Episode 55 – What determines if medical care was appropriate?

Opening Music: 0:00

Introduction: 0:10

This is Jean Fisher Brinkley, Communications Director for the North Carolina Medical Board, and this is MedBoard Matters. Every so often on this podcast we like to take a closer look at exactly how the North Carolina Medical Board fulfils its public protection mandate. We think of these episodes as a kind of MedBoard 101 course. On past episodes we've explored how and why patients might file complaints. We've discussed medical board investigations. We have even drawn back the curtain to talk about relatively obscure things like regulation of medical corporations. On today's episode, we are discussing one of the most important aspects of the medical board's work, which is how NCMB decides if medical care is safe and appropriate. This is the key question the Board has to answer when anyone files a complaint that questions the quality of the medical care they've received. It's not nearly as straightforward as you might think. NCMB isn't deciding whether medical care is good or bad. In accordance with state law, what the Board must actually establish is whether the medical care met the minimum accepted and prevailing standards of care in North Carolina. If you don't quite know what standards of care are, never fear. My guest Patrick Balestrieri has got you. Patrick is an attorney with NCMB and a member of the internal team that investigates quality of care cases.

Interview with Patrick Balestrieri: 1:35

JFB: Patrick, welcome and thank you so much for speaking with me. I wonder if you could briefly introduce yourself and describe your role with NCMB.

PB: Sure. My name is Patrick Balestrieri, and my current position at the medical Board is Deputy General Counsel. But I've been an attorney at the Board for about 17 years, and I do a lot of general in-house attorney functions. And with regard to what we're going to be talking about today, I'm a member of the Board's quality of care team, what we call it the QOC team, which is a group of people who handle getting quality of care or patient treatment cases reviewed by outside medical reviewers.

JFB: Awesome. Great. So, as you said, you know, this podcast is going to explore how the Board makes those difficult decisions in quality of care cases. Let's start by defining terms then. What does standard of care mean in the context of medicine?

PB: Sure. Standard of care basically is a case specific determination. So, looking at individual care rendered to an individual patient and in most cases, it answers the question, "Was the care rendered to this patient at the time it was rendered within the minimum standard of what's considered to be acceptable and prevailing medical practice?"

JFB: Thanks. I think some people, especially laypeople, might find that definition a little bit surprising. What would you say is a good way to explain that concept of standard of care to someone outside of the medical or the legal profession?

PB: Sure. So, they can think of it as something that is a generally accepted minimum set of things that must be done, or in some cases not done with regard to diagnosis, treatment, and then documentation by a health care provider giving treatment to a patient in any given situation. While medicine relies on a strong scientific foundation, it's also an art. And different people may have different approaches to treating a patient, and those different approaches may all be considered to be within the minimum standard of care.

JFB: So, I was going to ask you who sets the standard of care, but the way you just described it, it sounds like it's…it's more of a continuum. Could you talk a little bit about how we, the Board and house of medicine sort of arrives at what standard of care is?

PB: Sure. So, in most situations, the standard of care is established by medical reviewers. The Board usually uses medical reviewers in cases to assist them in answering the critical question that we talked about when we started, which is whether the care at issue was within or below the minimum standard. And for purposes of this general discussion, a medical reviewer is generally considered to be a health care provider who, based on their education, their training, their skill, and their experience that they have sufficient knowledge such that the Board staff and the Board members can rely on their standard of care opinion about the patient care under review.

JFB: So, that sounds a lot like we ask a knowledgeable physician to take a look at what happened and then tell us, “Did this meet standard of care?”

PB: Yes.

JFB: But it's not quite that simple, I know. Can we talk about clinical guidelines and how that is part of standard of care? I don't want to leave anyone with the impression that it's just somebody’s gut sense.

PB: Sure. This is a bit nuanced, but there is really no book or guideline that you can go to that tells you what the minimum statewide standard of care in North Carolina is for any given specific case, and whether it was met or not. If we had that, we wouldn't need reviewers. So medical reviewers, in giving their opinion, they can cite or refer to a book or a guideline about what the standard of care is. And they can also say that their opinion is the same as are consistent with what is provided for in a book or a guideline, but the actual book or guideline itself generally does not constitute what the minimum standard of care is in any given specific case. The medical reviewers opinion, in most cases defines the minimum standard of care in a specific case, and I understand that's a bit nuanced, but it's an important concept to grasp when we're talking about books and guidelines.

JFB: Yeah, it is a little esoteric when you talk about all those points, but I think you've partially answered this question, but is standard of care something that's fixed or does it change as medicine changes and advances?

PB: That's great question. So, it's important to understand that the standard of care changes as…as medicine changes, evolves and advances. For example, the minimum standard of care for how certain types of cancer were treated ten years ago may be different than how it's treated today. And for that reason, the Board, when they're looking into a case, they assess standard of care as of the date that the treatment was rendered to a patient and not the date that they're looking at a case.

JFB: Okay, great. I mean, that makes a lot of sense, actually. So, if somebody was treated for cancer ten years ago and they later feel that their care was below standard and they file a complaint, the Board is going to judge that case by the standards that were in place ten years ago, not the standards of today.

PB: Yes, exactly.

JFB: Awesome, okay. For patients and families specifically, why is it important for them to understand the idea of standard of care?

PB: I think it's very important for them to understand that, because really, it makes them better informed health care recipients. If you're the patient and better informed health care advocates, if you're someone, a friend or a family member who's assisting the patient in their health care journey.

JFB: It seems like it could also be really important in setting patients' expectations. You know, in the work that I do, I frequently will talk with patients who are not always pleased you know, with the outcome of a Board case, for example, and I think it's really important for those patients to understand that standard of care does not mean perfect care, or even that they received the best possible care.

PB: Yes. Well, so standard of care generally refers to in lay terms, as treatment that's a generally accepted minimum set of things that has to be done or not done. It does not mean care without complications, and it does not mean that a patient will be completely satisfied. The practice of medicine, it has inherent risks and complications in it that can occur in the presence of entirely appropriate care.

JFB: Right. I think that's really key. So, do standards of care vary depending on the context of the clinical situation? So, for example, between a specialist and what a general practitioner would do? And if so, why is that the case?

PB: So yes, the standard of care is generally different for different specialties. And that is why the Board gets assistance from medical reviewers who are either in the same specialty or a related, similar specialty where they do the same type of treatment or procedure at issue in any given case.

JFB: Okay. So how does ensuring that standards of care are met, protect patients and maintain accountability in the health care system?

PB: Sure. So, the Board's main function is to regulate the practice of medicine in North Carolina and to protect the public. And so, patients can be at risk of harm if they're being treated by health care providers that are practicing below the minimum standard of care. And when the Board becomes aware of a situation where a licensee that they regulate is practicing below the minimum standard, they can intervene and take appropriate action to make sure that the public is protected. And I think these actions to protect the public really result in the Board maintaining accountability in the health care system.

JFB: So, as you know, the Board receives hundreds of complaints that raise concerns about the quality of the medical care that was provided every year. And under state law, the medical Board is authorized to act only if it has evidence that care fell below accepted standards. Could you walk me through the Board's process for determining that?

PB: Sure. So first of all, what is a quality of care case? I think of a quality of care case as something that involves care rendered or not rendered to a patient. And with the Board can arise when a person applies for licensure in North Carolina, say you apply and you have prior quality of care issues in another state that the Board needs to review as part of an application process, and it can also arise after licensure has been granted. These are the most frequent types of quality of care cases, and quality of care cases usually come to the Board's attention in one of the following ways. One. A complaint is made to the Board by an individual. Jim is upset because he thinks Doctor Smith did not perform his knee surgery correctly. That's the vast majority of the information that we receive to open investigations, complaints made by a patient, a family member, sometimes another health care provider. We also get professional liability or malpractice, as it is sometimes referred to. Settlement or a verdict can be reported to the Board. Something happens at the hospital, their privileges are restricted or taken away, and that's reported to the Board or another medical Board in another state, or another agency can report concerning activity to the Board. So, when these things get reported to the Board, they usually investigate. And the first step in the investigative process with quality of care cases involves getting the materials at the Board's staff level that are relevant to the investigation. And these materials include the following: One, you have to have the document that started the whole thing. The complaint, the professional liability settlement information, the hospital information, the information from another Board and then a licensee response. The Board, when there's a complaint received and they open an investigation, they allow a licensee a chance to provide an explanation of the care that was rendered, i.e., they can tell their side of the story. And then the Board staff will also get the relevant treatment, medical records, obviously, from the person who's being investigated, but sometimes to investigate the records of the person at issue, you have to get records from other medical providers or hospital admission records. And then really, depending on the case, any other document that could be relevant to the case. In a controlled substance prescribing case, there is something called the North Carolina Controlled Substance Reporting Service, which gives us a lot of information about the prescribing patterns for the licensee. And you can get specific prescribing pattern information for patients. And so, once these materials are obtained, they're reviewed by people at the Board staff level in the medical director's department and the legal department. And at this point, once all the information is gathered and then the medical and the legal staff start to review it, the Board staff may determine that the case should be sent out for what’s sometimes called an outside expert review, so that a reviewer can assess the case and give an opinion, which is usually in writing about whether the care met the minimum standard or not. Now, a Board member can also request an outside review, and that's almost always done when the case is presented to the Board. And the staff have said, I don't think for whatever reason, this case needs an outside review. But regardless of who requests the outside review, the process is generally the same. And once the reviewer’s evaluation is complete and a report is received, it becomes part of the investigation or the licensing file, and it's reviewed by the Board staff and the Board members. Now, once an outside review is requested, it goes to a section of the Board staff called the Quality of Care Team, the QOC team, which has attorneys, paralegals and a coordinator. And the QOC team is the main contact for all things related to outside review. They send materials, communicate with the expert about the case as needed, and the reviewer sends their reports or worksheets, as we sometimes call them, back when their evaluation is completed.

JFB: Wow, that was a lot of process. You mentioned something I wanted to follow up on, which is that Board members can sometimes request outside reviews. Why would that occur? Would that be a situation where, let's say, staff had reviewed the case, and they felt like either the violation was so clear that you didn't need to ask an expert. Is that a reasonable guess?

PB: I think it would be a rare situation where a review was not requested because the violation was so clear. But I think how it frequently comes up is the Board staff did not think that there was any type of violation of the Medical Practice Act. The Board staff, for whatever reason, thought the care was within the standard. But that's not a perfect assessment. And different people may look at a case. Some may have concerns about the case, some may not have concerns. And you can have a situation where the Board staff may look at it and say, we think the care was within the standard, but it goes to a Board member and for whatever reason, the Board member says, I'm not saying that you're wrong, but I do have a concern with regard to whether it really was within or below the minimum. So as a matter of due diligence, I'd like to send the case out for review.

JFB: I see, so it would be a situation where staff didn't necessarily see a violation, but the Board member had some concerns. So, you mentioned reviewers a couple of times, and I wanted to talk a little bit more about those reviewers who review the quality of care cases and offer opinions on standard of care. Can you talk about who those reviewers are?

PB: Sure. So, the Board usually uses physician reviewers in quality of care cases. The Board has at times used reviewers with other types of licenses, but physicians are used most frequently, and they're generally expected to be in practice and have sufficient credentials at or around the relevant dates of treatment that they're reviewing. Like, for example, a person would not be chosen to review a case if they were in medical school or a resident at the time the relevant treatment was rendered. Generally, reviewers have the following credentials and experience: One, a full and unrestricted active North Carolina license at or around the dates of treatment at issue in the case. And then for physicians, uh Board certification at or around the dates of treatment at issue in the case. And then this is where I call it matching the expert to the case, we want them to be engaged in the same or a similar area of practice or having performed the same or a similar procedure at or around the dates of treatment at issue. You don't want to have a pediatric neurosurgeon review a dermatology case, but having said that, the reviewer doesn't always have to be in the same exact specialty. For example, if the care at issue concerned a back surgery performed by an orthopedic surgeon that's mostly performed by neurosurgeons, but some orthopedic surgeons perform the back surgery, that is a case that may be able to be reviewed by an neurosurgeon or an orthopedic surgeon, as long as they're doing the exact same operation at or around the time that the treatment at issue was rendered. And then another thing that we do from time to time, if we have an internal medicine case, say it's treating a 25 year old for hypertension and high cholesterol, if for some reason we send it out to 5 or 6 internal medicine physicians and they can't do the review for whatever reason, we may send it out to a family medicine specialist if they're treating the same type of conditions, same type of patient population at the time of issue. But there's also a screening process we engage in to vet the reviewers and licensees with concerning histories or questionable past conduct are usually not chosen as reviewers.

JFB: And I don't know if we mentioned this specifically, but what are the reviewers looking at? How do they form their opinion?

PB: Sure. So, we send the reviewers what's called a reviewer package, which almost always includes whatever the document was that brought it to the Board's attention, the complaint, the other state action, and then the response. And then we send the relevant medical records and then any other records that would be relevant to the case in order to enable them to render opinion. And we try to send it in a book marked with a hyperlink, table of contents, to try to make it as easy as we can for the review.

JFB: So, my next question then is how important is it for there to be good documentation in the medical record?

PB: So, documentation, when we ask the experts to give an opinion, we break it out into three categories. And we ask that a specific opinion regarding was it within or below the minimum standard be rendered for diagnoses, treatment and documentation. So those are the three big things, and documentation is one of the and documentation is essential because if you have a case with poor documentation, it could be very difficult to know if it's poor documentation of otherwise good care or poor documentation of otherwise inappropriate care. Now, I understand that you can't write everything down that happens, but the essentials of care rendered, they need to be appropriately documented.

JFB: Sometimes when I have conversations where I'm talking with people about this, I'll say the Board and the Board's expert reviewer should be able to look at the records and understand what you did and why you did it.

PB: Exactly.

JFB: So why is peer evaluation so important? You've talked about the importance of having a physician or another medical professional who's familiar with the specific area of practice so they can render a judgment. Why does it have to be a peer, or is it desirable for them to be a peer and not just any physician, like a member of the Board or a member of the Board's medical staff?

PB: Sure. So, it gets back to what I said about matching the expert to the case. You could have an internal medicine physician review a neurology case like you could do that, right? But I don't recommend it. And if you have someone who's basically been in the same or similar specialty, been doing the same or similar thing, and in practice several or a few years in advance of the dates of treatment at issue, it really, really helps the Board determine, in a much better sense and a much more meaningful sense, whether the care rendered was acceptable or not. And you really need appropriate, qualified, specialty specific reviewers to evaluate that care.

JFB: What specific specialties are involved in performing outside reviews?

PB: All specialties…we try, you know, matching the expert to the case…to match the specialty of the physician to the expert that we're sending the case. So, it's really every specialty that you could imagine. We have a long list of experts and we have it broken out into specialty and subspecialty.

JFB: If a licensee is listening to this podcast and wants to offer their services as an outside reviewer, how can they do that? How can they indicate their interest?

PB: So, towards the very end of every renewal application is a question that says something to the effect of would you like to be an expert reviewer for the Board, So you can do it, when you go to renew, it's got instructions there. You can email: its reviewers at all one word NC med Board dot org, and you can attach your CV and let us know of your interest. You could also, you know, if you want to, you could call the main number, tell them you're interested in being a reviewer. They'll probably connect you to me or someone on the QOC team or staff.

JFB: Right, Well, we'll be sure to put some information on our show page so that people can reach out if they want to do that. We've covered a lot of the basics of standard of care and Board process. Now, I would like to spend a little bit of time exploring some of the aspects of standard of care that could be a little confusing or hard for patients to understand. So first, can a patient have a bad outcome, maybe even die, and then the investigation comes back and finds that standard of care was in fact followed?

PB: Yes, that can be the case. Care can be appropriate in all respects, and patients can still have what they consider to be a bad outcome.

JFB: So, could you give an example that illustrates how this might happen?

PB: Sure. So, let's take three examples. One, cancer treatment. Suppose someone is diagnosed with cancer. They receive chemotherapy and radiation. Entirely appropriate care, entirely appropriate diagnosis. The cancer is treated appropriately. Person is in remission doing as well as can be expected. But the patient ends up with peripheral neuropathy, hands and feet, and an entirely new form of cancer. They're not happy with the peripheral neuropathy. They're not happy with the new form of cancer. But those are risks of the chemotherapy and the radiation that can happen in the presence of someone being treated appropriately. Let's take another example. A person goes to the emergency room, and they think I have an appendicitis. Right? Person is appropriately worked up. They get a CT scan, they get a laboratory tests, and there's no indication of an appendicitis. And they get discharged with a diagnosis of gastritis. So, fast forward five days later, they go back to the emergency department, and a ruptured appendix is diagnosed. So, the patient thinks that the appendicitis should have been diagnosed at the initial emergency room visit. But there was no indication of appendicitis at that visit, so the care was appropriate. But the patient, you know, was unhappy.

JFB: So, the reason that it would fall within standard of care is because they did the right things. They checked, okay. So, they did the CT scan, they did the labs. And when they looked at those results, the normal clinical indicators that would suggest appendicitis weren't there.

PB: Yes.

JFB: Ok.

PB: And so, what would likely happen in those situations in very similar cases, real cases that I've seen is that the signs and symptoms where you would entertain appendicitis in the diagnosis or a possible diagnosis didn't occur until a few days after the first emergency room presentation.

JFB: Ok.

PB: Okay, so I have one more. You could have a ruptured abdominal aortic aneurysm, and you could die shortly after an entirely appropriate surgery to address it is done. And the unfortunate situations with ruptured abdominal aortic aneurysms is that they…they have a high mortality or a high death rate. So, it's possible that you could do an appropriate surgery, but the patient could die shortly thereafter.

JFB: So, somebody is just too sick or too injured, you do everything you can, and you do it appropriately, but you're just not able to save that person.

PB: Exactly.

JFB: Okay. Those are good examples. Now, I wonder, could you also give an example where the care clearly falls below accepted standards?

PB: Sure. Say you have a patient who, for whatever reason, needed to have amputation of one of their legs below the knee. And so, it's the day of surgery. You go in to have the amputation. Everyone says we're going to amputate the left leg. The patient puts an X on the left knee and writes this one on the left leg. The surgeon initials it. They go into the operating room, and the surgeon cuts off the right leg. Example number two. Take the appendicitis example that we were talking about before and change the facts where the patient who goes to the emergency room for the first time has every sign and symptom of appendicitis. The CT scan that was done says strong suspicion for appendicitis in all of the laboratory values were suspicious for appendicitis. In cases that I've seen that are similar to that which is not many, those I think would likely be considered below the standard of care because they fail to make the appropriate diagnosis when they had the medical information in front of them where it should have been made.

JFB: Right. So, the difference between this case and the previous appendicitis case is that in the previous case, they did the tests and the indicators were not there. In this case that you just mentioned, all of the signs and symptoms are there. And the licensee, the clinician just didn't recognize them.

PB: Exactly. Yes.

JFB: So let me ask you this. Are opinions on standard of care consistent or are there situations where reasonable professionals disagree? And if that happens in an NCMB's case, how does the Board make the final call?

PB: That's a really great question, and the Board, they get opinions on whether the standard of care was met from qualified, vetted reviewers. But having said that, reviewers are human and at times they may have slight differences in disagreements about how they define what constitutes the minimum standard of care for any given case. And so that's just the reality that we have to deal with. And the Board recognizes that. And they factor that into their decision making process. And so, take like sometimes radiologists may disagree about whether something should have been seen on an image or not. We see

that from time to time. Sometimes OBGYN physicians taking care of a woman in labor, they may disagree on how long to wait during labor to recommend a C-section to be consistent with the minimum standard of care, and we see that from time to time. And if the Board have conflicting medical reviews, they will discuss it in one of their committees among the full Board. And what they'll do is they'll discuss the substance of each review in depth, and they'll weigh the credibility of the reports through their lens in deciding what decision to make. And the decision to make could also include sending it to another reviewer for review. If you have two reviewers and they disagree about 1 or 2 things regarding whether the care was within the minimum standard or not, sometimes the Board will say, you know, send it out to a third expert to break the tie.

JFB: So, we've talked about how the Board obtains an outside review to establish standard of care. Sometimes licensees who are defending themselves against a quality of care allegation or allegation of substandard care, they will get their own outside review and submit that to the Board to say, see, my expert says I did all the right things.

PB: Absolutely. And if that happens, that will be part of the investigative file.

JFB: So, as we've discussed this podcast, we're hoping we'll offer some insight to laypeople, patients, family members out there about, you know, how the Board goes about deciding whether care falls below standard. I'm wondering if you could offer any guidance or advice on how a patient might better prepare themselves or their family members for the possibility of complications or side effects, because that seems to be the thing that a lot of times will tip them towards filing a complaint.

PB: Sure. So, I would say three things communication, communication and communication with your health care providers. Read the papers and the documents that they ask you to sign before signing them. And if you don't understand them, ask the health care provider or someone else at the practice to explain what the document says. Sometimes I'll be at the doctor's office, and they'll give me these things to sign, and I'll…I'll say, just give me about five minutes. I'm going to need to read this and they give me like an odd look that I read it. And that makes me a better informed health care consumer. If they give you information to send you home with or there's something that pops up on the patient portal, here's a summary of your visit. I would suggest that you read it, and if you don't understand any part of it, ask to have it explained to you. If there's something that's recommended to be done to you, a procedure or medication prescribed, I would say, you know, don't hesitate to say, hey, you know, I'm fine with what you recommend, but like, what am I getting into if I do this, you know, what are the risks?

JFB: Yeah, yeah. Great advice. It can be a little bit difficult for people to ask those questions to, to know that it's okay, that it's acceptable for them to do that. We've been developing, in communications, some resources to try to help people with that, health literacy informed consent that hopefully is helping people to develop those skills. Well, Patrick, thank you so much. This has been really informative. I really appreciate your time and your expertise.

PB: Thank you so much for having me, I appreciate it.

Closing: 32:03

That brings us to the end of this episode of MedBoard Matters. I hope you have a much better idea of what the North Carolina Medical Board is looking for when it investigates allegations of substandard care. Perhaps you even have a better understanding of why a complaint that involves poor patient outcomes – maybe even patient deaths - may not result in discipline. Before we wrap up, I want listeners to remember that patients are not expected to know if the care they or a friend or family member received was below accepted standards. The only way to know that is to file a complaint with the medical board so it can be investigated and evaluated by qualified individuals. That's why NCMB never discourages someone who has concerns about care from filing a complaint. It's just important to understand that, if the facts don't support that the care was, in fact, below accepted standards, the Board does not have the authority to take action against the medical professional. If you are interested in learning more about how you can become a more informed patient and go into any medical encounter with a good understanding of the risks and potential side effects of treatment, please visit our podcast show page at www.ncmedboard.org. NCMB has developed multiple resources that can help and we have linked some of them for easy access. If you have comments or questions, please email them to podcast@ncmedboard.org. Thanks so much for listening. I hope you will join me again.