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Health Care Law Today Podcast

Episode 16: Community Health Centers: Issues Facing FQHCs Today

In this episode, Foley Senior Counsel Adam Hepworth talks with Trent Stechschulte of Equitas Health about current hot issues related to Federally Qualified Health Centers (FQHCs).

Adam Hepworth is a senior counsel and health care lawyer with Foley & Lardner LLP. His practice focuses on Medicaid and Medicare, internal audits and investigations, health privacy laws, and compliance with health care fraud and abuse laws. Adam has represented hospitals, Federally Qualified Health Centers (FQHCs), and other providers in numerous Medicaid administrative appeals. He argued Tulare Pediatric Health Care Center v. State Department of Health Care Services, resulting in a decision from the California Court of Appeals recognizing the State's obligation to pay FQHCs a Medi-Cal per-visit rate that reflects their full costs when they contract with an outside medical group.

Trent Stechschulte is the General Counsel & Compliance Officer at Equitas Health. Trent received his Bachelor of Arts degree in History from The Ohio State University and a Juris Doctor from Cleveland-Marshall College of Law, where he earned a Certificate in Health Care Law from the Center of Health Law & Policy. At Cleveland Marshall College of Law, Trent was elected Editor-in-Chief of the Journal of Law & Health. Currently, Trent oversees the legal department and compliance program at Equitas Health. As General Counsel, Trent regularly works with the leadership, providers, pharmacists, and other personnel on a wide variety of health care and corporate issues. He is the Chair for Equitas Health's Compliance Committee and works with department Directors to carry out their Compliance Plans.

Please note that the interview copy below is not verbatim. We do our best to provide you with a summary of what is covered during the show. Thank you for your consideration, and enjoy the show!

Adam Hepworth

My name is Adam Hepworth and I am an attorney with Foley focusing on Medicaid and Medicare, compliance with health care fraud and abuse laws, and administrative appeals. I work a lot with federally qualified health centers or FQHCs, which are the topic of this podcast. For

those who aren't familiar with them, FQHCs are community health centers that receive a special status in exchange for serving an underserved population and meeting a basic set of requirements set forth by HRSA, the Health Resources and Services Administration. FQHCs primarily serve low-income patients who have Medicaid or are uninsured.

For today's podcast, we will talk about hot issues for FQHCs. They've emerged as a critical part of the pandemic response, receiving significant government grants and other support because of how well positioned they are to target the most vulnerable individuals who needed health care, included COVID testing and vaccines during the pandemic. We're fortunate today to have with us Trent Stechschulte, general counsel and compliance officer at Equitas Health, an FQHC that serves tens of thousands of patients each year in Ohio, Kentucky, and West Virginia, with 21 offices in 13 cities. Equitas Health is one of the largest LGBTQ plus and HIV/AIDS serving health care organizations in the United States. It also operates pharmacies serving patients in Ohio and Texas. Trent has been with Equitas for about seven years. And I've had the privilege of working with Trent recently in this last year, including doing some presentations together. So I'm excited to have him here.

Trent, welcome to the podcast.

Trent Stechschulte

Thank you, Adam, so much. And if you want, I think we can just jump right in since we only have a short period of time. Is that okay with you?

Adam Hepworth

So the first thing I wanted to talk to you about, Trent, is that we're now in a bit of a weird space where the country is really starting to open up again after the pandemic, but some people are still hesitant and a lot is happening remotely that would have been in person just a couple of years ago. What are the biggest operational and legal hurdles that are challenging your FQHC in our current transition period?

Trent Stechschulte

That's a really good question, and it goes back to what you said before is that FQHCs predominantly serve Medicaid populations and the uninsured population, so budgets and cash flow have always been a challenge for FQHCs. At the beginning of the COVID pandemic, a lot of FQHCs were nimble and were able to transition to telehealth quite quickly, but it's not surprising that many could not because they don't have the capital investment for a telehealth infrastructure or the ability to hire talent to really operationalize that type of program. So as we've gone over—as regulatory health lawyers—FQHCs were expected to track and operationalize Medicaid waivers, Medicare waivers, licensure waivers, and other regulatory waivers that their businesses were built on. So, the health care community, of course, nurses, providers, MAs were very nimble and quick to this. The legal community, lawyers like you, Adam, and the law firm of Foley, were impressive in giving guidance in real time and you actually saw that guidance in real time impacting health centers.

Most in-house lawyers like me were scrambling just to stay organized and create some sort of compliance framework for those waivers, and that's something that we're still dealing with on a day-to-day basis. The response to COVID from my perspective was this, constant messaging around the changes, meetings about how to appropriately operationalize the changes, and conversations around what waivers will stay forever and will go away once the public health emergency goes away. At the beginning, we did not know how long the lockdowns would last, how long the waivers would remain, what the real impact of COVID would have, and the worry was whether we should be changing our business model and I think that's what a lot of community health centers are dealing with.

So, with the professional boards lifting a lot of the rules around practicing for telehealth, that's what we've been talking about. But one thing that I think that we're not talking about enough is the impact that the COVID had on behavioral health and how important it was for telehealth to open up in the behavioral health sphere, but also is the operational challenges that many community health centers have that are dealing with social workers and how to coordinate care with our high-risk patients. So social workers are responsible for coordinating housing, food assistance, health care education resources, ensure that a patient has health insurance, and coordinate prescriptions for some patients. Since COVID meant working with grantors on understanding the best ways to serve patients, a lot of those grant rules, like you said, changed. A lot of grants came through to address this, but COVID already shocked the system that was dealing with homelessness, poverty, and an issue where otherwise avoidable infectious diseases were being spread around communities at much higher rates than others.

Adam Hepworth

I mean, that's really interesting. I just wanted to jump in for a second because I heard you talking about social workers and coordinating these other areas and I think some people might not realize the extent to which FQHCs are involved in those sorts of efforts. I've done some work in the past on the social determinants of health, which I know we've chatted about too. For those who don't know what that term means, it's defined by U.S. government agencies as the conditions in the places where people live, learn, work, and play that affect, basically, their health and quality of life risks and outcomes. So the idea is that medical care only gets you so far and that it's things like education, food security, housing, and public safety that sometimes matter a lot more, particularly in the most vulnerable communities that don't have those. So I think it would be really interesting to hear a little bit about how FQHCs are on the front lines of addressing some of those issues because it might be news to some people that a health care organization, a community clinic, would be involved in those efforts.

Trent Stechschulte

Many of those public health priorities you're talking about are actually going to be stalling or are inflamed right now. For instance, substance abuse and overdose deaths in Ohio are at its highest rates. Our community health center offers a needle exchange program, we have care coordinators and testing specialists on site. The mental health concerns coming from the pandemic is really inflaming that epidemic that's running rampant across Ohio, but also what we're seeing is that community health centers are being tasked with many of the prevention activities that otherwise would be managed by health departments. So the health departments are using their resources to respond to COVID, as they should, but they've asked community

health centers and other partners to really manage the patients that are traditionally within the department's purview.

So one example in Ohio is a drastic, drastic increase in syphilis. At this time, we are unsure why, but now we are starting to see congenital syphilis and babies born with syphilis, something that is so rare is now happening with almost alarming regularity. So our staff is working on the departments of health like that, but when you talk about social determinants of health, we talked a lot about telehealth, right? And so telehealth, for sure, it's opening many doors for community health centers, but it's also moving us towards health care being a privilege if the only way to access that health care is through telehealth. There are so many people that we try to reach that we do not have the ability to access with technology.

We've talked about, and I think even you on a podcast have talked about the aging population and finding unique ways to have them access technology, but what we're seeing is we're trying to reach out to the transgender teen that's kicked out of their parents' house and has no phone, or the drug abuser that has no cell phone number or reliable cell phone number, or the recently unemployed service worker that couldn't afford a monthly fee to keep their phone and is no longer seeing their primary care doctor for diabetes management. So when you talk about social determinants of health, yes education, yes poverty, yes where live, even race is a social determinant of health, but now we're starting to see that access to technology is also a social determinant to health.

Adam Hepworth

That's so interesting, and when you're taking on these new roles and the public health departments are understandably overwhelmed by all the COVID responses, do you think this is triggering long-term systemic change or do you think it's something where things will just go back to the way they were in a few years after hopefully COVID is behind us and public health departments return to doing the things they were doing before?

Trent Stechschulte

Well, one, I don't think telehealth is going to go anywhere. I think there may be some regulatory changes around what you can do through telehealth, but I think a renewed focus on funding for things like syphilis and HIV is really important. Ohio had a very aggressive goal at decreasing the transmission rate of HIV and AIDS by 90% by 2030, and not that the numbers are going up, but they are stalling out, which is concerning. At this point—and I mean, you're a corporate health lawyer, many of the people listening to this podcast may be corporate health lawyers—the civil monetary penalties along the anti-kickback statute does allow some exceptions for FQHC to provide incentives, but most of those incentives may encourage patients to seek low cost preventative or primary care, and at some point, we need to have a conversation where public health departments are subsidizing technology or subsidizing more incentives for these low-income patients, right?

So I think that what this has shown is that though telehealth is reaching more people, there are still a lot of populations falling through the cracks, and just to kind of underscore how important community health centers are at this time, I want to give a specific example because I don't

want everyone just to think I'm talking in platitudes here. So last week, we had a story where a 22-year old lost a serving job at the beginning of the pandemic, has since contracted HIV because he was worried he couldn't afford PrEP, which is pre-exposure prophylaxis—it's just a once a day pill that if taken daily is 99% effective at protecting against HIV.

He was jobless without insurance, did not think he can afford it, but to us, it's very inward. What should we have done better with marketing? How could we have reached him where we could have given him that PrEP without him being worried about the cost of it? How can community health centers reach out to show how even if you lose your job and insurance, there are still options for you to stay safe? Adam, to your point, that's a lot of the creative thinking that we're constantly going over with each other.

Adam Hepworth

It's heartbreaking, but powerful, to have a concrete example like this to understand the stakes of some of the things we're talking about. You mentioned something that I think is a recurring tension in health care, which is on the one hand, you have these fraud and abuse laws that are concerned with incentives to patients because they're concerned with overutilization and unnecessary care and in safeguarding against those harms to the delivery system. But on the other hand, we have these trends of whole person care and addressing the social determinants of health and providing a more comprehensive package of health and non-health services to patients to really be more effective in our outcomes. And those two things sometimes come into conflict, so you have this weird situation where innovative Medicaid waiver programs, or other government efforts like accountable care organizations, want you to be doing comprehensive care management outreach to patients, but without particular waivers of fraud and abuse laws, you're running against the traditional health care regulatory regime.

It would be interesting to hear how you feel that tension. To pivot that way, one thing I wanted to ask you about was during the pandemic, something that was very striking was the speed with which government actors came in and tried to give regulatory flexibility to health care providers, to waive a lot of the traditional fraud and abuse laws, or to increase reimbursement, or to make it easier to use technologies like telehealth. I know that that was hugely important to probably all health care providers, but especially to FQHCs. Could you talk a little bit about what that was like, and then also the lessons learned? What do you think needs to be made permanent as we move forward?

Trent Stechschulte

I did mention this a little bit earlier about the sprint of operationalizing all of these changes, the sprint of trying to educate patients on this technology and how to access this technology, and listen, we serve a very diverse patient population when it comes to payers. We have young employed folks with private insurance and we have Medicaid folks. We serve a lot of different patient populations, so we were extremely effective on the telehealth process in our social workers, which I think are a super integral part of our health care space and really helped with organizing and helping patients address those changes. Right? So we're still dealing with it. We didn't have a lot of patients fall out of care—thank goodness—but we did have some fall out of care, so that's something that we're constantly catching up on.

The second question about which I think should stick around is obviously the patient and provider site rules. The provider site rules, meaning providers can be wherever they want when seeing patients and patients can be outside of the service area or in scope service area for hearses purposes. And what I mean by that is FQHCs were really built around the premise that certain areas of a city or a rural area are underserved, and so community health centers were established to address the needs of this community. Now with telehealth, we are seeing a lot of the patients within our scope, meaning in our service area, but we're also seeing a lot of patients that move away that don't want to lose their provider, that see us, Equitas Health specifically as an LGBTQIA plus service site where they can go and not feel stigmatized for, for instance, behavioral health.

So I think there needs to be some sort of changes around the in-scope and out-of-scope expectations for FQHCs, and I think that other community health centers are feeling the same, that a lot of patients are moving away and they want to be seen by their provider.

Adam Hepworth

And this is really, I think, related to the explosion of telehealth that we've touched on a few times, because 20 years ago, if you moved to a different state, I think that would be the end of it. You couldn't continue to see the same primary care provider you had, but now we're in this world where telehealth accelerated so much during the pandemic that it's actually possible to keep that relationship going. So, I'm curious…did Equitas make major shifts in its capacity and delivery of telehealth during this time that were accelerated beyond what anyone was expecting? Am I on base with what's causing this here or am I missing something?

Trent Stechschulte

No, no. You're exactly right, and I think that we are seeing a lot of patients that were moving away. I mean, that's causing—just from a compliance standpoint—that's causing a separate headache where we have to make sure that the patients we're seeing, our providers are licensed in those states. So for instance, if a patient goes up to Michigan, one state away, our provider must be licensed in Michigan to see that patient sitting there. So if you don't have a workflow in place where you're checking with the patient every step of the way where they're at or where they're living, that's where you get into a little compliance issue, but that's not what we're talking about here.

But, yes, what I'm seeing is that patients that otherwise were traveling an hour or an hour and a half to come to Equitas Health can now see our providers through telehealth. We're getting a lot more patients that want to come to us because we're more accessible now through telehealth. We've consistently grown throughout my last seven years at Equitas Health. We continue to grow, but it hasn't been where all of a sudden we're getting a huge influx in patients. It's just slow growth and we're seeing that patients are choosing us instead of having to choose a provider that may be on the corner.

Adam Hepworth

And when you had to make those changes suddenly to operationalize an expanded telehealth program, was there anything you think was unique about it being an FQHC? I know you've

already said you tend to be a cash strapped organization. These are low-income patients. That creates its own barriers. How did you confront those challenges?

Trent Stechschulte

So I'll give you one example. We had a lot of concerns around public transportation being shut down, even patients that could do telehealth still had to pick up their prescription somehow. So a lot of the waiver rules and certain insurance carriers and PBMs lifting their delivery restrictions was huge. So now that we can deliver prescriptions to patients that we otherwise couldn't deliver patients to was important because now our patients can receive their medication that they otherwise either couldn't or were stopped from doing. So we actually had our pharmacist calling saying, "Hey, listen, this patient can't get here. Can we drive the patients to them? What's the legal risk of doing that? Are we insured? Is that a fraud, waste, and abuse issue?" So we had to analyze each one of those instances and it is, delivering medication was a big one.

Another one just to kind of piggyback off that that I think is worth noting is that the virtual visits and the e-visits being reimbursed were huge for FQHCs because a lot of those short 10 to 15 minute conversations or virtual visits can happen. And I think it actually helps with over utilization of services because instead of telling patients they have to come into the clinic, these virtual visits can address the patient's care needs. And so we're not filling up our providers' schedules on a daily basis with patients that otherwise could be dealt with through short virtual visits.

Adam Hepworth

That's really interesting. So I work with a lot of FQHCs in California where the state Medicaid agency started reimbursing telephone visits under an emergency state plan amendment to FQHCs during the pandemic. It was really a lifeline for a lot of these clinics who that was the only way they could reach some patients. Some patients don't have the technology to do a whole audiovisual encounter, but they can get on a phone call and do a telephone visit. And I was wondering what's your experience with that in Ohio and the other states you serve?

Trent Stechschulte

That's actually interesting you brought that up because we did have some questions early on where, what happens when you do audiovisual for half the visit and then the other half has done by just telephone because the internet goes down or the technology fails. And so we have run into a lot of issues with that because you have templates and you have certain things built into your EMR and your operations just to make sure that a lot of this risk is kind of absorbed, right? And so you don't have your providers having to make all these choices, so if it is an audiovisual template that they're using, but they switched over to a telephone visit, there's a lot of training that needs to go on around switching that to a telephone visit.

So you are right. It helps us be very flexible, especially with the more vulnerable populations, I do think that offering different ways to get health care will be really beneficial to FQHCs and their patient population.

Adam Hepworth

I want to transition to a different area just because I know you have an experience there that I think is really interesting and valuable. So you're the general counsel at Equitas Health, but you're also, I know, very involved with the 340B efforts of the National Association of Community Health Centers, and 340B is just a super-hot topic today, particularly for FQHCs. It was less than a year ago that the association of FQHCs sued the Department of Health and Human Services to compel an administrative dispute resolution process for 340B controversies with manufacturers to handle certain alleged violations. And even since that lawsuit, there's been a number of important developments in 340B that I think are putting pressure on the 340B providers like FQHCs. So because you have such unique insight into this issue, would you be willing to just give us a little bit of a reality check or an update on where some of those issues stand today?

Trent Stechschulte

Of course, and honestly, it may be helpful just to start to underscore the importance of 340B. Many safety net providers depend on the discount provided by the 340B program to fund their services. And the program was built with the understanding that FQHCs are required to accept patients regardless of their ability to pay, and with such high Medicaid population, the discount became essentially essential for continuing to care for patients. So, yes, I do serve as on the executive committee of the Ryan White's HIV/AIDS 340B committee, or RWC 340B, and we do talk a lot about this. And I know I do have some colleagues at Equitas Health that serve on various boards and executive committees nationally. But there has been a lot of activity around the 340B program. That's been happening for years, but recently there has been a lot of pressure.

So the first would be the contract pharmacy exclusions, so within the last couple of years, there've been manufacturers explaining that they will only provide 340B discounts through one contract pharmacy for each covered entity. It's a strange restriction, right? It's essentially saying that covered entities cannot get a discount if they contract with pharmacies that serve their patient population, right? It is very rare that any FQHC have all of their patients use one pharmacy. Sometimes there's a CVS and Walgreens across the street from one another, right? The manufacturers know that, and it's something not contemplated by the statute. And these manufacturers are hoping to ensure that they do not have to provide the discount that's required by law.

Another push has been manufacturers trying to get pay and claim information for fills at contract pharmacies. There's no rules requiring that covered entities provide that level of data to manufacturers, and it's one of those things where it's just another line of we want to collect this information to try to find a reason why we want to exclude that. And actually, manufacturers have been excluding specific high priced drugs from the 340B program. Again, something not contemplated by the statute in a bizarre requirement because discounts should not be based on the price of the medication.

So the government, as you said, the government has reacted to the manufacturers by saying that they do not have the authority to enforce the contract pharmacy rules. HRSA and HHS

even went as far as to say that manufacturers are violating the statute. Hospitals filed a lawsuit demanding HHS order manufacturers. Grantees filed a lawsuit. And so at the same time, there's litigation around the administrative dispute resolution process or ADR process. So in January—and I believe the first rule came in 2010—in January HHS implemented the long awaited ADR process that resolved the overpayment process to hospitals and covered entities, and again, there was immediate manufacturer push back on that.

So all of these processes are currently being worked out through the court in various ways. There's several manufacturers and lawsuits going on at one time, and then you have the issue of modifiers, specifically PBM modifiers, and the ongoing concerns with discriminatory reimbursement. So PBMs and manufacturers through their provider manuals are requiring that covered entities identify their 340B claims on the front end so they know how much 340B stock each covered entity is utilizing them. They're doing this, we think, because they're hoping to reimburse discriminately, meaning PBMs and manufacturers are actually reimbursing covered entities at a lower rate, depending on whether they're a 340B provider. Some of them are doing this at the application process, meaning in order to join the network, you have to note whether you are dispensing 340B drugs, and if you do, they're going to give you reduced reimbursement from a state level.

There have been several states and advocates that have gotten anti-discrimination language on the books—states like Ohio, Utah, West Virginia, Oregon, South Dakota, Minnesota, Montana, Tennessee—the laws vary based on whether they apply to just contract pharmacy, whether they must outright prohibit discriminatory reimbursement. But one issue that many policy folks in these states are running into is the confidentiality provisions and the payer agreements and applications themselves. So we're saying, what I'm telling you right now, we're telling lawmakers. And when they asked to see the agreements, we're saying we cannot share the agreement with you because it would violate the contract if we did so.

So we always say that the argument that we don't have proof that discriminatory reimbursement is happening should not curtail lawmakers passing a rule prohibiting it, because either which way, it should be prohibited. And if they don't pass a rule, Adam, quite honestly, if they don't pass a rule, it's almost like they're implicitly encouraging these manufacturers or PBMs to put in place discriminatory reimbursement. So that's a very high-level review of the attacks on the 340B. And it's keeping community health center CEOs awake at night. It's keeping HIV/AIDS service providers awake at night quite a bit. This is probably the biggest attack that we've had on a 340B program in quite some time.

Adam Hepworth

I mean, even just hearing your summary, it's complicated and it's multifaceted. I know you don't have a crystal ball, but I wonder, do you think if this gets resolved, it's going to be through the courts through litigation, or do you think there's going to need to be federal congressional action or maybe the state laws will do it, or is it just something where it's just fought on many fronts and you have to take it issue by issue?

Trent Stechschulte

Yeah. I do think there probably may be statutory clarification from a legislative standpoint with the contract pharmacy exclusion or the medication exclusion. The claim identification issues and the ADR process will likely be worked out through litigation. The discriminatory reimbursement is already being handled by state legislatures. The problem is, is it's how applicable is it to Medicare and the federal Medicare program? And so that's where I think a lot of litigation will work that out.

Adam Hepworth

Yeah. Because we've talked about commercial payers, but I know that a lot of Medicaid programs and Medicare also pay a different rate for 340B drugs. So those are eating into the health center margins as well on the federal government side.

Trent Stechschulte

Exactly, and so a lot of it is grassroots efforts. So, for instance, here in Ohio, Equitas had a wonderful grassroots effort with the local community health center association and grantees and making the case to the department of Medicaid and the lawmakers. And it was very successful. And we're seeing that repeated in other states, just because once you provide the basic gist of PBMs shouldn't be able to discriminatory reimburse FQHCs, they look at it and they don't even think it's happening. That's why they're asking for the contract language because they're saying, "They were not doing that." So, it's all about advocacy and at the state and local level, and it's working.

Adam Hepworth

Okay. That's very, very interesting to hear. I think our time is wrapping up here. So I want to thank you, Trent. It's been an absolute pleasure to speak with you today. I've been working with FQHCs since the beginning of my career at Foley and they are one of my favorite provider types, both because of the critical mission that they serve and the really interesting complex of legal issues that surround their operations. And I think we got a taste of that today with the sort of depth and breadth of the experiences that you shared. So it's always a treat to talk with individuals in the FQHC community, and I'm really happy that we had this chance to chat.

Trent Stechschulte

I appreciate it, Adam. And it's always nice, and again, you and Foley and attorneys like you in law firms like Foley make FQHC's job so much easier because of how well you responded to the COVID pandemic. And I sometimes don't think that we celebrate law firms enough in that regard, is how amazing the legal community's response to the COVID pandemic was. And so again, thank you so much for everything you and Foley does.

Adam Hepworth

Thank you. That's very kind.