The rise of global telehealth

[00:00:00] Kristi Kung: Hello everybody, I'm Kristi Kung. I'm a healthcare regulatory partner in the Washington, DC office of DLA Piper and I'm joined here by my colleague, Greg, in Sydney, Australia. We are going to talk about digital health, and in particular, its rise during the COVID pandemic and how the world is dealing both with COVID as well as advancements in technology to address healthcare access. So Greg, thanks so much for joining, and I'll let you introduce yourself.

[00:00:30] Greg Bodulovic: Thank you very much, Kristi. My name is Greg Bodulovic, and I am a partner at DLA Piper's Sydney office, as Kristi has mentioned. My specialty is the regulatory side of healthcare and life sciences, as well as intellectual property, and I have had quite a bit of involvement in the telehealth sector over the last few years.

[00:00:56] So Kristi, to start with, obviously we've seen a significant increase in the use of telehealth globally, since the start of the pandemic. But it might be useful at the outset to basically just explain our understanding of what telehealth is.

[00:01:14] Kristi Kung: Sure. Actually, great question, Greg, because there are a bunch of different definitions. I mean, how I think of tele-health is the delivery of healthcare services via telecommunications technology. Whether that means live interactive video and audio, or if that is an asynchronous, meaning, store and forward technology or recorded videos that are reviewed later, or uploaded images that are sent across through a technology to a healthcare provider to then review and interpret. I consider all of that within the definition of telehealth. And with respect to telehealth, it could be medicine, it could be nursing, it could be physical therapy, anything related to health care services. Greg, do you have a different view?

[00:02:05] Greg Bodulovic: Yeah, absolutely completely agree with that. The definition that we use here is fairly broad. It encompasses everything you've just said, as well as, in a lot of cases, medical consultations and affiliated healthcare consultations by way of radio. A lot of Australians living in remote areas, 500 miles from the nearest town with a hospital. And often radio is used to relay instructions from treating doctors, even in the case of first aid. So it's quite important, in this country, and it has been around for a long time pre the pandemic, particularly in very remote areas.

[00:02:52] Kristi Kung: That's a great point, and it's an interesting thing here in the US too, because, pre COVID pandemic many state laws that define telemedicine expressly stated that it didn't include telephonic communications or text messages. But during the pandemic, when CMS, our Centers for Medicare and Medicaid Services, came out with their waivers with respect to telemedicine, they did allow for reimbursement and billing for telephonic visits and also text-based communications, particularly in the mental health space. So we've seen some changes in that, in the US as well, in order to increase that access.

[00:03:33] Greg Bodulovic: Absolutely the same here. I think it was March 2020, so the start of the pandemic, that the Australian government made amendments to Medicare, which is our universal healthcare system that allows, firstly, medical consultations, and secondly, pharmaceuticals to be subsidized for Australian citizens. So that was amended in March 2020 on a rolling basis to allow reimbursement on medical consultations by way of telehealth.

[00:04:17] Kristi Kung: I was going to ask you about what it was prior to COVID. If any coverage was available for telemedicine services prior to the pandemic, in Australia?

[00:04:25] Greg Bodulovic:

[00:04:29] In rural and remote areas, there were programs, absolutely. But for run of the mill telehealth consultations in urban areas where people could see their, as we call them, general practitioner or you call them family physician, no, that was not subsidized under Medicare. However the pandemic created a seismic shift in this country, as it did in many others. And healthcare systems have adapted to meet that challenge. This is one of the ways that the government here is addressing the ongoing effects of the pandemic on the provision of healthcare services. It's interesting because the figures bear out that last year. So 2021, approximately 29% of Australians had at least one telehealth consultation. And, of those, more than 80% felt that telehealth practitioners listened carefully, showed respect, and spent enough time with them and indicated that they would use a telehealth service again. So the uptake is not only significant, it's quite positive.

Kristi Kung: Interesting personal story. So I've been doing telehealth work in the US since probably about 2008, 2009. And I did not have a telehealth visit until COVID. So even though I was practicing in the space, and I was doing a lot of the legal work in this area, I never personally chose to use it. One, I don't go to the doctor as much as I probably should. And two, I live in a big city, so it's not like I have an access issue. If I need healthcare, I can just go and get it. But my personal feeling on using telehealth services during COVID was that it was phenomenal. It was very convenient. I still felt a personal connection with my physician. It took a lot less time, obviously, than going in and sitting in the waiting room and having everything run 20 minutes behind. And I don't know that I would ever go back to only having in-person visits, even when the pandemic hopefully passes us by. So personally speaking, I think that a lot of people

feel the same way I do, and that this is something that is not going to go away and will continue, even post pandemic.

[00:07:08] Greg Bodulovic: I definitely agree with you, Kristi. From being a father of two young children who tend to pick up colds all the time, it's definitely been helpful and a time saver to be able to have telehealth consultations with my children's GP. But there are, some fields in medicine where perhaps it is easier than others.

[00:08:09] Greg Bodulovic: One of the challenges with telehealth is the prescription of medicines. Not all doctors are able to electronically prescribe medications. And as a result, there's often the issue of getting access to those prescriptions. So in our case, we've had to, after having a telehealth consultation, physically drive to the doctor's office to collect the prescription, which defeats the purpose of a telehealth consultation in some ways, but obviously this is an area that's improving day by day.

[00:09:07] Kristi Kung: Do you have any mail order pharmacies?

[00:09:08] Greg Bodulovic: We do. We have mail order pharmacies. I haven't used one personally, but they exist. And obviously, where doctors are signed up for electronic prescribing, it's a lot easier. It can be sent to the pharmacy electronically, and the medicines can be delivered. And in the same way that we have rapid grocery delivery services, there are a number of services for the delivery of pharmaceuticals.

[00:10:13] Kristi Kung: The issue of prescribing via telemedicine is an interesting one here in the US, as well. Pre COVID, we have, and we still do, the Federal Ryan Height Act, which essentially prohibits the prescribing of a controlled substance via the internet, unless the physician or some physician in the physician's group practice had seen the patient in person, prior to the telehealth visit unless the requirements of a very narrow telemedicine exception were met. That telemedicine exception required that the patient be present in a DEA registered facility or in the presence of another clinician who was also authorized to prescribe. So it kind of defeated the purpose. It was very challenging for telehealth models that did require the prescribing of medications to operate pre COVID. And the law obviously was put in place with the best of intentions.

[00:11:16] In fact, it was passed in response to the opioid and narcotic prescribing via internet questionnaires, and it was felt that clinicians could not appropriately assess an individual's medical condition and prescribe via internet means only. And so even pre COVID, the telehealth advocates were pushing for additional allowances for prescribing via telemedicine. There was a special registration process that our drug enforcement administration was working on at the time, and it still has not been released. We've been waiting on that special registration for years now. But, when COVID hit, there is another exception under Ryan Height for public health emergencies.

[00:12:12] So the US government's declaration of a public health emergency with respect to COVID meant that telehealth physicians could prescribe. So that federal law is currently waived. When the public health emergency is lifted here, it would go back into effect. So that is a big issue in the US and a lot of telemedicine companies are grappling with how they're going to change their processes or what responses might need to be put in place to switch operations, to make sure that they're in compliance with federal law, if there is not some sort of relief before that PHE is lifted. If there's no legislation passed or the DEA doesn't come out with our special registration, what could be done to ensure that their platforms do not violate federal law? I'm curious if you've had similar limitations with respect to prescribing in Australia pre COVID and if those have been similarly waived?

[00:13:20] Greg Bodulovic: That's a good question. To the first point that you raised, there is still a requirement to have an existing clinical relationship with the telehealth provider to make eligibility requirements for Medicare. So, limited exemptions aside, what this means is that in the year prior to the telehealth appointment, there must've been at least one face-to-face appointment between the treating doctor and the patient. When it comes to prescribing, medicines of the type that you just discussed Kristi, so opioids. those types of medications are restricted in Australia, and typically speaking they are not prescribed as widely as in the US.

[00:14:51] Kristi Kung: I should clarify. So the law came into place, because of opioids and narcotics, but the law is broader than just opioids and narcotics in the US. It's any controlled substance. It would apply to things like ADHD medications, anxiety medications, antidepressants. So it is broader, it's not just relating to those opioid or narcotic drugs.

[00:15:15] Greg Bodulovic: When it comes to prescribing, the law has changed. Australia has six states and two territories. So eight different entities, each of which have their own laws relating to prescribing.

[00:16:05] Now, each of those states have amended their laws to allow for electronic prescribing. Individual doctors need to sign up to become electronic prescribers and meet the necessary requirements. That process is still ongoing, but once that is complete, doctors will need to use their professional expertise and knowledge of the patient to be able to prescribe the appropriate medicines. Where, it's not possible to make a determination via a telehealth consultation as to whether a patient is suited to the particular medicine, then it would need to be an in-person consultation, particularly if it requires diagnosis that's not possible via the internet.

[00:17:02] Kristi Kung: I'm glad you raised the state and territory piece as well, because in the US, obviously, we have 50 states, the District of Columbia, and telehealth is very much regulated at the state level. So even though I've been speaking about the

Medicare waivers with respect to coverage, our Medicare program only covers our elderly individuals, 65 and older, and certain individuals with chronic conditions like end stage renal disease or black lung. So there's a lot of individuals that are not covered under that. Our Medicaid programs at the state level will define coverage, differently than one another. Commercial payers can cover telehealth differently. The states themselves can define telehealth differently and permit certain things that other states will not, you know, both in terms of prescribing as well as the various telehealth modalities that are used.

[00:17:58] So here in the US if you're a telemedicine platform and you're looking to go national and enroll this out in all 50 states and DC, you are going to have to account for all of those differences at the state level, and it's quite the undertaking. And it does sound like, at least in Australia with the six states and the territories that, they all have their own laws, but perhaps, maybe they're coordinating a bit better than we are here. Is that a correct assumption based on what you said?

[00:18:32] Greg Bodulovic: Absolutely. So when it comes to Medicare and coverage for healthcare in Australia, that is definitely at a national level. It's more the technical requirements around, for example, prescribing that's dealt with at a state level. Until recently electronic prescriptions were still not quite there, but significant progress was made in a short period of time.

[00:19:13] It's interesting to me that you've talked about the difficulties of rolling out in all 50 states. One of the areas that I've worked in and helped clients in and also have a significant interest in is rolling out telehealth services, globally or multi-nationally. So often we have clients come from the US that have a model that works in the US, and they want to roll it out to other countries. And typically, it goes US, Canada and often Australia is the third country that many providers pick. And that raises some issues. Typically, it's easier if they hire or engage healthcare professionals in the country that they're moving into to provide the advice.

[00:20:19] However, we have had questions about being able to provide telehealth advice by doctors located in one country to patients located in the second country. Have you come across that? And what is your view on that from the US perspective?

[00:20:38] Kristi Kung: Absolutely. And Greg, I think that we first met actually, in trying to set up one of these global telemedicine networks, and this was pre pandemic. I think it certainly expanded during COVID. But you know, from the US perspective, as I said, telemedicine is regulated at the state level. What that means here is that wherever the patient is located, at the time of service, that is the state law that will control. So let's say the patient is in Florida and the physician is in New York, that New York physician needs to be licensed in Florida, and the laws, the regulations, that are going to cover that particular service are going to be Florida's laws and regulations.

[00:21:27] If a company is trying to offer telehealth services to individuals in the US but using healthcare providers in another country, then whatever state that patient is located in at the time of service, would require that that physician in that other country be licensed in that state. Now, whether they could actually, enforce that requirement and go after somebody who was outside of their jurisdiction, there may be some challenges with that. But the law is that, that clinician needs to be licensed where the patient is located. The US kind of views services provided in other countries, but using clinicians that are in the United States as relatively hands-off, because the view is that it's the jurisdiction where the patient is located, that controls. So, let's say the clinician is located in New York and the patient is located in Australia. New York is probably not going to care much about how that telehealth service is rendered, because in our view, that telehealth service would be covered under whatever the requirements are in Australia. So that's at a high level, the general US perspective.

[00:22:47] Greg Bodulovic: Very similar to here. There are , within Australia, no interstate restrictions, so a doctor located, for example, in Sydney could provide telehealth services to someone located in Western Australia on the other side of the country.

[00:23:01] But when it comes to doctors in other countries providing services to Australians, that's an interesting point. The Australian law, basically the way it deals with it, is it prohibits the use of restricted titles,for example, Dr for medical doctors who are not registered as such in Australia.

The question arises, firstly, if such services were able to be provided and if the regulators did not raise any concerns, how would they be paid for? [00:24:26]Would such treatments be covered by Australia's universal healthcare system, Medicare? They wouldn't be, because the doctor is not registered for Medicare in Australia. But it also raises issues of insurance. So if there's a misdiagnosis or some issue with the advice provided in that case, if it was provided by an Australian general practitioner, there would be no issue [regarding insurance]. If the practitioner was in another country, then obviously the difficulty arises.

[00:25:25] Kristi Kung: It's similar in the US with respect to coverage, because our Medicare program will not pay for services that are rendered by clinicians that are outside of the United States, or its territories, and many Medicaid programs are the same. I think the difference is that with a national health system like Australia has, you're used to having healthcare covered, and here in the US, we are used to a lot of things falling outside of our coverage. And quite honestly, that's the problem with our healthcare system, is that it's so expensive.

[00:26:01] So when I think about telehealth services that are delivered from clinicians outside of the United States, it's pretty much a given that those aren't going to be

covered by anybody, and we're going to be paying out of pocket for it. But it's possible from a regulatory perspective, so long as that clinician is licensed in that particular jurisdiction. So it's a personal choice as to whether, a patient is going to pay out of pocket for that service or not.

In Australia, in addition to Medicare, which covers basic healthcare, we also have private health insurance. Now, some of the private health insurers were slow to provide coverage for telehealth services. However, over the past year or two, they have increased coverage for certain types of consultations. These include, for example, occupational therapy, psychology counseling, speech pathology, physiotherapy, and antenatal and postnatal midwife consults.

[00:29:26] Now, one thing that I thought we could just touch on, Kristi, is the issue of privacy, particularly in the context of going global with telehealth. I know that in the EU with GDPR, the privacy laws have become significantly stricter, particularly with respect to health information. Now, from what I've seen, it seems to me that a lot of other countries are going that way. That is, where GDPR was previously the high watermark. It seems to me that it's now almost a default and that many countries are reforming their privacy systems to the same level as GDPR. Would you agree?

[00:30:29] Kristi Kung: Well, I agree. With respect to the US, so we have the health insurance portability and accountability act, or HIPAA, and that is essentially like a floor of privacy and security rights in our country. It only applies to limited participants in the healthcare industry, though. It applies to covered entities, which are health insurance companies, healthcare clearinghouses, and healthcare providers who engage in electronic standard transactions, which at a high level, would just mean billing electronically for some service. Apart from that, HIPAA doesn't apply unless you're a business associate of a covered entity.

[00:31:13] So a lot of these services that are direct to consumer could potentially fall outside of HIPAA's coverage. And the way that we work in the US is that there is authority at a federal level, under section five of the Federal Trade Commission Act, that essentially says, if the practices are unfair or deceptive from a privacy or security standpoint, then the FTC could take action. So wherever HIPAA doesn't apply, there is potentially other coverage at a federal level, through the FTC. Some action could be taken by both the FTC, as well as our department of health and human services office for civil rights for HIPAA violations.

[00:32:01] And then we also have separate state laws with regard to privacy and security. There's talk about amending HIPAA or coming up with a federal law to apply to privacy and security more generally. To be quite honest, I'm not overly optimistic that that's coming anytime soon. But we have had a lot of changes at the state level in our privacy and security laws. And we had California, for instance, pre pandemic come

out with the CCPA and then amend it through the CPRA. And then, other states have followed since then. So we've had laws from Virginia and from Colorado. And I do see a trend in strengthening the privacy and security requirements, but from a US perspective, that is mostly happening at the state level.

[00:32:55] Greg Bodulovic: It's quite interesting. Well, I guess we'll have to wait and see.

[00:33:00] Kristi Kung: You know, I would say too with the cybersecurity issues during COVID, you know, increased hacking and everything else that there it is a lot of concern with respect to the security of information, especially when conveyed electronically.

[00:33:15] So I completely agree, Greg, that we're going to continue to see advancements in that area, both within the US, as well as in other countries.

[00:33:23] Greg Bodulovic: Oh, absolutely. And I think that we'll have to wait and see what comes next in terms of the technology. At the moment we're in the very early stages of the telehealth revolution, if you want to call it that, and I'm excited to see what the next five, 10 years bring in terms of improved technology for the facilitation of telehealth a

[00:33:53] Kristi Kung: I agree, and I think globalism, with respect to telemedicine, is also very interesting and how we're going to be able to adapt to cross border services in the healthcare and life sciences space, particularly through the telecommunications technology.

[00:34:20] Greg Bodulovic: Absolutely. I think that'll be one of the key challenges. What would a podcast be without a plug?

[00:34:28] So I'm going to plug our Going Global Guide to Telehealth, which listeners can access at www.DLAPiperintelligence.com/telehealth. And that guide, which Kristi and I worked on, provides information about the regulation of telehealth in over 45 countries and enables comparisons to be made, between countries .

[00:35:03] Kristi Kung: Well, thank you, Greg. And thank you for everyone who's tuned in, and we're all looking forward to seeing where digital health takes us in the future.

[00:35:11] Greg Bodulovic: Thank you, Kristi, always a pleasure, and thank you for listening.