

West Virginia Health Care Authority
LITHOTRIPSY CON STANDARDS MEETING

10/15/2008 – 1:00 pm EST

Conference ID # 137202

On the conference phone:

Dr. Rocco Morabito in Huntington

Raymona Kinneberg, Bill Crouch & Associates

Ann Stevens, Vice President of the American Kidney Stone Management

Phil Wright, The Health Plan

Rick Hughes, American Kidney Stone Management

Allen Burgenthal, American Kidney Stone Management

Pat Woods, BMS

Ms. Sonia Chambers: Why don't we go ahead and get started. We may have some other folks straggling in here. My name is Sonia Chambers. I'm Chair of the West Virginia Health Care Authority. With me today I have Marilyn White and Sam Kapourales who make up the rest of the Board, all three of us. The purpose of today's meeting is to talk about lithotripsy services and their reviewability under Certificate of Need. In West Virginia, lithotripsy is reviewable and we are going through a process with the legislature of re-examining Certificate of Need and what services are covered and in agreement with the legislature, we are holding these meetings, public meetings, stakeholder meetings, to let everybody have some input as to whether they think these services should continue to be reviewed or not. So that's the purpose of today's meeting. We are having a whole series of these around all the services that are subject to review, so if anybody's interested in any of the rest of them, they're on our website. The schedule is on our website and we encourage you to participate. We've had everybody identified on the phone and we can now go around the room here, so you can know who is here and then Dayle, I guess, will go through the Certificate of Need Standards for lithotripsy and then we'll open it up for public comment. I would also tell you that if you would like to submit comments in writing, please feel free to do that. They would be due 30 days from today. That's what we've done with the others, so we would encourage you to submit comments in writing. Please direct those to Dayle Stepp, who is the Director of Certificate of Need Review. We will compile the results of today's meeting and those comments and present them to the administration and the legislature. This call is being recorded. We will have a transcript of the call, so please, when you're speaking, identify yourself so that we can accurately reflect who says what. All right, so with that why don't we go around the room? Dayle, we'll start with you.

Mr. Dayle Stepp: Dayle Stepp, CON section.

Mr. Tim Adkins: CON.

Ms. Shelia Kelly: Shelia Kelly, CON.

Ms. Marianne Kapinos: Marianne Kapinos, General Counsel.

Ms. Cynthia Dellinger: Cynthia Dellinger, Assistant General Counsel, Health Care Authority.

Mr. Ed Hamilton: Ed Hamilton, Mountain State Blue Cross Blue Shield.

Mr. David Jarrett: David Jarrett, CAMC.

Mr. Joseph Letnaunchyn: Joe Letnaunchyn, Hospital Association.

Ms. Martha Morris: Martha Morris, Consumer Advocate, Insurance Commission.

Ms. Sonia Chambers: All right, Dayle. Yes, I'm sorry. The list of people on the phone, I can show this to you or has anyone else joined us on the phone? We haven't heard anybody click in, I guess or beep in, as it were. All right, Dayle, why don't you go through the Standards?

Mr. Dayle Stepp: Okay. The need methodology for lithotripsy services is the facility defines its proposed service area and then has to calculate a use rate based on information available from the Authority by the use rate to the service area population, get a projected number of patients, then you look at the current utilization of providers within that service area to see whether there is still an unmet need. As far as the quality, of course it has to be FDA approved that you have a full-time board-certified physician with appropriate training. You have to have a written plan for training technologists, someone trained in CPR, and you have to have utilization quality and peer review policies in place. You have to have on staff with the referral-qualified physicians in the medical specialties appropriate for the service to be provided. Such service has to be part of an integrated program of services with on-site access. And you have to have a data base to include factors that may become part of a national data base. As far as the cost, you have to provide a three year projected revenue and expenses to show that it's financial feasible, that you have enough capital to [noise inaudible] project, that all indigent persons needing the service can be served without jeopardizing the viability of the project, that they're willing to participate in utilization management programs, and that the cost and charges are similar to other hospitals providing the same service, and that you're in compliance with all applicable state and federal laws regarding access to the disabled. And you also have to provide additional information that may be requested by the Authority regarding demographics data, financial data, and clinical data for the patients. That about covers it.

Ms. Sonia Chambers: Okay. Just as a point of information, you have, I guess, handed out a table based on information from our uniform financial report that outlines, I guess, the places where lithotripsy is provided. They are certainly acute care hospitals and the volume associated with each of those.

Mr. Dayle Stepp: There's one correction to this chart from our previous meeting. Previously we had Greenbrier Valley at 936 procedures for 2007. We contacted them. They said that was incorrect and they corrected it to 225 procedures.

Ms. Sonia Chambers: It is certainly more in line with others, although it's not the highest in the state. It's second to Weirton. No, I'm sorry. St. Francis, then Weirton, then Greenbrier Valley. Okay.

Mr. Phil Wright: Sonia, the people on the phone don't have a copy of that. Is there any way we can get a copy?

Mr. Dayle Stepp: It should be on the website.

Ms. Sonia Chambers: It is on our website?

Mr. Dayle Stepp: Yes.

Ms. Sonia Chambers: And if you go our homepage, how do you...

Mr. Dayle Stepp: Well, it will be at the bottom of the homepage. There's a list of all the meetings and it will be there.

Mr. Phil Wright: Okay.

Ms. Sonia Chambers: Right and at the bottom of that same spreadsheet, it lists the other states that have Certificate of Need review for lithotripsy and just for those of you who don't have it, it's Alaska, Connecticut, Delaware, Washington D.C., Georgia, Hawaii, Maine, Massachusetts, Michigan, Missouri, North Carolina, South Carolina, Tennessee, Vermont, and Virginia.

Dr. Rocco Morabito: Sonia, this is Dr. Morabito. What is the website so we can go ahead and access that, whether we do it now or a little bit later?

Ms. Sonia Chambers: It's www.HCAWV.org

Dr. Rocco Morabito: HCAWV.org. Thank you.

Ms. Sonia Chambers: And our Standards are also right there on the website, correct?

Mr. Dayle Stepp: Go to Certificate of Need and under Certificate of Need go to Standards and there's a list of all the Standards there.

Ms. Sonia Chambers: Okay, but this Excel spreadsheet is on the homepage at the bottom with a list of meetings.

Mr. Dayle Stepp: Right.

Ms. Sonia Chambers: Okay. All right. Okay, well why don't we just throw it open for discussion.

Mr. [??] [??]: Questions?

Ms. Sonia Chambers: Yes.

Mr. [??] [??]: I'm looking at the standard. It was approved July 7, 2000?

Ms. Sonia Chambers: That's correct.

Mr. [??] [??]: And at that time any acute care facility that had fixed or shared service mobile lithotripsy don't need a certificate going forward? They're not subject to review, is that right?

Ms. Sonia Chambers: The issue is they were updated then. They have always been subject to review. That date indicates the last time these Standards were updated.

Mr. [??] [??]: Once they were updated at that time any acute care facility that had those do not need further review?

Ms. Sonia Chambers: Well, any facility that had a Certificate of Need for lithotripsy...lithotripsy has always been reviewable since Certificate of Need came into existence in the '80s. Well before that.

Ms. Marianne Kapinos: Well actually [inaudible] was created in '77.

Ms. Sonia Chambers: Okay, in 1977 and any facility initiating lithotripsy services after that time would have had to go through Certificate of Need review.

Mr. [??] [??]: But if you had one you didn't have to go through anything else.

Ms. Raymona Kinneberg: But it is correct, I believe, that if you received an exemption, so you went through the exemption process and had mobile lithotripsy service for x period of time, that you didn't have to get a CON to do either fixed or the little mobile services. I think that's correct.

Ms. Sonia Chambers: And that was Raymona Kinneberg, correct?

Ms. Raymona Kinneberg: Yes, sorry.

Ms. Marianne Kapinos: Mobile services exception is separate from...

Ms. Raymona Kinneberg: Right, but I think that the gentleman's correct, and I'll have to pull up the standard, in that if you have an exemption for mobile services, and this is the kind in a van, not the little lithotripter, and had it for x period of time that you don't have to go through CON or at least the need methodology for CON.

Ms. Sonia Chambers: Actually that does, it's on page 2 under the need methodology. It says that if you have fixed or shared mobile services, well you won't be subject to further review for the acquisition of a mobile.

Mr. Dayle Stepp: That's the small unit that they move around within the hospital, not the shared unit on a van.

Ms. Sonia Chambers: The little mini ones?

Mr. Dayle Stepp: Right.

Ms. Sonia Chambers: Okay, so you don't have to go through further for the little mini ones. However, if for some reason if you had lithotripsy services under a shared mobile exemption by a van that was coming around and coming to your campus periodically, if you wanted to then have a fixed service, you would have to go through Certificate of Need review.

Mr. Phil Wright: But if you had it prior to then you don't. You didn't need to.

Ms. Sonia Chambers: Prior to when, Phil?

Mr. Phil Wright: Prior to the standard being updated July 7, 2000.

Ms. Sonia Chambers: The update is not the issue.

Mr. Phil Wright: Okay, I understand now. The question I have, if you're an acute care facility and you're trying to put in a mobile lithotripter, do you have to do anything?

Ms. Raymona Kinneberg: As long as you've had fixed or shared services. If you haven't had lithotripsy services and want to get the mobile lithotripter, you have to go through CON.

Mr. Phil Wright: Okay.

Ms. Cindy Dellinger: If you've never had it before and...

Ms. Sonia Chambers: If you've never, ever offered the service...

Ms. Cindy Dellinger: [cross talk inaudible] you can go to the shared level...

Ms. Sonia Chambers: Right.

Ms. Cindy Dellinger: It's a new service and it's subject to appeal and review and it's mobile, you can go through the shared.

Mr. Phil Wright: And if you're a non-acute care facility, you have to go through the CON?

Ms. Sonia Chambers: If you are a non-acute care facility, yes.

Mr. Phil Wright: Okay.

Ms. Marianne Kapinos: Everyone would have to have [inaudible].

Ms. Sonia Chambers: Right. Everyone has to have, anyone who wants to offer lithotripsy services has to go through Certificate of Need review. There are different kinds of review depending on the way in which you want to offer the service.

Dr. Rocco Morabito: Can you define the non-acute care facilities that are available in West Virginia?

Ms. Sonia Chambers: I don't know that there are any that offer lithotripsy services. I think we were just answering that theoretically.

Dr. Rocco Morabito: Okay, okay, thank you. Because as I understand it, currently only acute care facilities have lithotripsy services available in West Virginia.

Ms. Sonia Chambers: I think that is correct.

Dr. Rocco Morabito: Okay.

Ms. Sonia Chambers: When we went and did the inventory it was certainly only acute care facilities.

Dr. Rocco Morabito: Okay.

Ms. Sonia Chambers: I think certainly some of the questions that I have relate to what is the standard of care or current practice for lithotripsy services? I was a bit surprised at the low number of them and it seems to be generally a declining number, particularly since like 2004, it seems to be a much lower number and the larger tertiary facilities seem to have less than some of the smaller or medium sized facilities and I would really be interested to hear from the practitioners as to why that is.

Dr. Rocco Morabito: Well, lithotripsy is a treatment that is a specific treatment. In other words, it's a treatment for a kidney stone only, so if a patient doesn't have a kidney stone the treatment is usually not performed, so it is for a definite disease entity, kidney stones. Now, with our population base in the state somewhat declining in certain areas, there will be fewer patients available with kidney stones. I know that I've asked representatives from American Kidney Stone Management, this company provides I think the majority of the mobile lithotripsy services for West Virginia Hospitals, and with the experience that we've got in the state, as well as the other states that provide service, is that trend true in other states? I might ask Ann or Rick, are the numbers the same in other states as we're experiencing here in West Virginia?

Mr. Rick Hughes: Across the country, lithotripsy is up slightly, just a couple of percent. Definitely in West Virginia it is down, which is different from the rest of the country.

Ms. Sonia Chambers: Well for instance, I don't know if those of you who have been able to pull up this spreadsheet, but the numbers are, it's fairly significant. Let's take CAMC, for instance. In 2000 they did 993, in '01 they did 726, in '02 they did 460, and went back up in '03 to 702, and then has dropped down in '07 to 136. That's a pretty significant decline and for Cabell Huntington, let's see, the high in '04 was 143 and in '07 was 69.

Dr. Rocco Morabito: Sonia, I might be able to throw out a couple of things that might affect those numbers. One is the fact that other kidney stone treatment technologies are also being used to treat certain kidney stones that may have been treated previously with lithotripsy, such as ureteroscopy, laser treatment through a cystoscope or ureteroscope, so I think that's probably cut into some of the numbers for lithotripsy. As all of you are aware, the total number of urologists

in this state is dismally low. We are in desperate need of urologists in West Virginia, so certainly the fewer practicing urologists we have, the fewer patients that are going to have kidney stones treated in our state, so that might have some bearing on it. I can't speak directly for CAMC. I understand there is a CAMC representative in the room there, but it is my understanding that the technology or the machine that CAMC has was not well received by some of the practicing urologists because of the efficacy of the machine and they may have taken their stones elsewhere, so those are three things that just popped out that might be affecting some of these numbers.

Ms. Ann Stevens: This is Ann Stevens, Vice President of American Kidney Stone. When you gave the numbers for Cabell Huntington, what was the total for 2007?

Ms. Sonia Chambers: 69.

Ms. Ann Stevens: Well, we did 96 cases at Cabell Huntington in 2007.

Ms. Sonia Chambers: Okay, so these numbers may be incorrect.

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: That is a possibility, especially like I said, with Greenbrier Valley, because their numbers were triple anybody else's and they have a third of the beds of a number of hospitals, we asked them about their number. So you did 96 at Cabell?

Ms. Ann Stevens: That is correct, in 2007.

Ms. Sonia Chambers: And you are the provider there for them?

Ms. Ann Stevens: We are the mobile provider at Cabell, correct.

Ms. Sonia Chambers: Okay. Well we could probably ask you to clarify a lot of these numbers and you can tell us that. I'm just curious, do you have a spreadsheet there with the numbers?

Ms. Ann Stevens: No, I don't.

Ms. Sonia Chambers: You don't, okay.

Ms. Ann Stevens: But I have easy access and I just accessed it through our data base.

Ms. Sonia Chambers: Okay. Would you be willing to provide those numbers to us?

Ms. Ann Stevens: I certainly would.

Ms. Sonia Chambers: That would be helpful.

Mr. Phil Wright: What has happened to the cost of lithotripsy over the years?

Mr. [??] [??]: What was the question?

Ms. Sonia Chambers: What has happened to the cost of lithotripsy? I guess maybe, Ann can you speak to that in terms of your charges....

Ms. Ann Stevens: Yeah, I think since the inception of mobile providers in 1989, the cost has gone down somewhat, but not significantly. Might I ask you a question? For St. Francis in Charleston in CAMC, how many do you have in 2007 for St. Francis?

Ms. Sonia Chambers: 279.

Ms. Ann Stevens: They're close. We did 289.

Ms. Sonia Chambers: Okay.

Ms. Ann Stevens: But I will be glad to send you the statistical data.

Ms. Sonia Chambers: That would be helpful. We try our best, but all of this data is self-reported.

Ms. Ann Stevens: It's very difficult.

Ms. Sonia Chambers: and we can't really help it if they don't send the right data to us.

Mr. Phil Wright: This may be a bad question again. What's the success rate of lithotripsy?

Ms. Ann Stevens: The success rate is about 88 to 90%. Now, having said that, depending on the size of the stone, the location of the stone, and the composition of the stone or stones, there could be what we call planned re-treatment. In other words, the patient would require, for a very large stone, a very hard stone, would require more than one treatment to be stone-free.

Dr. Rocco Morabito: Phil, this is Dr. Morabito. The definition of stone-free varies across the county, but I think most people feel that if there are insignificant-sized remaining fragments, 2 to 3 to 4 mm is the gauge that we kind of use as whether the treatment is successful or not, but it is, it's probably in that 80 to 85%+ range for the majority of treatments.

Mr. Phil Wright: And when you can't use lithotripsy for the method of elimination of the stone, surgery is the next step?

Dr. Rocco Morabito: Well, various forms of surgery. Usually the percutaneous approach, like a laparoscopic approach. We rarely, rarely do open surgery anymore. When I did my training 30 years ago, that's all we did was operate on kidneys for stones and now it's the exact opposite. We rarely operate for a kidney stone. We have different modalities available, yeah.

Mr. Phil Wright: Which are much more expensive.

Dr. Rocco Morabito: Yeah, sure.

Mr. Phil Wright: Okay.

Ms. Sonia Chambers: I'm just curious. Dr. Morabito, do you have an idea of the magnitude of the difference between lithotripsy and one of these other laparoscopic procedures?

Dr. Rocco Morabito: Well, certainly lithotripsy is the most non-invasive of any of the treatments. It's not without complication by any means at all, but certainly it is the least invasive of any of them and we try our best to manage the patient in the most least invasive manner first. Just as Ann mentioned, certain sized stones and composition of stones and multiplicity of stones and some of those issues and location of the stone is important. We try lithotripsy initially and I think across the country...you know, the American Urological Association has standards of treatment that they're trying to get urologists across the country to adhere to and a lot of these include trying the least invasive treatment, lithotripsy, first, so to answer your question, lithotripsy is probably tried initially on a lot of stones. The other modalities will then be brought into place if lithotripsy doesn't do the job for us.

Mr. Phil Wright: But there are certain sized stones you wouldn't think of lithotripsy, aren't there?

Dr. Rocco Morabito: Once again, yeah, that's an individual call by the physician, but personally, yes. I think if you've got a large, we call it stone burden, if you've got a large stone burden, then certainly I think alternative measures are probably better used, such as the percutaneous or something like that.

Ms. Raymona Kinneberg: Sonia, I'm looking at Greenbrier Valley again and I believe that if there's the difference in what we saw for 2007, that the numbers from prior years are probably also wrong, because you've got 725 for 2006, so the bottom line difference in terms of the numbers between 2006 and 2007 is probably not what it looks like if Greenbrier Valley numbers are not correct.

Ms. Sonia Chambers: Right.

Mr. Dayle Stepp: Yes. We didn't ask him to go back from 2000 on. We were checking on the 2007 numbers.

Ms. Raymona Kinneberg: Right, yeah I'm just going back and looking at Sonia's discussion about the decline, that maybe it's not quite as dramatic as it looks like in terms of the bottom line.

Ms. Sonia Chambers: Right. Well I think it would be useful to the extent that we can correct these numbers. Whatever Ann can provide us, whatever the facilities would be willing to provide us, we'd certainly be happy to...what we may do, Dayle, is probably send out a request to the facilities to check the accuracy of the information, although they're the ones that submitted it to us in the first place.

Mr. Phil Wright: Sonia, who provides services for Greenbrier?

Ms. Sonia Chambers: I'm sorry. Ann, do you provide services for Greenbrier?

Ms. Ann Stevens: No ma'am, I do not.

Ms. Sonia Chambers: It's a fixed unit, okay.

Mr. Phil Wright: It is a fixed unit. Okay.

Ms. Sonia Chambers: Yes.

Mr. Phil Wright: In the past, Dr. Ford and his group had a mobile unit that ran across southern West Virginia to two or three hospitals and I didn't know whether they maintain that and maybe some of those numbers are spread out to other facilities, but I guess if you say that there's a fixed unit there now then that would be the only provider for Greenbrier.

Mr. Dayle Stepp: The administrator there said they had five urologists on staff and they had patients from 84 different zip codes, including nine in Virginia.

Ms. Raymona Kinneberg: That's consistent with what I've heard from other hospitals, that Greenbrier Valley draws from a fairly large area given the reputations of the urologists.

Ms. Sonia Chambers: Sam has a question.

Mr. Sam Kapourales: This is to Dr. Morabito. As far as lithotripsy goes, do you consider this treatment something that basically will be in the past when you look at all the new and different procedures coming into play?

Dr. Rocco Morabito: Hi Sam, by the way. No, you know I think lithotripsy has been proven, I think it was approved in 1984, if I'm not mistaken, and you can correct me, but if it's been around now for what, 24 years and there's nothing out there in the market or in the foreseeable future, because I know that American Kidney Stone looks at future technologies and there may be various lithotripters, people talk about the office lithotripter or the compact lithotripter, well it's down to a size right now where it's transportable, as you mentioned, just in a bread truck-type van, so to answer your question, Sam, I think that lithotripsy is here to stay for kidney stone treatment. Nothing's going to be eliminated in the near future, probably in the next, probably 10 years.

Mr. Sam Kapourales: Okay, thank you.

Mr. Phil Wright: Question?

Ms. Sonia Chambers: Yes Phil.

Mr. Phil Wright: Lithotripsy unit mobile person on there, if you were not to use an acute care facility would the cost be cheaper if you were to do it on your own, on the side?

Ms. Ann Stevens: Well you really need, this procedure requires anesthesia and ability to admit to an acute health care facility, so you really do need the acute health care facility, hospital, or an ASC.

Mr. Phil Wright: A surgical center, you could do these at?

Ms. Ann Stevens: Yes, you certainly could do them in a surgical center that provides anesthesia services.

Mr. Phil Wright: The question is, when you do it that way would it be cheaper than in the hospital setting, in the acute care setting?

Ms. Ann Stevens: No, not necessarily. It could be, but not necessarily.

Mr. Phil Wright: What do you mean it could be?

Ms. Ann Stevens: It's a volume-driven business and to my knowledge, and correct me if I'm wrong, there's not very many ASCs in West Virginia, so that's difficult.

Mr. Phil Wright: Well what is the difference between what you charge and what the acute care facility would add to the bill?

Ms. Ann Stevens: I have no idea. I'm certainly not privy to any facilities' billing processes.

Mr. Phil Wright: Okay.

Ms. Sonia Chambers: Do you, Ann, just to follow on that, I presume you all operate in other states?

Ms. Ann Stevens: That is correct. We operate in about 22 other states.

Ms. Sonia Chambers: Okay, and some of them are Certificate of Need states and some of them are not?

Ms. Ann Stevens: That is correct.

Ms. Sonia Chambers: Okay, so do you see a difference in the location of your units in non-Certificate of Need states?

Ms. Ann Stevens: No, not necessarily. I think it's pretty even throughout.

Ms. Sonia Chambers: So your units are primarily at acute care hospitals?

Ms. Ann Stevens: Acute care hospitals and some ASCs. I think out west we have a greater number of ASCs, but certainly not in this part of the United States.

Ms. Sonia Chambers: Okay, so in some other states, there may be more in ASC?

Ms. Ann Stevens: That's correct.

Ms. Sonia Chambers: Do you see any difference in the practice patterns in different states or any difference in the practice patterns between your units at acute care hospitals and those at ASCs?

Ms. Ann Stevens: No, not noticeable or not that I'm familiar with. You know, it is certainly, as Dr. Morabito says, when a patient presents with a renal calculus, it is certainly the physician who determines the treatment required for that patient.

Ms. Sonia Chambers: Okay, Dave?

Mr. David Jarrett: I have a question for you. What size are the cities out west, population-wise, that these ambulatory surgery centers are located in?

Ms. Ann Stevens: Mostly the very large cities.

Mr. David Jarrett: That's what I thought. How many million people?

Ms. Ann Stevens: Well, I'm not a real good census person, but if I had to guess I would say yes.

Mr. David Jarrett: Okay, thank you.

Ms. Marilyn White: I have a question, Ann, also. Have you noticed any difference in, let's say volume of the units themselves or just volume of procedures that are performed versus CON states versus those that are not CON states?

Ms. Ann Stevens: Statistically and Rick please correct me, Rick Hughes is on who really is our numbers person, but no, I believe throughout our catchment area of the states we service, overall we are ahead around 2% over 2007. That's for 2008 thus far.

Mr. Rick Hughes: I can add that, of our equipment around the country, if you look at CON states versus non-CON states, there is not an appreciable difference between number of procedures done on a machine. It doesn't seem to lead to greater or less utilization or different routing or any different practices. It's really, when it comes down to the operations and the physician's and patient's decisions, it doesn't seem to make a difference in states where we have CONs versus where we don't.

Mr. Sam Kapourales: How about number of machines out there?

Mr. Rick Hughes: I don't understand the question.

Mr. Sam Kapourales: The number of machines in the CON states and the non-CON states. Are there more of them in the non-CON states?

Ms. Sonia Chambers: Well I guess let me ask you the question perhaps a different way. You said volume per machine, but do you look at the volume per capita? Do you understand my question?

Mr. Sam Kapourales: I'm wondering about machines, though. If they're easier to get in a non-regulatory state more facilities would have them.

Ms. [??] [??]: But I think if you don't have a stone, they can't use it and I think that probably the end result is you've got to have a patient with a stone before they can use it.

Ms. Ann Stevens: Without a doubt. If there is no stone, there is no treatment.

Ms. Sonia Chambers: Well, but do you have the answer to either Sam's or my question? I'm guessing you do know the answer to that. You seem to be pretty good with numbers.

Ms. Ann Stevens: [Laughter] There you go, Rick. You know, with the population of each state being so different, I'm not sure that I can answer that because of the population centers of some of your CON states. For example, Virginia, in the Richmond and Roanoke area, etc, population differences do make a difference.

Ms. Sonia Chambers: Well, but it shouldn't make a per capita difference.

Ms. Ann Stevens: Right, but I am unfamiliar with the per capita of the states, I guess is what I'm saying. I've never really delved into that.

Dr. Rocco Morabito: I'm kind of wondering if in the non-CON states, because I can see where this is probably going here in just a little bit, but in the non-CON states who actually owns these lithotripters or runs these lithotripters? Are they acute care facilities who purchase their own lithotripter or are there groups of urologists or other personnel who own these lithotripters? Have you all looked into that, into the non-CON states?

Mr. Rick Hughes: Are you addressing that to HSM?

Dr. Rocco Morabito: Well, any entity, yeah, anybody who might have the answer to that question. Rick, you might know.

Mr. Rick Hughes: Well from our standpoint, in the states where we operate where there are CONs, there are hospitals that own their own machines and there are physician partnerships that run it on a route and that's true in states that don't have CONs, so I guess what we're seeing is that it really doesn't matter in the states where we're operating. The access is there and you can't see a business difference or you can't see how the business is done just because of whether the state has or does not have CON for lithotripsy.

Mr. Sam Kapourales: So there's there owners: The mobile lithotripter owner, the physicians that purchase them or rent them through the mobile lithotripter, and the acute care facility. Is that the answer to the question?

Mr. Rick Hughes: That's correct.

Ms. Ann Stevens: That's correct.

Mr. Rick Hughes: Individual owner.

Mr. Sam Kapourales: One more question. The original lithotripsy machines that came out, there have to be some that are much older in the state than some of the newer ones. Are there any differences in what they do today versus what they did when they built them 15 years ago?

Dr. Rocco Morabito: Yeah, the original came out, most people still think of the bathtub lithotripter. CAMC had one for a long time, one of the first ones in the state, and yeah, the technology has changed. There are different manufacturers who make different types of machines. The technology has gotten smaller where patients are not immersed in water, their anesthesia requirements are less, they're obviously all out-patient procedures unless some catastrophic complication occurs, so yeah, the technology has changed to the point where most lithotripters now are what we call transportable units where they will fit into a regular OR room, or something like that in an acute care facility, and utilize a similar space as opposed to an 18-wheeler that pulls up along side the hospital using a big space.

Ms. Ann Stevens: Are there really any hospitals in the state that have a fixed, large unit anymore?

Dr. Rocco Morabito: I can't speak for CAMC. The representative is there. Is it a transportable unit that CAMC has currently?

Mr. David Jarrett: We have all the transportable units.

Ms. Ann Stevens: Yes.

Dr. Rocco Morabito: Yeah. To my knowledge, I don't think there are any...I don't know what Greenbrier has. Do they have their unit listed on their stat sheet?

Ms. Sonia Chambers: No. The specific kind of unit is not listed.

Dr. Rocco Morabito: Okay. I would find that it unlikely for anybody to have any of the larger machines anymore. I think they're pretty much all, they've all been transported to third world countries for use over there. Most of the United States uses the transportable technology currently.

Mr. Sam Kapourales: But there is no standard for that in West Virginia?

Ms. Ann Stevens: For what?

Ms. Sonia Chambers: What type of machine? No. We don't have a standard for that. All right. This has certainly been a very enlightening discussion, so actually let me ask one more line of questioning and then I want everybody to have their say about continue to review these things or

not. In West Virginia, the ownership structure of the lithotripsy machines are the American Kidney Stone Management folks with their mobile units, there is at least one or two fixed...well, some of the hospitals own their own units, whether be it fixed or mobile and whatever definition of mobile you want to use, I guess, and then are there units that are owned by physicians that reside at facilities or are mobile to facilities? Did I hear some mention of that, the Greenbrier Valley ones going across **[noise inaudible]**?

Dr. Rocco Morabito: Initially I know that Kyle Ford and his group did have, they owned their own lithotripsy, but now once again, that may have changed over the last 10 years. I haven't had that much contact with them except trying to get some of their doctors to come to Huntington, but otherwise, I don't know of any other physician groups because our numbers are so small in West Virginia, urologists who actually own their own lithotripter.

Mr. Sam Kapourales: Or they could rent the lithotripter from the company.

Dr. Rocco Morabito: Yes, that's true, that's true. They could rent it, but the physicians themselves don't have a CON process to use the machine. It's wherever they practice and do their treatment, i.e. the acute care facility.

Ms. Sonia Chambers: Well, let me ask this. Ann, can you tell me which of these facilities, I guess, you service? You did tell me Cabell...

Ms. Ann Stevens: That's correct.

Ms. Sonia Chambers: Beckley ARH?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: CAMC?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Camden Clark?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Okay, City Hospital in Martinsburg?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Davis?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Okay, Fairmont?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Greenbrier Valley, no.

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Jackson General?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Monongalia General?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Ohio Valley?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Pleasant Valley?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Princeton?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Raleigh?

Ms. Ann Stevens: I'm sorry?

Ms. Sonia Chambers: Raleigh General?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: St. Joseph's, Parkersburg?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: St. Francis?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: St. Luke's...well, St. Luke's is now closed. St. Mary's?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: United?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Weirton?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Wheeling?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Williamson?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: WVU Hospital?

Ms. Ann Stevens: No.

Ms. Sonia Chambers: Okay, all right. And Dave, do you guys own your own? Yes? Okay. Raymona, of your clients, can you answer for any of these others?

Ms. Raymona Kinneberg: No, but I can find out and let you know.

Ms. Sonia Chambers: Okay, if you would let us know, that would be great.

Ms. Raymona Kinneberg: I will do that.

Ms. Sonia Chambers: Yeah, Tim?

Mr. Tim Adkins: I did a survey and called some of the hospitals. There's another group called United Medical Systems and another one called Healthtronics, and those were American Kidney's.

Ms. Sonia Chambers: Okay, and Healthtronics?

Mr. Tim Adkins: Healthtronics is out of Kennesaw, Georgia.

Ms. Sonia Chambers: Okay, and...

Ms. Ann Stevens: Austin, Texas.

Ms. Sonia Chambers: Austin, Texas?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: This is probably a simple question that is going to elicit a complex answer, but are these competitors of yours? Do they do some of the same things?

Ms. Ann Stevens: These are competitors of American Kidney Stone Management.

Ms. Sonia Chambers: Okay, so Healthtronics and United Medical Systems are?

Ms. Ann Stevens: Yes.

Ms. Sonia Chambers: Okay, my question relates more to are they similar to you all or are they small physician-owned...okay, but the answer is no, they're more along the lines of what you guys are?

Ms. Ann Stevens: Yes, they're two of the top 10 providers in the United States, along with us.

Ms. Sonia Chambers: Okay.

Ms. Shelia Kelley: Ann, can I ask you, American Kidney Stone Management is the same as Ohio Valley Mobile Lithotripsy?

Ms. Ann Stevens: Ohio Valley Mobile Lithotripsy is one of our partnerships and is managed by American Kidney Stone Management.

Ms. Shelia Kelley: Okay, thanks.

Ms. Sonia Chambers: Okay, so then the question is, who would like to weigh in on should lithotripsy be subject to Certificate of Need or not, and why?

Ms. Raymona Kinneberg: Our position is that given the numbers that we're talking about, it should stay reviewable.

Ms. Sonia Chambers: Who is us?

Ms. Raymona Kinneberg: Raleigh General and Logan. Logan doesn't provide it, but they tried to and they were not able to get a urologist to come in. I mean, we got a CON for them to do mobile lithotripsy and they weren't ever able to get the physician coverage.

Ms. Sonia Chambers: Okay. Maybe you guys should go to Greenbrier, too.

Ms. Raymona Kinneberg: Greenbrier has a very large service area.

Ms. Sonia Chambers: I'm kidding. All right, Raymona. Ann, I'm sure you have an opinion.

Ms. Ann Stevens: Well certainly. American Kidney Stone Management would encourage a continued review of the potential for lithotripsy services and I'm very pleased that we have an opportunity to put in writing our feelings and we will be doing that shortly.

Ms. Sonia Chambers: Dr. Morabito, do you have an opinion?

Dr. Rocco Morabito: Yeah, we need more urologists. Certainly I tend to agree with the flavor of the group that I think that reviewability on lithotripsy is still needed. I don't see a reason not to make it reviewable. I personally look at quality issues a lot when it comes to providing services for our patients, just like a lot of physicians do, and certainly I think if you've got that stamp of reviewability it does tend to enhance that quality issue, so I tend to say in favor.

Ms. Sonia Chambers: Okay. Dave.

Mr. David Jarrett: For continued review.

Ms. Sonia Chambers: Ed, do you have an opinion?

Mr. Ed Hamilton: Yeah. I think the way that the CONs written at this point, it needs to be tweaked a little bit, because it seems to be more or less pointed at acute care facilities, acute care facilities, acute care facilities rather than the availability of the service. Let's point it toward the availability of the service.

Ms. Sonia Chambers: Okay.

Mr. Ed Hamilton: If I were going to tweak it, I would tweak it to go more or less away from pointing out specifically acute care facilities and to whomever would want to bring that service online.

Ms. Sonia Chambers: But that relates more to how the Standards are specifically drafted than whether it should remain reviewable or not.

Mr. Ed Hamilton: Right. I think it should remain reviewable. I don't see a threshold as far as the number of services to be projected and to be continued. In some states they have a standard that says if you're not doing this number of services per year, don't come to us and ask for a new machine at some point down the road. It seems to be that, at least on a fixed basis, 1000 procedures per year is the threshold. Obviously nobody in the state's hitting that. Based on that standard, we could probably qualify for three machines in the state. That brings up the fact that obviously you've got access problems in West Virginia. That's the big thing that we'd have to deal with is access problems, so that's where your mobile providers come in.

Ms. Sonia Chambers: If we're going to do specific Standards, let's have that discussion at another time. I think once we reach the end of the session and conclusion as to what is going to remain covered and what is no longer going to be covered, then we are going to start back through the process of those things that continue to be covered, you need to examine which of these we need to review.

Mr. Ed Hamilton: Well, just to say one more thing, the long-term concern that we have is that somebody goes out and buys the equipment and it sits there and they have to pay for it, which means we have to pay for it. It goes to the rate base, it goes to the cost of health care, it goes to the bottom line on our rate, employer rates, and everybody else's rates, so yes, we think it needs to be reviewed and yes we feel that there probably ought to be something more specific in the way of Standards.

Ms. Sonia Chambers: Some changes to the Standards? Okay, I think that's a fair statement. Phil, while we're on payers...

Mr. Phil Wright: I'm sitting here thinking. We haven't studied the cost of this, but I'm sure it's different in every acute care facility and the mobile lithotripter has they're price, but I don't know what the hospitals have approved in the HICAA filings for these. We'd have to take a look at that.

Ms. Sonia Chambers: Well, just remember we don't set individual price lists.

Mr. Phil Wright: I know. It pretty much depends on how the hospital prices it and I'm sure there's major differences in prices at different facilities.

Ms. Sonia Chambers: I would guess that is the case.

Mr. Phil Wright: We'll think about this one and probably write something to you.

Ms. Sonia Chambers: Okay. Joe? Okay, Joe from the Hospital Association.

Mr. Joseph Letnaunchyn: [inaudible]

Ms. Sonia Chambers: Okay.

Ms. [??] [??]: Did Joe say something?

Ms. Sonia Chambers: Joe said that the Hospital Association supports continue review, not surprisingly. Martha?

Ms. Martha Morris: I would say we would support...

Ms. Sonia Chambers: Continued review? Amy, do you have anything to say about this?

Ms. Amy Tolliver: We actually haven't determined a position on the need or not and we're going to review need [inaudible] listening to this discussion, so at this point I don't have a definitive answer.

Ms. Sonia Chambers: Okay.

Ms. Amy Tolliver: But I do have a question for Ed. In your recommendation, were you focusing on kind of opening it up for like the ASCs [inaudible]?

Mr. Ed Hamilton: I think the way it's written that you could interpret that it doesn't apply to an ASC, because it says acute, acute, acute, acute, acute, meaning that this standard applies to acute. I think it ought to apply to any provider that wants to provide the service rather than an acute facility.

Ms. Sonia Hamilton: Well, and Mary Ann, I would presume that anybody who wanted to offer lithotripsy services would have to go through review correct? I guess when these Standards were developed, that's probably the only place the service was being provided and it hasn't been updated, but if an ambulatory surgery center came in seeking to provide the service, they would have to meet the same criteria as are in the Standards currently, even though it says acute care facility.

Mr. Ed Hamilton: I would hope so, yes.

Ms. Sonia Chambers: But you're right, if this is going to continue to be reviewed, then we certainly need to change that language to indicate place of service or facility as opposed to acute care facility.

Mr. Joseph Letnaunchyn: Just to respond to the comments and to cross. I agree about looking at where the services are provided, but the issue of cost was raised and I would just suggest that if the Authority continues to, I know we're talking about services, but if you look at things from that perspective of cost, [inaudible] quality and I'm just putting that now, because I know you do and I'm just focusing on cost and not looking at access which is rural areas in the state, whether it's going to a hospital or physician or whatever, we're not in a metropolitan area. We have 55 counties and I think 11 that don't have hospitals, so those people are already traveling to access this, but it has to be balanced with cost and quality.

Ms. Marianne Kapinos: Maybe Ann, I don't know who can answer this. What is the average cost of a mobile unit versus a fixed unit?

Ms. Ann Stevens: You mean to purchase?

Ms. Marianne Kapinos: Right, the purchase price.

Ms. Ann Stevens: Well the mobile unit and fixed unit, the difference is the transport vehicle, the lithotripter cost would be...

Ms. Marianne Kapinos: The same...

Ms. Ann Stevens: Yes.

Ms. Marianne Kapinos: And what is that cost?

Ms. Ann Stevens: It varies. There has to be a dozen manufacturers and I'm not familiar with all the prices of the manufacturers, unfortunately, but they range anywhere from, for just the lithotripter and not the associated equipment, anywhere from probably \$200,000 to probably \$650,000, \$700,000.

Ms. Marianne Kapinos: And that's just for the lithotripter itself?

Ms. Ann Stevens: That is correct.

Ms. Marianne Kapinos: Does that include one of the small mobile lithotripters?

Ms. Ann Stevens: Well, as medical technology has changed, there are not very many in the United States of the “large machines that were on semi trucks”. They’re now all what we call transportable in the mobile environment, in other words, servicing multiple facilities, so most machines are transportable at this time, almost all machines. In other words for example, we pull up to a facility in a Ford 550 with an 18-foot box on the back, we unload the equipment with a hydraulic lift, take it into the facility to treat cases, and reverse the process at the end of the day.

Ms. Sonia Chambers: Okay, so the treatments are now done in the facility with the mobile thing as opposed to patient’s going out to the semi?

Ms. Ann Stevens: That is correct.

Ms. Marilyn White: On the same vein there, are what 90%, 95% of these performed as an outpatient even though they’re at an acute care setting, would it be an outpatient procedure in billing?

Ms. Ann Stevens: Yes, I believe probably, Dr. Morabito correct me if I’m wrong, probably 95% are done as an outpatient. There are times when something is askew and obviously the patient is admitted for a stay, but yes, it’s a hospital-based outpatient procedure.

Dr. Rocco Morabito: Right and the only other circumstance might be a patient, since these mobile units are not housed at each hospital every day, they may come once a week or once every other week, if a patient is admitted on a Monday, say for example with a kidney stone, and the lithotripter is there on Wednesday, they may be an inpatient at that time, but most of the treatments are done as an outpatient.

Mr. Rick Hughes: Just to clarify a little bit what Ann said, probably when you include the table, the imaging, and the machine and the transport vehicle, really the lower end that Ann mentioned as \$200,000 is probably more like \$500,000. I just wanted to make sure that we clarified that the lithotripter is one piece of it, but all in, what you need to do to service, probably the lowest end is half a million dollars and you can find manufacturers of equipment out there that are still around a million dollars.

Ms. Sonia Chambers: Okay. All right, is there anybody that didn’t have their opportunity to speak their mind, about this issue in particular? All right, if not, I really appreciate everybody taking the time today. This has been very informative. I think for those of us here at the Health Care Authority, this is not something that we’ve spent a lot of time on, but we appreciate that and we welcome your written comments.

Ms. Ann Stevens: Thank you very much for letting us have the opportunity.

Ms. Sonia Chambers: Thank you all very much.

[END OF AUDIO]