

CROSS-BORDER TELEMEDICINE NEW AREA, SAME LEGAL CHALLENGES?

by

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The availability of medical services and products online (telemedicine) creates serious regulatory challenges. Those challenges are complex where the provider and receiver are in the same country, and even more complex when the provider is not in the same country as the recipient.

Focusing on Australian law, this paper examines the regulatory challenges associated with cross-border telemedicine.

KEYWORDS:

Telemedicine, e-health, privacy, private international law, licensing, e-regulation

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“The adage that technology outpaces the law at every turn is perhaps nowhere better demonstrated than through the practice of telemedicine.”¹

1. INTRODUCTION

The legal issues associated generally with e-commerce have gained considerable attention in the literature. Further, certain specific areas of e-commerce, such as e-gambling, e-banking and e-payment systems have also been discussed at length and in detail by legal commentators. In contrast, the e-commerce aspects of medicine have largely been neglected. This is somewhat surprising considering the enormous values involved in the health care industry. No less than 9% of Australia's Gross Domestic Product (GDP)

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¹ Daar, J. F. and Koerner, S. 1997-1998, 'Legal and Practical Implications', Whittier Law Review 19(3).

is spent on health care.² Expressed differently, in 2006-2007, Australia spent \$94 billion on health.³ As these figures show, health care is big business, and with many Western economies struggling with aging populations, it can be expected that the cost of health care will increase rather than decrease.

Focusing on Australian law, this paper examines the regulatory challenges associated with cross-border telemedicine. It is not aimed at proposing solutions. Rather, this article seeks to raise and bring attention to some serious legal obstacles standing in the way of telemedicine.

2. WHAT IS TELEMEDICINE?

There are many ways in which the term telemedicine may be defined:

At its most basic level, telemedicine amounts to all health aspects of practicing medicine at a distance. Practicing medicine includes diagnosing and treating patients, physician education, patient education, administrative functions, video conferencing, and continuing medical education. Therefore, telemedicine can be described, broadly, as the use of telecommunication technology to deliver medical services.⁴

This paper is focused on telemedicine carried out over the Internet, and looking at the Internet we can identify and distinguish between five different types of health care related activities:

The sale of medical products such as prescription drugs, non-prescription drugs, dietary supplements and medical tools;

General medical information provided over the Internet directly to consumers;

Medical advice specific to a particular person provided over the Internet where the provider does not otherwise interact with that person;

Medical advice provided over the Internet by a doctor specifically to her/his patient; and

Outsourcing and other task distribution, amongst medical service providers, over the Internet (including e.g. telepathology, teleradiology and telesurgery).

As to the first of these five categories, most Internet users would have received offers from so-called spam-pharmacies in their inboxes. In fact, spam messages relating to medical products and services such as Viagra tablets,

² Health and welfare expenditure series no. 35 <http://www.aihw.gov.au/publications/index.cfm/title/10659> (accessed 22 December 2008)

³ Health and welfare expenditure series no. 35 <http://www.aihw.gov.au/publications/index.cfm/title/10659> (accessed 22 December 2008)

⁴ Daar, J. F. and Koerner, S. 1997-1998, 'Legal and Practical Implications', *Whittier Law Review* 19(3).

Prozac tablets and penis enlargements make up a healthy share of the spam messages. Such spam messages are obviously regulated by spam-related legislation, such as the Spam Act 2003 (Cth) and nothing else will be said here about them. Further there is a wealth of websites selling medical products and it seems there are no limits to the effectiveness of the products you can order online. For example, on www.1cure4cancer.com⁵ the claim is made that: "Cancer can be cured and prevented naturally and scientifically". On the site one can order products to that aim.

There is a wealth of websites providing general medical information. Indeed, studies conducted in the US has indicated that as many as 40 - 60 % of adults in the US have used the Internet for health information.⁶ While the quality of the information varies greatly, when properly used, this information may make people more alert to medical issues leading to earlier detection of problems.

It is important to distinguish between websites that merely provide general medical information and those that provide advice in response to individual enquiries. Some of the websites that provide medical advice do so for free while other charges a fee. In some cases, the fee depends on the situation, for example, the urgency and intended use of the advice.⁷ Where a website provides medical advice rather than just medical information, it may be easier to argue that the website operator intentionally has come into contact with a particular person it is interacting with.

The fourth and fifth categories are focused on situations where telemedicine crosses over with traditional medicine. The fourth category – medical advice provided over the Internet by a doctor specifically to her/his patient – is exemplified where a patient communicates with her/his health care provider through the Internet, for example, via e-mail, chat (whether or not it is combined with images through a webcam) and Internet telephony. In such a case, the telemedicine component simply complements or supplements the physician/patient relationship. The fifth category includes the most advanced forms of telemedicine such as telepathology, teleradiology and even telesurgery.

The above highlights that several diverse activities may be classed as telemedicine. This means that it would be imprudent to speak of a regulatory model that fits telemedicine; the various forms of telemedicine are simply too different for that to be possible. Therefore, it can be argued that

⁵ (accessed 6 December 2008)

⁶ NOIE, Findings from national workshops, 1998-1999 (http://www.noie.gov.au/projects/ebusiness/Developing/ehealth/rise_of_ehealth/ehealth3.htm) (accessed 23 December 2008)

⁷ See e.g. <http://www.medicaladvice.com.ar/> (Accessed cached version as of 28 November 2008).

it is not of any real importance to seek to define telemedicine in very specific terms.

3. WHY IS TELEMEDICINE IMPORTANT?

As established above, the cost of health care is an enormous burden on the economy. Consequently, it is only logical that governments search for ways of improving the efficiency of their respective health care systems.

While telemedicine operations may be expensive to set up, they will often be cost-effective in the long run. For example, where a patient can be satisfactorily monitored in the comfort of her/his own home, both the patient and the health care provider benefits; the patient gets out of hospital faster and the health care provider saves money.

The value, or indeed necessity, of being able to provide health care over distance has been recognised for many years. As far as Australia is concerned, the Royal Flying Doctor Service (established in 1928 as the Aerial Medical Service) is a good example of a system aimed at providing medical service over distance. Put simply, it makes a lot more sense to have a system in place where doctors are flown out to remote communities when needed, than it does to build fully equipped hospitals all over Australia's regional areas. Telemedicine is the more efficient alternative in any country with large regions with sparse population, and Australia is by no means unique. Telemedicine involving the use of the Internet may in many cases be an even more effective way of providing medical services.

While speaking of the benefits of telemedicine, it is also worth noting that it may lead to a fairer distribution of medical resources – telemedicine makes it easier for wealthy countries to help people in poorer countries.

Furthermore, telemedicine encourages efficiency. With a global medical organisation, we may have a patient being examined during office hours in her/his home country, with the results being analysed during office hours in a country in a different time zone.

Other benefits that have been mentioned include, for example, continuing medical education.⁸

To summarise the above, there are at least three important benefits that may flow from telemedicine:

- Lower costs;
- Greater access; and
- Faster service.

⁸ Daar, J. F. and Koerner, S. 1997-1998, 'Legal and Practical Implications', *Whittier Law Review* 19(3).

All three of these benefits are crucially important to countries under pressure to provide adequate health care to its aging populations.

4. WHAT IS THE PROBLEM?

Telemedicine gives rise to a range of legal issues. In the interest of space, I will discuss most of those issues briefly while I pay more attention to the three areas of private international law, licensing and privacy.

As telemedicine may give rise to both civil and criminal actions, we must take account of both private and public international law. While this overlap is largely unexplored, it is becoming more and more apparent that further research on the topic would be beneficial. As far as telemedicine is concerned, the most interesting aspects of public international law are the rules that relate to jurisdiction and extradition. Under public international law, a state where the victim of a cross-border is located (i.e. the jurisdiction where the crime is consumed) may claim jurisdiction by reference to the objective territoriality principle or the so-called effects doctrine. However, if the state where the offender is located refuses to extradite the offender, there is typically little the victim's state can do.

Telemedicine may also give rise to Constitutional issues. In many federations, health services are regulated on a state level, while telecommunications and cross-state-border trade is regulated on a federal level. So telemedicine (particularly when crossing state borders) fits into both regulatory schemes. Also telemedicine is typically one part of a health service that involves both telemedicine and traditional medicine. In such a case it is clear that both the state governments and the federal government may claim a right to regulate the activity.

As any other form of cross-border activity with a commercial element, telemedicine may give rise to complicated tax issues. Addressing those complications would require a short monograph, but put simply, where a patient is located in country A, and the treating doctor is in state B, but is working for a hospital in state C, using pathology services in state D, taxing the operation can become complicated.

Another legal issue that may be more difficult to address in the telemedicine context is the requirement that the patient gives informed consent to the procedure. Different countries take different approaches to what constitutes informed consent. So it is necessary to examine which country's standard should be applied in a telemedicine procedure such as telesurgery. Should the standard established in the patient's country be applied? That would perhaps be the preferred option for the patient, but may be unfair for the health service provider. On the other hand, applying the standard of the

doctor's home state may provide certainty for the doctor but may be unfair for the patient. A related issue is whether various forms of telemedicine are to be viewed as experimental medicine or not. If they are classified as experimental a different standard may apply. While telemedicine is typically not experimental in purpose (after all it is aimed at the same goal as normal medicine), it may be seen as experimental in delivery method.

One of the largest challenges for telemedicine will be to devise a fair and workable insurance scheme. Any medical procedure involves risks, so a sound risk allocation is a necessity. If the premiums for such insurance are too high, it will stifle the development of telemedicine.

The sale of medical products can clearly give rise to product liability claims. Indeed, the standard and quality of medical products is extremely important as the consequences of failure may be directly life threatening. Product liability is of course of concern both as civil matter and as a criminal issue.

Finally, just to mention a few other potential issues, spam pharmacies are obviously subjected to the same regulation as other forms of spam, the sale of medical products is heavily regulated and a permit is typically necessary for the sale of such products. The geographical limitation of such permits does not fit well with the global nature of the Internet. This is further complicated by fact that even advertising the goods for sale may be illegal without a permit. This is clearly a criminal law issue.

5. PRIVATE INTERNATIONAL LAW

Where a civil legal dispute crosses borders, private international law (or conflict of laws as the discipline typically is referred to in common law countries) comes in to play. Private international law addresses four questions: (1) Where can the parties sue each others? That is; which courts may have jurisdiction over the dispute? (2) Which state's law will govern the dispute? (3) Can a chosen court decline to exercise its jurisdiction over the dispute? And, (4) Where can the resulting judgment be recognised and enforced? I will here focus on the first two questions, and I will examine these two questions in light of Australian law.

Regardless of whether a plaintiff sues in breach of contract or torts, the first issue the court will consider is whether or not it can exercise jurisdiction over the dispute. In Australia, the courts' jurisdiction is determined in legislation, and different courts have slightly different rules on the matter.

A common feature, however, is that courts can exercise jurisdiction over a contractual dispute⁹ when:

The contract was formed within the forum;

The contract is governed by the law of the forum; or

The contract was broken within the forum.

In disputes in tort, a court can exercise jurisdiction when:

The tort was committed within the forum; or

The proceeding is brought in respect of damage suffered within the jurisdiction.¹⁰

A court can only ever exercise jurisdiction if the domestic laws of the forum, in which the court is located, allows for it to do so. Putting the above-listed grounds for jurisdiction, in the context of somebody providing medical advice, information or products from outside of Australia, it is obvious that the Australian rules have a very wide reach (particularly in relation to those courts that allow for jurisdiction based on the location of the damages). However, such wide jurisdictional rules are not particularly uncommon.¹¹

A court will also have to identify which substantive law should be applied in resolving the dispute. In contractual disputes, the court would seek to identify the so-called proper law of the contract. The proper law of the contract can be determined in three different ways: Express choice of the proper law, inferred choice of the proper law or the objective approach to the proper law.

In relation to torts a different approach has been adopted. Under Australian law, the law to be applied is the so-called *lex loci delicti* – the law of the place of wrong. That is a fairly new rule in Australia,¹² and was not established for international cases until about a year ago.¹³ Hence, this rule is still rather untested in Australia. It also requires further explanation; What is the place of wrong if a patient in state B suffers damages due to advice, or a product, provided by a medical practitioner in state A?

⁹ Including disputes relating to “the enforcement, rescission, dissolution, rectification or annulment of a contract, or otherwise affecting a contract, or are for damages or other relief in respect of a breach of a contract”. Nygh, P. & Davies, M. 2002, *Conflict of Laws in Australia* 7th ed., Butterworths, Sydney, p.57.

¹⁰ Available under the court rules of the Federal Court, and the courts of the Northern Territory, New South Wales, Queensland, South Australia and Victoria.

¹¹ The jurisdictional rules of several states in the US, for example, arguably provide for even wider jurisdictional claims. See further: Spang-Hanssen, 2001, *Jurisdiction in the U.S. – The International Dimension of Due Process*, Norwegian Research Center for Computers and Law, Oslo, pp. 187-188.

¹² Established in *John Pfeiffer Pty Limited v Rogerson* [2000] HCA 36 for domestic cases.

¹³ *Regie National des Usines Renault SA v Zhang* [2002] HCA 10

6. LICENSING

To practice medicine one is typically required to have a valid license, This is no different to many other professions. For example, in some countries lawyers must be licensed. Since a license normally is geographically restricted, these licensing requirements cause some complications in a global economy. The difficulties facing practitioners of telemedicine are well illustrated in a recent US case.

In *Hageseth*¹⁴, a doctor licensed to practice medicine in Colorado prescribed drugs for a 19 year old man, McKay, in California. While under the influence of alcohol, McKay used the prescribed medicine (fluoxetine, a generic brand of Prozac) to commit suicide. The situation is complicated as the doctor, Hageseth, was physically located at his home in Colorado when issuing the prescription. Further, while he was aware of McKay's home being in California, he never interacted directly with McKay. Hageseth had been asked by a Florida-based company to assess McKay's request for medication and the medicine was shipped from a pharmacy in Mississippi to McKay in California. Complicating things further, the website and indeed the whole set up was arranged by a company in India.

When attracting police attention for a minor offense in Nebraska, Hageseth was extradited to California. There he argued that the court lacked jurisdiction as no part of his conduct took place in California and, in his view, his act of practicing medicine began and ended in Colorado when he wrote the prescription.

While this situation could arise in both domestic and international settings, it is important to understand the Californian law in question. Under Californian law, like the law in many other jurisdictions, it is a crime to practice medicine in California without a Californian license.

Further, Californian Penal Code permits the punishment of a defendant under Calif. Law for any criminal act committed in whole or in part in California: "persons are liable to punishment under the laws of this state ... who commit, in whole or in part, any crime within this state"¹⁵

Importantly, Californian law encompasses the principle of objective territorial jurisdiction (effects doctrine); ie where crime is committed outside, but consumed inside jurisdiction, then court can claim jurisdiction.

In light of this, the Court concluded that the Californian Court could claim jurisdiction:

¹⁴ *Hageseth v. Superior Court* 150 Cal. App. 4th 1399.

¹⁵ Californian Penal Code section 27.

"A preponderance of the evidence shows petitioner prescribed medication for a resident of this state, aware of the virtual certainty his conduct would cause the prescribed medication to be sent to that person at his residence in California. This state is thus the place where the crime is "consummated." The fact that other parts of the crime were committed elsewhere is immaterial, as there is no constitutional or other reason "that prevents a state from punishing, as an offense against the penal laws of such state, a crime when only a portion of the acts constituting the crime are committed within the state." (People v. Botkin (1908) 9 Cal.App. 244, 251 [98 P. 861].) Accordingly, respondent court possesses the necessary jurisdiction."¹⁶

This may very well have been a both logical and desirable outcome. However, some care must be taken in where we view the practice of medicine as taking place. If we had conclude that Hageseth practiced medicine only in Colorado, Hageseth could not have come under the jurisdiction of a Californian court. However, also viewing his conduct as taking place in California has an undesirable implication. In such a case, Hageseth's conduct may not be regulated by the Medical Board of Colorado.

Consequently, it is submitted that the solution lays in concluding that, in doing what he did, Hageseth practiced medicine in both Colorado and California. This is no different to the fact that a telephone conversation between a person in California and another person in Colorado takes place at both places – there is no need to identify a single location. Or at least the disadvantages of identifying a single location outweigh the advantages of doing so.

Alternatively, the rules of the license issuing authority must make clear that the doctor's conduct, wherever it is carried out, is regulated by the authority.

Interestingly, the Court in Hageseth acknowledged that under certain circumstances Internet technology may be so different as to warrant novel legal interpretations. This is certainly a step in the right direction. The Court also noted that it was for the defendant to prove that that was so, which is an appropriate approach.

In arguing that the Internet made his situation different to offline situations, Hageseth presented three arguments, all of which were criticised by the Court. First, Hageseth argued that he lacked notice of the unlawfulness of his conduct, and consequently it would be unfair to find that he has to defend the action in California.¹⁷ On this issue, the Court noted that the Californian approach is neither obscure nor unusual and that particularly a

¹⁶ *Hageseth v. Superior Court* 150 Cal. App. 4th 1399, at 1418.

¹⁷ *Hageseth v. Superior Court* 150 Cal. App. 4th 1399, at 1422.

licensed medical practitioner ought to be aware of this approach.¹⁸ Second, Hageseth suggested that claiming jurisdiction will not deter others from unlawful conduct.¹⁹ In response the Court pointed to the absence of national and international regulation, which it argued meant that states need to regulate.²⁰ Third and last, Hageseth asserted that the Court claiming jurisdiction in this situation will deter telemedicine.²¹ The Court did not agree.²²

The Hageseth case highlights the significant complications that face telemedicine due to the limited geographical reach of medical licensing schemes. It should be clear that telemedicine can never reach its full potential unless these complications are addressed.

7. PRIVACY

When looking at privacy concerns in the telemedicine setting, the first thing to note is that health information is typically regarded as particularly sensitive information.²³ Therefore, while privacy is a major concern in traditional e-commerce, those concerns are further amplified in telemedicine.

A detailed discussion of the privacy concerns that arise in the telemedicine context goes beyond the scope of this article. Here, focus is placed on two privacy issues specific to cross-border telemedicine; the extraterritorial scope of privacy law, and the regulation of transborder data flow.

In Australia, the Privacy Commissioner's jurisdiction originates in the sovereignty of the state and as such is regulated in the domestic legislation of each state. The Privacy Act 1988 (Cth), allows the Commissioner to exercise extraterritorial jurisdiction only when:

The personal information in question is about an Australian citizen or other person with a continuing presence in Australia;²⁴ and

The organisation collecting the personal information has sufficient connection with Australia.²⁵

Since carrying on business in Australia is a sufficient connecting factor, the extraterritorial effect of the Australian Privacy Act 1988 (Cth) would seem to cover a situation in which a medical practitioner in another state collects personal information about an Australian citizen or other person with a continuing presence in Australia.

¹⁸ Hageseth v. Superior Court 150 Cal. App. 4th 1399, at 1422.

¹⁹ Hageseth v. Superior Court 150 Cal. App. 4th 1399, at 1422.

²⁰ Hageseth v. Superior Court 150 Cal. App. 4th 1399, at 1423-1424.

²¹ Hageseth v. Superior Court 150 Cal. App. 4th 1399, at 1422.

²² Hageseth v. Superior Court 150 Cal. App. 4th 1399, at 1424.

²³ See e.g. Privacy Act 1988 (Cth), National Privacy Principle 10

²⁴ Privacy Act 1988 (Cth) s. 5(b)(1a)

²⁵ Privacy Act 1988 (Cth) s. 5(b)(2-3).

Cross-border distribution of personal information is often strictly regulated. In Australia, National Privacy principle 9 regulates transborder flow of personal information.²⁶ The restrictive approach taken in the Australian privacy regulation is, however, not unique in any sense. For example, the European Union's position is that personal information may only be distributed to non-Union states that have an adequate level of privacy protection.²⁷ So far, only a limited number of states are considered to meet this standard. However, personal information may be exported if a contractual arrangement, ensuring the safe handling of the information, is in place. Consequently, a GP in Greece could, for example, seek the advice of an expert in Brazil even if the procedure required personal information about the patient to be distributed to Brazil, provided that a sufficient contract is entered into between the Greek GP and the Brazilian expert.

8. THE WAY FORWARD

Using the categorisation outlined above, category one (i.e. the sale of medicinal products such as prescription drugs, non-prescription drugs, dietary supplements and medical tools) and category two (i.e. general medical information provided over the Internet directly to consumers) can be dealt through litigation and the work of effective consumer protection agencies. Consequently, they are not discussed further here.

The more interesting issues arise in the context of the regulation of categories three (i.e. medical advice specific to a particular person provided over the Internet where the provider does not otherwise interact with that person), four (i.e. medical advice provided over the Internet by a doctor specifically to her/his patient) and five (i.e. outsourcing and other task distribution, amongst medical service providers, over the Internet including e.g. telepathology, teleradiology and telesurgery).

To assess how best to address these issues it is useful to start by establishing any relevant basic "truths". I would suggest that it is a basic "truth" that these forms of telemedicine via the Internet are so valuable that it would be a mistake to simply make them unlawful. My second basic "truth" is that changing the rules of private international law, public international law and the rules regulating extradition would be too complex and time consuming to constitute the answer to the question of how we best can regulate these forms of telemedicine. In other words, litigation is not the answer to the regulation of telemedicine.

²⁶ See: <http://www.privacy.gov.au/publications/npps01.html#i> (accessed 23 December 2008)

²⁷ Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

If one accepts those two basic “truths”, one can conclude that we must find a way to regulate telemedicine in a manner that allows it to flourish while maintain an appropriate quality control other than through the legal system.

Several commentators have pointed to an international accreditation scheme as the answer. I think that is the best path forward. I would add that such a scheme needs a well developed Alternative Dispute Resolution arrangement capable of handling cross-border disputes. It also requires a suitably robust insurance arrangement that can cope with the potentially large claims that can arise, without being prohibitively expensive for the practitioners.

I acknowledge that my suggestion above is put in very basic terms and does not provide a suitable level of detail. However, questions such as who could appropriately administer such a scheme, and other details that must be addressed are left for future research.

9. CONCLUDING REMARKS

This paper has kept the promise made in the introduction – it has offered virtually no solutions! However, it has hopefully, nevertheless, provided a useful introduction to the legal issues/obstacles facing telemedicine. As such it will hopefully constitute a valuable point of departure for future research in this area.