

## Chapter 2

# Regulatory Issues in Telehealth: It's More Than Just About Data Jurisdiction

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### ABSTRACT

*Telehealth and digital health more broadly have become two of the fastest growing IT sectors in the world. They have the potential to transform lives everywhere, often before regulation has had the chance to catch up to everyday reality in healthcare. This chapter is grounded in clinical practice occurring at the time of writing and discusses at a high level regulatory issues in telehealth. This chapter argues that complexities regarding regulation over clinical applicability, patient identification, bandwidth, and funding mechanisms, as well as data storage, jurisdiction, and usage should not prevent uptake of telehealth and digital health given the clinical benefits of telehealth in countries such as Australia and internationally.*

### INTRODUCTION AND BACKGROUND

Telehealth and digital health more broadly have significant potential to overcome shortcomings in the health system that affect people's lives through improving accessibility and efficiency of treatment, which ultimately improves effectiveness of treatment, as exemplified below in Table 1.

The regulatory issues affecting telehealth are myriad and ever-changing, and are further complicated by the fact that telehealth is already a reality in Australia: the internet is already facilitating the practitioner-patient relationship and treatment, such as online consultations as well as online medical records that are both practitioner- and patient- generated that necessarily facilitate online consultations as well as remote diagnosis and tracking. This chapter focuses on online consultations and to a lesser extent on remote health tracking. It leaves deeper consideration of broader telehealth areas, such as apps for diagnosis and treatment of conditions, to other areas of this book.

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*Table 1. Health system wide limitations that can be overcome by telehealth and digital health*

Issue	Problem	Cause	Comments
Rural access	Rural people in Australia have up to 4 years less life expectancy than urban dwellers	Lack of access to health services in rural areas is a contributing factor	Online consultations overcome this barrier by enabling patients to see practitioners online through video conferencing facilities
Waiting times	Patients can wait months to see a practitioner of their choice in private practice and years for elective surgeries in public hospitals	The structure of the healthcare sector: most practitioners do not need more patients as they are busy enough with their existing patients, but waiting lists show patient populations need more treatment, with practitioners not necessarily located optimally to patient need	Practitioners can see more patients per day with efficiency tools such as: <ul style="list-style-type: none"> <li>• Efficiency-driving electronic patient and practice management systems</li> <li>• Patient-driven personal health records enable patients to complete health tracking and administrative tasks which make each appointment more efficient</li> <li>• Apps that enable patients to self-diagnose and self-treat similarly ease pressure on private practice.</li> <li>• Online consultations can overcome mismatched practitioner-patient locations by making location obsolete where online consultations are practical and clinically effective</li> </ul>
Emergency medical record access	Patients can have adverse reactions if treated by doctors who do not know their medical histories	Lack of access to patients' medical records with records held in multiple locations	Online medical records that are accessed in times of emergency overcome this by providing treating doctors with up to date medical histories of presenting patients
Dependence on service providers for medical devices	Patients have been dependent on pharmacists and practitioners to provide and to customise their devices, before patients can begin using them	Devices have had to be customised manually to each patient's needs and patients have not been able to do this themselves	A burgeoning opportunity is for patients to self-customise devices, saving patients money, practitioners time so they can treat more patients and enabling speedier use, thus ultimately easing pressure on the healthcare system

The growth of telehealth and digital health will only continue with improvements in IT privacy and security, increased internet access and bandwidth, cloud computing enabling rapid deployment, consumer push, and increased practitioner acceptance of technology driven by government and funding body incentives. For example, in the USA practitioners can claim up to \$44,000 p.a. for using 'meaningful use certified software'. In Australia, practitioner computerization has been encouraged by Medicare's practice incentive payments (PIPs).

However, as with other technology-based industries, the technology – and its application – is ahead of the law and regulatory issues, but these regulatory considerations should not be considered as limitations curtailing the use of telehealth and digital health more broadly, given the significant health improvements achievable through telehealth.

Moreover, the very nature of healthcare and of health systems means that there will always be a high level of government involvement and regulation over the sector either through general regulation or through financial mechanisms, such as which services are – and are not – covered by rebates or other incentives.

This paper does not provide an in-depth summary of all laws relating to telehealth and digital health in Australia let alone globally; to do so would be a book in itself that would rapidly become obsolete particularly given that practice is ahead of regulation. Rather this paper is based on what the authors see in clinical practice. It discusses the issues to be considered in telehealth, and argues that many of the

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