

Wilma: ... and it relates to this topic. Next slide. Next slide.

We have four objectives that we want to be able to bring to you today as far as this webinar ... The first one is to increase your knowledge units so that you'll be able to understand the usefulness of them, and also what some of the barriers are. Secondly, we want to demonstrate how medication units can increase capacity and access to care for individuals. Then we want to look at some of the current demographic settings where medication units are currently existing, and then lastly, what are some of the cost benefits of medication units.

Next slide please. What you'll hear from people today is our goals are a little bit of the rules and regulations that relates to SAMHSA, and then we have the speaker from DEA who's going to talk about their rules and regulations. Then we're going to have someone from a state who's going to talk about his experiences developing some of the state's medication units, as well as we're going to have someone from the program and they going to be talking about their experiences, successes and barriers in starting up a medication unit. Then, we'll talk a little bit about what the cost benefits of medication units are. Next slide please.

As far as SAMHSA and what our regulations say this right here will give you a definition of what a medication unit is. A medication unit is a facility that is geographically separated from the home OTP. Their main job is to administer medications at that facility, and they also can do collecting of samples and drug testing and analysis. Next slide.

The other part of the definition, it states that, again, it has to be a separate facility. If you are going to do a medication unit, you must resubmit a [SMA-162 to us, and mark off the medication room. It has to come from the home OTP. Please do not give out a separate OTP number for a medication unit. We use the same OTP number as the home OTP.

Sorry, 21 CFR, part 1300, which is DEA, and our speaker could go into a lot more detail about that in a few minutes.

Medication units shall comprise of all pertinent state laws and regulations. The medication unit cannot provide counseling and medical services at the unit. This needs to be provided at the home OTP. There is no Federal rule about the number of persons that can be seen by a medication unit, but the home OTP should always be looking at what the cost factors and there's a number of persons that you get. The point there, is it economically feasible to keep it as a medication unit, or do you get a larger number of people? When is it that you should think about linking as a full OTP? Next slide please.

We sent out a survey to all of the SOTAs to ask them about medication units. We ended up with ... When I say we, it was compiled by NASADAD on behalf of SAMHSA. There were 34 states in Puerto Rico who responded to the survey and those who responded, there was only 2, Kentucky and Massachusetts, and Puerto Rico who said they had medication units. Kentucky have 4 medication units, Puerto Rico had 2 and Massachusetts did specify the number of medication units they have within their state.

Five states indicated to us that Medicaid will reimburse for client travel to access an OTP and over 60% of the states reported that some clients travelled over 76 miles to be able to even get to an OTP. Out of that 60%, 40% of them travelled over 100 miles to get to an OTP. For us, that is an access issue because we know that a lot of people don't come to the OTP if they have to travel that far. Eight states reported to us that their state had policies or issues that will prevent them from the development of a medication unit. Some of those states, we're probably going to work with to see whether we can give them any technical assistance if they're interested in setting up a medication unit.

Then, 20 states reported to us that they would like to have more information and technical assistance about medication units and again, that's the reason why we're having this webinar today. Next slide.

Some states have Medicaid reimbursement for the transportation, for transporting patients to OTPs. The reason why we are bringing that up is because sometimes the cost of paying for people to get to the OTP is more costly than what it would be to set up a medication unit. We want states to really think about that and look at that, and see whether they can do some different type of planning. We know that for you to do this, it has to be part of your Medicaid plan, and a lot of people forget to just put it in there.

States may want to evaluate the cost of the Medicaid reimbursement, as I've stated, of transporting a person, versus the cost of establishing a medication unit. There's one state, Minnesota, where they have quite a bit of experience in this, and I'm going to ask Mr. Moldenhauer if he could speak just for a few minutes about his experience of Medicaid reimbursement for transportation of clients].

Rick: ... hear me. Hi, can you hear me?

Wilma: Yes.

Rick: Hello, hi. Yes, this is Rick Moldenhauer. I'm the state opioid treatment authority for Minnesota. The situation we have here is in Minnesota we have 87 counties,

11 tribes, 86,939 square miles of what is increasingly frozen tundra. I have 18 OTPs here right now and as of today, 5700 and some odd change number of clients. In the past, we have had a smaller number of OTPs, but we had both medication units and mobile methadone units. The problem that we're faced with is geographic, primarily. Most of our OTPs are huddled right in and around major metropolitan areas, specifically the twin cities in Minneapolis and Saint Paul. It is not at all uncommon for us to have people who drive 2, 3 hours each way in order to get here. We also have a significant amount of border bleeding from other surrounding states, when they fill up or something happens where they come over to us to Minnesota.

One of the ways that we were able in the past to really affectively serve a lot of those clients was through remote dosing and/or mobile methadone units. Our Medicaid plan does allow for reimbursement to transportation agencies for someone who is on a medical assistance. Let me give you one example of the cost of that. Last year one of our programs in one calendar year billed the state for 3.2 million dollars in taxis, buses, and cabs, just taking clients back and forth, to and from the program for dosing. That is far in excess of what it cost us to establish remote sites or a mobile unit that simply drove around to other locations.

As we're in winter now and increasing problems with that, folks who live remotely simply can't get to the OTP. The solution that we had for a quite a while was remote sites and a mobile unit. What we have been told by our local DEA here is that and NTP in their language is an NTP, is an NTP. They do not recognize remote dosing sites; ergo you have to establish new OTPs under their rules, and that's been the end of the discussion now for some time. This creates a lot of problems for us as a state, financially. It creates a tremendous barrier to people who live deep and far out of state where they are shoveling out as we speak right now.

We would certainly prefer to be able to establish additional medication sites and units in some of those remote areas. When we had them in the past, it was never a problem or an issue. None of the mobile units ever broke down. None of them ever got hit by somebody stealing the methadone. We never had any problem with them, and so from our perspective, we would strongly encourage and support the allowance to reestablish those units.

Wilma: Okay, thank you. I think part of the issue that we're trying to bring up with what Rick was just talking about is to say okay, if one OTP have clients that come in there and Medicaid has paid 3.2 million dollars to establish a medication unit. Now, in a place that's out, that's very rural like that. Even if they had to go through the full certification with DEA, it's not going to cost that amount of

money. It's much more advantageous if you can set up a smaller medication unit, versus not having anything out in some of the areas.

Another thing that we've seen is urban areas, when they've set up medication units is that they set them up because they had such a long waiting list of people. When they had those long waiting lists, taking different ones in and out the medication unit but they still had to come to the OTP for their counseling and have a medical appointment, but it gives them more flexibility to be able to do that. Okay, next slide please.

We have three additional speakers for you today. The first one is Mr. Jim Arnold with the DEA. He'll be able to tell about their rules and regulations and why you have to go through the full certification through them. Then we have Mr. Mark Fisher, who is the SOTA] from Kentucky who's going to talk about what's some of the things they had to do in Kentucky to prepare themselves to get medication units within Kentucky. Then lastly, we have Ms. Holly Broce, who is going to talk about establishing and implementing medication units within Kentucky, and she's with Pinnacle Treatment Centers.

At this point, let me give you a little bit ... The next slide please ... a little bit of instructions on how we're going to do these three presentations. Each individual is going to do their presentation. At the end of their presentation, you have the opportunity to ask questions. How you do that, if you look to the right hand side of your computer, there's a question can be submitted within the question panel on that right hand side of the webinar page. You can type them in and what I'll do is read them off to the presenter, who will answer the questions.

Because we have limited time, if we don't get to your question, we're asking the presenter to be able to write the answers to the questions. We will make sure that we will get those answers up on our website, the DPT website with the slides, so you can see what the answers are, if we don't get to the questions. Next slide.

Lastly, once we sign off, you'll find an evaluation will pop up on your screen. Please fill out the evaluation, so you'll be able to help us to be able to have other webinars and to establish some things in terms of making our webinars better. Lastly, please tell us of any topical areas that you would like to do a webinar or some other type of training in, so that we will be able to assist you within the future.

With that, let me turn it over to Mr. Jim Arnold. Jim, again is with DEA and he's going to go over the rules and regulations within DEA. Thank you, Jim. Jim.

Mark Fiery: Wilma, this is Mark Fiery. I'll see if I can get Jim back on the line here. Hold on one moment.

Wilma: Okay.

Jim: Hello.

Wilma: Hi, Jim ...

Jim: Can you hear me.

Wilma: Yeah. Thank you.

Jim: I can continue now.

Wilma: Yes.

Jim: All right, very good. I am quite familiar with the subject and I will do my best to address the issues as they are presented. Mark, my slides won't advance. Maybe you might have to do it for me.

Mark Fiery: No problem, I'll take care of that. Just let me know when you want to go ahead.

Jim: Yeah, I pushed a couple of times here and it won't go forward.

Mark Fiery: Okay, I'll take care of that for you. There we go.

Jim: Thank you. The DEA's mission, The Office of Diversion Control's mission is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels, while at the same time ensuring that there's an adequate and uninterrupted supply of those substances to meet ... And this is the important part ... legitimate medical, commercial, and scientific needs.

We really have a two-part mission. Our basic function concerns the public health and safety; that's our basic mission but, like I said, we have this two-part mission in terms of investigating diversion and trying to keep those controlled substances from going to places that they're not supposed to be going; to keep them from going out onto the street for illegal sale and diversion of those substances. At the same time, making sure that these substances, there's enough available to make sure that people get what they need for legitimate medical need. Next slide Mark.

The authority for this, it comes to the law, the regulations, and policy; this all works together when we look at an issue or make a determination about what can or cannot be done when it comes to controlled substances. Next slide Mark. As you've already heard from Wilma, this is the definition that's listed under their regulations, in terms of a medication unit. The reason why I am bringing this up again, or looking at this issue, the important part, it is a facility established and it's separate from the main NTP. The important part it is a location where controlled substances are dispensed or administered; that's the important part of this whole issue as far as DEA is concerned and Federal law, and regulation are concerned. Next Mark.

By law, by statute, by Federal law, any person who manufactures or distributes ... Next Mark ... or who dispenses controlled substances, anyone at all, has to get a registration from DEA in order to conduct those activities with controlled substances. Next. As such, each and every location, physical location where controlled substances are stored and dispensed, distributed, manufactured, imported, exported, had to have a registration with DEA and have to have a central point where DEA can come and look at the situation in making sure that the appropriate thing is being done with controlled substances. These controlled substances can only be ordered under that number, they can only be dispensed under that number and they can only be destroyed under that number.

Everything is contingent upon a DEA registration. How much controlled substances you have coming in the door and how much controlled substances are going out in terms of dispensing, in terms of destructions, if there's a loss or a theft, everything works together to account for all the controlled substances that come into a particular DEA registration. This all has to do with accountability and a large assistance in making sure that the drugs get to where they need to go and stay off the street, and do not get involved in illegal distribution schemes and dispensing schemes. I'm sure you read the newspapers and look at the TV, and know that there's plenty of that kind of activity going on, unfortunately.

The important part about the law, and once again I keep referring to the law because it's very, very important. We can't change the law. We can't change the statute, so we are tied to what the law says in terms of controlled substances. Each and every location where controlled substances are dispensed or distributed, manufactured, whatever, have to have a separate registration. That is the important part of this slide. Next Mark.

Each and every registrant, DEA registrant, each and every DEA registration, whoever is responsible for that registration has certain responsibilities and things that they have to do, once again, under the law in terms of keeping inventories, in terms of taking a biannual inventory every 2 years; that is all part

of Federal statute and that is something that cannot be changed by DEA. That can only be changed by congress. Next Mark.

Also, the important part is in this responsibility of receiving and dispensing and distributing controlled substances, there must be a complete and accurate record of each substance from start to finish, in terms of what happens with the controlled substances, where they go, who they're sold to, if they're disposed of. There has to be complete accounting for the controlled substances. Once again, the important part is maintaining control over the controlled substances, once again, to make sure that they then are not being stolen or not being diverted and end up in the illicit market. Next Mark.

The records have to meet certain information and be in a form that is required by regulation. They have to be readily retrievable and the records have to be kept for 2 years. Next. Although medication units are exempt from NTP/OTP licensing requirements by CSAT under Federal law, as I showed you, under Federal law, we have to have a separate DEA NTP registration for each and every location, the principal place of business where controlled substances are sold, dispensed, stored et cetera. These medication units, just like NTPs, narcotic treatment programs is what they will be registered as, are required to maintain separate inventories, records, reports, and security, which is a large part of our program to help prevent diversion and the movement of the controlled substances onto the street. Next.

The only other way of expanding narcotic treatment are regulations. The regulations in general allow currently approved medications, methadone, buprenorphine, buprenorphine combination products be dispensed directly to the patient by a practitioner registered with DEA as a narcotic program. The important part of that, the medical director is the one who is ultimately responsible for insuring that all these conditions in terms of keeping track of the controlled substances and the record keeping and everything is being complied with. As you know, as a narcotic treatment program, prescribing is still prohibited under a registration. Next Mark.

At the same time, DEA, the Attorney General and DEA is authorized to inspect any DEA registrant or any establishment that's registered with DEA, or any applicant for registration, in order to make a determination, make sure that the registration or the registrant is working appropriately and complying with the regulations. That's our important role in this whole mix. Next. Some of the record requirements. You'll probably find this very helpful. The presentation is here. If you have questions about inventories, what needs to be done or kept for how long, or dispensing records, and when information needs to be kept as far

as dispensing records are concerned, or drug distraction, or reports that there's a loss, all these particular sites can give you that information and direct you in terms of record keeping and reporting, and inventories. Next.

Basically, dispensing records, whatever that might be, a dispensing log, these are the requirements as far as the regulations are concerned, in terms of the methadone or the dispensing that occurs; the name of the substance, the strength, the dosage form, the date dispensed, the dispenser's initials, and the amount consumed, the amount and dosage form taken home by the patient. Like I said, it all has to do with accountability and making sure that the controlled substances are actually being distributed for legitimate medical purposes, and aren't being, like I said, diverted onto the street. Next Mark.

There's also security involved. When we come in to inspect an establishment or look at a new application, there is certain security that has to be present in order for the controlled substances. Once again, the whole point of the regulations is to protect the controlled substances and do everything humanly possible to secure the controlled substances. Here are the particular sites, or if you want to know about the regulations when it concerned what is required in terms of safes or for the methadone, this is what's involved; the alarm systems basically and accessibility to controlled substances.

You may want to take a quick look at this particular section. It has a lot of really good information in it. It's very quick, short, and to the point, and it tells you exactly who is responsible from start to finish when the controlled substances come in the door and what should happen. That should be very, very helpful to you. Next Mark.

One of the regulations and this comes up a lot in terms of security. Each and every situation is unique and different. There are different building types. There are different building structures. There are different locations. There are a different number of individuals involved. They are sometimes located in bad parts of the city, sometimes in good parts of the city. All of that are factors and we take into consideration and look at the overall picture in making determinations about security, and what's required for security

In one location, we may ask a little bit more than another location, and it has to do with, once again, with the overall situation, what we're seeing on the ground. This is an area where our expertise can help you and help us as well, in terms of trying to keep the drugs off the street. We see things because we're trained and because we have experience in this area that you may or may not see. We see blind spots. We see motion detectors. We see camera. Over my 26 years of experience, if there's a way to divert a controlled substance, we've seen it, from

manufacturers, distributors. There are all kinds of schemes and all kinds of ways that this is done.

Like I said, that's our prime responsibility, is to make sure and try to help and prevent, and detect and keep that kind of activity from occurring. We're not here to interfere with legitimate business. We're not here to interfere with the practice of medicine. Contrary to what people may have heard or seen that's not our function. Our prime function is the public and their safety. That's our prime directive. Next.

The point of that whole slide is discretion, and when it comes to security; that's the whole point. We have a website and if you would want to submit a new application for a medication unit you would go online, and you see the red arrow at the top of the screen. If you click on registration, it will take you into the DEA forms. You'll pull up a DEA 363, and once again, you'd be registered as narcotic treatment program. Medication units are not a problem, but like I said, because of the law, the way it's written, the way it is, each and every location ... any location where controlled substances are stored and dispensed must have a DEA registration.

If you look over to the right, you will see publications and manuals. If you click on that ... Next Mark ... and you click on manuals again ... Next Mark ... we have a lot of information on our website. One of the things that we have on our website is a best practice guideline when it comes to narcotic treatment programs. You may find this helpful; that might be helpful to you. Next.

If you have any questions, I can listen to your questions and if it's a relatively simple matter, I can answer them. If it's a little more complex, we'll probably want to get back to you in writing. If you do have questions, especially when it comes to policy issues or whatever, you can send them to us at this address: [ODL@dea.usdoj.gov](mailto:ODL@dea.usdoj.gov). Next. That's the end of my presentation for today. I hope I wasn't too long-winded, and I hope everybody was able to hear me.

Thank you very much for having us.

Wilma: Thank you Jim. We have two questions for you.

Jim: Okay.

Wilma: The first one is if someone is thinking about starting a medication unit, what would you recommend how they should work with DEA?

Jim: Well, the first thing is to go online and fill out an application. That automatically goes into our computer system and sent to the field. The field will be in contact

with you. One of the important parts of the inspection and the overall approval of the application or the registration is security. If you have questions about security or even before you put it in, if you want to pick up the phone and call DEA and submit plans or tell us this is what you envision or have in mind, and would that be okay with DEA, that would probably be helpful, just so you don't go ahead and do something that you don't need to do, or you go ahead and do something that may be incorrect. That might help in the beginning, communicating with us directly about what you intend to do as far as security is concerned. That probably might be very, very helpful to both of us.

Wilma: The second question is in relationship to mobile vans that people know you no longer approve mobile vans, but they wanted to know ... The question was, did you grandfather in those that was already up, or did you just close them all down?

Jim: That's a question that we would have to look at, and could be sent to us online and we could get back to them.

Wilma: Okay.

Jim: This issue is being looked at. I don't know what's going to happen but you could submit that issue to us online if you so desire.

Wilma: Okay, it sounds good. Thank you very much Jim.

Jim: Thank you.

Wilma: Let's now move to Mark Fisher, who is the SOTA of the State of Kentucky, and talk about his experience at the state level, of what they did to assist in getting a medication unit in the State of Kentucky. Mark ...

Mark Fisher: Thanks Wilma, I appreciate it. I'm going to get my slides up. We can start. There we go, thank you very much Mark. I want you to take particular attention, and you might want to even Google at the top of this slide, this is the regulatory authority that gives us the ability to expand our narcotic treatment programs by Kentucky medication units; that is that 908 KAR 1;340 at the top of the page. You may want to write that down separately and take a look at our regulations. It gives you a pretty good, clear idea on how we do operate from the authority from the state government.

Mark, I believe I will need for you to advance my slides as well. Okay, thank you.

What we have done, we have set up a protocol for establishing of a medication station. So if a narcotic program voluntarily decides to establish the medication

station, there's more different folks that you should be contacting in letting for notification. I would actually start with the Office of Inspector General within your state, the drug enforcement administration CSAT, and also your state narcotic authority so that plans within 90 days of your proposed relocation or location of your medication station. These medication stations, again, back into your regulation, and it's within that body of 908 KAR that they can only be opened no closer than 45 miles and no further than 90 miles to the main OTP.

Within those regulations as well, it indicates that the medication can provide 2 different services. They can provide the medications dispensing and they can do the drugs screening component. However, they have to go back to the main OTP, of which the medication station is assigned, or their counseling component and that again, is by regulation from 908 KAR. Next slide.

Continuing with our statement of purpose is that to insure that all regulatory compliances and requirements across the state and procedure obtain ... Your first step is obviously to obtain a certificate of occupation and a local business license. This is the last week. This is part of regulation, but it is an issue that public forums, sitting approvals other than that are certification of occupancy are not a regulatory requirement.

However, I strongly encourage the providers to make intent of helping a facility in whatever community you've got to be as transparent as possible to all key players within that region, both the city, the county, the [civic leaders 00:38:39 during this process. Also, involve either your community mental health center and/or your other provider of substance use services that you intend to operate a medication station. Let your intent be known and be as public transparent as possible in this process, to affect a good start up, and starting out on the right foot. Next slide please.

Other protocols to apply, not only with CSAT, but that you submit an early intent application through the Office of the Inspector General here within the state, and then apply for your alcohol and other drug entity outpatient license from the Office of the Inspector General. I've given you a link to what ours look here in the State of Kentucky, there. You can click on that. Then, literally, you will have an inspection by the Office of Inspector General, and then the AOB new license is obtained. Then you can apply for a license with CSAT and DEA in Washington. Next slide please.

Also, it is part of the Kentucky regulation that you should have a memorandum agreement that you would have cooperation from law enforcement, hospital, mental health, also rehabilitation and a private therapist. Then lastly obtain, like Jim had mentioned, obtain the DEA inspection after the building alarms and safe were in place at the facility, also your security cameras and your panic alarms,

and all of those things that both the DEA office and the SOTA office will be looking for.

Then, your final inspection, in Kentucky, by the Division of Behavioral Health. Lastly, then that would free you up to complete all of your DEA form, 222 for ordering your medication. Next slide.

I gave you a highlight of the controlled substance usage in our state. As you can see, in the far eastern part of the state and north and north central is a real hot bed of activity in regards to controlled substance usage. As I talked to our potential providers, we go over this type of information that wherever would be better suited to increase capacity, and as far as in the areas of need within our state ... Next slide.

This is also a duplication of our drug holder overdose stats that we saw mostly in the ... Then again, it's in the far eastern part of our state and north central, and that's for 100,000 in our state, and then again on that, where the providers, if they work to better provide to expand services to those of need in regards to overdose stats and the prescription of drugs, of prescribing of those safe substances in our state. Next slide.

If I can overlay this map, you can see that they pretty much correspond to the areas with the greatest need. We're currently up to 20 OTP programs within the state, 6 of which are medications patients. We've had really good success in expanding capacity. As we continue to work and to increase capacity ... Next slide ...

The overall benefit of medication stations has been a real Godsend for the folks in Kentucky, because not only have we increased the ability to have capacity within the state since only August 2013 by having these facilities, we have increased overall capacity by 63%. Also, as another benefit that we have got more people into treatment in the past several years. It's 62% of what we're treating up to, almost 4500 individuals currently here in the State of Kentucky. It's been a real win-win system to expand capacity and to go into these areas so we don't have those prohibitive drives that are 70 miles and 80 miles away.

One other thing that I would like to note and it is a huge cost within your Medicaid budgets is the transportation issue. Well, Kentucky, when we expanded our medication assisted treatment to include medications, assisted treatment programs, we have done that with everything, and we cover all of the services except the drug itself, methadone, within these programs. That in itself does take the transportation portion of the expansion of capacity, because pretty much it would be a Medicaid budget buster if we were to travel and have to provide transportation to some of these folks that live 50 or 60 miles away

from these facilities. That was one area that we could circumvent the added transportation cost, but in turn, increase capacity and having more people in receiving treatment in our state.

This is my contact information on the next slide, please. I welcome any questions and comments, or email me directly, and we're glad to help you out. Okay, Wilma, it's all yours.

Wilma: Okay, thanks Mark. One of the things about your presentation that I think people really need to think about is that you were able to establish some protocols on the state level that when you go to set up the medication units, a lot of the time people don't think of about it in the bigger picture what the protocols the state needs to be established. Then, the other thing is you've really done your homework to figure out where it is that you needed some medication units, which is very, very, very important. With that ...

Mark Fisher: Thanks Wilma, and one more point, and you are totally correct that not only to Office of Inspector General, but the DEA and all of those groups have to come together and agree together on this is the direction that we're going, and work closely with each other to go ahead and expand our capacity for this very much needed field. I'll leave you with that and thank you very much for your time.

Wilma: I have a couple of questions for you. One is how will you handle the transportation? Do you provide it up to a certain mileage limit?

Mark Fisher: No, I just have talked about that. Since we do not cover the cost of the medication, only we cover the cost of the all of the ancillary services, that the transportation portion of that is not included. We don't transport any residents anywhere across the state in regards to medication-assisted treatment.

Wilma: The second question is what is the average census at your state medication unit? I don't know whether you want answer that, or wait for Holly to answer it.

Mark Fisher: I can tell you historically that one of the medication units has grown to capacity to the point where they can be self-sustaining financially, and have applied for and have gotten a full OTP licensure, and is operating as a full OTP. That's our goal, is to grow these medication stations. As we help more and more people in need and as they're growing to be financially established for these providers and work that way to continue to increase capacity state-wide.

Wilma: Mark, what was the census of that place, once they got to the place that that's going to be a full OTP? About how many clients do they have coming there?

Mark Fisher: I have talked with several of the providers and they say a lot of times that they, level of 100 clients, is kind of like a tipping point of being financially viable.

Wilma: Okay, great. Thank you again.

Mark Fisher: All right, thanks.

Wilma: Now, let's turn it over to Holly Broce, who has implemented starting medication units throughout Kentucky. She's going to talk to us about her experiences in doing that 00:48:24. Holly ...

Holly: Than you Wilma. Yes, again, my name is Holly Broce. I'm at Pinnacle Treatment Centers. I am a regional director for the southern region, which includes Kentucky. We can move to the first slide. As a SOTA, your OTPs may ask you, where do I start in all of this? Most everything on this slide has been mentioned previously, but just to reiterate, you must submit a CSAT SMA 162 application online, as Ms. Townsend mentioned. Also, you apply for a separate DEA registration number, as Mr. Arnold mentioned.

Then, at your state level, I can't stress enough the importance of the provider having communication with the SOTA. Mr. Fisher mentioned that we have state regulations that speak to medication units, when I think, maybe, many states in our nation do not. So 908 KAR 1:340, section 18 talks to that. In addition to the state and Federal items, we also ... As Mark Fisher mentioned, you need to make sure that you speak with your local community, you know how to apply for the local business license and your certificate of occupancy. We can move to the next slide.

In Kentucky, we have regulations, and the 2 main that we've talked about already today, if a medication unit can be located within 45 to 90 miles of the main facility. Strategically, you need to look at where's the best area to place this facility. I was able to work with Mark Fisher and talk about what areas are in the greatest need. Secondly, the medication must be obtained from the main clinic. Because of that, your facilities, you need to make sure they have policies and procedures in place of how they're going to do that. The DEA and the state will look at your policies and make sure that they're in compliance. Next slide.

Under the Drug Enforcement Administration, you need to think about it as the medication unit must meet all the same requirements of a full clinic. They should have a narcotics safe that meet all the requirements, as well as a security system in place. You also will have all the same diversion control practices in place, and the DEA registration number. Next slide.

Then, under the center for substance abuse treatments, the SMA 162 application is done online through the OTP extranet site, which everyone on this call is familiar with. I was required to attach some language to this application, indicating that I understood we could only do medication and drug counseling, or drug screening at those medication units, meaning we could not do counseling. I put some language here to help you with that. Secondly, as a program sponsor, I had to affirm that I have oversight and patient care in both the main site and the med unit location. Next slide.

Then the medication unit would go through all the same inspections pretty much as you would for a full clinic. I work closely with Mark Fisher. He actually made a couple of visits to our medication unit. He came to visit during the construction of the facility, as well as at the pre-opening final inspection. Then, the DEA, once you've completed the online application, the local field office will reach out to you, as Mr. Arnold mentioned, and will schedule a time for their visit. They will come and do a full security system test, look at all the procedures and policies, and meet with the staff that will have administration over this facility.

Then, important to mention is your accreditation body, where you use KAR or a joint commission, or COA. You have to let the accrediting body know that you intend to open a medication unit. If you have a survey upcoming, which we did because we were very new in the state of Kentucky ... At the time of our first CARF survey in northern Kentucky, one of our medication units was open and so CARF actually to visit that facility during the survey. Their focus as a medication unit is to look to see that all the same health and safety practices are in place, as well as all the same standards are followed, so the health and safety of the patients is maintained. Next slide.

Current medication units in Kentucky; another program in Kentucky under Center for Behavioral Health, has one in Elizabethtown. Actually, Elizabethtown is the main clinic, and then they have a med clinic Bowling Green, Kentucky. I work for Pinnacle Treatment Centers, and we have 2 main clinics in the state under Northern Kentucky Med Clinic. In Covington Kentucky, we have located and successfully opened 3 medication units, all within the 45 and 90 mile radius we mentioned earlier. Those are located in Georgetown Kentucky, Carrollton Kentucky, and Maysville.

I believe someone asked the question earlier about how many patients we have attending those clinics. I'll be happy to share those numbers. We have at those 3 med units I've just mentioned, off the northern Kentucky Med Clinic, around 50 patients that attend those 3 sites right now. Again, we are very new; all of those were opened in 2014.

Our next main clinic in Kentucky is in Hopkinsville, and the name of that is Western Kentucky Medical. We have opened one med unit so far in Owensboro, Kentucky; it opened in September. We have another one in process. We're actually in the final stages of opening that. We hope to have all the final approvals next month. That will be located in Franklin, Kentucky. Next slide. Next slide.

Why medication units? This is call is all about why would you go to this trouble? In Kentucky, it's really a no-brainer. Kentucky is much like Minnesota that was mentioned earlier. It's a very rural state. We have 120 counties and our patients drive very long distances to get to facilities. The Kentucky regulations do require daily attendance for longer than some other states in the country, and so it's very prohibitive for patients to get to work and do the things they need to do when they are having to drive to the main clinic on a daily basis. It was mentioned, many patients drive 1 hour or 2 hours one way, or even longer to get to a facility. By adding these medication units, we have definitely increased access for patients. Next slide.

The medication assisted treatment goals; obviously, we all want our patients to be working. We want them to reenter society and be successful, and by taxpaying citizens. We want our patients to care for their families. We want them to become financially stable. My experience is they're not able to do that if they're driving 2 to 4 hours a day just to get their medication that they need. Next slide.

In summary, the access in Kentucky was increased. Mark talked a little bit about just how adding all the new clinics and the med units added capacity and options for patients. Just adding the med units themselves increased treatment options by 28%, which I think is great.

Another question that may be interesting to you all is just to talk a little bit about the cost of medication units. You're increasing access for the patients, and that's our goal, but it does add a little bit of a burden to the main site. You are adding staff, and you have to look at where the facility should be placed. Can your staff get there easily to assist nursing and receptionist at the location? The build out of a medication unit is very similar to a full clinic, although you don't need the counseling space or the medical exam space. You have to look at your square footage, and then think about do you have room to expand into a full clinic if indeed the med unit can support that.

That concludes my portion. Wilma, I'll hand it back to you.

Wilma: Thank you Holly. We have a couple of questions for you that have come through. One, that you said with the 3 units that this 50 people. Is it 50 people as a total for all 3, or 50 people in each one of the clinics?

Holly: At this time it is 50 total.

Wilma: Okay. Then, someone also asked do you have border creeping going on?

Holly: I'm sorry, can you repeat that Wilma?

Wilma: Do you have border creeping, where people are coming across from other states?

Holly: Oh, border creeping. Well, we actually have the opposite issue here in Kentucky. For many, many year patients have been driving out of state to get treatment, to get services. By adding the medication units we've actually seen residents of Kentucky transfer back in to a Kentucky program, when they were driving out of state. For example, our Owensboro facility that we opened up the end of September, we have about 20 patients that go there now. Most of those were actually Kentucky residents that were driving over to Indiana.

Wilma: One other question for you, Mark Fisher, someone asked was it difficult to get the regs for the medication unit's passed. Mark ...

Mark Fisher: I'm sorry ...

Wilma: Someone asked a question was it difficult to get the state [inaudible 01:00:58] for Kentucky to pass the medication units?

Mark Fisher: Was it ... I'm still not sure exactly ... what was what in place?

Wilma: Was it difficult to get your regulations passed for medication units, your state regulations?

Mark Fisher: No they were not. That 908 KAR 1:340 has been in place for several years now. They had the foresight to include medication stations in that process, knowing that access was such a huge issue within our state, and the folks would have to travel so far. That's been in place for a long time. It's just that we really, in the past couple of years, have really opened that up and tried to develop and take advantage of that rule so we can expand the capacity within the state. It's been a real good thing.

Wilma: This is for both you and Holly. From the time that we did the survey, you had 4 medication units. Then you reported that now you have 6 and you're getting

ready to open up a 7<sup>th</sup> one. They're beginning to worry. What's happening in Kentucky that's making for people to understand to start using medication units as a method of access to treatment for people? Could you hear me?

Mark Fisher: Yes, we do a lot of pre-opening work, if you will, by offering to speak to the Rotary clubs and to the different civic organizations to explain and help them understand what the magnitude of the problem is in their community, because a lot of times they do not. They explain the intent on what treatment options will be happening for those in those communities. We do a lot of transparency work beforehand to get an eye into recovery. I don't know if Holly wants to add anymore to that or not, but that's the process which we take.

Holly: Yes, I agree with that. In Kentucky, there is a memorandum of agreement that's required with local providers and services. That definitely is key and Mark and I have teamed up to present to local communities. That's been very helpful, but I think also, it's just working for an organization that's willing to look outside the box. Pinnacle Treatment Centers had not opened any medication units previous to this. We thought we would give it a try and see if it will help patients, more patients get help and get treatment.

Wilma: Very good. Thank you so much Holly. Your presentation really brings it home about what it is that people need to do, that it does help in getting individuals to come in for services. Anytime you can state that you have people from your state that are going to another state, and now they're able, it seems that they can get services right in their home communities; that's a wonderful thing.

At this point, we don't have any additional questions. If people have any, if you could type them in real quickly, we have a few more minutes before we all close off. I think this has been a wonderful communication. We've got to hear from people that told us about the regulations. We got to hear from the state perspective, and how they're able to set up their system in a way that supports setting up medication units. And you got to hear from someone who's implementing medication units, and how those units are being able to help people to access services, and being able to get treatment in a way that's more advantageous to them, rather than driving an hour to 2 hours a day, each way, to be able to get services.

I do have a couple more questions that just popped up. Someone is asking whether any of the medication units are using buprenorphine products, being dispensed in their OTP, within their state, or are you just doing methadone in all of them?

Holly: At the Pinnacle treatment centers programs, we are only using methadone at this time.

Wilma: Okay, do you know of any Mark, where they're using buprenorphine and any of the other ones?

Mark Fisher: The ones that were listed for Center of Behavioral Health, they do have that second treatment option that they give the clients or that there's that option... Most of them are methadone clients; I would say upwards of 90 to 95% of them are straight methadone clients, yes.

Wilma: The next question is do our clients have to be stabilized at a home clinic before they can go to a medication unit?

Holly: Yes, we have a protocol in place for induction. The Medical Director will make that determination when it's safe for the patient to transfer to the medication unit. But again, we have the same nursing staff at both locations. As long as a Medical Director approves that, they can transfer to the medication unit.

Wilma: Holly, can you talk a little bit about the counseling and medical services that are not available at the medication unit; how do they go about getting this at their home OTP?

Holly: One day a week, we require that the patient return to the main location to receive their counseling services and any follow up medical services that they need. The way that we handle that is we actually close the main unit one day a week and we do a survey with the patients to figure out what day would be best for them and also, what works best at the main location. On that particular day, those patient drive to the main location for those services.

Wilma: Good, thank you. Okay, at this point we do not have any additional questions for the 3 of you, but do you have any closing remarks that you want to say? Okay, well, I think it has been wonderful. I think you've gotten the experience of 3 people who are out in the field, who are really doing this. For those of you who are thinking about putting ... Because again, we have a problem with people accessing services and more and more people are needing services. Medication units is one of the ways and one of the methods in which people can use to try to make sure that locals get services.

We will put these slides and answers up on our DPT website so that you can see them. We also recorded this session today, so you'll also be able to hear the recording as well. I want to thank everybody, especially for these presenters, and thank all of the audience who also was a part of this today. Hopefully you really think about whether or not medication units can be something that's beneficial for your state.

Thank you and goodbye everyone.