U.S. Federal and State Telehealth Law & Policy— 2024 & Beyond

The Background

If you're in healthcare and you're interested in the current regulatory landscape as it relates to digital health, this ebook is for you. You'll learn more about the key considerations when using telemedicine to prescribe controlled substances under DEA rules, the new opportunities that exist for remote patient monitoring services, and what you can expect for the remainder of 2024.

The Goal

This content has been designed to help you answer the question "Am I compliant when it comes to how I run my practice?" If you are reading this paper, you are probably interested in telemedicine, telehealth, digital therapeutics (Dtx), and virtual care, and how you can ensure you are running your business in adherence with state and federal laws. Read on for a breadth of information delivered by a healthcare attorney who has his finger on the pulse of transactional and related regulatory issues for the health industry.

Learn more about

1. The current regulatory landscape as it relates to digital health
2. The key considerations when using telemedicine to prescribe controlled substances under DEA rules
3. New opportunities for remote patient monitoring services
4. What you can expect for the remainder of 2024

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Background

On June 12, we were lucky to sit down with Thomas (T.J.) Ferrante, a Partner in Foley & Lardner's Telemedicine Industry Team and Digital Health Group, to learn more about the current regulatory landscape as it relates to digital health.

The conversation was focused on:

- The current regulatory landscape as it relates to digital health
- The key considerations when using telemedicine to prescribe controlled substances under DEA rules
- New opportunities for remote patient monitoring services
- What you can expect for the remainder of 2024

TJ Ferrante is a business-oriented health care lawyer with a practice focus on telemedicine, telehealth, digital therapeutics (Dtx), and virtual care, as well as a wide range of transactional and related regulatory issues for health industry clients, including hospitals, health systems, assisted living facilities, providers and start-ups to build telemedicine arrangements across the United States and internationally.

The majority of his practice is working with healthcare industry clients to build out and operate digital health arrangements and models that are scalable. He works with clients who range from large, sophisticated academic medical centers, to hospitals and health systems, but also has a growing portion of innovative earlier stage clients that he helps to understand how they can build exciting models and use healthcare technology to scale nationally.

Introduction

Federal and state telehealth laws are important for several reasons. For starters, it ensures patient safety and quality of care. Telehealth laws establish standards and regulations to protect patient safety and ensure the quality of care provided through telehealth services. These laws cover areas such as provider licensing, prescribing practices, informed consent, and privacy/security of patient data. Telehealth laws at the federal and state levels determine which telehealth services are eligible for reimbursement by government programs like Medicare and Medicaid, as well as private insurers. Telehealth laws also address the issue of provider licensure and the ability to practice across state lines.

TJ always advises people to consult with their own legal counsel, or a billing and coding expert when we get into those types of concepts. He doesn’t spend a lot of time on definitions and context but he does want to set the table for the discussion, by starting with a very short description of what we're talking about—at least when he uses the terms telehealth or telemedicine.

In general, what he means for the purposes of this ebook, is how it relates to the delivery of healthcare services. *Telehealth and telemedicine as it relates to the technology that bridges a provider who may be in one location, and the patient who may be at another remote location*.

He doesn’t consider it nor does he think it should be considered a separate medical specialty in and of itself. But rather, he focuses on how it really characterizes the technological conduit through which medical care is provided. So keep that framing in mind. And when you want to think about what that means, from a real world application perspective, he provides some examples that are certainly not an exhaustive list but an important roundup nonetheless. The following encapsulates the areas that have been gaining traction out in the marketplace over the past five to seven years.

Telehealth applications

The following rounds up the applications that have been gaining traction out in the marketplace over the past five to seven years.

Direct-to-consumer (DTC): DTC telehealth refers to a model where patients can access virtual medical care directly from healthcare providers or companies, without needing a referral or an existing relationship with the provider. The key aspects of DTC telehealth include direct access for patients, no prior relationship required, and async or synced care.

Destination medicine: This is where a center of excellence at a hospital or an academic medical center can use technology to draw patients from around the world or around the country.

Hospital-at-home: This scenario enables some patients who need acute-level care to receive care in their homes, rather than in a hospital. During COVID is when the hospital-at-home programs really started to take off.

Remote patient monitoring (RPM): This is a telehealth option that allows patients to monitor their health from home using digital medical devices. Healthcare providers can then remotely observe patients' physiological parameters and intervene if abnormalities appear. This rose in popularity once Medicare started reimbursing for that back in 2018.

Employers: Many employers now provide telehealth services as part of their employee health benefits package. This gives employees access to virtual doctor visits, often at lower costs compared to in-person visits.

Health plans: Many health plans now cover telehealth visits under their benefits, allowing members to access virtual care from providers. This includes services like medical visits, therapy, speech therapy, and occupational/physical therapy. Plans often apply the same member cost-sharing (deductibles, copays) for telehealth as in-person visits.

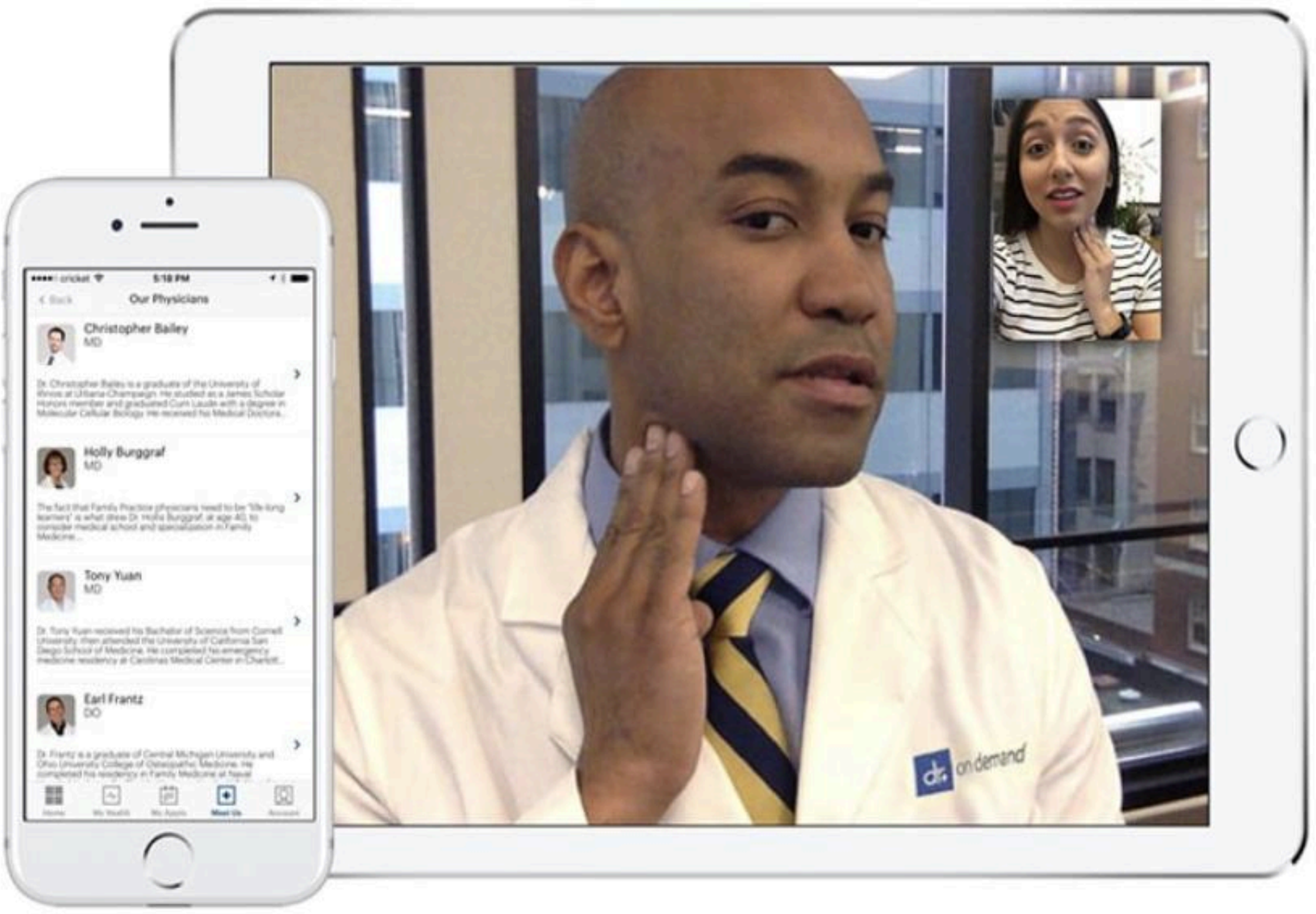
Government payers: Both Medicare and Medicaid have taken steps to expand access to telehealth during the COVID-19 pandemic, such as temporarily allowing telehealth from home for Medicare beneficiaries and requiring Medicaid programs to cover a wider range of telehealth services. This has helped facilitate telehealth usage and has driven a lot of the innovation in the industry.

Telehealth applications - TJ’s perspective

I like to give the example of how we saw the banking industry develop because it was driven a lot by consumerism. It used to be that you’d have to actually walk into the bank to cash checks. And then there were some innovative banks that said, ‘Hey, we have this great online banking or mobile banking service.’

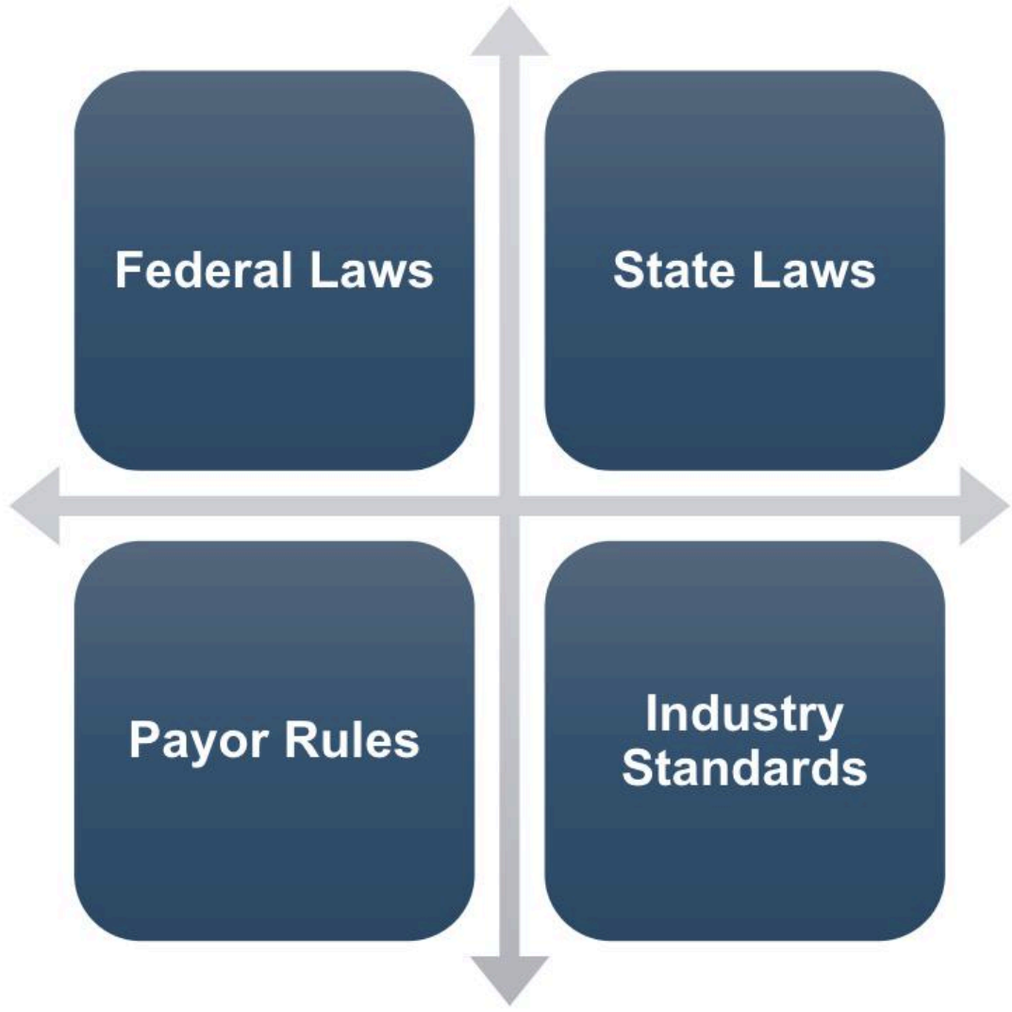
They began using those terms for marketing purposes—mobile banking and online banking. Now most people just call it banking. You have an app, you have a website, and that's what you consider banking today. Maybe you go inside the bank from time to time because you need to get a loan or sign a document or something. But you just consider it all together as one uninterrupted experience.

I think that's where we're eventually going to get to for a lot of telehealth, or digital health. It is just another form of healthcare. And it's going to be natural and expected from the industry, driven by expectations from patients on the convenience of it, and the ability for those to have access in places where they historically may not have existed.



Overlapping layers of regulation - TJ's perspective

A big part of why our healthcare system is so complex has to do with the maze of laws and regulations that exist and how they interact with each other. There are four key layers that interact with each other, at least from a legal and regulatory perspective.



You have the federal law, that's typically the floor. You want to make sure you're complying with federal law when you're looking at the issue. That's one of the first considerations. Is there a federal law on point and does it apply? And what does it say about what I'm trying to do?

Whenever we're talking about healthcare, it often has a lot of federal components to it. Even if you're complying with federal law, the analysis or your inquiry won't stop there, you will also want to make sure you're going to meet any state law requirements that you're in. State laws at times can be more restrictive than the federal laws. From an operations perspective, you will have to look at federal law AND state law.

Then there are payer rules and industry standards. You may ask yourself 'Am I going to get in trouble from the state medical board or State Attorney General, and can I get paid for what I'm doing?' And that's where the payer rules come in. So you don't only have those legal requirements, but you have payment requirements, and those can be from your commercial payers, it can be from the relationship you have with the self insured employer, it can be from Medicare, and government payers, etc. These are all things that you have to pay attention to and it can be complex, because they can differ in the different contexts.

But that's the system we live in today. It's why healthcare lawyers have jobs. And why it can be tricky to navigate these laws. You're operating in a highly regulated industry, you have to pay attention to that. I'll give you a concrete example of how this all plays together. Let's discuss the federal Ryan Haight Act.

Overlapping layers of regulation - TJ’s perspective

The federal Ryan Haight Act relates to controlled substance prescribing, and it's an old law. It's been on the books for a long time, it's a federal law, and what it says in summary, with limited exceptions, is that a provider must first have a physical, in person, face to face visit with a patient before that provider can prescribe a controlled substance with that patient via telehealth.

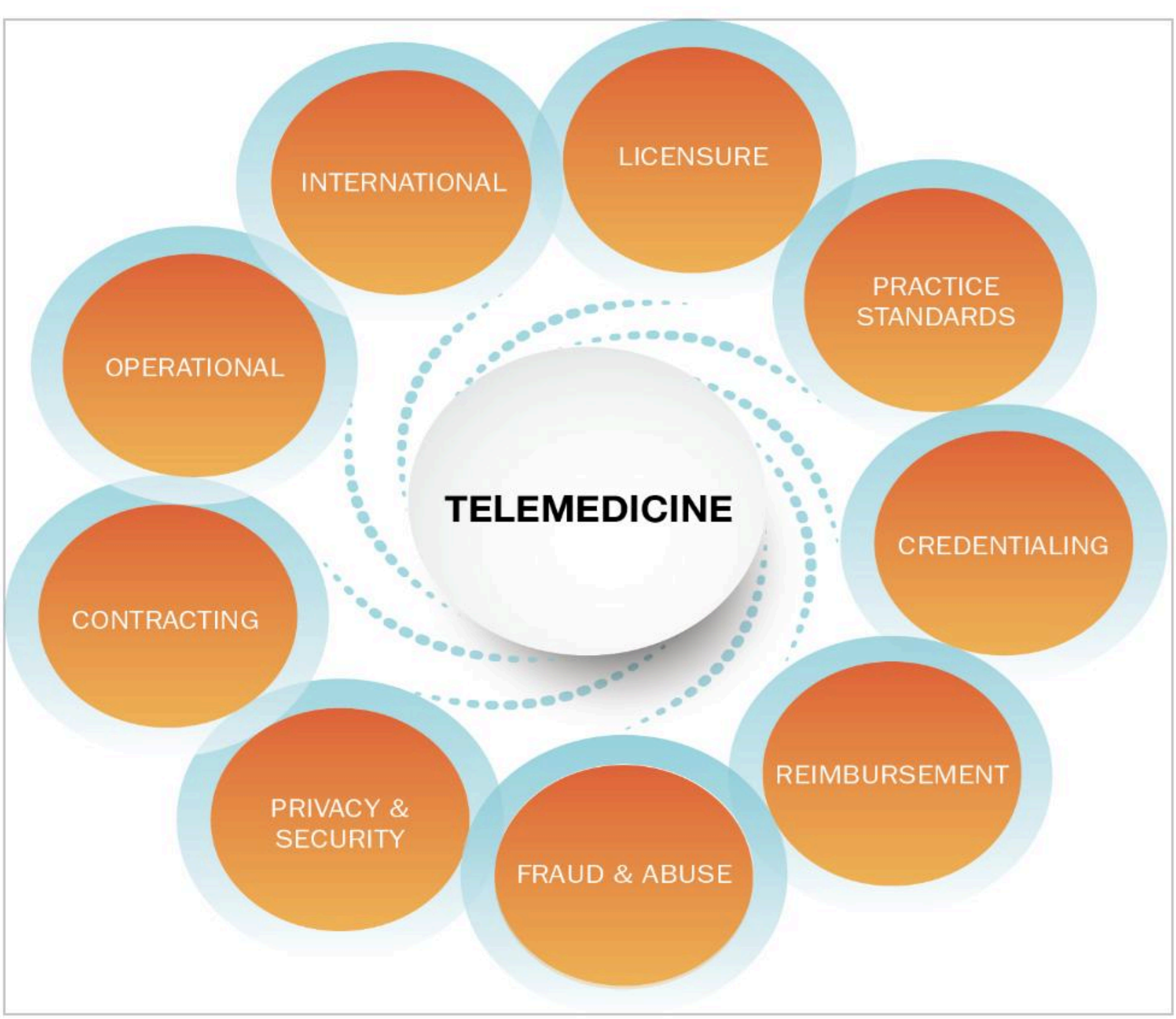
That’s been on the books for a while and existed pre COVID. If you have a telehealth company, or if you're a provider that wants to prescribe controlled substances to patients via telehealth, you have to comply with that law. You have to see the patient in person. So even if you live in a state that says, ‘Hey, you know, go ahead, we don't care, we think telehealth is great...we have no restrictions prescribing via telehealth for controlled substances.’ That’s all well and good, but you still have the federal law to contend with. And so given that the federal law is more restrictive, you have to comply with the more restrictive law.

Another good example, along the same line of thinking, is the public health emergency created during COVID. That federal law, the Ryan Haight Act, was waived during COVID. And that has continued to be waived since the public health emergency has ended. So now you may think there is no federal law restriction on that, but there could be a state that says, ‘We don't care what the Federal law says we want to be more strict in the state of x here. We are not as bullish on telehealth, and we think there's issues and so you can't do it.’ Again, the more restrictive law applies. So the analysis is that you still have a regulatory issue in that particular state. Just an example of how all of these can work together. Let’s jump into discussing some of the other legal and regulatory issues that can arise when implementing and operating telemedicine arrangements.

Overlapping layers of regulation - TJ’s perspective

This pinwheel addresses some of the more common regulatory issues affecting telemedicine. These are examples of laws and concepts in areas that are constantly changing. They're in flux, they can vary from state to state. Again, this is not an exhaustive list, but enumerates the more common or important issues that you should be cognizant of in order to effectively deploy telemedicine services.

I'm going to show you not only the issues associated with some of these, but some trends that we've seen both pre and post COVID. Let’s start with the issue of licensing. The reason you hear about licensing exhaustively from lawyers like myself or from industry stakeholders on telemedicine is because one of the key advantages of telemedicine is the ability to provide healthcare to a patient, no matter the patient or the provider's location.



Overlapping layers of regulation - TJ's perspective

Since providers are licensed to practice in a specific state, they're only legally allowed to offer telemedicine services to patients in that state. So to put it very simply, the basic rule of thumb is that the physician has to be licensed in the state where the patient is located at the time the telemedicine consultation takes place. So if the doctor is located in Texas, and the patient is located in Florida, the doctor who's physically in Texas has to have a Florida medical license in order to diagnose and treat that patient via telemedicine.

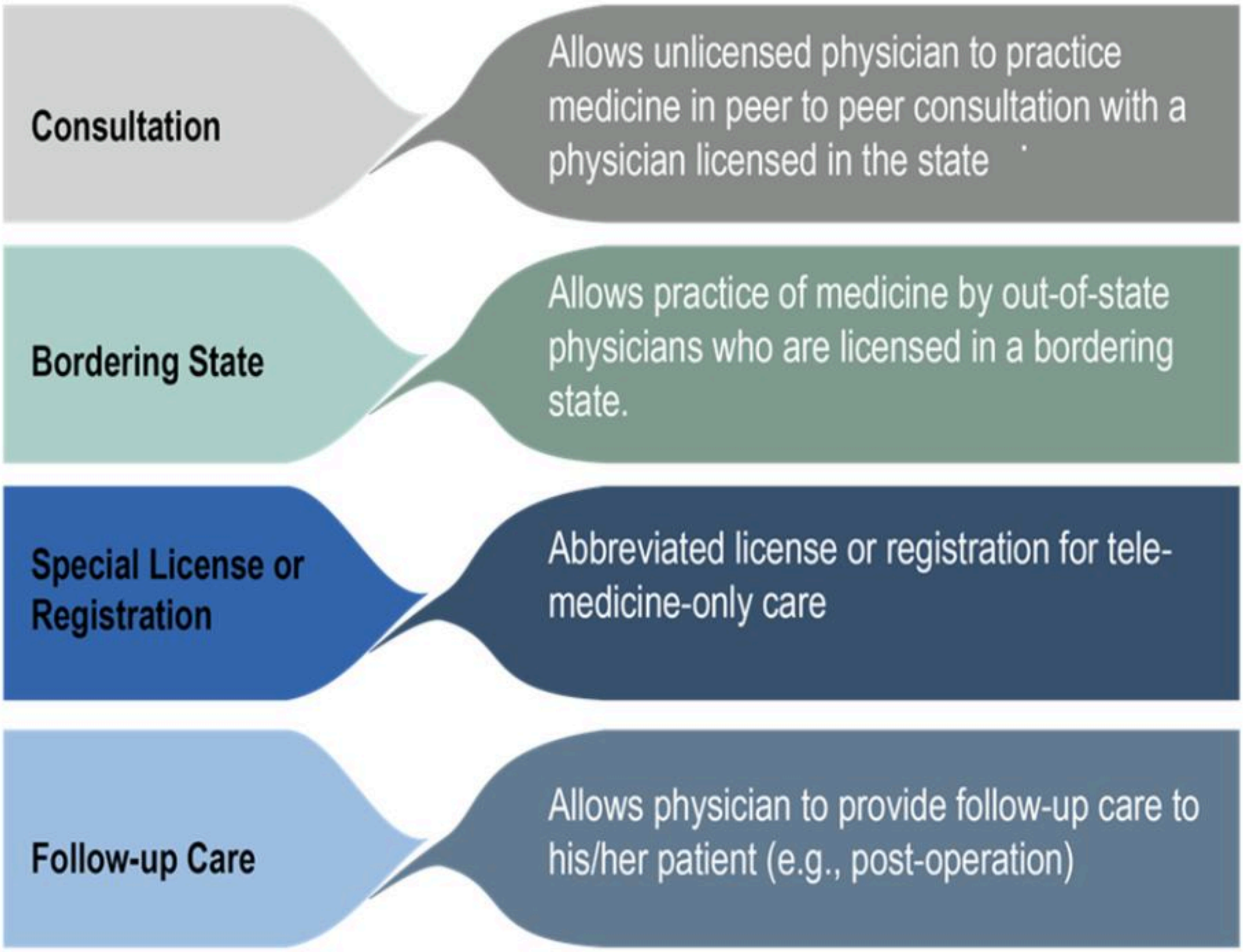
Using that same example, if that doctor is licensed in Texas, and the patient is located in Texas, then the doctor who has a Texas license for the patient that is physically in Texas could be physically located anywhere from a telehealth practice standards perspective. They can be located in Maine, New Jersey, or the surface of the moon.

From a licensing perspective, that's the well established rule. If you're a practitioner and you're just focusing on patient populations within your own state, this licensure requirement may not be an issue. However, in my experience, the types of companies, clients, and practitioners I work with that want to leverage telehealth usually have an app or website or some technology, and they usually want to scale to see patients in multiple states, if not nationally.

So once you get into that multi state practice posture, that means you're going to have to watch this licensing issue and make sure your providers are licensed in the state where the patients are, and it means you're going to have to submit license applications, pay dues, get continuing medical education, etc. So it's just a paperwork thing, but you want to be aware of it. It's an operational challenge. It's a staffing challenge. And there are solutions and consultants that can help with the licensing. There's the different licensing compacts that can help streamline the process. And there are technologies that exist that can help match up the geographic location of the patient with the provider.

The rule of thumb is the rule of thumb, but there are exceptions. And the exceptions can vary by state.

Telehealth and licensing - TJ's perspective



The rule of thumb is the rule of thumb, but there are exceptions. And the exceptions can vary by state. That's shown on the illustration above.

- Physicians offering care via telemedicine are subject to licensure rules of the state in which the patient is physically located at the time of the consult.
- State law expressly or implicitly requires licensure if the patient is located in the state at the time of the consult.

The exceptions are not exhaustive. They're the ones that are common by way of informed consent, and a lot of clients I work with leverage these in certain situations.

Telehealth and licensing - TJ’s perspective

If you look at the follow up care exception, there are about 14 states that have a follow up care medical licensure exception. Let's say a hospital physician provides post op follow up consults without having a license to practice medicine in the state where the patient goes home. So for instance, the patient is an Illinois resident, they fly to Massachusetts for a specialty surgical procedure, they then fly back home to Illinois and receive a follow up consultation, virtually. That physician in Massachusetts doesn't have an Illinois Medical License. There's an exception for this. That's the follow up care exception.

Another exception is the special telemedicine license. More states have this variation of a telemedicine special purpose license. The gist of these is they're often cheaper than a full fledged medical license and more streamlined. Sometimes they have restrictions, like you can only provide services via telehealth or you can't have a brick and mortar location or presence. Around 12 state medical boards issue a "special purpose license", "telehealth license", or certificate that allows for the practice of medicine across state lines for telehealth services. The requirements and scope vary by state.

Bordering state exceptions allows for exceptions for contiguous states. Several states have implemented a "bordering state exception" or "border state emergency temporary license" that allows out-of-state healthcare providers to provide telehealth services to patients located in the state, as long as the provider is licensed and in good standing in a neighboring or bordering state. Some examples include:

- Arkansas allows out-of-state physicians to provide "episodic consultation services" without an Arkansas license.

- Montana previously had a border state emergency temporary license during the COVID-19 pandemic that allowed physicians licensed in bordering states to provide telehealth services to Montana residents.

- Utah has a provision allowing out-of-state physicians with at least 10 years of experience to provide telehealth services for non-commercial purposes if licensed in a bordering state

Peer-to-peer consultation exception - TJ’s perspective

Probably the most powerful one I see is the peer to peer consultation exception. And it exists or some form of it exists in almost every state. It allows physicians or other healthcare providers licensed in one state to provide consultative services to a provider licensed in another state regarding a patient's care, without obtaining a full license in the second state. There are a lot of limitations and caveats to that, depending on the states and what you can or cannot do, utilizing that exception. But I see it used a lot.

	Must be free	Frequency limitations	No established connections or contract/ arrangement	No primary diagnosis	No Pathology	No Radiology	Informal/ Curbside/ No Written Opinion	No in-state office or meeting place	Other Restrictions
DE		X							X
ID				X				X	X
KY		X			X				X
NM		X					X		X
NJ		X			X				X
NC		X			X	X			X
PA									X
TN	X		X						X
WV		X		X	X	X			X

This chart is an example of some states that have nuanced interpretations of peer-to-peer consultation exceptions. A good concrete example of a peer to peer consultation exception is in the context of online Second Opinion offerings. In online Second Opinion models, the patient typically will be curious about consulting with the world renowned specialist at a famous hospital. But maybe the patient is out of state and they think they have a disease like cancer or some specialty condition. But they're far away, and they don't really want to commit. The Second Opinion model allows the patient to have that initial consult, such that the patient can get initial feedback and decide this is the clinician they want to see. This is where they want their full time care to be for the specialty condition they have, and then they reach out to the hospital’s intake staff and schedule an in person visit or session. That model removes the entire need for that first speculative initial visit. And it's immediately reducing a significant cost barrier and geographic barrier at the same time. Many leading healthcare systems like Cleveland Clinic, UCSF, Cedars-Sinai, and UCLA now offer virtual or online Second Opinion services to patients anywhere in the world through telehealth platforms.

Peer-to-peer consultation exception - TJ’s perspective

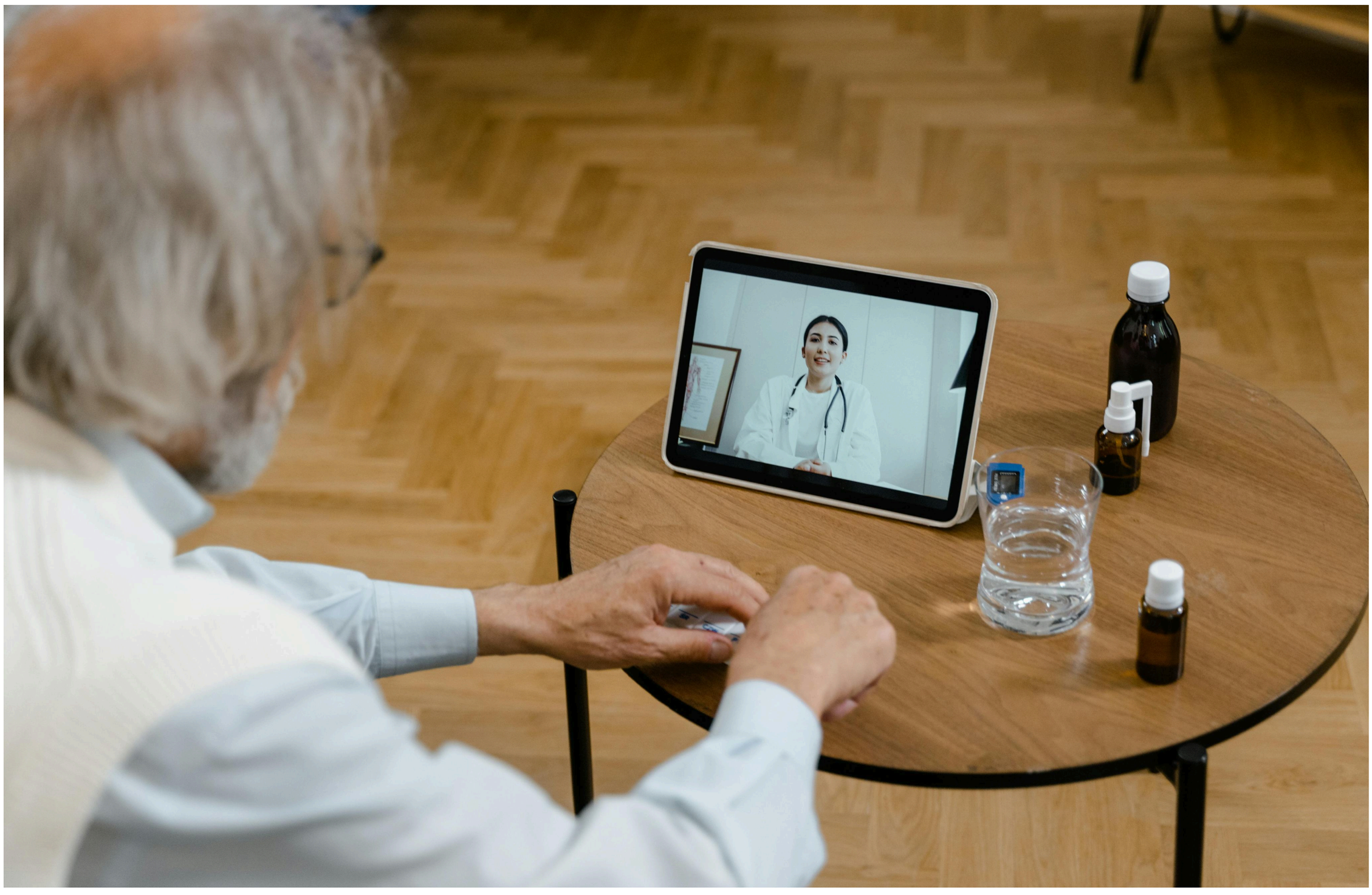
For patients, the benefits include:

- Convenient access to world-renowned experts and specialists from anywhere
- Multidisciplinary review for complex cases by teams spanning multiple specialties.
- Opportunity to get reassurance, understand all treatment options, and make more informed decisions.
- Over 40% of second opinions result in a change or refinement of the initial diagnosis or treatment plan.

For Physicians, it means:

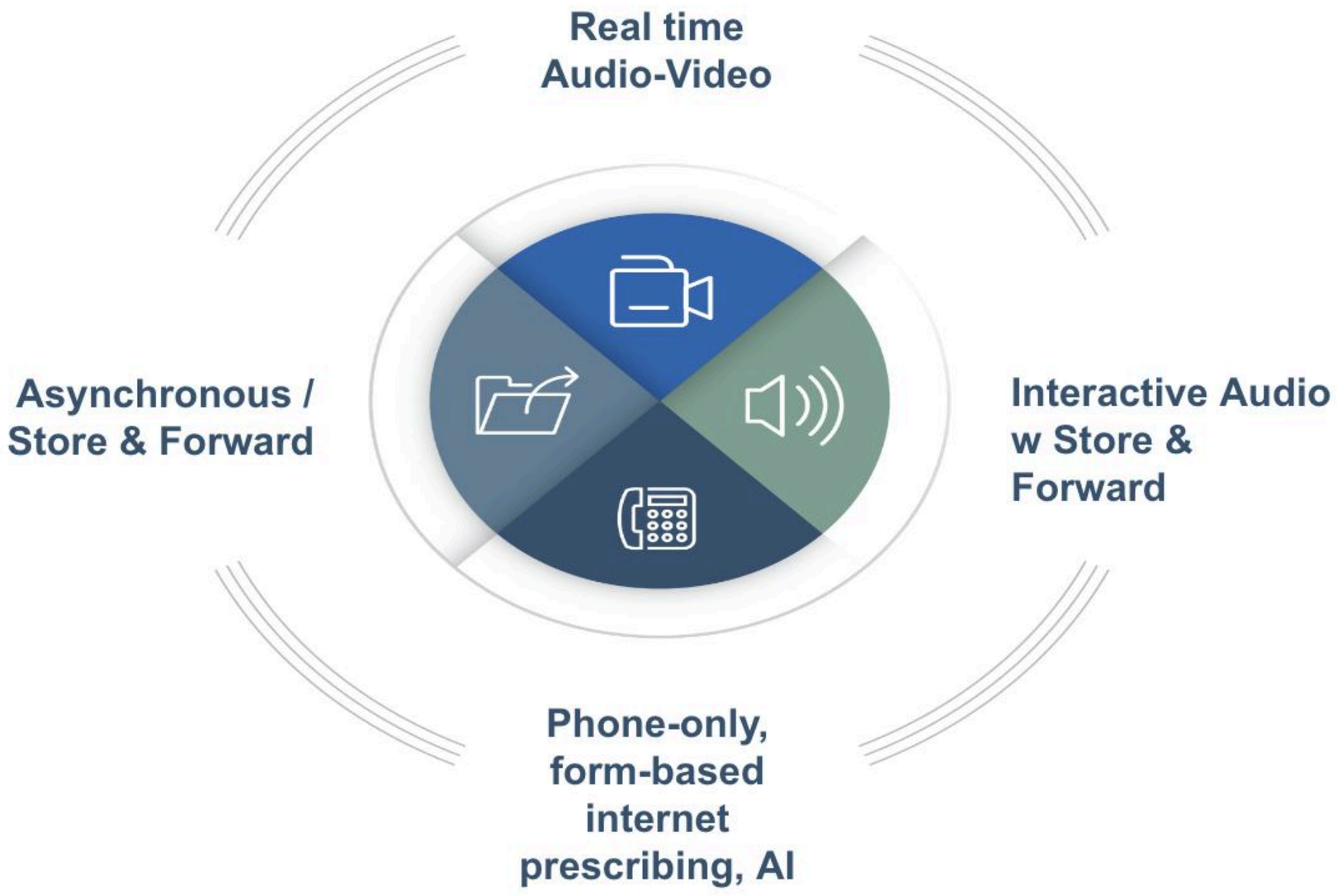
- Referring physicians can also request physician-to-physician consultations to get expert second opinions on their patient's case from specialists at institutions like UCLA.
- Helps provide patients with all possible options and develop tailored treatment plans.

These Second Opinion models and destination medicine attracts more patients across the country and provides better access to specialists.



Modalities - TJ’s perspective

Another hot topic that I deal with are modalities. And those also vary by state. Modality is a fancy term for talking about the type of technology or communication that providers must utilize to interact with the patient at different points during the patient journey.



If you're a practitioner, there are really four buckets that I put technology modality types into: the first is synchronous. If you and I were talking on Zoom, that's a real time interactive audio video communication. That is considered the gold standard from a regulatory perspective. And every single state will allow you to establish a doctor patient relationship with real time audio and video.

The other bucket is asynchronous telehealth, also known as "store-and-forward" telehealth, a modality where patients send medical information (such as images, videos, or data) to healthcare providers for review at a later time, rather than communicating in real-time. This approach offers several advantages.

Modalities - TJ’s perspective

Convenience and Flexibility: Patients can share information at any time convenient for them, without needing to schedule a live appointment. This improves access to care, especially for those in remote areas or with busy schedules.

Privacy and Comfort: Some patients may feel more comfortable sharing sensitive information asynchronously rather than face-to-face.

Efficient Use of Provider Time: Providers can review patient data when it's convenient for them, rather than needing to be available for a live interaction. This can improve workflow efficiency.

Chronic Disease Management: Asynchronous telehealth is well-suited for monitoring and managing chronic conditions like hypertension, diabetes, and mental health issues, where regular data sharing is beneficial.

Specialty Care Access: This modality enables patients to easily share information with specialists (e.g., dermatologists, radiologists) who can review images or test results remotely. It ultimately allows providers to time shift the delivery care by allowing them to tackle a large group of consults at a single time and on the providers’ schedule.

Then there’s remote patient monitoring, where the patient has data collected from some sort of technology like a wireless scale or wireless blood pressure cuff, and then the provider care team can provide ongoing monitoring assessment of the patient's health status and symptoms, and if necessary, intervene.

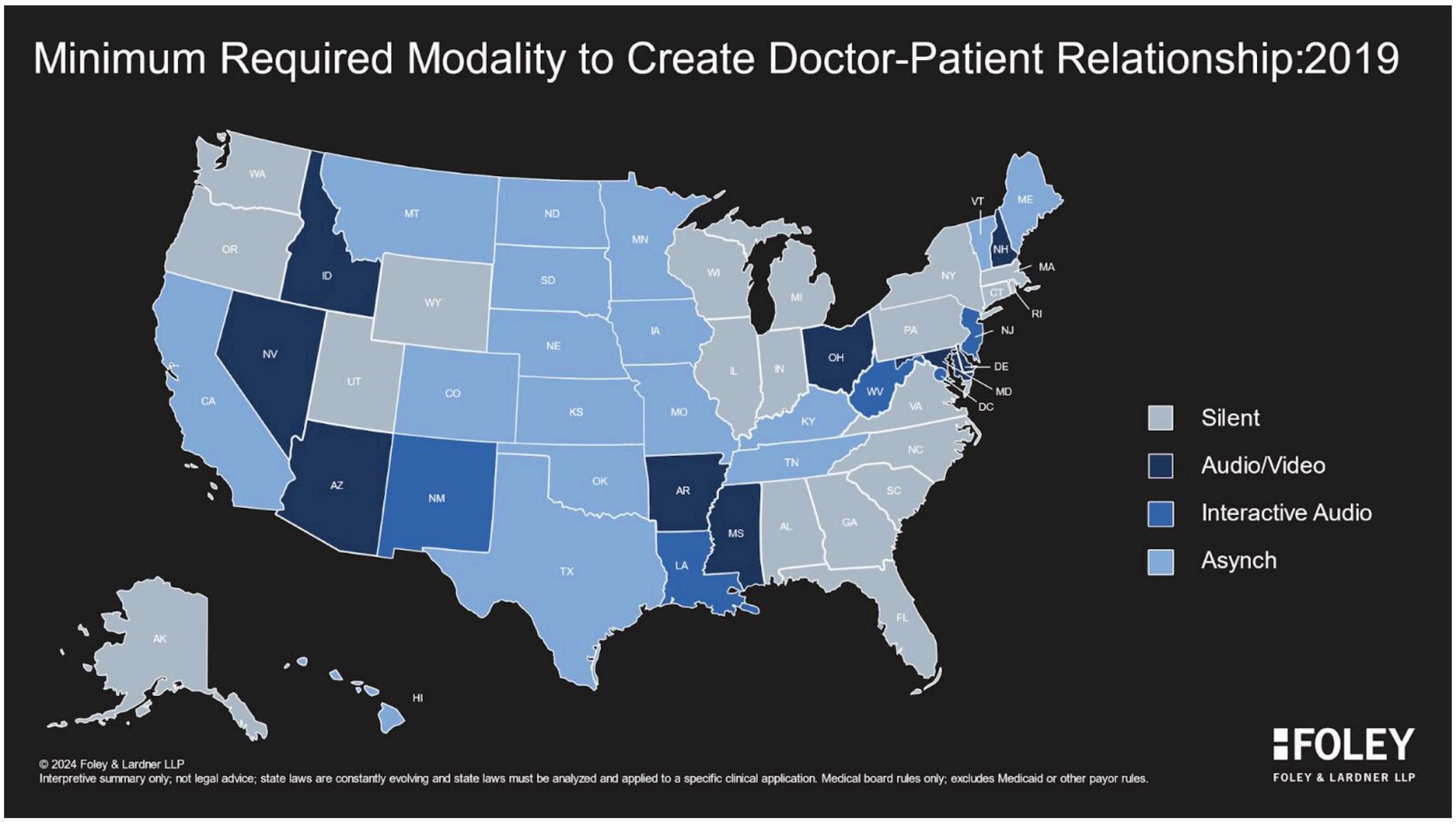
Let’s look at some heat maps nationally (on the next page) that will show you the changes that states have had with respect to modalities.

Modalities - TJ’s perspective

You can kind of see where things are headed, or have been heading when you compare the 2019 map to the 2024 map (next page). In 2019, no state prohibited a physician patient relationship from being established solely through telehealth. So, you could have a virtual-only encounter. But then, you can see that there's a little less than a third that actually requires some sort of synchronous or real time component to initiate that physician patient relationship. That's what the color coding is there.

You can also see that some states even required a live video exam for real time video visits. So Arizona, Maryland, Ohio, Idaho, and Nevada required that video visit and then some states required at least the interactive audio as well.

Back in 2019, only a third of the States recognized asynchronous for establishing the relationship. And by numbers, most states are actually silent on that, which means the rules didn't address it. And oftentimes back then the boards hadn't thought about it. Below is the 2019 map.

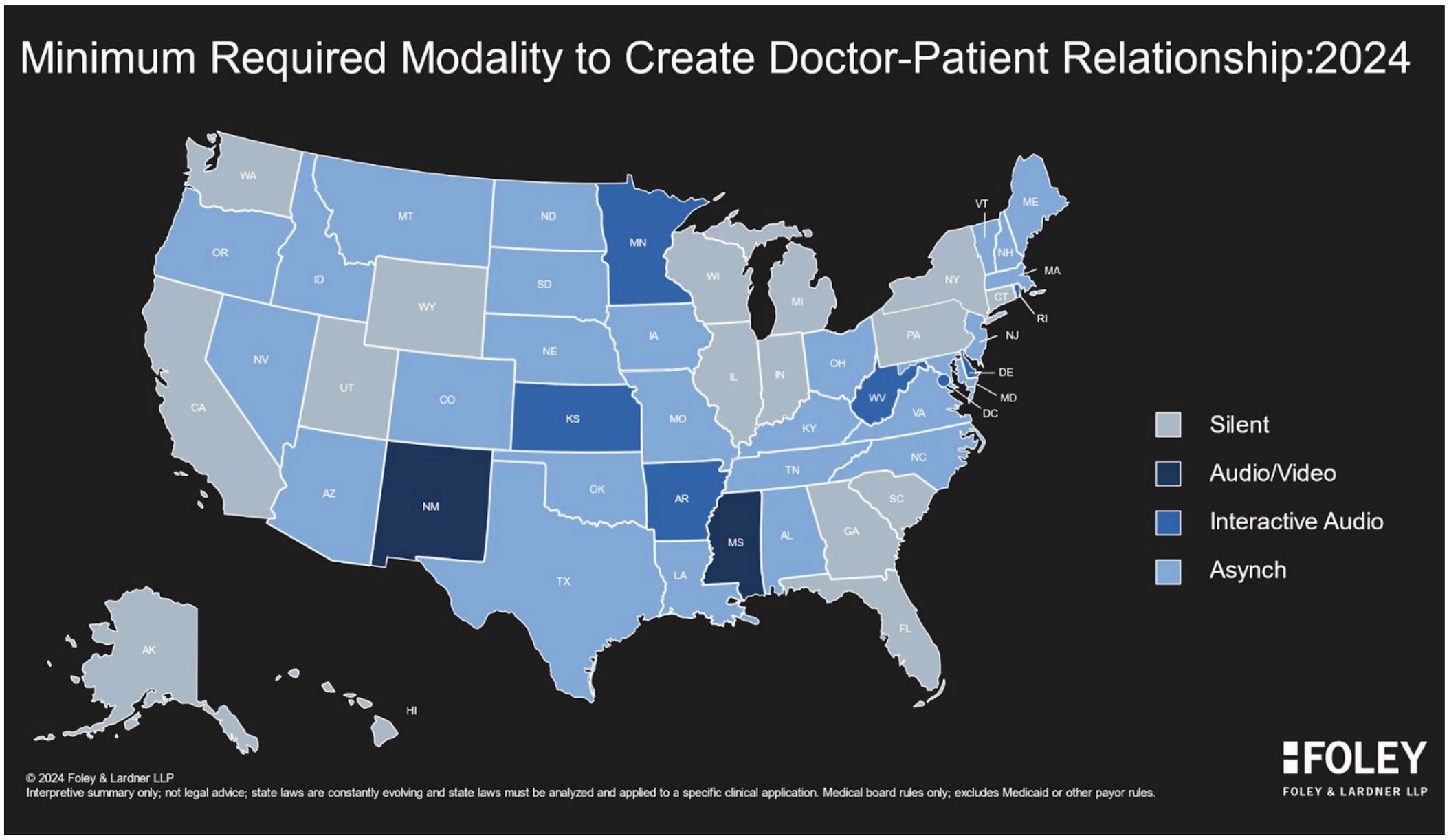


Modalities - TJ’s perspective

The boards didn't do this on purpose. They just didn't have it on the radar as much back then. And so let's jump into the present day here. If you toggle back and forth you can see some of the color changes.

In 2024, the map looks a whole lot less dark blue. And most strikingly, you'll see states like Idaho, Nevada, and Ohio have moved from requiring that video visit to expressly permitting asynchronous modalities. And then New Mexico and Mississippi are now the only states requiring a video visit interaction.

You can have all other states require more flexible technology modalities. I think a few reasons we’re seeing this is that the public health emergency and COVID prompted a reexamination of the regulations to be more flexible, it became a hot topic politically, and it's on people's radar. People were more accepted into the concept and buying of telehealth. So there's more utilization, more experience, and less of the unknown—less fear. And then there's also a lot of advocacy led by agencies and organizations like the American Telemedicine Association, for example, as well as others.



Async telemedicine by the numbers - TJ's perspective

	2019	2024
States with laws that ***expressly ban asynchronous*** telemedicine to be used to establish a valid doctor-patient relationship, instead requiring the use of either audio-video or "interactive audio with store & forward" as the modality.	**13 States**	**9 States**
States with laws that ***expressly allow asynchronous*** telemedicine to be used to establish a valid doctor-patient relationship.	**17 States**	**28 States**
States with ***do not mandate or proscribe a*** specific modality, instead choosing to more broadly define telemedicine to allow for new changes in technology and innovation (e.g., the use of secure electronic communications and information technologies between a patient at an originating site and a physician at a distant site).	**21 States**	**17 States**

So now, there's only nine states that basically do not allow establishing the doctor patient relationship virtually and 28 states that allow for it.

So nine say you can't do it async and 28 say you absolutely can.

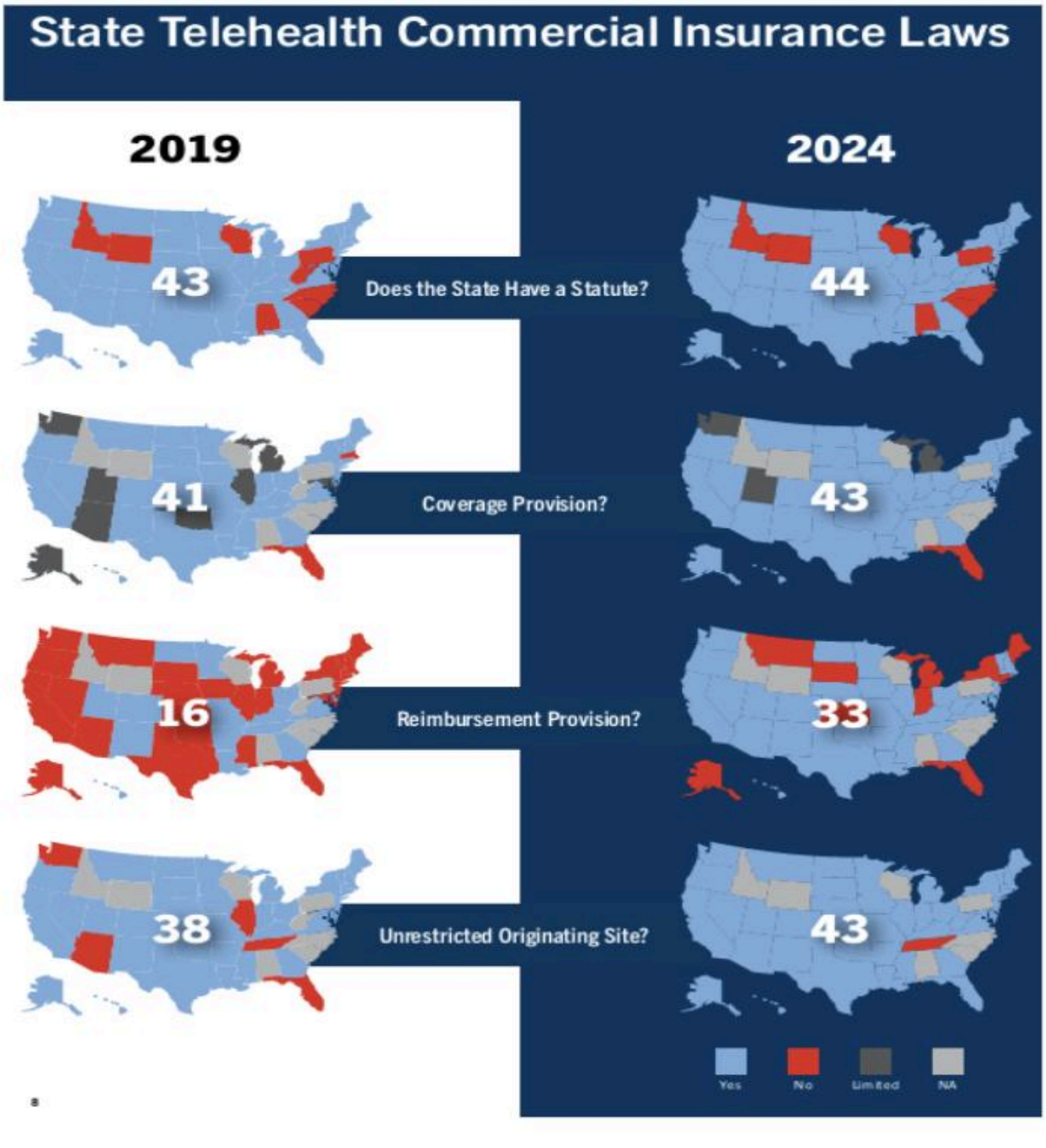
And then there's the 17 states that I consider modality-neutral, which means they don't mandate or talk about a specific modality type.

They usually use broad language that says something like "secure electronic communication and information technology", like Florida State.

The broad nature of the verbiage means they will usually incorporate the asynchronous type of technologies.

Commercial health insurance - TJ's perspective

- 43 states and D.C. maintain some sort of state telehealth commercial payer law.
- 33 states maintain laws on payment parity or reimbursement rates for telehealth services (an increase from 16 states in 2019).
- 18 states passed audio-only telehealth laws to make such coverage permanent for health plans.



This is also trending in a positive way. This is an updated 50 state survey on telehealth insurance loss and it's a report on each state's law about commercial insurance coverage and payment and reimbursement laws. We compare what the laws looked like before the public health emergency and then after and you'll see we also have heat maps representing all the states that have some sort of commercial insurance law on the books.

Commercial health insurance - TJ’s perspective

Most states, 43 states plus DC, have some sort of commercial insurance law. And what's important to know. There are two main concepts when I talk about commercial insurance laws. One is coverage.

Is there a law that says, ‘Hey, health plan, you have to cover telehealth’?

And then the second concept is payment parity, which is not only ‘Hey, health plan, you have to cover this telehealth service, but you also have to pay for it in the equivalent manner that you would pay for an in person setting’.

It's not like you can charge or pay the doctor $100 in person and only $50 via telehealth.

So two concepts converge, are we going to pay you at all? And then, how much are we going to pay you? Will it be equal to or similar to an in person context?

Telemedicine prescribing & controlled substance - TJ's perspective

Up for discussion:

- Federal Ryan Haight Act
- DEA Registration Requirements
- Forthcoming Rule on Special Registration
- Interaction with State Laws

There's a lot of focus on controlled substance prescribing, particularly, in the mental health vertical. And, it's becoming more of a growing concern across the country.

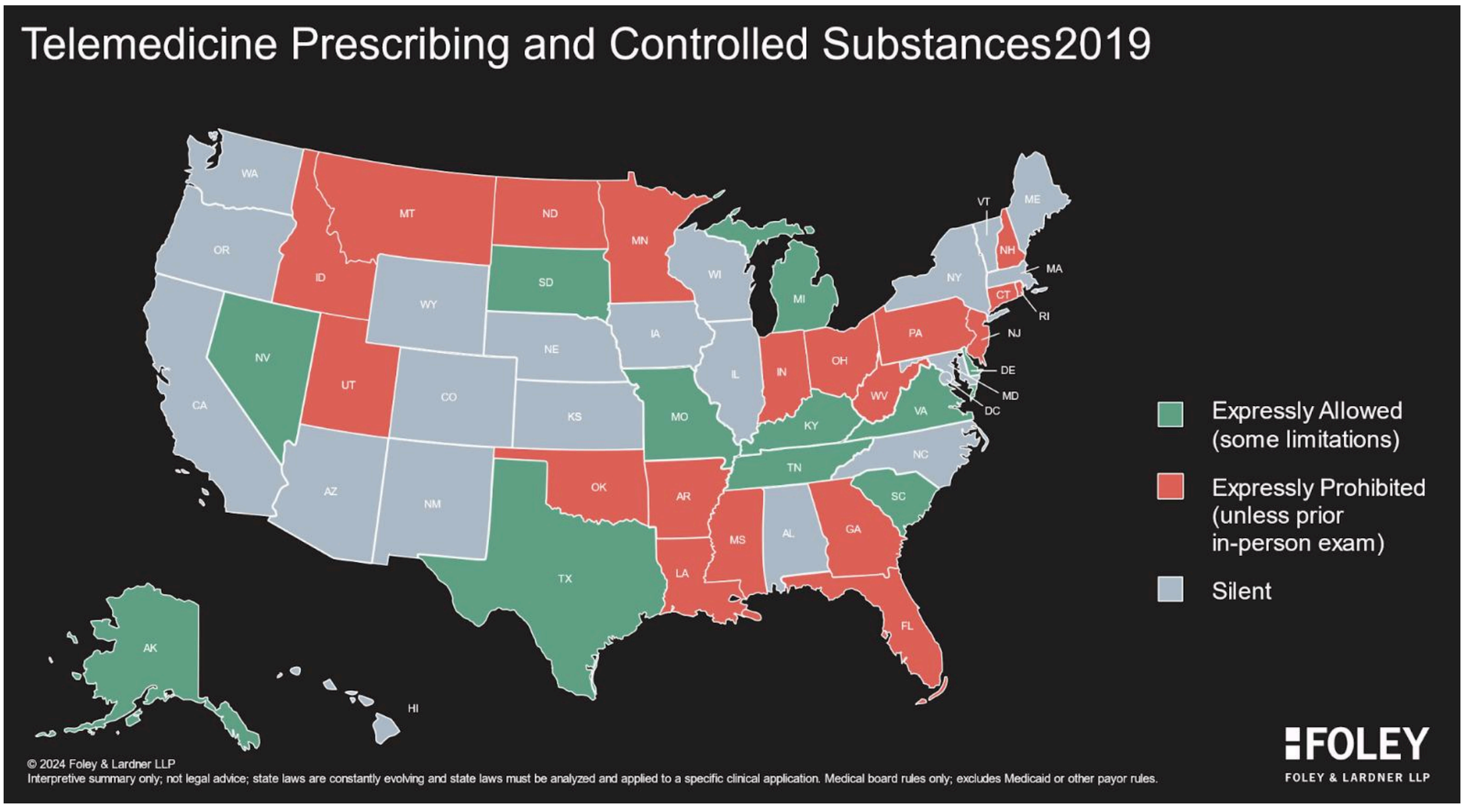
We briefly touched on the Ryan Haight Act. It's the federal statute that says, with limited exceptions, that there has to be a physical, in-person visit before you can prescribe controlled substances. Then COVID happened, and that was waived because of the public health emergency. So the DEA announced the exception and that there would be a waiver. And throughout COVID, patients were able to get controlled substances without ever seeing their prescribing physician in person.

There was a whole cottage industry that sprouted out of that. There were actually virtual-only mental health providers that came out of this. There were opioid use disorder clinics that were virtual-only and there were psychiatric and other mental health providers that leveraged controlled substances. And then the public health emergency ended. And everyone wondered what was going to happen. Would patients be grandfathered in? Would patients be cut off all of a sudden? Would this affect the treatment that people had been receiving? There were a lot of unknowns. And essentially, some fumbling by the DEA on how to handle this. But ultimately, a whole lot of nothing happened, and they just punted it a little bit further down the road.

Telemedicine prescribing & controlled substance - TJ’s perspective

Although there's no guarantee that we’ll learn more sometime this year, the DEA is going to come out with a process, and it's going to be under this special telemedicine registration that Congress and the statute has allowed them to promulgate 10 to 15 years ago. It would allow for a process by which a practitioner could be in the system and get approval to do prescribing of controlled substances using telehealth without ever having had that in-person physical examination of the patient. This is super important, particularly given the psychiatric shortage that we have, and particularly given a lot of these do have clinical efficacy behind these programs that are virtual only. So that's the federal law of the Ryan Haight Act. But remember the overlay of regulation. So let's say we get some permanence or some clarification around it by way of process. That's great. But then, we cannot forget that we have the state laws, and that's something that also has to be met. So not only do you have to comply with federal law but the state law.

You can see here, in the 2019 slide about controlled substance prescribing, there are some states that have limitations, some expressly prohibited without a prior in-person exam.



Telemedicine prescribing & controlled substance - TJ’s perspective

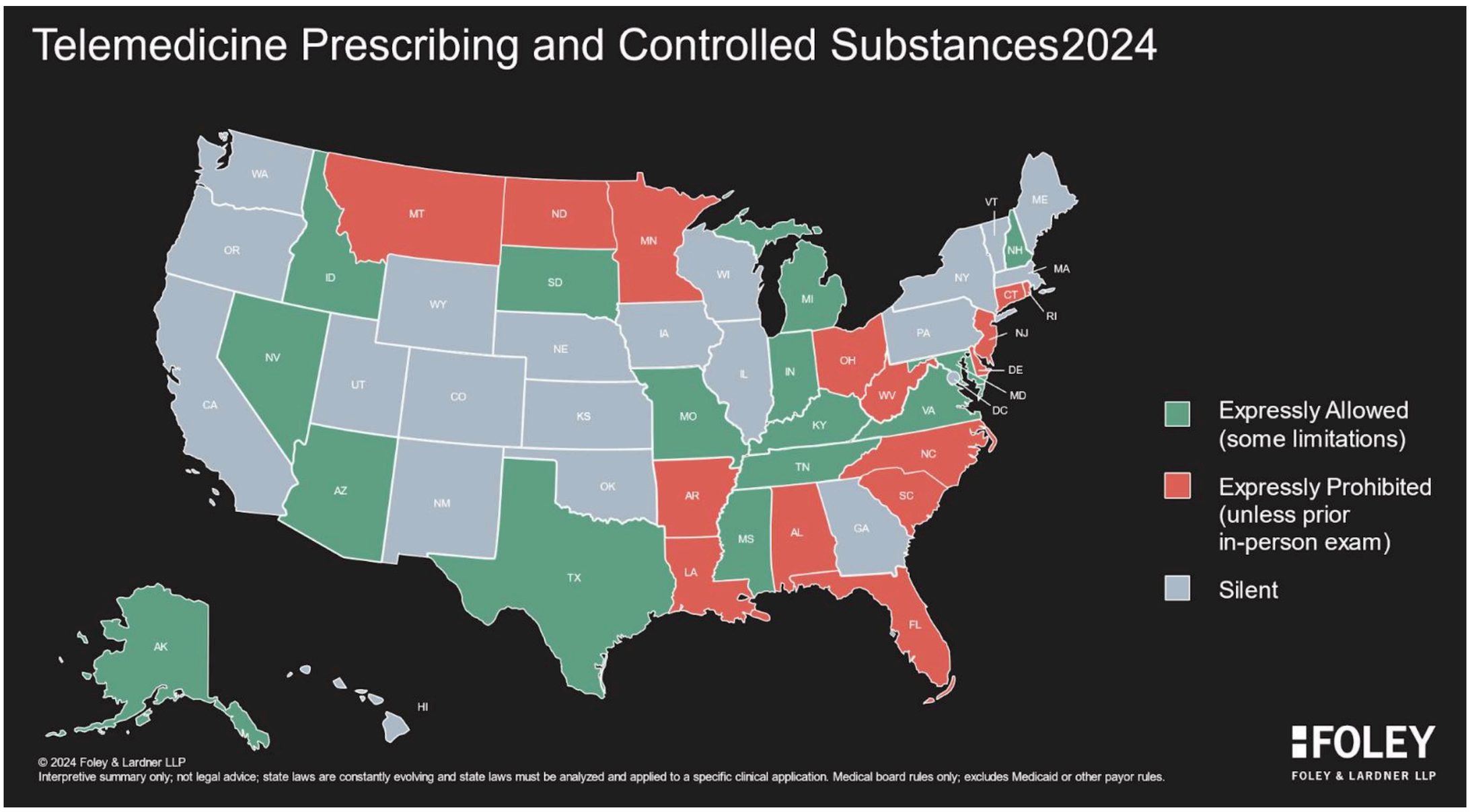
I think this is an interesting area in 2024.

You can see the color changes over the five years, and see there's a good amount of difference here.

So in this five year period, we had a good chunk of transition to be more flexible. But there are some states that actually became more restrictive, like Alabama.

Alabama actually was silent and then basically said no to controlled substance prescribing via telehealth without an in-person visit.

I think that if we come up with a favorable DEA policy, we're going to see more favorable state policy too on this issue. It will allow more states to feel more comfortable if the DEA has a mechanism and is more expressly signing off on it from a federal policy perspective.



Remote patient monitoring - TJ’s perspective

Up for discussion:

- Medicare Reimbursement of RPM & RTM
- AMA Declines to Add Proposed Codes
- Recent Peterson Health Technology Institute Study
- Expansion of SaMD and DTx

RPM, or, remote patient monitoring has existed for a long time—at least the actual ability to do it. The reason it's become a lot more popular dates back to 2018. Medicare started to separately reimburse remote physiologic monitoring. And it was the first CPT code issued. Then the year after, they expanded it into three additional codes because the first code was kind of clunky. And they've continued to provide additional guidance as the years have gone on. They were basically building the plane as they were flying it (so to speak). And this caused them to do a lot of work in the RPM space, largely because of the expansion of Medicare payment.

That's not to say that at the moment, in 2024, there haven’t been some pretty significant speed bumps for RPM. Because of recent changes, there have been RPM hurdles to contend with. The first one involves the AMA, in their CPT editorial panel. And for anyone that's familiar with RPM, or works in this space, or an RPM vendor or company or provider, one of the requirements for reimbursement under Medicare is that you collect at least 16 days of RPM or remote therapeutic monitoring data from a patient over a 30 day period.

Remote patient monitoring - TJ’s perspective

And that is one of the criteria for Medicare billing. It’s been a sticking point because that 16-day requirement is not grounded in any sort of clinical requirement. It's a bit arbitrary and created by the AMA and adopted by CMS. There are a number of clinical use cases or disease states where you don't need 16 days of data in a 30-day period, or it could even be bad for the patient to collect so much data. So a lot of industry stakeholders have been pushing back on it for a while. It's hard because of patient adherence issues. And it directly affects the bottom line of some of these companies that are trying to offer this service. And so earlier this year, there was a proposal before the AMA that they have a CPT editorial panel, which is responsible for creating medical billing codes. In the main meeting, the committee talked about it, and the discussion of the code changes to potentially modify that to a 60-day requirement or develop a new code with a lower requirement.

Those discussions stalled out and appear to have been postponed indefinitely. The next meeting is scheduled for September of 2024, so we'll see if they try to take it up again. But there was a lot of fanfare before the main meeting because it was on the agenda. People thought they might actually have momentum and make some changes that then could be adopted by CMS. But that does not appear to be the case.

The other setback is of note because it got a lot of press and it came in the form of a report released by the Peterson Health Technology Institute. So the PHTI issued a fairly scathing report that scrutinized using remote monitoring diabetes management solutions, and the report suggested that rather than reducing expenditures and costs, which is what they're generally advertising to be the value at work, they said that these digital management solutions are generally adding cost to the healthcare system and not really improving it. If you were a remote monitoring company, you were not happy with this, and there was a lot of back and forth, and arguments on both sides about the validity of the clinical study. Thus, there have been some speed bumps in the RPM space.

This year we will see some expansion in guidance related to software as a medical device and digital therapeutics, and we’ll see more experimentation and a hopeful expansion of some of those technologies.

Expansion of telehealth - TJ’s perspective

Up for discussion:

- Medicare Telehealth Reimbursement Legislation
- 2025 Proposed Physician Fee Schedule
- DEA Special Registration for Controlled Substance Prescribing via Telehealth
- Corporate Practice & Private Equity in Health Care
- Fraud & Abuse Enforcement

I want to talk about 2024, maybe a little bit into 2025. There's going to be a lot going on this year. The American Telemedicine Association has coined the phrase, “this is the Super Bowl year of telehealth”. And the reason is because there's a lot of big policy issues that could be impacted here this year. One of the biggest ones is what Congress is going to do with respect to passing or not passing legislation to make the Medicare billing flexibilities for telehealth permanent.

The big deal is synthesizing it to allow patients to receive telehealth services while they're at home and to have doctors get paid by Medicare. That’s putting it in the most simple terms. It will have to be done through Congress, not CMS, because this is a statutory reimbursement issue.

What I'm seeing is that we think Congress is going to punt on this again, and maybe pass another two-year patch that will allow for further study and review on the impact of making such policies more permanent. So, it's a two-year interim piece of legislation. It’s not great, but certainly better than actually resetting to what it was prior to COVID. Because prior to the public health emergency, Medicare did not pay very much for telehealth because there was a list of draconian requirements that had to be met. One of the biggest ones is the patient couldn't be at home. It had to be a real time audio visit and had to take place in a hospital. It would be a major setback if it were to relapse.

The Physician Fee Schedule is a big one every year and we're probably going to get the proposed rule in about a month. It's the Medicare Part B Physician Fee Schedule proposal. There's a lot of stuff in there that relates to telehealth—they can propose new billing codes, they can give guidance about things like RPM and supervision, etc.

All by way of saying, there’s a lot coming down the pike this year, so stay informed!

Expansion of telehealth - TJ’s perspective

And so that is where some of the blocking and tackling from a regulatory perspective of what you can and cannot do and the guidance to give you confidence about what you can and cannot do with respect to payment comes into play. It's also a super, super important part of the process. Because when the proposed rule comes out, you can comment on it. And if you have any sort of passion or you're involved in telehealth in this industry, you should comment on it! Let your voice be heard, because they do read those comments.

DEA special registration has been discussed already and that we're expecting that this year. But I think that's another big one. Corporate practice and private equity is kind of a new trend that we've seen this year. And there's been a series of state bills and also some talk at the federal level, but we should be more interested in seeing how the states play this out. These bills are getting traction. And in these bills, the way they're being written could significantly restrict how a non-physician owned healthcare company operates. The target has been on private equity backed or venture capital backed or privately held healthcare companies that operate in the healthcare industry. Oregon had a fairly robust bill on the corporate practice of medicine that ended up not passing. But it had some very restrictive language. Right now California has some pending legislation that would make a big ripple in the industry if any of the laws were to pass. Whether you're for or against it, it would likely bring in a lot of change in how companies and healthcare is looked at from a structural perspective and from an investment perspective in those states. So keep an eye on those.

The last one is another big one. The Department of Justice and the Office of Inspector General released a special fraud alert, which basically means they're seeing a lot of fraud in the RPM space. And they said, ‘Hey, everyone, just want to let you know, we're putting this on notice there's a lot of fraud here so don't do that. We are keeping an eye on it’. And there's been other fraud - let’s call it telefraud arrangements - that they've been cracking down on. But when that type of fraud and abuse enforcement increases, it starts to get into the fringes where you get more technical payment audits when as a provider, you thought you were doing the right thing. Your interpretation of the law was different from the government's and they want all their money back. That has been in existence in hospital medical systems for years, and it will eventually start to creep into the virtual care world as well, including telehealth. Remain vigilant and do your best with all of this information!

Learn more about Spruce Health

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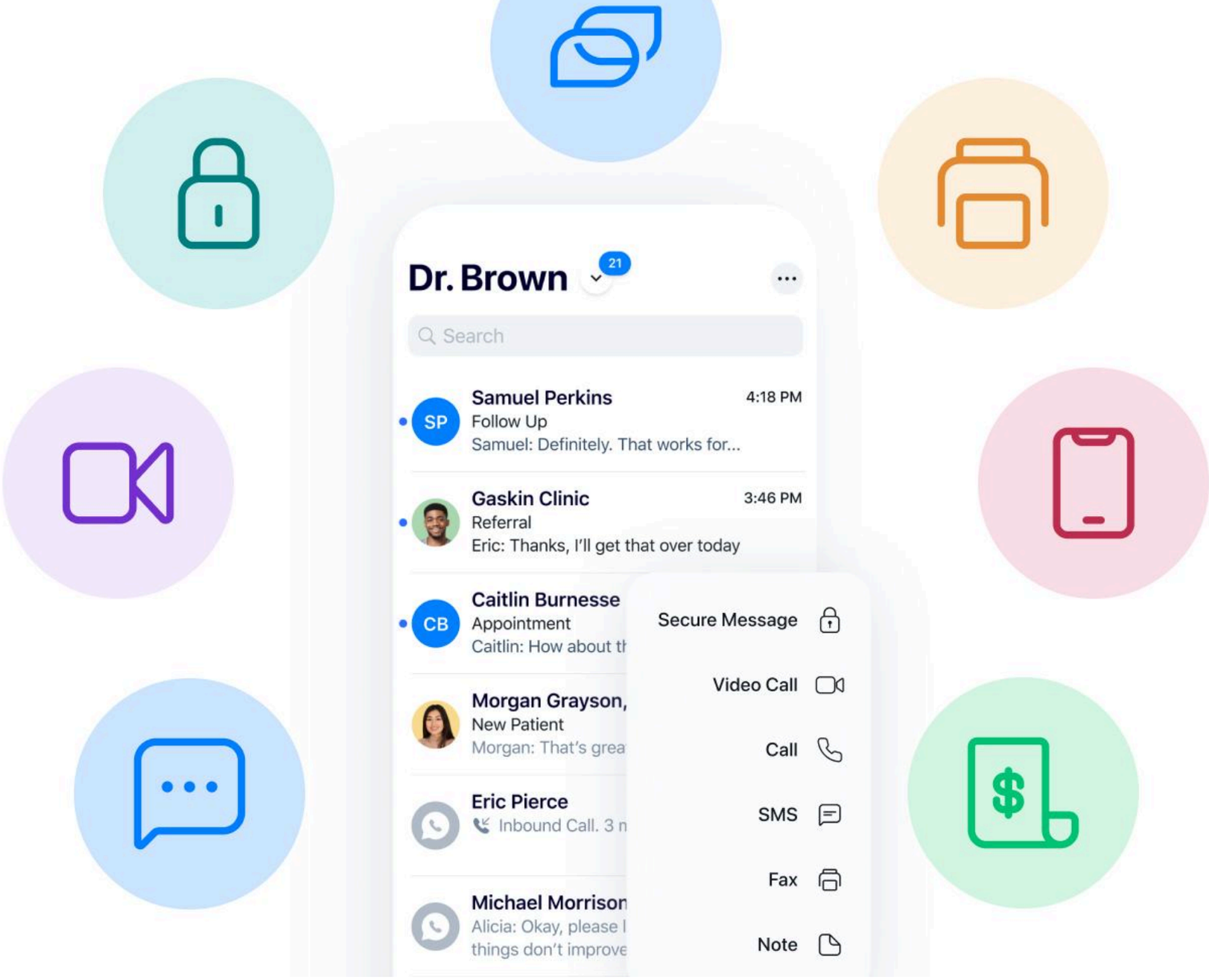

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