
**DOCTORING IN THE DIGITAL AGE: A DISCUSSION OF POTENTIAL REGULATORY SOLUTIONS
FOR INTERNATIONAL TELEMEDICINE IN NEW ZEALAND**

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To my Mum and Dad, for being with me on the long uphill and because even if you weren't my family, I would still choose you.

...

Ma Te Mahi Ka Ora

...

‘The human body is the same throughout the world, laws are different. I see no reason why a good licensed physician cannot consult on patients anywhere in the world. I see many reasons why bad physicians should practice nowhere...’¹

¹ J. M. Kearney “Telemedicine: Ringing in a New Era of Health Care Delivery” (1997) 5 CommLaw Conspectus 289-301 quoting J. C. Stern M. D., Assistant Professor, Director, Head and Neck Service, Department of Otolaryngology, The New York Eye and Ear Infirmary.

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INTRODUCTION

With the rapid advancement of the internet in the past decade, health care has undergone a revolution. It is now possible for doctors to have direct, real-time, video and audio ‘teleconsultations’ with patients on the other side of the globe. The internet has created a whole new market for ‘international telemedicine’, the provision of health care services across international borders.

International telemedicine is set to revolutionise health care. The potential benefits of international telemedicine are obvious. International telemedicine can reduce the overall costs of health care delivery and increase accessibility to health services. For a country like New Zealand, where health resources and practitioners are in short supply, international telemedicine could clearly provide substantial benefits.

However, the provision of medical treatment across international boundaries also magnifies potential dangers. Keeping patients safe and practitioners honest in the ‘wild wild west’² of cyberspace is a significant challenge for policy makers and regulators world -wide.

This dissertation will explore international telemedicine in the New Zealand context. The aim of this dissertation is to identify and evaluate potential regulatory solutions for the practice of international telemedicine in New Zealand.

This dissertation will be divided into three chapters. Chapter I will set the topic of international telemedicine in context. After defining and explaining central concepts, the chapter will focus on the particular benefits that international telemedicine could bring to New Zealand. The chapter will then set out rationales for the need to regulate international telemedicine in New Zealand. Finally, to provide a comprehensive foundation on which to analyse regulatory solutions, chapter I will consider the wider implications of the introduction of international telemedicine in New Zealand.

Chapter II will then consider a range of potential mechanisms for the regulation of international telemedicine in New Zealand. Seven regulatory mechanisms will be identified as providing possible solutions. Each mechanism will be described in detail and analysed as a potential regulatory solution for international telemedicine in New Zealand.

² G. Gulick “E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, And Organizational Obstacles” (2002) 12 Albany Law Journal of Science and Technology 404.

Finally, chapter III will bring the dissertation to a conclusion by identifying the best next steps for the regulation of international telemedicine in New Zealand. The chapter will begin by summarising the regulatory goals for international telemedicine and reviewing the strengths and weaknesses of each potential regulatory mechanism in relation to those goals. From a close evaluation of each proposed regulatory mechanism, the chapter will come to the conclusion that an international licensure system is the solution that comes closest to providing an ideal solution. The dissertation will conclude with a summary of recommendations for the successful regulation of international telemedicine in New Zealand.

CHAPTER I. STARTING OUT: INTERNATIONAL TELEMEDICINE AND REGULATION IN THE NEW ZEALAND CONTEXT

The purpose of this opening chapter is to set this dissertation in context. As well as defining central concepts, this chapter will explain why the regulation of international telemedicine is needed in New Zealand. Chapter I will then emphasise the wide range of potential implications of international telemedicine that may be relevant to the regulation of international telemedicine in New Zealand.

1.1 Setting the Scene: International Telemedicine in New Zealand

Telemedicine may be defined as ‘the use of telecommunications for medical diagnosis and patient care’.³ In its most simple form, telemedicine is not new. Telephones and other devices have been used in health care for many years.⁴ With the increasing capabilities of internet technology, however, telemedicine has undergone a revolution.⁵ With new satellite and fibre-optic technologies, practitioners can have direct and instantaneous ‘teleconsultations’ with patients anywhere in the world, regardless of geographical borders.⁶

Examples of telemedicine are wide ranging. Telemedicine can be as simple as distant practitioners providing medical advice in response to patient questions (teleconsultations) or as complex as telesurgery, where surgeons use robotic surgical devices to operate from distance.⁷ Currently, two of the most common forms of telemedicine are teleradiology⁸ and teledermatology⁹, where specialist practitioners diagnose and treat patients from electronically transmitted computer images.

³ B. Stanberry “Telemedicine: barriers and opportunities in the 21st century” (2000) 247 *Journal of Internal Medicine* 615-628.

⁴ As early as 1910 the analogue telephone was used to transmit electrocardiograms and in 1920 there was a medical service for seafarers using morse code (Ibid, pg 616).

⁵ To distinguish the use of the *internet* to provide medical advice and treatment (as opposed to other communications technologies) some commentators have called internet mediated telemedicine ‘e-medicine’ or ‘cyber-medicine’ (see for example, C. E. Lewis “My Computer, My Doctor: A Constitutional Call for Federal Regulation of Cyber-medicine” (2006) 32 *American Journal of Law and Medicine* 585-609). However for the sake of simplicity this article will use the broader phrase ‘telemedicine’ to refer to internet mediated medical care.

⁶ B. Stanberry *The Legal and Ethical Aspects of Telemedicine* (Royal Society of Medicine Press Ltd, 1998) at pg 1.

⁷ The technology for international telesurgery currently exists although the practise is not yet main stream. For a discussion on telesurgery see T. R. McLean, P. B. McLean & A. B. McLean “Have a surgical robot, why not provide cyber-surgery?” (2008) 5 (2) *Expert Review of Medical Devices* 103-108.

⁸ Teleradiology is the most economically and practically viable form of international telemedicine for two main reasons. First, because there is very little difference between ‘reading’ a digital image on-site and ‘reading’ the same digital image from kilometres away. Secondly, the technology required to set up a teleradiology system

Telemedicine in New Zealand

Many New Zealanders live in rural areas where access to medical care is limited.¹⁰ Like many other countries in the world, New Zealand has a shortage of medical practitioners, particularly specialists.¹¹ Access to quality care is therefore limited, waiting lists are long and travel is often necessary.

The focus of health care in New Zealand is also shifting. In recent years concentration has moved away from tertiary institutions and more to primary care and prevention.¹² Additionally, health demands are evolving with New Zealand's changing demographics. New Zealand has an ageing population¹³ and an increase in chronic disease.¹⁴

With these factors in common, it is clear that New Zealand is in an ideal position to improve its health care services using telemedicine. Telemedicine increases accessibility to medical services and is well suited to primary and preventative care. The elderly and those suffering from chronic illness would clearly benefit from reduced travel for medical consultation and, of course, every patient in New Zealand would benefit from increased accessibility to practitioners.

is minimal and cost effective. For further discussion see T. R. McLean & E. P. Richards "Teleradiology: A case study of the economic and legal considerations in international trade in telemedicine" (2006) 25 *Health Affairs* 1378-1385.

⁹For further discussion on teledermatology see A.W. Darkins & M. A. Cary *Telemedicine and Telehealth, Principles, Policies, Performance and Pitfalls* (Springer Publishing Company, 2000) at pgs 105-113.

¹⁰ According to statistics from the 2001 New Zealand census, 28.9% of New Zealand's population (or just more than one in four New Zealanders) live a 'rural area'. For exact statistics and definitions of 'rural' areas, see <<http://www.stats.govt.nz>>. For further discussion on New Zealand population demographics in relation to telemedicine see A. C. Patel "Telehealth in Maine, USA : a model for New Zealand? a thesis submitted for the degree of Master of Public Health" (2003) The University of Otago at pg 22.

¹¹ For a discussion on New Zealand's practitioner shortages see Medical Training Board, *The Future of the Medical Workforce: Discussion paper* (Ministry of Health, Wellington, 2008) at pg 12, available online at <<http://www.moh.govt.nz>>, last retrieved 28/09/09.

¹² The New Zealand Primary Health Care Strategy was first published in 2001 to focus primary health development. See The Ministry of Health *The New Zealand Primary Health Care Strategy* (Ministry of Health, Wellington, 2001) available at <<http://www.moh.govt.nz>> last retrieved 28/09/09. See also 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.

¹³ For a discussion on New Zealand's ageing population see J. Cornwall & J. Davey *Impact of Population Ageing in New Zealand on the Demand for Health and Disability Support services, and Workforce Implications. A background paper completed for the Ministry of Health in June 2003 by the New Zealand Institute for Research on Ageing and the Health Services Research Centre* (Victoria University of Wellington, Wellington, Ministry of Health, 2004). This paper also briefly discusses the potential role for telemedicine in care for the ageing at pg 75 and is available at <<http://www.moh.govt.nz>> last retrieved 28/09/09.

¹⁴ For a discussion on chronic disease in New Zealand see, National Health Committee *Meeting the Needs of People with Chronic Conditions*. (National Health Committee, Wellington, 2007) at chapter 2, available at <<http://www.moh.govt.nz>> last retrieved 28/09/09.

The potential benefits of telemedicine for New Zealand have been recognised at high levels,¹⁵ and as a result 'inter-country' (local) telemedicine has been slowly but surely growing in New Zealand. In a review in 2004, 22 'inter-country' telemedicine programmes were identified.¹⁶ A current example is the West Coast Telemedicine service. This service allows isolated West Coasters to consult doctors at Grey Hospital from a local primary care centre in Westport 100 kilometres away. This telemedicine service provides video teleconsultations for after-hours emergency care and scheduled outpatient clinics for pre-operative and post-operative surgical assessments.¹⁷

Another well established telemedicine service is the telepaediatric service centred at Auckland's Starship hospital. This programme links all specialist tertiary and secondary child health care centres nationwide for education and teleconsultation purposes.¹⁸ These two examples clearly show that telemedicine is increasingly becoming accepted as a beneficial and legitimate health care service within New Zealand.

International telemedicine in New Zealand

International telemedicine involves the provision of health services via communication technology across international borders.

The benefits of telemedicine are increased in an international context. International telemedicine has all the advantages of local telemedicine, but patients have access to a larger, international pool of practitioners 24 hours a day. For a small, isolated country like New Zealand with a national shortage of practitioners, international telemedicine could clearly provide substantial benefits.¹⁹

¹⁵ For example in the Ministry of Health's Statement of Intent for 2008-2011 the Ministry recognised the importance of improving internet connectivity between District Health Boards to allow for the benefits of telemedicine, see Ministry of Health *Statement of Intent: 2008-2011*. (Ministry of Health, Wellington, 2008) at pg 4. The Health and Disability too has recognised the benefits of telemedicine technologies. In a letter to the Chief Executive of the Medical Council of New Zealand, the Commissioner stated '*I recognise that improvements in technology and communication create opportunities for consumers in New Zealand to receive quality and timely health services from an accessible overseas workforce...*' a copy of this letter is available at <<http://www.hdc.org.nz/files/hdc/publications/mcnz-teleradiology.pdf>> last retrieved 28/09/09.

¹⁶ Kerr & Norris, above n 12.

¹⁷ The West Coast telemedicine service also uses 'Health Presence technology' to allow the distant practitioner to interface with diagnostic equipment such as stethoscopes and to monitor vital signs (measuring blood pressure, temperature and pulse rate). For more information see <<http://www.digitalstrategy.govt.nz>>, last retrieved 28/09/09.

¹⁸ For more information see <<http://www.telepaeds.co.nz/>> last accessed 28/09/09.

¹⁹ The Health and Disability Commissioner has recognised the potential benefits of international telemedicine in New Zealand, see above n 15. The potential benefits of international telemedicine have also been long recognised world-wide. The World Health Organisation has actively promoted telemedicine as a tool for improving world health since 1997 (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

The practice of international telemedicine has not been discussed in any national governmental health policy.²⁰ However, international telemedicine does have a presence in New Zealand. As well as international teleradiology being used in New Zealand hospitals,²¹ there is also a plethora of ‘cyber-doctor’ medical advice sites that offer medical advice to New Zealand patients via instant messaging or video consultation.²²

As prices of medical care increase and internet accessibility becomes more common,²³ use of cyber-doctor sites is growing. In fact, in a recent internet usage survey, 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’.²⁴

However, the potential of international telemedicine for New Zealand is not limited to this type of ‘cyber-doctor’ teleconsultation. Like local telemedicine, international telemedicine has the potential to provide full professional medical services to New Zealand patients. A good example is the international teleradiology service ‘NightHawk’. NightHawk is an American company that hires fully qualified American radiologists to provide teleradiology services to American hospitals. The

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)).

²⁰ Although there is currently no central governmental policy there is an increasing amount of policy from non-governmental medical authorities. This policy growth signals a growing recognition of the current and potential use of international telemedicine in New Zealand. For example, the Medical Council of New Zealand (MCNZ) has had a policy for distance medicine across international borders since 2006, see *MCNZ Statement on the use of the internet and electronic communication* (MCNZ, Wellington, 2006) available at <<http://www.mcnz.org.nz>> last retrieved 28/09/09. The New Zealand Medical Association (NZMA) also has a Position Statement on international telemedicine that sets out policy for international practice, see *NZMA Telemedicine - Position Statement* (NZMA, Wellington, 2008) available at <<http://www.nzma.org.nz>>, last retrieved 28/09/09.

²¹ While international telemedicine is far from main stream in New Zealand, there is some (albeit secondary) evidence of current use of international telemedicine in New Zealand. For example in the NZMA’s position statement (ibid) the NZMA states ‘NZMA is aware that in some instances medical practitioners are utilising the services of doctors based overseas...’. Also see ‘E. Watt (28 April, 2009) “Abortion Blunder as Scan Misread”, *Dominion Post*, last retrieved from <<http://www.stuff.co.nz>>, 27/09/09.

²² While there are currently no New Zealand based cyber doctor sites, multiple international cyber doctor internet sites offer medical advice in exchange for payment in New Zealand dollars (for example see <www.justanswer.com>;<www.simplyanswer.com>, last accessed 28/09/09).

²³ In recent months the New Zealand government has affirmed a \$1.5billion broadband initiative that aims to increase broadband internet access for New Zealand towns. For more information see T. Pullar-Strecker (16 September, 2009) “Govt moving ahead with Broadband Investment Initiative”, *Dominion Post*, last retrieved from <<http://www.stuff.co.nz>> 12/10/2009.

²⁴ Results from the 2009 NetGuide Telecom Broadband Survey, see Telecom Media Release (18 August, 2009) “Kiwis going online for medical diagnosis” available at <**Error! Hyperlink reference not valid.**>, last retrieved 27/09/09.

radiologists are located across the world in an opposite time zone and are able to provide professional, high quality radiology services during the night-shifts of American hospitals.²⁵

Programmes such as NightHawk demonstrate that international telemedicine should not just be dismissed as a fringe service for ‘quack’ practitioners or daring patients. Neither is international telemedicine limited to teleradiology: there are a wide range of potential international telemedicine services, including teledermatology,²⁶ telepathology,²⁷ teleoncology,²⁸ and even, telesurgery.²⁹

Overall, if administered by appropriately qualified practitioners, international telemedicine could provide New Zealand with increased access to international services that are in many cases just as good, and in some cases even better, than traditional face to face consultations.³⁰ The benefits that international telemedicine could bring to New Zealand patients are quite clearly immense.

Currently, the use of international telemedicine is only modest in New Zealand. However, given the substantial benefits that New Zealand could gain from international telemedicine and the increasing economic pressures on health services, the use of international telemedicine in New Zealand is likely to increase. This dissertation will therefore contend that regulation of international telemedicine is required, both to protect those patients already using international telemedicine and to encourage further growth of international telemedicine as a legitimate health service in New Zealand.

1.2 Justifications: Why Regulation of International Telemedicine is needed in New Zealand

²⁵ See <<http://www.nighthawkrad.net/>>; S. Singh & R. Wachter “Perspectives on Medical Outsourcing and Telemedicine – Rough Edges in a Flat World?” (2008) 385(15)The New England Journal of Medicine 1622.

²⁶ There is already an International Society of Teledermatology (see <<http://www.teledermatology-society.org/default.htm>> last accessed 28/09/09) and also an international interactive teledermatology site for teledermatologists to discuss appropriate diagnoses, see <www.telederm.org>, last accessed 28/09/09. For discussion on teledermatology generally see Darkins & Cary, above, n 9.

²⁷ See Darkins & Cary, above, n 9 at pg 93-104.

²⁸ Ibid at pg 127

²⁹ See McLean, McLean & McLean, above, n 7.

³⁰ Reviews on patient satisfaction with telemedicine services have indicated that in some cases patients actually prefer telemedicine to face to face consultation. For a discussion see P. Whitten & B. Love “**Patient and provider satisfaction with the use of telemedicine: Overview and rationale for cautious enthusiasm**” (2005) 51(4) *Journal of Postgraduate Medicine* 294-230.

Regulation may be defined as sustained and focused control over activities that are valued by a community.³¹ Necessarily, regulation involves a degree of restriction on a society's freedoms and as a result, there must be an underlying rationale to justify regulation of that activity.³²

Section 1.1 has contended that there is a need to regulate international telemedicine in New Zealand. The aim of this section is to elaborate on the various rationales that justify the call for regulation of international telemedicine in New Zealand. This section will consider a range of rationales and will conclude that there is strong case for a need to regulate international telemedicine in New Zealand.

Rationale 1: Public Protection

In the context of health care where the consequences of error can be, quite literally, life or death, the protection of public safety is the foremost rationale for regulation.³³

In the faceless world of the internet, the potential for malpractice, fraud and negligent conduct is immense. The provision of medical services across the internet therefore magnifies the potential for serious harm. Consequently, for both current and future applications of international telemedicine in New Zealand, the protection of public safety remains the central and the most compelling rationale for regulation.

Rationale 2: The 'green light': Facilitation of International Telemedicine

In considering the rationales for regulation, the preventative and restrictive 'red light' rationales for regulation often overshadow the potential 'green light' uses of regulation to facilitate and enhance activities for the public good.³⁴

In the context of international telemedicine the 'green light' rationale for regulation, to serve as an 'enabler' for the growth of international telemedicine, is particularly relevant. As discussed above,³⁵ there are immense potential benefits to be gained from international telemedicine. The safe and

³¹ R. Baldwin & M. Cave *Understanding Regulation, Theory, Strategy and Practice* (Oxford University Press, 1999) at pg 2. This dissertation takes a broad view of regulation that incorporates both 'input' and 'output' forms of regulation. Input regulation is what may be thought of as the 'typical' notion of regulation, a proactive form of control such as registration or licensure schemes. Conversely, output regulation is reactive and aims to control the 'output' of the quality of services provided. Common examples of output regulation in the health sector include civil liability and practitioner discipline by professional bodies (T. Epps *Regulation of Health Care Professionals* at pgs 75-78 in J. Downie, T. Caulfield & C. Flood (Eds.) *Canadian Health Law Policy* (Lexis Nexis Canada Inc., 2007)).

³² Epps, above n 31 at pg 70.

³³ Ibid

³⁴ Baldwin & Cave, above n 31 at pg 2.

³⁵ See above, section 1.1.

legitimate use of international telemedicine has the potential to increase the accessibility and decrease the cost of health services for New Zealanders.

Despite the available technology, international telemedicine is yet to bloom in New Zealand. At present, international telemedicine is operating in an uncertain legal and ethical environment that hinders the development of international telemedicine services. Both the health industry and patients are reluctant to fully utilise international telemedicine because of liability, safety and accountability concerns.³⁶

Regulation of international telemedicine would provide legal certainty and commercial order that would encourage the growth of international telemedicine as a legitimate and safe health service for New Zealanders. The 'green light' facilitation rationale of regulation is therefore a strong justification for the regulation of international telemedicine.

Rationale 3: Market Justifications

Protection of public safety and the importance of developing international telemedicine may be seen as the two keystone rationales that justify the call for regulation of international telemedicine in New Zealand.

Additionally, there are a number of 'market failure' rationales that provide further justification for regulation of international telemedicine.

One such rationale is the 'informational asymmetry' between practitioners and patients. Competitive markets cannot function properly without 'consumers' being fully informed and able to evaluate competing services.³⁷ In the 'market' of health services, patients are at a disadvantage because of the highly specialised knowledge of practitioners. Regulation is therefore required to counteract the informational imbalance and prevent failure of the health service market.

Another market rationale that underlies regulation of health services and logically applies to international telemedicine is the 'needs driven' as opposed to 'wants driven' nature of health care utilisation.³⁸ As stated by Drache and Sullivan:

*...health care does not have a line of people clamouring voluntarily for gall bladder surgery; it is driven by need rather than want.*³⁹

³⁶ H. L. Daly "Telemedicine: The Invisible Legal Barriers to the Health Care of the Future" (2000) 9 Annals Health Law at pg 74.

³⁷ Baldwin & Cave, above n 31 at pg 12; Epps above n 31 at pg 70.

³⁸ D. Drache & T. Sullivan in *Health Reform and Market Talk, Rhetoric and Reality* at pg 4 in D. Drache & T. Sullivan (Eds.) *Health Reform, Public Success Private Failure* (Routledge, London, 1999).

Because of the 'needs' nature of much health care, health care services do not trade in the way normal services do. Regulation is therefore justified to prevent failure in the health services market.

Overall, both the needs driven nature of health services and the informational asymmetry between practitioner and patient provide strong market based rationales for the regulation of international telemedicine.

Rationale 4: Social Policy

Finally, linked to the need for regulation of international telemedicine to prevent market failures is a final justification for regulation based on social policy.⁴⁰ Current social policy in New Zealand emphasizes the notion of equity in health services, the idea that all people should be able to access at least a threshold level of health care services, regardless of their means.⁴¹ Regulation of health services, including international telemedicine, is therefore justified on social policy grounds to ensure equity of access to health care services.

Overall

This section has identified a number of justifications for the need to regulate international telemedicine in New Zealand. There are two justifications that may be seen as the 'keystone' rationales for international telemedicine. The first is the need to protect public safety. The second is the need for regulation to facilitate the growth of international telemedicine in New Zealand. Other rationales for regulation of international telemedicine in New Zealand include 'market failure' justifications and the maintenance of equity in health services.

Overall, it is clear that the call for the regulation of international telemedicine services in New Zealand is more than a knee jerk reaction to a new technology. This section has demonstrated that there is a clear and justified need for regulation of international telemedicine in New Zealand.

1.3 The Bigger Picture: Background Considerations for the Regulation of International Telemedicine

International telemedicine is not just a new technology to deliver health services, but has the potential to dramatically change the 'health care market' both in New Zealand and globally.

³⁹ Ibid at pg 5.

⁴⁰ Baldwin & Cave, above n 31 at pg 14.

⁴¹ See The Ministry of Health *The New Zealand Health Strategy* (Ministry of Health, Wellington, 2001) available at <www.moh.govt.nz/publications/nzhs>, last retrieved 01/10/2009.

The aim of this section is to briefly set out the background considerations of international telemedicine that must be taken into account when considering potential regulatory mechanisms for international telemedicine in New Zealand.

Big Business: The International Telemedicine Market

The first factor that must be taken into account when analysing potential regulatory options for international telemedicine is the huge commercial potential of the international telemedicine industry.

Statistics from India show that employment in activities providing cross border health services increased from 30,551 in 2000 to 242,500 in 2005, and revenue rose from US\$264 million to \$4072 million during the same period.⁴² Commentators have even go so far as to label the export of medical expertise from The United States of America as '*one of the most untapped multi-million dollar resources in America*'.⁴³ This enormous commercial potential has not been overlooked elsewhere; Australia, Singapore and Malaysia have all developed aggressive strategies to capture telemedicine markets⁴⁴ and the number of international telemedicine providers worldwide is on the rise.

For those businesses and nations wishing to capitalise on the export value of the telemedicine industry, regulation will be a major concern. The commercial potential of telemedicine is therefore likely to encourage some nations and businesses to lobby for styles of regulation that are conducive to increasing the telemedicine market.

When considering potential regulation controls for international telemedicine the strong commercial undercurrent that underlies international telemedicine must be taken into account.

The Potential for Good: Reducing Health Inequality via International Telemedicine

As well as having enormous potential as a profit making venture, international telemedicine also has potential to change the global health care market for the good of developing nations. There are

⁴² R. D. Smith, R. Chanda & V. Tangcharoensathien "Trade in health-related services" (2009) 373 *The Lancet* (British Ed.) 594, citing at pg D. Singh "Country experiences with GATS and trade in health services: report on cross-border trade (Mode 1). Findings from Indian e-Health Study, Expert ICTs" (2004) Trade and Health Inter-regional Workshop on Trade and Health, New Delhi , Oct 12–13.

⁴³ 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* at pg 499.

⁴⁴ Daly, above n 36 at pg 85

currently major disparities in health status between developed and developing countries. Developing nations are plagued by shortages of finances, of health professionals and also by the poor distribution of health services in rural areas.⁴⁵

International telemedicine has the potential to greatly improve health care in developing nations and could significantly reduce global inequities in health care.⁴⁶ Aside from the obvious benefits of improving access to health services in remote areas and lowering overall costs of the delivery of health services for developing nations, international telemedicine could also improve training and supervision of local practitioners by spreading the wealth of medical knowledge from developed countries.⁴⁷

This potential to improve global health using international telemedicine has to be considered when discussing regulatory mechanisms. The type of regulatory system selected for international telemedicine could influence the potential of international telemedicine for developing countries. Over-rigid regulation would hinder the potential benefits for global health and impair the opportunity to make significant advances in addressing international health inequities. International aid and public health organisations such as the World Health Organisation will therefore be advocating for regulatory options that facilitate the use of international telemedicine to improve global public health.

The potential benefits that international telemedicine could provide for developing countries must be taken into account when considering potential regulatory solutions for international telemedicine in New Zealand, and beyond.

Protection of the Profession: Underlying Self-interests

While the central rationales behind regulation in the health sector as discussed in section 1.3 may be categorised as ‘public interest’, it has long been recognised that regulatory restrictions also provide significant ‘private interest’ benefits to the medical profession by restricting market competition.⁴⁸

These ‘private interests’⁴⁹ should also be borne in mind when considering regulatory options. There will always be a degree of underlying self interest in any regulatory solution proposed by health

⁴⁵ L. B. Mendelsohn “A piece of the puzzle: Telemedicine as an instrument to facilitate the improvement of healthcare in developing countries?” (2004) 18 Emory International Law Review 151-210.

⁴⁶ The World Health Organisation has recognised the potential for telemedicine to improve global health see WHO Press Release, above n 19.

⁴⁷ Mendelsohn, above n 45.

⁴⁸ L. O. Gostin, J. P. Koplan & F. P. Grad *The Law and the Public's Health: The Foundation* at pg 18 in R. A. Goodman, M. A. Rothstein, R. E. Hoffman, W. Lopez & G. W. Matthews (Eds) *Law in Public Health Practice* (Oxford University Press, 2003).

professionals: in all probability, practitioners are likely to be slow to support regulatory options that significantly increase the degree of competition in the health care market.

Further, the preservation of their economic position in a limited health services market is not the only consideration that will weigh with practitioners. Issues of education and reputation will also be important. As Lord Denning said of medical practitioners; '*His professional reputation is as dear to him as his body, perhaps more so*'.⁵⁰

Although the traditional elitism of health practitioners has significantly reduced, there is still a significant degree of exclusivity in the health professions. Allowing a wider range of variably trained professionals to practice medicine in New Zealand may undermine the exclusivity of New Zealand trained practitioners and could affect the overall reputation of New Zealand practitioners. This is another relevant factor to take into account when analysing regulatory options for international telemedicine.

Patients or Consumers? The Commoditization of Health Services

The growth of international telemedicine highlights the increasing tension between health care as a public good and health care as a 'for profit' industry. The past 20 years has seen a major shift in the approach to medical services. There has been rapid growth in for profit 'corporate medicine'⁵¹ and major shifts in social expectations of the medical profession. Patients have increased consumer oriented expectations of health services and practitioners can no longer expect automatic respect.⁵²

A discussion on the relative merits and pitfalls of the corporatisation of the practice of medicine is beyond the scope of this dissertation. However, when considering potential regulatory options for international telemedicine it must be recognised that regulation of international telemedicine will influence the 'market nature' of the practice of medicine. Strict regulatory controls would decrease the viability of an international telemedicine market in New Zealand, while looser controls would encourage international services. The 'corporate' future of medicine in New Zealand therefore depends on the degree of market control created by regulatory options.

⁴⁹ For a discussion on private interest theories of regulation see Baldwin & Cave, above n 31 at pg 13; Epps above n 31 at pg 71.

⁵⁰ *Hatcher v Black* (1954), *The Times*, 2 July.

⁵¹ For a discussion see J. P. Geyman "The Corporate Transformation of Medicine and Its Impact on Costs and Access to Care" (2003) 16 *The Journal of the American Board of Family Practice* 443-454.

⁵² A. Dix *Disciplinary Regulation* at pg 56 in R. G. Smith (Ed) *Health Care, Crime and Regulatory Control* (Hawkins Press, 1998).

The potential impacts of 'privatisation' or 'corporatisation' of the health care system are therefore important factors to be borne in mind when analysing regulatory options for international telemedicine in New Zealand.

Overall: Wider Considerations for the Regulation of International Telemedicine

Potential regulatory solutions for international telemedicine cannot be analysed in a vacuum or divorced from the wider implications of international telemedicine.⁵³ This dissertation does not purport to exhaustively discuss the wider ramifications of international telemedicine but this section has identified a number of major social, economic and political implications that may arise with the introduction of international telemedicine in New Zealand.

1.4 Chapter I: A Summary

Chapter I has introduced essential concepts and justified the call for regulation of international telemedicine in New Zealand. After an introduction to international telemedicine in a New Zealand context in section 1.1, section 1.2 identified a number of justifications for the regulation of international telemedicine in New Zealand. Among others, the two central rationales behind the need for regulation were the serious harm that sub-standard practitioners could cause New Zealand patients and the vast potential benefits that international telemedicine could bring to New Zealand health services.

The implications of international telemedicine were briefly discussed in section 1.3. The range of implications identified highlight the need for regulators to tread carefully when considering potential regulatory solutions for international telemedicine in New Zealand.

⁵³ J. D. Blum "The Role of Law in Global e-health: A tool for development and equity in a digitally divided world" (2002) 46 Saint Louis University Law Journal at pg 86.

CHAPTER II. FUTURE SOLUTIONS: ANALYSIS OF POTENTIAL REGULATORY MECHANISMS FOR INTERNATIONAL TELEMEDICINE IN NEW ZEALAND

Chapter I has demonstrated that there is a justified need to regulate international telemedicine in New Zealand. The purpose of this chapter is to identify and discuss potential regulatory mechanisms for international telemedicine in New Zealand.⁵⁴ Each section in chapter II will describe an individual regulatory mechanism and discuss its advantages and disadvantages as a potential solution for international telemedicine in New Zealand.

2.1 The Suing Solution: Can Civil Litigation Fill the Gap?

If a patient chooses to take civil action against a telemedicine practitioner, the combination of private international law and civil liability provide an established framework of regulation for international telemedicine. However, there are significant reasons why civil liability alone is unlikely to provide an adequate form of regulation for international telemedicine in New Zealand.

First, the scope of civil liability for personal injury suffered in New Zealand is severely restricted by New Zealand's no-fault compensatory scheme.⁵⁵ As a result of the statutory bar on civil actions for

⁵⁴ Of course not *all* the potential regulatory mechanisms will be discussed. Instead this dissertation will focus on a range of typical regulatory solutions used in the health context that may be feasible solutions for international telemedicine. One regulatory mechanism that will not be discussed but is interesting to note is the potential for New Zealand to block internet access to unscrupulous cyber doctor sites. This 'hard' form of regulation is a technical possibility: the New Zealand website for Havana House Cigars prevents New Zealand internet users from accessing areas of its site that breach New Zealand tobacco advertising provisions (for a discussion see D. Harvey *internet.law.nz* (2nd Ed, Lexis Nexis New Zealand, 2005) at pg 42). However, a bar on telemedicine websites is an extremely authoritarian form of regulatory control and is unlikely to be utilised in New Zealand.

⁵⁵ The 'Injury, Prevention, Rehabilitation and Compensation Act 2001' (IPRC Act) sets a 'legislative bar' preventing civil actions for damages for personal injuries that occur in New Zealand. Section 317 (1) (a) of the IPRC Act states;

*(1) No person may bring proceedings independently of this Act, whether under any rule of law or any enactment, in any court in New Zealand, for damages arising directly or indirectly out of—
(a) personal injury covered by this Act...*

The majority of personal injury claims will fall under the definition of personal injury in the IPRC Act (see s 26 IPRC Act). New Zealand patients may still claim for exemplary damages (s 319, IPRC Act). The IPRC Act sets out a regime of compensatory entitlements to replace the common law rights to damages from civil litigation. For a discussion on the IPRC Act see J. Manning in *Civil Proceedings in Personal Injury Cases* at pg 725 in P. D. G. Skegg & R. Paterson (Eds) *Medical Law in New Zealand* (Brookers Ltd, 2006). Equally, it should be noted that it may be possible for a New Zealand patient to travel to the practitioner's jurisdiction and bring a case in that jurisdiction. This may provide a possible way for New Zealand patients to avoid the IPRC Act if they are able to convince a court to exercise jurisdiction and apply the foreign (practitioner's) law. This is an interesting and complicated legal issue but will not be pursued in this dissertation.

personal injury,⁵⁶ civil liability is an almost a non-existent form of regulatory control for international telemedicine in New Zealand.

Second, even with the statutory bar aside, there is currently great uncertainty as to the legal issues that would arise in an international telemedicine action. Fundamental legal questions such as which court should have jurisdiction⁵⁷ and more importantly, which law to apply⁵⁸ are currently unclear. Further, there is also uncertainty in substantive legal issues. For example, in a contract action, where and when was the contract made? Or, in a tort action what is the standard of care for telemedicine practitioners?⁵⁹

With the laws in such a state of uncertainty, any civil action for international telemedicine will inevitably be a protracted and expensive exercise that few New Zealand plaintiffs would be able to undertake.

In addition, it is questionable whether civil liability on its own could ever be a sufficient form of regulation of health services. Given the potential for permanent and serious harm in the practice of medicine, health services require a preventative ‘fence at the top of the cliff’ and not just a compensatory ‘ambulance’ at the bottom. For many years therefore it has been considered necessary to have supplementary, *preventative* forms of regulation. Practitioner regulation in health services is therefore widely accepted as necessary in *addition* to civil litigation. Even in the United States of America, where civil litigation plays a large role in health regulation, practitioner regulation has long been considered necessary. As early as 1649 Massachusetts passed a law that stated that those ‘...Physicians or others employed at any time about the body of men...for preservation of life,

⁵⁶ Section 317 (1) of the Injury, Prevention, Rehabilitation and Compensation Act 2001.

⁵⁷ Since the new High Court Rules came into force in February 2009 (see Judicature Act 1908, Second Schedule) the law is now clear that to give the court prima facie jurisdiction it is sufficient for the damages to have occurred in New Zealand (Clause 6.27 of the Second Schedule of the Judicature Act 1908). This clarifies the position from common law (see [Baxter v RMC Group plc](#) [2003] 1 NZLR 304 (HC)). Applying this rule, if a patient was harmed in New Zealand then the New Zealand court would have *technical* jurisdiction. However, the court would still need to apply the ‘forum non conveniens’ rule to determine whether jurisdiction should be exercised (see Clause 6.28 (5) (c) of the Second Schedule of the Judicature Act 1908) and uncertainty as to whether New Zealand is the appropriate court to *exercise* jurisdiction would then arise.

⁵⁸ If the plaintiff can bring a case (outside of the statutory bar) the rules of private international law set out 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 the most up to date 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 June 2009). For a discussion of conflicts of laws in telemedicine and the American context see Kelly Barnes, above n 43.

⁵⁹ For a discussion on the substantive legal issues that would arise in a telemedicine scenario see Kelly Barnes, above n 43; 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.

or health...’ were not to practice ‘...without the advice and consent of such as are skilful in the same Art’.⁶⁰

Altogether, it is clear that international civil liability on its own will not be a sufficient form of regulation for international telemedicine in New Zealand.

2.2 If it ain’t broke? The Current Health Practitioners Competence Assurance Act 2003

Currently the Health Practitioners Competence Assurance Act 2003 (HPCA Act) provides a comprehensive registration and quality control regime for a wide range of health practitioners in New Zealand. The aim of this section is to explore whether the regime created by the current HPCA Act could be a feasible mechanism for the regulation of international telemedicine in New Zealand.⁶¹

Does the HPCA Act Apply to Telemedicine Practitioners?

The HPCA Act does not appear have been drafted with telemedicine in mind. Given that the HPCA Act came into force in 2003, this lack of recognition is surprising.⁶² Overseas jurisdictions had been amending legislation since the early 1990s to incorporate telemedicine issues⁶³ and in New Zealand itself the ‘Australia New Zealand Telehealth Committee’ had been established since 1998.⁶⁴

⁶⁰ D. B. Hogan “The Effectiveness of Licensing: History, Evidence, and Recommendations” (1983) 7 [Law and Human Behaviour](#) at pg 118.

⁶¹ Other New Zealand legislation that may provide some regulation of international telemedicine, but will not be discussed in this dissertation is the consumer protection legislation of the Fair Trading Act 1986. For a discussion on the Fair Trading Act and its extra territorial application in internet trading see C. Hawes, *Butterworths Introduction to Commercial Law* (2nd Ed, Lexis Nexis New Zealand, 2007) at pg 210; Harvey, above n 54 at pg 97.

⁶² The lack of any specific attention for the practise of telemedicine is especially remarkable when the explanatory note of the Health Practitioners Competence Assurance Bill is considered. The explanatory note began with; ‘*The Government ...recognises that ongoing changes in technology, models of care and health service delivery mean that the regulatory statutes need to be flexible enough to allow health practitioners to vary their practice to meet new and challenging environments...*’.(see the Explanatory Note to the First Version of the HPCA Bill 2003, last retrieved from <<http://www.parliament.nz>> 28/03/2009).

⁶³ The Federation of State Medical Boards (FSMB) of the United States of America first issued a report covering interstate telemedicine issues as far back as 1996, complete with a ‘Model Act to Regulate the Practice of Medicine Across State Lines’. This report referred to a previous review of telemedicine related legislation that had already been enacted in South Dakota, Kansas and Texas (see FSMB *Report of the Ad Hoc Committee on Telemedicine* (FSMB, undated), at pg 2, available at <<http://www.fsmb.org/>>, last retrieved 29/09/2009). For an updated synopsis of American state licensure trends for telemedicine see The American Medical Association *Physician Licensure: An update of Trends* (The American Medical Association, 2009), available at <<http://www.ama-assn.org>> last retrieved 29/09/2009.

⁶⁴ New Zealand first joined the Australia Telehealth Committee in 1998 (the Australian Committee had been established since 1996). For a discussion see Kerr & Norris, above n 12 at 5.3.

However, the definition of ‘the practise of medicine’ in the HPCA Act is generic and at no stage does the HPCA Act make any specification as to the required *location* of practitioner or patient. ‘Practise’ is defined in section 5 of the HPC A Act as;

Practise a profession or practise means to perform services that fall within the description of a health profession

In turn, the definition of health services in section 5 states;

Health service means a service provided for the purpose of assessing, improving, protecting or managing the physical or mental health of individuals ...

Given the extremely broad definitions of ‘practise’ and ‘services’ in the HPCA Act, the majority of telemedicine services provided to patients in New Zealand are very likely to fall within the definition of ‘services’ and therefore the definition of ‘practise of medicine’ in the HPCA Act.

However, countering this literal interpretation of the ‘practise of medicine’ is a principle of statutory interpretation, the ‘territoriality principle’.⁶⁵ This principle presumes that in the absence of direct statements to the contrary, New Zealand statutes apply only to acts and people within New Zealand.

However the principle of territoriality is not absolute.⁶⁶ If there are other interpretive factors to indicate that the definition of ‘practise of medicine’ in the HPCA Act should be read to include international telemedicine then the territoriality presumption may be rebutted.

The purpose of the HPCA Act provides a strong argument to suggest that the territoriality presumption should be rebutted. Section 3 of the HPCA Act states the ‘*principal purpose of this Act is to protect the health and safety of members of the public...*’ Unregulated international practitioners clearly present a significant risk to New Zealand patients. Taking a purely purposive approach the HPCA Act could therefore be justifiably interpreted to apply to international practitioners who are treating New Zealand patients.

Supporting this purposive approach is the view of the Medical Council of New Zealand (MCNZ). The MCNZ is the statutory authority responsible for registration and quality control of medical practitioners in New Zealand. In policy writings on international telemedicine in New Zealand the MCNZ states;

⁶⁵ D. Greenberg (Ed) *Craies on legislation: a practitioners' guide to the nature, process, effect and interpretation of legislation* (9th Ed, Sweet and Maxwell, 2008).

⁶⁶ *Ibid* at pg 456.

*Where doctors are located in New Zealand but provide a telemedicine service that caters only for patients in another country, the Council's view is that they do not need to be registered in New Zealand. After all, these doctors do not pose a risk to the health and safety of New Zealand patients.*⁶⁷

Further the MCNZ states;

*...the Council's preferred position is that any person providing care to an [sic] New Zealand patient is registered in New Zealand.*⁶⁸

The emphasis on patient safety leads the MCNZ to take a wide interpretation of the 'practise of medicine'. The MCNZ clearly believes that the protection of New Zealand patients provides sufficient justification for extending the scope of the HCPA regime to include international telemedicine practitioners.⁶⁹

Overall, despite the presumption of territoriality, the purpose of the HPCA Act to protect New Zealand provides a strong argument to interpret the definition of the 'practise of medicine' to include international telemedicine services.⁷⁰

A Different Approach: The 'act' occurring in New Zealand?

As an alternative approach, it may also be valid to interpret the 'practise of medicine' in international telemedicine to be an 'act' that occurs in New Zealand.

⁶⁷ The Medical Council of New Zealand "The implications of telemedicine for the profession" (2007) 43 Medical Council News at pg 8.

⁶⁸ See MCNZ, above n 20.

⁶⁹ The Health and Disability Commissioner has also expressed a purposive view as to the regulation of telemedicine practitioners. In a letter regarding the MCNZ's policy proposal ' (see above, n 15) the Commissioner stated '*...my primary focus is also on ensuring that health consumers in New Zealand receive high quality and safe services, regardless of whether the healthcare provider practises locally or internationally. Patient safety is clearly paramount.*'

⁷⁰ Another possibly relevant factor to the interpretation of the 'practise of medicine' is the history of the HPCA Act. Before the enactment of the HPCA Act the Medical Practitioners Act 1995 set the registration requirements for New Zealand doctors. Under section 12 of this Act, practitioners were required to satisfy the Council that they intended to '*reside and practise medicine in New Zealand*'. The specification to '*reside ...*' in New Zealand has been removed from the registration requirements in the HPCA Act. Accordingly, the legislative history could be interpreted to suggest that Parliament intended for the HPCA Act to apply to all practitioners who provide services to New Zealand patients, regardless of whether they *physically reside* in New Zealand. On this interpretation of the history of the HPCA Act, the definition of 'practise of medicine' could be validly extended to apply to international telemedicine practitioners. However, there is no legislative commentary confirming the intention of the removal of the term 'reside'. It could therefore be validly argued that the removal of 'reside' was simply a bi-product of the plain English approach to modern legislation.

This interpretation of the 'practise of medicine' occurring in the patient's jurisdiction is supported by the approach that both the United States of America and Australia have taken to 'interstate telemedicine', the practice of medicine through *internal* state boundaries.

Overall, the general trend in both Australia and the United States of America⁷¹ is to interpret telemedicine practitioners as 'practising medicine' in the state where the patient is located. For example, in 2003 all the Australian state and territory medical boards established a National Agreement that stated;

*...in a telemedicine service involving a doctor in state/territory A and a patient in state/territory B, the relevant jurisdiction from a registration perspective is state/territory B, where the patient is located at the time the service is provided...*⁷²

If this approach was applied to international telemedicine services provided to New Zealand patients, the *act* of practising medicine would be deemed to have occurred in New Zealand. This approach could therefore circumvent the territorial presumption as the *act* of practising medicine would be defined as occurring *in New Zealand*. On this interpretation of the 'act' of practising medicine, the HPCA Act could be validly read to apply to international telemedicine practitioners.

Overall: The Interpretation of 'the practise of medicine' in the HPCA Act

Whether by rebutting the presumption of territoriality using the purpose of the Act or interpreting the 'act' of the 'practise of medicine' to occur in New Zealand, there are two credible lines of reasoning to support an extension of the HPCA Act to include international telemedicine in New Zealand.

But...is the Current HPCA Act Really the Answer?

Despite the possible interpretation of the HPCA regime to apply to international telemedicine practitioners, there are a number of disadvantages that would arise in attempting to use the current HPCA Act as a regulatory mechanism for international telemedicine.

⁷¹ See M. A. Cwiek, R. Azhar, A. Qamar, C. Tobey & R. C. Merrell "Telemedicine Licensure in the United States: The need for a Cooperative Regional Approach" (2002)13 Telemedicine and E-Health at pg 142.

⁷² As cited in the Medical Practitioner Board of Victoria *Policy Statement on Telemedicine* (Medical Practitioner Board of Victoria, undated) available at <<http://www.medicalboardvic.org.au/content.php?sec=62>>, last retrieved 30/09/2009. Also, Australia is currently in the process of creating a single *national* licensure standard for all states and territories. In June 2009, the draft of the 'Health Practitioner Regulation National Law 2009' that sets out the legal framework for the new national registration and accreditation scheme for the health professions was released. The proposal is due to come in to force in July 2010. For more information see <<http://www.nhwt.gov.au/natreg.asp>>.

First, there is the problem of registration pathways. Currently, if international practitioners wish to be registered under the HPCA Act they have to follow the same paths of registration as if they were located in New Zealand and providing 'regular' face to face services. Such a situation is clearly not suitable for the majority of international telemedicine practitioners who will provide limited, specialised services across the internet.

Further, the onerous requirements for international practitioners to be able to register in New Zealand are likely to discourage legitimate international providers from 'setting up shop' in New Zealand. The use of the HPCA Act in its current form is therefore unlikely to encourage the growth of legitimate international telemedicine services in New Zealand.

Finally, the most significant disadvantage of the regulatory mechanism of the HPCA Act in its current form is the difficulties of enforcement that would arise when attempting to apply the HPCA regime internationally.

The major enforcement difficulty facing the HPCA Act in its current form is that the quality control and disciplinary sections of the Act apply only to 'health practitioners'. By definition, health practitioners are only those professionals who are *registered* under the Act.⁷³ Because the majority of international telemedicine practitioners providing services to New Zealand patients will not be registered under the HPCA Act, the only disciplinary option under the current HPCA regime will be section 7(2).

Effectively, section 7(2) makes it an offence for any person to claim to be practising or to practise medicine without a current practising certificate.⁷⁴ This summary offence⁷⁵ could not suffice to protect the New Zealand public from wayward cyber-doctors. The enforcement of a summary offence over international borders is nigh impossible. Costs of enforcement aside, it is highly unlikely that New Zealand will request extradition of international practitioners who have breached section 7(2).⁷⁶

⁷³ See the definition of 'health practitioner', s 5 HPCA Act 2003.

⁷⁴ Section 7(1) states;

'No person may claim to be practising a profession as a health practitioner of a particular kind or state or do anything that is calculated to suggest that the person practises or is willing to practise as a health practitioner of that kind unless the person-

(a) Is a health practitioner of that kind; and

(b) Holds a current practising certificated as a health practitioner of that kind.

⁷⁵ Section 7(5) of the HPCA Act 2003 states *'every person commits an offence punishable on summary conviction by a fine not exceeding \$10,000 who contravenes this section'*.

⁷⁶ 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).

The lack of effective enforcement of the HPCA Act is therefore a major limitation of the HPCA Act as a potential regulatory mechanism for international telemedicine in New Zealand.

Overall: The HPCA Act in its Current Form

The HPCA Act in its current form has a number of limitations as a potential regulatory solution for international telemedicine. The HPCA Act does not provide an appropriate registration pathway for telemedicine practitioners, contains onerous criteria that are likely to discourage the growth of international telemedicine, and, lacks an effective mechanism of enforcement. Overall, despite the potential interpretation of the HPCA Act to include international practitioners, it is unlikely that the HPCA Act in its current form could effectively regulate international telemedicine in New Zealand.⁷⁷

2.3 Extending the HPCA Act: The Medical Council of New Zealand's Current Proposal

Recognising the inadequacy of the current HPCA Act as a regulatory mechanism for international telemedicine, an alternative regulatory mechanism has been proposed by the Medical Council of New Zealand (MCNZ). The MCNZ have proposed that the current HPCA regime be modified to include a specialised registration pathway for international telemedicine practitioners.⁷⁸ This section will describe this proposal and assess its advantages and disadvantages as a potential regulatory mechanism for international telemedicine in New Zealand.

The Suggestion of the MCNZ

The Medical Council of New Zealand (MCNZ) is the statutory organisation responsible for the registration of medical practitioners under the HPCA Act.⁷⁹

In the past few years the MCNZ have recognised the need for regulation of international telemedicine. In a statement on telemedicine in 2007, the MCNZ stated;

Technology and the ability we now have to communicate easily and effectively across international boundaries hold a good deal of promise for improving patient care. However,

⁷⁷ The MCNZ itself has recognised the difficulty of using the HPCA Act in its current form for international telemedicine. In a consultation document for international telemedicine the MCNZ stated; '*In New Zealand we have found implementing the law can be problematic, so we need to come up with a more practical limit*' (see Medical Council of New Zealand *Telepathology and teleradiology across international boundaries A consultation* document (MCNZ, 2008) an abridged copy of which is in Appendix One.

⁷⁸ Since receiving consultation feedback the MCNZ has adjusted the proposal that is in Appendix One (above, n 77). It is this modified proposal that is discussed in this dissertation see MCNZ *Consultation on amendments to scopes of practice and prescribed qualifications* (MCNZ, 2009), available at <www.mcnz.org.nz>, last accessed 30/09/2009. An abridged copy of this amended second stage proposal is in Appendix Two.

⁷⁹ The MCNZ is an 'authority' for the purposes of the HPCA Act (see s 5) and has powers to set scopes of practice for the medical profession (s 11).

*developments in technology also present challenges for medical regulators such as the Council: we need to decide who we regulate.*⁸⁰

Since early 2008 the MCNZ has been developing a proposal for regulation of international telemedicine under the HPCA Act. In its current form, the proposal is for a specialised scope of practice for international teleradiology practitioners who are treating New Zealand patients.⁸¹

Essentially the MCNZ's proposal is for a locum tenens style of limited registration where international teleradiology practitioners are required to register with the MCNZ for a specialised 'teleradiology' scope of practice.

The proposal sets out a strict set of conditions for registration. As well as relevant experience requirements and academic qualifications, the MCNZ has proposed that for registration;

- The applicant must have a contract with a health provider located in New Zealand. That provider must have carried out 'a comprehensive credentialing process' of the applicant; and
- The New Zealand provider must have a dispute resolution process to facilitate the resolution of patient complaints. This process must include a mechanism for automatic notification of both New Zealand authorities and authorities in the applicant's home country if complaints are received. Additionally the contract must contain a clause that requires the New Zealand provider to fund the practitioner's travel to New Zealand if necessary; and
- The dispute resolution process must also permit and facilitate external review of the applicant by New Zealand and overseas authorities; and
- The New Zealand provider must provide a New Zealand supervisor. The supervisor must provide details of the responsibilities of the applicant as well as a detailed supervision plan; and
- The New Zealand supervisor must provide supervision reports to the MCNZ every 3 months.

The MCNZ's proposal also includes relevant English language qualifications. Registration is for a maximum of 12 months.⁸²

⁸⁰ The MCNZ Consultation document (2008) above, n 77 (Appendix One).

⁸¹ The MCNZ's proposal was in its original form intended to regulate both international teleradiologists and telepathologists (see The MCNZ Consultation Document (2008) Appendix One). However, after the first round of consultation on this proposal (completed in October 2008) the MCNZ revised its proposal and limited the specialised scope of practise to teleradiologists (see the modified proposal Appendix Two).

⁸² This is a summary of the conditions of the proposal, another condition of note is that the overseas facility the applicant works for must be accredited by an accrediting body recognised by the International Accreditation

Is the MCNZ's Proposal the Answer?

There are number of positive aspects of the MCNZ's proposal. First, there are clear advantages to regulating international telemedicine using the HPCA Act. Having an already established legal framework means that the MCNZ's proposal would be relatively simple and inexpensive to set up. Additionally, the proposal is likely to gain approval from both the medical community and the general public because it makes use of a conventional style of regulation.

The biggest benefit of the proposal is the strong protection that it provides for New Zealand patients. The proposal's strict qualification standards, close supervision and prerequisite of a contract with a New Zealand health provider, represent a strict form of regulation that gives high priority to patient safety.

However, the patient safety focus of the MCNZ's proposal also has its disadvantages. Because of the strict registration and supervision requirements, the proposal is unlikely to facilitate the growth of international telemedicine in New Zealand. The onerous criteria are likely to discourage both telemedicine practitioners from providing services to New Zealand and New Zealand providers from seeking international services.⁸³

In the same vein, the limited scope of the proposal, which includes only *teleradiology* practitioners, limits the growth of international telemedicine in New Zealand. Indeed it seems strange for the MCNZ to propose regulating only one small part of the whole range of telemedicine services.⁸⁴

Further, the strict supervision standards in the proposal are likely to significantly limit the benefits that international telemedicine could provide for New Zealand. The main advantage of international telemedicine is that it reduces pressure on the local workforce by providing access to surplus international practitioners. However, under the MCNZ's proposal the number of international practitioners who may provide services to New Zealanders remains limited by the number of available local supervisors.

New Zealand (IANZ) (for information on IANZ see <<http://www.ianz.govt.nz/>>). A full copy of the revised proposal is in Appendix Two.

⁸³ Although requiring international practitioners to register in multiple states may discourage the growth of international telemedicine, it should be noted that despite NightHawk's teleradiologists having 38 licenses on average and NightHawk needing to employ 35 people to deal with licensure requirements, NightHawk still has a viable business model. The hurdle created by multiple licensure requirements therefore may not be as great as it first seems (for a discussion on NightHawk see section 1.1 above). However, the onerous nature of the MCNZ's proposal is still less likely to encourage telemedicine development compared to more practitioner friendly regulatory regimes (see Singh & Wachter, above n 25).

⁸⁴ See above at n 81.

In terms of overseas enforcement and discipline, compared to the unworkable alternative of the using the HPCA Act in its current form, the MCNZ's proposal is a significant improvement. By requiring an agreement for dispute resolution, submission to the authority of the MCNZ, and an automatic notification system for the practitioner's home jurisdiction, the proposal makes real progress toward providing accountability for patients and extending control over international borders.

However, while the proposal makes innovative attempts to deal with enforcement of the HPCA Act, in many cases the difficulties of international enforcement are likely to continue. If practitioners do not voluntarily come to New Zealand to face disciplinary action or partake in dispute resolution, then the practical difficulties of enforcing a regulatory system over international borders still remain.⁸⁵

On the other hand, even though the MCNZ may struggle to enforce the HPCA regime over international borders, the proposal does provide for an alternative 'surrogate' form of enforcement. Under the MCNZ's proposal all international practitioners must be registered in their home state and all New Zealander providers must have a notification system that informs the practitioner's home state if complaints are made. Through this notification system the practitioner's home state may launch an investigation of the practitioner within their jurisdiction. Essentially the practitioner's home state may therefore provide enforcement 'on behalf' of the MCNZ and the New Zealand patient.

A recent Health and Disability Commissioner's (HDC) opinion⁸⁶ has demonstrated the effective use of this surrogate style of enforcement. In this opinion, an Australian practitioner who had operated on a New Zealander while visiting for a conference was investigated by the HDC after a complaint was laid by the New Zealand patient. The practitioner (living in Australia) did not respond to any of the correspondence from the HDC. Consequently, the HDC wrote to the equivalent medical board in the practitioner's home state, outlining concerns about the practitioner's conduct while in New Zealand. The HDC also provided a professional medical report on the practitioner's conduct that had been formed in the course of investigation.

As a result of the HDC's correspondence, the practitioner's home medical board then conducted its own formal investigation. On investigation the practitioner was found guilty of 'gross carelessness' in his treatment of the New Zealand patient and was punished accordingly. The Australian Board also

⁸⁵ Enforcement may not be such a problem in cases of Australian-New Zealand telemedicine. As to be discussed in section 2.4, the problems of enforcement between Australia and New Zealand are likely to be significantly reduced by upcoming Australian/New Zealand legislation.

⁸⁶ *Opinion 99HDC13041* (Health and Disability Commissioner, 15/06/2009).

found the practitioner guilty of improper conduct for not cooperating with the HDC's investigation. Although in a slightly different context, this HDC opinion is an apt illustration of the alternative 'surrogate' approach that could be used to enforce the MCNZ's proposal across international borders.

However, this surrogate style of enforcement is not without limitations. The system relies on the practitioner's home state electing to investigate the incident and having similar standards of care as New Zealand. While this may be entirely feasible in a trans-Tasman context, surrogate enforcement is unlikely to be so effective on a global scale. Further, reliance on informal, co-operative measures means investigation and discipline is likely to be subject to large delays. The HDC opinion discussed above is a prime example. It took more than eight years for the state of affairs in that opinion to finally come to a conclusion.

The separation of the place of incident and the place of discipline may cause difficulties. Especially in the situation where a patient suffers considerable harm, it seems unfair that the harmed party should have to travel long distances for redress. Of course, it would be possible for the disciplinary process to be conducted using video conferencing technology. This would mean that the injured party could be 'present' at the disciplinary process without requiring physical travel. In the international telemedicine context it seems quite feasible that this type of 'telediscipline' would be accepted as a tolerable substitute to 'real life' attendance. The separation of the place of incident and the place of harm may therefore not be as major an obstacle as it first appears to be.

However, the surrogate form of enforcement does remove a degree of authority and power from the patient's home jurisdiction. Such an approach interferes with the deep-seated notions of sovereignty and local boards may find it difficult to forfeit their traditional realm of control in this way. Overall, however, the MCNZ's solution does at least provide a partial remedy for the difficult problem of enforcement and discipline across international boundaries.⁸⁷

A final and significant shortcoming of the MCNZ's proposal is that it does not deal with the 'cyber-doctor' situation where patients directly seek medical advice from international 'cyber-doctor' websites. Instead, the MCNZ proposal presumes that international telemedicine services will be provided through an intermediary local health provider.

⁸⁷ Even if the international practitioner cannot be disciplined effectively there may be some accountability via the New Zealand supervisor or provider if the New Zealand supervisor or provider was negligent in supervising or credentialing the international practitioner. This additional accountability does add some strength to the MCNZ's proposal.

As discussed in section 1.1, cyber-doctor websites are easily accessible in New Zealand and the use of such services is likely to grow. Any regulatory solution for international telemedicine in New Zealand has to take this sort of cyber-doctor interaction into account. It is a major weakness of the MCNZ's proposal that it does not attempt to provide any mechanism to regulate, or even acknowledge, the 'cyber doctor' form of international telemedicine in New Zealand.

Summary: The MCNZ's Solution

The MCNZ deserves to be commended for taking steps toward regulating international telemedicine. The moves by MCNZ reflect increasing recognition of the need for regulation of international telemedicine in New Zealand.

As a potential regulatory system for international telemedicine in New Zealand, the MCNZ's proposal has both strengths and weaknesses. The proposal strongly protects patient safety by providing strict registration standards. Further, the proposal provides innovative enforcement solutions that improve the accountability of international practitioners and provide a partial remedy for the problems of international enforcement.

However, if an international practitioner chooses not to comply with their contract then the MCNZ and the patient must rely on 'surrogate enforcement' by the practitioner's home state. Additionally the proposal does not address the current and growing use of 'cyber-doctors' by New Zealand patients.

2.4 The Simple Solution? Mutual Recognition

Another possible regulatory solution for international telemedicine in New Zealand is a system of mutual recognition. Mutual recognition is a regulatory system in which different jurisdictional states agree to recognise the licenses or registration systems of other states.⁸⁸

Mutual recognition is different from the MCNZ's current proposal for a specialised scope of practice as it does not require telemedicine practitioners to undergo a full registration assessment process.

⁸⁸ Another regulatory option similar to mutual recognition is the idea of 'licensing by endorsement' where local medical authorities 'endorse' the qualifications obtained in a different jurisdiction. In 'licensure by endorsement' the practitioner still must apply for New Zealand registration, the registration process is just made easier as the New Zealand board accepts the qualifications of the practitioner as equivalent. Mutual recognition does not require a separate New Zealand registration application as a practitioner is automatically entitled to a New Zealand registration certificate by virtue of registration in their home state. Because licensure by endorsement is really just a simplification of the registration process it will not be discussed as an individual regulatory option in this dissertation.

Instead, if a practitioner has a license or is registered in a jurisdiction that New Zealand ‘mutually recognises’ then the international practitioner is automatically entitled to practice in New Zealand.

Mutual Recognition in General: Advantages and Disadvantages

There are a number of advantages of mutual recognition as a regulatory solution for international telemedicine. First and foremost, mutual recognition avoids the administrative burden of multiple of registration applications for various jurisdictions. Mutual recognition therefore is likely to encourage the growth of international telemedicine services, as the system does not require practitioners to complete multiple, onerous registration applications.

However, in return for administrative ease, mutual recognition reduces a local state’s role in regulation and compromises the control the local state has over practitioners who treat patients within its jurisdiction. Mutual recognition requires local states to trust the qualification and registration standards of the mutual state and relies on those standards to provide protection for patients. The level of protection of patient safety is therefore lower in mutual recognition systems than in full scale registration schemes such as the current proposal of the MCNZ.

In terms of enforcement, if an international practitioner registered to practise in New Zealand in consequence of mutual recognition causes harm to a New Zealand patient, the MCNZ would face the same difficulties of international enforcement that have arisen in all the options discussed so far. Mutual recognition still requires the MCNZ to attempt to enforce a local registration scheme across international borders. Further, while mutual recognition does allow for a surrogate form of enforcement, the same difficulties with surrogate enforcement as discussed earlier⁸⁹ remain relevant.

A further weakness of the mutual recognition mechanism is that it does not provide a solution to the difficult problem of patient mediated use of ‘cyber-doctors’. Mutual recognition does provide a slight improvement on the MCNZ’s proposal: if a patient seeks advice from a registered practitioner located in a jurisdiction that New Zealand mutually recognises, that practitioner will be able provide services directly to the New Zealand patient without breaching New Zealand law. However, mutual recognition does not provide a solution for discipline or control of *unregistered* practitioners.

Overall, like the proposal of the MCNZ, mutual recognition has both advantages and disadvantages. While the level of local control and patient protection may be reduced with mutual recognition, the

⁸⁹ See section 2.3

administratively simple nature of mutual recognition provides a regulatory solution that is likely to facilitate the growth of international telemedicine.

The Trans-Tasman Context: Advantages of an Australian/New Zealand Mutual Recognition Approach

For a range of reasons, regulation by mutual recognition may be a particularly viable option for ‘trans-Tasman’ telemedicine.

New Zealand and Australia have a strong history of cooperative relations in health. There are many ‘trans-Tasman’ health related bodies,⁹⁰ and an established trans-Tasman authority on telemedicine, the Australia New Zealand Committee on Telehealth.⁹¹ There are also close registration and qualification bonds between Australian and New Zealand practitioners. For example, Australian doctors are excluded from the ‘provisional’ stage of registration that most international doctors have to complete and are able to immediately practise medicine in New Zealand.⁹²

Additionally, New Zealand already has a mutual recognition system with Australia in the form of the Trans-Tasman Mutual Recognition Act (TTMR) 1997. The central principle of the TTMR Act is that an individual who is registered for an occupation in an Australian jurisdiction is entitled to be registered in New Zealand for the equivalent occupation.⁹³ Currently, medical practitioners are specifically excluded from the mutual recognition principle of the TTMR Act⁹⁴ but it would take only a minor addition to this established framework to form a mutual recognition agreement for medical practitioners in Australia and New Zealand.⁹⁵

Most importantly however, a future mutual recognition agreement between New Zealand and Australia may not struggle with enforcement problems. As demonstrated by the HDC opinion discussed above⁹⁶ New Zealand and Australia have similar standards of care and trans-Tasman discipline can be effectively imposed. Additionally, as a result of the “Trans-Tasman Court Proceedings and Regulatory Enforcement Treaty” signed in July 2008, New Zealand and Australia

⁹⁰ Such as The Royal Australian and New Zealand College of Psychiatrists (<<http://www.ranzcp.org/>>), The Royal Australian and New Zealand College of Radiologists (<<http://www.ranzcr.edu.au/>>), the Australasian Health and Research Data Manager’s Association (<<http://www.ahrdma.com.au/>>)

⁹¹ See section 2.3

⁹² There are also some legal agreements and conjoined regulatory agencies between Australia and NZ in health for example, the ‘[Health Benefits \(Reciprocity with Australia\) Act 1999](#)’ and the Australia New Zealand Joint Food Standards Agreement which sets up a joint food safety regulatory system, the Food Standards Australia New Zealand to enforce the [Australia New Zealand Food Standards Code](#) (for information see <<http://www.nzfsa.govt.nz/index.htm>>).

⁹³ S 15 TTMR Act 1997.

⁹⁴ See Schedule 4 of the TTMR Act 1997 .

⁹⁵ The upcoming single license system in Australia (see above, n 72) would make implementation of a trans-Tasman mutual recognition agreement even easier.

⁹⁶ See section 2.3

have both agreed to introduce legislation to make the resolution of legal disputes across the Tasman cheaper, more effective and more efficient.⁹⁷ The legislation resulting from this treaty is likely to significantly reduce any enforcement problems that may arise in a ‘trans-Tasman’ telemedicine regulatory scheme.⁹⁸

Overall, mutual recognition is a regulatory option well suited to ‘trans-Tasman’ telemedicine. Because of the strong relationships and close similarities between Australia and New Zealand, a trans-Tasman form of mutual recognition may be an ideal way to regulate trans-Tasman telemedicine.

Outside Australia: Mutual Recognition as the Solution for Global Telemedicine

Of course, a mutual recognition agreement between Australia and New Zealand cannot be the final solution for the global problem of international telemedicine. To truly embrace international telemedicine and gain the full benefits of an ‘international market’ for health services, New Zealand would need to have mutual recognition agreements with a wide range of countries.

However, there are a number of disadvantages in using mutual recognition for regulation of international telemedicine on a global scale. First, to maintain an appropriate and satisfactory level of patient safety, the mutual recognition principle relies on other countries having health care systems similar to New Zealand. Use of mutual recognition is therefore limited to those countries that have similar qualification and registration standards. Alternatively, New Zealand may elect to have mutual relationships with countries that have less demanding qualification and registration standards, but as a necessary consequence patient safety will be compromised.

Finally, the ease of enforcement and discipline that supports the use of a mutual recognition agreement between Australia and New Zealand is unlikely to exist with other nations. Due to the inhibitory costs and legal barriers to international enforcement, mutual recognition with countries other than Australia must rely on enforcement and discipline carried out by the practitioner’s home state.

Overall, while a global mutual recognition system may be an administratively simple and cost effective form of regulation, the limited control over international practitioners and consequent reduction in patient protection are significant disadvantages.

⁹⁷ For a summary see “Trans-Tasman disputes” (Feb. 2009) 722 LawTalk at pg 27.

⁹⁸ Of course the same ease of enforcement would be true for the trans-Tasman enforcement of the MCNZ’s proposal as discussed above, n 85.

2.5 Going Global: An International Licensure System

From the analysis thus far, it is apparent that there are two significant weaknesses common in all the mechanisms. First, there is the inability to have a fully effective form of enforcement across international borders. Second, there is the difficult problem of controlling and disciplining independent 'cyber-doctors'.

It is the locally structured framework of each of the mechanisms discussed so far that gives rise to these two major weaknesses. While all of the mechanisms have an international aspect, they still remain centred around the traditional framework of a *local* authority attempting to enforce *local* standards of care. Such locally bound mechanisms cannot be expected to cope with the multi-jurisdictional nature of telemedicine. The bottom line is that full and effective regulation of international telemedicine requires an international solution.

One 'true' international solution that has been proposed is an international licensure system. An international licensure system involves a single set of international licensure requirements for all international practitioners. Once licensed under the scheme, a telemedicine practitioner can provide telemedicine services to all the countries that are party to the scheme. Additionally, as a necessary part of an international licensure system, there is an international system for the enforcement of the standards of care set out in the scheme.⁹⁹

An international licensure system therefore differs from the 'quasi international' regulatory mechanisms that have been so far discussed. The international licensure system is not centred on individual local bodies and jurisdictional borders; but has a truly international set of licensure criteria and enforcement capabilities.

This section will examine an international licensure system as a potential regulatory solution for international telemedicine in New Zealand.

Advantages of an International Licensure System

⁹⁹ An international licensure agreement does not *require* an attached disciplinary regime: it would be possible to have an international license for telemedicine practitioners without any enforcement. This option would be similar to the website accreditation notion as discussed in section 2.7 below. However, because a pure accreditation system will be discussed in section 2.7, for the purposes of this dissertation the term international licensure system will refer to an international licensure system *that includes* an attached international enforcement mechanism.

There are two central advantages of an international licensure system. First, with a single set of licensure criteria an international licensure system provides great administrative ease for international practitioners. Once licensed, a practitioner could practise in any nation that is party to the scheme and would be held to the same standard of care in all nations. An international licensure system is therefore likely to encourage the growth of international telemedicine and promote consistent practice of medicine worldwide.

The most significant advantage of an international licensure system is its potential for an *international* enforcement regime. International cooperation would provide for accountability and control of practitioners regardless of their location. With the co-operation of multiple jurisdictions, a global enforcement system provides a solution to the difficult problem of unregistered and uncooperative ‘cyber-doctors’. Under an agreed system of international enforcement, miscreant ‘cyber-doctors’ could no longer hide behind international borders.

Of course, as with any international agreement, devising a workable mode of international enforcement is no easy task. Nonetheless, there are several potential modes of enforcement for such a system that will be discussed below.

Possible Forms of International Enforcement

This dissertation does not present an in depth analysis of the legal and political implications of each mode of enforcement. This section merely highlights and briefly discusses several options that may provide workable international enforcement mechanisms for an international licensure system.

- *The Draft Convention of the International Bar Association and ‘surrogate’ Enforcement:*

In 1999 the International Bar Association (IBA) drew up a draft convention for an international licensure system.¹⁰⁰ The IBA’s draft convention is one possible form for an international licensure agreement.¹⁰¹

¹⁰⁰ The International Bar Association Section on Legal Practice, Committee 2 (Medicine and Law) ‘Draft International Convention on Telemedicine and Telehealth’, (July 1999) (‘the Draft Convention’), an abridged copy of which is in Appendix Three. For a discussion see Callens, above n 19 at chapter 6.

¹⁰¹ The IBA’s Draft Convention does not set out an entirely ‘typical’ international licensure system with a central set of standards. Instead it provides *two* possible structures for the licensure system. First the convention does allow for a ‘true’ international licensure system with an international set of licensure standards recognised by each party (see clause 3). However, additionally under clauses 3 and 4 the convention allows each state party to have its *own* licensure requirements with a system of mutual recognition (clause 13). Because mutual recognition processes have already been discussed and the most relevant part of the IBA Convention for the purposes of this dissertation is the enforcement mechanism, this dissertation will discuss the IBA Draft Convention as if the ‘true’ international route is taken and there is one set of internationally agreed standards.

The IBA's draft convention sets out a system of international enforcement where each of the member parties agree to carry out discipline of practitioners within their jurisdiction 'on behalf' of the patients home state. Under the IBA's system of enforcement, if a practitioner breaches the international licensure standards the practitioner's local jurisdiction will investigate and discipline that practitioner in their home state.¹⁰²

This 'surrogate' system of enforcement has already been discussed in the context of the MCNZ's proposal and in section 2.4 on mutual recognition. However, the consistent, central standard of care in an international licensure system may provide an enhanced form of 'surrogate discipline'. Rather than the patient having to rely on the practitioner's home state having an analogous standard of care, the unitary international standard would provide certainty and consistency for patients by ensuring that each practitioner was held to the same standard of care, regardless of their home location.

However, as discussed in section 2.3,¹⁰³ enforcement that separates the place of incident and the place of discipline has disadvantages. Where a patient suffers considerable harm, it may be unreasonable to require that party to travel to be present at disciplinary hearings, although video conferencing 'telelitigation' may provide a tenable solution for this problem. Nevertheless, the surrogate style of enforcement does require local states to relinquish their authority to enforce discipline and protect patients within 'their' jurisdiction. Such a notion runs counter to the entrenched notion of sovereignty and may be difficult for local medical authorities to accept.

- *Enforcement by extradition:*

An alternative form of enforcement for an international licensure scheme could be via an extradition style of agreement. In this type of enforcement member parties would agree that, if there is some balanced proof that a practitioner has breached the international standards, then the practitioner's home state would extradite that practitioner to face discipline in the *patient's* home state.

This type of enforcement avoids the disadvantages associated with the surrogate style of enforcement, as the home state retains control over 'their' patients' protection and the injured party gains the benefit of the disciplinary process occurring within their jurisdiction.

¹⁰² Clause 8 of the Draft Convention states; '*Each state party shall take all appropriate measures to ensure the holder of an authorization complies with all the medical, health, legal and disciplinary rules on the practice of medicine...*' the section is actually ambiguous as to what 'appropriate measures' would entail, but for the purposes of discussion it is assumed the 'appropriate measures' would include investigation and discipline (see Appendix Three).

¹⁰³ See pg 26 above.

Conventionally extradition processes have only been used for offences of the most serious nature.¹⁰⁴ Use of an extradition process in this context might well be considered a disproportionate response for an allegation of a breach of the international standards. Further, countries such as Malaysia and India who have chosen to actively encourage the growth of the telemedicine as a commercial venture in their jurisdictions¹⁰⁵ may oppose an extradition style of enforcement. Such countries are unlikely to be willing to extradite their 'entrepreneur' practitioners who are making commercial gains by practising telemedicine.¹⁰⁶ Overall, such an extradition style of enforcement is likely to struggle to gain approval in an international discussion.

- *A compromise? Combinations of enforcement possibilities:*

A form of enforcement that may be more palatable for the international community could be a compromise solution that combines local 'surrogate' enforcement and extradition. State parties could agree that, for the majority of alleged breaches of the licensure standards, practitioners would be disciplined in their home state on behalf of the patient's state. However, if the allegations of harm reach some agreed threshold of 'seriousness', then the practitioner's home state would extradite the practitioner to the patient's home state.

This combination approach respects the rights of both practitioner and patient and seems likely to provide a feasible mechanism of international enforcement for an international licensure system.

- *An International Tribunal:*

Another mechanism of enforcement for an international licensure system could be the establishment of a specialist, international disciplinary tribunal. The tribunal would be set up with the agreement of multiple nations and would investigate and decide cases of alleged breach of the international standards of care.¹⁰⁷

¹⁰⁴ See the Extradition Act 1999 discussion above, n 76.

¹⁰⁵ See Daly, above, n 36; Singh, above, n 25.

¹⁰⁶ R. R. McLean & A. B. McLean "Hageseth's principle of extraterritorial jurisdiction and international telemedicine" (2008) 14 *Journal of Telemedicine and Telecare* 282-284.

¹⁰⁷ An international tribunal is not a completely novel idea. For example the [United Nations Convention on the Law of the Sea](#) has 'The International Tribunal for the Law of the Sea' to adjudicate disputes arising out of the interpretation and application of the Convention (see <http://www.itlos.org/start2_en.html>).

Another example of an international dispute tribunal is the Dispute Settlement Body of the World Trade Organisation (see D. Palmetier & P.C. Mavroidis *Dispute settlement in the World Trade Organization: practice and procedure* (2nd Ed, Cambridge University Press, 2004)).

At first blush the establishment of an international disciplinary tribunal may seem like the ideal solution for the regulation of international practitioners. An international tribunal avoids the clashing of local state jurisdictions and sits well with the global nature of international telemedicine.

However, the establishment of an international tribunal would be an ambitious undertaking that may not be entirely suited to international telemedicine. The tribunal would rely on local patients having both the knowledge and the motivation to initiate an international complaint. Given the often vulnerable nature of patients and the sensitive nature of health care, it may not be reasonable to expect patients to be willing or capable of bringing an international complaint.¹⁰⁸

- *Overall: The various forms of enforcement in an international licensure system*

As with any international agreement, finding a method of proper and effective international enforcement for an international licensure system is a critical challenge. Nevertheless, the range of enforcement possibilities that have been identified and discussed above demonstrate that there are feasible foundations for effective international enforcement systems in the future. International enforcement of an international agreement will always be a significant challenge, but as the options discussed above show, where there is an international will, there can be an international way.

In Reality: Obstacles to an International Licensure System

The significant obstacle in the way of an international licensure system, and indeed any international agreement, is the difficult goal of reaching international consensus.

The competing range of motivations behind the regulation of international telemedicine will make attaining international consensus a tremendous challenge. For countries such as India and Malaysia, who focus on the commercial benefits of international telemedicine,¹⁰⁹ a 'free market' style of international telemedicine will be the ultimate goal. In contrast, countries such as New Zealand who place high values on the equal distribution of health services and consider the protection of patient safety to be paramount¹¹⁰ will oppose any agreement that takes a pure 'for profit' approach or risks endangering patient safety.

¹⁰⁸ There may also be the problem that in most cases both the practitioner and the patient involved would be required to travel in order to attend the disciplinary hearing. The logistics of such international travel and the likely costs of bringing such an 'action' may inhibit the success of an international tribunal. However of course, as noted above in section 2.3 at pg 26, it would be possible for the tribunal to make use of video conferencing type technology.

¹⁰⁹ See Daly, above, n 36; Singh, above, n 25.

¹¹⁰ Of course the policy position of New Zealand could change and New Zealand could come to support a commercialised approach to international telemedicine. However gauging from the current New Zealand focus

Other implications of the proliferation of international telemedicine such as the immense benefits for global public health, and the corporatisation of health care services will play into the mix of international agendas. Altogether, gaining international consensus for an international licensure scheme is likely to be an almost overwhelming task.

However, an international solution should not be dismissed as an entirely impossible pipe dream. As technology develops and the profile of international telemedicine grows, the prospect of an international agreement to regulate international telemedicine is gaining momentum. Influential international organisations are beginning to recognise the advantages of international telemedicine and make calls for international action. Writing for the World Health Organisation in 2002, Beaglehole, Woodward and Drager stated;

Globalization presents us an unprecedented opportunity to deliver better health for the world's poorest. It is becoming ever clearer that our increasingly interdependent and interconnected world means that domestic action alone is not sufficient to secure better health...¹¹¹.

Additionally, for almost a decade, non-governmental organisations have been developing policies and setting standards for the practice of international telemedicine. The draft convention from the International Bar Association is one such example. Additionally, both the World Medical Association and the International Telecommunications Union have developed comprehensive principles to guide and encourage international telemedicine.¹¹² Hence, while the significant challenge of gaining international consensus must be acknowledged, there are indications that an international agreement may not be as far from reality as it first may appear.

Overall: International Licensure Systems

on equity in health care, the 'no fault' compensation scheme of the IPRC Act 2001 (above, n 55) and the principal of the HPCA being 'to protect the health and safety of members of the public' (s 3 HPCA Act 2003) it seems unlikely New Zealand will make a complete turn around and support a 'free trade' approach to international telemedicine in the foreseeable future.

¹¹¹ R. Beaglehole, D. Woodward & N. Drager (Eds) *Global Public goods for health: Health economic and public health perspectives* (Oxford University Press, 2003) at pg vii.

¹¹² World Medical Association *World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine* (World Medical Association, 1999) available at <<http://www.wma.net/e/policy/a7.htm>>, last retrieved 30/09/2009. These original guidelines were rescinded in 2006 and replaced by World Medical Association *World Medical Association Statement On The Ethics Of Telemedicine* (World Medical Association, 2007) available at <<http://www.wma.net/e/policy/t3.htm>>, last retrieved 30/09/2009; International Telecommunications Union *Second World Telemedicine Symposium for Developing Countries, Final Report*, (International Telecommunications Union, 1999) as cited in Blum, above n 53 at pg 87.

Overall an international licensure system has significant advantages compared to the quasi-international mechanisms already discussed. With the central, consistent standards of care the system is likely encourage the growth of international telemedicine and promote consistency of practice internationally. Moreover, there are a range of potential enforcement mechanisms that would allow an international licensure system to have full and effective international enforcement. International licensure would therefore provide accountability regardless of international borders and provide protection against uncooperative, unregistered 'cyber-doctors'.

However, despite the clear advantages of an international licensure system, such a system requires international consensus. Given the wide range of motivations behind regulation of international telemedicine, gaining international consensus will inevitably be complicated and protracted. Even with the indications of a groundswell toward international regulation, an international licensure system is unlikely to be an immediate solution for international telemedicine in New Zealand.

2.6 Regulation by Deregulation: The General Agreement on Trade in Services

Another option for the regulation of international telemedicine is the possibility of an international trade agreement for telemedicine services within the framework of the General Agreement on Trade in Services (GATS)¹¹³.

The central objective of the GATS regime is to encourage international trade in services by reducing national trade barriers. The essential rationale behind the GATS is that the free market of services will result in the best allocation of resources.¹¹⁴

As discussed in above,¹¹⁵ international telemedicine has an underlying commercial nature and the potential to be a vast 'for profit' trade industry. From this angle, an international trade agreement is well suited to regulate international telemedicine.

The main advantage of regulating international telemedicine under the framework of the GATS system is that the GATS regime is already well established. GATS members would simply need to make 'commitments' on behalf of their health sectors to include telemedicine within the range of

¹¹³ 'The General Agreement on Trade in Services' available at http://www.wto.org/english/tratop_e/serv_e/serv_e.htm, last retrieved 30/10/2009. For a discussion on the possibility of using GATS for international telemedicine see K. Cameron "Facilitating International Telemedicine: The Way Forward" (1998) 23 International Legal Practitioner at pg 93; Blum, above n 53.

¹¹⁴T. Epps "Merchants in the Temple? The Implications of the NAFTA and GATS for Canada's Health Care System" (2003) 12 Health Law Review at pgs 3-8.

¹¹⁵ See section 1.3

services covered by the GATS regime.¹¹⁶ The GATS regime could be extended to create an international telemedicine agreement with relative ease.

However, although a trade agreement fits with the commercial aspect of international telemedicine, there are other characteristics of international telemedicine that are not so well suited to a commercial trade approach. While a full discussion of the merits and downfalls of a 'free market' approach to health services is beyond the scope of this dissertation, it is worth noting that there is scepticism as to whether health care services would trade in the same way as other commercial services.

As discussed above¹¹⁷ the 'consumption' of health services is largely driven by need as opposed to want. Additionally, the informational asymmetry between practitioners and patients produces an unfair market advantage for practitioners. These and other aspects of health services provide strong reasons against a free market approach to the health sector¹¹⁸, therefore a 'free trade' approach to international telemedicine services may not produce positive results for the telemedicine 'consumer'.¹¹⁹

Moreover, taking a trade liberalization approach to the provision of health services would require a major shift in the ethos of the New Zealand health care system. A free market for health services is not compatible with current New Zealand health objectives of distributive justice, public funding and close practitioner regulation.¹²⁰ Use of the GATS regime for regulation of telemedicine would therefore require a major political shift to accept globalization and commercialization of health services in New Zealand.

Overall, while extension of the GATS framework may appear to be a reasonable and straight forward regulatory solution for international telemedicine, there is valid scepticism as to the benefits of a free market approach to health services. Additionally, putting that scepticism to one

¹¹⁶ This is a very simplified analysis of the potential application of GATS to international telemedicine. There are of course further complications, such as whether the provision of health services fall within the definition of 'services that are supplied in the exercise of governmental authority' and so excluded from the GATS regime (see Article I.3b of GATS). This dissertation does not seek to provide a detailed analysis of the potential application of GATS to health services. For in depth discussion see C. Blouin, N. Drager & R. Smith *International Trade in Health Services and the GATS, Current Issues and Debates* (The World Bank, 2006); Cameron, above n 113; Epps, above n 114.

¹¹⁷ See section 1.2 above.

¹¹⁸ For more discussion see Drache & Sullivan, above n 38.

¹¹⁹ After more than a decade of market style reforms in New Zealand, the overall health expenditure (as a proportion Gross Domestic Product) has increased. Additionally, evidence indicates that privately run health services are almost always more expensive than public services (Drache & Sullivan, above, n 38 at pg 6).

¹²⁰ For a discussion on similar issues in the Canadian context see Epps, above n 114.

side, a free market form of regulation for telemedicine services would require a fundamental change to the current political views on health care in New Zealand.

2.7 The Sealing Solution? Regulation by Accreditation

A final potential mechanism for the regulation of international telemedicine is the idea of accreditation or rating systems for telemedicine provider websites.

As discussed above,¹²¹ the character of medical care has dramatically changed in the recent past. Patients are becoming independent 'consumers' in the market of health care services.

Part and parcel with this change in attitudes towards health care has been an increasing trend for patients to seek health related information on the internet. For example, statistics from the United States of America indicate an exponential rise in use of the cancer related health information site Oncolink (www.oncolink.org). Monthly accesses have increased from 30,000 per month in 1994 to nine and a half million per month in 2004.¹²² Similarly in 2002, the United States National Institutes of Health database 'MEDLINEplus' (www.medlineplus.org), was consulted 11 million times a month by users from 177 countries.¹²³

As a result of the increasing use of health information on the internet there has been a worldwide recognition of a need to regulate health information on the internet.¹²⁴ Notably, regulation of health information sites faces the same challenges that arise in international telemedicine. As in international telemedicine, traditional regulatory frameworks struggle to cope with the 'a-jurisdictional'¹²⁵ nature of the internet and the global accessibility of health websites.

Nevertheless, health regulators have persevered and over the past decade have devised regulatory solutions for health information on the internet. The prevailing form of regulation selected for health information sites is the use of accreditation (or rating) systems.

¹²¹ See section 1.3 above.

¹²² D. Martin "Decade of Oncolink empowers cancer patients" (2004) Abramson Cancer Center News, <<http://www.oncolink.org/resources/article.cfm?c=3&s=39&ss=159&id=356>> as cited in J. A. Gilmour "Reducing disparities in the access and use of Internet health information. A discussion paper" (2007) 44 *International Journal of Nursing Studies* 1270-1278.

¹²³ E. Lacroix & R. Mehnert "The US National Library of Medicine in the 21st century: expanding collections, nontraditional formats, new audiences" (2002) 19 *Health Information and Libraries Journal*, as cited in Gilmour (ibid).

¹²⁴ For a discussion on health information site regulation see P. Wilson *Sealing in the Quality: A classification of Quality Assurance Initiatives for Health-Related Information on the Internet* at pg 57 in Callens, above n 19.

¹²⁵ T. Fuentes-Camacho (Ed) *The International Dimensions of Cyberspace Law* (Ashgate Publishing Ltd, UNESCO Publishing, 2000) at pg 6.

There are various forms of ‘accreditation systems’ but each has the same essential underlying structure.¹²⁶ Basically, health information websites must meet a set criterion of standards to become ‘accredited’ by a third party. The third party assesses the standard of the information on the website and, if adequate, ‘accredits’ the applicant site. The site is then able to display a ‘trust mark’ or ‘web-seal of quality’.¹²⁷ In most cases the health information site pays for the third party ‘accreditation’ in order to promote the reliability of their site and increase consumer use. Accreditation systems protect the consumer by promoting ‘accredited’ health sites that provide safe and reliable information.

One of the oldest health information site accreditation systems ‘The Health on the Net Foundation’ (HON) was established in 1995. HON is a non profit organisation endorsed by the Economic and Social Council of the United Nations.¹²⁸ The foundation sets out an international code of conduct for the provision of health care information on the internet. To be ‘approved’ under the HON system, websites must meet the standards of the code of conduct and agree to abide by the 8 central principles¹²⁹ set out in the code. Once approved by the HON foundation, the website may then post the ‘HONcode’ logo.¹³⁰ Use of the HON system is considerable: the HON home website has more than 27,000 visits daily.¹³¹

The regulation of health information sites by accreditation systems such has blossomed over the past decade and there are multiple other examples of health related accreditation systems in place worldwide. As well as not for profit systems like HON there are also privately run, commercial webseal programmes. An example of a well established private accreditation programme is ‘TRUST e’.¹³² Although not specific to health information sites, TRUSTe operates the world’s largest privacy seal program.¹³³

¹²⁶ For a discussion on the various forms of accreditation systems see Wilson in Callens, above n 124 at pg 58.

¹²⁷ Ibid

¹²⁸ Ibid at pg 59; see also <<http://www.hon.ch/Global/index.html>>, last accessed 30/09/2009.

¹²⁹ The guiding principles are; authority, complementarity, confidentiality, attribution, justifiability, transparency of authorship and honest in advertising and editorial policy as cited in Wilson in Callens, above n 124.

¹³⁰ HON also sets up a number of other online health-information services, such as an online health information search engine accessible through the HON site and linked only to reliable health information sites and the ‘HON tool bar’ which can be downloaded and added to a web browser where it automatically assesses health websites for their reliability. See <<http://www.healthonnet.org/>> for more information (last accessed 30/09/09).

¹³¹ Statistical information from the HON Home site (undated but website was last updated in 2009) available at <<http://www.hon.ch/HONcode/Patients/Visitor/visitor.html>>, last retrieved on 28/09/09.

¹³² See <<http://www.truste.com/>> (last accessed 28/09/09).

¹³³ See Ibid and Callens, above n 19 at pg 26

State governments have also begun to initiate accreditation systems for health information sites. Often these accreditation systems operate in a slightly different form to the commercial 'webseals' and employ a 'gateway' approach with an approved list of links to 'trusted' health information sites. An example of this sort of state run accreditation site is the 'healthinsite'¹³⁴ website run by the Australian government. This site provides a single gateway of access to a list of 'trusted partner' health information sites.¹³⁵

Application to International Telemedicine

Clearly, accreditation systems are an accepted and effective mechanism for the regulation of health information on the internet. Considering the similarities between international telemedicine and health information websites, it is perfectly possible that accreditation systems could also be successfully used to regulate telemedicine sites.

There are number of advantages to an accreditation style of regulation for international telemedicine websites. First, compared to full blown registration mechanisms, accreditation systems are likely to have very low administration costs. In fact, as shown by privately run programmes such as TRUSTe, if administered as a 'user pays' system, accreditation systems can be self-sufficient, profitable businesses.

A second advantage of the regulatory mechanism of accreditation is that accreditation approaches sit well with the trend for patients to act as autonomous consumers in the health care market. There is some strength in the notion that the traditional, more paternalistic rationales behind regulation in the health context may not suit the commercial and consumer oriented nature of international telemedicine. Instead, a mechanism of regulation such as accreditation that respects and defers to the growing autonomy of patients may be more fitting for international telemedicine.

¹³⁴ See <<http://www.healthinsite.gov.au>> (last accessed 28/09/09).

¹³⁵ Ibid; there is no New Zealand based accreditation system specific for health information sites although the Ministry of Health does provide a gateway of free access to '<www.besttreatment.com>' (an information database run by the British Medical Journal). Further, New Zealand is a member of the international consumer watchdog site <www.econsumer.gov> (last accessed 10/09/2009). Econsumer.gov is for all e-commerce sites generally but could be used for telemedicine. This site is primarily a complaints mechanism rather than an accreditation programme. For more discussion see Callens, above n 19 at pg 7. For an example of a New Zealand run accreditation system in health see <www.psnz.org.nz> (last accessed 28/09/09). This site, run by the Pharmaceutical Society of New Zealand (Inc), sets up a webseal accreditation process for New Zealand *pharmaceutical* sites. Once accredited, sites are able to display the 'PSNZ Quality Seal of approval'. The quality seal both informs users that the pharmaceutical site is reliable and also 'hyperlinks' back to the home PSNZ site where verified information on the pharmaceutical site is maintained. At this stage the site has only one accredited pharmacy but the framework may be useful for any future developments of telemedicine accreditation systems.

Another advantage of regulation by accreditation is that an accreditation process will necessarily increase the profile of international telemedicine in New Zealand. To be successful, accreditation programmes must promote information on the service they regulate and consumers must be educated on the workings of the accreditation system. An accreditation system will only succeed in protecting consumers if those telemedicine consumers are aware of its existence. Consequently, an accreditation programme for international telemedicine sites in New Zealand would encourage the growth of international telemedicine in New Zealand by increasing the awareness of international telemedicine as a legitimate health service.

Finally, the most significant advantage of an accreditation mechanism of regulation is that such an approach may help to reduce the risk of harm from un-registered (and potentially unqualified) cyber-doctors. Accreditation will not prevent 'quack' or miscreant practitioners offering telemedicine services, but it would at least provide a clear, simple and low cost way to help patients avoid unscrupulous telemedicine sites. Indeed, aside from an international enforcement system that can extend over international borders to discipline miscreant cyber-doctors beyond New Zealand's jurisdiction, an accreditation approach may be the only feasible way to reduce the risk of harm from 'quack' cyber-doctors.

Of course, the patent weakness of the accreditation mechanism for regulation is that accreditation does not provide any of the customary forms of punitive sanctions or any accountability for harmed patients.¹³⁶ However, this is not to say that accreditation mechanisms have no means of discipline or enforcement at all. There are alternative, less direct forms of enforcement available such as blacklisting of miscreant sites and, in the most sophisticated accreditation systems, complaints channels for patients to inform the accreditation authority of bad conduct.¹³⁷ While these forms of enforcement and discipline may not be as robust as practitioner discipline and other 'legal' actions, they should not be entirely dismissed.

Given the low administrative resources required to establish an accreditation system, it is quite feasible that an accreditation system could be run in conjunction with one of the other stricter

¹³⁶ Of course it is possible to establish accreditation programmes with attached enforcement and discipline measures but for the purposes of this dissertation 'accreditation schemes' are discussed in terms of pure 'accreditation only' systems (enforcement and discipline was discussed in the context of international licensure at section 2.5 above).

¹³⁷ Naturally, the more complex the enforcement and discipline measures for an accreditation system becomes, the more resource intensive the system will be.

regulatory options already discussed. A central advantage of the accreditation style of regulation is therefore the ability of the mechanism to act as a 'complementary' regulatory mechanism.¹³⁸

Overall

Overall an accreditation system is an innovative regulatory mechanism that recognises the increasingly consumer oriented nature of medical services. An accreditation system would be cost efficient and could provide some preventative measures to protect against 'quack' cyber doctors who, without an international enforcement agreement are otherwise almost impossible to regulate.

In addition, while accreditation systems on their own provide only 'soft' forms of indirect discipline and accountability, the low administrative costs of an accreditation system mean that accreditation could easily be used in conjunction with other more stringent regulatory mechanisms.

2.8 Chapter II: A Summary

The aim of chapter II was to identify and discuss a range of potential mechanisms for the regulation of international telemedicine in New Zealand. Overall, seven different mechanisms were identified and the advantages and disadvantages of each were examined.

Of the seven mechanisms, two are already established structures that could be extended to apply to international telemedicine (civil litigation and the current HPCA Act); two were variations of locally based forms of regulation (mutual regulation and the MCNZ's proposal); and three were 'true' international mechanisms (an international licensure system, regulation by GATS and an accreditation system).

A full review of the advantages and disadvantages of each of the regulatory mechanisms discussed in this chapter will be provided in the next.

¹³⁸ Indeed the proposal from the MCNZ does combine the specialist teleradiologist license with the IANZ accreditation system, see section 2.3 above.

CHAPTER III. THE RECOMMENDED REMEDY? THE BEST NEXT STEPS FOR REGULATION OF INTERNATIONAL TELEMEDICINE IN NEW ZEALAND

Chapter II has identified and discussed potential mechanisms for the regulation of international telemedicine in New Zealand. This chapter takes these matters further and examines which of the regulatory mechanisms would provide the ‘best’ solution for New Zealand. This chapter aims to conclude with practical recommendations as to the next steps that should be taken toward effective regulation of international telemedicine in New Zealand.

3.1 Defining ‘best’: The Problem of the Conflicting Goals of the Regulation of International Telemedicine

It is easy to describe an ‘ideal’ regulatory system for international telemedicine. From the underlying rationales for the regulation of international telemedicine that are discussed in section 1.2, a number of regulatory goals are apparent. Among other factors, the goals of an ideal regulatory system for international telemedicine in New Zealand would be;

- A cost and time efficient system that requires low levels of resources both to set up and maintain
- A system that provides optimum protection for New Zealand patients
- A system that encourages the growth of and facilitation of the full benefits of international telemedicine
- A system that provides accountability for harm
- A system that provides effective punitive sanctions
- A system that is accepted by the public
- A system that is accepted by the medical community in New Zealand
- A system that is in line with current social policy and health objectives
- A system that supports the global development of international telemedicine for the benefit of developing nations
- A system that optimises the full commercial value of international telemedicine

Simply reading through this list of ‘ideal’ goals highlights the central difficulty with selecting the ‘best’ regulatory solution for international telemedicine. The various goals of regulation are not always compatible. For example, a regulatory mechanism that provides accountability and robust

punitive sanctions is unlikely to be maintained at a low cost. Furthermore, a mechanism that provides optimum protection for patients will struggle to simultaneously encourage the full development of international telemedicine.

It is impossible to design a perfect system of regulation for international telemedicine. All potential mechanisms will necessarily involve some 'trade-offs' between conflicting goals. The 'best' regulatory solution will therefore be the solution that comes closest to providing the ultimate balance between conflicting goals.

3.2 The Easy Part: Unworkable Regulatory Mechanisms

Despite the complications of finding an 'ideal' solution for international telemedicine, it is fairly easy to demarcate regulatory mechanisms that are likely to be completely unworkable. From the analysis in chapter II it is apparent that there are three mechanisms that are very unlikely to provide feasible solutions for New Zealand.

The first regulatory mechanism that is unlikely to provide a feasible solution is civil litigation on its own. The bar on personal injury litigation in New Zealand makes civil litigation almost non-existent as a form of regulation in the New Zealand health context. In addition, for any remnant areas of litigation that may be still available to New Zealand patients, the current degree of legal uncertainty is likely to severely impede plaintiffs. Civil liability on its own is therefore unlikely to be a viable form of regulation for international telemedicine in New Zealand.

Neither is the use of the HPCA Act, in its current form, likely to provide a feasible form of regulation for international telemedicine. As discussed above,¹³⁹ while interpreting the definition of the 'practise of medicine' to include telemedicine practitioners is technically possible, the use of the current HPCA Act to try and regulate international practitioners would be practically unworkable.

Finally, regulation of international telemedicine in New Zealand under the GATS regime would represent an extreme favouring of the commercial development of international telemedicine over the protection of patients. This dissertation does not examine all the policy considerations behind a trade style regulation of international telemedicine however, it is suffice to say that embracing this regulatory approach would require an almost complete turnabout in the current policy goals of health care in New Zealand. It is difficult to imagine New Zealand electing to regulate international telemedicine services under the GATS, or any other international free trade style of agreement in the near future.

¹³⁹ See section 2.2 above.

At this stage, none of these three regulatory mechanisms can be considered to be realistic solutions for the regulation of international telemedicine in New Zealand. They do not warrant further consideration in this dissertation.

3.3 Review: Potential Regulatory Mechanisms and the Goals of Regulation

The other mechanisms discussed in chapter II may be feasible regulatory solutions for international telemedicine in New Zealand. However, because of the contradictory nature of the goals of regulation, none of the proposed mechanisms provides a perfect solution. Inevitably, each regulatory mechanism will maximise some goals at the expense of others. This section will review the strengths and weaknesses of each of these mechanisms, taking the various goals of regulation of international telemedicine into account.

The Proposal of the MCNZ

The MCNZ has proposed a specialist 'teleradiology registration pathway' for international practitioners. The central advantage of the MCNZ's proposal is that the regime would provide a strong form of protection for New Zealand patients. Its strict, closely supervised form of regulation would ensure that only high quality practitioners would be treating New Zealand patients.

However, this proposal is unlikely to encourage the growth of international telemedicine in New Zealand. Because of the administrative burdens and the limited scope of the proposal to include only teleradiologists, this proposal is unlikely to allow New Zealand to utilise the full range of the benefits international telemedicine has to offer.

Furthermore, the MCNZ's proposal provides only a moderate means of international enforcement. In the absence of any international agreement, this proposal does not provide any protection from unregistered 'cyber-doctors', or any accountability mechanisms to control overseas practitioners who do not cooperate with the MCNZ's requirements.

Overall, the MCNZ's proposal is the epitome of the 'safe not sorry' style of regulation. In terms of the goals of regulation, the proposal heavily favours patient safety over the advancement of international telemedicine.

Mutual Recognition

Section 2.4 essentially discussed two sub-types of mutual recognition. First, a trans-Tasman mutual recognition agreement and second, a 'global' mutual recognition agreement.

The main advantage of both of these mutual recognition mechanisms is that mutual recognition is administratively simple and therefore likely to be cost efficient. Compared to the onerous registration process proposed by the MCNZ, the simple process of mutual recognition is also more likely to encourage the development and growth of international telemedicine in New Zealand.

For a trans-Tasman agreement, the upcoming legislative changes and established close legal relationship between Australia and New Zealand would make enforcement of a mutual recognition regime relatively straight forward. Additionally, the close similarities of qualification and practice standards in Australia and New Zealand would mean there is unlikely to be any concerns over practitioner quality and patient safety.

The obvious limitation of a trans-Tasman agreement is that it will not encourage the full development of international telemedicine for New Zealand. A bi-lateral agreement between two similarly placed nations clearly cannot encourage the full development of international telemedicine or allow New Zealand to gain the full global advantages of international telemedicine.

Using mutual recognition with multiple countries would encourage the expansion of international telemedicine in New Zealand. However, once mutual recognition was used for countries with which New Zealand does not have such close legal relationships, problems of discipline and enforcement would inevitably arise. A global mutual recognition scheme may therefore encourage the development of international telemedicine in New Zealand but at the expense of patient safety and practitioner accountability.

International Licensure

From the earlier discussion, it is clear that an international licensure system would be likely to provide the solution that is has the closest to ideal balance of regulatory goals. An international licensure agreement provides the same degree of patient protection as other 'local' regulatory solutions by ensuring all patients are treated by competent, appropriately qualified practitioners. However, international licensure has the additional advantage of a global enforcement regime. The degree of patient protection and practitioner accountability is therefore stronger in the international licensure mechanism than in the locally based mechanisms of the MCNZ's proposal and mutual recognition. Additionally, the single standard of care and registration requirements would encourage the growth of international telemedicine by providing a consistent, central administrative system for prospective international practitioners.

For all of the other regulatory mechanisms discussed in chapter II, the increase in patient protection comes at the expense of the full development of international telemedicine in New Zealand. An

international licensure agreement is different because it would not need to sacrifice patient protection in order to encourage the growth of international telemedicine. An international licensure system can achieve these two central goals simultaneously.

However, the international licensure mechanism is not a panacea. The most significant problem for international licensure is that international consensus will be difficult to achieve. While there are indications that point toward an eventual convergence for an international agreement, the process required to achieve international agreement will be time consuming and arduous. An international agreement is therefore unlikely to provide a solution for the regulation of international telemedicine for New Zealand's immediate future.

Accreditation

The final mechanism of regulation discussed in chapter II was accreditation of international telemedicine websites.

The strength of the accreditation mechanism is that it would be economical and simple. Because of the simplicity of the process for prospective providers and the necessary promotion of the profile of international telemedicine, regulation by accreditation would be likely to encourage the growth of international telemedicine in New Zealand.

The necessary corollary of the 'hands off' style of accreditation would be the lack of full patient protection and practitioner accountability. Regulation by accreditation leaves safety in the hands of the patient and, on its own, does not provide any traditional forms of discipline or accountability.

3.4 Famous Last Words: Recommendations for the Regulation of International Telemedicine in New Zealand

So far the sections in chapter III have taken a number of steps toward determining what may be the 'best' future solution for regulation of international telemedicine in New Zealand. It is now time to take this preceding analysis further and make some practical conclusions about what should be done to regulate international telemedicine in New Zealand.

Going for Gold: An International Licensure Agreement

The first and most obvious conclusion is that an international licensure system would provide the closest to ideal mechanism for regulating international telemedicine in New Zealand.

An international licensure system is unequalled in its capability to provide strong patient protection while simultaneously advancing the development of international telemedicine. Despite the significant challenge of gaining international consensus, there are indicators that an international agreement may well be a possibility in the future. This dissertation therefore recommends that New Zealand takes active steps toward promoting an international licensure agreement for international telemedicine.

In the Meantime? Solutions for Now

Nevertheless, an international agreement for international telemedicine is not going to transpire in the immediate future. What then are the best steps that can be taken *at this stage* to regulate international telemedicine in New Zealand?

First, it is clear that further research is needed to better inform policy makers of the potential implications of the introduction of international telemedicine in New Zealand. There are a range of social, political and economic implications associated with international telemedicine that need to be taken into account. Further research on these and other potential implications is required to ensure future policy makers and regulators are fully informed of the implications of their decisions.

In terms of actual regulatory mechanisms for the current use of international telemedicine in New Zealand, this dissertation proposes that an accreditation system for international telemedicine providers would be an ideal starting point. This regulatory mechanism would be simple and economical. A governmental organisation such as the Ministry of Health could easily initiate an accreditation system that promotes the safe and legitimate use of international telemedicine services in New Zealand. A potential model for an accreditation system for New Zealand would be the Australian governmental site 'Healthinsite' (discussed in section 2.7).¹⁴⁰

As well as an accreditation system for international telemedicine providers, this dissertation also endorses the use of the MCNZ's special license proposal. However, it is recommended that, before being brought into force,¹⁴¹ the MCNZ's proposal should be modified to include all international telemedicine practitioners. Such an extension would provide the same degree of patient protection as the teleradiology pathway but would advance a greater degree of international telemedicine development in New Zealand.

¹⁴⁰ The pharmacy accreditation system of the Pharmaceutical society of New Zealand may also provide a useful template. See above, n 135 .

¹⁴¹ The proposal from the MCNZ is currently in its second round of consultation, see the amended copy of the proposal in Appendix Two.

3.5 Chapter III: A Summary

The purpose of this chapter was to formulate practical conclusions for the regulation of international telemedicine in New Zealand.

After summary and analysis of the various strengths and weaknesses of the regulatory mechanisms discussed in chapter II, chapter III has arrived at the conclusion that an international licensure system would provide the closest to ideal regulatory regime for international telemedicine in New Zealand. Accordingly, the first recommendation of this dissertation is that New Zealand should take active steps to promote the future development of an international telemedicine licensure agreement.

Additionally, this dissertation has also made recommendations for the regulation of international telemedicine in the immediate future. Until an international agreement comes to the fore, or at least until there is full policy analysis as to the best alternative regulatory solution, this dissertation recommends that New Zealand implements an accreditation system for international telemedicine providers and a modified version of the MCNZ's specialist license that includes all telemedicine practitioners. The combination of these two mechanisms would provide a safer environment for the current use of international telemedicine in New Zealand while at the same time allowing a modest scope for the development and advancement of international telemedicine.

Finally, as an additional step to ensure policy makers and regulators are fully informed, this dissertation has highlighted a need for further research into the wider implications of international telemedicine.

CONCLUSION

The future of international telemedicine has already begun. This dissertation is about finding ways to catch up with the present.

There is a persuasive case for the regulation of international telemedicine in New Zealand. With changing demographics and an increasing focus on primary and preventative care, New Zealand has much to gain from international telemedicine. International telemedicine would increase access to health services for all New Zealanders and reduce the costs of health care delivery. However, the faceless nature of international telemedicine leaves patients open to fraud and abuse. Regulation is therefore needed to facilitate the safe and legitimate use of international telemedicine in New Zealand.

However, international telemedicine is more than just a new technology. It is a whole new approach to health care that transcends traditional notions of jurisdiction and has wide ranging, global implications. Finding an effective mechanism for the regulation of international telemedicine is not a simple task.

Nevertheless, from analysis of a range of potential regulatory mechanisms for international telemedicine in New Zealand, it is apparent that an international licensure system would provide an almost ideal regulatory solution. An international licensure system would provide strong protection of patient safety while still facilitating the growth of telemedicine. For that reason, this dissertation has recommended that New Zealand should take steps to actively promote an international licensure system for international telemedicine.

But, what of the present? An international agreement does not provide a satisfactory solution for the current need for regulation of international telemedicine in New Zealand.

For the short-term, a regulatory regime that combines an accreditation system and an expanded version of the MCNZ's specialist registration pathway has been recommended. Until alternative policy choices are made, or an international licensure system comes to the fore, this regulatory combination would provide an environment where international telemedicine can expand as a safe and legitimate health service for New Zealanders.

Appendix One: Medical Council of New Zealand *Telepathology and teleradiology across international boundaries A consultation document (MCNZ, 2008)* (abridged, a full copy is available at www.mcnz.org).



Medical Council of New Zealand

Telepathology and teleradiology across international boundaries

Background

Medical Council of New Zealand (the Council) is the statutory organisation responsible for protecting public health and safety, by ensuring doctors are competent and fit to practise medicine. The Council meets this responsibility by setting standards for the medical profession.

In recent years, the issue of telemedicine gained some prominence.

Technology and the ability we now have to communicate easily and effectively across international boundaries hold a good deal of promise for improving patient care. However, developments in technology also present challenges for medical regulators such as the Council: we need to decide who we regulate.

Meeting the legal requirements for registration and practice

According to the law doctors who provide advice or treatment for patients in New Zealand, or overseas as part of their New Zealand practice, must be registered by the Council and hold a current annual practising certificate. (See the *Health Practitioners Competence Assurance Act 2003* and the definition of the practice of medicine.)

In the eyes of the law, a doctor living in New Zealand who is working in a New Zealand hospital and providing care to New Zealand patients must be registered. But so must a doctor in another country who provides a one-off opinion to a New Zealand-registered doctor about a patient who is actually under the care of that New Zealand-registered doctor.

Setting practical limits on who we register

In New Zealand, we have found that implementing the law can be problematic, so we need to come up with a more practical limit. But where do we draw the line? How do we decide who should be registered to practise and who should be exempt?

To a degree we can assume that hospitals, health services, funders and insurers will only choose to use reputable providers. However even if this is the case the question remains: who will monitor the performance of those doctors? Consider a doctor registered in New Zealand, located in Canada and providing advice to a patient in India. If that doctor gave inappropriate advice to the patient, who

would keep a record of the incident? Who would investigate any complaint? Who would set up a competence programme and notify the doctor's employers?

The Council's preferred position is that any person providing care to an New Zealand patient is registered in New Zealand.

Even if some telemedicine providers do not present a risk to public health and safety the Council must be satisfied that procedures are in place should something go wrong and that some agency does have responsibility for the doctors' practice.

Using the particular examples of teleradiology and telepathology, the Council has strongly recommended that doctors registered and located in New Zealand should be used, particularly if services are provided as part of a medium or long-term arrangement. This recommendation was made because:

- It protects patient safety by ensuring services are provided in accordance with standards set by the Council.
- Onsite salaried staff are less likely to perform unnecessary tests than distant providers who are paid for per report.
- Employing New Zealand located and registered staff is important in terms of training the future workforce and for attracting doctors to the specialty.
- New Zealand registered doctors are more likely to have a better knowledge of New Zealand conditions and investigative thresholds.

Although Council made this recommendation, the registration of overseas-based doctors has been impractical even when a doctor in another country is heavily involved in caring for patients. In particular it is often not possible for an overseas based doctor to meet the CPD requirements expected of New Zealand registered doctors.

Purpose of this consultation

The Council has been reviewing its *Statement on use of the internet and electronic communication*. One of the key issues Council has considered in reviewing this document is what limits are appropriate for practicing medicine across international boundaries, in particular teleradiology and telepathology.

The purpose of this consultation is to gather feedback from stakeholders in regard to developing a pathway for registration for radiologists and pathologists practising in another country but providing medical services to patients in New Zealand. This pathway is intended to provide reassurance to Council, providers and the public that radiologists and pathologists providing care to patients in New Zealand via telemedicine have appropriate skills and expertise and that mechanisms are in place to

address concerns about their practice, while at the same time providing enough flexibility so that they will allow doctors to register without undue difficulty.

Council has decided that a new registration pathway should be established based on the criteria for registration within a special purpose scope of practice, locum tenens pathway. The criteria an applicant must meet for registration along this pathway would include:

English

- Achieve, or be exempt from achieving, an overall band of 7.5 in the IELTS Academic Module, scoring at least 7 in the four individual components.

Qualification

- Have a postgraduate qualification approved by Council in the scope of practice in which the doctor wishes to work. (see Appendix 1 and 2)

Experience

- Must have been in active clinical practice (20 hours per week) relevant to the branch of medicine registration is applied for, for at least 24 out of the past 36 months.

Position

- Provide telemedicine services to New Zealand patients for a maximum period of 12 months. If the doctor intends to practise in New Zealand beyond 12 months he or she must apply for renewal of approval from Council. In considering whether to approve renewal Council will consider the advice of the relevant BAB taking into account the doctor's supervision reports, results of audits carried out, and any other relevant information. Further approval must be sought every 12 months thereafter.
- Has a contract with a health provider located in New Zealand. This health provider must carry out a comprehensive credentialing process for the doctor prior to applying for registration. This means that the health provider will be assured that the doctor has the qualifications, training and experience to carry out the specific procedures that the health provider requires. The health provider must credential CPD throughout the period of registration.
- The New Zealand based provider must have a dispute resolution process to facilitate the fair, simple, speedy and efficient resolution of complaints. This process must include automatic notification of the relevant authorities in New Zealand and the doctor's home country should a complaint be received and must also permit and facilitate external review and investigation by those authorities.

Supervision

- Responsibility: The proposed supervisor must provide details of the level of responsibility to be delegated to the doctor.
- Induction and supervision: The proposed supervisor must provide an induction and supervision plan including:

- details of orientation
- supervision meetings are going to be held and the frequency of meetings¹⁴²
- availability by telephone and email of the supervisor.
- Supervision reports are to be provided to Council for each three-month period

The closing date for comment is 13 October 2008.

All submissions will be collated and carefully considered by Council. If and when an approach is agreed by Council, the Council will develop the policies required to support and implement the registration approach for doctors practising in another country but providing services to patients in New Zealand. For more information please contact Joan Crawford at consultation@mcnz.org.nz.

¹⁴² Meetings are not expected to be held face to face

Appendix Two: MCNZ Consultation on amendments to scopes of practice and prescribed qualifications (MCNZ, 2009) (abridged to include only the summary of the Teleradiology Scope of Practice information (pgs 6-7 only)). For the full document see <http://www.mcnz.org.nz>).

Consultation on amendments to scopes of practice and prescribed qualifications

Pgs 6-7

Providing teleradiology services

In December 2008, the Council undertook consultation to gather feedback from stakeholders on the development of a pathway for registration for radiologists practising in another country but providing medical services to patients in New Zealand. The wording of the Gazette noticed has been guided by that consultation process.

The proposed registration pathway is intended to provide reassurance to the Council, providers and the public that radiologists providing care to patients in New Zealand through teleradiology services have appropriate skills and expertise. The proposed registration pathway will ensure that mechanisms are in place to ensure public health and safety, while at the same time providing enough flexibility so that doctors are able to register without undue difficulty.

The proposed new registration pathway is based on the criteria used for registration within a special purpose scope of practice, locum tenens pathway. Under it a doctor must:

- (1) have a postgraduate qualification in radiology, approved by Council and published on the Council website (see appendix 3 for current list of approved qualifications)
- (2) be registered in the jurisdiction in which they gained the postgraduate qualification
- (3) be providing radiology services under contract to a health provider located in New Zealand on terms that meet Council policy published from time to time¹.
- (4) Have been in active clinical practice (20 hours per week) in the vocational scope of diagnostic and interventional radiology for at least 24 out of the last 36 months.

1 • The doctor must have a contract with a health provider located in New Zealand who has undertaken a comprehensive credentialing process for the doctor prior to applying for registration.

The New Zealand-based health provider must have a dispute resolution process to facilitate the fair, simple, speedy and efficient resolution of complaints. This process must include automatic notification of the relevant authorities in New Zealand and the doctor's home country should a complaint be received and must also permit and facilitate external review and investigation by those authorities.

The overseas facility the doctor works for must be accredited by an accredited body recognised by International Accreditation New Zealand (IANZ).

Supervision for the doctor is to be provided by the clinical director of the New Zealand health facility who must carry out an audit of 30 consecutive cases to coincide with the first three month period supervision report. Details of how audit will continue over the time of supervision are to be provided to Council.

Appendix Three: The International Bar Association Section on Legal Practice, Committee 2 (Medicine and Law) 'Draft International Convention on Telemedicine and Telehealth', (July 1999) ('the Draft Convention') (abridged to include only relevant sections for this dissertation, for a full copy see <http://www.ibanet.org>)

International Bar Association Section on Legal Practice, Committee 2 (Medicine and Law)

DRAFT INTERNATIONAL CONVENTION ON TELEMEDICINE AND TELEHEALTH

The States Parties to the Convention,

Inspired by recent advances in the provision of health care and medical education through the use of technology,

Recognizing the common interest of all mankind in the health and welfare of the peoples of the world,

Believing that the promotion of telemedicine and telehealth will contribute to the availability and quality of medical services to those in need, and hence to significant alleviation of human suffering and to improvement of health care and the quality of life for mankind,

Believing that these telemedical services should be available for the benefit of all peoples,

Recognizing that discrimination in the provision of health care services on the basis of race, color, descent, national or ethnic origin, sex or creed would be inconsistent with the principles established in the International Convention on the Elimination of all Forms of Racial Discrimination of March 7, 1966,

Recognizing the right to privacy and confidentiality in health matters,

Desiring to contribute to broad international cooperation in the scientific, legal, and ethical aspects of the use of telemedicine,

Believing that such cooperation will contribute to the development of mutual understanding and to strengthening of friendly relations between States and peoples,

Encouraging continued support for the advancement of telemedicine and its applications,

Convinced that a convention on telemedicine and telehealth will further the goal of providing all people with the highest practicably attainable standard of health care,

Have agreed as follows:

ARTICLE 1: TELEMEDICINE AND TELEHEALTH DEFINITIONS

For purposes of this Convention and unless otherwise indicated in a provision of this Convention or required by the Context the terms below shall have the following meanings:

1. Health care information is information or data, from whatever source, in any communicable form or medium, obtained in the course of the diagnosis, treatment or care of a patient, that either identifies or can readily be identified to that patient and that relates to the patient's health care or condition.
2. Telehealth refers to a diverse group of health-related activities, including health professional education, community health education, public health, research, and administration of health services.
3. Telehealth information means information used in the course of delivering health care and related services via electronic media.

4. Telemedicine means clinical or supportive medical practice delivered across distances via telecommunications and interactive video technology, performed by licensed or otherwise legally authorized individuals.

5. A telemedicine physician is a physician licensed by the appropriate body to provide health care through a telemedicine medium.

ARTICLE 2: GENERAL PRINCIPLES

1. The Convention shall be binding in all cases of telemedicine and telehealth delivered across state boundaries:

a. when the States are Contracting States; or

b. when the rules of private international law lead to the application of the law of the Contracting State.

2. For purposes of this convention, the States Parties agree that, whenever possible health care delivered through electronic means, regardless of form, shall be treated no differently from health care delivered face to face, directly between health care worker and patient. This Article includes, but is not limited to, issues of financial reimbursement that may arise in relation to this convention.

3. The States Parties shall take reasonable steps to ensure the protection and confidentiality of intellectual property developed to facilitate telemedicine, including, but not limited to, the provision of patenting or other formal recognition in accordance with national laws and international treaties.

4. State Parties shall undertake, with appropriate protection of intellectual property rights:

a. to foster international dissemination of scientific knowledge concerning

telemedicine and telehealth equipment and associated information for the purposes of research and of provision of medical services;

- b. to develop and implement telemedicine and telehealth technology safely and efficiently, particularly in remote, under-served or developing areas; and
- c. to foster scientific and cultural cooperation, particularly between industrialized and developing countries.

5. No provision of this convention may be used by any State, group or person to ends contrary to the principles set forth herein.

6. Each State Party will emphasize and encourage infrastructure development.

7. Each State Party shall ensure, through legislation or other means as appropriate, that all telemedicine and telehealth research carried on within its jurisdiction is conducted in accordance with internationally accepted medical, scientific and bioethical standards.

8. Each State Party shall endeavor to prohibit and bring to an end, by all appropriate means, discrimination by any persons, group or organization in the provision of health care services on the basis of race, color, descent, national or ethnic origin, sex or creed.

9. The singular includes the plural and the masculine includes the feminine within the text of this Convention.

ARTICLE 3: REGULATION OF TELEMEDICINE AND TELEHEALTH; AUTHORIZATION TO PRACTICE

1. State Licensure. Each State Party shall ensure that its health and medical licensing boards provide for reasonable opportunity for [full and unrestricted] licensure to physicians and other health care providers who wish to provide telehealth services.

Where sub-jurisdictions of State Parties regulate licensure requirements within the State Party's general jurisdiction, the State Party shall require such sub-jurisdictions to comply

with the provisions of this Convention and ensure that sub-jurisdiction's licensure procedures are no more onerous or time consuming than is contemplated below.

2. License. No health care professional shall practice telemedicine or those activities of telehealth which would otherwise require licensure within the State Party's jurisdiction unless he has obtained an authorization to practice issued by the competent authority of the State Party or organization recognized by the State Party to grant licensing authorization.

3. License Application. To obtain authorization to practice telehealth as provided for in Article 3.2 the applicant shall apply to the competent authority of the State Party, or to an internationally recognized organization whose standards are recognized by the State Party concerned. Each State Party shall ensure that the competent authority is clearly set out by the State Party. The following particulars and documents shall accompany the application by the applicant:

- a. the name and permanent residence address of the applicant;
- b. the address of the applicant's place of practice;
- c. a certified copy of the professional diploma or other professional certification;
- d. certification of good standing with the applicant's current professional body in the jurisdiction in which the applicant is currently practicing or a proof of inscription on the list of the Order of Physicians;
- e. description of the experience or expertise, if any, which the applicant has in the delivery of the applicant's services via telecommunications media;

- f. description of the area or practice specialty, if any, which the applicant wishes to pursue;
- g. not less than two professional references; and
- h. description of the means of communication, including, but not limited to, software to be used to practice telehealth.

4. Types of licenses. Except as limited by the provision of this convention, each State Party may establish categories of license for telehealth professionals, and may define the scope of practice applicable to each.

5. Approval Timing. Each State Party shall take all appropriate measures to ensure that the procedure for reviewing and making a determination with respect to the telehealth care license application is completed within thirty (30) days from the date on which the applicant's submission is complete. Each State Party shall ensure that incomplete applications are noted to the applicant within thirty (30) days of the date of submission of the application. Each State Party shall be entitled to extend the thirty (30) day period for a further fifteen (15) days upon notice to the applicant provided such notice is given to the applicant prior to the expiry of the thirty (30) day review period. A State Party may authorize telehealth practice at a level lower than that applied for. Refusal to grant the higher level may be appealed in the same manner and to the same extent as the State Party provides for applicants for licensure to practice conventional health care.

6. License Refusal. Authorization provided for in Article 3.2 may be refused if:

- a. the applicant has not provided the competent authority the requirement particulars and documents set out in Article 3.3; or

- b. after verification of the particulars and documents set out in Article 3.3, the competent authority of the State Party reasonably determines that the applicant cannot provide for the safety of patients in the State Party's jurisdiction in accordance with the standards of the State Party and the reasons for such a conclusion are set out in writing.

7. License Refusal Disputes. The World Health Organization may establish a non-binding mediation service to help resolve disputes regarding license refusal and/or suspension or revocation.

8. Compliance with Rules. Each State Party shall take all appropriate measures to ensure that the holder of an authorization complies with all the medical, health, legal and disciplinary rules on the practice of medicine, other health practices or telehealth as such may apply in the State Party's jurisdiction.

9. Liability. Remedies prescribed by this Convention are not intended to deal with other potential disputes between a patient and a telemedical physician, such as claims arising out of misuse of patient records or claims for payment for services where no dispute exists as to the quality of the services.

10. Term of License. Authorizations granted by the competent authority of the State Party shall be valid for a period of not less than three (3) years and may be renewed for further three (3) year periods on application by the holder not less than three (3) months before expiration of the then current authorization. Notwithstanding the term, the State Party may require an annual report by the holder to confirm the particulars of the holder and the holder's activities in the preceding year.

11. Suspension or Revocation of License. The competent authority of the State Party may suspend or revoke an authorization to practice granted by such competent authority where:

- a. it is found that the applicant/holder no longer possesses the qualifications set out in Article 3.3;
- b. the particulars and documents supporting the application under Article 3.3 are found to be false or materially incorrect;
- c. where the applicant/holder is, in the reasonable determination of the competent authority, not able to conduct a practice in a reasonably safe manner or without adversely affecting the health of patients; or
without adversely affecting the health of patients; or
- d. where the applicant/holder has breached any professional, disciplinary or legal rules relating to the practice being undertaken.

12. License Appeals. Each State Party shall ensure that processes are available to an applicant/holder that will allow the applicant/holder to know in detail and in writing the determination and reasons for any negative determination relating to an application, renewal, suspension or revocation. Each State Party shall inform applicants of the remedies available to him/her under the laws of the State Party and of any time limits allowed for the exercise of such remedies.

13. Mutual Recognition. In the absence of an international licensing system, each State Party agrees to utilize a combination of consulting, mutual recognition and full licensure with the goal of moving toward mutual recognition. No State Party shall impose

documentation or other requirements upon applicants beyond those reasonably necessary to ensure a reasonable standard of care for the people of the State.

14. Hospital Credentialing. Those State Parties that require specific authorization to be granted by the health care facility where telehealth care will be provided before a health care provider may provide that care in the facility will ensure that such facilities treat telehealth care providers in a manner similar to that applied to those providers whose practice brings them physically into the facility. It is the express intention of this provision that no one be treated differently solely because he is providing health care at a distance with the assistance of electronic media.

15. Prescriptions. Health care workers providing services through electronic means shall have the same authority to prescribe medications as a similar type/category of health care worker in the State Party in which the patient receiving care is located.

16. Common Standards and Guidelines. Each State Party shall work with other State Parties and with the World Health Organization to establish and implement international standards, guidelines and protocols for licensure for telehealth and telemedicine professionals, organizations, technology providers and suppliers of goods and services.

17. Harmonization. To the extent permitted by national and political norms, each State Party shall encourage the harmonization of its rules and regulations of telehealth and licensure with those of other State Parties. Further, each State Party shall encourage harmonization of the rules and regulations relating to telehealth and licensure within the sub-jurisdictions of such State Party.

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