
TELEMEDICINE IN NZ AND ACROSS BORDERS - THE LEGAL CHALLENGES

A supplementary paper for a seminar presented at the Conferenz Medical Law Conference July 2015 - Holly Hedley, Senior Solicitor, Buddle Findlay.¹

Introduction

Communication technologies can be used to facilitate a wide range of interactions between patients and their health care providers. The use of such technology is broadly known as 'telehealth', or in the case of the practice of medicine (as is the focus in this paper), as 'telemedicine'.²

The potential benefits of telemedicine are obvious. Telemedicine can reduce the overall cost of health care delivery and increase accessibility. For a country like New Zealand, where resources are in short supply and rural communities are common, telemedicine has real potential.

The idea of telemedicine is not particularly new. The World Health Organisation has actively promoted the use of telemedicine since 1997³ and New Zealand first joined the Australia Telehealth Committee in 1998.⁴ However, the use of telemedicine in New Zealand is still relatively modest. In 2014, the New Zealand Telehealth Forum's stocktake on the use of telehealth in District Health Boards said: "*Progress is certainly being made, but we have a long way to go to realise the full potential for telehealth technologies ...*".⁵

As is often the case with emerging technologies, one of the barriers to the uptake of telemedicine is uncertainty about potential legal implications. This particularly so in the case of international telemedicine, where practitioner and patient are separated by international borders.

The purpose of this paper is to discuss some of the legal challenges that arise in telemedicine. In particular, this paper will focus on the regulation of telemedicine in New Zealand and on the legal framework that may apply when things go wrong. The paper will also touch on the more complex legal challenges that arise in international telemedicine. Finally, the paper will provide brief guidance on steps that providers may take to help mitigate risk when implementing telemedicine initiatives. These issues are of course complex. This paper does not attempt to capture them all or to provide certain answers.

¹ The content in this paper is based in part on a dissertation written in 2008, see: H. Hedley '*Doctoring in the digital age: a discussion of potential regulatory solutions for international telemedicine in New Zealand*', published in the Otago Yearbook of Legal Research (OYLR) 2009. Available online at <http://www.otago.ac.nz/law/research/journals/otago036807.html>.

² This paper focusses only on the regulation of medical practitioners (i.e. doctors) but for the most part the same principles can be applied for other health practitioners.

³ See the World Health Organisation Press Release '*Telehealth and Telemedicine will henceforth be part of the strategy for Health-for-All*' (World Health Organization, 1997) as cited by D. Crolla in '*Cyberlaw: A Potent New Medicine for Health Law on the Internet*' at pg 5 in Callens (Ed) '*E-Health and the Law*' (Kluwer Law International Publishers, The Hague and the International Bar Association, 2003)).

⁴ See the discussion in K. Kerr & T. Norris '*A review of telehealth and its relevance to New Zealand*' (Revised ed, University of Auckland, 2004) at pg 12.

⁵ See P. Kerr (Principal Consultant, NZ Telehealth Forum) '*NZ Telehealth Forum Stocktake – Phase 1 DHBs*', August 2014 at pg 7. Available online at <http://healthitboard.health.govt.nz/health-it-groups/new-zealand-telehealth-forum/telehealth-resources-and-case-studies>

Rather, the goal of this paper is to encourage further discussion. The secret to getting ahead is, after all, getting started.

The legal framework

In very broad terms, the practice of medicine in New Zealand is regulated in three main ways.⁶ First, registered practitioners are regulated by the Health Practitioners Competence Assurance Act 2003 ("HPCA Act"). Second, the provision of health and disability services is regulated by the Office of the Health and Disability Commissioner ("the HDC") through the Code of Patient Rights.⁷ Finally, the use of medicines is regulated by the Medicines Act 1981 and associated regulations (referred to in this paper as "the medicines legislation").⁸ Unlike in other countries, civil liability does not provide much of a form of regulation for the practice of medicine in New Zealand. This is of course because of our unique statutory bar on civil claims for personal injury (s 317 of the Accident Compensation Act ("ACC") 2001).

THE HPCA ACT – APPLICATION TO DOMESTIC TELEMEDICINE

The purpose of the HPCA Act is to "*protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions*".⁹ The Act regulates a number of different professions under one common regime. Each profession has a specific registration authority. For medical practitioners (doctors), the relevant registration authority is the Medical Council of New Zealand ("MCNZ").

Importantly, the HPCA Act sets out a certification rather than licensing regime. This means that the HPCA Act does not prohibit unregistered persons from providing health services. Rather, the HPCA Act simply makes it an offence for unregistered people to hold themselves out as registered health practitioners.¹⁰ However, once a person is registered under the HPCA Act then they must meet the requirements set out in the Act when they are practising their profession. Failure to do so may result in professional discipline through the Health Practitioners Disciplinary Tribunal ("HPDT").

There is little doubt that the provision of medical services via communication technologies would fall within the MCNZ's definition of the 'practice of medicine'. The definition is broad and contains no limitations based on the location of the patient or the medium by which services are provided.¹¹ Accordingly, the requirements in the HPCA Act (and the professional standards set out by the MCNZ) will apply to registered medical practitioners who practice 'domestic' telemedicine within New Zealand.¹²

⁶ There are of course many other rules and regulations that apply to the practice of medicine more generally but that are not discussed in this paper. Among other things, this includes the rules imposed by the Privacy Act 1993 and the Health Information Privacy Code 1994, the Crimes Act 1961 and, the Health Act 1956.

⁷ The Health and Disability (Code of Health and Disability Services Consumers' Rights) Regulations 1996.

⁸ There are a number of regulations under the Medicines Act, but the Medicines Regulations 1984 are the most detailed and most relevant for telemedicine. It is also worth noting that the Misuse of Drugs Act 1975 and its regulations also set out special requirements for controlled drugs. These requirements are not addressed in this paper.

⁹ Section 3.

¹⁰ See s 7 of the HPCA Act for further detail. Note that there are also some 'restricted activities' that only registered practitioners are lawfully entitled to perform (see s 9 of the HPCA Act and the specified list of restricted activities set out in the Health Practitioners Competence Assurance (Restricted Activities) Order 2005). For more information see: <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/restricted-activities-under-act>.

¹¹ It includes "*assessing, diagnosing, treating, reporting or giving advice in a medical capacity, using the knowledge, skills, attitudes and competence initially attained for the MB ChB degree (or equivalent) and built upon in postgraduate and continuing medical education (CME), wherever there could be an issue of public safety*". See the definition online at <https://www.mcnz.org.nz/news-and-publications/definitions/>.

¹² For telemedicine, there are a number of standards that may be relevant, but in particular see the MCNZ's 'Statement on Telehealth' (July 2013) and 'Statement on use of the internet and electronic communication' (July 2013). For a full list of the MCNZ's statements and standards see <https://www.mcnz.org.nz/news-and-publications/statements-standards-for-doctors/>. Note that there is no direct statutory requirement for registered practitioners to adhere to the standards of the MCNZ, however both the HPDT and the HDC will use the MCNZ's publications to gauge what is appropriate professional conduct

THE CODE OF PATIENT RIGHTS AND THE HDC – APPLICATION TO DOMESTIC TELEMEDICINE

Any person providing telemedicine services within New Zealand will be a provider of health or disability services and will, therefore, be subject to the obligations set out in the Code of Patient Rights.¹³ This obligation will apply regardless of whether the provider is a registered practitioner under the HPCA Act.

The particular rights that may be in issue in a telemedicine situation will of course depend on each case. However, some of the more relevant rights in the telemedicine context are likely to be:

Right 4 - the right to services of an appropriate standard

In order to assess a provider's compliance with this right the HDC may (among other things) look to professional guidelines and standards (see right 4(2)). In the telemedicine context this means that the MCNZ's statements (in particular the Statement on Telehealth)¹⁴ will be particularly relevant. Equally, the technical standards that apply to the information systems or technology used (such as those issued by the Health Information Standards Organisation) will be relevant, as will any standards and expectations set down by the various professional colleges.¹⁵

Right 4(4) of the Code also includes the right to have services "*provided in a manner that minimises the potential harm to [a consumer]*" and it is quite likely that any issues to do with the quality or suitability of the technology and equipment used in the telemedicine context would be considered by the HDC under this heading.¹⁶

Right 5 – the right to effective communication

Obviously, ensuring that there is effective communication between the patient and the telemedicine provider will be a critical part of providing a quality telemedicine service. Among other things, telemedicine providers will have to consider and uphold the patient's right "*to an environment that enables both consumer and provider to communicate openly, honestly and effectively*" (right 5(2)).

Right 6 – the right to be fully informed

As with any health services, telemedicine providers will have to ensure that their patients are provided with the information that "*a reasonable consumer, in that consumer's circumstances would expect to receive*" (right 6(1)). In the telemedicine context this could include, for example; information about the limitations or risks of the telemedicine service and technology or (where relevant), information about alternative service options.¹⁷

Right 7 – the right to make an informed choice and give informed consent

The ever important right to informed consent is just as relevant in the telemedicine setting. Patients must give their informed consent before receiving telemedicine services (and they have the right to refuse to consent).

¹³ See the definition of 'provider' in cl 4 of the Code of Patient Rights and 'health services' within the Health and Disability Commissioner Act 1994. The author could not find any HDC opinions that deal directly with the issue of telemedicine but the HDC has publically stated that the Code applies to health services provided over the internet (see <http://www.hdc.org.nz/publications/other-publications-from-hdc/media-releases/code-applies-to-internet>).

¹⁴ See n 12 above.

¹⁵ For a useful list of some of the professional standards that may apply see <http://www.telehealth.co.nz/resources/standards>.

¹⁶ The HDC has previously considered complaints involving lost or delayed referrals and has found that providers have a duty to "*have robust systems for managing referrals so the referred patients do not fall through cracks in the system*". For further discussion on this issue see "*Referrals trip up GPs and DHBs*" an article published by the HDC in New Zealand Doctor Magazine in October 2012 (and available on the HDC's website at: <http://www.hdc.org.nz/publications/other-publications-from-hdc/articles/2012/referrals-trip-up-gps-and-dhbs>).

¹⁷ The HDC's decision in 08HDC20258 (an opinion relating to the use of robotic technology during surgery) provides an indication of the type of approach that the HDC may take in this regard.

THE MEDICINES LEGISLATION

The Medicines Act 1981 and the various regulations that sit beneath this Act¹⁸ govern the manufacture, sale, and supply of medicines and medical devices within New Zealand. Of particular significance in a telemedicine context are the various restrictions and controls on prescription medicines. These include, among other things, the requirement in regulation 39 of the Medicines Regulations 1984 for a patient to be "under the [authorised prescriber's] care" before the prescriber can lawfully prescribe prescription medicines. For further discussion on this requirement and its particular application to telemedicine, see the "Ink" case study that follows at the end of this paper.

What if things go wrong?

The section above sets out the broad legal framework for telemedicine within New Zealand. So, applying that framework, if something goes wrong during the provision of telemedicine services within New Zealand, then:

- The provider will be subject to the Code of Patient Rights and may be investigated by the HDC.¹⁹ The HDC may publish their investigation findings (including, if applicable, publishing their opinion that there was a breach of the Code). The HDC may also make recommendations.
- An investigation by the HDC may also lead to proceedings being brought against the provider in the Human Rights Review Tribunal ("HRRT"). If the HRRT finds that there has been a breach of the Code, then the HRRT has a range of powers, including the ability to award damages.
- If the practitioner is a registered health practitioner under the HPCA Act then they may also be subject to investigation by their relevant registration authority. This could result in professional discipline by the HPDT. If the HPDT makes an adverse finding then they have a range of disciplinary options open to them, including suspending the practitioner or striking them off the register.
- If the practitioner is dealing in medicines then the various requirements in the medicines legislation will apply. If the relevant provisions are not adhered to then prosecution for a breach of the medicines legislation could well follow.
- As mentioned above, the chances of a civil action for personal injury being brought against a telemedicine provider are slim. This is because s 317 of the ACC Act bars proceedings for damages for personal injuries covered by the Act. Although a detailed analysis of this issue is outside of the scope of this paper, it seems at least possible that a physical injury caused as a result of the provision of telemedicine services *within* New Zealand would be covered as a treatment injury under the ACC Act. The definition of 'treatment' in s 32 is broad and includes "*the failure of any equipment, device, or tool used as part of the treatment process...*").

¹⁸ See n 8 above.

¹⁹ The HDC has a wide range of powers available to them, including less formal resolution options such as referring the matter to advocacy or mediation or, conducting an investigation.

What about international telemedicine?

The sections above have discussed the legal framework for domestic telemedicine. But telemedicine can equally be used in an international context, where practitioner and patient are separated by international borders.

Arguably, the potential benefits of telemedicine are increased in this international context. International telemedicine provides all the same advantages as domestic telemedicine, but with access to a much larger, international pool of practitioners 24 hours a day.

The use of international telemedicine in New Zealand is not as far-fetched as it first may seem. There are several examples of international telemedicine having been used in New Zealand hospitals²⁰ and the MCNZ has had a special purpose scope of practice for international teleradiology since 2010. In addition, there is a plethora of 'cyber-doctor' websites where international practitioners can provide medical advice to New Zealand based patients.²¹

So, given the potential for good and the increasing use of international telemedicine in New Zealand – what is the legal and regulatory framework that applies in these circumstances?

THE REGULATORY AND LEGAL FRAMEWORK FOR INTERNATIONAL TELEMEDICINE IN NEW ZEALAND

Aside from the MCNZ's special purpose scope of practice for teleradiology (which is discussed below), there is no specific form of regulation for international telemedicine in New Zealand. In some circumstances, particularly where there is a New Zealand based practitioner, it is possible that New Zealand's usual forms of 'domestic' regulation would apply, because the practitioner's conduct will have (at least arguably) occurred within New Zealand.²²

However, things become much more complex when internationally based practitioners are considered. To start, there is the 'territoriality principle' which presumes (in the absence of direct statements to the contrary) that New Zealand's statutes apply *only* to acts and people that are within New Zealand.²³ Further, even if this principle could be rebutted,²⁴ there is the obvious practical difficulty of enforcement. Short of extradition (which is highly unlikely in all but the most serious of cases)²⁵ there is no clear process by which New Zealand's regulatory entities such as the HDC or MCNZ could enforce their legislative regime against international practitioners thousands of miles away.

Civil liability too would have its challenges. First, there is the obvious question of whether our statutory bar would apply. Should the ACC regime cover injuries suffered by New Zealand patients as a result of the advice or actions of international practitioners? At first glance the answer to this question is quite

²⁰ While international telemedicine is far from mainstream in New Zealand, there are examples of its use. For example see NZ Doctor, V.McMillan 'Long Distance Stroke Care' 19 February 2013 available at <http://www.nzdoctor.co.nz/news/2013/february-2013/19/long-distance-stroke-care.aspx>. See also E. Watt 'Abortion Blunder as Scan Misread', Dominion Post 23 April 2009, available at <http://www.stuff.co.nz/national/health/2367688/Abortion-blunder-as-scan-misread>.

²¹ In fact, as the price of medical care increases and internet accessibility is more common, use of cyber-doctor sites is growing. In fact, in an internet usage survey in 2009, Telecom New Zealand reported that '...well over a third of those surveyed...had sought medical advice from the array of internet-based resources available today rather than visiting their GP' - results from the 2009 NetGuide Telecom Broadband Survey, see Telecom Media Release 'Kiwis going online for medical diagnosis' 18 August 2009.

²² There is discussion on this point in the case of *Ink Media Limited and Ors v Ministry of Health* (HC Hamilton, CRI-2006-419-67, 22 August 2007). This case will be discussed further in the seminar.

²³ D. Greenberg (Ed) "Craies on legislation: a practitioners' guide to the nature, process, effect and interpretation of legislation" (9th Ed, Sweet and Maxwell, 2008). For criminal provisions see also ss 6 and 7 of the Crimes Act 1961, however note the High Court's interpretation of these sections in the decision of *Ink Media Limited and ors v Ministry of Health* (HC Hamilton, CRI-2006-419-67, 22 August 2007) – this case is particularly relevant for telemedicine and will be discussed further in the seminar.

²⁴ Ibid at pg 456.

²⁵ Under the current law New Zealand will only request surrender of a citizen for 'extradition offences', defined as "offences that are punishable by a maximum penalty of not less than 12 months imprisonment or any more severe penalty..." (S 4 (1)(b) The Extradition Act 1999).

possibly yes as cover under s 20 of the ACC Act applies to "*personal injuries suffered in New Zealand*". However, on a closer look the answer is not as straight forward, as cover for treatment injuries is generally limited to injuries that are suffered by persons receiving treatment from practitioners who are registered under the HPCA Act.²⁶ As for the opposite scenario – it seems very likely that New Zealand based practitioners are at risk of civil liability if their conduct causes an injury to an internationally based patient.

Further, even with the issues relating to our statutory bar aside, there is uncertainty as to the legal framework that would apply in a civil action. The most basic legal questions such as which court should have jurisdiction and which country's law to apply would need to be tested.²⁷ There is also uncertainty about the substantive legal issues. For example, in a tort action for personal injury what is the appropriate standard of care for telemedicine practitioners? Or, in a contract action, where and when was the contract actually made?²⁸

THE MCNZ'S SPECIAL PURPOSE (TELERADIOLOGY) SCOPE OF PRACTICE

Although there is still a great deal of uncertainty about the legal framework for international telemedicine in New Zealand, there is one area where proactive steps have been taken. This is within international teleradiology, where the MCNZ has designed and implemented a special purpose scope of practice under the HPCA. Broadly, the MCNZ's special purpose (teleradiology) scope of practice allows internationally based radiologists to register with the MCNZ under the HPCA Act to provide international teleradiology services to New Zealand based patients.

In order to register in the special scope, the practitioner has to meet a number of requirements. In addition to holding the necessary qualifications, the practitioner must be employed by an overseas facility that has a contract with a New Zealand health provider. They must also be fully credentialed and supervised by that New Zealand provider.

The MCNZ also imposes requirements on the New Zealand provider, including a requirement that the provider has a robust dispute resolution process. Among other things, the MCNZ expects:

- A requirement that automatic notification is given to the relevant authorities in New Zealand *and* in the practitioner's home country if a complaint is received; and
- An agreement to fund the practitioner to travel to New Zealand if an investigation is necessary.

The idea behind these requirements is ensure that any complaints about the international practitioner are able to be dealt with fairly, simply and efficiently. The requirements also give the MCNZ a practical mechanism that allows a degree of control and oversight over the overseas practitioner.

Unfortunately, while the special purpose scope of practice was introduced in 2010 it has not been widely used, and in December 2013 the MCNZ considered withdrawing it. However, after consultation, the MCNZ decided to maintain the scope, but with further consultation planned "*to identify ways in which to make the ... scope of practice more efficient, without detracting from the rigour of the process*".²⁹ The

²⁶ See the definition of 'treatment injury' at s 32 and the definitions of 'health professional' and 'medical practitioner' at s 6.

²⁷ If the plaintiff can bring a case (outside of the statutory bar) the rules of private international law determine which law to apply. There are a number of conflicting rules in private international law that could all apply in a telemedicine scenario, analysis of which could be a dissertation in itself. For discussion of the New Zealand approach to private international law see M. Pawson '*Conflicts of Laws: Choice of Law*' in W. Young (Ed) '*Conflicts of Law*' (Lexis Nexis The Laws of New Zealand) (online database last updated May 2015). For a discussion of conflicts of laws in telemedicine and the American context see J. Kelly Barnes '*Telemedicine: A conflict of laws problem waiting to happen – How will interstate and international claims be decided?*' (2006) 28 Houston Journal of International Law 499.

²⁸ For a discussion on the substantive legal issues that would arise in a telemedicine scenario see Kelly Barnes, above n 27; P. G. Gulick '*The Development of a Global is Closer than we think: An examination of the international implications of telemedicine and the developments, uses and problems facing international telemedicine programmes*' (2004) 11 Indiana International and Comparative Law Review 184-213.

²⁹ See the MNCZ News 15 February 2015 available online at <https://www.mcnz.org.nz/news-and-publications/media-releases/outcome-of-council-s-consultation-on-withdrawal-of-the-special-purpose-teleradiology-scope-of-practice/>

MCNZ also resolved to undertake further research in telehealth to help develop its approach in this area in the future.

The MCNZ should be applauded for recognising the need for some form of regulation of international telemedicine and for making a start with the special purpose scope. The question for future debate is how the MCNZ and the other New Zealand bodies who are tasked with safeguarding and regulating the practice of medicine in New Zealand can develop a form of regulation that strikes the right balance. The aim (and the challenge) is finding a form of regulation that both encourages and fosters innovation whilst still providing sufficient protection to the New Zealand public.

So what can you do?

Although the law remains unclear in many areas, there are steps that practitioners and organisations can take when implementing telemedicine initiatives. In addition to undertaking the usual due diligence processes (and seeking legal advice where necessary), providers should:

- **Contract well** - this means having contractual arrangements that clearly articulate each party's responsibilities. In addition to the practical issues (such as insurance cover, indemnities, liability and dispute resolution processes) a wide range of more specialist issues may also need addressing, such as IT and intellectual property. Telemedicine contracts can be complex, and for that reason, legal advice is always recommended.
- **Monitor and review** - as with any new service, providers need to consider how they will monitor and review the quality of the services that are provided. In this regard, the various supervision and credentialing requirements set out in MCNZ's special scope of practice may provide a useful starting point.
- **Know and apply the relevant standards** - the relevant professional standards and guidelines will be relevant and should be researched, considered and applied.
- **Work hand in hand with the MCNZ** (and other relevant authorities) - don't be afraid to ask if you are unsure about what a registration authority (or other agency) expects in a telemedicine context.
- **Remember the basics** -all of the usual medico-legal considerations apply when you are providing telemedicine services. So don't forget about the basics, including upholding the ten core rights under the Code of Patient Rights.

Questions? Please contact

HOLLY HEDLEY

Senior Solicitor
DDI: 64 4 462 0925

holly.hedley@buddlefindlay.com

This article is dated July 2015. It is provided for general information purposes only and not as legal advice.

To subscribe to our health sector legal updates - <http://www.buddlefindlay.com/subscribe-to-legal-updates>

PRESCRIBING MEDICINES VIA TELEMEDICINE - A CASE STUDY

The meaning of the phrase "under the care" in regulation 39 of the Medicines Regulations was the subject of discussion in one of New Zealand's only 'telehealth' cases so far: *Ministry of Health v Ink Electronic Media Ltd and ors* (HC Hamilton, CRI2004-419-000084, 18 August 2004).*

In this case the defendants were involved in a scheme exporting prescription medicines to overseas customers via the internet. The Ministry of Health prosecuted the defendants for a range of offences under the medicines legislation. Among other things, the Court in *Ink* had to consider whether the phrase "under the care" required a 'face to face' consultation with the patient (as had been suggested by the MCNZ's guidelines at that time). Ultimately, the Court concluded that there was no absolute requirement for a face to face consultation. However, in order to comply with regulation 39 there did have to be (as a minimum):

- Some information given about the patient to the doctor.
- An acknowledgement by the patient that the doctor is his or her medical adviser for this purpose.
- An acceptance of responsibility by the doctor for treating the patient for the condition referred to.

It is important to note at this point that there is a difference between what is required to meet the medicines legislation (which is what was at issue in *Ink*) and what is more generally expected as a matter of appropriate professional practice. In terms of professional standards, the MCNZ has specifically addressed the issue of prescribing medicines via telemedicine in their "Statement on Telehealth" (June 2013). This statement says:

*Before issuing a prescription for any medicine you should have a face-to-face consultation with the patient or, in the absence of a face-to-face consultation, discuss the patient's treatment with another New Zealand registered health practitioner who can verify the patient's physical data and identity**.*

These guidelines set a benchmark for good practice. Registered medical practitioners who fail to comply with the guidelines could be subject to disciplinary action (even if their actions would not necessarily breach the relevant medicines legislation).

*This case has a very complex history with various appeals and cross appeals arising out the same set of circumstances. For a full discussion of the background see: CRI-2006-419-67, 22 August 2007. ** There are a few exceptions to this general rule listed in the statement – see the full text online at: <https://www.mcnz.org.nz/news-and-publications/statements-standards-for-doctors/>

