Abraham should be here and then we'll start with the first on our list which is D.A. Ryan.

(Pause - Off the record)

DOCTOR SLOANE: All right, we're going to D.A. Ryan. Everything that is said today

is going to be transcribed so Doctor Abraham will get to actually read specifically what he has missed. Welcome.

MS. RYAN: Thank you, Madam Chair, thank you Members of the Board. I am here today both in my capacity as District Attorney of Middlesex County and as the president of the Massachusetts District Attorney's Association.

We are supporting, and I have a letter indicating the basis of the testimony today, supporting the proposed regulations that would require that as part of the licensure process that training be given to medical professionals in domestic violence and sexual violence recognition and response as well as child abuse and neglect recognition and response.

We strongly support the inclusion of that measure and really for two reasons: One is the greater public safety piece. All of us across the state and myself personally have prosecuted hundreds of cases over the years where the case either came about as a result of a report made by a physician or the testimony of a physician about the conversations they had, and the things they observed was critical

to the successful prosecution of the case.

So we know that professionals who go into that exam room who meet with their patients and are trained to recognize the signs of physical, sexual or child abuse know how to have a conversation about that and how to document what they see keep all of us safer because they are a critical point in a case. And particularly as is often the case in many of this type of prosecution, it essentially becomes the claim of a victim against either no testimony or a denial by the defendant. So the fact that when we are able to present as well solid testimony from a medical professional, disinterested in the prosecution in terms of not having a stake, that's a very valuable asset to us.

And the second piece is, and I think this is where it's really hard to think of any reason why we wouldn't want to do this, I prosecuted a case a number of years ago where a little boy was being horribly physically abused. He was living with a family member. He was repeatedly and terribly being abused. There was no real recourse, for some reason, and the abusers were clever enough to make sure there would not be.

It wasn't abuse that would be visible when he went to school, the school wasn't seeing it. The child, even though he was only 8 years old, at some level knew that a doctor or a nurse would be helpful to him. And he had to be taken to the doctor for some kind of shots that he was getting or whatever, and the little boy took his shirt off, even though he didn't need to when he was in the exam room, and of course the doctor came in and saw the terrible injuries on his back.

Would we ever want a patient as young as 8 years old or 80 years old to be seeking that kind of help from their physician and not have a physician who was trained in recognizing it? Maybe not as direct as seeing welts across a child's back, but being trained in recognizing abuse, knowing how to compassionately have a conversation in a way that would best get the information that was needed as well as reassure the patient and then know what the obligations were about making reports and documenting what they had seen. I think there really cannot be anything that would be more part of the oath to do no harm and to do good for patients than having this kind of training.

We would be suggesting two things, one of which is that the training should be training that happens across a physician's career, that it not just be something that's added to a curriculum early in their practice or during their medical school education and then they practice for 30 years without getting a refresher in that. Things change, the way that we suggest things, questioning being done, information testing that can be done, all of that changes. There should be some requirement that that periodically be updated.

And the second piece is that on behalf of my own office, as well as the district attorneys across the state, we would be happy to provide whatever resources, to be a consulting voice in the development of that training. Obviously, the proposal doesn't indicate what the plan is for what this training would look like. We would be happy to do whatever would be helpful in planning that training.

I appreciate the opportunity to be heard. I do have a written letter from the District Attorneys Association with respect to our position on this, thank you.

DOCTOR SLOANE: Thank you very much.

Doctor Dorkin.

DOCTOR DORKIN: Thank you for your time today. My name is Henry Dorkin, I'm a pediatric pulmonologist and I've been in Boston practicing for approximately 40 years. I am here as the president of the Massachusetts Medical Society and I would like to go over some thoughts.

The first one is on the elimination of Delegation of Medical Services in 2.07, Section 4. We have reviewed this and the Medical Society opposes the proposed prohibition of delegation of medical services by physicians to non-licensed individuals in Massachusetts. Medical assistants, for example, are not licensed in Massachusetts, they assist in medical care exclusively under the delegation of authority of those regulations and those who are licensed.

The regulations as currently in effect provide strong, safe and quality protection requiring that all services be within the skill set of the person to whom the service is delegated and that the responsibility and reliability of the delegate ultimately lies with the delegating

physician.

The broad definition of "practice of medicine" means that many common procedures such as taking of blood or using a metered dose inhaler would be considered the practice of medicine. And these are things we teach families to do at home on their spouses, their children, their parents, things that are very commonplace, and if all of these had to be done by the physician, it would be perhaps not the best use of the physician's time and would significantly alter the flow of patients going through the office at a time when we don't have as many physicians as we would like to have. Anything that's going to slow down and impede their ability to practice probably is not in the patient's best interest.

The second point I'd like to go over is the proposed increase in length of time to maintain medical records in 2.07, Section 13. The society has looked at this and opposes the extension of the medical record retention requirements from 7 to 10 years. A recent survey of state laws across the country with an emphasis in this geographic region shows that 5 to 7 years is still the

predominant requirement.

Medical records are something that unfortunately often are dependent upon the particular electronic medical record program that is being used to generate them. And with iterations changing, sometimes those records may not be readily available to the current iteration and might have to mean setting up a previous version of an electronic medical record to go over them.

And at the point that's over 5 to 7 years beyond that point, they're probably less relevant than the information that's carried forward on the day-to-day medical records. So we think that this extension is really not consistent with the underlying thoughts and that it unnecessarily burdens physicians' offices.

Finally I'd like to comment on 2.07, Section 14, Providing Cancer Patients With Treatment Information. This is something that I understand that the Society of Medical Oncologists is also going to be addressing and we are not in favor of this change in the regulation.

Any time you're faced with a patient with either a new cancer diagnosis or in my

practice, for instance, a new diagnosis of cystic fibrosis in a young child or young adult, when they hear just the words either "cancer" or "cystic fibrosis" or anything, that causes them to really focus on that particular aspect, and we have to tailor make exactly what we explain to them at that point in time to what we think they can actually understand and utilize properly.

As far as I know in my own personal experience, medical oncologists have done a superb job of listing what the options are for the patients at the appropriate time. But there are times when if you try to give them everything all at once in this set or format, they won't understand 80 percent of it and some of the stuff that you want them to understand will go -- they just will miss. So we think to keep the signal-to-noise ratio properly, that it ought to be up to the physicians to make the decision of how this is going forward.

MR. ABEL: Thanks, Doctor Dorkin.

For the record, my name is Brendan Abel, and I am, too, from the Massachusetts Medical Society. We have submitted extensive written testimony. There are a number of points that we

have detailed in our written testimony, but I want to just highlight a few additional issues to bring to your attention.

First in Section 2.01, 1(b) and in about a dozen other sections throughout the regulations, the Medical Society has significant concern about the addition of all of these references and the seeming change of the burden of proof for good moral character.

So to be perfectly clear, we are proud of the good moral character of the physicians of Massachusetts and we want to see that continue with all applicants in the state, but the Medical Society believes that the longstanding good moral character licensure requirement that we see in regulation today is more than sufficient.

We have concern about two aspects of the changes regarding good moral character. First, moving good moral character into the purpose section at the outset of the regulation provides the opportunity for unilateral authority to deem whose moral character is sufficient and whose is not. This is particularly concerning given the lack of definition in regulations of good moral character

and the individual value based interpretation of such a definition.

And, second, the Medical Society opposes the changes to this 2.01, 1(b) which require not only possession of good moral character, but now satisfactory evidence of it. That's 2.01, 1(b), and we think that that is really problematic. It appears to shift the burden to the applicant now implying a presumption of bad moral character upon application unless they prove evidence otherwise, and that to us is quite concerning.

Second, the Medical Society opposes the language in Section 2.04, Paragraphs 9 and 10, which add malpractice and criminal history requirements to the application. The language in each of these which include disclosure and requirements for documentation for every malpractice proceeding to which an applicant was a party and every criminal proceeding to which they were a defendant are seriously flawed in their overreach and we fear show a lack of respect for the legal process. Requiring a physician to provide documentation regarding a malpractice suit which was thrown out at a tribunal for lack of factual basis

or one from residency where they were mistakenly added to a suit is simply unreasonable. The latter example was a real example I heard from an out-of-state physician applying in Massachusetts who had to spend hours trying to find documentation about a frivolous lawsuit that was filed decades prior when he was a resident.

And perhaps most serious, though, and most concerning is the requirement to provide information of all criminal proceedings in which an applicant was a defendant. This requirement would include requiring documentation from a criminal proceeding which was dismissed, one at which an applicant was found innocent or a record that has been sealed or expunged in the eyes of the law disrespects the criminal justice system.

If you're asking for this information it means that there must be some possible relevant use in the application process and we really believe that there's no room for falsely accused or exonerated criminal proceedings to enter into the BORM application process.

So, again, our written testimony details these issues and several others discussed by

Doctor Dorkin and by me and others that we have not had time to address. We sincerely thank you for your time and we appreciate your due consideration of the comments of the American Medical Society.

DOCTOR SLOANE: Thank you very much.

MR. ABEL: Thank you.

DOCTOR SLOANE: John Erwin.

MR. ERWIN: Good afternoon, my name is John Erwin, I'm the executive director of the Conference of Boston Teaching Hospitals which is a group of 13 Boston area teaching hospitals. Thank you for the opportunity to provide testimony this afternoon. We are submitting -- I actually have submitted testimony already to Eileen that goes into more detail on more issues but I'd like to concentrate on a couple of issues that are high priorities for our members.

The first is in several places. Almost like the good moral character it's interspersed throughout the regulation 2.01, 2.02, (1)(p). This is the requirement that requires -- the provision that requires licensees to be enrolled in the MassHealth program. This is both the provision of the Affordable Care Act, and quite

frankly, good policy so we fully support the initiative, however, we have serious concerns about the implementation and fear that more work needs to done between the Board and MassHealth to ensure that the requirement does not overburden either party and issues such as timing and fees from the different agencies be taken into account. So we want to make sure the Board and MassHealth are not overburdened to the point where there are delays in licensing or delays in the MassHealth enrollment process potentially causing access issues.

Another issue of high priority is the delegation of medical services and here would echo the comments made by Doctor Dorkin. This section eliminates the ability of physicians to delegate medical services to other trained professionals. At a time when new models of team based care delivery such as ACOs and patient-centered medical homes are being encouraged, we believe it's unwise to eliminate this provision and recommend it be retained in the current language.

Third, again echoing Doctor Dorkin's testimony, this is 2.07 (14), Providing Cancer Patients With Treatment Information. This new

section without any statutory authority would require physicians treating patients with cancer or suspected cancer to provide information on treatment options, risks and benefits, and the physician and the patient to provide documentation and attestation that the conversation took place.

It's a standard practice for all physicians, obviously, to discuss treatment options and potential risks and benefits whether they are treating a patient for cancer or any other condition. Providing information on options and risks and benefits is not a one-time event, it's an ongoing discussion that evolves during a patient's care. Requiring written documentation and attestation to demonstrate compliance with this section would unnecessarily and overly burden and add to already considerable regulatory requirements.

It may also serve to weaken the physician-patient relationship by inserting regulatory requirements with no apparent benefit into important conversations about a patient's care, so we strongly recommend that this change not be adopted. And as we testified back in March, Section 2.07 (26) the new section on informed consent and

patient rights continues to be a major concern of ours and I would echo a lot of the issues that we raised back in March.

DOCTOR SLOANE: Can you go back to what you just said again? I missed the most recent comment you just made.

MR. ERWIN: On informed consent?

DOCTOR SLOANE: Yes.

MR. ERWIN: So the informed consent piece is also mirrored in 2.43, 3.0 which we heard back in March, so our comments pretty much reflect what was said back then.

There currently are requirements and guidance on best practices including CMS standards, ACS standards and the Board's current regulations, which we believe are clear and highly effective, ensuring that patients are provided all relevant information prior to deciding on a clinical course.

Among the concerns we have is that the application of this provision is to, quote, any diagnostic, therapeutic or invasive procedure, medical intervention or treatment, which pretty much could mean every patient encounter. The proposal also requires information that may not be known at

the time of the consent. For example, a patient must be informed of, quote, who will be participating in the procedure, intervention, or treatment, including the names of all physician extenders.

While a physician may know that residents, fellows, physician assistants and others will be present during a procedure, in a teaching hospital with a large number of residents and complex trainee schedules, he or she most likely will not be aware of the particular trainees assigned to the case until shortly before or even during the procedure.

We don't believe the proposed amendments to the section should be adopted, instead, we have recommended back in our testimony in March, and it's in the written testimony, amending the Section 3.0 with the additional language.

So, again, those are some of our highlights, I have, again, more detail and more issues raised in the written comments and I thank you for the opportunity today.

DOCTOR SLOANE: Thank you.

Bill Ryder.

MR. RYDER: Good evening.

DOCTOR SLOANE: Welcome.

MR. RYDER: I'm going to hand you copies of our testimony. We submitted it electronically, but this is also our letterhead which will show the members of our organization.

Bill Ryder, I'm executive director of the Professional Liability Foundation. As you can see in the margin of the letterhead, the foundation includes virtually all self-insured hospital systems, Harvard Risk Management, Baystate Boston, Tufts. We also include Coverys, the Massachusetts Hospital Association and the Medical Society, so it's a very broad based group that is involved in the development of these comments.

First of all, I'll raise the same procedural issues that I raised in March. There's an apparent, to our organization and to others, a conflict of interest inherent in the participation of Kathleen Meyer in the process. We have looked back over the minutes, they have been provided, your staff has been very good in providing minutes to us and background on memos, but from those we can't

tell who engaged in the development of the regulations from the Board. But we think there's an inherent conflict there which is described literally in the language of the text.

Second procedural issue again is the question about whether the regulations are consistent with the Governor's directive and the specific points of the Governor's directive I'm looking at regulations are cited in the footnotes. And it seems to me that, again, a review of the minutes does not indicate that the Board has taken the time to look in depth at alternatives to changes to requirements on physician practice which would be very difficult, expensive, cumbersome and whether you've seriously looked at alternatives and whether the public benefits from those things.

And specifically the areas that we looked at are the retention of records, the seven to ten years. Three more years for -- I have a relative who is winding up his practice and he asked me about how to do this and seven years and ten years, it's a significantly different change in the amount of space required, the amount of time, the expense to a small practice. Now, a large group may

have those kinds of things, but an individual practice, I think you should really question the value of what those records are going to be to an individual patient or their family, as opposed to the cost of trying to keep those.

There's another procedural question, when you go immediately from seven years to ten years, as Doctor Dorkin mentioned, many records aren't going to adapt that way. So to say immediately on the effective date of the regulations that now you have to keep everything that's current now, now you have to keep them for ten years, people aren't necessarily going to have that. They're still going to have automatic things that purge records at seven years and their software does that. I think that's worth an analysis to try and find out what are you actually asking people to do, how are they going to do it, what's the patch for that.

From our perspective on liability, which is what's of interest to us, who benefits from ten years of records? There are movements in the Trial Bar to try and get around the statute of limitations, try and get around the statute proposed. So far seven years has held but there are

efforts to move that. There have been changes in the three year requirement. So I think that's a clear benefit to the Trial Bar that concerns us.

Another issue that we would have is on the cancer requirements. You've heard testimony against how that -- the complexity of that and asking every physician to do that. We would ask you to look at in our testimony the issues on loss of chance as a new grounds for liability which is a significant liability case. You don't have to have caused something, you have to have lost the chance, and if you're required to document that you told people what their other chances were, again, who benefits from that requirement? And from a liability perspective our members are extremely concerned about that. And I refer you to the written testimony for the details on that.

The informed consent is exactly the same issue that it was as John indicated last time, why you would duplicate that. If you're going to do it, it should be in there once. But from our perspective it really shouldn't be there at all. And, again, there's one addition in that there is a requirement that people be given a copy on request

of their informed consent. The rules and regulations of practice on giving people a copy of their medical record is well established, why would you have to have this in regulation as well? Specifically, again, who benefits from this requirement that this was not documented?

Final thing I'll mention and we have other things in our testimony and I'd ask you to take a look at it at your leisure, but on profiles there's an additional mention of out of state liability cases and somebody who was involved in the development in '96 of the profile statute. I can tell you that this is something that people didn't really look at in the Legislature or at the Board, people were looking at what information do we have for certain and how can that be presented, is the information going to be accurate? So we were looking at reports from the courts, reports from insurers, reports that we understood.

What I don't understand in the language of the out of state that you're trying to include is how are you going to put that in if you don't get that in a three rank system which the statute specifically literally requires. You have

to rank where a case is in Massachusetts and you've come up with a system that's very good in terms of ranking above average and below average, and you've got the software to do that, how are you going to do a case from New Jersey? How are you going to do a case from Iowa? How are you going to do that? The amounts that are given in different locales vary tremendously.

Oddly enough Louisiana is huge. So an average award in Louisiana could be an extremely high award here. How would you do that? The implication might be that you might not invest in all the effort to do that and you might just put down, Louisiana, med-mal $3 million. The statute doesn't allow you to do that. It says you have to do it in graded form, you have to put it in perspective.

So admittedly the Board's never been able to do that and so those have never been done. Those have never been included to my knowledge, the out-of-state cases generally. So good luck to you on that on how you're going to solve that one, but I think that one's a real issue. Thank you very much and I direct you again to our written testimony.

DOCTOR SLOANE: Thank you.

Andy Hyams and Ken -- I'm sorry, I can't read the signature?

MR. KOHLBERG: Kohlberg, Ken.

DOCTOR SLOANE: Thank you, welcome.

MR. HYAMS: I'm Andy Hyams, and I'm here with Ken Kohlberg and we're on behalf of, as of this afternoon, eleven defense attorneys who represent physicians at the Board. We're going to provide the final submission tomorrow. I submitted before the -- before we started I submitted a draft and we'll get that to include everybody's name after. One of the attorneys, Jim Hilliard, said he's endorsing this on behalf of the Massachusetts Psychiatric Society as well.

DOCTOR SLOANE: Okay.

MR. HYAMS: I'm going to make one procedural point and then Ken will address a couple of items and then I will address four items. And stop Ken after five minutes so that I get mine.

MR. KOHLBERG: I have three minutes so I don't think he's going to need to stop me.

MR. HYAMS: The first is a procedural issue and that's the adequacy of the notice for this

hearing. The statute requires that the notice either state the express terms to describe the substance of the proposed regulation, and as I -- you know, if I can try to quantify it, about 80 percent of the proposed changes are not referenced, described in any way by the notice. And I believe there's going to be a legal flaw in your enacting a tremendous number of the regulations that you're proposing. Ken?

MR. KOHLBERG: So I'm Ken Kohlberg, I'm an attorney in private practice. My law office is in Concord, I've been practicing since 1990, representing physicians before the Board since around the mid 1990s. I'm a graduate of the Harvard School of Public Health, I've tried jury cases on behalf of both physicians and patients, and like all of us here I support strongly the Board's mission which is to protect the public. But in review, this is the second time this year that I've looked at these regulations, I just would emphasize that I believe the regulations need to be fair to everybody.

With respect to the good moral character that was addressed nicely previously

today, but I just want to point out not only is that not mentioned in the notice of public hearing but the concept and the phrase itself is not defined anywhere in your regulations. And, yet, in our view the insertion of this phrase constitutes a substantive change in your regulations and it's very problematic.

Here you're not only enabling but you're actually requiring yourselves to determine as a prerequisite for licensure that a person is of good moral character. And so all I would point out is that in our view the purpose of a regulation is to provide a clear understanding of an otherwise broad and perhaps undefined or poorly understood statutory standard, and here the Board's proposed regulation doesn't even attempt to accomplish that. There's no definition, and in fact, we believe that the insertion of this phrase really muddies the waters.

And that's because this concept of good moral character we believe is hard to dispute the fact that that's subjective by nature. There are limitless interpretations of how you can define what is moral and what is good. We would ask -- I

mean, can you tell us today whether a conscientious objector to war has good moral character? Can you tell us whether our presidents of our country, past or present, have good moral character? Who among us has good moral character? This sort of phrase really has no place in a regulation and for that reason we think it should be stricken in its entirety. And I don't give you a specific section because it's all over these regulations.

But, anyway, the placement of this sort of term we believe is problematic in so many ways. It's going to give rise to inconsistent interpretations not only by the Board, by the way, but by others seeking to interpret it like hospitals, clinics, physicians themselves. And obviously the lack of clarity here becomes particularly problematic when the conduct at issue is not related to the practice of medicine.

But in any event, by requiring a physician or applicant for licensure to shift that burden and make them demonstrate their good moral character, without any explanation from the Board as to what that means, is requiring unfairly an applicant, we believe, to attest to the fact that

they meet some unknown and subjective moral code which the Board itself cannot and certainly has not defined.

And then finally we are concerned that this is a shift of the burden or that this could constitute a shift in the burden of proof if a good moral character issue were to become the subject of an adjudicatory hearing, so if that's the case that that is what the Board is intending to do, I think the notice provision becomes even more important because the Board should say so, let us know, and provide the required notice under 30A.

The only other point I'll mention is just with respect to the malpractice disclosure, Section 2.04 (9) is here you are adding to the licensure application requirements, as I understand it, the disclosure of information regarding, quote, any malpractice claim in which he or she was involved. We would suggest that that factor is very poorly worded because "involved" can mean anything. What if they are just a witness and as a prior person mentioned today, what if it's just the person was the subject of some sort of demand that was completely meritless and it was dismissed?

So we oppose the elevation of the importance of malpractice history, and you know, we don't want to belabor the point but there's a lot of resources that the Board puts into and that physicians and applicants are required to put into to go back and investigate when they have been involved in a malpractice case when there's really, in our view, may not be a sufficient connection to require that sort of expenditure of resources. Thank you.

MR. HYAMS: So the Medical Society a few minutes ago made a very cogent argument regarding the relevance of expunged criminal records and the fact that those should not be requested as part of a license application, and I want to add to that that the requests from the Board for expunged criminal records are also unconstitutional. Those requests violate the Full Faith and Credit clause of the U.S. Constitution which states: Full faith and credit shall be given in each state to the public acts, records and judicial proceedings of every other state.

And, I mean, just as Massachusetts expects other states to respect what its courts do,

Massachusetts should respect what other state courts do. If another state has made the determination in a court order that a record should be expunged, that's the end. If the court order in the other state says, in effect, or using the other state's expungement statute that the person whose record was expunged, if they are asked to swear that whether or not they have a criminal record, they can swear that they don't. They can swear that they have never been arrested.

And the Board, unfortunately, has not respected that and at some point maybe an applicant will have the temerity, have the finances, have the will to challenge the Board on that, but you know, as it stands typically it's not a practical thing to do. But the applicant is a supplicant, they're not going to come in and sue you for having asked for an expunged record. My advice to them is, you know, be practical. But it is an unconstitutional request.

I want to address also the regulation that speaks of withdrawal of -- the ability to withdraw an application. It certainly is -- there are circumstances where it is certainly justified

for the Board to refuse a physician's request to withdraw a pending application, but there are -- I'd like you to consider the distinction between derogatory information that because of this Board's investigation because of the way the applicant filled out the application here, derogatory information that only this Board knows, and derogatory information that is available through the FCVS through ACGME, through any other national sources that this Board does not have exclusive knowledge of.

I represented a physician a few years ago who had repeated a year, repeated a year of residency, and was taken to task for that. This was information that was available through FCVS, available at ACGME. It was no secret. While her application was pending here she obtained licensure in another state, obtained employment in another state, and asked to withdraw her application and she received a denial. She received, you know, a recommended denial. She didn't -- she did not have the funds to challenge the recommended denial, could not go to a full hearing, you know, did not have 20, $30,000 to pay for a few days of hearings.

She took the denial, went to the National Practitioner Databank. The job she thought she had in another state, the employer saw the report in the National Practitioner Data Bank, got spooked, withdrew the offer and that denial has been following her career for the past three years like a wrecking ball.

Now, that denial was based on information that is available to any state where she applies and there's no service provided to a sister state, there's no lack of transparency. There was nothing accomplished. The public was not protected one iota, in Massachusetts certainly. The public was not protected one iota by not allowing her to withdraw her application.

MR. ZACHOS: Attorney Hyams.

MR. HYAMS: Three more sentences.

The change you're proposing on the seven year rule. I implore you to retain your ability to waive it. You don't have to waive it, but there will come a time when a -- you know, a disabled veteran offers a disability related reason for failure to comply with a seven year rule and passed on the fifth attempt and you're going to want

to waive it. And these regulations say that you can't anymore.

One last thing, your changing the rule on retention of original documents. There are physicians who are -- they're refugees, they have fled oppressive regimes. They went to medical school, and I don't know, the Taliban took over or something, all they have is the original document from their country of origin. They're not going to be able to get a certified copy from the primary source as you're requiring.

The Board's practice in the past was the original document, bring it in, you'll make a copy. You can -- you know, if you want, you can keep the copy and do all the forensic testing you want, but eventually let the physician have that copy back. Let the physician have the original back. The reg. as it is is fine, thank you.

MR. ZACHOS: Thank you.

DOCTOR SLOANE: Steve Adelman and Deb Grossbaum. Good evening.

MR. ADELMAN: Good afternoon.

MS. GROSSBAUM: My name is Deb Grossbaum, I'm general counsel for Physician Health

Services. We have heard a lot of testimony already on some of the topics that we care a lot about, we've put it in writing, and so rather than reiterating those I'm just going to briefly mention one and then go into one other topic that hasn't been mentioned yet today.

The one I have to reiterate, even though I know you've heard it a couple of times and very well said by both Brendan Abel and Ken Kohlberg, is that good moral character concern because it's so significant. And we wholeheartedly agree that a prerequisite of good moral character or an assumption of good moral character at the front end is fine, it's in the law, that's great the way it stands. But if it's not broken, this attempt to fix it isn't working very well.

And the particular piece I'd like to focus on, I know that they have already indicated that it's problematic to have this arbitrary and subjective standard with no definition and you can't have them, but then there's a provision that says you must demonstrate good moral character. So the question is even if you were going to try to do that, what would you be looking for? Should I be

asking a priest or a rabbi to write a letter of good moral character, some clergy letter? Is it something from a friend, my mother? How does one demonstrate good moral character to an entity that doesn't know us.

And then interestingly as you read in the regs, it says, The Board shall determine whether an applicant is of good moral character. And that is 243 CMR 2.02 (6)(a) and then several other locations. So you get to decide, and you don't know me, and I don't know what to show you to help you understand I'm of good moral character, whoever comes before the Board. So clearly we understand that that's something that we want but the inevitable arbitrary application of this regulation and the undefined requirement creates a legal fragility that can't stand up. So it really doesn't belong here.

But the provision that we really want to focus on, because it hasn't been focused on yet to date and it's really our area of expertise, is the exception to the mandated reporting. And that's at 243 CMR 2.07 (23). The mandated reporting law, when that was created, the Legislature, this is

actually in the statute, recognized that it would benefit the health and safety of the public to create an exception in the case of physicians who are suffering from substance abuse disorders. They wanted to have an incentive to be able to get people who have those illnesses into treatment and well instead of just punishing them.

And this happened years ago when there was a first recognition that this was an illness, it wasn't something to be punished or treated in a punitive way. We want to encourage people who have this illness to get help. So they created the exception to mandated reporting, excellent. Again, if it's not broken, don't fix it.

There are two flaws in the current iteration that we want to point out. And the first one has to do with this word "other." In the law it recognizes that if a physician is ill and if they can get help from a program that you've vetted and it has been supported by the Board and they can do it within a reasonable period of time, you get that confirmation that they're on board and doing this and there's been no allegation of patient harm, so no one's been harmed and now we're ahead of the

game, it's good, let's encourage that treatment.

And it wasn't intended to be a shield from other wrongdoing. This wasn't intended to be used to cover up other wrongdoing, so there was a provision in the law that said no other violation of law. This isn't intended to be an exception for other violations of law, just for the substance use issues. And by taking out that word "other" we have now taken it out and said any violation of law, including -- you actually specifically say "including the drug laws" this doesn't apply.

So now we really don't have an effective provision because necessarily somebody who has a substance use disorder involving drugs is in violation of drug laws. That's the nature of the disease. And you can't really be abusing addictive substances without having done something that runs askew of the drug laws, maybe a very limited scope.

So we don't really want to undermine the entire provision by saying have you violated any laws. Instead, I think what was intended was that the Legislature and past boards made the active decision to encourage treatment in cases where there hadn't been harm.

Like if you are lucky enough and fortunate enough to have gotten in there before any harm has occurred, great, that's what we want. So let's get them to treatment. There hasn't been harm yet and we don't have to worry so much about pointing the finger and punishing them if they're getting the help and there hasn't been harm. So I think that's what is intended by the law and when we take out the word "other" we undermine that.

And one other piece. The second flaw in that provision is that you've added the fact that you can't use the exception if the impairment is determined when they're in the workplace or on call. This is a provision for calling -- for health care providers looking at physicians, it specifically applies to health care providers.

Health care providers seeing physicians at work and on call, it's not for spouses or people at home. This is a provision for health care providers to notice it in their colleagues and we want them to notice and be concerned for their colleagues and get them help. And if you say but if you notice it at work or if you notice it on call, you can't send them for help, you have to just

report them and make it a disciplinary matter. I think what's going to happen is it's going to go underground and you're not going to get the reports that you need.

And, again, it undermines the whole purpose of this provision. We think it's a great provision. We know it requires an understanding that we're going to shift priorities from discipline to assistance, but in the case of these illnesses it's been recognized as the way to protect public safety and it works. Thank you.

MR. ADELMAN: I thought Debby spoke very, very well. I'm going to give a couple of examples to flesh out what she said. I'll put a toe in the murky waters of moral character. I'm really worried about how this plays out with foreign medical graduates. I think there are lots of ethnic and cultural differences between people. We often see physicians who are viewed as insensitive, angry communicators. Someone called them a jerk. A patient or a nurse said, you know, that doctor treated me like a jerk. They come to us, we assist them with coaching, with sensitivity training, with communication training.

I can think of one physician in particular who went really from being the only doctor in her specialty in a community hospital, went from being someone who was viewed with fear and trepidation to be being beloved by all after a few months of one-on-one coaching. I can imagine that same doctor getting reported to the Board and this being experienced as a physician of not good moral character, pulled out of that practice, that community loses the only doctor in that specialty. I just think this is a very slippery slope if the Board regulations go onto it. And I have countless examples like that.

And then to just talk more about the exception -- this exception to mandated reporting. It really is the cornerstone of referrals to PHS. We're working with 400 docs a year. Our referral rate has gone up about 50 percent over the last four years. There's a lot of confusion about the distinction between PHS and the Board. It's a big deal to even call PHS, it's an even bigger deal for anybody to call the Board, I'm sure you realize that. By narrowing this exception I think you're going to cut down or narrow the pipeline to the

solution to the problem and that's going to have an unintended consequence of things progressing.

To be specific with a case, I'm reminded of a call I got from a department chair a year or so ago. The hospital operator called the doctor on call and thought the doctor didn't sound right. Maybe the doctor had been drinking, wasn't clear. With great trepidation that department chair called PHS, with great trepidation made the referral because of the assurance that there's an exception to mandated reporting. Got the doctor in, we did our thing, we identified an early stage alcohol use disorder. Got the doctor on a monitoring contract, it ends very, very nicely.

I do think that if the exception is narrowed and the perception in the community is everything needs to go to the Board, that phone call, phone calls like that would not have taken place, and instead a patient gets harmed. So that's really why, if anything, the exception should be broadened, it should not be narrowed in any way.

I'll say one other thing which is kind of a meta-analysis, if you will, of what I see going on. And you can take it for, you know, as

Steve Adelman's meta-analysis. There's a sense I get in reading through all of this that the Board believes that by getting tougher it's going to promote good behavior in physicians. Tougher regulations equals better behavior equals patient safety, I think that's the hypothesis. I worry that it's going to go the other direction.

Tougher regulations engender more fear, engender more under-the-radar behavior, fewer self-referrals to PHS. Fewer referrals to PHS, more physicians crashing and burning, more patient harm. So I do think, looking at the larger picture, I would encourage you to consider whether you're going in the wrong direction in a general sort of way with being tough, okay.

DOCTOR SLOANE: Thank you very much.

Omar Eton.

DOCTOR ETON: Hello, thanks for having us come up and testify. I am Omar Eton, I'm a practicing medical oncologist for the last 27 years or so, and I am representing today the opinions of the Massachusetts Society of Clinical Oncologists and the 42,000 plus members of the American Society of Clinical Oncology.

Both professional societies are dedicated to ensuring patient access to high quality cancer care and are deeply concerned by the proposed regulation 243 CMR 2.07, No. 14, and that's providing cancer patients with treatment information. This would impose disruptive counterproductive requirements by asking physicians to discuss a specified list of alternatives to patients with cancer. This is whether such treatments are even relevant or appropriate. This mandated robotic approach could confound or dilute the messaging between patient and provider.

We already heard from Doctor Dorkin and from John Erwin about this, so I'll be the third one today talking about this one paragraph. We want to be clear an oncologist routinely presents available treatment options tailored to the patient's cancer diagnosis and circumstances. Any mandatory and non-tailored information could overload a patient and detract from the focus on how to manage what comes next, therefore, we ask that the regulation be reconsidered.

As anti-cancer regimens are inherently very dangerous, an oncologist has to be

an expert in educating and informing a patient in the context with the patient's unique circumstances. Patients receive cancer treatments according to established pathways and protocols which are becoming increasingly individualized as we leverage new technologies. These technologies in turn also facilitate the off-label use of anti-cancer agents or enrollment into a clinical trial.

Regardless of the chosen pathway, informed consent is a critical and required first step in obtaining access to any proposed anti-cancer agent. These are very expensive drugs. To avoid overwhelming a patient oncologists routinely tailor options by taking into account the patient's performance status, comorbidities, emotional wellbeing and ability and willingness to manage logistics.

The overarching goals are to comply with the patient's wishes while optimizing safety and reducing and managing risks from side effects either expected or unexpected. Each patient, therefore, is educated to become an active member of the team. Therefore, for oncologists educating and supporting patients to make informed decisions is

the center of gravity from which all else emanates in the physician-patient relationship. We're already there.

Under the Board's proposal the physician would be required to present and discuss a series of specific alternatives with a patient unless the patient states that he or she does not want to discuss anything further. This conversation could then be either overinclusive or non-existent. This would interfere in many instances with the ability of the treating physician to imprint on the patient key information and this during a very emotional and challenging time for the patient.

The proposal would compel physicians to discuss options that may be unreasonable or a poor fit for the patient. It is already challenging enough to inform the patient in a manner that the specific patient can understand, remember and operationalize.

So I pulled out the references. Even before treatment options today which have multiplied, it is already known that 30 to 80 percent of medical information provided by health care practitioners is forgotten immediately. No. 2,

the greater the amount of information presented, the lower the proportion correctly recalled. No. 3, almost half of the information that is remembered is incorrect. And No. 4, in the elderly who have the highest incidence of cancer, the accurate retention of complex medical data is much, much worse.

So the proposed regulation has other problems. It will compel physicians to speak about options that may be better discussed by other experts. We can't have a radiation therapist talk about chemotherapy options as part of their consent and we can't have a chemotherapist talk about radiation algorithms that they don't know anything about. That's not really informed consent.

So, finally, existing -- and this is the most important paragraph: Existing professional ethics and standards of care already govern physicians' duty to their patients. That duty includes the need to provide relevant information to a patient regarding their condition and their treatment options. The Board already has the authority to discipline a physician and to respond to complaints whenever a physician's actions do not meet the standard of care. New regulations specific

to informed consent for cancer care are unnecessary in light of the Board's existing authority and the Board should not create this new requirement.

MSCO, Massachusetts Society of Clinical Oncologists, and ASCO, the American Society, urge the Board to eliminate the proposed Clause 14 of Section 2.07, thank you.

DOCTOR SLOANE: Thank you very much.

DOCTOR ETON: You're welcome.

DOCTOR SLOANE: Ed Brennan.

MR. BRENNAN: No, I'm all set.

DOCTOR SLOANE: You're all set?

MR. BRENNAN: Yes.

DOCTOR SLOANE: I want to thank everyone for their comments. You may submit written comments during the public comment period which will end Friday, May 19th, at 5 p.m. I will now close the public hearing. Thank you very much for attending.

(Whereupon the proceedings concluded at 5:25 p.m.)

C E R T I F I C A T E

Commonwealth of Massachusetts
Suffolk, ss.

I, Donna J. Whitcomb, CSR No. 135593, and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that the foregoing record is a complete, accurate and true transcription of my computer-aided notes taken in the aforementioned matter to the best of my skill and ability.

I further certify that I am neither related to or employed by any of the parties in or counsel to this action, nor am I financially interested in the outcome of this action.

IN WITNESS WHEREOF, I have hereunto set my hand this 1st day of June, 2017.

DONNA J. WHITCOMB

My commission expires: 12/04/20