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EMERGING TRENDS IN HEALTHCARE TECHNOLOGY

KEYNOTE SPEAKER:
DR. ALEX JAHANGIR, *METRO NASHVILLE CORONAVIRUS TASK FORCE CHAIR*

[edited for reading]

FEBRUARY 19, 2021

Casey Goggin: Next up we have Dr. Alex Jahangir. He is an orthopedic trauma surgeon and professor of orthopedic surgery at Vanderbilt University Medical Center. He serves as the Associate Chief of Staff at Vanderbilt, the Director of the Division of Orthopedic Trauma, and Executive Medical Director of Vanderbilt Center for Trauma, Burn and Emergency Surgery. In addition to being a surgeon, he also serves as the current chair of the Metropolitan Board of Health of Nashville and was appointed head of Nashville's Coronavirus Task Force in March by Mayor Cooper. In this capacity, he led Nashville's response to the COVID-19 pandemic, including implementation of policies that mitigated the spread of the virus, increased access to testing, established public health infrastructure, and served as a principal source of COVID-19-related information to the public. Dr. Jahangir was raised in Nashville, graduated from Martin Luther King Magnet High School, received his Bachelor of Science from George Washington University, Doctor of Medicine from the University of Tennessee, and Master of Management and Healthcare from Vanderbilt University Owen Graduate School of Management. So, we welcome you!

Dr. Alex Jahangir: Thank you. I never thought I'd actually learn so much at a CLE course and I appreciate the previous speaker . It hits at home as a trauma surgeon, the things that were discussed, so thank you. When I had an opportunity to prepare for this discussion, rather than do a formal PowerPoint, I think I wanted to really speak to where Nashville is currently, where we came from regarding COVID, and specifically open up to a lot of questions but focus on the topic of technology and how it's impacted our response.

Let me start by just talking about where we are as a city. This morning we announced that we have about 2,100 active cases in Nashville and that sounds like a lot, but just a few months ago or, gosh, about six weeks ago we were up to about 8,000 people in Nashville who actually had COVID, which, if you think about a city of 700,000, I mean that means over 10% of the city was infected. And what is great is I think we are finally off of our third wave. The first case of COVID came to Nashville on March 7th, and nobody in this city had ever, or really around the world, had thought about what do we need to do to fight COVID or any pandemic. So on March 8th, we announced the first case and really, really quickly we started [inaudible] city leaders, health systems, really started thinking how do we figure out what we need to do? How do we get to the most vulnerable populations? How do we set up testing centers? How do we, one day, prepare for vaccinations? And what we kept coming back to was using technology to be able to best do that.

Furthermore, this sounds somewhat simple, but the other question was what data do we need? How does one collect that data, what is impactful in the data we collect? And I'm happy during the Q&A to maybe get into some of that, but again we started on March 7th, went through a small wave, and another wave, and we're coming off the winter wave, which, again, as I mentioned earlier about 12-15% of city had infected and now we're heading down to a really manageable number compared to where we were. But now we're starting to roll out vaccinations and in the city of Nashville we have now vaccinated about 71,000 individuals out of the 700,000, and just this morning we're vaccinating more. And so it's a question of where do we need to focus our energies? Again, technology can come into it, maybe some discussion driving maybe passports and so forth moving forward, but I want to just lay that quick lay-down of where we were, but I would love to maybe have more dialogue with Q&A over the next 20 minutes or so to really dive into the question of technology. So thanks for giving me this floor.

Paige Goodwin: Okay thank you so much for that. We have questions. During the pandemic, there has been a rapid increase in the types of data being generated and used to inform and evaluate public health policy, so how has Nashville used digital data to guide and evaluate its COVID-19 response?

Dr. Alex Jahangir: There's so many–let me just step back. As mentioned in the intro, which was very kind, I'm an orthopedic surgeon, right? So one question a lot of people ask is, "What the heck did an orthopedic surgeon do getting involved in COVID response?" and so forth. So I want to say I've had to rely on a lot of epidemiologists and [inaudible] who really have taught me the data that's out there. One data point that was very interesting early on was cell phone data and this is something that, as a city, we didn't necessarily use per se in making policy but it did inform decisions. And what cell phone data, that one of our academic colleagues demonstrated to me, was we could see early on where the hotspots were in Nashville, and I believe a lot of the people on this call are from the Nashville area. Really our initial hot spots in the spring and in the early summer was in Southeast, so a lot of our Spanish-speaking residents and people who were typically younger, had jobs that wouldn't allow them to stay at home. And we were able to see quickly is this cell phone data showed that there's a lot of motion in Southeast and less motion in, for example, in Belle Meade and Oak Hill and other parts of town. But you could see where those people were going. They were going to the Walmart, they were going to a grocery store of some sort there, and what that started telling us is first of all, there's a lot of traffic down there. But then as we started

looking at where do we put testing sites and mobile testing sites specifically, we knew we needed to focus on that area because we need to give people access.

Furthermore, the other thing that was really interesting to me is simple things, such as when I mentioned to you earlier about the number of active cases we have and how many per 100,000 how many cases there are, and right now by the way we just dropped behind below 30 for the first time since September, which puts us in the bottom third of the state as far as disease activity–that was data that was not really generated early on. So being able to get that data pretty regularly has been really helpful. And as that data shows where clusters are, as that data shows where motion is, so the cell phone that I mentioned earlier, it allowed us to really fine tune what we did. As I mentioned, we put the testing site at a location, we started seeing a lot of activity around people going out of county and coming back into county and recognizing certain trends there that allowed us to maybe do certain policy things, not only to put in safer-at-homes but also as things got better being able to turn the dial so that we re-energize our economy and our businesses and maybe, frankly, avoid some of the people who were leaving town anyway to do whatever services that need to be done to come back

As we've moved forward, especially in this winter peak, one of the other things that became very difficult was our contact tracing. Initially we were doing contact tracing, meaning we had at one point up to 200 people calling anyone that tested positive, figuring out who they were in contact with, and then following up on a daily basis ideally with those individuals. See how they're feeling, make sure they're not getting sick, make sure they are staying at home and not spreading the disease. Again, early on it was a phone call thing. We first had our own public health people but then later we used a call center. But it took a while to really develop a texting SMS-type system that allowed us to send people messages, ensure they replied back, and it kept track of data points like what's your temperature today, how are you feeling, do you need help? Sounds simple enough but again early in this pandemic those technologies weren't as easy available in our community, and you have to also then consider HIPAA compliance and compliance with people that actually want to do it. So those are the types of things that we've developed in our response thus far.

Paige Goodwin: And then we had another question in the chat. It says is Metro Health Department using the state's immunization tracking system? Is Vanderbilt?

Dr. Alex Jahangir: So there's something called TennIIS[1], I believe that's where they referring to, in which anyone that's been vaccinated has had a form put in that. So whether it's metropolitan health – in fact, this morning we had (the wet winter weather has done a heck of a number) we had eighty vaccines that were about to expire in another part of town and this morning I drove those vaccines and we provided them to eighty individuals in North Nashville. And those individuals' information we put into our system. If Vanderbilt's doing a drive or HCA's doing a drive, those will be putting in the system. So short answer is yes, Metro is using that information because having accountability where the vaccines are and then knowing who they're put into is really important. And the state really has the jurisdiction over that and it allows the state and us as Metro to really make decisions about, alright is the phasing criteria being met? Are we at a point where we can move forward in our phasing? Is there an area of town that we're not emphasizing and need to really focus our limited supply of vaccines to? So we are using TennIIS and I suspect that's what the question was asking about.

Paige Goodwin: Yeah, they did mention that I just missed it in the question, sorry. And then we have a question that says, "I'm curious about that home COVID testing kits that were recently developed. Do you see a use for those in the coming months in Nashville and how does that play into data tracking since those tests would be presumably not logged?

Dr. Alex Jahangir: Yeah, that's a concern of mine a lot as well. So, I think the home tests though that are being developed, you still have to send them in if I'm not mistaken. There's some of the rapid antigen tests, which, those even have to be reported. But you have to send in the results to a company, if I'm not mistaken. At a certain point COVID as we know it will be different, right? COVID will never go away, I suspect. It will become endemic, so by that I mean we'll have enough people vaccinated, we'll have enough treatments out there that there won't be people getting really sick or dying at the rates are currently dying, and it rather will be like the flu. The flu is endemic, right? You'll see the flu, it'll spike up, a few people get sick, but most people won't get as sick. So as time moves on, we probably won't have a you know exact case count. Rather, we'll do a sample of the community and get a sense of the prevalence of the disease in the community based off said sample, and I suspect that'll happened with COVID. Now that may happen in six months or a year. To answer the question, the home COVID test though, I do

[1] TENNESSEE IMMUNIZATION INFORMATION SYSTEM, https://www.tennesseeiis.gov/tnsiis/ (last visited Jan. 8, 2022).

believe still need to be reported to a central entity, whoever is the one who provides them, and hopefully will have better tracking of that. But sure, it is a concern of course.

Paige Goodwin: And then we have one about privacy. The question is, "Were there relaxing of any privacy standards during any point in the pandemic due to the public health and safety concerns, and how did you work around the need to disclose?"

Dr. Alex Jahangir: That's a great question that I, as the doctor, sometimes get anxious talking to 200 attorneys about. But in all sincerity, the Trump administration did provide some HIPAA, I guess I don't know if "relaxation" is the right word, but some clarity around things that can be provided, specifically around data sharing when it came to law enforcement and EMS and first responders.[2] Early on in this pandemic, certain jurisdictions, Metro Nashville being one of them, felt that for the safety of our first responders and we needed to, in what initially wasn't a thoughtful manner, in full disclosure but I think has become a very thoughtful manner with stakeholders involved making it better–how do they know that if somebody is actively infected and they're picked up, whether it's to go to jail or to come to the hospital, and they had tested positive that the provider, the policeman or EMS provider, would be aware of their status of positivity. That was done under, I think we had a lot of Metro attorneys look at the HIPAA rules and the Trump administration relaxed some of the HIPAA rules that allowed for that.

But short of that, there hasn't been much relaxation of rules. And frankly, I think, even if the rules are relaxed, for me and I know most of my colleagues in Metro Public Health and in the state, we want to always try to protect people's privacy as long as it doesn't jeopardize public health to a great extent, right? And so there is always that constant tension of, at what point do we need to disclose if this person is positive or perhaps put a quarantine order on them? I mean, few cases we've actually had to be very strict about a person's movement. It has always been a tension that has been in existence throughout this pandemic, but we've not intentionally done anything that we didn't need to.

Paige Goodwin: Thank you. The next one says, "Should people abide by the criteria/phases for getting the vaccine, or is it better for

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[2] *See* DEPT. OF HEALTH & HUMAN SERVS., COVID-19 & HIPAA BULLETIN: LIMITED WAIVER OF HIPAA SANCTIONS AND PENALTIES DURING A NATIONWIDE PUBLIC HEALTH EMERGENCY (March 2020).

people to just get vaccinated and maybe go to a neighboring county?"

Dr. Alex Jahangir: There's two ways to answer that. In all sincerity though, I think everyone who can get a vaccine through the proper channels should get a vaccine. I want to be clear – I don't care if you're 30 or you're 60, if you have the opportunity to get a vaccine, get a vaccine, period. Now the phasing criteria though that the state set up based on recommendations of national organizations and some guys from federal government does prioritize vaccines to those around most risk, and I commend the state for doing this. They do it both by profession, so high-risk profession such as healthcare workers, and age. People over sixty-five have a much higher mortality rate than those under sixty-five, so the State of Tennessee's disease vaccine distribution has it as such.

Now, if you're able to sign up for a vaccine in the surrounding county, the reason you're probably able to sign up for that vaccine is because the uptake of people wanting to have vaccine is not what we thought it would be. We average about 30% of people who are eligible for the vaccine just choose not to take it. A surrounding county may not have that 30%. This vaccine, once it's thawed out, will expire. A great example, as I mentioned, this week there are 700, between what we did today and Wednesday, 700 vaccines in Nashville and surrounding area that were about to expire and they expire because you thaw it out and then you refrigerate it and it's good for five days. Well in that scenario, we prioritized giving this vaccine to as many people in-phase, but also vulnerable population, so going to the rescue mission where we gave 400 vaccines on Wednesday. A lot of people in that rescue mission may not have been in-phase by the aging criteria or by the employment criteria but those are individuals that have other medical conditions that make them really high risk of having really bad outcomes.

So the basic criteria is really important to follow. As an entity responsible for the vaccine process, we do follow it. But if an opportunity is presented for whatever reason, and often a reason is the vaccine is set to expire and just not the uptake needed, then I think anyone who has access to the vaccine should get it, just don't game the system. Just go through the process and if you're eligible and whoever is the entity overseeing that vaccine says you're eligible, get the vaccine. I said about six times now, didn't I?

Paige Goodwin: Kind of going off of that, you mentioned in a previous interview how it's harder to reach minority communities with information and that you were using creative avenues such as

social media to try and reach them. What have been some of the biggest challenges reaching these vulnerable populations?

Dr. Alex Jahangir: So I think the biggest challenge around reaching vulnerable populations is trust and trust in the in the government entity. And then also trying as an entity to not have the arrogance of knowing how best to do it, right? So, early on we figured we'd put our assessment sites, which we did based on criteria and vulnerable areas, North Nashville, downtown, and southeast Nashville. And we have these sites but people for different reasons wouldn't access them, right? Our immigrant population in southeast Nashville, there's a lot of hesitancy to come to a site that requires certain information: phone number, date of birth, name. Because they're worried about immigration things.

Now, I'm a first generation American. I moved here to Nashville when I was six years old, so I could relate to that in some of the concerns there. The best way to mitigate those concerns was to, and now with vaccination, similar thing, is we actually started going into the communities and finding people who are trusted people in that community. Community organizers, health clinics, Siloam Health has been a great partner to us for that population. And allowing them to drive the message but giving the resources to do so, whether that is giving vouchers to help give people food and housing security when they need to quarantine or giving vaccines to places like Siloam Health, to now encourage people who meet the phasing criteria to get vaccines. That's the best way we found to do it.

Social media wise, and we also have worked with a PR firm, but also the PR firm with the people on the ground there to message appropriately in the right languages. There are about 130 different languages, I think, spoken in Metro Public Schools, which tells you how broad language is here in Nashville. I did this week a Spanish press conference. I don't speak Spanish [inaudible] but it's been so important because these are reporters who I, previous to this role, never knew existed and now they have really broad distribution of reach. North Nashville and our minority and African American community–same concerns. May be a little bit different, they're not as concerned about you know ICE or other entities having information but really a distrust in the health system and the government providing that health system for a lot of very valid reasons. So finding people in the community who are trusted and then convincing them that what we're doing makes sense. And then messaging again, similar to that community, whether it's through geofencing, so around our assessment center for a while we had

geofencing when people would come in. And when you go into a certain thing, you'd get on your Facebook page information about COVID, or sign up here, here's what here's what the testing process is going to be like, here's an app that you can sign up for, when we rolled into our SMS texting contact tracing, sign up for this text, sign up for this app and you will get your message of your test results as well as somebody to recheck in on you that way. That's how we've used social media, especially for our vulnerable populations.

Paige Goodwin: Sorry about that, my screen got away from me. I think we have time for about one more question. What do you think is the biggest lesson learned from the pandemic that will help in the future?

Dr. Alex Jahangir: You know, I do a lot of these interviews and that's the first time anybody has asked me that question, that's a really good question. That's one that I think a lot of us are still trying to process. And I think it's several, right? I think there's several lessons is. One is in a in a moment of crisis, and I tell this to my residence in surgery, loading the boat is critical. One single individual does not have all the answers, and what I'm really proud of about Nashville's response is early on, literally day two, we brought in all the health system leaders, nonprofit leaders, that seemed germane to that issue, state and local officials, places like the Mission, the nursing homes, to talk about our response as a city We did that on Wednesday. Our first press conference announcing it was on a Sunday.

And moving forward, recognizing throughout the whole thing, transparency and letting the science drive has been really important for us. There's been times when I think we as a response have been caught, admittedly something wasn't done right. I mentioned the data sharing early on, and recognizing that being transparent about how one fixes it but also being transparent how one got there is a lesson that that I think is really critical of moving forward on any crisis. And then I hope recognizing the issues of health disparities that has been a big problem this country for 400-500 years – these health disparities are not something that just happened, right? I mean, you know, infant mortality is three times higher in African Americans than white. A kid that was born in the same hospital as my kid at the same time who lives three miles from my house they have a twenty-year less life expectancy. These are not things that just happened because of COVID. COVID has highlighted that, and I hope that these are these are things that we will address.

And then on a technology front, I think as a society we really need to really get comfortable with, what is our level of comfort with tracking? One thing we haven't really talked about is there's these great apps you put on your phone and you could quickly have known, if enough people in community have it, you can very quickly get told if you were exposed to someone who is infected with COVID. How comfortable are we as a society to have somebody, whether it's the government or Microsoft or Google or Apple, knows this about you? And are we willing to give up that little bit, or a lot of privacy for the betterment of society? I know those issues [are] also not due to this, but I hope maybe this pandemic will allow us to really explore this further and talk about it, and maybe have a more comfort level if this ever happens in our lifetime again.

Paige Goodwin: Yeah, knock on wood that it doesn't. And I wanted to fit in one more question. How did the city deal with neighboring counties that haven't taken the same initiatives to slow the spread of virus? I know there's only so much you can do, but were steps taken or anything?

Dr. Alex Jahangir: It is really interesting, again, I'm not somebody who was ever in government, never planned on being in government and I'm still a volunteer just for the record, I'm still a full-time surgeon. I think what I've seen is most of the regional mayors and the local governments obviously want to do what's best for their community. And early on especially, obviously we as a city are 700,000 or MSA is I think 1.7, 1.9 million, so Nashville has to do well for the surrounding counties do well, and the surrounding counties have to do well for Nashville to do well. Mayor Cooper, I know, had spent a lot of time dialoguing back and forth with these county mayors early. Now when it came to things such as mask mandates, we were the first in the region to put one in. We were in the first in the region to put a safer-at-home order in. A lot of county mayors, because of dialogue and with the support of the governor, I know the governor did allow county mayors to make certain decisions around mask mandates and so forth, they partnered pretty well with us. But then it became, some of it became politicized, and then some of it is just the needs of a community of 30,000 is different than the needs of a community of 700,000.

So yes, there's been some differences in policy but early on if you really go back and look at how we responded as a region, the original response was actually relatively uniform early on, it has splintered little bit. But that came from intentional work between Mayor Cooper and the county mayors. The state government has been a great partner to us as a city, and I know they've been good

partners to other regional counties. There's been a lot of cooperation and I know some people hate seeing that because people like to always see there's this turmoil, but for the most part, most of the region has responded well and we've stepped forward together.

Paige Goodwin: Alright. Well, we are almost out of time, so thank you so much for making time to talk to us, because I can imagine how busy you must be, so we appreciate that.

Dr. Alex Jahangir: I'm very grateful for this opportunity. This was fun.

EMERGING TRENDS IN HEALTHCARE TECHNOLOGY:
RURAL-URBAN HEALTH RESPONSES TO COVID-19

PANELISTS:
LINDA RIPPEY-MOORE, *GENERAL COUNSEL, MAURY REGIONAL HEALTH*
LUKE HILL, *CHIEF LEGAL COUNSEL, COOKEVILLE REGIONAL MEDICAL*
GABE ROBERTS, *SENIOR STRATEGIC ADVISOR, SELLERS DORSEY*
ERIC GRAY, *MANAGING COUNSEL, TECHNOLOGY LAW GROUP AT HCA*

Moderated by Alexander Mills, Senior Corporate Counsel at DaVita Kidney Care

[edited for reading]

FEBRUARY 19, 2021

Casey Goggin: Without further ado, I'm going to go ahead and introduce our first moderator for our first panel: Alexander Mills. Alexander Mills is currently the senior corporate counsel at DaVita Kidney Care. Before joining DaVita, Mr. Mills worked as the Director of Operations and General Counsel at High Plains Crop Production and worked in the Healthcare Compliance and Operations group at Waller. He also served as judicial clerk to W. Neal McBrayer at the Tennessee Court of Appeals. Mr. Mills graduated from Western Kentucky University with a Bachelor's degree in psychology and received his J.D. here at Belmont College of Law. He had an impressive law school career at Belmont, graduated summa cum laude, and was a member of Law Review. He also participated in moot court and mock trial competitions. So I'll kick it over to you, Alex.

Alexander Mills: Thanks Casey. I appreciate the kind introduction and I really enjoyed that video a lot. Chase Doscher was actually a former mentee of mine in the Inn of Courts program, so it's kind of cool to see him on the video. And then I saw Caitlyn Page as one of the panelists in the past and she's also a former colleague, so that was pretty cool to see how this is developed over the past few years and how everything's coming along. As Casey said, my name is Alex Mills. Fellow Belmont College of law alumni and senior corporate counsel at DaVita Kidney Care. I'm going to be moderating today's panel discussion on rural and urban healthcare responses to COVID-19. Joining me today is Linda Rippey-Moore, General Counsel at Maury Regional Healthcare; Luke Hill, Chief Legal Counsel at Cookeville Regional Medical Center; Gabe Roberts, founder and CEO of Roberts Consulting Group; and Eric Gray, Managing Counsel of the Technology Law Group at HCA.

Just as a reminder: all views and opinions expressed here are those of the individual and do not necessarily reflect the positions of the clients or businesses they represent. With all that said, let's just go ahead and kick things off. I'd like to take a little bit of time here at the beginning for the four of guys to have a chance to introduce yourself and kind of talk a little bit about your practice and your experiences in healthcare, and with that I guess maybe we could start with you Linda.

Linda Rippey-Moore: Great. Thank you for letting me be here this morning. I'm General Counsel for Maury Regional Health. We are a four-county hospital system servicing a nine-county service region. Our flagship hospital is in Columbia, Tennessee, and is a 255-acute-bed hospital. We also have two other hospitals, a critical access hospital in Marshall County and a solo community hospital

in Wayne County. And being the sole in-house counsel I run the gamut of practice, both being a lawyer and on the operational side. I do a lot of contracting, physician-hospital relationship contracting, compliance, legal, risk management, and internal audit run up through me through a reporting structure, so I get a lot of exposure to those areas as well, so.

Alexander Mills: Great, thanks Linda. We are going to appreciate you sharing your experience with us today. Luke, why don't you go next?

Luke Hill: Thanks Alex, thanks for having me on the panel. Similar to Linda, I am the sole attorney at Cookeville Regional Medical Center, Chief Legal Counsel, been here about four years. We're a little smaller than Maury Regional in that we've got just one hospital and a good outpatient practice of about seventy-five employed physicians. Prior to this, I was at Baptist Memorial Health Care over in Memphis, and I appreciate you having me on the panel.

Alexander Mills: Glad to have you, Luke. Gabe, I think we've got you next on the screen.

Gabe Roberts: Sure, hey, thanks Alex, really great to be here. This is the second or third Belmont panel I've participated in. It's really a great resource for us and our community so I appreciate having me. I'm Gabe Roberts, I do consulting work now and have been for the last year or so, but before that I was at TennCare. I was the TennCare director, which is the Medicaid agency here in Tennessee, and then I was in previous roles before that including General Counsel. Started my law career at Sherrard & Roe and graduated from Vanderbilt, so been in Nashville for almost twenty years and I think Linda and Luke are probably glad that I'm out of TennCare. [inaudible] Looking forward to the conversation.

Alexander Mills: Thanks so much, Gabe. And last but certainly not least we've got Eric.

Eric Gray: Thank you. Morning everybody, my name is Eric Gray. I'm Managing Counsel of the Technology Law Group at HCA. First of all, thanks for having me and thanks for setting this up. It's an awesome experience for all of us, I think it'll be a good conversation. Everybody kind of brings a little bit of different flavor and backgrounds, so I think it's really good. I work for HCA. HCA is based out of Nashville, it's a healthcare company. We spread across I think around twenty states across the US. We have 186, I think, hospitals along with physician offices, ambulatory surgery

centers, urgent cares. We have a few practices in the UK, mainly around London, but that's our only international area.

So we're a little bit different. Luke and Linda run the show, I do not. We have around 120 or so attorneys at HCA with various different legal departments, kind of [inaudible] groups within the legal department. Our group is the technology law group. We support HCA's IT arm, so the [inaudible] of HCA providing all the technology and IT to all the facilities and other healthcare operations out there. We're kind of their general counsel support for them. A lot of my work, I'm not in the facility on day to day basis. We're more kind of in the background supporting. We do a ton of contracting–one of our kind of key areas we support is supporting and contracting with IT vendors, so a little bit of my perspective is how the contracting process has changed during the pandemic. Again, thanks for having me. Alex, back to you.

Alexander Mills: Thanks Eric. I think to start us off here I'm just going to kind of lob up kind of a larger question on the topic and we'll kind of get into more pointed questions as we go on. So to start us off, you know, the pandemic has generated this need for a wide range of innovations to kind of help overcome obstacles that it's presented, and find new and creative ways of meeting patients' needs. And I guess as a first question, what kind of challenges has the pandemic caused in your practice or at your business, and what kind of strategies have you guys had to implement to overcome these challenges? Kind of as a sub question, what kinds of digital initiatives have you worked with to try to overcome some of those challenges, or have you seen in the field? What have you guys found that's been successful, and maybe what kind of things have you done that have been not so successful that you've kind of had to rethink. I think we can start that one off–Luke would you like to take the first shot at it?

Luke Hill: Sure. You know, anytime you're talking telehealth, the starting point is HIPAA compliance. You know, security, safety. An old HIPAA mentor of mine always said there's bad people – the bad guys are trying to infiltrate at every opportunity that they can, so the starting point's always got to be HIPAA compliance. When we started–when the pandemic started early last year, it was–telehealth was on our radar but it was all of a sudden thrusted upon us that, you know, okay we've got this little run up and now it's, "We gotta go full boar into telehealth."

The technical opportunities, we went in all sorts of different directions. Started with Zoom, started with the go-to meeting, and

what we saw was there's a lot of bad actors out there. When back in March of last year, no one really knew even what Zoom was and then the whole Zoom hacking issue…A lot of people had to duck and weave and start going, you know, start focusing in on that security aspect of telehealth. And we here at Cookeville Regional ended up landing on a system called doxy.me[1], which I think a lot of other entities have utilized. We use that for our inpatient side, and then our outpatient side we use Athena Health.[2] So lots of different avenues for those connections to our patients, but the starting point's always got to be security, patient health security, HIPAA, and what avenues can we use to bring access to the patients that we treat.

Alexander Mills: Thanks Luke. Linda, do you have anything you'd like to add to that?

Linda Rippey-Moore: I guess we were blessed. We hired a manager of telehealth in 2017, sort of already viewing that this was going to be the direction that we would like to be heading. So we had already implemented at Maury a tele-stroke program, we had a few avenues of remote patient monitoring, we had implemented an agreement with IRIS, which was for diabetes patients for retinal imaging, and offsite, obviously, provider reading in a read-only format integrated with our server network. So we had done a few things and we had also started our Maury On-Demand, which is, you know, the app for urgent care visits. So we had already dipped our toes in to a number of different areas but obviously the pandemic changed, as Luke said, all those were HIPAA compliant, you know, it had been vetted completely. You knew the privacy, security aspects, you had your SOC reports, you had NIST standards being met–all of that stuff which is way beyond my expertise. But we had all our key players, stakeholders weigh in on all of that.

And then, obviously, to Luke's point–not that it went by the wayside, but with the waivers and more latitude on, okay, you know, Zoom isn't HIPAA compliant but how are we going to utilize that? Because we have patient care needs that aren't being met. We don't want the patients in the offices, there is a much greater risk of, obviously, bad outcomes for patients if we (a) don't see them or (b) bring them into the office because of PPE limitations.

All of those things played in and so to Luke's point, we deployed those same sorts of things and it was challenging, obviously, because it required a change of mindset where compliance didn't look the same way. And it was compliant under

[1] See DOXY.ME, https://doxy.me/en/ (last visited Jan. 8, 2022).
[2] See ATHENAHEALTH, https://www.athenahealth.com/ (last visited Jan. 8, 2022).

the law but it wasn't the way we had previously viewed compliance. And obviously the education, getting the technology, getting staffing to be able to support that change of workflow. So our experience was similar to Luke's in that regard.

Alexander Mills: Thanks Linda. I think you raise an interesting point there that I'd like to explore a little bit further in just a minute. But first just to kind of get maybe a different perspective on that first question, Gabe I'd like to hear some of your thoughts with your background at TennCare and your current consulting work. What kind of things are you seeing in your field as reactions to the pandemic, and what's been successful and maybe not so successful?

Gabe Roberts: Yeah. So what I think is one of the most interesting things really kind of builds on what Linda and Luke were talking about. You know, we had this rapid deployment and this rapid acceleration–perhaps we went years in advance in just a few months with respect to adapting to a telehealth environment, a virtual care environment, to payors kind of maybe coming off, to some level, kind of their, not hesitancy, but just concern around utilization, control, etc. So what I think is going to be really interesting is, what I've seen a little bit with some of my clients is, what are the policy implications kind of down the road post-public health emergency? I think, you know, from my perspective as a board member on a couple of providers, we've gone to almost entirely virtual care. And all of our quality marks have either been maintained or increased in some cases, which is a really interesting thing that the payors have said, this is really interesting and eye-opening for us to kind of see that.

And so when we kind of get back to whatever the new normal is, is there a chance to holistically review reimbursement in U-type, utilization management-type policies with providers? And maybe even as regulators, right? Say these are the outcomes that we want and we're going to be a little bit less prescriptive in how our providers get there. So I think that's helpful. I think maybe the second- or third-order, perhaps, policy implications are that do we get away from, or do we at least start talking more seriously about alternative payment arrangements for providers. I mean the rural providers in this state, and really across the country, have been really kind of at crisis points for a lot of reasons for many years.

And so, you know, you can't necessarily code yourself out of that. Now I'm not an expert like Linda and Luke are in their teams but that's really important. And so if you're driving cost reductions and you're driving efficiencies as a provider, there have some

bottom line impacts to you. And is there an opportunity for you to enter into symbiotic relationships with payors and/or regulators to be able to share in some of those efficiencies so that you're not just getting paid, you know, at a code level, so I think that's also interesting.

The third thing I would say that I've seen that I think works really well, in addition, clearly, to the virtual health piece is a lot of the providers reaching out, kind of especially in the last few months at the end of calendar year 2020, around trying to get folks re-engaged in the healthcare system. I mean there's wellness visits that have been missed, there are really important quote unquote electives that haven't been, that haven't happened, there is some education effort that's, you know, had to be taken back on by the providers. And I think that's going to be really interesting from a trust and relationship standpoint with the patients, and so I think that's also a value that providers can bring to the payors that might inform some policies down the road.

Haven't really seen a ton that hasn't worked. It seemed like early on it was kind of like whatever it takes let's do it. And then to Luke and Linda's point, you start realizing there's some pretty serious vulnerabilities legally, and so, you know, you've seen some really good adaption there. But I really think that this idea of a patient and provider relationship that can really drive value to payors and regulators is going to be something that will be a lasting legacy of this, and I hope that provides a little bit more fiscal sustainability to providers in all areas of the states and of the country.

Alexander Mills: Thanks Gabe. I think that both you and Linda have raised this at this point, and I think it's an important question to consider in all of this. You know, I think that in healthcare there's often a kind of a fine balancing line between innovation and regulation and that we want to find new and better ways to serve our patients but because of the highly regulated nature of the field, it's often difficult to adopt or try new things. And there's a lot of, call it "legal red tape" that we have to wade through before we can kind of offer those kind of solutions and, you know, it makes sure that guys like me have jobs so that's great.

But I'm interested in kind of hearing your all's experiences and how maybe that balancing act has changed a little bit during the pandemic given the urgency of being able to provide these new and innovative healthcare methods now, you know, with the need today. And I can kind of fill it up generally, or Eric would you like to start us off on that one?

Eric Gray: Sure, yep, thanks Alex. Yeah I mean a couple things come to mind on that, and maybe I guess my perspective may be a little bit different. I mean a lot of what we do in our group is focusing on data protection. So I mean looking at privacy issues, thinking how are these vendors, how are they accessing the data, number one, what are they doing with the data, number two, and then where is it going to be stored? Stored on our location, is it stored at their location, is it stored in some cloud for someone else that we don't know?

So back prior to the pandemic, you know, kind of like Linda said, it was a longer process. We had time, we had the ability to go do all these checks. We'd go through security checks, privacy checks, contract negotiations, operations…there's a whole bunch of different areas that get involved and areas we've got to kind of check off on the checklist to make sure we've gone down that road. With the pandemic, contract negotiations that used to take months or longer took days and weeks. And so we were doing things that hadn't been quicker, and again it was patient-care focused, I mean it was obviously needed to be done and we had to do it. But it was either we were, you know, taking on more risk or we were just doing things that we didn't have the answers, so it's kind of like we're jumping into the unknown. May be perfectly private, secure, all may be well, we just didn't know at that point.

And so our job was a little bit, I don't know if it was more difficult, it may have been easier because we had less time to go through things and to talk about it, but we had to take on a little more risk. So I think with COVID, obviously some of the regulations were eased. We had more rights, more abilities under HIPAA and other areas to kind of use some alternative options which we normally would not have been able to, so that was good and that was helpful. You know, obviously that took a while from when COVID started to actually those regulations and waivers kind of changed and came into play. But I think a little bit of it was taking on more risk, and it was finding how to, and we still do it today, but how do we get to the end quicker? How do we on the legal side get our boxes checked to make sure we feel comfortable from a risk perspective? How does operations get things out for the patients, get patient care going? So kind of like the groups are almost getting together and talking quicker.

And again maybe Linda and Luke and others have a different perspective. From our perspective we have, because HCA is big, there's so many different people talking and getting involved–things

take a long time. Now we're trying to get, kind of, all together quicker up front, and maybe that's, like I said, easier from their perspective because it's less people, maybe not, I don't know. But just from my perspective, it's hard to get everybody, all the right people in that room at the same time to make that decision. So it's just been a tough, interesting run.

And I'll just say from a legal contracting perspective, it's just funny because, again, we're trying to tell people what the risks are. So they tell us hey, this is the most important thing, got to be done, got to do it, legal is slowing us down. So we drop everything, focus on it, and then the next day they're like, "Well you know what, no that didn't work. We're now doing this." So it's kind of a funny thing of like, hey we're trying to run with you guys, just tell us which way to run! It's been an interesting time, good and bad.

Alexander Mills: Eric, thanks for your response. And given my experience relatively recently at DaVita, I think I know what you're talking about when you're trying to steer a ship that large with that many people, it can oftentimes take a long time to turn it and I think it provides the perfect follow up there. I may be wrong, but Luke and Linda I suspect that you guys are a little bit lighter on your feet as a smaller organization and able to pivot a little bit more quickly and kind of deal with some of this stuff, but maybe I'm wrong there. Has that been your experience or how are things working at your institutions? Would one of you guys like take that one?

Luke Hill: I'll just take that one. Yeah we're a little smaller obviously than large HCA-, CHS-type of systems. We do have the ability to make some changes and do them quickly, but that doesn't change the fact that the regulations are the same. And that we have those same considerations like Eric said. It's, you know, this direction one day and then the next day it's this direction. It changes fluidly and you have to be able to duck and weave.

You talk about innovations versus regulations…we saw a great relaxation from our friends at the government with regards to regulations and simple things like being able to do telehealth via phone quickly after the pandemic hit. You used to require the face to face interaction, that regulation was relaxed to allow our providers to have visits via phone. It's been all hands on deck, not just with making quick decisions here at the local level, but the government's been great with interim final rules and waivers and what not to help us meet that demand. So yeah, we're able to make those changes quickly but it applies to everybody.

Alexander Mills: Sure. Linda, Luke just mentioned some of the waivers and things that the government has been passing through the pandemic to make things a little bit easier on providers, give you guys the leeway that you need to react. Is there any waiver or allowance in particular that you found that you guys have kind of relied on more than another to really help you guys to react to these kind of changes?

Linda Rippey-Moore: Well I guess that the two things that really come to mind, and I'm certainly not an expert on exactly the minutiae of the waivers, but obviously the ability to use video for visits was huge. You didn't have to have the level of privacy and security all put in place, you could deal with it through patient consent, saying you understand that this is not a HIPAA-compliant format and yet you are consenting to have this virtual visit with me. So that's an obvious one.

The second thing is the reimbursement aspect, which is huge because obviously if a physician is going to provide the service, they also want to be paid for the service. And so the insurers paying for the services, which isn't quite exactly what you said, but that's a huge component. And obviously though that aspect has not been resolved for the long term, where it's resolved for the moment but not for long term. Also, site-specific, and I say waivers, but the ability to have the patient be at home versus be in a particular clinic site or ambulatory site location also is a factor.

And the long term impact of that is not clear. So for the time being it works, but at some point in time, and this kind of goes to Gabe's point of where that shakes out from a policy standpoint, from a payer standpoint, is going to have a huge impact on how we deliver care on an ongoing basis. Because the patient can like it, the doctor can like it–all that may work but if you can't get paid for it or the government says, "This isn't going to be an ongoing platform" via regulatory means, it's not going to be workable. So that that's where policy comes in.

Luke Hill: I'll step back in here, Alex. And I'll just say to Gabe's point and Linda's point that there's uncertainty with regards to payment, but I think that that will shake out because I think the general consensus is that everybody appreciates and likes telehealth. They like being able to do this, the convenience, the increased access to care. Yes, those conversations need to happen, but at least from what we've seen, the benefits are far outweighing the downside. And when you can move the needle on population health through telehealth, why wouldn't you have full payment parity for a

telehealth visit as if it was an in-person visit? At least that's what we're seeing.

Alexander Mills: Luke, I appreciate that perspective. I think that in general, we're seeing or finding that businesses can operate remotely, as we've been challenged to work from home over last year, and I don't see why it shouldn't be applied in a healthcare context as well. Particularly, with rural providers who may not have access to the same specialist or may have difficulties finding those and this being a potential workaround.

Gabe, I'd like to throw two questions your way, if you don't mind. The first being your take on how you advise your clients on the whole "innovation versus regulation" risk perspective, and then I'd like to get some of your thoughts on the issues that were just raised by Luke and Linda. What do you think the future of telehealth may look like after this pandemic, as far payor parity and side of service and some of these other issues that they've raised?

Gabe Roberts: Because I always do this, I'll start with the second question.

Alexander Mills: Oh good!

Gabe Roberts: You know, I think the jury is out, clearly, on what's going to ultimately end up being the case. I mean to Luke's point, I think there's a growing body of evidence that full parity of payment may very well be appropriate. I also think there's some growing evidence that, well, if we don't do full parity in payment, are there some alternative payment mechanisms that we can get involved in that may not be as beneficial to the provider at the point of service, but might over the long haul be beneficial to them. And I think that's going to be an interesting conversation to have. I think it depends on the provider's willingness to do that. I think it's going to be dependent on–can the larger health systems or the hospitals, or even physician groups, find participating physicians, and providers and NPs, etc., to be willing to do that? So I think that's going to be interesting. I think that then gets into some downstream issues from a policy standpoint around cross-border licensing, and whether doctors or NPs in Kentucky in their downtime can provide services in Tennessee, and what that looks like. And that'll take many more months, if not years, to regulate or resolve. And I'm staying clearly out of that fight. I've been there before too many times!

But I do think that's going to be a really interesting post-public health emergency piece. The providers, in my opinion, are

for the most part going to be able to show really good quality, really good outcomes. The question's going to be, okay, what does it look like, in amount-wise? And I think the jury's out on that. And I think that from the providers' perspective, clearly, I think there's a lot of really good evidence. But from the payors' perspective, and I'm kind of shooting the middle here, perhaps maybe too much, but I think the payors also probably have some really valid, if not concerns, at least thoughts around "What do we do?" and "How do we do this?", and "What does it look like going forward?" But where I'm hopeful, and what I do predict (and the only thing I feel comfortable predicting), is that whatever ultimately happens is going to be better, I think from a payment perspective than it was pre-COVID, pre-pandemic.

And look, I'm talking as a former Medicaid director that testified at length about both the benefits of telehealth in our Medicaid population and also the concerns around utilization, control, etc. So I mean, I get it. Frankly, I was part of the interests that probably weren't really good in advancing the conversation. The point is we're beyond that. I think we're beyond either the regulators or payors completely winning the argument and maybe the providers completely demanding full payor parity in payment. I don't know how it'll shake out. And it could be different depending on setting. I mean, rural and underserved and even in densely, underserved urban areas may have a much better shot at full parity than someone in a metropolitan areas where there's a lot of access. So I think it's just going to be interesting to watch, and my only prediction around how that gets resolved is it'll be a little bit down the road. So those are my thoughts on that piece of it.

With respect to innovation versus regulation and risk, I think that's really important. Luke hit on some really interesting topics there, and so did Eric. I think that at the end of the day when you're trying to advise your clients, I take the same perspective that I took with my team when I was with the state, like tell me what the risks are, and then I can weigh, pretty good, what is the need for access? What are the patients' needs? And if the risk is not completely mitigated, depending on what the needs are and how exigent they are, I might be willing to take that risk and just deal with what happens down the road. I don't know if that's how every provider is, but my perspective is that all the providers that I've worked with, both as clients but also when I was at the state, the patient needs always will come first.

Reimbursement is a close second, because you can't keep the lights on and continue to increase access if you don't get paid

for what you're doing, to Linda's point. But I think it just becomes, how comfortable are you and how comfortable are we as a system, being able to weigh that risk in operating gray areas where there may not be clear answers because of things that we didn't anticipate. And I think that goes to preparedness, right? I mean one of the things that I've seen that I was really impressed with was how fast state regulators, and I mean all of the regulators, so the governor's offices, the legislators, the Medicaid agencies, the public health departments, as well as CMS, really activated and came quick to say, "We may not be able to provide the silver bullet to make this work for everybody, but we're going to start relaxing things and we're going to start taking the low hanging fruit, and we're going to do that quickly, and then we're going to try to look at some more incremental steps." And I think that's been pretty interesting.

The last thing I'll say on it–you know, there's a lot of frustration I think, even well-intended policy, well-intended regulation, protection-type issues…There can be some real frustration when on-the-ground operations realize they're inhibiting us from providing better care. I think the part two regulations around connecting folks with substance use to better care, depending on who can see that, and how it's been one of those things that have maybe gummed up the works a little bit, with respect to continuing care and handoff between providers, etc. And so again I'm hopeful that those types of things have not only…we've realized as a system that they may not work, but I also think we realized that maybe some of these are creating some barriers to access of care, maybe some health inequities that really are going to advance the conversation to try to address those down the road.

I don't know that we'll ever get to an innovator's dream with respect to health care regulation, but hopefully we at least have a better working construct in context for the next generation of leaders to come in and say, we need to be able to have legitimate protections and control the system, also allow, around significant issues, some flexibility, and if something doesn't work just right, let's don't throw the book at him. Let's just stop, reassess, and go in a different direction, as long as everybody was well intentioned. So that's my hope. That's not a great answer, but those are my hopes.

Alexander Mills: I think that's actually a really interesting point and I really keyed in on the word you used: flexibility. I think that's a good hope to have going forward, maybe a less-rigid environment where innovation's a little bit more encouraged and looked at a little bit more positively as we try to change and adapt through strategies to promote access to health care.

I think everybody's already touched on this question a little bit but just to maybe dig in a little bit further, or if any of you guys do want to comment on it. What kind of impacts are you seeing from telehealth, as far as access to care of you patients, the effects on quality of care, how is it affecting your overall system? I guess I'll just throw that one out there generally, is there anyone who would like to take it?

Linda Rippey-Moore: I'll take it, at least the tee up of it. It's interesting being in more rural communities, I think Luke said that their community has embraced it, ours has been a little less embracing. In the beginning, and we're pretty far flung in our in our service area, our telehealth manager said it was probably telehealth visits, these virtual visits, were probably 30 to 35% of what was being utilized in the spring. Dropped off at the end of the summer to about 10%–actually no, take that back– dropped off to about] 5%, and then in the peak in January was back up to about 10 to 15%. So it's not clear that, from our experience anyway, that it is being embraced.

What we've concluded is that a lot of it is doctor-driven, that if the doctor is gung-ho and on board with it, then the patients are more apt to embrace it. If the physician is not gung-ho and wants to see them, which is more common in a more rural setting, then the patients aren't insisting upon it. From a quality standpoint, from what we can tell, there has not been a decrease in quality. There has been an increase–our satisfaction scores, generally, have been higher, which is awesome.

So those aspects are good but I don't know what others are seeing, obviously, Eric and Luke, in terms of the patients coming in, but we are seeing patients that are continuing to delay care. Our cancer diagnoses for patients coming in are at a–and I'm throwing this out there, I don't know exactly what the statistics are–but more stage-three, stage-four, than we have historically seen. We are seeing a decline in volumes in our clinic, just encounters (however you want to count them, virtual or just in the office), a decline in encounters across our system, in our ED. So our patients just delaying care, not necessarily embracing the technology per se or not, just opting out. And that has, obviously, financial implications but also public health implications. And I don't know what the others have experienced.

Luke Hill: I'll jump in right here. What Linda says, you know, the physicians really drive this. If you can convince your providers that

teleheath is good, and we struggled with that as well. We had a lot of physicians that just didn't want to embrace it and we had to have a plan for, okay, what does this physician need to be able to embrace telehealth? Do they need additional staffing, do they need additional equipment? Those are some of the hurdles that we encountered.

But once you get the physician on board and they realize, this isn't so bad. I can still deliver a good solid diagnosis via telehealth, be comfortable with it. We found that a lot of them–we turned to them, they liked it and the patients seemingly do as well. You talk about some of the hurdles, good lordy. For two months we had trouble getting laptops, we had trouble getting into webcams and microphones, I mean it was like buying toilet paper there for a little while. But once you got that infrastructure down, once you got the staff needed for our physicians, and you help them see that telehealth was a good option, it seemingly was well received by physicians and the patients that they saw.

Eric Gray: Hey Alex, I'll jump in real quick if you don't mind, I'll go kind of fast. From HCA's perspective we've had an area focusing on telehealth for a couple of years, probably longer. I think it was just a slow slog, trying to push people that direction, trying to explain the benefits and how it could work here and there, and everything else. And from their perspective this just ratcheted it up, this just pushed them ahead years and years based on a few months just because everybody was going towards it.

And probably everybody else has said, once people started using it, they saw that it actually was working and was workable in many different areas, and there was a patient satisfier. If you have a communicable disease, instead of coming in and sharing with everybody, you're actually calling on the phone and maybe they direct you to the right place. Say, hey wait a minute, no no, don't come in, don't sit in the waiting room around all these twenty other people, wait over here, we'll get to you. I mean it's just trying to direct them to the right place has been a huge new area for HCA, and again for everybody's health, to make sure that patients are safer, to make sure the doctors are safer, to use less PPE, waste less equipment. It's just been a big dramatic positive, for the most part.

To everybody else's point, with all providers. If you've got all different providers, not everybody's going to love one system. Not everyone's going to love it or not everybody's going to think it's going to work for their practice. But I think with training and education, can kind of help get them going. Once they started it and saw it was working, that obviously increases things dramatically.

From what I've heard, a lot of it was really based on patients' technology. The patient didn't have access to something or didn't have the technology they needed, then it just didn't work well. It was either a choppy interaction or just didn't go well. Those, from what our perspective was, was the main area where it didn't work very well, some people didn't like it. I think as long as people had Wi-Fi it worked well, the connection was good, people like it and enjoy it. It definitely has uses but just making sure it works going both ways was it was a big key.

And again, into the future what it's going to look like, I don't know. I think our telehealth visits went up dramatically, have kind of come down a little bit. People think they're either going to level off or go down a little more once it gets back to normal. From a personal perspective, I've used it a couple times, I thought it was great. Didn't have to go drive 30 minutes to the doctor, sit in the waiting room for 20 minutes, sitting in the back room for 20 minutes, talk to your doctor for two minutes. I mean I felt like it was a nice process, I think there definitely are uses. I think to Gabe and everybody else's points it's going to be, what are those uses? How does that work, how does payment work, what's proper? Getting all that together is just going to take some time.

Alexander Mills: Great! I definitely want to try to find some time to dive into some questions about HIPAA with you, Eric. But first I'd like to just kind of pick up, it's a point that you guys have all just touched on, and Linda I actually wrote it down when you said it. Adoption of telehealth has been doctor-driven and maybe that's a little bit more self-evident for those of you guys have been practicing or involved in the health care industry longer than I have. But the adoption of a new treatment method, looking at telehealth and that kind of lens, I guess I thought of it as initially, you have to sell this to the patients. But really it's the doctors in large part who are driving this practice.

So I guess the question then is what efforts are being made to educate doctors about telehealth? Is this a situation where you have to get the boomers to get comfortable with Zoom and new technology, or how do you get them more comfortable with using telehealth? And as a follow up to that, are there certain practice areas that adopt themselves more readily to telehealth and other ones that maybe are not as appropriate, and that you think that going forward, post-pandemic, will probably revert more naturally to face-to-face encounters.

Linda Rippey-Moore: I think it was directed at me, at least to start.

Alexander Mills: Wide open!

Linda Rippey-Moore: Obviously there are some specialties, if you have to have a hands-on exam, orthopedics, surgeons, for the most part. Obviously, you can do the pre-surgery, post-surgery education, follow up. But for a surgeon, wound debridement…there are certain things that you've got to be there and they do not lend themselves typically to telehealth.

Primary care certainly does, we've seen neurology, like I said we've got tele-stroke. We're utilizing some outpatient initiatives like two nursing homes in our community where we're using our critical care nurses. They round virtually with the nursing home facility to say, is this a particular patient that needs to come in, basically. They do education on sepsis, on antibiotic stewardship, so like I said behavioral health is a perfect one, I think because it is a critical need in our community. We actually have a joint venture with HCA for a behavioral health hospital in our community, but apart from an inpatient admission, needing that virtual visit. And we are looking into that platform to provide that for our staff, for our employees, for patients, and for the community generally through an app and through artificial intelligence because that is a critical need.

But back to your point about the doctors being on board–yes, some are, some aren't. It's driven by specialty, it's driven by their own belief about it, you know, back in the day, not thinking that nurse practitioners could do or be as valuable to their practices as they are. Can you do a virtual visit? That's confidence. Can you do a virtual visit as well as you can do it in person? So it's education to them and convincing them that, yeah they're as good virtually as they are in person. Some feel that way, some don't, some like to see the patients. It's preference. That's the way they've always practiced, that's the way that they want to practice. It's how savvy they are technologically, it's multifactorial, it really is.

Luke Hill: Even a piggyback on that, some of the areas that people don't realize that we implement some form or fashion of telehealth is, when the pandemic hit, all hospitals put a stop to visitation. Get the foot traffic down. And what that resulted in was the inability to communicate with families and we struggled with that. I think everybody struggled with that. When you have a patient in a bed that has a family member standing next to them, that they're serving as a surrogate. And when you take that surrogate out of the situation, and because of COVID we thought, "Hey you can't be in the facility,

zero visitation," you take that person out of the care plan and out of the communication loop. We struggled with that, and so there's a telehealth aspect there. What strategies should we be implementing to allow the family member that's serving as the surrogate to communicate with the patient, to communicate with the physician, to serve in that role as the caregiver at home.

Another aspect that we struggled with was, when the whole PPE thing was happening and we had to conserve, can we create some sort of telehealth communication between the patient in the room and the caregiver just out in the hallway. You know, reduce the number of visits into the room so we can conserve PPE. We don't have to don and doff all the protective equipment. To say that we're still struggling with that today, even though the COVID numbers are down, we're being very mindful of our PPE and if we don't have to don and doff all the gear, we're trying not to. Telehealth is a lot more than just patient and physician, it's communication with family members and in the patient rooms. The breadth of telehealth is a lot more than just that, "what can I bill for, is this a visit and a diagnosis."

Alexander Mills: Thanks Luke. We are running somewhere short on time, but two things I would like to do is Gabe, I'd like to get your perspective on this question. You disappeared–there you are, everybody just rearranged on my screen really quick, and it threw me off. I'd like to get your perspective on this question, Gabe. And then, Eric, I would like to talk to you a little bit about HIPAA before we close.

Gabe Roberts: Yeah, I'll be quick. I mean, Luke's point he just made is so smart and it's so good about there's so much more from a real doctor and patient interaction, often times. Especially in hospitals, but it can be in nursing facilities; it can be in a whole host of cases. That there are surrogates and advocates and caregivers and family members that are really important to that equation. And really thinking about and reminding us to think about that telehealth can't just be between the doctor and the patient. I mean, it can. But it doesn't have to be, and it shouldn't be considered that way. It's too much of a false constraint. That's such a good point.

The only other thing I'll say is that everybody did a great job explaining my thoughts. What I've seen is more of a, this is not profound, but continued disaggregation of care from institutions. So, trying to partner some type of virtual care with some type of in-home. Or, you know, providers in different locations and trying to be better about resource allocation. I think that's going to be

interesting to see how that shakes out. And then I think the earlier point about consumer behavior. I think the point was that consumer technology drove a lot of the ability for doctors to really drive in on telehealth early. I think consumer behavior is also interesting. I mean, I know a couple years ago when I had friends that would do Skype, it seemed like *Back to the Future*[3] to me, or *Demolition Man*[4], like my 1980s movies references. And now with FaceTime, and how normal that is with my kids trying to talk to my parents six hours away, it now kind of seems like a normal call is like a telegram. And so, I feel like, that whole consumer evolution of behavior is also perhaps going to be a boon to whatever the kind of post-public health emergency looks like from an adoption standpoint.

Alexander Mills: Thanks Gabe. Eric, so this next question could probably be the topic of an entire panel, but we've got around three minutes.

Eric Gray: Perfect.

Alexander Mills: Do with it what you'd like. You know, we spent a lot of time talking about the telehealth regulations and kind of how they've changed during the pandemic and how we expect some of those changes to kind of continue after the pandemic and then kind of change how healthcare practice is working going forward. But what about HIPAA? I mean, I think we've had to loosen up some of these regulations in order to allow people to react to the pandemic, but I would suspect that you will probably see that stuff tightening back up in a post-pandemic world. What kind of changes do you think might occur with how we control privacy given that, you know, there's probably going to be this wider adoption of telehealth moving forward?

Eric Gray: Yeah, and like you said, I think I have one minute or maybe less, I that's a ton of time. Well, and I guess couple things on that. I mean, I think the, and I'm not sure if this is where you're going but I guess I want to talk about, privacy laws overall are just scattered. There's nothing that's, not a one law that's kind of on point. I mean you have HIPAA.[5] You have the new Cures Act, which puts out these new information blocking laws.[6] You have state privacy laws. You have the CCPA.[7] You have GDPR in the

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[3] BACK TO THE FUTURE (Universal Pictures, 1985).
[4] DEMOLITION MAN (Silver Pictures, 1993).
[5] 42 C.F.R. § 164 *et seq*.
[6] 21st Century Cures Act, PUB. L. NO. 114-255, 130 STAT. 1033 (2016).
[7] CAL. CIV. CODE § 1798.100 *et seq*.

U.K.[8] You don't have a unified federal privacy law on point, other than HIPAA. And so, kind of keeping track of all of those I think is making our job really, really hard. Cause, I mean, HIPAA is telling us, you have to restrict data, you can only use PHI in a certain way. These new information blocking laws actually tell you they want to expand that. They're trying to say, "Hey, the patient wants you to give all of their data to this app developer. You need to do that." And it's kind of like, we're trying to say, "Hey, wait a minute. HIPAA is very restrictive about what we do. Now we've got these new information blocking laws that tell us, we have to kind of open it up. It's just very confusing right now. Then you got, we have patients in California, so you got the CCPA. We have, we're in the U.K., we have the GDPR.

So it's just, I don't know if I'm answering the question, and I'm kind of doing it in a roundabout way. But it's just, right now, it is very difficult to comply with all of those different laws. So, I mean, we're hoping that the government is going to say, "Hey, let's actually think about that. Let's get something more on point and more unified so that actually it's an easier way to kind of get yourself through all of those different laws." So, right now we're having, we're struggling a little bit between, "Hey, we're protecting our patients' data," which we think is very, very important and that's our goal. But, then there's these other laws about that, "Hey, don't restrict how you send data to an EMR or to a payer or to an app developer. And so, kind of, making those all work together I think has been really tough so far and it's going continue to be, so.

Alexander Mills: That's an interesting point. That whole idea that we need a unified theory of privacy law or maybe a unified thing. I see Casey popping back on. We're out of time. I probably went a little bit over. I just want say, thank the four of you so much for coming on and thank you to the Belmont Health Law Journal. I've had a lot of fun doing this. This has been great.

Eric Gray: Agreed. Thanks.

Linda Rippey-Moore: Thank you.

[8] 2016 O.J. (L 119).

EMERGING TRENDS IN HEALTHCARE TECHNOLOGY:
FRAUD AND ABUSE PANEL

PANELISTS:
ELLEN MCINTYRE, *ASSISTANT U.S. ATTORNEY FOR THE MIDDLE DISTRICT OF TENNESSEE*
LISA RIVERA, *MEMBER, BASS, BERRY & SIMS*
AMY LEOPARD, *PARTNER, BRADLEY ARANT BOULT CUMMINGS*
TONY HULLENDER, *DEPUTY ATTORNEY GENERAL, MEDICAID FRAUD AND INTEGRITY DIVISION OF THE OFFICE OF THE TENNESSEE ATTORNEY GENERAL*

Moderated by Deborah Farringer, Associate Dean of Belmont Law

[edited for reading]

FEBRUARY 19, 2021

Casey Goggin: Next up, we have our second panel of the day, which is the Fraud and Abuse panel, and that will be moderated by Dean Deborah Farringer. Dean Farringer received her Bachelor's from the University of San Diego and her J.D. from Vanderbilt School of Law. Dean Farringer is the current Dean of Academic Affairs and the Director of Health Law Studies here at Belmont. At this time, please help me welcome Dean Farringer and she will introduce the rest of the panel.

Deborah Farringer: Thanks, Casey. Thanks so much to everyone for coming. We're really excited. You know, every year we rethink whether the third week of February is a good week to have this symposium, and I'm really glad for COVID right now because it would have been rather disastrous if we had spent all of this time planning for an in-person event and the snow had hit us. So, thanks everybody for coming. We're really excited that you're here and I'm really excited to share this panel today.

I'm going to let the panelists introduce themselves a little bit. I'll probably just give a little bit of a brief background for each of our presenters and then let them talk a little bit about their practice on a day-to day basis, what they do, and sort of where their practice is. So, I'm going to start out first, we've got Tony Hullender, who is to my left here, and Tony is the Deputy Attorney General for the Medicaid Fraud & Integrity Division for the Office of the Tennessee Attorney General. He's been in that position since 2016. And prior to that, he was in-house counsel for BlueCross BlueShield of Tennessee and worked at Miller Martin as a civil litigation attorney and was in the Army for 12 years attaining the rank of captain. He received his Bachelor's degree in English from the University of Georgia and graduated Order of the Coif from University of Tennessee College of Law. So Tony, welcome. Tell us a little bit about what you do on a day-to-day basis, Tony.

Tony Hullender: Good morning. Well, we have a very narrow mission. We call ourselves "MFID" so we don't have to use that long name. But we have a narrow mission: we civilly enforce the Tennessee Medicaid False Claims Act[1], which is patterned after the federal False Claims Act[2]. So, we are only dealing with Medicaid fraud, unlike the Federal False Claims Act. It covers a lot of different kinds of fraud. We focus solely on Medicaid fraud and solely on providers and solely civil. So, we basically have two kinds of cases. One are qui tam cases which a whistleblower files a case under seal and then we decide whether Tennessee is going to intervene or not.

[1] Tennessee Medicaid False Claims Act, TENN. CODE ANN. §§ 71-5-181 *et seq*.
[2] False Claims Act, 31 U.S.C. §§ 3729-3733.

And then the non-whistleblower cases, typically are referred to us from TennCare. But they usually get them from one of their three MCOs, managed care organizations, BlueCare, United, Amerigroup, which all have their own fraud divisions. If they see potential TennCare fraud, they refer it to TennCare. TennCare does a preliminary investigation. If they think it has merit, they refer it to us for civil investigation and then they refer it to TBI for criminal investigation.

Deborah Farringer: Alright. Thank you. Okay, next we've got Lisa Rivera. So, Lisa is currently a member at Bass, Berry, & Sims and focuses on advising healthcare providers and pharmaceutical manufacturers, medical device companies, on civil and criminal matters. So, she's going to tell us a little bit about her practice. She was formerly Assistant United States Attorney for the U.S. Attorney's Office for the Middle District of Tennessee where she was the civil and criminal Healthcare Fraud Coordinator and has also worked with Medicaid Fraud Control Unit with the TBI. She was an Assistant U.S. Attorney in Puerto Rico and a state prosecutor in Florida, and also has a commercial litigation defense practice background. She got her J.D. from the University of Memphis and a Bachelor of Science from Tennessee Tech University. So, tell us, Lisa, about sort of your day-to-day.

Lisa Rivera: Hi, good morning. Thanks for having me. Really, my focus is in civil, potential civil and criminal healthcare enforcement by state and federal authorities, primarily False Claims Act investigative requests that are served on various types of healthcare providers, from large healthcare systems to individual private practices, device manufacturers and folks that use those devices, look in the government review for any sort of anti-kickback concerns and physician Stark concerns. So, it could be at any level. It could be the Board of Pharmacy. It could be state. It could be Tony; it could be Ellen, for a variety of issues. And, also, a lot of internal investigations and proactive compliance counseling with clients on a regular basis. As we all know, this is a highly regulated industry and it's constantly evolving and changing, which makes it very challenging and exciting practice area of law. And, so, it's always interesting for sure. But that's really it on a day-to-day basis.

Deborah Farringer: Alright. Thanks. Our next panelist is Amy Leopard. She is a partner at Bradley Arant Boult Cummings. And her practice focuses primarily on health IT and regulatory compliance and she's a certified Information Privacy Professional and formerly chair of the AHLA Health IT Practice Group. So, she's going to tell us a little bit about her practice with over 25 years in

health care. She graduated high honors from Auburn University and earned her master's degree from the University of Alabama at Birmingham and has her J.D. from Case Western Reserve University, where she graduated *cum laude*, and was the Editor in Chief of the Health Matrix Journal Law-Medicine, which is one of the, a great health law journal out there that does a lot of, publishes a lot of interesting work. Amy, tell us a little bit about your day to day.

Amy Leopard: Yeah, hi Debbie. Good morning everybody. And, yeah, so when I was in law school, much like many of your students, I knew I wanted to be a health lawyer. And I came to law school from hospital administration. So, one of the things I did when I was in law school was intern in the Justice Department, and that kind of started off a 10-year career in Cleveland as a fraud and abuse lawyer. I came to Bradley about 9 years ago to head up the Health Information and Technology Practice. So, that's 90 plus percent of what I do every day, whether that's on the fraud and abuse side, on the payment side, on the I procurement, looking at HIPAA. Right now, a lot of cybersecurity incident response is going on in the hospital communities. But also looking at technology, technology transfer, and artificial intelligence. So, it's a lot of fun. I think my role today on the panel is more compliance oriented than the rest of the panel.

Deborah Farringer: Alright. Thank you. And our final panelist today is Ellen McIntyre. She's an Assistant U.S. Attorney here in Nashville with the Middle District of Tennessee. She's been there since 2003 and she handles various cases, primarily on the False Claims Act and other health fraud on the civil and criminal side. And before she was an AUSA, she served as a Senior Trial Attorney for the Justice Department's Civil Rights Division and a staff attorney at the Southern Poverty Law Center. She graduated *cum laude* from the University of Pennsylvania and received her J.D. from Columbia Law. So, Ellen, talk to us a little bit about your practice.

Ellen McIntyre: Thank you so much, Deborah, for having me today. So, I am the Affirmative Civil Enforcement Coordinator for the U.S. Attorney's Office here in the Middle District. And what that means is, essentially, I help coordinate the team of people who do the plaintiff's side work on behalf of U.S. Most of that work in our office, I would say, maybe 90%, 85-90%, is under the False Claims Act. And, of that work, you know, the vast majority is healthcare fraud, in particular, because obviously we are a healthcare fraud center. And, you know, sorry to say it, but there's a lot of healthcare fraud in this district, right? So, anyway, that's what we pursue, and

we have big team that do it. And I think that we are one of the leading units in the country. So, you know, we have a lot of cases cover, that run the gamut in terms of different types of healthcare fraud. And, you know, we try to obviously do a great enforcement job for the district.

Deborah Farringer: Alright. Thanks. So, we're going to kick it off here by asking some questions about fraud and abuse trends. So, I'm curious, first we'll talk maybe to our practitioners and then we'll talk with our government attorneys here, about what fraud, waste, and abuse trends you're seeing now as a result of the pandemic that you didn't see prior. So, after COVID kind of hit us in March of last year, what are any new trends, what are you seeing now from a fraud and abuse perspective that's maybe new or different? Lisa, let's start with you.

Lisa Rivera: Well, so, in my experience there were a momentary lull in investigations that were ongoing and sort of in the pipeline, initially. And then, I think the government adjusted and began picking back up speed, having to do things virtual. I mean, that's not something the government would typically like to do when gathering up evidence and judging credibility of witnesses and evaluating their cases. But they decided, they're going to go forward and do that, they weren't going to postpone it any longer. And so, that picked up speed again.

We've all had to adjust in terms of responding by Zoom, having some back-and-forth presentations with the government, which we typically do in a lot of cases, having witnesses and clients interviewed over the internet with government counsel. We've all had to adjust in order to continue in working in those investigations. I think that from an enforcement standpoint, you saw initially, and still do occasionally, a headline about sort of what I would consider more low hanging fruit related to COVID funding where you know, somebody bought a Maserati with those funds and provided fraudulent representations about perhaps, COVID vaccines or other remedies. So, but I think eventually it will, I think we view this as sort of a perfect storm in an already highly regulated industry. I mean, just when you thought it really couldn't become more scrutinized. It looks like the perfect storm for that because you have an unprecedented amount of money that was earmarked and distributed to the healthcare industry, unlike before, any time before.

And at the same time, when that money is being received, I mean provider and healthcare organizations' hair is on fire. And they're dealing with a crisis and you also had as part of that, sort of

evolving government guidance, or still trying to determine what the guidance would be with respect to the funds, as well as the applications and type of information that's requested for those funds. And then you're going to have, because of the amount of money, guaranteed retrospective scrutiny over the eligibility for the funding, the use of the funds, and the certifications around entitlement and representations to the government about the funding. So, I think that that is going to be something that the government will be gearing up for. Those sort of complex matters are not going to [inaudible] immediately, but I think as time goes by, that's what we're gearing up for and that's what we anticipate from the government.

Deborah Farringer: Alright. Thanks. So, Amy, what about you on the technology side? What kinds of things are you seeing from your clients in terms of new or different issues that are coming about as a result of the pandemic that you feel like has really started to become really commonplace in your office?

Amy Leopard: Well, I think like Lisa, a lot of it is the provider relief payments and the, you know, let's just recognize that the government funding was critical to keep our industry running. Right? But there are strings attached, and so, you know, thankfully when HHS started to promulgate some of these rules they decided that you, providers would have a little extra time to reject the additional terms and conditions that were being imposed during all of the chaos. And so, what you've seen is, are clients that have, you know, good compliance programs have had to do that, and, you know, reject those terms and sometimes return the money. And so, hopefully, if you've got that documentation and some grace from the government to, you know, have time to take a more organized approach to certifications that were made during, you know, what now in hindsight we see was pure chaos. That has been extremely helpful.

Those same certifications come into play on technology as providers have to attest to CMS, to Medicare, that they are using updated technology to be eligible for the EHR incentive programs. And, we've seen just within the last month, where the Justice Department has begun to prosecute an EHR vendor, kind of on a new theory goes beyond some of the theories in the past under the False Claims Act against vendors that, you know, didn't have the security that's required by the EHR rules, or failed to provide a functionality that's required, and then now going into whether or not EHR technology vendors are paying kickbacks in the form of Kentucky Derby and other kind of boondoggles, so to speak. So it's

a real evolving climate right now both on the technology side and on the provider side. But I think paying attention to those attestations, recognizing that there are statutes for False Claims Act and false attestation liability. So maintaining that compliance documentation is key.

Deborah Farringer: Yeah, it sounds like, the both of you, it's really a little bit of you're not quite sure what's going to happen when things sort of all shake out, right? It's difficult to tell at this point in time because unlike in the past when you're sort of aware of Stark Anti-kickback False Claims Act what the rules are this is sort of a whole new set of regulations, a whole new set of compliance concerns. And so it's a little bit difficult to try and figure out what exactly the challenges are going to be before we before we hit them.

So, Tony and Ellen, from your perspective what sorts of things are happening in your office in terms of what you're focused on right now, for purposes of post-pandemic fraud and abuse? You obviously, both the Department of Justice and I think the Medicaid fraud unit, had things that they were focused on in the pandemic. How has that shifted in the last year as things have sort of changed globally here?

Ellen McIntyre: Well thanks Deborah. So I'm of course going to be talking about things that are public, because I can't talk about non-public things that are under investigation, and same for Tony. But I think that there we're going to see different types of schemes and there have already been some, you know, there's been a number of public things that have that we can look at publicly.

So the first type I wanted to talk about was kind of like classic criminal schemes that have arisen in the pandemic in terms of healthcare fraud. Just this month actually, in February, the HHS issued a fraud alert actually to the public.[3] In other words, not to providers but to the public, to warn the public about types of COVID-related schemes, like people calling and saying "We'll give you a vaccine or we'll give you, you know, something related to the pandemic if you give us your Medicare prescription number" kind of thing. That's really important that the public not fall for those total scams.

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[3] Press Release, DEPT. OF HEALTH AND HUMAN SERVS. OFF. OF INSPECTOR GEN., FEDERAL AGENCIES WARN OF EMERGING FRAUD SCHEMES RELATED TO COVID-19 VACCINES (December 21, 2020), https://oig.hhs.gov/documents/coronavirus/245/Vaccine-Fraud-PSA.pdf

And then also there have been some indictments already, there's even been like some guilty pleas. The kinds that I've seen are there are indictments of ads for vaccines that cannot be verified as real; in other words, people are marketing a fake product that could reel people in, in this climate of fear that we live in. Of course we've all seen the ads about hoarding or price gouging of personal protective equipment, and then there is also one of the things that you know some of the defense lawyers here talked about is there could potentially be fraudulent bank loans seeking CARES Act relief or other kind of advance payments under the Medicare program due to the pandemic. And so whether that's a fraudulent bank loan or whether that's you know a certification 'hat people don't live up to, that could fall into the realm of possibly criminal, possibly civil, depending upon what the conduct turns out to be.

In the terms of like the civil stuff that we might end up seeing as a result of this, obviously you could see a misuse of COVID relief money which again could be from Medicare or from the CARES Act. That money, if it's from the Medicare program, is intended to be spent on healthcare. And so if recipients of 'hose funds don't spend it on healthcare or if they've misrepresented something such as like having ghost employees'(you know, you've seen this, you've see this in the media anyway), that what if somebody says well we've got 100 employees and we need those funds to continue paying them, but actually maybe they've laid off those employees and they don't bring them back, and they use the money for something else–all of that is obviously fair game in terms of being investigated.

Another thing that, I don't know how much it's been in the press, but I think there is a potential for additional worthless services investigations in the nursing home, skilled nursing facility context because even though obviously the government can't get into those facilities at this moment in time, there may be uncovered that some of these spread in the facilities could be linked to poor infection control, that sort of thing. And so down the road that is something that might come up around the country and we'll be looking in those in those areas.

Deborah Farringer: Alright, thanks. Tony what about you from the Medicaid side and TennCare? From your perspective what have you guys been either seeing that's public, you can talk about, over the last year or anticipate is going to become a new area that's really going to be a focus for you?

Tony Hullender: First of all, I think Lisa mentioned this initially there was a real lull on all sides. So for a long time we've just been catching up on our non-COVID related cases. I think Ellen mentioned, the last thing she mentioned she said that's something she anticipates might happen, and I think that's where we are in terms of what I think of sort of classic provider fraud. And other things we talked about misuse of CARES funds and that sort of thing, like consumer fraud you know selling a fake vaccine, that's really not what my division does. You know, we're more about a physician files a claim for payment and it's false because he didn't do it or he up-coded it or something like that, and for those kinds of things I think it's a little early' My office isn't seeing any COVID-related fraud like that yet. It will probably start with those TennCare managed care organizations. And I've talked to those fraud department of these MCOs and they're not seeing it yet in Tennessee, but they're looking. They're concerned, if for no other reason, because it's new. And whenever there's something new and there's a high volume it can take a while for everyone to figure out what's going on. You can be pretty sure there's going to be a small percentage of providers that will do something that they shouldn't do.

A couple things that they're looking for which are kind of traditional but not in the COVID-19 context: they're going to be looking at the tests because there's so many of them, they're going to be looking for providers that bill for tests they didn't do, they'll be looking for providers that bill for tests that weren't medically necessary, that one might be kind of hard given the pandemic. Another one I found interesting that one of the heads of the fraud Department from one of the MCOs told me is they're looking at add-on services. I think they've seen that in some other states where someone's there for COVID testing or COVID treatment and the provider adds on test that, at least from the government standpoint, are not medically necessary. Genetic testing for something that was mentioned, and there's a type of pulmonary test (I wrote it down because I don't know what it is) respiratory pathogen panel. That must be happening in another state because it's sort of on the radar.

Deborah Farringer: Thanks, that's a good segue, because one of the things you mentioned is we're sort of waiting and watching. And I think one of the things that's really been on the uptick, they talked about it in the first panel a little bit, is the use of telemedicine, right, the increased use of telemedicine during the pandemic. Obviously one of the things that's really been different in terms of telemedicine is the total relaxing of the rules. Telemedicine was previously relatively restrictive at least from a Medicare perspective in terms of

Medicare payments only for certain rural providers and only for certain specific sites and that sort of thing, and all of those have been waived now.[4] So with the increased use of telemedicine, how do you feel like that is impacting the fraud and abuse analysis and what's your advice to physicians regarding what to do now the interim when everything seems to be the Wild West? And then how to anticipate what might happen later when we go back to an end to the public health emergency and there is some reinvigoration of some rules here. Do we have somebody? Amy, do you want to start there?

Amy Leopard: Sure, yeah so that expansion of benefits has had a huge impact on the delivery system. The relaxation of the HIPAA rules has helped with vendor contracting, the ability to use cell phones on both sides, and allowing facilities to provide their medical staff with a telemedicine platform–all of these things have had an immediate public health benefit. I listened in on your panel this morning and you can hear just over and over again the public health tool that telemedicine has provided in the middle of the storm. Keeping up with those challenges and just where all of the changes have been made has been difficult. I mean that's kind of settled down a bit, but the hard part is going to be when the party is over. We saw that just recently in looking at a telemedicine program between Tennessee and Mississippi that, after all the state medical boards had relaxed licensing requirements across state lines with great fanfare last year, Mississippi quietly rescinded their rule and now requires a license.[5]

And so, we're in Tennessee, we might be aware of that you need to have a license to telemedicine with Mississippi residents but do providers in Maine know that? That's what I see is there could be some gotcha moments, and hopefully providers will not so much be in the crosshairs as we take down the waivers but there there's some type of grace period

Deborah Farringer: Lisa what about you? What are you seeing from your clients that are sort of similar, how are you advising your clients right now on telemedicine, and how to be cautious because we're in this in-between moment?

Lisa Rivera: Yeah, there's this, I think, an initial feeling of, hey, the government is here to, as Amy put it, in this public health crisis the government's here to help and lend support both financially and in in relaxing some of the requirements that might otherwise be in

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[4] 42 U.S.C. § 1395 *et seq*.

[5] MISS. CODE ANN. § 73-25-34(2) (1972, As amended); CODE MISS. R. 30-026-2635, RULE 5.2 (2021)

place because we just want to get patients treated. We want to not have, as you know, too many barriers in the system for patient care right now in this crisis. Frankly, that's not going to be the perspective of the government later when they're coming back to look at what was happening during this time period.

When you think about large health systems right now dealing with all of the COVID issues, stopping many procedures, moving employees around within a system to render aid for certain issues and certain health concerns, and sort of transitioning to telehealth, I think CMS issued something that said that there was an 11,000% increase in telehealth services post-pandemic. That's a lot. That's a lot of money and that is just not going to go unreviewed going forward. They're coming! So I think for clients right now understanding that there's so much on their plate and so many things in the air. If you think about it, a lot of clients will have sort of a central command center for COVID because there's so many plates in the error related to responding to COVID. You know, pulling from here means there's an issue over there, but you're trying to jump on a fire that's happening in this area, and so you pull your resources from other areas within your enterprise. So I think that trying to help clients understand and document the reasons that exist right now for why they're going what they're doing is going to become very important when the government is later looking at telehealth services and others with skepticism, because of the numbers, and a different lens than maybe health care providers are reviewing right now.

In September of 2020, DOJ has a big nationwide takedown every year, and in September 2020 they had theirs and it was primarily related to telehealth enforcement. I think that the allegations around the alleged telehealth fraud was about $4.5 billion in fraudulent billing related to telehealth, and that's pre-pandemic. I couldn't tell you about each and every case because that's a coordinated effort, those cases aren't all related to one another, but the number that the government had in their press release related to telehealth services and frankly I think the majority of that may not necessarily be post-pandemic.

Deborah Farringer: Thanks! So Ellen and Tony, I want you to kind of get in here and we also just had a question from the audience as well that was something I was thinking about. The usual tools, right, and oftentimes what defense counsel will tell their clients is just make sure you're not an outlier. Watch your data to make sure you're not doing anything that sort of gets you on the radar. And with the increase that Lisa just talked about, so with the increase in

telehealth at 11,000% I think is what she said, how is that data is going to be used? Will it be used? Should that be something that providers pay attention to? Can you talk to us just a little bit about how the government might be thinking about this interim time period.

Tony Hullender: Yeah, this is so new that I've not had any cases that were based on telehealth but I think there is going to be some similarities. My experience tells me, when you have something this new, two things happen: One, there's a tiny percentage of providers that will spend some time figuring out a way to defraud TennCare with this new scenario, and two, there's going to be a period of time where there's confusion about the rules, the regs, how it all works. And I don't know if there would be an official grace period, but I think there'll at least be a practical grace period where it's going to be pretty hard, unless somebody billed for services the' didn't do, it's going to be pretty hard to prove fraud as everybody's trying to get this done.

In terms of spotting it, I think it'll still be, we'll still use the same tools. I'm not a data analyst but I work with a lot of data analysts, and I think they will still be looking at 'he data but it's going to take them a while to figure out how to massage that and how to interpret it. But like you said, they're still going to look for outliers, it just may be the outlier number is a lot higher than you would've thought because the baseline is low. I told you I talked to the chief of the fraud division of one of the TennCare MCOs, and for example, he said they've already seen some labs that they thought were outliers, but then when they dug into it there were reasons, non-fraudulent reasons, for it. One of them had an exclusive contract with very large health plan. Another happened to have a lot of customers in an area that was hit harder than most by the pandemic.

So yeah, I think there may be some challenges but I still think it would be the same sort of thing. You're right about, you know, providers should try to not be outliers. I would take it a step further and say if you're going to be an outlier, well even if you're not an outlier, know your codes, the codes that you're using, CPT codes. If you're using one that gets you a lot of revenue, pay particular attention to that Don't take someone else's word for it, physically read the description of the code. And then I would say focus on medical necessity, make sure that what you're doing is medically necessary. And if you do those two things, I think more often than not you're going to be okay.

Deborah Farringer: Thanks. Ellen, what about you? [inaudible]

Ellen McIntyre: Thanks. Well, I think some of this is kind of common sense. If you have a provider that is billing this many in-person visits and then they shift to telehealth when there's the waiver during the pandemic, and you see that the total numbers add up to the same – that is not going to be this big red light in our mind I would think. But if you see a situation in which they were only billing this many in-person visits and then their telehealth visits go up like to the roof, I mean that would be the kind of thing that would look suspicious, potentially, and might be looked into.

In general, although I don't think people have talked too much about the specifics of telehealth, I thought it might be helpful if I could tell a few of the government's concerns in this area. Lisa had mentioned that there was a prior telehealth takedown and that's correct. That involved a lot of possibly criminal kinds of conduct in which you saw pre-pandemic use of telehealth in a way that there was not really a legitimate service being provided. Often you would have some improper marketing that would get maybe by leads of customers and then pay a kickback to a physician to either sign an order for DME or genetic testing, or maybe they don't have any visit at all. So we're not really talking about the legitimate shift that, to some extent, is obviously underway right now, but before that you had different kinds of abuse of telemedicine and those could be kickback relationships and there could be resulting prescriptions for non-medically necessary items.

The other area I wanted to mention briefly was electronic health records cases. There are two different types of schemes schools in this area. Amy alluded to one of them and she was referring to this $18 million settlement that was announced from in January of 2021 from the district of Massachusetts.[6] That did involve traditional kickbacks in the sense of the company allegedly was marketing their electronic health systems to either existing customers or prospective customers by giving them improper kinds of kickbacks, like tickets to these really expensive items, luxury things, just classic stuff. The other type of arrangement which we've seen in this district in the Inform Diagnostics case is when there was actual provision of reduced-cost electronic healthcare record systems, or linked-in technology to assist with those systems – we've

[6] Press Release, DEPT. OF JUSTICE OFFICE OF PUB. AFFAIRS, ELECTRONIC HEALTH RECORDS TECHNOLOGY VENDOR TO PAY $18.25 MILLION TO RESOLVE KICKBACK ALLEGATIONS (Jan. 28, 2021).

seen that in our district and that resulted in a $63 million settlement.[7] But all of these are kind of part and parcel of what goes into what the government looks at in the telemedicine field so far, and of course that may change if there is abuse of the current telemedicine increase that's been going on.

Deborah Farringer: Yeah, let's talk about that for a second. Interesting that you point out electronic health records since our theme here is technology. Amy and Lisa, that was an area of focus that the Department of Justice has previously, last year pre-COVID, had ramped up and said we're going to start paying attention to more of this. We were seeing more certification cases when it came to EHR certification, we were seeing an increase – there actually has been a few instances of EHR vendors being subjected to False Claims Act violations or settlements in connection with False Claims Act for certain hard-coding in connection with meaningful use payments. As you have shifted focuses here and the pandemic has distracted providers with other things, these new things to be worrying about, how are you still keeping your clients aware of what was already-existing fraud that has been the focus of the Department of Justice and making sure that people are still keeping these things in mind? Have things shifted so much people have forgotten about it? How are you making sure that your clients are keeping on track with this previous fraud concerns as well?

Amy Leopard: They haven't forgotten about it. They've probably developed a better understanding that they should be worried about it, as they see what's going on in the enforcement would. And so I guess I'm seeing more clients each year who ask, "Is this compliance documentation that I have sufficient for me to make this certification?" Like getting a second opinion on whether or not all the 'yes are dotted and T's are crossed, and that seems to be each year, more and more people, as they're sitting down to sign that certification and make that, you know, "I swear to the federal government that everything is true, accurate, and complete," they start to get hypertensive. And when that happens, they're looking for someone to kind of come in and help them understand, is my compliance documentation sufficient. I've seen a lot more of that each year, so I think the awareness is there.

Lisa Rivera' Yeah, I think that's right. I think it's been an incredibly stressful year for these organizations having to switch gears and decide, after patient care, under these circumstances what is the next

[7] Press Release, DEPT. OF JUSTICE OFFICE OF PUB. AFFAIRS, PATHOLOGY LABORATORY AGREES TO PAY $63.5 MILLION FOR PROVIDING ILLEGAL INDUCEMENTS TO REFERRING PHYSICIANS (Jan. 30, 2019).

fire we should put out? I don't know how well-reported it was but a lot of health systems (maybe you mentioned this earlier, Amy, or maybe it was in the earlier panel) but there was a real cybersecurity scare that was going on with a lot of health systems in the country while they were trying to respond to COVID. It's just really unfortunate that that happened but it impacted their abilities to communicate with one another because of the measures that they had to take during that time. It was very concerning so that's a regular concern, you have those kinds of things in place already but your system is constantly being pinged, I mean thousands of times a day, looking for an open window by people that want to do it harm. And that's just a normal day. So with all of this going on and having to adjust to protecting their information while they're trying to adjust to the COVID crisis that has evolved really throughout the year from time to time has been very stressful.

I think that their compliance teams, the communications about that have been more regular in trying to keep all the trains running on time and stay within the guardrails at the same time, just like they would typically do. But it has been a very stressful year to try to make sure that there is no ball dropped anywhere during the middle of all that. And talking to them about it and documenting things that are happening, because when somebody comes to call and ask about it two years from now or eighteen months from now, or whistleblower files a suit about some portion of any of that, they're going to have to reflect on, from two years earlier and understand with everything that was happening at that time, what were the considerations that that were impactful for any particular decision-making or the ability to refute what is being alleged is going to be it's just going to be so important because they just have so many things going on. People move on, they need to document to the extent that they can based on the information that that they know right now that supports the decision-making around all those issues.

Deborah Farringer: Thank you. So, documentation, documentation, documentation–that's what I'm hearing. Let's switch gears here a little 'it and talk about…we've been talking about COVID and telemedicine waivers. Simultaneously, sort of ongoing with this, was a push already to try and ease up some of the restrictions under Stark and anti-kickback, and we had some Stark sanctions that have been waived during the COVID pandemic.[8] Talk

[8] Social Security Act § 1135; 42 U.S.C. § 1320b-5; CMS, BLANKET WAIVERS OF SECTION 1877(G) OF THE SOCIAL SECURITY ACT DUE TO DECLARATION OF COVID-19 OUTBREAK IN THE UNITED STATES AS A NATIONAL EMERGENCY

to me a little bit about those changes in terms of some easing of the Stark regulations, and then also proposed regulations for purposes of trying to make Stark more flexible. How has that sort of altered your practice in any way? How has it changed how you advise your clients? Have clients been receptive to that or is it like there's just so much going on they can't even focus on any one of these things as an advantage or disadvantage? Lisa I'll probably start with you, just cause (I know you spoke last) but this probably gets to the heart of what you do day-to-day'

Lisa Rivera: So I'll tell you, our healthcare clients–I mean we had a crack team trying to gather all of this information and understand what the guardrails would be going forward based on the information available and what would that look like. Unlike telehealth where we, as a panel talked about how we think telehealth is probably the horse is out of the barn there, we don't really see it reverting back to the way it was even from a government perspective, it's just how is it going to look, what's it going to look like going forward?

But a lot of the Stark and the other issues where waivers have been issued, I think the government is intending to revert back in a large way. Look, the government doesn't like to bring cases where the rule was one way Friday and by Tuesday you weren't back in line, I mean that's not the kind of case I'm talking about. But they are going to be looking at how providers do transition, if they moved away from it in the first place, whether or not they still did so in a compliant way and going forward how that looks. I think it's going to be very difficult to argue a justification, as more time is removed from COVID when the waiver time period has passed, to justify not getting back on track. And again, you know, I don't think the government is looking for those kinds of close-call cases but a' the same time I don't think that providers can be comfortable thinking that that they're going to be able to justify that moving forward even after the storm is over.

Deborah Farringer: Amy, do you have any thoughts on that from your perspective, for your clients?

Amy Leopard: Yeah, I think providers need to remember to document that they met all of the other requirements that were not waived' right? Because that's going to shine a big light on things. But as far as the waivers that we had, those waivers have permitted hospitals to pay hazard pay to physicians, to provide free on-site

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(March 1, 2020), https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.

child care to doctors that are working long hours, to rent medical office space where there's surge capacity needed for ambulatory, the share PPE with referral sources, to make loans to specialists who were hard hit when elective procedures were paused and they want to retain this anesthesia group. So there's a great deal of flexibility there but you still need to, I think as Ellen said, have commo' sense right? If you're providing something under a waiver and the rationale for that waiver has started to dissipate, it's really time to start getting your exit plan in place. And you really should enter these waivers with an exit plan so that you're level-setting expectations that this benefit is tied to the COVID pandemic and it is not going to go on forever and you can easily unwind them.

Lisa Rivera: Yeah, and Debbie the language in the waivers require otherwise fraud and abuse concerns and considerations,[9] so you can't just throw everything to the wind. There are still the straight and narrow that has to be followed in order for those waivers to really be valid, or at least arguably from the government's perspective.

Deborah Farringer: Great, thanks. Ellen and Tony, do you have– obviously, Tony, you don't deal with Stark specifically, that's a federal law or the anti-kickback statute but from a perspective of thinking through a post-waiver environment, it can't be a light switch probably, right? It's going to have to be some sort of a dial where things are sort of dialed back in. From your perspective how is it that the government is thinking through what life might look like post-pandemic?

Ton' Hullender: And you're right there are scenarios where we're involved in Stark and anti-kickback, but not enough that I've dug into these waivers. I figured by the time I have another one of those cases, the waivers will be gone, so I haven't given that much thought.

Ellen McIntyre: Yeah I don't have much to add either on that' but I mean, also we're in a new administration, all these things are up in the air, but I think that the right note is sort of what the defense counsel struck about you've got to be careful with this stuff.

Tony Hullender: By the way Deborah, did you say somebody had sent in a question or did we cover that?

Deborah Farringer: I think we've had–I was going to ask Paige, too. I think we had one specific question, then maybe another question that might have been posed to our director here. One was on how might the government, federal or state, be employing data

[9] *See* 42 U.S.C. § 1395nn.

mining to look for some of the alleged COVID add-on test fraud? So to what extent are you monitoring this and thinking through certification and some of the COVID add-ons that are part of the federal dollars?

Tony Hullender: Yeah, we don't do our own data analysis. That starts with those MCOs that I keep mentioning, cause all three of those MCOs are huge and they have their commercial business too. So I'm sure they have a room full of brilliant data analysts that come up with different algorithms to try to find that sort of thing, but I don't I'm not privy to exactly what they're doing right now. And TennCare here has a bunch of data analysts as well, and they do some of that. They do a lot of other things with it too, but I'm sure they're looking at if you decode the diagnostic codes and doing peer comparisons, the same sort of things we do with other fraud schemes.

Deborah Farringer: Ellen , what about you?

Ellen McIntyre: I would just generally say that the DOJ and the US Attorney's offices do ongoing data analysis, and so we're just on the lookout for things and whether they corroborate allegations or whether we find things trends of concern. But I can't really tell you specifics about what we do in that regard. I also think it's worth noting that there's also there's always whistleblowers who could report on specific things going on if they have concerns, and so those end up coming to us at some point often. And I do think that the potential for upcoding exists in the pandemic because even just the nature of telehealth–some things are less likely to be happening, right? You're not going to have a physical exam, the visits might be shorter. That's my personal experience, there's just different things and I think the coding has to be linked to what's really occurring, obviously, what's appropriate.

Tony Hullender: Yeah, for example, good that you mentioned the whistleblower, I meant to do that as well. For example, and I don't know what the deal is with genetic testing, why they're looking for genetic testing as an add-on, but they could have a whistleblower come in and say, "Hey, this doctor that I work for is putting genetic testing on every single COVID person that comes in here." And that could alert the MCO or TennCare that, say, well let's run a check on all the primary care providers in Tennessee. How many of them are using that code for genetic testing? If a whole bunch of them were using it, they'll still look at it but there may be a valid reason if nobody else is doing it, then that person is probably going to have their medical records reviewed.

Deborah Farringer: Yeah, thank you so much. It sounds like a lot of what is going on is that, or there is an increase in data but that the idea of an outlier is actually not changing at all, right? That there are still going to be things that are present in the data that are out there that there are going to be general upticks, and then there will be individuals probably who are beyond what should be the normal or the general. And so probably all of the same advice that was given before should be given now in the sense that everything needs to be justified and documented, and that you need to have appropriate justification for exactly why you are doing everything, and that we are going to continue to watch the data in the same way we did before.

Well we're about out of time. Thank you so much to the panel, I really appreciate all of you. This has been a really helpful panel from my perspective. I think it's always interesting to think through. I would love to have all of us back in a year, because I think it would be a very different discussion. We're in the middle of it right now, and so I think it would be interesting to be able to have the same discussion a year from now and figure out maybe what we didn't know now that we will know then.

Tony Hullender: Maybe we can be in person next year. Does this mean I don't get my Belmont coffee mug?

Deborah Farringer: Oh we will be sending it, no worries. It's just coming in the mail.

Amy Leopard: Maybe there will be some rest for the weary by then.

Deborah Farringer: I hope, I hope. Thank you so much all of you.

EMERGING TRENDS IN HEALTHCARE TECHNOLOGY:
PRIVACY ISSUES WITH HEALTHCARE TECHNOLOGY

SPEAKER:
PROFESSOR CHARLOTTE TSCHIDER, *LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW*

[edited for reading]

FEBRUARY 19, 2021

Casey Goggin: Next up we have Professor Charlotte Tschider. Ms. Tschider is current an assistant professor at Loyola University Chicago College of Law. She was previously a visiting professor at the University of Nebraska College of Law and the Jaharis Faculty Fellow in Health Law and Intellectual Property at DePaul University College of Law. In 2017, she was named a Fulbright Specialist in Cyber Security and Privacy Law by a Fulbright Scholar program. She received her J.D. from Hamline University School of Law where she was a member of the Law Review. She received her M.A. from the University of Minnesota Twin Cities, as well as her Bachelor's degree. Her primary scholarship is information privacy, cybersecurity law, and artificial intelligence, with a focus on the global health care industry. She has written or spoken about many topics, ranging from data collection in the medical industry and internet privacy to global data protection. She is the author of *International Cybersecurity and Privacy [Law] in Practice*.[1] And with that, I'm going to hand it over.

Charlotte Tschider: Well, hello everybody. It's just a pleasure to be here. I was actually supposed to present last fall and it's amazing how much can change in just six months. I think that this first panel was excellent in demonstrating how technology is really changing things for a variety of people in a variety of locations. And the investment in artificial intelligence and big data use has really transformed that to even a greater extent. And so, I'm hoping today that I can illustrate some of the challenges related to the current privacy regime.

But I'd like to start by talking a little bit about the technology. And before I jump into the slides, I always think it's fun to talk about certain scenarios that I've been faced with from a consulting perspective that kind of put things into a little clearer focus. So, one of the devices that I have consulted on in the past actually came out of Finland. And for many of you who might have some familiarity with the EU data protection directive that preceded the GDPR and the GDPR, one the challenges we faced in those spaces is related to data sharing, data use, and data reuse. And we know that data has become tremendously important for both the treatment of health conditions and for the technology that is associated with the treatment of those healthcare conditions. In this case, I was talking with a company and they had produced a really amazing type of technology where you can actually look at somebody's cornea and do it without the puff of air that many of us are familiar with from getting eye exams. And they said to me,

[1] *See* CHARLOTTE A. TSCHIDER, INTERNATIONAL CYBERSECURITY AND PRIVACY LAW IN PRACTICE (Wolters Kluwer, 1st ed. 2017).

"Well, what do we do if we want to use the images we've collected for other purposes?" And I said, "Well, what is the value in doing that?" And they said, "We think that it might be possible to diagnose early-onset Alzheimer's before there are ever clinical symptoms simply by analyzing the images using AI technology, and in something like 75% of the cases, we would be effective in doing that." And unfortunately, even just talking about this from an EU privacy perspective, which we know tends to be a little bit more, I'm going to say, advanced, perhaps, in the privacy space than what we see in the United States. Even in that scenario it was tremendously difficult to identify a justification for reusing those data. And yet we know that it could have enormous impacts on our ability to diagnose very serious diseases, get individuals on the right pharmaceuticals or other treatments needed to prevent the further progression of some of these diseases. And it kind of got me thinking, what do we do in the United States? How might we evolve our privacy models to better provide support for these types of technologies and other data uses?

And so, I'm going to start today by talking a little bit about the technology and then go into, what are the primary privacy considerations we have. And then how might we think about evolving those models, both under HIPAA and outside of HIPAA. And it was great that we had this previous panel because there was a great introduction into HIPAA and some of the considerations for that. So hopefully I won't have through too much detail there. I'm going to share my screen and hopefully you can see that okay. Alright, can everybody hear me? I just want to make sure you heard my, did you hear my introduction?

Paige Goodwin: No, I think you cut out as soon as you screen shared.

Charlotte Tschider: Oh, excellent. Okay, well I didn't say anything after the screen share, so I think we're alright. I wanted to illustrate at least for you where we're seeing these considerations around big data and AI in healthcare, at least initially. And then we'll go into some specific examples related to the technology implementations and some of the challenges associated with those technology implementations.

So, at least initially, we know that data are tremendously useful for operational support. Whether that is the efficiency of operating in a large health system, the cost and value analysis that goes into reimbursement calculations for Medicare and Medicaid, we know that there is a huge focus on quality. And understanding

how provisioning healthcare is going to increase or decrease quality is certainly a huge goal and a goal that actually is incentivized by a lot of our other healthcare laws related the ACA, MACRA, and others. And then there is sort of this benefit potentially in AI in administrative automation. So, if there is the ability to automate more administrative tasks, we might be in a scenario where we can repurpose staff, use hours in different ways, and certainly provide better quality healthcare to individuals because we're able to sort of shift things around.

But we also know that big data is heavily, heavily used in the diagnostic medicine area. Especially around imaging, we've seen incredible developments related to x-ray image evaluation and others. And we have diagnostic AI now that applies to treatments, you know, what is the best treatment for an individual, given characteristics of that individual that we've seen in other types of individuals who have received certain types of treatments? And we know that diagnostic medicine, for example, is often developed using base data and that base data usually come from health systems that are, what I would say, high-resource types of contexts. They're the types of situations where, for example, you have the best machines, and you have people who are specifically focused on certain types of cancer diagnosis who may be actually identified as the best in the world in doing that. And so, when we create this type of AI it's really wonderful. But how do you take that and apply it to new contexts? One of my colleagues, Professor Nicholson Price, has written a great deal on this concept. And certainly dovetailing from the rural health conversation we just had, think of the myriad of ways where using those types of diagnostic tools in rural contexts where you may not have access to highly specialized cancer diagnosticians. That might be tremendously valuable. But at the same time, you need to make sure that the data you have behind the algorithm is going to represent those new populations. And we've seen it in a variety of scenarios, not just in rural settings, but also in big cities, and situations where you potentially have more diversity of living conditions, housing conditions, and individuals from a variety of different backgrounds. So, we know that data are tremendously important in making sure that those algorithms are actually going to facilitate better treatment and facilitate better diagnosis.

And then finally, and this is the area that I spend a lot of my time focusing on, is artificially-intelligent-enabled Internet of Health Things. If you see IoHT, it was a term that was coined quite a long time ago, to represent healthcare technologies. So not consumer technologies, but consumer technologies that are really

oriented towards health. And the interesting thing and the distinct thing about AI in these technologies is that it actually drives the functioning of medical devices. So, the data you have actually informs, for example, what amount of insulin might be recommended for someone with an insulin pump to use. Or, what is the charge that we need, for example, for a brain stimulus device to reduce pain in an individual. All of those data can actually inform not only privacy concerns, but also safety concerns regarding their functioning. And ensuring that data free flows back and forth is tremendously important for the effective functioning of those types of devices. And often those data are considered a personal information, whether they fall under the de-identification safe harbor in HIPAA, or if they properly are identified as protected health information. So, we know that data are tremendously important.

Okay. Just switching slides here. Just give me a minute. It's a little bit slow. Alright, so as I figure this out, I'm just going to stop the share and reshare here a minute. My apologies, I'm having some network issues due to a lot of snow. So that makes this a lot of fun. So hopefully you can see my screen again. Let's see if we can get it to switch.

Alright, so instead of switching to the next screen for now, what I'll explain is that, when we're talking about medical devices, we're not just talking about the thing that is implanted in somebody's body, you know, the implanted pacemaker, for example, that enables somebody's heart to function properly, or an insulin pump that is pervasively attached to somebody's body, or a hearing aid that somebody wears regularly. In those situations, actually, we're not just talking about the physical thing that connects with the person's body or is inside a person's body. We are also talking about applications. So, applications though a mobile device or another type of user interface that's available to the individual. I know with insulin pumps, for example, there's usually a user interface that's sort of attached to the pump that someone uses to actually make decisions about how much insulin to deliver to their body. Something that I think was actually in clinical, the third range of clinical trials, or the third stage of clinical trials, was the artificial pancreas. And the artificial pancreas doesn't have a user interface in the same way that an insulin pump does. It's generally designed to function almost independently of the user.

Now, whether you have a user interface or whether you don't have a user interface, usually individuals, especially individuals with health conditions, trust the technology, or we're expecting

them to trust the technology. So, for example, if you have instructions that are delivered to an individual about an insulin pump that says, "this is the amount of insulin that you should deliver your body based on the value we've ascertained of your blood sugar," to what extent do we really expect that individuals will challenge that kind of a direction. Probably not, right? Individuals tend to believe what the technology tells them, so we really need to make sure that the information we have behind the technology, that are often stored in offshore locations, that are stored in big data implementations, such as Amazon Web Services and the like, and which use machine learning technologies in those locations, it can get a little bit challenging if the data are not correct or we don't have enough data, and if we don't have really any control or ability to influence third parties and their practices with regard to those data from a cybersecurity perspective. So, because we have this broad distribution of what a medical device means, we have additional challenges related to how HIPAA typically manages these types of scenarios.

Okay. So, let's try this one more time. Alright, I am seeing a chat, but I cannot get to it. Feel free to just jump in. Okay, can you see this screen now? I believe maybe you can. Aha, excellent. Alright, we are back in business.

So, from an historical perspective when we look at privacy, there are really four categories of privacy considerations that we have. The first is from a notice and consent perspective. In the EU we call this "lawful basis." In the United States it's just generally "notice and consent." That is the primary vehicle that we use across most privacy laws. So yes, there are additional requirements in any privacy framework that you have from a legal perspective, but notice and consent tends to be the most powerful, all in all. I'll talk about here in a second why that is maybe not the right focus for any privacy framework, including HIPAA. Although in HIPAA we have notice with a kind of a reasonable acknowledgment, at least at the federal level. Most of the states have an additional consent that's sort of added on to that. But outside of that, so under general Federal Trade Commission jurisdiction, and what we're increasingly seeing at the state law level, is that consent is usually required. And I think that there are some limitations to that, both in terms of data usage, and the practicality of managing those processes, as well as just the efficacy of consent and how that works.

We also have this focus on data minimization. So not collecting, using, retaining data in a way that is exceptional to the purposes that are disclosed and the purposes for collecting them.

Now that in and of itself is also a little bit challenging and we'll talk about that first here in a second. And then we have identifiability issues. So, as I was just mentioning, under HIPAA we have the de-identification safe harbor.[2] The de-identification safe harbor is used primarily to reduce risk to individuals. So, if, for example, an organization wants to reuse data, they take a certain number of steps, usually it's removing 18 identifiers or obtaining an expert opinion from somebody who is a statistical expert, to determine there is very, very low risk to an individual person. And that renders the data non-PHI. So, it's no longer Protected Health Information when it has been de-identified. The problem, of course, is the larger data set you have. When you take data sets from a variety of places, say a public record from another organization, say an insurer, and from what you've collected as a medical device manufacturer or as a health care provider, suddenly you have a variety of data that are tremendously useful, but nevertheless may actually be more identifiable. And even removing those 18 identifiers could indeed result in identifiability of the individual. So, there are some interesting challenges related to that.

And then finally data subject rights. Data subject rights with AI are, I think, for the most part still intact. The challenges related to data subject rights, though, are related to that technology model that I was just talking about. When you have a variety of different third parties, you potentially have a variety of different partners, affiliates, or just customers, if you happen to be selling data. It may be very difficult for you to undo what you've already done. We know that data flow pretty easily. And so, for example, if somebody wanted to restrict further processing of their data by revoking their consent, it can be very difficult to get those data back. So, some interesting challenges here.

These are just kind of the primary privacy challenges. But as a backdrop in the medical space, at least modern medical technology today, we have other issues that complicate these. One of them is market concentration. So, for example, there are only, I believe, two manufacturers in the world that manufacture insulin pumps. What that means functionally is that where we expect the market to jump in and for individual customers to sort of choose their options and choose an option that might be better from a privacy perspective, if they desire that, there just aren't that many options. And further, there are, you know, additional challenges because a lot of these devices are prescribed or recommended by physicians. They're not the type of thing that an individual is likely to go out and choose on their own, so they are really depending on

[2] *See* 45 C.F.R. § 164.514.

the expertise of another individual. And there aren't a lot of alternatives. Many of these devices are moving towards this kind of a digital footprint with AI and other types of functional technologies behind the scenes, which ultimately means that an individual would not, number one, might be less likely to choose an analog device because the technical features are so much more superior in a more digital or connected or algorithmic type of an implementation. But additionally, they may not even exist. So, in this movement, individuals who are already reliant on these types of devices for either just the ability to live if we're talking about pacemakers, or for quality of life if we're talking about hearing aids. There is inherent coercive bargaining. What we mean by coercive here is that we have contracts of adhesion that apply. So anytime that somebody is actually signing up for the mobile application that helps their technology run or to kind of keep them in the loop – those are not the types of things that individuals can actually bargain about. You know, there's one form, there's one piece of information. And it's sort of like a supersized coercive bargaining because, again, you have individuals who are dependent on these technologies, either to live or for quality of life.

There's a disproportionate knowledge barrier here. And I don't just mean between the patient and the manufacturer. I mean, that's a pretty big chasm. But often we have disproportionate knowledge between the physician and the manufacturer. A lot of physicians don't actually understand how a lot of these technologies work, but are trying to find the best technology fit for their patient. And so we have pretty much one organization that knows a lot about the technology and what's happening with it, and you have an individual downstream that is really trusting in their doctor and trusting in the manufacturer to ensure that it is going to be a safe and privacy-rich type of functional technology. And I would also argue that when somebody has to choose between their life and their quality of life versus privacy, usually those first things are going to win out. And they are more likely to give up their data for purposes that are beneficial to an organization but maybe less beneficial to themselves.

Alright so data minimization, I wanted to just show you an illustration of what artificial intelligence can look like. And this really illustrates why it is very, very challenging, for example, to adequately inform somebody at the point of a privacy notice. Data is tremendously useful, we know that. Data reuse is tremendously useful. And it can be used in a lot of different products. But that use can continue indefinitely. And, again, we may have data that functionally are de-identified, but actually are tremendously

identifiable that are used. At the same time, data go into each one of these layers and you can see a picture here of the input layer, hidden layers where calculations are happening. For example, if you look here on the right, the skin cancer diagnostic app, some of you may be familiar with this. I was fortunate enough to present with somebody who actually created this app. And they told me that they have 1,000 hidden layers. So, at a thousand points, there are different calculations, different weighing, that happens between those data points. And there might be additional injections of additional data in each one of those layers. You can imagine how difficult it would be to explain to somebody, especially a downstream user, how the calculations are happening or why certain data points are going to useful in a particular calculation. Describing the purpose and use at the point of forming a relationship with that individual is tremendously difficult.

Identifiability. So, we talked a little bit about the need for big data in AI implementations. But additionally, we're dealing with a personalized kind of medicine. So, the entire purpose why we have AI diagnostics and AI technologies is that we believe they will be more effective than the alternative. They will be more personalized, they will be more effective. And so, for that reason, actually, if you want to facilitate personalized medicine, it usually requires more collection of personal information and less de-identification or anonymization of the of the data sets you have. And AI can be used to be used to identify and create inferences and so usually it's very difficult to achieve things like de-identification and anonymization. And as I mentioned before, HIPAA's current de-identification safe harbor is not really a great fit for this kind of a model. So, we're kind of in a difficult position.

Let's make it a little more complicated. I previously wrote a paper on the concept of consent and why it is tremendously difficult to achieve in the healthcare environment in particular.[3] But often, from a legal perspective, we position notice and consent as sort of curative. And I'll that even from a Federal Trade Commission perspective, if somebody files a complaint and they look at the notice and consent and the person consented, and the notice was reasonably informative, we're often in a situation where it's almost a rebuttable presumption that what they did was legal. But there are a lot of problems with the function of notice and consent just functionally and logically.

[3] Charlotte A. Tschider, *The Consent Myth: Improving Choice for Patients of the Future*, 96 Wash. U. L. Rev. 1505 (2018).

First of all, we have again the voluntariness problem with contracts of adhesion and coercive care. When I say coercive care, I don't mean somebody is forced to have healthcare, but rather that they don't really have a choice. When a person is seeking healthcare or seeking use of a technology, they don't really have a lot of better options. The choices really are to live or have some quality of life or not. And because a lot of these technologies are functionally more effective than some of their analog counterparts, your choices are "Do I get the less effective technology?" or "Do I give all of my data away and use this more effective technology?" And it's not really a fair calculus.

Secondly, we have what's called a structural problem. In the structural problem we have privacy policy fatigue, I think most of us are familiar with that. When an individual is forced to go through privacy notice after privacy notice all day long, they can actually stop paying attention. And there was a study that was done that estimated that if somebody read every single privacy policy that they were confronted with, it would take seventy-six full-time days of the year to do it.[4] We know that individuals just simply don't have seventy-six days a year to look at everything and we would presume that they care enough in a healthcare context to look at it. But the reality is that the way that privacy policies or privacy notices have been written historically, is in some ways to kind of provide the formality without tremendous information even being offered.

Then we have a "cognition problem," so privacy as risk. When we're in a situation where privacy is something that somebody has to think about in terms of whether or not they're going to agree, they have to be able to think about it from a risk-to-themselves perspective. But the concept of privacy harms and what kind of challenges a person might face if they give too much data away are highly attenuated and very, very difficult to imagine in a really visceral and specific way. And then we what I call an "exogeneity" or "abstraction" problem. And I was referring to this in the beginning when we look at the technology implementations. It's very hard from the position of a patient to imagine all of the third parties who might be two or three steps back in these technology implementations. And, in fact, when I work with organizations, often they don't really even know what the practices of their third parties are. And they haven't even functionally agreed to appropriate terms from a contracts perspective. So, if you're dealing with, you know, an organization or manufacturer that probably doesn't even

[4] Aleecia M. McDonald & Lorrie Faith Cranor, *The Cost of Reading Privacy Policies*, 4(3) J. of L. and Policy for the Info. Soc'y 543, 543-568 (2008).

know their third parties are doing, how can we expect health care providers or individual patients to do the same? And then finally, we have a temporal problem. When we provide a privacy notice and we offer consent, usually that is based on the purposes that have been specified in the information that's been specified in the notice. But AI actually benefits from more and different information that's presented along the way. And for that reason it becomes tremendously difficult to ensure that somebody knows what data are going to be used for at the time when they consent. It's just almost impossible.

Alright, and I'll skip "Data Subject Rights." I kind of mentioned this, but, it's very difficult to actually get information about your data when it's handled by third parties throughout the process. And I talked a little bit about the market dynamics and coercion piece so I'm going to skip past that.

So, what might this look like functionally? Well, a HIPAA-compatible privacy model would relate to, number one, "minimum necessary" still being in place. Reliability, safety, and efficacy purposes might be justification for keeping data for a period of time that is reasonable. But we refocus it from a legitimate interest perspective, so it's like another kind of lens in which we evaluate "minimum necessary." So "minimum necessary" is not necessarily what is needed right now, but what may be needed overall in the course of the life and the improvement of these AI. De-identification and retention are positioned more explicitly as an ambit of "minimum necessary." So, one of the problems I see with a lot of organizations is that they only use de-identification when they want to do something with the data that probably the patient or the doctor might not like. But they often have almost no retention practices whatsoever, in that data are not securely deleted on a regular basis. Perhaps we can kind of bolster that side of it, while at the time offering a little bit more fluidity in data use and reuse.

And demonstration of reidentification risk might be a way to bolster the de-identification space, so, shift from an 18-identifier a model to a model where we really do focus on expert determination as the basis for de-identification. And then finally, reevaluate this concept of an "information fiduciary." This is something that's actually been raised in the privacy community as a way of refocusing towards organizations that are taking on responsibility in receiving data and creating a fiduciary responsibility to the individuals whose data they have collected. Now, I don't necessarily endorse a broad model like this, but in something like healthcare when we're talking about manufacturers and downstream patients,

this might actually be a really nice model that we could look at a state level if HIPAA is not in a position to expand in any meaningful way over the next few years.

And then finally, and I'll kind of go to this interest balancing because I think it's probably the most interesting part, is that instead of focusing on a notice and consent model, perhaps we instead refocus towards a legitimate interest model. And I know from talking with a lot attorneys that many of you don't like balancing tests. From a court perspective, for example, they can be a little bit challenging, especially in the criminal law space. But perhaps we put the onus on organizations to actually conduct a risk assessment to determine if the benefits to the individuals, whether they're a class of individuals or just individual people, would actually be advanced by processing the data further. You can see some examples I've included here and how you might do legitimate interest balancing. But the overall function is that the organization would have to demonstrate and would have to record and document that, if they're going to use data for additional purposes, that the interests of the individual, the users of these devices or the subjects for diagnostic tools, would actually benefit more with further processing. It's a way to sort of reformulate how we're thinking about the concept of notice and consent. Thank you so much for your patience with my technology issues and I look forward to your questions.

Casey Goggin: Thank you so much. That was a fantastic presentation. It's unfortunate that we're running out of time, I would love to do questions.

EMERGING TRENDS IN HEALTHCARE TECHNOLOGY:
DOSING DISCRIMINATION: REGULATING PMDP RISK SCORES

SPEAKER:
PROFESSOR JENNIFER OLIVA, *SETON HALL LAW SCHOOL*

[edited for reading]

FEBRUARY 19, 2021

Casey Goggin: Next up, we have Professor Jennifer Oliva. Professor Oliva currently serves as an Associate Professor and the Director of the Center for Health and Pharmaceutical Law at Seton Hall University where she specializes in health law and policy, FDA law, drug policy, evidence, and complex litigation. Prior to teaching at Seton Hall, Ms. Oliva was an Associate Professor of Law and Public Health at West Virginia University, where she was selected as the College of Law's 2017-2018 Professor of the Year and the West Virginia Law Review's 2017-2018 Professor of the Year. She received her J.D. from Georgetown University Law Center where she graduated with honors and served as the Executive Notes & Comments Editor on The Georgetown Law Review. She earned her MBA from Oxford she was a Rhodes and Truman Scholar while also a cadet at the United States Military Academy. She has worked in the appellate and health/FDA practice groups at national firms and has served as the General Counsel and Vice President of a regional behavioral health care company. Please help me welcome Professor Oliva.

Jennifer Oliva: Thank you so much. Thanks for having me today and huge thanks to Professor Farringer and everybody at the Law Review at Belmont it's a true honor. I'm going to see if I can share my slides. Did that work out? Alright awesome.

I'm really appreciative of Professor Tschider's presentation earlier because I am going to do a really specific example of many of the broad-based problems that she pointed out with potential health care technology. She talked about diagnostic medicine and predictive algorithms, coercive treatment, and really importantly the knowledge gap that often exists between physicians, providers, healthcare clinicians and the software manufacturers who are developing this AI because of course those algorithms, the models, the platforms are often proprietary and clinicians have a lot less knowledge about what the proxies are, the data, the input data that's being used, and how the algorithms actually work and evolve, than the software manufacturer has on its end. So she really introduced for me, really helped me out with her wonderful talk earlier.

This paper is called "Dosing Discrimination." I am going to have that published soon, so I look forward to feedback. I'm going to stop early, I promise to take questions because I've got to get this in shape for the California Law Review which I'm working on right now. This is just my agenda for you guys for later when you look at the slides, we can go ahead and get moving. So the first thing I want to talk about is predictive algorithms and risk scoring that has been implemented in use in the United States in response to our drug

overdose crisis. Let's talk about the drug overdose crisis first and then frame this technology and its widespread introduction in the United States in response to the crisis.

So we have this drug crisis. It's frequently called, or has been called for years, "prescription overdose crisis." That was true in wave one, which we sort of trace back to 1999, started seeing an uptick in 1999. Unfortunately, and partially to blame the response, this is a shape-shifting problem that has evolved. We're now at least in phase three, some people say we moved into phase four. So you can see the prescription opioid overdose deaths going up, and then around 2010, we see a huge uptick in heroin overdose. And very quickly after that, just three years later, we see things shifting to synthetic opioids. In fact, today, synthetic opioids are responsible (and you'll see some slides on this) for the overwhelming majority of overdose deaths in United States. Why I alluded to this introduction of a wave four is we're seeing huge upticks, especially since COVID has started, in methamphetamine-related deaths, cocaine-related deaths, and many of those are also polysubstance deaths with other substances including benzodiazepines and other sedatives. So this is shifting quite rapidly and it's evolving and it's really moved away from prescription opioids, and one of the reasons why is because we have really cracked down on the availability of prescription opioids.

One other thing I wanted to show here: U.S. overdose deaths have been escalating. Our tactics right now, our responsive tactics, quite frankly have not been successful. From 1999 when we first identified this as a crisis, you see about almost 17,000 deaths and we're up to over 81,000 deaths in the last 12-month period. That's the worst 12-month period ever recorded in U.S. history for overdose deaths, and certainly COVID is a contributing factor. Again, as I've already told you, the CDC issued a "high alert "recently talking about how this is very much driven, 60, 70% of this is driven by illicit street fentanyl, not drugs that are prescribed or are obtained for medical reasons or even diverted drugs that are obtained that way. So it's becoming much more dangerous, much more concerning drugs, and a very illicit, deadly supply that is on the street in the United States right now.

I've already told you this but there's just some slides, again directly from the CDC, not my opinion. We're looking at a synthetic opioid and now a stimulant problem. So how does the US respond? Well the U.S.'s response to this overprescribing of opioids that we had starting around 1999, in response to under treatment of chronic pain conditions the United States, has been a lot of public health

rhetoric. We've heard a lot about, "Let's have harm reduction," "Let's do evidence-based reactions," "Let's get people in treatment," "This is a health care problem, it's not a criminal justice problem." However, the United States rely very heavily on law enforcement agencies to serve as "fixers" of the crisis instead of evidence-based public health professionals. As a result, law enforcement agency does one thing and one thing only with drugs: they try to control the supply. Right? They try to control the licit supply and they try to control the illicit supply. That's what the DEA's responsible for, that's their statutory mandate. So what the DEA has decided to do was heightened surveillance, and now it's very smart AI surveillance, on prescribers, dispensers like pharmacists, and patients who are being prescribed or using prescription opioids like Oxycontin.

You can see three techniques that have been used since 1999, and they get enhanced and more powerful every year and more widespread. I'm going to focus on number 3, but we have prescribing guidelines where physicians are supposed to be really careful about how many milligrams they're prescribing, the dose amount, really evaluating patients. Number 2, opioid treatment contracts. Professor Tschider talked about form and consent, all these kinds of things. Opioid patients, whether they have substance use disorder or chronic pain conditions, have to sign contracts where they agree to all sorts of types of surveillance, up to and including having private investigators check on them, coming in for random pill counts so they can't go out of town, coming in for drug tests and things like that. I'm not going to talk about that today but that's part of this. And then number 3, prescription drug monitoring programs. These are state laws, there's been an explosion in them that I'm going to talk to you about. And these are databases, smart databases driven by AI, that assess patients and prescribers in the area of controlled substances and determine how much at-risk they are for substance use disorder and flag those patients so that they're not prescribed certain drugs by prescribers.

So what's happened over time here, again with opioids, this response I just told you about has been very successful in de-prescribing. We have much less prescribing now, as you can see in 2019 here, we're below where were in 2005. The CDC concedes that opioid prescribing is down 60% since 2012, so over the last eight years. So opioid prescribing is way down in the United States. It's down in any of the metrics (I just add this slide for people who like to get into the weeds): days per person, pills per person, scripts, overall total dosage – every single one of these metrics is way down from peak prescribing.

So, let's talk about persistent pain. Persistent pain is the number one reason why, it's the number one disability in the United States. 50-100 million people, depending on how you define the term "persistent pain," which is somewhat amorphous and hard to capture. It's the number one reason why people seek treatment, and I would say why everyone should be concerned about this kind of surveillance and be in-the-know about it is because we will all have some kind of pain in life if we live long enough to be privileged to experience it. And most of us will have some sort of disability or healthcare condition as we age. It's just a process of aging, it's something that all of us will face at some point. Pain has a long history in the United States, and I have pages and pages on this in my paper but I won't bore you with it, but a long history in this country of underassessment and under treatment. Some folks like Professor Dan Goldberg who studies pain and the history of pain suggests that this comes from the sort of "Cartesian-dualism" of medicine is an objective science, pain is hard to see, objectively verify and test. So that mind-body divide creates problems for clinicians, it's much more challenging than something they can physically see and evaluate. Pain patients have been viewed as difficult to treat, we have a poor understanding of the causes of various different pain conditions. They've been viewed as malingerers and untrustworthy in the literature.

There's also sexism and racism that sort of goes through this history, which I detail in the paper. Women are often viewed as psychosomatic and hysterical. Women's pain–and this has been evaluated by any number of scientists that are way smarter than me–women's pain is usually viewed very differently than men's pain. Doctors think that when men say that they're in pain, they wouldn't come to the doctor or seek treatment or give themselves a 10/10 unless it was serious, but that women over-evaluate or over-assess or overreact to pain. Also, on racism, this dates back to slave-breeding concepts that unfortunately have persisted over time, that African Americans have a higher pain tolerance because of their physical superiority (these are all myths and not true), and therefore they do not need to be prescribed pain the same as other populations. In response to some of these things of course, it's a little bit disturbing. You'll see I have this New York Times piece here written by these two white men.[1] A lot of people have made an argument that African Americans were spared opioid use disorder because they were prescribed fewer prescriptions. So, this is widely

[1] Austin Frakt & Toni Monkovic, *A 'Rare Case Where Racial Biases Protected' African Americans*, N.Y. Times, Nov. 25, 2019, https://www.nytimes.com/2019/11/25/upshot/opioid-epidemic-blacks.html.

acknowledged that Black people's pain was undertreated comparatively. And then this is the spin on it now and I take huge issue with that in my paper, as I'm sure you can imagine.

This is one of my favorites, John Oliver, I don't know if anybody ever follows him, but he does a lot of health law stuff, so I'm able to entertain the students a bit with some of his commentary, and he did a piece in August of 2019 on bias and healthcare. And this is Wanda Sykes in the frame with him, who is a Black comedian, and she does a bit that he plays on the show here at the twelve-minute mark where she talks about having to have a prophylactic double mastectomy. And she said at the end of the surgery, she was prescribed Ibuprofen, and she goes on to make a joke, which is grounded in truth, about how because she was a Black woman, she didn't receive any serious pain medication because of these myths that exist even though at the time she had her surgery, a very painful surgery and recovery, opioids were widely prescribed to other populations. There's been all sorts of other articles about this, I'm just desperately backing myself up here with these pictures.

So, the real question is, did persistent pain patients during this sort of transition and this phase I'm talking to you about, were they at high risk for opioid use disorder overdose deaths? And really, honestly, it's exceedingly low in this population, and that makes sense because these folks have been taking the drug for a very long period of time. Studies range from 1%-8% of people with persistent pain who are legacy patients who have been taking opioids for a long time ever developed problematic opioid use disorder. It's a very low percentage. The majority of the people who developed opioid use disorder as a result of overprescribing, received those drugs outside of the medical context – they were diverted to them – and they used the drugs recreationally, not to treat a pain or other medical condition.

I say that all to say, what about these prescription drug monitoring programs, which is my AI tool here. Law enforcement developed these prescription drug monitoring programs a long time ago and their most basic form at the turn of the 20th century, New York had the first one, followed by California. Well, what happened is, you would get a highly controlled substance, a Schedule II substance like an opioid, the doctor would fill out a form and give you a prescription in triple kick carbon. The doctor would keep one, the patient would take two to the pharmacist, the pharmacist would turn in one of the slips to the state health agency so that they could control where the opiates were going and watch out for diversion.

That was the basic gist and that was what was collected, just Schedule II drugs, and it was a carbon-based paper system.

By 1999 we had 17 states that used this system, they were pretty minor in their scope and context. Today in the United States in 2020, 49 states and the District of Columbia have these systems. They collect all schedules of drugs, II through V. Many of them also collect a lot of other drugs that aren't even controlled substances or scheduled, they're called "drugs of concern." If you've had a cat or dog spayed in the United States in the last ten years, you are in the prescription drug monitoring program because those animals are prescribed a very small dose of an opioid after that surgery. They collect all sorts of other information in addition and it's a smart database. They go and pull information from people's criminal history, court records, sexual trauma history, their general medical records, etc. And every year, whatever these PMDPs are collecting are enhanced more and more and more.

They've now layered on over the last several years algorithmic functions, and what these algorithms do is that they go in and mine through all these troves of data that apply to the patient and the prescriber. To the patient, see over here, they give three scores: a narcotic risk score (you're at risk for narcotic use disorder), sedative risk score, stimulant risk score, and it's not on this slide but it's on my next one, over here you see that 650–that's your overall NARX score. So that shows whether you're at risk. These particular slides don't show it but once you hit a certain score a bunch of red flags come up. They also, by the way, do a prescriber report, that says if a prescriber is running afoul of how the algorithms view risk. So, what kinds of things are in the criteria? The number of providers you see, the number of pharmacies, the amount and strength of your medication, you can see this. And then some very odd things that I spend a lot of time critiquing from a data science perspective in my paper: the distance you have to travel to your provider, the method that you pay, sexual abuse and trauma history, and criminal history. There's the prescriber report card, just so people have it.

So, the question is, "Are PDMPs effective?" And I'm going to go right back to that criteria here in a minute. They've been great at reducing prescribing behavior, I've already showed you that. We've had a huge reduction in opioid prescribing. But they also do three other things that have been well documented. They change prescriber behavior. Prescribers are very reticent to take on complicated pain patients right now or even treat people with substance use disorder. The treatment for people with substance use disorder are opioid agonists like buprenorphine and methadone, and

those also are Schedule II controlled substances that are opioids, so that's monitored by the prescription drug monitoring program. It creates problems for both populations. They've forced rapid taper for people so that their prescribing numbers go down, so that they don't trigger concern in the system and DEA surveillance, and they've abandoned patients and said I'm no longer going to continue to treat you.

Opioid withdrawal is extremely painful, resource intensive, and can be deadly. It causes change in patient behavior, bullet number three. Patients then go and look for a new prescriber/dispenser, that makes their risk score go up, they avoid healthcare delivery system, and the worst thing is they switch to more dangerous illicit substances. The cost of somebody in the United States switching from a prescription drug to heroin is astronomical. Injection drug use has all sorts of comorbid conditions associated with it like hepatitis, bloodborne diseases, HIV, and we're seeing upticks in that compared to taking a safe, prescription drug. Safe insofar as it's been approved by the FDA and we actually know what's in it. And dispensers have refused to fill. So, we have a huge reduction in prescribing, but we have a lot of other bad things going on. We have the highest rate ever of overdose deaths, we have a lot of switching to much, much more dangerous substances that are easier to get and cheaper and are really available on the street, and we have a lot of people who have been forced into withdrawal, depression, suicidal ideation, and are suffering and no longer able to function. So, we have a tough situation.

Don't take my word for it folks, here's a 2021 Journal of Health Economics paper where these economists, who are much smarter than me, again, went in and looked at the unintended consequences of this prescription drug monitoring.[2] And they basically say that any decrease in prescription opioid deaths (only 17% of the deaths in 2020 involved prescription opioids and the majority of those, by the way, involved another substance), they're completely offset by a large increase in illegal deaths around heroin and fentanyl.

So here are my NARX score concerns. These are secret proprietary algorithms. The company that makes NARX scores called Appriss, it's a private company, it sells this platform to the states, the states use them and then they mandate that prescribers use them. So, clinicians make clinical treatment decisions about patients

[2] Bokyung Kim, *Must-Access Prescription Drug Monitoring Programs and the Opioid Overdose Epidemic: The Unintended Consequences*, 75 J. Health Econ. 102408 (2021).

based on these secret algorithms that we don't know a lot of things about. They've never been externally validated or subjected to any kind of regulation. They're completely unregulated, so we have no idea how good or bad they are. I'm actually going to tell you they're really bad in a minute, of course, based on the little bit that we do know. They purport to measure, objectively measure something, which is a patient's risk of drug misuse, overdose, but we're bad at measuring that as experts. Experts in the field are bad at predicting who's going to develop substance use disorder. It makes you ask a question: what does Appriss know that the experts in the field do not know right now? Folks in this area of expertise are very upfront about this. They concede that it's very difficult to make a risk projection around this. Certain of the criteria are automatically going to disparately impact certain groups.

Let's just go back to that criteria again, I want to spend a little bit of time on this and then take questions. Method of payment– if you pay by cash, if you have to pay by cash for your prescription, your NARX score goes way up just based on that criteria. Well, who does that impact? That impacts people who are underinsured, or uninsured because they have to pay for their prescriptions if their insurer isn't covering it or they don't have one. So we're automatically now discriminating against people who are poor and don't have robust insurance that covers this kind of treatment. Moreover, as opioids have become more stigmatized and we had the overprescribing problem, many more private providers have a lot of obstacles to covering, prior authorizations, covering these kinds of prescriptions. So, looking at method of payment and escalating someone's risk score based on that is very questionable about which groups you're targeting and why that's an appropriate proxy for risk. And like I said, Professor Tschider told you, the information that goes out–if it's garbage in, it's garbage out. So, if we're using bad proxies to assess risk, we're not doing a good job measuring it on the back end.

Distance traveled–there's some states, there's nine states in fact, Wyoming is one of them, that don't have a single methadone program for people with substance use disorder in the entire state. Why do I say that? People in Wyoming, through no fault of their own, have to leave their home state to get the drug, can only be prescribed at these facilities. So they're going to be penalized because their state doesn't have a single prescriber in-state that even does this work. That's certainly not their fault. The view is, the more you're traveling away from your home, it's surreptitious behavior and you're drug-seeking, but lots of people who live rural, and lots of people who live in these states that I'm talking about, are forced

to do this through no fault of their own. Moreover, you can imagine the compound problem we have here as more and more people want to get out of this business. It's risky, I've got law enforcement after me. The state professional licensing boards are looking at these risk scores, I don't want to treat as many patients if it challenges my livelihood as a physician or a provider. Less and less people want to do this which means that more and more people, even suburban people, have to travel further and further away from home to fins a provider that will actually provide this service. So that's a very arbitrary factor to have in there, distance traveled, and raise risk scores.

Sexual trauma and criminal history – this is very well documented in the literature, it's not my opinion. If you're going to include sexual trauma, again, if you have a history of sexual trauma, that automatically raises your risk score notwithstanding anything else. This is going to disparately impact women patients because women are more likely to report a history of sexual trauma than men are because of the stigma and all sorts of gender and sex stereotypes that go along with that. But women are much more willing to go and seek treatment for that and are much more willing to report it. So, again, seeing elevated risk scores for this kind of stuff. Criminal history–this is well documented again, this is really going to affect minorities. On every single criteria in the criminal justice system stops, arrests, incarceration, charges, people of color are way more likely than their white counterparts to have encounters in the criminal justice system even when those groups are controlled for drug use. Meaning they use a drug at the exact same amount, you're still going to see a great disparity there. So, we know that just the addition of criminal history is, again, going to double down on certain people who, again, are already under evaluated and under treated for pain. We can see this happen to women, poor people, people who live rural, people who are underinsured, people with chronic disabilities, people of color–doubling down on disparately impacting already vulnerable groups that already were under treated in the system through this long history that I described earlier.

Again, I've already said this, but I just really want to emphasize that patients are punished under these criteria for things that are completely out of their control. Even on the multiple prescribers, if your doctor simply retires, let's just make it really benign: Your doctor retires, goes to Florida, "I'm done, I'm gone." You have to find a second provider. Your risk score goes up through no fault of your own. If you have a job, if you're in the military and you move around a lot, and you have to get different providers as you move around–your risk score goes up automatically simply

because you're serving your country and you have a job that requires a lot of movement. This can get less benign when providers automatically stop treating people and they're forced to switch pharmacists and providers, again through no fault of their own, but because people are getting out of the business. But it's an important thing to understand that these risk scores are questionable and discriminatory on their face based on the other data that we know, and that the system is creating even more discrimination by incentivizing people to stop serving these patients and to deprescribe, which PDMPs are excellent at, as I've already shown you. I've told you all this stuff, I got ahead of myself.

My argument in my paper is that these NARX scores are aggravating an already atrocious situation. Here is another health economist who tried to model the Appriss model, she recreated it, and here's what she says, and I'll end on this note. The proxies that they use basically are uncorrelated with the risks that are generates. They're not helpful, they don't work, they don't produce a valid proxy for patients. And this is the only study that I know of, and it's very recent, that tries to recreate the model and the algorithms to see if they are actually accurate at producing risk. My argument in the paper is that the FDA has the authority under the Software as a Medical Device regulatory authority to regulate these things, and the FDA actually concedes that this is true in a new regulatory document. My argument is that if the FDA subjected this risk scoring platform to its robust regulatory criteria, which I've laid out here for you, the PDMPs would fail on all three of these criteria and the FDA would be required to pull it from the market. That's the paper in a nutshell and I'd be happy to take questions. Thank you so much for having me today.

Casey Goggin: Alright, so it looks like we've got a couple of questions in the chat box. We have one question, it says, "I had trouble getting opioids recently for kidney stones for twenty-four hours until I could actually go in and see a physician despite having been a patient for years and having needed surgery for a stone. It was a long period of really intense pain. Should it really be that hard to get opioid medication? Are some practices overreacting?"

Jennifer Oliva: Yeah, I mean they're overreacting because it's been forced. You have to make a decision because the DEA can immediately suspend your license and begin an investigation that affects you, your family, your livelihood, your professional reputation. You're always going to make the decision to undertreat because there is much less chance that–you're going to say I followed the guidelines, the flag popped up, I followed the

algorithm. That's what the clinician is going to say. I really appreciate this question. I have a lot of people who have contacted me who have said something exactly like this. I'm not a doctor, kidney stones are egregiously painful, bottom line, period. Kidney stones are also a side-effect of a lot of chronic pain diseases like Crohn's disease. These folks go into an emergency room and they're just left to sit there and writhe in pain because, again, these PDMPs. So I agree with that. I have had examples with children with stage four cancer and in a practice the physician not wanting to give pain medication to a small child with an egregiously painful condition because it would affect their report for law enforcement or the DEA. I cannot emphasize enough that this is the only algorithm, platform, in the history of medicine that has ever been used by clinicians that was developed for and by law enforcement for criminal surveillance and has never been validated or evaluated by medical experts.

Casey Goggin: Great, thank you. I also asked a question earlier, because you said the algorithm is secret, proprietary data, and I assume they'd be considered PHI, and Charlotte chimed in and kind of helped me with my question. Would you be able to give us a sense of whether the data would be able to be disclosed under the statutory scheme? Would I be able to get my own score, personally?

Jennifer Oliva: I'm going to try to answer this quickly, but that is a really good question. I have a paper on this called "Prescription Drug Policing" in the Duke Law Journal[3] and would be happy to send you a link. Many of the states allow law enforcement willy-nilly to just log in to these systems and just get your individual information. They collect your name, address, whoever picks up the record for you, gender, sex. And then imagine this: all of this other history is in there. In North Carolina, I'll just give you an example, the police, when they pull you over, can pull up your PDMP if they pull you over for a traffic stop.

Now, let's go to the opposite. In some states, more than half the states, they have automatic access and then it ramps up to the highest level, which is you've got to get a warrant. But the states that have a warrant protection, which the doctors asked for, have lost case after case in the courts. The DEA has issued an administrative subpoena and asked for this information in an investigation. Utah, Colorado, New Hampshire – these states have fought the DEA in court and they lost, saying you need to get a warrant and have probable cause and the DEA has persistently won under Section 876

[3] Jennifer D. Oliva, *Prescription-Drug Policing: The Right To Health Information Privacy Pre- and Post-Carpenter*, 69 Duke L.J. 775-853 (2020).

power under the Controlled Substance Act[4] because it has the right to regulate controlled substances and has worked and end-round around the warrant requirement. I would say to you that is super concerning that the police can go in and get this stuff, even on a routine traffic stop in many jurisdictions. The jurisdictions that have stronger protections, they've been undermined by this federal law. And number three, many states actually do not allow patients to access their PDMPs, some do, and so when you think about the rampant-ness of medical errors, simply in medical records – can you imagine never being able to see your own record and make corrections? Because we have to assume that any number of those records are incorrect because medical records are riddled with mistakes.

Casey Goggin: Thank you. We have one more question but unfortunately we're out of time, so I will send this to you personally if that's alright with you. I think it's a really great question, it's about studies on the effects of improving treatments. But we will have to keep going. Thank you for your time and that excellent presentation, I would love to read that paper.

Jennifer Oliva: I'll send it to you! Thank you.

Casey Goggin: Thank you.

[4] 21 U.S.C. § 801 *et seq*.

INNOVATOR LIABILITY AND PRESCRIPTION MEDICATION: A STOPGAP MEASURE PATIENTS DESERVE

WILL TRUE[1]

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I. INTRODUCTION

Prescription medication has been a vital component of health care in the United States throughout the past decade.[1] Data from the National Center for Health Statistics highlighted that 48.6% of persons in the United States from 2015-2018 had used at least one prescription drug in the previous 30 days.[2] These statistics are not surprising due to the effectiveness of a wide variety of medications to treat a myriad of diseases and conditions.[3] However, prescription medications are not always safe and often result in side effects, which may be serious or minor in severity and which may not be disclosed on a medication's warning label.[4] In the event an individual suffers from a severe undisclosed side effect of a prescription medication, two factors currently pose tremendous consequences concerning potential recourse: (1) the jurisdiction in which the individual resides and (2) whether the individual ingested either the generic or brand-name version of the drug.

For instance, suppose Person A, like millions of other Americans, suffers from gastroesophageal reflux disease (GERD).[5] The person consults with his or her doctor and decides to seek treatment for GERD in the form of a prescription medication. To the relief of Person A, in 1983 the FDA approved the prescription drug ranitidine, under the brand-name Zantac, to help alleviate symptoms of GERD suffered by millions of Americans.[6] To Person A, the choice of whether or not to take Zantac seems clear based on the prominence and satisfaction with the drug; indeed, in 1988 Zantac became the world's best-selling drug and one of the first drugs to

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[1] *See* CRESCENT B. MARTIN ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L CTR. FOR HEALTH STATISTICS, NCHS DATA BRIEF NO. 334, PRESCRIPTION DRUG USE IN THE UNITED STATES, 2015-2016, at 4 (2019), https://www.cdc.gov/nchs/products/databriefs/db334.htm.

[2] U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2019, at xi (2019), https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm.

[3] *See* Sarah Lewis, *The Top 50 Drugs Prescribed in the United States*, HEALTHGRADES (Sept. 5, 2019), https://www.healthgrades.com/right-care/patient-advocate/the-top-50-drugs-prescribed-in-the-united-states.

[4] *See* Reuters Staff, *Timeline: Popular heartburn medicine Zantac pulled off store shelves*, REUTERS (Oct. 21, 2019), https://www.reuters.com/article/us-health-fda-heartburn-timeline/timeline-popular-heartburn-medicine-zantac-pulled-off-store-shelves-idUSKBN1X014E [hereinafter "Timeline"].

[5] *See* Linda Searing, *The Big Number: 60 Million Americans suffer from heartburn at least once a month*, WASHINGTON POST (Dec. 2, 2019), https://www.washingtonpost.com/health/the-big-number-60-million-americans-suffer-from-heartburn-at-least-once-month/2019/11/29/8f9f730a-106b-11ea-b0fc-62cc38411ebb_story.html.

[6] Timeline, *supra* note 4.

ever top $1 billion in annual sales.[7] In this hypothetical, suppose Person A began taking Zantac prior to the release of generic equivalents and continued to take brand-name Zantac after the release of generic equivalents. Tragically, Person A later develops cancer. Although Person A is not immediately aware, he or she has been ingesting a drug which potentially contains a dangerous level of NDMA, a probable human carcinogen.[8] On April 1, 2020, Person A reads the FDA's public announcement that the agency plans to recall Zantac and all generic ranitidine products after discovering an increased risk of cancer from taking the drug.[9]

Although nearly identical to the facts involving Person A, Person B also decided to begin taking ranitidine in order to alleviate the symptoms of GERD. However, unlike Person A, Person B received the generic version of the drug and never ingested brand-name Zantac. As with Person A, Person B later develops cancer. Despite the nearly identical factual scenarios of Person A and Person B, the two individuals will have drastically different abilities to recover damages under a products liability failure to warn claim. Person A, having ingested brand-name Zantac, will potentially have a viable tort claim against the brand-name drug manufacturer. However, in the vast majority of state jurisdictions, Person B will be completely without recourse involving a failure to warn theory of recovery against the generic drug manufacturer, even if Person B can allege a strong prima facie case. As later discussed in this Note, due to FDA regulations mandating that generic drugs use the same warning labels as the brand-name equivalent, generic manufacturers are shielded from liability involving failure to warn claims.[10]

Person B would only have potential recourse in a handful of jurisdictions. In these jurisdictions, despite still being unable to recover against the generic manufacturer, plaintiffs may sue the brand-name manufacturer for the harm caused from ingesting the generic version of the drug. This theory of recovery, termed "innovator liability," remains controversial throughout the United States.[11]

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[7] *Id.*

[8] *See* Gianna Melillo, *FDA Recalls All Ranitidine (Zantac) Products, Citing Increased Risk of Cancer*, AJMC (Apr. 1, 2020), https://www.ajmc.com/view/fda-recalls-all-ranitidine-products-zantac-citing-increased-risk-of-cancer.

[9] *See* FDA News Release, FDA Requests Removal of All Ranitidine Products (Zantac) from the Market: FDA Advises Consumers, Patients and Health Care Professionals After New FDA Studies Show Risk to Public Health (Apr. 1, 2020), https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market.

[10] *See* 21 U.S.C. § 355 (2018); 21 C.F.R. § 314.94 (2020).

[11] *See*, *e.g.*, Huck v. Wyeth, 850 N.W.2d 353, 380 (Iowa 2014).

This Note argues that in the absence of an updated statute and FDA regulation, states should permit plaintiffs to recover under the theory of innovator liability. Despite the theory's arguable contravention of "traditional common law tort principles" and potentially unfair results against brand-name manufacturers, victims of defective drugs and inadequate warnings should have an avenue for recourse.[12] Forfeiting one's ability to recover potentially hundreds of thousands of dollars in damages in exchange for paying a cheaper price for medication is not a fair trade. Indeed, the Supreme Court in *PLIVA, Inc. v. Mensing* (discussed in Section II and arguably the most consequential case involving innovator liability) concedes that the opinion and pertinent federal regulations created an "unfortunate hand" for the plaintiffs and "others similarly situated."[13] However, this Note recognizes the substantial shortcomings and legal obstacles that innovator liability poses. Nevertheless, this Note argues that adopting innovator liability in more jurisdictions throughout the United States will exert greater pressure upon the federal government to rethink the current state of the law.

Thus, in the presence of statutory latitude, state courts should permit plaintiffs harmed by generic pharmaceuticals to recover under the theory of innovator liability against brand-name manufacturers due to the current federal legal framework. Alternatively, if a state's statutory code explicitly rejects innovator liability, thereby preventing the courts from adopting it in the common law, legislatures in those states should reverse their current approach. As discussed further below, adopting innovator liability would likely incentivize a change to the current federal framework. Ideally, the federal government should alter the current statutory and regulatory scheme involving prescription drugs in order to strike a better balance of providing recourse to generic prescription drug consumers, while also continuing to strive for the FDA's policy goals involving cost and safety.[14]

Section II of this Note provides the history and current background involving pharmaceutical failure-to-warn claims, innovator liability, and prescription medication law. The statutory and common law progression leading up to the current state of the law is further detailed in Section II. Section III of this Note analyzes two defenses raised by brand-name manufacturer defendants, including more typical arguments relating to the tort law, as well as

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[12] *Id.* at 370 (quoting Schrock v. Wyeth, Inc., 727 F.3d 1273, 1285 (10th Cir. 2013)).

[13] PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011).

[14] *See* Scott Gottlieb, M.D, *Looking ahead: Some of FDA's major policy goals for 2018,* USDA (Dec. 14, 2018), https://www.fda.gov/news-events/fda-voices/looking-ahead-some-fdas-major-policy-goals-2018.

the less-explored issue of personal jurisdiction as it relates to innovator liability. Specifically, Section III highlights recent case law involving personal jurisdiction serving as a useful threshold question if a jurisdiction decides to adopt innovator liability, as well as the obstacles of more rigid common law tort principles. Section IV presents this Note's primary proposal relating to innovator liability with the goal of attaining both short-term and long-term legal recourse for consumers involving pharmaceutical drug failure-to-warn claims. In summary, this Note argues that state governments should adopt innovator liability to accomplish two objectives: (1) provide injured plaintiffs with a more short-term stopgap avenue for recovery and (2) encourage the federal government to implement a more sustainable long-term solution involving pharmaceutical drug failure-to-warn claims.

II. HISTORY AND BACKGROUND OF PHARMACEUTICAL INNOVATOR LIABILITY

A. Pharmaceutical Drug Failure-to-Warn Claims

Because extensive warning labels are required to produce and distribute medication, plaintiffs often seek to recover against pharmaceutical companies for defective medications under a product liability theory involving "inadequate instructions or warnings."[15] The Restatement (Third) of Torts: Products Liability provides the following: "A product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings . . . and the omission of the instructions or warnings renders the product not reasonably safe."[16] Another torts text provides: "Strict liability for design defects or failure to warn does not apply to prescription drugs."[17] For instance, under the Restatement (Third) of Torts: Products Liability, prescription drugs are only defectively designed under a failure-to-warn claim "if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . "[18]

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[15] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (AM. LAW INST. 1998).
[16] *Id.* § 2.
[17] MEREDITH J. DUNCAN ET AL., TORTS: A CONTEMPORARY APPROACH 1102, 3rd ed. (2018) (citing RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (AM. LAW INST. 1998)).
[18] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (AM. LAW INST. 1998).

B. Federal Preemption Doctrine

As a result of the extensive federal statutory and regulatory framework involving prescription drugs, the federal preemption doctrine is pertinent to failure-to-warn prescription drug claims. Under the Supremacy Clause of the United States Constitution (Article VI Clause 2), federal law "shall be the supreme Law of the Land . . . [and] any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[19] In situations in which state law and federal law directly conflict, federal law controls.[20] Conflict occurs where it is "impossible for a private party to comply with both state and federal requirements."[21] In the context of prescription drug failure-to-warn claims, the preemption doctrine is the primary reason necessitating the adoption of innovator liability under the current state of the law, as discussed in the following subsections.

C. Statutory Background

i. Federal Food, Drug, and Cosmetic Act

The federal government has implemented substantial legislation regulating medication in order to protect U.S. consumers for nearly a century.[22] Congress enacted the Federal Food, Drug, and Cosmetic Act in 1938 in order to "prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes."[23] Concerning drugs, the 1938 law served as a predecessor of later and more stringent rules for the drug approval process by requiring persons to file an application including "(1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug," in addition to various other requirements.[24]

While the 1938 version of the law served as an overall positive predecessor by focusing on safety, Congress later amended the Federal Food, Drug, and Cosmetic Act in 1962 to impose stricter standards on the drug industry concerning the effectiveness of

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[19] U.S. CONST., art. VI, cl. 2.
[20] Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 486 (2013) (citing Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).
[21] English v. General Elec. Co., 496 U.S. 72, 79 (1990) (citing Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963)).
[22] *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).
[23] *Id.*
[24] *Id.* at 1052.

medications before approval.[25] Signed into law by President John F. Kennedy on October 10, 1962, the amendment requires drug manufacturers seeking approval of a new drug from the government to engage in costly and lengthy studies to prove a drug's safety and effectiveness.[26] These drug studies can be very costly,[27] which is important to some of the policy arguments involving innovator liability. For example, studies published by the *Journal of Health Economics* and *JAMA* indicated that the average cost of bringing a new drug to market may range from $985 million to as high as $2.8 billion.[28]

ii. Hatch-Waxman Amendments (Drug Price Competition and Patent Term Restoration Act)

As an effort to lower the cost of prescription drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) permits generic drug manufacturers to submit an "abbreviated application" for a new drug which contains "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved [as a listed drug]."[29] In the context of innovator liability, the requirement of attaining approval of a drug's safety and effectiveness is relevant because the initial manufacturer of the drug bears the expensive cost of proving these characteristics.[30] In contrast, generic manufacturers may utilize the previous approval of a drug developed by the initial manufacturer when seeking an abbreviated application.[31] Of substantial importance in the context of innovator liability, the statutory requirements under the Hatch-Waxman Amendments require a generic drug application to "show that the [safety] labeling proposed for the new drug is the same as the labeling approved for the [brand-name] drug."[32] Implementing this language, FDA regulations likewise require companies submitting an abbreviated new drug

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[25] *See* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.
[26] *Id.* at 781.
[27] *See* Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 JOURNAL OF HEALTH ECONOMICS, 20 (2016), https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/12742/DiMasi-Grabowski-Hansen-RnD-JHE-2016.pdf; Oliver J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323(9) JAMA, 844, 855 (2020), https://jamanetwork.com/journals/jama/fullarticle/2762311.
[28] *Id.*
[29] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2018)).
[30] *See id.*
[31] *Id.*
[32] *Id.*

application (ANDA) to ensure the warning label is the same "as the labeling of the [brand-name drug]."[33]

Also of importance in the context of innovator liability is the FDA's current regulation permitting a brand-name drug manufacturer to change its warning labels prior to official approval from the FDA.[34] Under a process termed "changes-being-effected" (CBE), the FDA permits brand-name drug manufacturers to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."[35] For example, in the event that a brand-name drug manufacturer discovers an urgent need to update its drug label to reflect newly discovered information vital for patient health, the manufacturer "need not wait for preapproval by the FDA, which ordinarily is necessary to change a label."[36]

iii. Generic Substitution Laws

In an effort to further promote the goal of the Hatch-Waxman Amendments to make "available more low cost generic drugs by establishing a generic drug approval procedure,"[37] many state legislatures passed generic substitution laws that "require a pharmacist to substitute a therapeutically equivalent generic for a brand name drug, unless the physician specifies that a generic must not be substituted."[38] Although "[s]ome states impose an additional limitation that the pharmacist must get consent from the patient before substituting a generic,"[39] consumers are unlikely to object upon explanation that the generic version has the same active ingredients as the brand-name version for a substantially lower price. For example, in Minnesota, the jurisdiction in which the generic substitution law was implicated in *PLIVA, Incorporated v. Mensing*, a pharmacist must dispense the generic version of a drug in the absence of an explicit request for the brand-name version from a physician and after disclosing the substitution to the purchaser.[40] Additionally, in other states, patients who do not express a preference to their physician or pharmacist are nearly certain to

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[33] 21 C.F.R. § 314.94(a)(8) (2020).
[34] *See* 21 C.F.R. § 314.70(c)(6)(iii) (2020).
[35] *Id.*
[36] *PLIVA, Inc.*, 564 U.S. at 614.
[37] H.R. REP. NO. 98-857, pt.1, at 14-15 (1984).
[38] U.S. DEP. OF HEALTH AND HUMAN SERV., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS, 7-8 (Dec. 1, 2010), https://aspe.hhs.gov/system/files/pdf/76151/ib.pdf [hereinafter "ASPE ISSUE BRIEF"]. *See* MINN. STAT. 151.21 (2020).
[39] ASPE ISSUE BRIEF, *supra* note 38.
[40] MINN. STAT. 151.21 (2020).

receive the generic version because those states' statutes do not require the pharmacist to obtain consent from the patient if their prescription is being substituted with a generic equivalent.[41]

In the context of innovator liability, generic substitution laws are relevant because patients frequently receive the generic version of a drug, either with or without a disclosure from the pharmacist depending on state law.[42] Therefore, under the Hatch-Waxman Amendments and state generic substitution laws, patients often forfeit their ability to recover under a failure-to-warn theory against both the brand-name and generic drug manufacturers due to either a lack of disclosure from the pharmacist (in a state that permits this) or the patient's consent to the generic substitution without fully understanding the potential of forfeiting recovery rights.

iv. Case Law Background

Two U.S. Supreme Court cases gave rise to the disparate impact of one's ability to recover for a failure to warn by drug manufacturers. The first case, *Wyeth v. Levine*, presented the question of whether the FDA's approval of a new drug application and later approval of changes in a drug label provided the defendant manufacturer "with a complete defense to [the plaintiff's] tort claims."[43] In that case, Wyeth manufactured the drug Phenergan.[44] Tragically, doctors were forced to amputate a patient's arm after doctors injected the medication directly into the patient's vein, a dangerous procedure the plaintiff alleged was not warned against in the medication's warning label.[45]

After the patient sued Wyeth alleging a product liability failure-to-warn claim, the Supreme Court ultimately held that federal law did not preempt the plaintiff's state law claim.[46] The Court resolved two primary issues. First, the Court held that Wyeth was capable of complying with both federal and state law because an FDA regulation permits brand-name drug companies to add a stronger warning label to its preexisting label before receiving the FDA's approval.[47] Second, the Court held that Congress did not intend to preempt state law failure-to-warn claims and that approval from the FDA of a drug's warning label does not block a plaintiff's ability to pursue a failure-to-warn claim under state law.[48] Notably,

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[41] ASPE ISSUE BRIEF, *supra* note 38.
[42] ASPE ISSUE BRIEF, *supra* note 38, at 2, 7-8.
[43] Wyeth v. Levine, 555 U.S. 555, 558 (2009).
[44] *Id.* at 559.
[45] *Id.* at 559-60.
[46] *Id.* at 581.
[47] *Id.* at 568.
[48] *Id.* at 556.

and of great significance in the case discussed in the following paragraph, Wyeth manufactured the brand-name version of the drug involved.[49]

The second significant U.S. Supreme Court case in the context of innovator liability, *PLIVA, Inc. v. Mensing*, clarified that a patient's ability to recover against a drug manufacturer based on a state law failure-to-warn theory depends on whether the patient received the generic or brand-name version of a drug.[50] In *Mensing*, two different patients were prescribed the generic version of Reglan in order to treat digestive tract problems.[51] After both developed tardive dyskinesia, a severe neurological disorder, the two patients sued the manufacturers of their medication under state law failure to warn claims.[52] Contrasting from *Wyeth*, the Court in *Mensing* held that the generic manufacturer could not comply with both federal and state law, and thus the patients' failure-to-warn claims were preempted.[53] The Court distinguished the case from *Wyeth v. Levine* by emphasizing that the generic manufacturers in this case could not unilaterally update their warning labels under the Hatch-Waxman Amendments and corresponding FDA regulations without violating federal law.[54]

Under the Court's holding, if there is an intermediate step requiring FDA approval between a generic drug manufacturer wishing to change its label and being permitted to do so, the manufacturer "cannot independently satisfy those state duties for pre-emption purposes."[55] This is because brand-name and generic drug manufacturers have different "federal drug labeling duties."[56] "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval … is responsible for ensuring that its warning label is the same as the brand-name's."[57] This holding prompted a small number of states to adopt the theory of innovator liability in order to ensure plaintiffs asserting failure to warn claims have the ability to recover.[58] Despite the holding of *Mensing*, the Court's majority highlighted the blatant inequity resulting from the decision by stating, "We acknowledge the

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[49] *Id.* at 555.
[50] *See PLIVA, Inc.*, 564 U.S. at 604-06.
[51] *Id.* at 609.
[52] *Id.* at 610.
[53] *Id.* at 617-26.
[54] *Id.* at 612-13.
[55] *Id.* at 623-24.
[56] *Id.* at 613.
[57] *Id.* (citations omitted).
[58] *See* Rafferty v. Merck & Co., 479 Mass. 141 (2018).

unfortunate hand that federal drug regulation has dealt [the plaintiffs] and other similarly situated."[59]

v. Prior Proposed Changes to the Law

In response to the holding in *Mensing*, the FDA issued a proposed rule change in 2013, likely in an effort to alleviate the harsh effects from the holding of the case.[60] The proposed rule's primary change would have permitted generic manufacturers "to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug (RLD) upon submission to FDA of a 'changes being effected' (CBE-0) supplement."[61] Under the proposed rule, a generic manufacturer would be able to unilaterally change its warning label, effectively extending the holding of *Wyeth* to situations involving generic medication and eliminating the harsh ruling under *Mensing*. Consequently, under the proposed rule, plaintiffs would have had the option to bring a state failure-to-warn cause of action against generic manufacturers rather than being preempted by federal law.[62]

However, after five years of contemplation, the FDA withdrew the proposed rule on December 13, 2018.[63] Former FDA Commissioner Scott Gottlieb rationalized this decision based on the possibility of an increase in the price of generic medications, effectively ensuring the continued immunity of generic manufacturers from state failure-to-warn claims.[64] Additionally, the FDA voiced concern about the possibility that different generic manufacturers of the same drug would distribute medication with differing warning labels, potentially increasing uncertainty for consumers.[65] In contrast with generic-drug makers expressing satisfaction following the decision, consumer groups vehemently

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[59] *Mensing*, 564 U.S. at 625.
[60] *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (proposed November 13, 2013).
[61] *Id.*
[62] *See id.*
[63] Thomas M. Burton, *FDA Withdraws Proposed Rule That Would Have Exposed Generic-Drug Makers to Liability*, WALL STREET JOURNAL, (December 13, 2018), https://www.wsj.com/articles/fda-withdraws-proposed-rule-that-would-have-exposed-generic-drug-makers-to-liability-11544726478.
[64] *Id.*
[65] *See* FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D. and Director of FDA's Center for Drug Evaluation and Research Janet Woodcock, M.D., on efforts to modernize generic drug labels while maintaining the efficiency of generic development (December 13, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-director-fdas-center-drug-evaluation-and-research [hereinafter "FDA Statement"].

opposed the decision.[66] For example, "Sidney M. Wolfe, founder and senior advisor of the consumer-oriented Public Citizen Health Research Group, said the FDA, in withdrawing its proposed rule, 'has perpetuated a dangerous double standard. The winners are the generic companies, and the losers are the patients.'"[67] Despite the debate surrounding the issue, the FDA did not indicate a plan in its press release to propose a similar rule after rejecting the 2013 proposal.[68] Rather, the FDA stated that it planned to exert greater energy and time in working with the brand-name companies to update the warning labels of older medications.[69]

III. ANALYSIS OF BRAND-NAME MANUFACTURER DEFENSES INVOLVING INNOVATOR LIABILITY

Although the issue of innovator liability became significant following the Supreme Court's decision in *Mensing*,[70] various nuances involving viable defenses for brand-name manufacturers have continued to arise. For example, recent cases (discussed below) demonstrate brand-name manufacturers often object to personal jurisdiction in an effort to avoid potential liability.[71] In the event that more states throughout the country opt to adopt innovator liability, more recent case law demonstrates that personal jurisdiction may serve as an effective defense for brand-name manufacturers when holding the brand-name manufacturer liable for the harm caused by the generic version is especially unfair.[72] In contrast with personal jurisdiction, which involves unique facts on a case-by-case basis, tort law arguments provide courts with less flexibility: either courts will reconcile long-established tort law principles with innovator liability, or they will not.

A. Personal Jurisdiction

While courts have long recognized a wide range of justifications for rejecting innovator liability,[73] personal jurisdiction

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[66] *See* Burton, *supra* note 63.
[67] Burton, *supra* note 63.
[68] *See* FDA Statement, *supra* note 65.
[69] *See* FDA Statement, *supra* note 65.
[70] *PLIVA, Inc.*, 564 U.S. 604.
[71] *See*, *e.g.*, Quinn-White v. Novartis Pharms. Corp., 2018 U.S. Dist. LEXIS 227024, at *3 (C.D. Cal. Mar. 7, 2018).
[72] *See* Henry v. Angelini Pharma, Inc., 2020 WL 1532174, (E.D. Cal. Mar. 31, 2020).
[73] *See* Huck v. Wyeth, 850 N.W.2d 353, 370 (Iowa 2014) (quoting *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013)).

is a more recent argument advanced by brand-name defendants.[74] Like any other lawsuit, there may be instances in which a plaintiff's failure to warn claim will fail due to a court's lack of personal jurisdiction over the defendant. However, personal jurisdiction should not serve as an outright bar to all innovator liability claims. Instead, as demonstrated in the upcoming discussion of recent case law, personal jurisdiction may serve as a beneficial threshold question to potentially limit liability in cases with especially unfair scenarios for brand-name manufacturers. Therefore, if more states permit plaintiffs to proceed under innovator liability (as advocated for in Section IV), personal jurisdiction objections may provide brand-name defendants with an avenue to prevent innovator liability from resulting in widespread and excessively unfair outcomes. This would strike an ideal balance in the interim until federal regulatory changes are implemented: plaintiffs would have an avenue for recovery while brand-name defendants would possess a potentially effective defense in the most unfair fact patterns.

i. *Stirling v. Novartis Pharmaceuticals Corporation*

Depending on the factual and legal background of a case, various state courts have come to different conclusions regarding personal jurisdiction in cases involving the theory of innovator liability.[75] A relatively recent Idaho state court decision demonstrates an instance in which a brand-name manufacturer successfully objected to personal jurisdiction in a lawsuit with the requisite facts for a plaintiff to argue in favor of innovator liability.[76] In *Stirling v. Novartis Pharmaceuticals Corporation*, the plaintiffs brought, among a variety of claims, a negligent failure to warn claim against Novartis Pharmaceuticals Corporation ("Novartis").[77] Novartis owned the New Drug Application ("NDA") for Brethine (or terbutaline sulfate) and "developed, manufactured, packaged,

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[74] *See Henry*, 2020 WL 1532174.

[75] *Compare* Stirling v. Novartis Pharmaceuticals Corporation, No. CV01-18-04880, at *3-5 (4th Jud. Dist. Idaho July 13, 2020), https://www.druganddevicelawblog.com/wp-content/uploads/sites/30/2020/07/Stirling-II.pdf ("Memorandum Decision and Order Granting Dismissal of Novartis Pharmaceuticals Corporation from Second Amended Complaint" finding a lack of specific personal jurisdiction), *with* Quinn-White v. Novartis Pharms. Corp., 2016 U.S. Dist. LEXIS 201328, at *7 (C.D. Cal. Oct. 7, 2016) (court finding specific personal jurisdiction).

[76] *See Stirling*, No. CV01-18-04880, at *3-5 (4th Jud. Dist. Idaho July 13, 2020); Stirling v. Novartis Pharmaceuticals Corporation, No. CV01-18-4880, at *2-4, *6-8 (4th Jud. Dist. Idaho Sept. 25, 2019), https://www.druganddevicelawblog.com/wp-content/uploads/sites/30/2019/10/Stirling.pdf ("Memorandum Decision Re: Novartis Pharmaceuticals Motion to Dismiss").

[77] *Stirling*, No. CV01-18-4880, at *1 (4th Jud. Dist. Idaho Sept. 25, 2019).

labeled, marketed, and distributed Brethine until around December 2001 when it sold the rights to the Brethine NDA to Alcami Carolinas Corporation."[78] In 2007, the plaintiff "was prescribed an injection of the generic drug terbutaline sulfate as a tocolytic – a drug to suppress premature labor in pregnant women."[79] The plaintiff alleged that because she used the generic version of Brethine, her child was later diagnosed with "cognitive and personality disorders."[80] Likely because FDA regulations and the Supreme Court decision in *Mensing* prevented the plaintiff from asserting a viable claim against the generic manufacturer, the plaintiff sued Novartis, the original brand-name manufacturer of the drug.[81] Ruling in favor of Novartis' on its motion to dismiss for failure to state a claim in 2019, the Idaho court in *Stirling* rejected the viability of innovator liability as it related to Idaho negligence principles.[82] However, later in 2020, the court addressed the issue of personal jurisdiction in an additional decision under the same case involving a second amended complaint that alleged fraud.[83]

Of importance, the plaintiff could not establish general personal jurisdiction over Novartis.[84] Therefore, the plaintiff needed to establish specific personal jurisdiction in order for the Idaho court to have authority over the defendant.[85] Regarding the Idaho standard for personal jurisdiction, the *Stirling* court provided the following:

> "[A] state [may] exercise personal jurisdiction over a non-resident defendant when that defendant has certain minimum contacts with the state such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice." *Profits Plus Capital Mgmt, LLC v. Podesta*, 156 Idaho 873, 883-84, 332 P.3d 785, 795-96 (2014) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). In determining the existence of minimum contacts, a court must focus on the relationship among the defendant, the forum, and the litigation. *Id.* (citing *Shaffer v. Heitner*, 433 U.S. 186, 205, 97 S. Ct. 2569, 2580, 53 L. Ed. 2d 683 (1977)). The minimum contacts required by *International Shoe's* minimum contacts requirement is satisfied if the defendant

[78] *Id.* at *2.
[79] *Id.*
[80] *Id.* at *3.
[81] *See id.* at *2.
[82] *Id.* at *6-8.
[83] *Stirling*, No. CV01-18-04880, at *1-3 (4th Jud. Dist. Idaho July 13, 2020).
[84] *See id.* at *5.
[85] *See id.* at *3-5.

> "purposefully directs his activities at residents of the forum state and the litigation arises out of or relates to those activities." *Id.* (quoting *Saint Alphonsus Reg'l Med. Ctr. v. State of Wash.*, 123 Idaho 739, 744, 852 P.2d 491, 496 (1993)); *Houghland Farms, Inc. v. Johnson*, 119 Idaho 72, 75, 803 P.2d 978, 981 (1990) ("It is not just any contacts by the defendant with Idaho that will sustain the exercise of specific personal jurisdiction, but only those out of which the suit arises or those that relate to the suit.").[86]

Concerning the "purposefully directs" requirement to qualify as sufficient minimum contacts, the *Stirling* court highlighted potential prior actions by the defendant that were "purposefully direct[ed] . . . at residents of the forum state . . . ."[87] Specifically, the court highlighted discovery cited by the plaintiffs which indicated Novartis, through an agent, called doctors in Idaho in 1999 for the purpose of promoting Brethine.[88] Additionally, the court highlighted discovery cited by the plaintiffs which indicated that Novartis was aware of marketing that took place for its benefit in Idaho in 1998.[89]

Nonetheless, the Idaho court held it did not possess personal jurisdiction over Novartis because the plaintiffs could not prove the litigation arose out of or related to Novartis' activities.[90] Explaining the lack of connection between Novartis' actions and the plaintiffs' cause of action, the court emphasized the importance of time as a factor by providing the following rationale:

> Important to the Court's decision is the lapse in time between the alleged contacts with Idaho (Horizon's marketing Brethine in calls in 1999) and Plaintiff Michelle's use of the generic form of Terbutaline Sulfate in 2007. This lapse in time, combined with the facts that Novartis sold the Brethine NDA in 2001 and then ceased marketing the product, support the Court finding this litigation does not arise out of the alleged marketing activities by Novartis.[91]

Additionally, the court acknowledged the need for overall reasonableness when analyzing specific personal jurisdiction: "It []

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[86] *Id.* at *3.
[87] *Id.* at *3-4.
[88] *Id.* at *4.
[89] *Id.*
[90] *Id.* at *5.
[91] *Id.*

is unreasonable that Novartis was on notice that it may be called into Idaho courts to answer for use of a generic form of Brethine as a tocolytic that was ingested six years after Novartis sold Brethine's NDA and seven years after its agent's direct marketing activity . . . ."[92]

ii. *Quinn-White v. Novartis Pharmaceuticals Corporation*

In contrast with the court in *Stirling*, in *Quinn-White v. Novartis Pharmaceuticals Corporation*, the U.S. District Court for the Central District of California held that the court did have specific personal jurisdiction over the brand-name drug manufacturer, despite the plaintiff ingesting the generic version of a drug.[93] In this case, the plaintiff experienced seizures and was "prescribed Tegretol, a brand-name, anti-epileptic drug manufactured and marketed by [Novartis]."[94] The plaintiff took the prescription to the pharmacy, "where the branded form of Tegretol was unilaterally substituted for a generic version called Epitol, which is manufactured and marketed by nonparty Teva Pharmaceuticals U.S.A., Inc."[95] The plaintiff later "experienced signs of conditions known as Stevens-Johnson syndrome ("SJS") and toxic epidermal necrolysis ("TEN")," resulting in the plaintiff becoming "blind in both eyes and with severe scarring over her body."[96] The plaintiff alleged causes of action for negligence, negligent misrepresentation, and fraud against Novartis.[97]

The court's initial holding determined that it had both general and specific jurisdiction over Novartis.[98] The court explained that Novartis was subject to specific personal jurisdiction because the plaintiff alleged that "her California-based physician reviewed and relied on Novartis's label and its warnings in California, where Novartis marketed its drugs."[99] In other words, without the California-based physician's review of Novartis's warning label and Novartis's marketing in California, the claim would not have arisen.[100]

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[92] *Id.*
[93] Quinn-White v. Novartis Pharms. Corp., 2018 U.S. Dist. LEXIS 227024, at *1-2, *13 (C.D. Cal. Mar. 7, 2018).
[94] *Id.* at *1.
[95] *Id.* at *1-2.
[96] *Id.* at *2.
[97] *Id.*
[98] Quinn-White v. Novartis Pharms. Corp., 2016 U.S. Dist. LEXIS 201328, at *7 (C.D. Cal. Oct. 7, 2016).
[99] *Id.* (citations omitted).
[100] *See id.*

Following this determination, the court later agreed to reconsider the question of personal jurisdiction in light of two U.S. Supreme Court decisions: *Daimler AG v. Bauman* and *Bristol-Myers Squibb Co. v. Superior Court*.[101] The court in *Quinn-White* emphasized that its holding considered the Supreme Court's holding in *Bristol-Myers Squibb Co. v. Superior Court*, but was unconvinced with Novartis's argument that attempted to analogize the facts of *Quinn-White* to the facts in *Bristol-Myers*.[102] *Bristol-Myers Squibb* involved plaintiffs who were not domiciled in California and ingested the harmful drugs outside California,[103] whereas *Quinn-White* involved a California domiciliary who suffered an injury due to the defendant's contacts with the forum state.[104]

iii. *Henry v. Angelini Pharma, Inc.*

While the court in *Quinn-White* was willing to hold that the court had personal jurisdiction over a brand-name drug manufacturer in the context of innovator liability, a more recent case from the U.S. District Court for the Eastern District of California demonstrates the limits of innovator liability when confronted with a strong personal jurisdiction argument.[105] In *Henry v. Angelini Pharma, Inc.*, "a California resident[] consumed a generic intermediate release formulation of trazodone hydrochloride after his physician prescribed the drug for insomnia."[106] After taking the medication, the plaintiff developed a prolonged penile erection (known as a "priapism") that resulted in a permanent state of impotence.[107] Importantly, the plaintiff in this case sued the brand-name manufacturers of the extended-release formulation of the drug, despite ingesting a generic version of the intermediate-release formulation.[108] The court in this case dismissed the plaintiff's claim due to a lack of personal jurisdiction, demonstrating an avenue through which a brand-name drug manufacturer can avoid liability in a state which permits plaintiffs to recover under the theory of innovator liability.[109]

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[101] *Quinn-White*, 2018 U.S. Dist. LEXIS 227024, at *7. *See generally* Daimler AG v. Bauman, 571 U.S. 117 (2014); Bristol-Myers Squibb Co. v. Superior Court, 137 S. Ct. 1773 (2017).
[102] *Quinn-White*, 2018 U.S. Dist. LEXIS 227024, at *12-13.
[103] *Bristol-Myers Squibb Co.*, 137 S. Ct. at 1778-79.
[104] *Quinn-White*, 2018 U.S. Dist. LEXIS 227024, at *1, *12.
[105] *See* Henry v. Angelini Pharma, Inc., 2020 WL 1532174, at *3-4 (E.D. Cal. Mar. 31, 2020).
[106] *Id.* at *1.
[107] *Id.*
[108] *Id.* at *1-2.
[109] *See id.* at *3-4.

Explaining its decision, the court in *Henry* referenced the three requirements of specific personal jurisdiction in California: "(1) the nonresident defendant must have purposefully availed himself of the privilege of conducting activities in the forum by some affirmative act or conduct; (2) plaintiff's claim must arise out of or result from the defendant's forum-related activities; and (3) exercise of jurisdiction must be reasonable."[110] Mirroring the Idaho court in *Stirling*, the court in *Henry* dismissed the claim because the defendant's contacts failed to "ar[ise], result[] from, or . . . even relate[] to Defendants' forum related activities."[111] The contacts that the plaintiff argued satisfied the requirements of personal jurisdiction involved alleged misrepresentations made by a salesman of the brand-name medication, which the generic company later relied upon.[112] However, the court in *Henry* emphasized that even if the allegations were true, the plaintiff's claim did not arise out of or relate to the salesman's actions.[113] Just as in *Stirling*, the defendant's contacts in this instance were slim and simply too attenuated to the harm alleged by the plaintiff.[114] The court in *Henry* provided the following rationale for its decision: "[E]ven if [the salesman of the defendant] perpetuated misrepresentations about the side effects of trazodone during his year as an Oleptro salesman, there is no indication that [the salesman's] conduct had any effect on how Teva eventually labeled the trazodone product that allegedly harmed Plaintiff."[115] This case demonstrates that even in states permitting innovator liability, there are instances in which a defendant's contacts may be insufficient and result in a dismissal of the claim based on a lack of personal jurisdiction.

B. Tort Law: Duty

In addition to the issue of personal jurisdiction, the tort element of duty is often analyzed in the context of permitting or denying innovator liability.[116] In contrast with certain fact patterns involving personal jurisdiction, the tort element of duty should not serve as a barrier to an injured plaintiff's ability to recover in an innovator liability action. Creating an exception to the tort element of duty in the context of innovator liability is more black and white than a court's analysis involving personal jurisdiction. Either courts impose a duty on brand-name manufacturers in order to provide

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[110] *Id.* at *2 (quoting Roth v. Garcia Marquez, 942 F.2d 617, 620-21 (9th Cir. 1991)).
[111] *Id.* at *4.
[112] *Id.*
[113] *Id.*
[114] *See id.* at *1, *4.
[115] *Id.* at *4.
[116] *See, e.g.,* Huck v. Wyeth, 850 N.W.2d 353, 369 (Iowa 2014).

plaintiffs with a chance for recourse, or they do not. Because the FDA abandoned the proposed rule discussed in Section II,[117] a duty of care should be imposed as part of a stopgap measure to address the flaws in the current state of the law, as described later in Section IV.

i. *T.H. v. Novartis Pharmaceuticals Corporation*

A late-2017 case decided by the California Supreme Court illustrates how courts should create an exception to the tort element of duty by using the concept of foreseeability to provide injured plaintiffs with an avenue for recovery in the context of innovator liability.[118] In *T.H. v. Novartis Pharmaceuticals Corporation*, a father brought suit on behalf of his twin children against the brand-name manufacturers of the drug Brethine.[119] The mother of the children was prescribed Brethine's generic bioequivalent, terbutaline, during her pregnancy in order to suppress premature labor.[120] The court summarized the basis of the lawsuit by providing the following:

> Plaintiffs brought suit against defendant Novartis Pharmaceuticals Corporation (Novartis), which manufactured Brethine until December 2001, and aaiPharma Inc. (aaiPharma), which purchased the rights to and manufactured Brethine thereafter—using the same label Novartis had used—when plaintiffs' mother was prescribed the generic bioequivalent in 2007. Plaintiffs claim that Novartis knew or should have known that its warning label failed to alert pregnant women or their physicians to the risk Brethine posed to fetal brain development; that manufacturers of terbutaline were compelled by federal law to include Brethine's deficient label on their own products; that it was foreseeable Novartis's successor (aaiPharma) would not change or update Brethine's deficient label; and that in reliance on the deficient warning label, plaintiffs' mother was prescribed terbutaline, which adversely affected plaintiffs' developing brains in utero.[121]

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[117] *See* Burton, *supra* note 63.
[118] *See* T.H. Novartis Pharmaceuticals Corp., 4 Cal. 5th 145, 166 (2017).
[119] *Id.* at 155.
[120] *Id.* at 155.
[121] *Id.*

The primary question the court addressed was whether the brand-name manufacturer of a drug owes a duty to persons harmed by a generic bioequivalent due to an inadequate warning label created by the brand-name company.[122] Answering in the affirmative, the court in *T.H.* held that to "determin[e] whether to create an exception to the general statutory duty of care, the . . . 'most important'[] consideration under California law is the foreseeability of physical harm."[123] Here, the court held "it [wa]s entirely foreseeable that the warnings included (or not included) on the brand-name drug label would influence the dispensing of the generic drug . . . because the warning label on the generic drug is legally required to be identical to the label on the brand-name drug."[124]

California's rationale in this instance is not an anomaly in the United States. For example, the Supreme Judicial Court of Massachusetts circumvented the general rules of duty by adopting an identical rationale involving foreseeability in the context of innovator liability in *Rafferty v. Merck & Company*.[125] For example, the court in *Rafferty* provided the following rationale for imposing a duty of care on the brand-name manufacturer for the warning labels of generic bioequivalent medications: "With generic drugs, it is not merely foreseeable but *certain* that the warning label provided by the brand-name manufacturer will be identical to the warning label provided by the generic manufacturer, and moreover that it will be relied on . . . by users of the generic product."[126] The court emphasized that the context of prescription medication is markedly different than most other contexts; in most other cases, the manufacturer of a product and its corresponding warning label only involve that specific product, not the products of competitors.[127] Thus, because generic drug manufacturers are required to copy the warning label of the brand-name alternative, it should be foreseeable for every brand-name manufacturer that its warning label may cause harm to consumers of the generic equivalent, thereby justifying the creation of a duty.[128]

ii. *Huck v. Wyeth*

In contrast with the California Supreme Court in *T.H.*, the Iowa Supreme Court in *Huck v. Wyeth* declined to impose a duty of

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[122] *Id.* at 155-56.
[123] *Id.* at 166 (quoting Kesner v. Superior Court, 1 Cal. 5th 1132, 1145 (2016)).
[124] *Id.* at 166-67.
[125] *See* Rafferty v. Merck & Co., 479 Mass. 141, 150 (2018).
[126] *Id.* (emphasis in original).
[127] *Id.*
[128] *Id.* at 150-51.

care on the brand-name manufacturer for harm caused by the plaintiff ingesting a generic bioequivalent.[129] In *Huck*, similar to other cases involving innovator liability, a drug's warning label failed to warn of a serious side effect, resulting in harm to the plaintiff.[130] The plaintiff brought suit against both the brand-name and generic manufacturers.[131] Rejecting the theory of innovator liability, the Court in *Huck* reasoned that "[u]nder Iowa law, manufacturers owe duties to those harmed by use of *their* products."[132] Additionally, concerning foreseeability in the context of the duty, the Court further rejected the plaintiff's claim by agreeing with the notion adopted by other courts that "holding name brand manufacturers liable for harm cause by generic manufacturers 'stretches the concept of foreseeability too far.'"[133] The difference between the courts in *T.H.* and *Huck* illustrates the more black-and-white nature of the duty analysis in the context of innovator liability, differing from a personal jurisdiction analysis which offers a court more discretion to rule one way or the other.

By declining to impose a duty of care on the brand-name manufacturer, the court in *Huck* demonstrates the current problem with the law: many individuals are without recourse in states hesitant to adopt innovator liability due to the possibility of a future correction by the FDA. For example, as a reason to decline imposing a duty of care on the brand-name manufacturer, the court in *Huck* stated the following: "The FDA has responded to *Mensing* through a proposed rule to allow generic manufacturers to update their labeling on their own, regardless of the brand manufacturer labeling."[134] However, as described in Section II, the FDA later rejected the proposed rule change which would have permitted generic manufacturers to unilaterally change the warning labels on their products.[135] This inaction by the FDA necessitates the proposal advocated for in the following section.

IV. PROPOSED SOLUTION

Innovator liability undoubtedly contains substantial flaws. For instance, the Iowa Supreme Court in *Huck* cited to a few common objections to innovator liability such as the theory's arguable contravention of "traditional common law tort principles,"

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[129] Huck v. Wyeth, 850 N.W.2d 353, 369 (Iowa 2014).
[130] *Id.* at 357-61.
[131] *Id.* at 360.
[132] *Id.* at 369 (emphasis added).
[133] *Id.* (quoting Schrock v. Wyeth, Inc., 727 F.3d 1273, 1284-86 (10th Cir. 2013) (citing Mensing v. Wyeth, Inc., 588 F.3d 603, 613 (8th Cir. 2009))).
[134] *Id.* at 369.
[135] *See* Burton, *supra* note 63.

as well as the public policy consideration involving the large expense incurred by brand-name manufacturers to market a new drug.[136] Despite innovator liability's arguable contravention of tort law principles and arguably unfair results against brand-name manufacturers, state legislatures and courts should adopt innovator liability to accomplish two objectives: (1) provide injured plaintiffs with a short-term stopgap avenue for recovery and (2) encourage the federal government to implement a more sustainable long-term solution involving pharmaceutical drug failure-to-warn cases. Pharmaceutical drug consumers in states that reject innovator liability are likely unaware of the drastic difference in available recourse between ingesting the generic and brand-name versions of a drug. In contrast, brand-name manufacturers are likely well aware that a generic drug manufacturer is "responsible for ensuring that its warning label is the same as the brand-name's."[137]Weighing the fairness of both sides of the argument tilts in favor of providing plaintiffs with an avenue for recovery. To solve for cases with substantially unfair circumstances, brand-name manufacturers may still be able to successfully argue other defenses to avoid liability, such as personal jurisdiction as seen in *Henry*.[138]

An expansion of innovator liability would likely incentivize the federal government to promulgate a new framework permitting generic manufacturers to update their warning labels to contain differences from brand-name drug warning labels, all while providing injured plaintiffs with an avenue for recourse in the meantime. Some courts understandably have concluded that Congress and the FDA are in the best position to correct the ramifications of *Mensing*, and thus innovator liability should be rejected as a solution to provide patients with legal recourse.[139] For example, the Supreme Court of Iowa in *Huck* stated, "In sum, we will not contort Iowa's tort law in order to create liability for brand manufacturers. The unfairness resulting from *Mensing* is best addressed by Congress or the FDA."[140] However, under both the Obama administration and the Trump administration, which represent opposing sides of the political spectrum, Congress and the FDA have demonstrated their unwillingness to change the current state of the law.[141] Therefore, additional pressure must be exerted on

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[136] *Huck*, 850 N.W.2d at 369-71 (quoting Schrock v. Wyeth, Inc., 727 F.3d 1273, 1285 (10th Cir. 2013)).
[137] *PLIVA, Inc.*, 564 U.S. at 612 .
[138] *See* Henry v. Angelini Pharma, Inc., 2020 WL 1532174, at *3-4 (E.D. Cal. Mar. 31, 2020).
[139] *See Huck*, 850 N.W.2d at 380.
[140] *Id.*
[141] *See* FDA Statement, *supra* note 65.

Congress and the FDA in order to correct the unfair ramifications of the holding in *Mensing*.

Ignoring the debate of whether federal lobbying is a benefit or hindrance to the lawmaking process, the reality in the United States is that lobbying plays a significant role in political decisions.[142] In 2019 alone, over $280 million was spent on lobbying involving pharmaceutical drugs and health products.[143] In the context of innovator liability, the pharmaceutical drug lobby would naturally be concerned about any potential change to the law following the holding in *Mensing* and would likely lobby the federal government to support a position most beneficial to their particular interests.

Both the brand-name drug lobby and the generic drug lobby invest substantial amounts of money in their lobbying efforts.[144] Pharmaceutical Research and Manufacturers of America (PhRMA)[145], a trade group representing many prominent brand-name drug manufacturers, spent a record-high $29 million on lobbying in 2019.[146] In comparison, the Association for Accessible Medicines (AAM), a trade group representing manufacturers of generic medication[147], spent a total of $3.5 million on lobbying the federal government in 2017.[148] Based on a statement from FDA Commissioner Scott Gottlieb following the FDA decision to reject the 2013 proposed rule change, as discussed in Section II, the interests of the generic drug industry affected the FDA's choice to continue the harsh ramifications following *Mensing*.[149] In Gottlieb's official statement regarding the FDA's decision, he explained that a key basis for the outcome centered on the increased liability imposed on generic manufacturers: "Importantly, we heard important feedback that the proposed rule, if finalized, would have imposed significant burdens on the generic drug industry, and that

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[142] *See* Karl Evers-Hillstrom, *Lobbying spending reaches $3.4 billion in 2018, highest in 8 years*, OPENSECRETS (Jan. 25, 2019), https://www.opensecrets.org/news/2019/01/lobbying-spending-reaches-3-4-billion-in-18/.
[143] *Id.*
[144] *See A bitter pill: how big pharma lobbies to keep prescription drug prices high*, CREW (June 18, 2018), https://www.citizensforethics.org/reports-investigations/crew-reports/a-bitter-pill-how-big-pharma-lobbies-to-keep-prescription-drug-prices-high/ [hereinafter "A bitter pill"]; Jessie Hellmann, *PhRMA spent a record-high $29 million on lobbying in 2019*, THE HILL (Jan. 22, 2020), https://thehill.com/policy/healthcare/479403-phrma-spent-record-high-29-million-lobbying-congress-trump-administration.
[145] *See generally* PHRMA, https://www.phrma.org.
[146] Hellmann, *supra* note 144.
[147] *See generally* AAM, https://accessiblemeds.org.
[148] A bitter pill, *supra* note 144.
[149] *See* FDA Statement, *supra* note 65.

it could have led to an increase in the cost of generic drugs or the market exit of certain products and manufacturers . . ."[150]

However, PhRMA's priorities in 2017, prior to the FDA's rejection of the proposed rule, likely would have been different if more courts across the country adopted innovator liability in the absence of an updated FDA regulation. For example, in 2017, PhRMA would have had a larger stake in the outcome of the proposed rule if innovator liability was adopted or appeared likely to be adopted in more states. While the FDA adopting the proposed rule in 2018 would have likely resulted in positive business ramifications for brand-name manufactures, such as the elimination of the need for plaintiffs to assert innovator liability in the small number of states it existed and an increase in the cost of generic medication, the relatively small number of states that permitted innovator liability did not make the stakes as high as the scenario described in the subsequent paragraph.

Contrasting with the circumstances around the time of the FDA rejected the proposed rule, if a larger number of states opted to permit innovator liability, the business interests of PhRMA would be substantially greater and would create a greater urgency in convincing the FDA to adopt a similar rule as proposed in 2013. For example, a wider adoption of innovator liability would naturally increase the potential liability facing brand-name manufacturers. Further, this additional liability imposed on the brand-name manufacturers would likely lead to an increase in the cost of prescription medication and temporarily hinder further innovation due to the added risk of the cost of litigation. In such a scenario, it is much more likely the FDA would reconsider its approach and remedy the harsh ruling for consumers following *Mensing*.

As previously mentioned in Section II of this note, the FDA stated it planned to exert greater energy and time in working with the brand-name manufacturers to update the warning labels of older medications.[151] This is not an ideal solution due to the inability to completely eliminate inadequate warning labels, despite a greater amount of energy and time being exerted to prevent mistakes from occurring. Even if the FDA is successful in updating warning labels to be more accurate, injured plaintiffs should have legal recourse in the event that a mistake does happen. With the current state of the law remaining flawed and the federal government seemingly remaining content with the status quo, there must be an impetus to encourage a change in the law. The adoption of innovator liability in more jurisdictions throughout the United States, despite the

[150] FDA Statement, *supra* note 65.
[151] FDA Statement, *supra* note 65.

theory's flaws, could serve as that impetus while also providing injured plaintiffs with an avenue for recourse.

VI. CONCLUSION

Admittedly, the proposed approach of this Note is not a perfect solution and is more difficult than other options, such as the FDA adopting a new rule without states adopting innovator liability. Nevertheless, this Note's proposal is a stopgap measure which would both encourage a change to the law and provide injured plaintiffs with an ability to recover until a change to the law is ultimately finalized. Although the Drug Price Competition and Patent Term Restoration Act of 1984 has been successful in promoting affordable generic drugs to consumers,[152] the current legal background involving pharmaceutical drugs is flawed due to the majority of the U.S. population currently ingesting generic drugs without proper recourse in the event of an inadequate warning. The purpose of generic drugs is to provide Americans with more affordable medication.[153] This purpose is greatly hindered if consumers are not adequately protected and provided with appropriate recourse in the event of tortious conduct by a generic drug manufacturer. Therefore, plaintiffs should be provided recourse in the interim before a more long-term solution is implemented. In addition to providing prescription drug consumers with a means to recover damages after suffering harm, adopting innovator liability would incentivize both the federal government to make a change to the current framework and the brand-name pharmaceutical drug lobby to exert influence in an effort to change the law.

[152] ASPE ISSUE BRIEF, *supra* note 38 at 3.
[153] *Id*.

AN UPDATE IS REQUIRED TO CONTINUE USING THIS REGULATION: WHY THE HIPAA PRIVACY RULE SHOULD BE MODIFIED TO PROTECT A BROADER RANGE OF HEALTH DATA

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I. INTRODUCTION

Bailey wakes up to her alarm at 7:00 a.m. She checks her smartwatch and learns she fell asleep at 11:37 p.m., completed four REM cycles, and woke up briefly at 3:24 a.m. She gets out of bed and goes to the bathroom, then to the kitchen to start a pot of coffee. Her smartwatch tracks the number of steps she takes on this short journey through her apartment. Bailey is a diabetic and before she prepares breakfast, she tests her blood sugar with a blood sugar meter. The meter is connected via Bluetooth® to a mobile app on her phone, where her blood sugar readings are visualized in neat graphics. After breakfast, Bailey opens a fitness app on her tablet and joins a virtual workout class from her apartment. Her smart watch tracks her heart rate, the number of calories she burns, and her blood oxygen levels during her workout, then summarizes trends in her weekly fitness and activity levels. Bailey gets ready for the day and sits down at her desk to start working. Once per hour, her smartwatch buzzes to remind her to stand and stretch for a few minutes. Before lunch, she checks her blood sugar level again and opens a different mobile app to track her menstrual cycle. By 12:00 PM, only five hours after waking up, Bailey's various pieces of technology have collected hundreds of data points related to her health.

Bailey probably wants to share information related to her diabetes with her doctor. She may want to share her workout stats with friends. But what control does she have over the health data collected on her personal devices that she wishes to keep private? In most of the United States, the answer is very little. While the Health Insurance Portability and Accountability Act (HIPAA)[1] protects sensitive patient health data through the Privacy Rule[2], its protection extends to more traditional relationships between patients and healthcare providers. The rise in popularity of personal health, combined with the tech boom of the 2010s has led to the creation of myriad technologies that allow individuals to record their own health data through web applications, mobile applications, and a variety of physical devices that can connect to mobile phones or other Internet-enabled devices.[3] However, federal regulation in the United States has not caught up to protect health data in this new arena outside the traditional healthcare model.

While there is no constitutional right to privacy of information, general public sentiment leans in favor of keeping

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[1] 45 C.F.R. § 160 (2021), 45 C.F.R. § 162 (2021), 45 C.F.R. § 164 (2021).
[2] 45 C.F.R. § 164.502 (2021).
[3] *What is Digital Health?*, U.S. FOOD & DRUG ADMINISTRATION (last updated Sept. 22, 2020), https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health.

personal health data private.[4] More precisely, individuals would like information known only to the individual and other parties to whom he or she chooses to disclose the information. This is because public knowledge of sensitive personal data may harm the individual economically, socially, or in other intangible ways.[5] The benefits of public knowledge of such individually identifiable health data do not outweigh these potential harms. Privacy should be the default.

To achieve this, HIPAA must be expanded to protect private health data beyond the confines of traditional patient-provider relationships and in the broader digital healthcare industry. This note will provide relevant background information on the current state of the HIPAA Privacy Rule and California's Confidentiality of Medical Information Act (CMIA)[6]. The primary issue this Note will discuss is that advancements in technology have fundamentally changed the healthcare landscape to the point where existing federal regulations neither address nor protect private health data when it is created or transmitted between non-traditional providers of healthcare. For example, companies that create technological products that allow consumers to track their personal health data are not covered by the HIPAA Privacy Rule. Thus, the collection, processing, and storage of such data is not subject to federal health regulations. This note will argue that more classes of entities, specifically businesses that track and store individuals' health data, should be subject to HIPAA privacy regulations. A state-by-state solution would be less effective than a federal regulation because it would likely cause confusion for businesses and consumers regarding when data is protected and when it is not. Furthermore, it is likely that such an approach would prove wasteful if Congress were to enact general data privacy regulations in the near future. Finally, this note will conclude that the most comprehensive and simple approach to addressing the issue of health data privacy is to modify the HIPAA Privacy Rule to cover a broader range of entities in the United States.

II. BACKGROUND

HIPAA is the primary federal authority regarding health data privacy in the United States. Signed into law in 1996, HIPAA was

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[4] Kaveh Safavi & Brian Kalis, *How Can Leaders Make Recent Digital Health Gains Last?: Re-Examining the Accenture 2020 Digital Health Consumer Survey*, ACCENTURE (last modified Aug. 26, 2020), *available at* https://www.accenture.com/_acnmedia/PDF-130/Accenture-2020-Digital-Health-Consumer-Survey-US.pdf

[5] BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH (Sharyl J. Nass et al. eds., National Academies Press, 2009).

[6] Codified at CAL. CIV. CODE §§ 56-59.

initially an attempt at broad healthcare reform.[7] Some of its original purposes were to improve portability and continuity of health insurance, such that employees would not lose coverage when changing jobs, and to combat waste, fraud, and abuse in the healthcare and health insurance industries.[8] In its twenty-four-year lifespan, HIPAA has been modified and added to six times.[9] Most notably, the HIPAA Privacy Rule became effective in 2003.[10] The Privacy Rule protects individuals' personal health information from unauthorized use and disclosure.[11] However, HIPAA has not been significantly modified in recent years to address the rapid advances in technology that have meaningfully changed the way Americans access health care and manage personal health data.

a. The HIPAA Privacy Rule

Broadly, the purpose of HIPAA's Privacy Rule is to protect individuals' personal medical records and personal health information from unauthorized access or disclosure.[12] While privacy of personal data has not been recognized as a constitutionally fundamental right, Congress has acknowledged the importance of protecting individually identifiable health information with the passage of the Privacy Rule.[13] The Rule is codified at 45 C.F.R. § 164, though definitions to several key terms are carried over from 45 C.F.R. § 160.

i. Definitions

The definitions provided at 45 C.F.R. § 160.103 indicate the scope of the Privacy Rule; that is, what information is protected and to which parties the Privacy Rule applies. Several definitions are relevant to the discussion in this Note, including "health information." Health information is defined as

> any information, whether oral or recorded in any form or medium, that (1) is created or received by a

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[7] *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in scattered sections of 45 U.S.C).
[8] *Id*.
[9] *The History of HIPAA*, ACCOUNTABLE (May 14, 2020), https://www.accountablehq.com/post/history-of-hipaa.
[10] *Id.*
[11] 45 C.F.R. § 164.502.
[12] *Id.*
[13] Standards for Privacy of Individually Identifiable Health Information; Final Rule, 67 Fed. Reg. 53181 (August 14, 2002) (Codified at 45 C.F.R. §§ 160 and 164).

> healthcare provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse, and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.[14]

The second part of this definition is quite expansive. Information must only "relate" to one of three healthcare aspects in order to be protected by the Privacy Rule. First, information may relate to an individual's physical or mental health condition, which includes information that the public traditionally associates with health care such as a vitals taken at a yearly checkup, genetic test results, or diagnosis or treatment of a disease.[15] But it also may include information such as a person's daily routine, eating habits, sleep patterns, and thoughts and feelings, as this type of information certainly relates to an individual's physical and mental health and condition. Second, information may relate to the provision of healthcare to a person.[16] This includes the conventional provision of healthcare by a doctor to a patient, such as assessing the patient, prescribing medication, performing operations. But it could also be broadly construed to include the work of professionals who are not traditionally thought of as "healthcare" workers, such as personal trainers or nutrition coaches, but whose work centers around improving individuals' health.[17] Finally, information may relate to past, present, or future payment for provision of healthcare.[18] Overall, the second part of the definition of health information covers a wide expanse of information conveyed orally or recorded in any form or medium.

However, the first part of the definition drastically limits the scope of the Privacy Rule, only offering protection if such information is "created or received" by one of the Privacy Rule's seven designated entities.[19] "Healthcare provider" is defined as

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[14] 45 C.F.R. § 160.103.
[15] *What is Considered Protected Health Information Under HIPAA?* HIPAA JOURNAL (Apr. 2, 2018), https://www.hipaajournal.com/what-is-considered-protected-health-information-under-hipaa/.
[16] 45 C.F.R. § 160.103.
[17] For example, a personal trainer works to improve the physical health of trainees and a nutrition coach works to help clients maintain a balanced diet. Neither is traditionally considered a "healthcare" worker.
[18] 45 C.F.R. § 160.103.
[19] *Id.*

> a provider of services (as defined in 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, codified at 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.[20]

"Provider of services" is defined as a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program.[21] "Medical or health services" has a broad definition that outlines specific activities and medical items related to particular illnesses, diseases, and treatments.[22] The catch-all provision at the end generally refers to health insurance companies.[23]

"Health plan" includes private health insurers, Medicare, and Medicaid, but explicitly excludes other types of private insurers (such as automobile or liability insurance companies) and other government programs.[24] "Employer" borrows its definition from 26 U.S.C. § 3401(d): ". . . the person for whom an individual performs or performed any service, of whatever nature, as the employee of such person."[25] "Health care clearinghouse" is defined as a public or private entity that processes health information received from another entity and either converts it into a specified data format.[26] In plain words, health care clearinghouses are simply data processing companies. A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency.[27] The other listed entities are not explicitly defined in this Privacy Rule and for this Note the dictionary meaning will be used for "life insurer"[28] and "school or university."[29]

Thus, "health information" for purposes of the Privacy Rule is any information relating to a person's physical or mental health, provision of healthcare, or payment for healthcare when it is created

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[20] *Id.*
[21] 42 U.S.C. § 1395x(u).
[22] 42 U.S.C. § 1395x(s).
[23] 45 C.F.R. § 160.103.
[24] *Id.*
[25] 26 U.S.C. § 3401(d).
[26] *See* 45 C.F.R. § 160.103.
[27] *See* 45 C.F.R. § 164.501.
[28] See *life insurance*, MERRIAM-WEBSTER DICTIONARY, (11th ed. 2014).
[29] See *school*, MERRIAM-WEBSTER DICTIONARY, (11th ed. 2014).

or received by certain entities traditionally associated with healthcare or health insurance. It appears that Congress intended for "health information" to encompass a broad range of information, limited by the requirement it be created or received by designated entities.

"Individually identifiable health information" is health information, as defined above, which identifies the individual.[30] "Protected health information" is individually identifiable health information which is transmitted or maintained in electronic or other form or media.[31] A select few categories of individual identifiable health information are excluded from protection, including information that is in education or employment records held by covered entities. Thus, the scope of protected health information under the HIPAA Privacy Rule can be summarized as individually identifiable information related to the physical or mental health or condition, the provision of healthcare, or the payment of healthcare of a person which is created or received by one of seven designated entities.

ii. Covered Entities

While several entities are designated in the definition of health information, as discussed above, the Privacy Rule applies only to three types of entities: health plans, healthcare clearinghouses, and healthcare providers who transmit any health information in electronic form in connection with a transaction covered by the Privacy Rule.[32] The definitions from 45 C.F.R. § 160.103 carry over into this section of the rule, and these entities are described as "covered entities." The Department of Health and Human Services has provided guidance on which entities qualify as covered entities: healthcare providers include doctors, clinics, psychologists, dentists, chiropractors, nursing homes, and pharmacies; health plans include health insurances companies, HMOs, company health plans, and government programs which pay for healthcare; and healthcare clearinghouses include entities that process nonstandard health information received from another entity into a standard (i.e., standard electronic format or data content), or vice versa.[33]

Therefore, the Privacy Rule does not apply to any business, person, or other entity that does not meet the definition of health

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[30] 45 C.F.R. § 160.103.
[31] *Id.*
[32] 45 C.F.R. § 164.104.
[33] Office for Civil Rights, *Covered Entities and Business Associates*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (last updated Jun. 16, 2017), https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html.

plan, healthcare clearinghouse, or healthcare provider.[34] This means that a business that does not meet HIPAA's definition of healthcare provider, even though it may present itself to the general public as a health-related company, may collect and disseminate individually identifiable health information from a person without running the risk of violating the HIPAA Privacy Rule.

iii. The Privacy Rule

The Privacy Rule addresses several aspects relating to keeping individually identifiable health information private, including permitted uses and disclosures, rights to request such information, and notice of privacy practices. The basic premise of the Privacy Rule is that a covered entity may not use, disclose, or sell protected health information except in situations explicitly permitted by the Privacy Rule.[35] When use or disclosure of protected health information is permitted, the covered entity "must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request ."[36] Furthermore, communication of such protected health information must be confidential.[37]

Covered entities are, naturally, permitted to use or disclose protected health information to the individual and in relation to treatment, payment, or healthcare operations.[38] De-identified health information, as it does not meet the definition of protected health information, may be used or disclosed by a covered entity without repercussion.[39] In nearly all other situations, the covered entity must obtain valid authorization or provide the individual with an opportunity to object to the use or disclosure of protected health information.[40] The Privacy Rule explicitly lists three situations where authorization must be obtained: psychotherapy notes, marketing, and sale of protected health information.[41] Marketing and sale of health information each present an opportunity for entities to profit off of data that is personal and integral to the well-being of a person.

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[34] The Privacy Rule also applies to "business associates," which are persons who participate in business practices alongside or on behalf of the defined covered entities, in specific circumstances. *See id.*; *see also* 45 C.F.R. § 164.104.
[35] 45 C.F.R. § 164.502(a).
[36] 45 C.F.R. § 164.502(b).
[37] 45 C.F.R. § 164.502(h).
[38] 45 C.F.R. § 164.502(a)(1).
[39] 45 C.F.R. § 164.502(d).
[40] 45 C.F.R. § 164.502(a)(1)(iv).
[41] 45 C.F.R. § 164.508(a)(2)-(4).

Overall, the Privacy Rule is a comprehensive regulation that allows use and disclosure of protected health information only in specific limited situations. The language and breadth of the Rule strongly suggest a preference towards keeping such information as private as possible, and only allowing disclosure when it would benefit the individual or when necessary for treatment or payment of healthcare. At the time of its promulgation, healthcare was mostly limited to traditional models of humans visiting doctor's offices to receive care, and technology was not as integrated into the daily lives of Americans as it is today.[42] This is part of the reason the entities to which the Privacy Rule applies are limited to those traditionally associated with healthcare. However, as will be discussed, technology has disrupted the healthcare industry in many ways, both positive and negative. Notably, businesses that operate primarily as technology companies and secondarily as providers of healthcare now collect significant amounts of health information. Changing times call for changes to regulations.

b. CMIA

California is the first state to significantly regulate health data, electronic or otherwise, and increase health data privacy protections for its residents with its 2013 amendments to the CMIA.[43] Most of the CMIA definitions resemble the HIPAA definitions. For example, "medical information" is defined as "any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment."[44] This is virtually identical in meaning to the HIPAA definition of "health information" because a broad range of information relating to a person's physical or mental health or condition is protected under the regulation if it is created or received by a designated entity.

However, more entities are covered by the CMIA than by HIPAA.[45] In addition to the traditional providers of healthcare, the

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[42] For example, a diabetes patient in 1996 would most likely communicate with her doctor in person or over the telephone. She would not be able to track her blood sugar levels with a biosensor device that connects to a mobile application on her phone and sends updates to her doctor.

[43] Nick Stamos, *California Expands the Confidentiality of Medical Information Act to Personal Health Records and Mobile Applications*, ALSTON & BIRD PRIVACY & CYBERSECURITY BLOG (Sept. 11, 2013), https://www.alstonprivacy.com/california-expands-the-confidentiality-of-medical-information-act-to-personal-health-records-and-mobile-applications.

[44] CAL. CIV. CODE § 56.05(i) (2019)

[45] CAL. CIV. CODE § 56.06 (2019).

CMIA applies to three types of business organizations in California.[46] First, it applies to companies that maintain health data:

> Any business organized for the purpose of maintaining medical information . . . in order to make the information available to an individual or to a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the individual to manage his or her information, or for the diagnosis and treatment of the individual . . . shall be . . . subject to the requirements of this part.[47]

For example, a technology company that builds, maintains, and licenses software to be used as a database for patient medical records is regulated by the CMIA.

Second, the CMIA applies to healthcare technology companies. Specifically, it applies to

> [a]ny business that offers software or hardware to consumers, including a mobile application or other related device that is designed to maintain medical information . . . in order to make the information available to an individual or a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the individual to manage his or her information, or for the diagnosis, treatment, or management of a medical condition of the individual . . .[48]

For example, a business that developed a mobile application for the purpose of allowing users to input and maintain their personal health information is subject to the CMIA regulation.

Finally, the CMIA applies to any business licensed to sell cannabis for medical purposes.[49] By expanding the types of businesses to which the regulation applies, California has broadly expanded the overall scope of medical data privacy to which its residents are entitled.

I. ISSUE

When the HIPAA Privacy Rule became effective in 2003, smartphones were clunky, expensive, and not widely used by the

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[46] *Id.*
[47] CAL. CIV. CODE § 56.06(a).
[48] CAL. CIV. CODE § 56.06(b).
[49] CAL. CIV. CODE § 56.06(c).

general American public.[50] The thought of using a mobile phone to track and maintain personal health data was nearly inconceivable. It was not until 2007 that Apple's iPhone kick-started innovation in the smartphone industry and spurred on a new wave of personal technology.[51] Over the past thirteen years, the popularity and usefulness of smartphones has steadily risen. In 2019, 81% of U.S. adults owned a smartphone[52] and that percentage has surely continued to grow since then. This is in addition to the 74% of U.S. adults who own a personal computer and the 52% who own a tablet computer.[53]

The market for digital health tools has grown exponentially with the widespread adoption of smartphones, tablets, and personal computers.[54] Many digital health tools are designed to be paired with a wearable device that can track a person's physical metrics, ranging from fitness trackers that count the wearer's steps to heartrate to insulin pumps which can be controlled from an app. A 2017 report found that there were over 318,000 health apps and 340 wearable devices on the market at the time with over 200 applications being added to app stores each day.[55] If this rate has remained steady, there were over half a million health apps on the market in 2020. This is in addition to digital tools that are available for use on personal computers or as web applications that individuals may access through a web browser.

Some people do not mind sharing their whole lives with the world; others are generally private people who wish to publicly share limited glimpses of their lives. Neither outlook on life is inherently better than the other. But the nature of information is such that once it is shared, it cannot be taken back. This is especially true in a digital world where data and information can travel far and wide once posted or shared.[56] Data posted on social media or logged in a mobile app is generally stored on remote servers. Even if a user

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[50] Owen Andrew, *The History and Evolution of the Smartphone: 1992-2018*, TEXT REQUEST (Aug. 28, 2018), https://www.textrequest.com/blog/history-evolution-smartphone/.

[51] Charles Arthur, The history of smartphones: timeline, THE GUARDIAN (Jan. 24, 2012), https://www.theguardian.com/technology/2012/jan/24/smartphones-timeline.

[52] *Mobile Fact Sheet*, PEW RESEARCH CENTER (Jun. 12, 2019), https://www.pewresearch.org/internet/fact-sheet/mobile.

[53] *Id.*

[54] Murray Aitken, et al., *The Growing Value of Digital Health*, IQVIA INSTITUTE (Nov. 2017), accessible at https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-growing-value-of-digital-health.pdf?_=1606164349006.

[55] *Id.*

[56] Lazaro Gamino, *How data travels across the internet*, THE WASHINGTON POST (May 31, 2015), https://www.washingtonpost.com/graphics/national/security-of-the-internet/bgp.

"deletes" the data, it is often stored in an unreadable, yet accessible, format on the host's servers for a set period of time.[57] Furthermore, a public post may be screenshotted[58] by anyone who views the post, which takes any control of the information away from the original poster. Because of this, individuals should have the right to choose whether or not certain personal data will be shared publicly, especially if that data is potentially embarrassing. Given the "no take backs" nature of information, public policy should skew in favor of protecting personal sensitive data. Policy should automatically allow those who wish to keep it this information private to do so, while also allowing those who wish to share it to do so as well.

This intrinsic harm may be difficult to quantify[59], but the risk of potential economic harm exists as well. While it is a violation of the Family and Medical Leave Act and the Americans with Disabilities Act to discriminate in employment matters on the basis of a medical condition[60], the reality is that employers may consider the overall health of employees when making hiring, promotion, or firing decisions. Should an employer gain unfettered access to a prospective employee's personal health records, the employer may use this information against him or her in making employment decisions. For example, if two candidates for an open position are equally qualified for the role, the employer may look to other factors that may indicate one is a better long-term investment. The employer may consider overall health as an indicator of which candidate would need to take less time off from work, which may use less health insurance benefits, and which candidates physical and mental health would allow him or her to advance or continue in the role for a longer period of time. Thus, if employers were able to access prospective employees' personal health data, employees may risk losing out on jobs, and consequently employer-sponsored health insurance.[61]

There are also social and psychological risks associated with public knowledge of an individual's medical or other health information.[62] Mental health issues and disorders in particular carry

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[57] Jada Green, *Here's What Really Happens When You 'Delete' Something on the Internet*, MEN'S HEALTH (Oct. 20, 2015), https://www.menshealth.com/technology-gear/a19547921/deleted-social-media-posts/.

[58] A screenshot, or screen grab, is when a digital image is captured of the entire screen, or part of the screen, of a smartphone, tablet, or computer.

[59] Richard S. Saver, *Medical Research and Intangible Harm*. 74 U. CIN. L. REV. 941, 945 (2006).

[60] *See* 29 U.S.C. § 2615; *see also* 42 U.S.C. § 12112.

[61] Nass, *supra* note 5 (citing LAWRENCE O. GOSTIN & LINDSAY F. WILEY, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT*, (3rd ed. 2016)).

[62] Norman Sartorius, *Stigmatized Illnesses and Health Care*, 48(3) CROAT MED J. 396 (2007).

significant stigma in American society.[63] Often, persons with mental health disorders such as anxiety and depression are reluctant to seek help. Furthermore, those who do seek help often fail to follow through with full treatment due to the stigma around mental illness.[64] Physical diseases also commonly carry stigma of different kinds. Persons diagnosed with contagious diseases such as HIV and other sexually transmitted diseases may be ostracized in social settings.[65] Individuals would be more likely to seek treatment and other help for physical and mental health conditions knowing that doing so would not expose them to societal stigma or exclusion.

Could a simple answer to alleviate the privacy risks associated with individually identifiable health data be to anonymize or otherwise de-identify the data in storage? The European Union's General Data Privacy Regulation (GDPR) contemplates de-identification as a method for maintaining data privacy.[66] Businesses which track and maintain individually identifiable health data can anonymize the data such that the individual is no longer identifiable.[67] However, the bar to do this is extremely high,[68] given that roughly 87% of Americans can be identified with three data points: zip code, date of birth, and gender.[69] Pseudonymization, an alternative to anonymization, is the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information that is kept separate.[70] However, depending on the specific method used to anonymize data, it could be relatively easy to re-identify such data.

As the use and development of technology in the healthcare industry has proliferated, so too has the amount of personal, individually identifiable health data being collected, transmitted, and stored. Unfortunately, because most of the companies who build and maintain digital health tools (and the data systems underlying them) do not qualify as a covered entity under HIPAA, there is little regulation regarding how this information may be used and disclosed. Health data is among the most sensitive categories of data, and individuals should have the right to keep such information private. Some may choose to allow limited or unlimited access to

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[63] Patrick Corrigan, *How Stigma Interferes with Mental Health Care*, 59(7) AM. PSYCHOL. 614 (2004).
[64] *Id.*
[65] 48(3) Croat Med J. 396.
[66] GDPR Article 11.
[67] Matt Wes, *Looking to comply with GDPR? Here's a primer on anonymization and pseudonymization*, IAPP (Apr. 25, 2017), https://iapp.org/news/a/looking-to-comply-with-gdpr-heres-a-primer-on-anonymization-and-pseudonymization.
[68] *Id.*
[69] Latanya Sweeney, *Simple Demographics Often Identify People Uniquely*, CARNEGIE MELLON UNIVERSITY, 2000 at 2.
[70] 2016 O.J. (L 119) 33.

their health data, but permitting others' access to personal health data should be a conscious choice.

The definition of "health information" as provided in 45 C.F.R. § 160.103 and the list of entities covered by the Privacy Rule should both be amended to include businesses that are not part of the traditional healthcare model, such as healthcare companies who solely operate digitally.

II. ARGUMENT

A. The HIPAA Privacy Rule Should Be Modified to Expand the Types of Entities to Which It Applies.

The most effective solution to fully protect individually identifiable health data is to modernize and expand the HIPAA Privacy Rule. The healthcare industry has changed significantly in the years since the Privacy Rule was promulgated such that the Rule no longer offers adequate protection of private health information. While the provisions of the rule are comprehensive enough to offer adequate protection, the entities to which the Privacy Rule apply and the definition of "health information" are outdated. The definition of health information should be expanded to include information that is created or received by the types of digital health businesses which process and store large amounts of consumer personal health data. Similarly, the Privacy Rule should be amended to apply to these types of businesses. The language in California's CMIA would be a logical point of reference for how to do this.

i. Effects of Increased Investment in Digital Health Companies

Digital healthcare is a rapidly growing industry, especially due to the COVID-19 pandemic. In the first three quarters of 2020, digital health companies in the United States raised $9.4 billion in venture funding.[71] This puts the industry on track to have its largest funding year ever[72] and demonstrates how more money than ever before is being invested in digital health products and services in the United States. Naturally, this influx of capital gives the digital health

[71] Elaine Wang & Sean Day, *Q3 2020: A new annual record for digital health (already)*, ROCK HEALTH (Oct. 2020), https://rockhealth.com/reports/q3-2020-digital-health-funding-already-sets-a-new-annual-record/.

[72] For comparison, these types of companies raised $5.8 billion and $7.8 billion in the 2017 and 2019 calendar years, respectively. *See* Nina Chu, et al., *2020 Midyear Digital Health Market Update: Unprecedented funding in an unprecedented time*, ROCK HEALTH (Jul. 2020), https://rockhealth.com/reports/2020-midyear-digital-health-market-update-unprecedented-funding-in-an-unprecedented-time.

industry the resources to produce more products and offer more services in the coming years. Some examples of new digital health products include a wearable cardiac defibrillator which can be monitored by a smartphone app and a software platform for health systems to manage patient payments.[73] Some examples of new services include a full-service digital pharmacy complete with prescription delivery and on-demand urgent care services.[74]

Consumer adoption of digital health products and services also surged in 2020 due to the COVID-19 pandemic.[75] For example, one healthcare provider reported a 50% increase in telehealth visits in one week and another provider reported a 2000% in increase in telehealth visits over a two month period.[76] One key impediment to wider consumer adoption of these products and services that a majority of consumers do not view digital products and services as effective when compared their tangible, in-person counterparts.[77] This issue has potential to be solved quickly: with increased investment in the digital health industry, companies will have the financial resources to improve the user experiences. Such capital is necessary to hire user experience (UX) researchers and designers, fund product teams with product managers and technical talent, and conduct behavioral analytics to further iterate on and improve existing products and services.[78] With key improvements to the user experience, digital health companies will be able to offer consumers more effective experiences. With this barrier to wider adoption removed, overall consumer adoption of digital health tools is likely to increase.

The surge in investment, combined with increased consumer adoption, means that the amount and types of personal health data being collected by digital health companies will grow exponentially in years to come. Consequently, the risks associated with leaving such data inadequately protected will also increase. The most comprehensive step to take to alleviate the risks is to enact federal regulations which require companies to adequately protect data.

ii. Benefits of Increased Regulation of Health Data Privacy

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[73] *Id.*
[74] *Id.*
[75] Safavi, *supra* note 4.
[76] *Id.*
[77] *Id.*
[78] Ivan Annikov, *How to Conduct Effective UX Research – A Guide*, TOPTAL (last visited Jan. 2, 2021), https://www.toptal.com/designers/user-research/budget-ux-user-research.

New technologies have spurred on innovation in the healthcare industry, but federal data privacy regulations have not matched pace. In fact, there has been no significant modification to the HIPAA Privacy Rule since 2013.[79,80] As described above, the Privacy Rule still focuses on and applies to businesses which have adopted traditional provider-patient models of healthcare. The scope of information which could be protected by the Privacy Rule is broad: information must only relate to an individual's health or provision or payment of healthcare. Many lawyers would say that the "relate to" standard is often open to interpretation in court and could be construed broadly to encompass any data tangentially relating to an individual's health. However, the Privacy Rule is limited by two requirements: (1) information must be transmitted between designated entities, and (2) the Privacy Rule only applies to these such designated entities.

Thus, many of the digital health companies that have formed since the Privacy Rule was enacted fall outside its scope. This includes the hundreds of thousands of companies whose primary product is a mobile application which collects or monitors an individual's health data, as well as the companies that have recently secured hundreds of millions of dollars in funding to improve or mass produce their products and services. Because there is no regulation addressing the privacy of individuals' health data, digital health companies are generally free to create their own policies for protection of such data. Some companies elect to place privacy at the top of their list of priorities.[81] Other companies choose speed over security, prioritizing quick growth, user adoption, and profit over data privacy and digital security.

Given the lack of data privacy regulation, it is understandable that concerns about data privacy or security is the number one barrier to adoption of digital health tools in the United

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[79] The HIPAA Omnibus Rule became effective in 2013 and was the most recent modification to HIPAA; *supra* note 9.

[80] New changes to the Rule were proposed in December 2020, but they do not meaningfully expand the scope of entities to which the Rule applies. Anna Kraus, et al., *HHS Announces Proposed Changes to HIPAA's Privacy Rule*, COVINGTON DIGITAL HEALTH (Dec. 21, 2020), https://www.covingtondigitalhealth.com/2020/12/hhs-announces-proposed-changes-to-hipaas-privacy-rule/.

[81] For example, Apple considers data privacy a fundamental right and lists it as one of the company's core values. Apple makes smartwatches which include fitness trackers and automatically includes a health app on its iPhones. Apple operating systems and mobile apps are designed to protect users' rights to control which data remains private and which data is allowed to be shared with Apple and with third parties. *Privacy*, APPLE (2020), https://www.apple.com/privacy/.

States.[82] A majority of individuals do not trust digital health companies to adequately protect their private health information or refrain from selling their data to third-party marketing companies.[83] Trust in traditional healthcare providers to keep private health information secure has also declined in recent years.[84] Most, if not all, digital health companies require consumers to agree to their privacy policies before engaging with their digital products or services. But these privacy policies are generally long and littered with legal language. The important information regarding how the company makes use of user data is used is often buried in pages of fine print.

It is a heavy, if not impossible, burden on the consumer to research exactly which data is collected, how and where it is stored, to whom the data may be disclosed, and what cybersecurity protections the company has in place to prevent breaches. For many, the effort involved in ascertaining the details regarding how each digital health company collects, analyzes, stores, and possibly sells data outweighs the potential benefits of engaging with new companies. And even when a company spells out its privacy policy succinctly in plain, simple terms, some consumers are leery that it may fail to abide by its own policy or that its cybersecurity is insufficient to prevent data breaches by third-party hackers.[85]

Modifying the Privacy Rule to cover digital health companies, in addition to traditional healthcare providers, would bolster consumer trust in digital healthcare. Because the Privacy Rule is set up to encompass a broad range of information, a provision should be added that reduces the limitations on the Privacy Rule. Digital health companies should be included as covered entities and the definition of "health information" should be modified to include information created or received by digital health companies. Given its nature as a state regulation of health data privacy, the CMIA is a logical point of reference for how lawmakers could implement these changes. Following California's example, a provision could be added that would deem digital health businesses as "healthcare providers" solely for purposes of the Privacy Rule. This would reduce the limitations of the Privacy Rule in the necessary ways without adding superfluous regulation. Digital healthcare businesses would be covered entities under HIPAA for Privacy Rule purposes and health information that is created or received by digital health businesses would be protected.

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[82] Safavi, *supra* note 4.
[83] *Id.*
[84] *Id.*
[85] *Id.*

Adapting the Privacy Rule to modern times this way would require any company that collects, processes, or otherwise handles personal health data to take steps to protect it. Increasing consumer trust in the data privacy of digital health would allow many more individuals across the country, not only in California, to reap the myriad benefits of digital healthcare at all stages of the patient journey. At the wellness and prevention stage, more consumers will feel comfortable using digital health tools, such as mobile apps, to track and manage their diet, exercise, stress levels, sleeping habits, and other aspects of daily life. If they choose, there may be opportunities for patient-consumers to connect and share these types of data with primary care physicians, specialty doctors, and other healthcare providers. This would allow healthcare providers to obtain a fuller picture of their patients' health than a normal patient information form could provide.

Digital health tools can offer convenience regarding to routine activities such as accessing medical records, managing appointments, and refilling prescriptions. Any patient can make use of these types of tools. Patients with diseases that require consistent monitoring could decrease the number of weekly, monthly, or annual visits to their doctor by making use of bio sensors that connect to a mobile phone or computer, and send data to the doctor. For example, Bailey, the diabetic woman from the introductory example, could use a digital health tools to monitor her blood sugar levels. She could log this information in a mobile application that tracks her blood sugar levels and automatically shares this data with designated persons, such as her doctor, a family member, and friends who live nearby. If there was ever an emergency in which Bailey was in immediate danger due to low blood sugar levels, nearby persons would be able to attend to Bailey quickly.

For these reasons, the Privacy Rule should apply to all business which operate in the digital healthcare space.

B. Why State-Specific and Other Legislative Solutions Would Be Less Effective and More Laborious

Amending the Privacy Rule to include the proposed changes is certainly not the only possible solution. It is, however, the most comprehensive yet simple way to accomplish the goal of adding privacy protection to individually identifiable health information without imposing any undue burden on digital health businesses. The Privacy Rule already exists, contains desirable language, and has been interpreted by courts. Instead of drafting brand new legislation from scratch, lawmakers could simply expand the scope of the Privacy Rule to include more businesses that are non-traditional providers of healthcare.

i. Confusion, Difficulty in Implementation, and Potential to Become Obsolete

California was the first state to implement a state-specific solution to regulate health data privacy with an amendment to the CMIA in 2013.[86] Considering no other states have implemented similar solutions in the past seven years, it is unlikely health data privacy regulations will begin appearing in all states. This leaves the majority of individuals in the United States without adequate legal protection of their private health data information. However, if each state were to decide to enact its own health data privacy regulation, the business of digital healthcare could soon become more confusing than it is worth.

For example, assume a digital health company was interested in conducting business in several states, each with its own set of health data privacy regulations. The company would need to analyze each set of regulations and determine if it is able to comply. To be able to conduct business in all states, the company would have to comply with the strictest set of regulations. Thus, the regulations of all other states would essentially be rendered null, unless or until they were modified to be stricter. Many digital health companies conduct business across all fifty states and internationally. If each state had its own regulations, digital health companies would have to constantly keep tabs on fifty sets of regulation (fifty-two, if you include Puerto Rice and the District of Columbia) to ensure they are in compliance with all regulations at any given point.

There is also potential for mass confusion among companies and consumers. The internet is not itself a physical location; technically, only the servers that host applications and websites have physical locations. These servers can be placed in locations far from a business's physical office, if it has one, often in another state. If some states chose to enact data privacy regulations and others did not, digital health companies would have to determine whether a given state's regulations apply if the company does not transact business there, but its application happens to be hosted on a server in that state. Consumers similarly could be confused about whether or not their data would be subject to privacy regulations depending on where they are in the country.

Furthermore, it is possible Congress will enact general data privacy regulations in the near future. Given how much technology has become part of Americans' everyday lives, this would come as no surprise. If each state were to enact its own health data privacy regulation, it could potentially become preempted by federal regulation that applies to all types of data, not only health data.

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[86] Stamos, *supra* note 43.

V. CONCLUSION

HIPAA is long overdue for an update. Just like software must be updated consistently to the safest and most useful versions, health regulations must also be updated to adapt to changing times to provide the most protection and usefulness. This note has discussed the state of the HIPAA Privacy Rule today as well as a potential model example for what the Privacy Rule could look like. The primary issue is that the rise of smartphones, tablets, and personal computers has paved the way for new technologies that have changed the healthcare landscape. Patients can connect with doctors and get prescriptions through mobile applications without ever speaking to them in person. Persons with mental health issues can speak with therapists and receive treatment via videoconference. Individuals can track and monitor hundreds of data points related to their individual health, such as calories burned, steps taken, and hours slept.

Digital health technologies show no signs of slowing down production; if anything, the demand for such technologies has greatly risen due to the COVID-19 pandemic. More individually identifiable health data, which should be kept private, goes unprotected each day simply because there is no requirement to protect it. Concerns about health data privacy stand as a key barrier to wider adoption of digital health technologies, which have the potential to offer better solutions to patient care than traditional models of healthcare. By modifying the HIPAA Privacy Rule to offer a broader range of protection to individually identifiable healthcare data, consumer trust in (and consequently, adoption of) digital healthcare would increase. Other solutions would be less effective and would essentially create a competition or race towards the most privacy protections. Amending the existing Privacy Rule is the best solution to address the issues of the day.

INDEPENDENT FREESTANDING EMERGENCY CENTERS:
THE FACE OF AN ALTERNATIVE MODEL TO HEALTHCARE IN RURAL AMERICA

ALISHA PATEL[1]

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I. INTRODUCTION

Stewart-Webster Hospital in Richland, Georgia closed its doors last year, leaving 1,500 anxious residents without care.[1] The critical access hospital in rural Georgia was one of the town's largest employers, serving residents for nearly sixty years until the hospital, riddled with high unemployment, high rates of uninsured and underinsured patients, and declining reimbursements from government payors, could no longer overcome financial obstacles to stay afloat.[2] Richland's residents were forced to travel thirty-five miles to the closest emergency department, which meant that, in situations such as cardiac arrest, car accidents, workplace injuries and other emergencies, lives were lost because residents did not have emergent care in their immediate vicinity.[3] Nationwide, more than two dozen rural hospitals closed between 2013 and 2014 alone, and more hospital closures continue during COVID-19 pandemic.[4]

Health care facilities devoted to emergency department (ED) services but physically separated from hospitals proliferated in the last decade.[5] Urgent care centers and retail clinics lack the specialized equipment and medical specialists available around the clock for patients with serious illnesses and injuries.[6] Thus, the number of these standalone EDs has multiplied since 2010, driven by a need to efficiently expand access to emergency services in communities facing gaps in healthcare delivery, primarily in rural America where hospitals are considered a high financial risk.[7] Rural hospital closures form a void in geographic areas which constrains people to seek care elsewhere, extending travel times and often

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[1] *See* Bob Herman, *When the tiny hospital can't survive: Free-standing EDs with primary care seen as new rural model*, MODERN HEALTHCARE (Sept. 27, 2014). https://www.modernhealthcare.com/article/20140927/MAGAZINE/309279952/when-the-tiny-hospital-can-t-survive-free-standing-eds-with-primary-care-seen-as-new-rural-model.

[2] *Id.*

[3] *Id.*

[4] *Id*.

[5] *See Freestanding Emergency Departments*, AM. C. OF EMERGENCY PHYSICIANS (Apr, 2020), https://www.acep.org/patient-care/policy-statements/freestanding-emergency-departments.

[6] *See The Real Story Behind Freestanding ER Costs*, BLUE CROSS BLUE SHIELD OF TEX. (July 2017), https://www.bcbstx.com/newsroom/category/affordability/freestanding-er-costs.

[7] *See* Zach Smith, *Freestanding Emergency Departments and Micro-Hospitals*, CTR. FOR MISS HEALTH POLICY (July 2019), https://mshealthpolicy.com/policy-points-freestanding-emergency-departments-and-micro-hospitals.

leading to an increase in mortality rate among those with time-sensitive diseases.[8]

Though independent freestanding emergency centers seem like an obvious solution to the issue, CMS's regulatory decisions complicate how these facilities remaining profitable. Independent freestanding emergency centers lack hospital affiliation and do not receive Medicare or Medicaid reimbursement. They are often concentrated in high-income areas with a growing population, a higher proportion of privately-insured patients, and a lower proportion of Medicaid beneficiaries. This is largely because they cannot remain afloat without serving patients who can pay out-of-pocket expenses because they do not receive recognition and reimbursement for services by Medicare and Medicaid.[9]

Standalone ED's provide emergency services, basic imaging, and laboratory services. They come in two forms: off-campus emergency departments (OCEDs), which are affiliated with hospitals and oftentimes reimbursed by Medicare and Medicaid, and independent freestanding emergency centers (IFECs), which are owned in whole or in part by independent groups or individuals not affiliated with hospitals. IFECs are ineligible for Medicare and Medicaid reimbursement. The American Hospital Association (AHA) defines an IFEC as

> ...a facility that provides unscheduled outpatient services to patients whose conditions require immediate care in a setting that is geographically removed from a hospital . . . [IFECs] can be either independently licensed facilities or satellite hospital emergency departments (EDs) that are physically separate and distinct from the conventional hospital ED.[10]

State licensing laws control IFECs. Yet reimbursement, including billing and collection, and thus conditions of participation, are governed at the federal level through federal government regulatory agencies. However, state licensing laws vary.[11]

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[8] *Id.*; *See Free Standing Emergency Departments and Alternatives for Rural Markets*, S.C. OFF. OF RURAL HEALTH (Oct. 2019), https://scorh.net/wp-content/uploads/2018/10/C2-Emerging-Models-in-Rural-Health-Care.pdf.
[9] *See* Zach Budryk, *Freestanding ERs may freeze out poor, minorities*, FIERCE HEALTHCARE (Jul. 2016), *https*://www.fiercehealthcare.com/healthcare/freestanding-ers-may-freeze-out-poor-minorities.
[10] *Id.*
[11] *Id.*

As of 2016, IFECs in the United States represented 36% of all standalone EDs, with most of these entities located in Texas, Minnesota, Rhode Island, Delaware, and Colorado.[12] Only four states license independent freestanding EDs to operate without hospital affiliation: Colorado, Delaware, Rhode Island, and Texas.[13]

As of 2015, over four hundred IFECs are in Texas, accounting for 90% of IFECs in the United States.[14] Texas's growth in IFECs came about as a response to the passage of the Texas Freestanding Emergency Medical Care Facility Licensing Act in 2009, allowing the licensure of facilities providing emergency care that are "structurally separate and distinct" from hospitals.[15] According to the Texas Department of State Health services, the number of IFECs increased from forty facilities to nearly two hundred fifty, with thirty-six new facilities licensed in 2016 alone.[16] However, many other states have not passed similar legislation. Therefore, the number of IFECs, types of services, quality and costs that IFECs offer patients may vary, impacting a patient's options for care.[17]

Another avenue to standardize requirements of IFECs is at the federal level.[18] The Centers for Medicare and Medicaid Services (CMS), a federal regulatory government agency for OCEDs affiliated with hospitals, fails to recognize "emergency services hospitals" like IFECs. As a result, CMS does not reimburse IFECs for services provided to patients with Medicare or Medicaid insurance because these IFECs do not provide inpatient services. This general rule notwithstanding, during the COVID-19 pandemic CMS waived their conditions of participation and reimbursed IFECs for care provided to Medicare and Medicaid patients.[19] CMS recognizes that IFECs provide a "critical resource to assist in expanding capacity for inpatient and outpatient hospital services for patients requiring a higher level of care," and that the expansion of

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[12] *See Guidance for Licensed Independent Freestanding Emergency Departments to Participate in Medicare and Medicaid During the COVID-19 Public Health Emergency*, CMS (Apr. 2020), https://www.cms.gov/files/document/qso-20-27-hospital.pdf at 1.
[13] *Id.* at 2.
[14] COLIN MCDERMOTT & VIC SCHERMERBECK, *Introduction to Freestanding Emergency Rooms and Microhospitals*, https://vmghealth.com/wp-content/uploads/2018/01/Introduction-to-Freestanding-Emergency-Rooms-and-Microhospitals_McDermott-AICPA.pdf.
[15] BLUE CROSS BLUE SHIELD OF TEX., *supra* note 6.
[16] *Id*.
[17] Budryk, *supra* note 9.
[18] *Id.*
[19] CMS, s*upra* note 12.

Medicare and Medicaid to IFECs is necessary to compensate for the influx of patients seeking emergency services.[20]

Therefore, standardizing requirements for IFECs at the federal level through CMS is potentially the easiest route to improve access to care issues by assisting patients in selecting the acute care site most appropriate for them, thereby avoiding unnecessary costs and treatment delays.[21] CMS must consider recognizing IFECs to standardize requirements for these entities even after the COVID-19 pandemic. As a result, CMS's recognition of these entities will require all IFECs to meet emergency regulations similar to EMTALA, so that any individual may receive medical screening exams or a transfer of care, if needed, regardless of their insurance status.

This Note will attempt to provide a background of rural healthcare disparities and the issues facing these regions. This Note will also explore the history of IFECs in the United States to better understand the context of the issues and reasons as to why emergency regulations such as EMTALA do not already extend to IFECs. Part 1 of this Note will examine the origin of IFECs and their role in the healthcare landscape today. Part II will discuss EMTALA and the challenges associated with IFECs during a public health emergency. Lastly, Part III of this Note will highlight the advantages and disadvantages of the current system to assess whether CMS should continue to recognize IFECs even after the COVID-19 pandemic as a potential solution to individuals' inability to access healthcare in rural areas of the United States. This Note will argue that expanding Medicare and Medicaid coverage to IFECs beyond a public health emergency will standardize regulatory concerns and allow these entities to provide emergency services to individuals living in rural areas with little to no healthcare access.

II. BACKGROUND

A. An Overview of Healthcare in Rural America

More than forty-six million Americans, or 15% of the U.S. population, live in rural areas as defined by the U.S. Census Bureau. These rural Americans face numerous health disparities as compared to their urban counterparts.[22] Rural poverty stems from challenges associated with health disparities, such as unemployment, poor education, and lack of opportunities, arising

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[20] *Id*.
[21] Budryk, *supra* note 9.
[22] *See About Rural Health*, CDC (last reviewed August 2, 2017) https://www.cdc.gov/ruralhealth/about.html.

from rural individuals' inability to access health care.[23] Rural Americans have a greater likelihood of dying from heart disease, cancer, unintentional injuries such as vehicular crashes, chronic lower respiratory disease, and stroke when compared to Americans living in urban areas.[24] The CDC states that some characteristics such as longer traveling distances to specialty and emergency care facilities place rural residents at higher risk of death than urban residents.[25]

Further, since 2010, eighty-three rural hospitals nationwide have closed due to the lack of Medicaid revenue because rural hospitals are particularly dependent on government health care program revenue to remain afloat since many patients are not privately insured.[26] Twenty-three of the fifty-one rural hospitals that closed from 2013 through 2017 were over twenty miles from the nearest hospital, reducing access to healthcare.[27] A 2016 study identified over six hundred fifty rural hospitals that are vulnerable to closure in forty-two states. Moreover, less than half of Critical Access Hospitals are rural hospitals, operating at a financial loss due to their rural location and size.[28] Every year, these rural hospitals continue to apply for federal government designation and financial support to keep their doors open.[29] Studies show that hospital closure is partially attributed to low admission volumes, contributing to financial and organizational hardship in rural hospitals.[30] Some hospitals achieved an average daily census of four inpatients a day, causing third-party insurance pays to reduce their reimbursement rates for these facilities.[31] Local residents fear health and economic ramifications since hospitals are major employers and business drivers within their communities. Thus, many advocates encourage pursuing a health care model with an outpatient delivery of care like Freestanding Emergency Departments.[32]

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[23] *Id.*; *see also* Elizabeth Weeks, *The Medicalization of Poverty: Medicalization of Rural Poverty: Challenges for Access*, 46 J.L. Med. & Ethics 651 (2018).
[24] CDC, s*upra* note 22.
[25] *Id.*
[26] Elizabeth Weeks, *The Medicalization of Poverty: Medicalization of Rural Poverty: Challenges for Access*, 46 J.L. Med. & Ethics 651 (2018).
[27] S.C. OFF. OF RURAL HEALTH, *supra* note 8.
[28] *See* Erika Rogan & Joy Lewis, *Rural health care: Big challenges require big solutions*, AMERICAN HOSPITAL ASSOCIATION (Jan. 28, 2020, 07:59 AM), https://www.aha.org/news/insights-and-analysis/2020-01-28-rural-health-care-big-challenges-require-big-solutions.
[29] *Id.*
[30] *See* Erika Rogan & Joy Lewis, *Rural health care: Big challenges require big solutions*, AMERICAN HOSPITAL ASSOCIATION (Jan. 28, 2020, 07:59 AM), https://www.aha.org/news/insights-and-analysis/2020-01-28-rural-health-care-big-challenges-require-big-solutions.
[31] CDC, *supra* note 22.
[32] Rogan & Lewis, *supra* note 29.

B. History and Origin of IFECs

The concept of freestanding emergency rooms that operate independent of hospitals began at the Newark Emergency Center, Inc. in Delaware in 1973.[33] Equipped to handle trauma and life-threatening situations, freestanding emergency rooms formed to provide comparable services while avoiding high costs and long delays associated with hospital ERs.[34] Serving as a historical offshoot of the emergency room, hospital ER visits increased steadily after WWII, creating a greater need for an alternative venue for emergency visits, especially in times of natural disasters such as hurricanes or pandemics.[35] Ultimately, freestanding EDs were designed to increase access to emergency care in rural and underserved regions as a response to a 2004 Medicare reimbursement policy change that allowed payment for services provided in IFECs. This policy only applied to OCEDs and not IFECs, thus differentiating the two types of freestanding EDs. However, only approximately fifty IFECs existed in the country at the time.[36] Today, IFECs are growing but are often confused by consumers for urgent care clinics.

IFECs are available to the public twenty-four hours a day, seven days a week, three-hundred sixty-five days per year. They have IV fluids and medications on-hand, are managed by experienced ED-trained medical professionals including physicians, are always staffed by a registered nurse certified in advanced cardiac life support and pediatric advanced life support, have policies and procedures to transfer patients in need of a higher level of care to appropriate facilities; and contain in-house lab test capabilities.[37] In comparison, urgent care clinics have set hourly days, have access to x-ray imaging, only some in-house lab testing, and no capability to transfer an individual to an ED or hospital.[38]

Most states have not adopted IFECs due to individual state licensure requirements regarding a Certificate of Need (CON), which requires approval for any new hospital or IFEC by a state CON board.[39] Currently, thirty-five states have CON regulations

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[33] Barba Rylko-Bauer, *The Development and Use of Freestanding Emergency Centers: A Review of the Literature*, 45 MED. CARE REV. 129, 129 (1988).
[34] *Id.*
[35] *Id.* at 131.
[36] *Id.* at 132.
[37] Alexander J. Alexander & Cedric Dark, *Freestanding Emergency Departments: What Is Their Role in Emergency Care?* 74 Annals of Emergency Med. J. 325, 326 (2019).
[38] *Id*.
[39] Herman, *supra* note 1.

which are difficult to overcome, as many boards have hospital representatives who utilize CON to control competition by voting to deny new approvals. Further, the IFECs current client base does not reach rural or underserved communities in need of care.

As IFECs continue to increase in the United States, they will require funding and a consumer base to utilize the entities' services. IFEC patients are most likely privately insured, non-Hispanic white, employed patients with a higher education level between the ages of twenty-four and forty-four years old.[40] IFECs in Texas are likely located in areas with residents of higher incomes and higher private insurance coverage. In contrast, in Ohio, freestanding emergency departments affiliated with hospitals are located in zip codes with fewer hospitals, which increases patient access to emergency care.[41] Though IFECs provide emergency services in populations of need, critics argue that the entities' services are too costly.

Historically, CMS failed to recognize IFECs as EDs and, therefore, does not reimburse for IFECs providing services to Medicare or Medicaid patients. CMS states that "'emergency services hospital' is not a recognized separate category of a Medicare-participating hospital."[42] Instead, a hospital attempting to apply for Medicare and Medicaid funds must satisfy the statutory definition of a hospital found in section 1861 of the Social Security Act, which requires hospital providers to engage in inpatient services."[43]

CMS interprets section 1861 of the Social Security Act and defines inpatient services as a "provider devoting 51% or more of its beds to inpatient care."[44] CMS recognizes that a "'51%' test" is not dispositive in all cases.[45] Therefore, the agency will consider the burden of proof to assess inpatient care as the primary health care service, and consider the burden to increase substantially as the ratio of inpatient to other beds decrease. At the request of the applicant, CMS may consider additional factors. For example, if an applicant solely specializes in emergency services, CMS will "pay particular attention to the size of the applicant's ED compared to its inpatient capacity" followed by a detailed analysis of the facts of the applicant's operations.[46]Further, IFECs cannot bill to Medicare or Medicaid and, thus, are not required to meet Medicare's conditions

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[40] *Id*.
[41] *Id.*
[42] CMS S&C Memo 08-08, 2008 Requirements for Provider-based Off-campus Emergency Departments and Hospitals that Specialize in the Provision of Emergency Services, January 11, 2008, at 5.
[43] *Id.*
[44] *Id.* at 2; *see also* 42 C.F.R. § 482.
[45] CMS, *supra* note 42 at 5.
[46] *Id*.

of participation or provider-based requirements. As a consequence, IFECs are ineligible for Medicaid and Medicare funds, unlike most hospital EDs.

As a response, health insurance providers claim that IFECs increase the cost of healthcare because insurance providers consider them "out of network." Consequently, insurance providers lowered FSED reimbursement rates, placings substantial costs for care on the medical care provider and the patient.[47] Subsequently, care is considered out-of-network and patients are responsible for all charges not covered by their insurance, including their copayment, deductible, or coinsurance, a practice termed "balance-billing".[48] Studies claim that the total price of an IFEC averaged $2,199 in 2015 vs. $168 for an urgent care clinic visit.[49] This includes a "facility fee" that an IFEC may charge for treatment that ranges "between five hundred dollars and one hundred thousand dollars" and an "observation fee" which ranges from "one thousand to one hundred thousand dollars."[50] Costs for the same diagnosis on average were nearly ten times higher for patients at IFECs than for patients treated at urgent care centers, where fifteen of the twenty most common diagnoses treated at the IFEC could have been treated at the urgent care center.[51] For example, the most common diagnosis at IFECs was "other upper-respiratory infections" and the average price was $1,351, compared to an average price of $165 at the urgent care center.[52] As a result, there is substantial overlap in services delivered.

Texas IFEC employers saw significant increases in their emergency services costs, particularly for groups with generous ER benefits.[53] While reimbursement to hospital EDs remained the same with overall increases in reimbursement, member data showed that there was an increase in ER costs directly related to more freestanding IFECs opening across the state, and that more individuals chose to use these centers for non-emergency services. Emergency service costs increased during the COVID-19 pandemic with patients complaining of a $2,479 charge for a drive-thru

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[47] *Id.*
[48] Marshall Allen, *How a $175 COVID-19 test led to $2,479 in charges*, THE TEX. TRIBUNE, (Aug. 1, 2020, 4:00 AM CST), https://www.texastribune.org/2020/08/01/coronavirus-texas-COVID-test-charges-emergency-room/
[49] BLUE CROSS BLUE SHIELD OF TEX., *supra* note 6.
[50] *Id.*
[51] *Id*.
[52] *Id*.
[53] Rogan & Lewis, *supra* note 29.

COIVD-19 test, after the IFEC charged a facility fee of $1,784 and a physician fee of $486.[54]

Further, in 2013, Davis Hospital and Medical Center in Layton, Utah opened a freestanding ER about eight miles away in the town of Weber.[55] The decision to open an IFEC here was prompted by the fact that freight trains passing through railroad crossings in the Weber area slow down traffic, causing a trip to the hospital to take longer. [56] The 16,000-square-foot facility has fourteen treatment rooms, a trauma bay, an orthopedic room, a negative pressure room with a separate bathroom for dealing with infectious diseases, and two overflow rooms[57]. It also boasts a full-service laboratory and x-ray capability; and soon it will perform MRIs.[58] Though visits are quick, the cost is considered astronomical per service and in terms of operation costs.[59]

In addition, the annual total costs to operate an IFEC also vary.[60] The annual total cost to operate a low, medium, and high volume IFEC is estimated to cost $5.5, $8.8, and $12.5 million, respectively.[61] The average cost of visit per patient declines with greater volume ($600, $380, and $347 for low, medium, and high volume IFECs, respectively).[62] IFECs must also consider low patient volumes, high rates of uninsured patients, minimum staffing requirements, provider shortages, federal reimbursement policies, and other factors when assessing the financial viability of IFEC in rural America.[63] These facilities may face very high fixed standby costs of coverage compared to the volume of services provided and, generally, a much less favorable payor mix compared to services provided by hospitals.[64] There are also issues in the provision of care from a regulatory standpoint.

Given concerns associated with quality of care, public understanding of IFEC capabilities, protecting the physician-hospital relationship, and financial resources, some states implemented regulatory laws to govern IFECs.[65] However, since

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[54] Allen, *supra* note 48.
[55] Weber Campus – Roy, Utah, DAVIS HOSPITAL AND MED. CTR. https://www.davishospital.org/weber-campus-roy-utah (last visited Jan 8, 2022).
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] NAT'L ADVISORY COMM. ON RURAL HEALTH AND HUMAN SERVS., ALTERNATIVE MODELS TO PRESERVING ACCESS TO EMERGENCY CARE: POLICY BRIEF (July 2016) at 5.
[61] *Id.*
[62] *Id*
[63] *Id.*
[64] *Id.*
[65] Rylko-Bauer, *supra* note 33 at 131.

very few states have IFECs, there are currently no federal regulations.[66] Therefore, states created their own regulations, reducing uniformity amongst IFECs in different states..[67] Some states, such as Rhode Island, Georgia, Florida, and Minnesota, implemented licensure requirements, whereas other states, including Ohio, Tennessee, and New York, created CON requirements.[68] In contrast, states such as Louisiana completely banned freestanding EDs with the intention of protecting rural hospitals from the encroachment of freestanding EDs. Lawmakers fear that rural patients will visit freestanding EDs instead of rural hospitals in an attempt to access medical care quickly, believing that their private or government insurance will cover the cost of care or that the out-of-pocket costs are insignificant With lawmakers arguing that IFECs select services that generate the most money, IFECs have bad reputation in Louisiana, which has a large rupral population. [69]

Researchers conducting a study at Harvard Medical School examined data on four hundred freestanding ERs located in the US as of December 2014.[70] These facilities were located across thirty-two states, of which seventeen must comply with state-specific regulations on staffing, licensing, and operation for their facilities.[71] The majority of these states had policies on freestanding ERs that were either associated with hospitals or operating independently. For example, states like New York and Washington regulate freestanding ERs on a case-by-case basis, while California's hospital regulations bar IFECs in the state.[72] Further, several states apply regulations similar to the Emergency Medical Treatment and Labor Act (EMTALA) to IFECs, and other states list specific equipment and services that such facilities must offer.[73] State-level regulation of IFECs vary widely in their standards. These regulations vary by the facilities' locations, staffing, and clinical capabilities, which result in a negative impact on a patient's option for care. This is especially true if a patient is in dire need of care but provisions like EMTALA are unavailable.

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[66] *Id.*
[67] *Id.* at 130.
[68] *Id.*
[69] *See* Steven Porter, *Louisiana Passes Bill to Ban Freestanding Emergency Departments*, HEALTHLEADERS (June 7, 2019), https://www.healthleadersmedia.com/strategy/louisiana-passes-bill-ban-freestanding-emergency-departments.
[70] Catherine Gutierrez et al., *State Regulation Of Freestanding Emergency Departments Varies Widely, Affecting Location, Growth, And Services Provided*, 35 Health Affairs 1857, 1859-1865 (2016).
[71] *Id.*
[72] *Id.*
[73] *Id.*

Ultimately, state licensing criteria governing IFECs which follow the intent of the Emergency Medical Treatment and Labor Act (EMTALA) vary by state and lack federal oversight.[74] Most states do not address licensing rules for IFECs and, thus, do not have laws requiring IFECs to follow the intent of the federal requirements for Medicare and Medicaid to screen and stabilize all patients requiring care under the Emergency Medical Treatment and Labor Act (EMTALA).

C. EMTALA

Under EMTALA, all hospitals that participate in Medicare and have an ED are required to provide a medical screening to all patients who present to the hospital campus, within the capability of the hospital's ED, to determine if a medical issue exists.[75] EMTALA provides individuals who are deemed to have an emergency medical condition with either stabilizing treatment or, if the facility is unable to provide care, an appropriate transfer to another hospital.[76] To abide by the provisions of EMTALA, the patient must first be screened for an "emergency medical condition."[77] This includes, but is not limited to, a condition that entails a serious impairment of bodily functions, organs, or acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably place the health of the individual (or for a pregnant woman, her unborn child) in serious jeopardy.[78] In the case of pregnant women having contractions, an emergency medical condition entails the prospect of inadequate time for a safe transfer to another hospital before delivery or the prospect that a transfer may pose a threat to the health or safety of the woman or the unborn child.[79] In essence, a priority of EMTALA was to create a set of categories where people facing certain dire conditions are not turned away.

Second, EMTALA requires hospitals to stabilize patients with identified emergency conditions before transferring them to other institutions.[80] This stabilization requirement entails the provision of medical treatment "as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency

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[74] *Id.*
[75] 42 C.F.R. § 489.24(a).
[76] 42 C.F.R. § 489.24(d).
[77] 42 C.F.R. § 489.24(a).
[78] 42 C.F.R. § 489.24(b).
[79] *Id*.
[80] 42 C.F.R. § 489.24(d).

medical condition."[81] A non-stabilized patient may only be transferred in two instances: if a physician certified that the benefits of the transfer would outweigh the risks, or if the patient (or surrogate) requested a transfer after being informed of the potential risks.[82] EMTALA allows for patient transfers to prevent hospitals from relocating patients whose condition may worsen during the transfer.

III. CHALLENGES REGARDING EMTALA

EMTALA does not apply to IFECs because they do not receive federal funding through Medicare. Consequently, without federal regulatory oversight, IFECs are currently not required by federal law to accept all patients for emergency screening and stabilizing treatment regardless of a patient's ability to pay. Only some states' laws require this.

Although CMS has not recognized IFECs in the past, during the COVID-19 pandemic, CMS acknowledged these facilities and provided financial reimbursement to patients under the Medicare or Medicaid programs to address the surge in patients fueled by COVID-19 hospitalizations.[83] By increasing hospital capacity and extending reimbursement to IFECs, CMS aimed to effectively establish care for its vulnerable citizens by waiving the conditions of Medicare and Medicaid participation. During the public health emergency, these entities were "temporarily certified as a hospital to increase healthcare system capacity" if certain conditions were met.[84] IFECs could participate in Medicare and Medicaid in one of three ways: (1) becoming affiliated with a Medicare/Medicaid-certified hospital under the temporary expansion 1135 emergency waiver; (2) participating in Medicaid under the clinic benefit, if permitted by the state; or (3) enrolling temporarily as a Medicare- or Medicaid-certified hospital to provide hospital services.[85] To qualify for CMS reimbursement, IFECs opted for either of these options and followed an urgent care fee schedule to appropriately reimburse physicians, ambulance services, clinical laboratory services, durable medical equipment, prosthetics, orthotics, and other supplies for the services they provide.[86]

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[81] *Id.*
[82] *Id.*
[83] David R. Wright, *Guidance for Licensed Independent Freestanding Emergency Departments (EDs) to Participate in Medicare and Medicaid during the COVID-19 Public Health Emergency*, CMS (April 21, 2020),https://www.cms.gov/files/document/qso-20-27-hospital.pdf.
[84] *Id.*
[85] *Id.*
[86] *Id.*

Further, CMS waived certain elements of EMTALA to allow for more flexibility if an IFEC temporarily enrolled as a or became affiliated with a Medicare or Medicaid-certified hospital. In particular, CMS loosened the in-person medical screening examination component of EMTALA. For example, if an IFEC qualified as a hospital under the public health emergency guidance, then patients could receive a medical screening exam via telehealth or offsite, if necessary, instead of traveling in-person for the exam like EMTALA requires.[87] Thus, CMS waived the enforcement section of EMTALA, allowing hospitals, psychiatric hospitals, and critical access hospitals to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, if not inconsistent with the state's emergency preparedness plan.[88]

Once approved through CMS, IFECs may provide and receive reimbursement for inpatient and outpatient services provided to Medicare beneficiaries. To maintain participating in Medicare and Medicaid, the IFEC must meet all of Medicare's Conditions of Participation and provide a Medicare Outpatient Observation Notice to all Medicare beneficiaries informing them that they are receiving outpatient observation services and are not considered an inpatient of the facility.[89] IFECs' temporary participation is terminated at the conclusion of the public health emergency.

Through the waiver, CMS acknowledges that "expanding the number of providers available to Medicare and Medicaid beneficiaries eases some of the burden shouldered by traditional hospitals and allows the healthcare system to treat more patients at a time when capacity is often limited."[90]

IV. CMS RECOGNITION OF IFECS IS THE APPROPRIATE ROUTE FOR RELIEF

Given the inefficient role IFECs serve in the rural healthcare industry due to differing state licensure requirements, high pricing, and lack of uniform EMTALA-like provisions, the most appropriate remedy for the ongoing issue of accessing healthcare in rural America requires CMS to recognize and reimburse care for services provided to Medicare and Medicaid patients at IFECs. In determining the components of this argument, it is most beneficial

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[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] Ayla Ellison, *CMS Lifts Freestanding ER Billing Restrictions During Pandemic*, BECKER'S HOSPITAL REVIEW (April 22, 2020), https://www.beckershospitalreview.com/finance/cms-lifts-freestanding-er-billing-restrictions-during-pandemic.html.

to analyze each aspect of the barriers IFECs currently face in the healthcare landscape.

First, lack of federal oversight and licensure regulation led to states enacting their own laws to regulate IFECs. Without any consistency and uniformity, IFECs fail to serve its true purpose: providing emergency services to those located in rural populations. In response to this issue, federal oversight and standardized regulations provided by CMS may best enforce uniform regulations to apply to IFECs. These federal licensure requirements will allow for greater adoption of IFECs in states where rural hospitals are unable to financially stay afloat.

Second, because IFECs lack CMS recognition and are not reimbursed for care provided to Medicare and Medicaid patients, IFECs must strategically place themselves in more affluent areas instead of rural communities in need of greater access to healthcare services. With CMS recognition, IFECs may receive reimbursement for services provided to Medicare and Medicaid patients, alleviating high facility costs placed upon patients. Finally, recognition of IFECs by CMS will require IFECs to act in accordance with EMTALA, ensuring that all individuals entering the IFEC will receive a screening for an emergency medical condition and stabilization, regardless of the patient's insurance status or ability to pay. In order for these changes to occur, CMS and the federal government must define "underserved" to narrow down which entities CMS qualifies as IFECs. A rural-specific definition under federal regulations is ultimately required to address the ongoing healthcare issue. Studies indicate that there is a discrepancy in the definition of IFECs among major US data sources. Therefore, a universal, standardized definition will allow IFECs to be identified and listed in national ED databases to carefully characterize ED care. Therefore, IFECs may provide high-quality emergency care to people in medically underserved areas, relieve the burden on overwhelmed hospital EDs, and provide convenient services with shorter wait times for treatment.

CMS already recognized the need for IFECs within healthcare by expanding Medicare and Medicaid recognition and reimbursement for services rendered during the COVID-19 pandemic. By issuing guidance and recommendations for IFECs to receive Medicare and Medicaid funding during the pandemic, the regulatory agency acknowledges that Medicare and Medicaid patients see IFECs as a source of care, especially in rural areas where access to COVID-19 care is scarce. Further, IFECs are one of several models proposed to aid rural communities affected by or at-risk of hospital closure. The Medicare Payment Advisory Committee (MedPAC) proposed altering regulations to provide

funding to failing Critical Access Hospitals to convert to IFECs.[91] With fixed stipends or grants to cover standby costs, IFECs can begin providing care.

Critics voice concerns stating that IFECs encourage the increased use of emergency services for nonemergency complaints, lead to an increase in the costs of health services, and compete with hospitals for ED services, which ultimately threatens access to services that are mainly provided by only hospital EDs, such as trauma care.[92] However, these threats are warrantless. Though many IFECs are placed in densely populated communities to generate higher volumes and revenues, this is of less concern in rural areas without OCEDs or with poor access to primary care. IFECs in rural areas are likely the only health care provider for hundreds of miles, providing both emergent and non-emergent services to patients in need in areas where rural hospitals closed due to their low inpatient volume. Yet, CMS will need to incentivize independent groups to open rural IFECs. These incentives could derive from critical access hospitals that have closed. The federal government should instead decide to shift current fund allocation from closed critical care access hospitals to IFECs.[93]

Nonetheless, many IFECs purposely locate their entities in affluent suburbs, targeting privately insured patients who visit EDs out of convenience.[94] For example, First Choice Emergency Room, a for-profit chain that is publicly traded as Adeptus Health, announced a dozen new freestanding ED openings within high income, suburban areas of Texas and Colorado.[95] Perhaps, not all IFECs aim to expand services to rural populations.[96] Thus, CMS may consider carefully defining "underserved" communities and IFECs eligible for reimbursement for services provided to Medicare and Medicaid patients.

To address concerns related to IFECs practice of charging facility fees to mitigate high costs associated with maintaining technologically advanced equipment and upholding the facility and its staff, research is necessary before investing into IFECs.[97] Researchers propose a hybrid model, separating IFECs and urgent

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[91] *See* Jenn Lukens, *Freestanding Emergency Departments: An Alternative Model for Rural Communities*, RURAL MONITOR (Nov. 30, 2016), https://www.ruralhealthinfo.org/rural-monitor/freestanding-emergency-departments/.
[92] Rogan & Lewis, *supra* note 29
[93] Rylko-Bauer, *supra* note 33
[94] Herman, *supra* note 1.
[95] *Id*.
[96] *Id.*
[97] Rylko-Bauer, *supra* note 33

care capabilities within the same facility.[98] Patients with acute care injuries would be triaged to the urgent care area of the IFEC and reimbursed using the lower-cost CMS urgent care fee schedule. In contrast, more severe injuries would be treated on the IFEC side and reimbursed under CMS's hospital facility fee.[99] Further, CMS could create a new IFEC fee structure for the hybrid IFEC model to economically support greater access to different types of care.[100] A new fee structure could take into account low patient volumes, high rates of uninsured patients, difficulty meeting minimum staffing requirements, and provider shortages, all of which are common occurrences in rural areas.[101]

An example of a hybrid IFEC-urgent care facility can be found in Wadesboro, North Carolina, a town of less than six thousand individuals. In 2012, Carolina HealthCare System, a large health system based in Charlotte, purchased the hybrid IFEC-urgent care facility that was staffed with one hundred twenty-five acute-care and nursing beds. Spending twenty million dollars, the hospital downsized the rural hospital's inpatient capacity from thirty beds to fifteen. This new facility provides "24/7 emergency care" with a limited number of acute beds, and it uses a patient-centered medical home model, offering residents access to primary-care providers with the assistance of a patient navigator.[102] By molding primary care and emergent care services together, this hybrid model is better able to remain afloat while tackling major healthcare issues in rural America.

For the privately insured individuals seeking care, in an effort to increase price transparency in IFECs for patient's ineligible for Medicare or Medicaid, CMS could implement a regulation requiring provisions similar to Senate Bill 425 in Texas. This bill requires all patients visiting IFECs to submit and sign documentation regarding the IFECs billing practices.[103] This documentation generally states that the facility will submit its bill to the insurance provider, but that the IFEC lacks a "contractual relationship" with the insurance provider, so that the insurance company is not obligated to cover any medical expenses incurred at the IFEC .[104] The law further requires the facility to post a notice in all rooms, stating the facility is a "freestanding emergency medical care facility", that the entity charges rates comparable to a hospital

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[98] *Id*.
[99] *Id*.
[100] *Id.*
[101] *Id*.
[102] Herman, *supra* note 1.
[103] TEX. HEALTH & SAFETY CODE ANN. § 241.251 et seq.; *see also* McDermott & Schermerbeck, *supra* note 14; *see also* Allen, *supra* note 48.
[104] McDermott & Schermerbeck, *supra* note 14; *see also* Allen, *supra* note 48.

emergency room including a facility fee, that the facility and/or physician providing medical care at the facility may not be a participating provider in the patient's health benefit provider network, and the physician providing medical care at the facility may bill separately from the facility for the medical care provided to a patient." [105]

Further, IFECs may be financially viable in different communities facing different situations, thus requiring the IFEC to find additional financial supports like grants, taxes, or the creation of other services in order to succeed. However, a successful IFEC may rely on designing services to meet patient needs within its specific population. Rural locations for IFECs will pose their own challenges in relation to staffing, higher fixed costs per patient, and longer transfer times. Therefore, even with new reimbursement methods, these factors may not be adequately compensated.

Strategies to remain financially viable include potentially staffing the IFECs with nurse practitioners and physician assistants, with fewer physicians a part of the facility. The entity may function as a satellite center and utilize telemedicine technology, an aspect that was allowed and encouraged during the COVID-19 pandemic. Further, community services may also be offered at the IFEC, forming a one-stop-shop model. Thus, patients may receive social and economic services to alleviate healthcare disparities in relation to their emergency.

In contrast to the proposed solution, states may independently adopt EMTALA-like regulations to apply to all IFECs within the state. However, these regulations will vary by state and not all state legislatures have adopted regulations following the intent of EMTALA. In order to insure IFECs meet EMTALA-like requirements, these entities must also receive adequate funding to compensate for this increased provision of care. Further, the proliferation of IFECs in rural states in America is necessary to increase access to care for residents living in these areas.

Critics may also state that with the establishment of IFECs, hospitals should also consider expanding their emergency departments to rural areas. With the ability to already access Medicare and Medicaid reimbursements for services provided to patients under either insurance program, many of these hospitals will have the ability to stay afloat and the capital to initiate a freestanding ED. However, larger health systems have become pickier about which rural facilities to absorb.[106] Hospitals want to build networks of providers to demonstrate a strong measure of

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[105] TEX. HEALTH & SAFETY CODE ANN. § 241.252.
[106] Herman, *supra* note 1.

quality of care that rural providers cannot provide.[107] Often Critical Access Hospitals and other rural providers exhibit below-average quality scores.[108] To become more marketable, rural hospitals and communities need to show that they have the capability to provide high-quality health care at a low cost.

Lastly, critics may argue that potential fraud issues may rise with the increase in IFECs in rural areas. Physicians and other providers may falsely claim payment for services that did not occur or are unnecessary, leading to issues with the Anti-Kickback Statute, Stark Law, and the False Claims Act. However, like other hospital EDs, IFECs are also subject to the same federal oversight to prevent any fraud or abuse issues. IFECs can help alleviate the stress that the current emergency care system faces and provide care to individuals with limited access to traditional hospital EDs. By implementing state-by-state regulations, uniform licensing criteria created on a federal level, encouraging freestanding EDs to operate in more rural and underserved areas, and increasing price transparency, IFECs can dramatically alter the rural healthcare landscape.

V. CONCLUSION

A broad solution should be for CMS to establish an Innovation Center pilot to test the solutions mentioned above and collect data on IFECs around the country. The Innovation Center supports the development and testing of innovative health care payment and service delivery models.

It is important to recognize that there is little research to support whether IFECs are viable in rural areas across the country. Most research addresses issues within each state and forms a potential solution. Therefore, CMS should first establish a definition for IFECs to further focus its research efforts on facilities that may qualify for Medicare or Medicaid reimbursement. Through a pilot test or routinely collecting data from IFECs during the COVID-19 pandemic, CMS may learn whether IFECs are a reliable and affordable source of care for individuals in rural America that qualify for Medicare and Medicaid reimbursement. By participating in Medicare and Medicaid, researchers with CMS may find whether IFECs are viable in all rural areas and what type of model will best suit each population. Further, CMS may explore whether to expand reimbursement to IFECs as well as provide federal regulatory oversight to these entities. Ultimately, CMS will continue to lend a

[107] *Id.*
[108] *Id.*

heavy hand in federal oversight to provide uniform and standardized regulations.

There are several potential solutions to increase access to care in rural areas in America. These may include establishing more urgent care centers or micro-hospitals. In Colorado, Arizona, and other non-CON states, IFECs established micro-hospitals recognized by CMS. These facilities encompass eight to ten inpatient beds where subsidiary IFECs are placed in underserved areas or hospitals continue to establish their own freestanding EDs under the hospital's license. However, these entities must still meet Medicare's conditions of participation, requiring that the freestanding ED remain within a thirty-five-mile distance from the main hospital campus. In an effort to further increase services in rural America, more research and conversation amongst lawmakers and rural communities must continue to discover an appropriate healthcare model.