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Hope on the Horizon: New Directions in the Treatment of Opioid Use Disorder

Dr. Chapa:
Currently, the United States is battling two deadly opponents running rampant, COVID-19 and opioid use addiction, but these two threats aren't entirely isolated. In fact, epidemiologists are sounding the alarm that the current COVID climate is a risk factor for substance abuse relapse. Thankfully, 2021 brought revived hope to the opioid crisis battle with the Department of Health and Human Services announcement of a plan to drop the X-waiver requirement for buprenorphine prescriptions. So now the question becomes, how might this elimination help us win the battle against opioid addiction?

Welcome to *Clinician's Roundtable* on ReachMD. I'm Dr. Hector Chapa, and joining me in this discussion is Dr. Joshua Lee, Associate Professor of Population Health and Medicine and General Internal Medicine at the NYU Grossman School of Medicine. He's also the Director of the NYU Fellowship in Addiction Medicine. Dr. Lee, welcome to the program.

Dr. Lee:
Thank you for having me. Glad to be here.

Dr. Chapa:
Alright, Dr. Lee, let's start right off the top, because we've got lots to cover. And there's some physicians that have been in practice, know what they're doing, may not even have heard of the X-waiver. So let's start off with some basic history here. What can you tell us about the X-waiver to begin with? Why was it implemented? And was it a good thing or was it a potential barrier for physicians in offering opioid use disorder treatment?

Dr. Lee:
The X-waiver came about through an act of Congress. It was called DATA-2000 of the Drug Abuse Treatment Act of 2000. It was a recognition around Y2K that we had a really big opiate problem, which we did. And then it was still largely the prescription opiate era and that has evolved into the heroin fentanyl era. We can talk more about that. But in the late 90s, there was political movement to do something about it, and there was also good timing in that buprenorphine was very well studied at that point, had been used routinely in France and other countries through the 90s and was showing really good effectiveness in terms of a community population-wide intervention for opiate use disorders. So in 2000, it was approved that a medication other than methadone could be used for the treatment of opiate use disorder in the United States. That medicine was buprenorphine, which was approved in 2002 by the FDA for the opiate dependance indication, what we now generally are calling opiate use disorder. And that ushered in a new era of office-based treatment in the United States, where previously we could use methadone but only in an opiate treatment program, AKA a methadone clinic with buprenorphine. It was safer. It had less potential, likely for abuse, also for overdose and over-sedation if you were to take too much of it. And so it was approved as a Schedule III controlled substance as opposed to a Schedule I or II, but a Schedule II is most other opiates, including methadone. And it was not restricted to licensed opiate treatment programs, but could be used in general practice, could be used by an obstetrician, by a family doctor, by a psychiatrist. And that was seen as a great leap forward that we could now treat opiate use disorder, which had become a kind of national problem, often centered in doctor's offices in terms of over prescribing prescription opiates. And now we would have a good treatment to prescribe in those same settings.

However, I wasn't there for this, but my understanding has been that the heads of the fields of addiction psychiatry, what was becoming known as addiction medicine, and in the federal government, didn't want to just have another opiate that could then be prescribed too cavalierly from the same pill mills as the oxycodone. And they didn't want buprenorphine to kind of share that fate of other controlled substances and other opiates that have been overprescribed, and so they tried to thread the needle with the X-waiver and caps on how

many patients a X-waiver provider could prescribe to at any one time, essentially limiting at the prescriber level the use of buprenorphine opiate use disorder treatment. And that is how it remains today. So the X-waiver became this exception to pretty much any other medication prescribing and controlled substance prescribing in the United States for this one medication, buprenorphine. You needed to do eight hours of training and you needed to have your own DEA, which anybody would who was prescribing. But you had to then get a second DEA with an X as the first letter of that DEA. And now you could write a buprenorphine prescription, and a community pharmacy could fill that prescription for opiate use disorder.

And those are now the kind of gold standard most likely thing you and I would get if we had an opiate use disorder and walked into our doctor's office and asked for help. We wouldn't have to go to a licensed drug treatment or opiate treatment program. However, if we were in rehab, we could also get it there. If we were in the hospital, we could get it there. So it's been quite flexible, quite effective, quite successful. And it's been a big reason why we feel somewhat hopeful about the opioid epidemic, even though it's gotten a little worse under COVID. And it's still a huge problem that we can do something about it when the time comes to treat a patient.

Dr. Chapa:
For sure. I mean, anything that you don't have to go to a treatment facility and to do anything in the office, I think was definitely, a game changer. I think what some physicians saw, Dr. Lee, is, you know, I have to sit for an eight-hour course and then get another DEA fee and another DEA, you know, an X number. And so I think for some, especially not those who are potentially used to writing for these medications, maybe saw that as a barrier. So in that vein, what do you think the elimination of this waiver, or at least the discussion - that's the plan as far as January of 2021 - so what does this mean now? Now that this eight-hour restriction and this other training may be gone, do you think that more physicians will be likely to enter this MAT program for patients?

Dr. Lee:
Yeah, I think eventually getting rid of it makes a lot of sense. A lot of thought leaders in addiction medicine would advocate for that. There's kind of a growing movement on Twitter and actually a bipartisan proposal legislation in Congress now to get rid of it. Because it was originally an act of Congress. And I think the general thinking, I'm not a lawyer, is that you need another act of Congress to kind of undo the original one. So it is confusing, though, in the last - literally in the last couple of days of the Trump administration, they made this proposal that we will kind of suspend it, not necessarily once and for all strike it from the books, but we will suspend essentially the use of the X-waiver. And now we have a new administration. And the reading is that the Biden administration and the new DHHS will not endorse this kind of, late midnight-hour change and that the X-waiver is still the law of the land. So in fact, it looks like right now nothing has changed. But it seems as though the new administration feels you can't just do it by fiat, and you probably do need legislation as opposed to the secretary making a change.

Dr. Chapa:
Understood. But nonetheless, it's a move in the right direction. Is that fair? I mean, hopefully it's a move in the right direction.

Dr. Lee:
Yeah, I think most people would agree with that. All you need is a state medical license and maybe not even that, but you need your DEA number and you can write all sorts of medications at that point, for you know, you can be a bad doctor and run a pill mill. You can be a good doctor and write a lot of prescriptions for people that need them, that happen to be controlled substances. It's absurd that we would restrict this one particular medication, which is generally not heavily abused, although it's abuse potential is not zero. And while it is an opiate, is really not the one people turn to to get high or to develop an opiate problem in the first place and is a wonderful treatment and very effective and very safe and and it’s got wheels. You can be on it for years, as many people are, and do great and get your life back and really stabilize.

On the other hand, there has been good, solid advocacy that, no, we want people who are getting buprenorphine to get it from someone that knows what they're doing, from a doctor who has had some type of training we can point to like a minimum level of competency.

And there's something to be said for requiring trainings. And we're seeing now with opiate prescribing, any doctors now expected, often regulated at the state level to do some kind of opiate medication and risk mitigation training now. So it may just be that we need all sorts of new training and professional standards around controlled substance and opiate prescribing. And this was, in a sense, something we need to duplicate for every other opiate and keep it intact. But because we don't have that yet and probably will not quite get to that level of requirements for other opiates, I would then remain in favor of getting rid of the X-waiver.

Dr. Chapa:
For those of you just tuning in, you're listening to *Clinician’s Roundtable* on ReachMD. I'm Dr. Hector Chapa, and I'm speaking with Dr. Joshua Lee about the potential new guidelines or at least new direction of treatment of opioid use disorder.

Now, I have a more practical question, Dr. Lee, for you, and that's for any physician who is considering doing this, whether it's with an X-

waiver persistence, or a version of it, or it's elimination. Are there some special malpractice concerns or coverage that a physician needs to do if they're going to offer medication-assisted treatment for opioid use disorder?

Dr. Lee:
I'm not aware of any. If you wanted to get your X-waiver and start prescribing buprenorphine, you don't need to do anything different in terms of your malpractice coverage. You're already covered, in a sense, because it's accepted part of standard practice. You're using the drug for a labeled use; it's totally within your scope of practice to do it.

If you don't have your X-waiver and you want to get it, they have made it easier and easier. It's getting to be more like the handwashing certificate. It's now available also for physician assistants and nurse practitioners. So there has been movement at the regulatory level to make it, you know, more widespread and more available to other prescribers. So in terms of like actually getting your X waiver, it's now free. It used to cost you $150, and now, nothing. And it will take some of your time and you've got to be a little more organized. And then you've got to follow that through with some paperwork back and forth to the feds to get your DEA reissued with a new second X number on it.

And I just want to assure people that when they do start to prescribe it, for now after getting their X-waiver, it's really rewarding. Patients appreciate it. Most patients these days have already tried it. They've been in treatment before or their brother gave them some. They understand kind of how to take it, why to take it, how it helps them not use heroin that week. And they've never gotten to a provider and now they've gotten to you. But it's pretty simple stuff, and the outcomes are usually pretty good. And, you know, good positive feedback is usually available immediately. So I'd encourage people to consider it if they already have these patients or if they'd like to spend some time per week with this type of patient. There's not a lot of downsides.

Dr. Chapa:
So, Dr. Lee, two things. One, I would like you to just give that website, for training. And then the second thing is, when your second DEA number is given with the X number, does that replace your original? Or do you literally have two DEA numbers? So please the website again, and then clarify a little bit about the – the new DEA number that's issued out.

Dr. Lee:
So, it's PCSSNOW.org. PCSS N-O-W.org. And then you just find the banner for X-waiver. You can go down to your level of practice. If you go under physician, it'll give you the options for the free online training. You can also find live trainings that might be happening in your area organized by an academic medical center or Department of Health or something like that. So the live trainings are also still being done, but often they're half and half or you do half online, half with the instructor.

And that completes the process. And youat some point have to do the post test and that gets you your certificate. Again, kind of like doing your BLS recertification online. You get your certificate and then you go to check out, you know, where you need to make that into a new card. And so that used to be by fax. I think it's now all upload, download, and emails where you will go to the federal SAMHSA C-SAT site for X-waiver registration, you'll feed in your certificate and your DEA and licensure and contact information. And then the DEA will follow through with the new certificate. And now you have a new DEA certificate. It's your name, your address of practice, your old DEA and then your new X-DEA, which is the same number. Just the first letter is going to be an X now.

Dr. Chapa:
Well, Dr. Lee, as you can see, I mean, I could continue this conversation with you for a very long time because it's so important and there's so many changes going on. And again, we're still in the middle of this fight, but at least there's movement going in the right direction.

But that does bring us to the end of the program. So I want to thank you, Dr. Lee, again for joining me to discuss the latest in opioid use disorder and potentially new treatment guidelines. It's still a moving issue with the DHHS, but at least we've got progress. It was great having you on the program, Dr. Lee.

Dr. Lee:
Thank you. Thanks for the invite.

Dr. Chapa:
And I'm Dr. Hector Chapa. To access this and other episodes in our series, visit ReachMD.com/CliniciansRoundtable, where you can Be Part of the Knowledge. Thanks for listening.