### TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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### LAWS AND REGULATIONS ON TELEMEDICINE

### 1. Is telemedicine allowed in your country? If so, how is it defined?

Telemedicine is allowed in Australia.

The Health Insurance (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021<sup>1</sup> ('Telehealth Determination') defines 'telehealth attendance' and 'phone attendance' as follows:

- telehealth attendance means a professional attendance by video conference where the rendering health practitioner:
  - (a) has the capacity to provide the full service through this means safely and in accordance with relevant professional standards;
  - (b) is satisfied that it is clinically appropriate to provide the service to the patient;
  - (c) maintains a visual and audio link with the patient; and
  - (d) is satisfied that the software and hardware used to deliver the service meets the applicable laws for security and privacy.
- phone attendance means a professional attendance by telephone where the health practitioner:
  - (a) has the capacity to provide the full service through this means safely and in accordance with professional standards; and
  - (b) is satisfied that it is clinically appropriate to provide the service to the patient; and
  - (c) maintains an audio link with the patient.

# 2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

Currently, there are no specific laws relating to telemedicine in Australia.

The existing laws and regulations that apply to the provision of health services apply to telemedicine, including:

- (a) the Health Practitioner Regulation National Law, which creates a national registration and accreditation scheme for registered health practitioners in Australia;
- (b) the Health Insurance Act 1973 (Cth) and associated subordinate legislation, which regulates Australia's national insurance scheme that provides free or subsidised healthcare for Australians (Medicare); and
- (c) the Privacy Act 1988 (Cth) and the Australian Privacy Principles (APPs), which regulate the collection, use and disclosure of personal information including health information.

## 3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

All health practitioners in Australia must have a current registration with the Australian Health Practitioner Regulation Agency (AHPRA) to practice medicine in Australia, including telemedicine. AHPRA is supported by 15 National Boards that are responsible for regulating the 15 health professions:

- (a) Aboriginal and Torres Strait Islander Health Practice Board of Australia
- (b) Chinese Medicine Board of Australia
- (c) Chiropractic Board of Australia
- (d) Dental Board of Australia
- (e) Medical Board of Australia
- (f) Medical Radiation Practice Board of Australia
- (g) Nursing and Midwifery Board of Australia
- (h) Occupational Therapy Board of Australia
- (i) Optometry Board of Australia
- (j) Osteopathy Board of Australia
- (k) Paramedicine Board of Australia
- (I) Pharmacy Board of Australia
- (m) Physiotherapy Board of Australia
- (n) Podiatry Board of Australia
- (o) Psychology Board of Australia

There is no 'Telehealth Board of Australia' or an equivalent. Telehealth providers will remain subject to regulation by AHPRA and their relevant Board.

Some jurisdictions have a Health Care Complaints Commission. For example, the Health Services Commissioner (HSC) in Victoria and the Health Care Complaints Commission in New South Wales. These are independent authorities that are responsible for dealing with complaints about doctors, hospitals, dentists, pharmacists, physiotherapists and other providers of health services, or any person or organisation that collects, holds, or discloses health information. As such, complaints made against a telehealth provider will be dealt with by these authorities in the same manner as if the practitioner or health service provider was providing the health service in a traditional, face-to-face consultation.

### 4. Was telemedicine authorised during the Covid-19 pandemic?

Telemedicine was legal in Australia pre Covid-19 by medical practitioners and some allied health registered to practice in Australia.

Commonwealth subsidies through Medicare Benefits Schedule (MBS) were authorised prior to Covid-19 for some limited services provided to remote Australian geographical regions. For example, for patients in rural and remote communities. This was largely due to Medicare, which restricted health practitioners to delivering services from a registered location (ie, their medical practice).

On 13 March 2020, temporary MBS telehealth items were made available to reduce the risk of community transmission of Covid-19. The Medicare Benefits Schedule (MBS) is a list of health professional services that the Australian Government subsidises. The temporary MBS telehealth items were introduced by the 'Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020'.

5. Is there any possibility of the regulatory landscape being changed in the postpandemic scenario? Or has there been already a change in the regulation in the postpandemic scenario?

Yes. From 1 January 2022, several temporary MBS telehealth items transitioned to ongoing arrangements.

6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis, telesurgery, among others)?

There is no specific licensing of telemedicine services in Australia.

The Telehealth Determination allows for subsidies for:

- (a) teleconsultations,
- (b) telemonitoring,
- (c) remote discussions between healthcare providers.2
- 7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.

Patient-doctor telemedicine services are allowed.

The medical practitioner must be registered in Australia.

As per section 7(5) of the Telehealth Determination, telemedicine services which are subsidised can only be performed by a patient's 'usual medical practitioner'. In other words, to be eligible for GP telehealth services, patients must have had a face-to-face consultation with their GP or another GP in the same practice in the 12 months before the telehealth service.

Section 7(7) of the Telehealth Determination defines 'patient's usual medical practitioner':

- '(7) For the purpose of subsection (5): patient's usual medical practitioner means a medical practitioner (other than a specialist or consultant physician) who:
- (a) has provided at least one service to the patient in the past 12 months; or
- (b) is located at a medical practice at which at least one service to the patient was provided, or arranged by, in the past 12 months.

For the purpose of this subsection, service means a personal attendance on the patient and excludes telehealth and phone attendances.'

8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.

<sup>2</sup> www.digitalhealth.gov.au/healthcare-providers/initiatives-and-programs/telehealth.

Some telehealth and phone services are available as Medicare Benefits Schedule (MBS) item numbers, which means they are subsidised by the Australian Government. The relevant legislation includes:

- (a) Health Insurance Act 1973 (Cth);
- (b) Health and Other Services (Compensation) Act 1995 (Cth);
- (c) Health Insurance Regulations 2018 (Cth);
- (d) Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020 (Cth);
- (e) Health Insurance (General Medical Services Table) Regulations (No. 2) 2020 (Cth);
- (f) Health Insurance (Pathology Services Table) Regulations 2020 (Cth); and
- (g) Current 3C Determinations under the Health Insurance Act 1973, including the Health Insurance (Section 3C General Medical Services Telehealth and Telephone Attendances) Determination 2021.

Any telemedicine services not covered by Medicare may be covered by private health insurance. The extent of cover depends on the policy wording of the private health insurance company. The relevant legislation includes the Private Health Insurance Act 2007 (Cth).

9. Please indicate whether any insurance requirements applicable to telemedicine services providers.

For reimbursement by Medicare, the medical practitioner must be registered to practice as a medical practitioner in Australia and registered with Medicare.

Most private health insurers require, as a condition to reimbursements, that medical practitioners be registered to practice as a medical practitioner in Australia.

## REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists, alternative health therapies providers, etc).

In relation to health practitioners who provide services to patients in Australia, they must be registered in Australia.

MBS telehealth items (subsidised by the Commonwealth Government) are available to:

(a) GPs;

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- (b) medical practitioners;
- (c) specialists;
- (d) consultant physicians;
- (e) nurse practitioners;
- (f) participating midwives;
- (g) allied health providers; and
- (h) dental practitioners in the practice of oral and maxillofacial surgery.3

www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Factsheet-telehealth-1July22.

# 11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?

Healthcare professionals (such as medical practitioners, nurses and specified allied health professionals) are required to have specified education requirements and training to be registered as health care professionals.

There is no specific qualification or education required for telemedicine services.

## 12. Is there any registration requirement applicable to physicians that provide telemedicine services?

At a minimum, all health practitioners in Australia must have a current registration with the Australian Health Practitioner Regulation Agency (AHPRA). The relevant legislation is the Health Practitioner Regulation National Law, as in force in each State and Territory.

Medical practitioners must also have a provider and prescriber number from Medicare Australia, which provides the practitioner with patient access to the Medicare and Pharmaceutical Benefits Schemes.

The registration requirements for medical practitioners that provide telemedicine services are the same as those who do not provide telemedicine services.

# 13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

There are no special licences or authorisations specific to telemedicine services. As discussed above, the typical registration requirements for medical practitioners apply to telemedicine.

### REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

### 14. Are there specific requirements applicable to the telemedicine platform?

No specific equipment is required to provide telehealth services. Services can be provided through telephone and widely available video calling apps and software, subject to privacy laws and the Health Practitioner Regulation National Law, including the Code of Conduct for doctors in Australia.<sup>4</sup>

## 15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

As per Question 16 above, there are no specific requirements regarding electronic equipment and internet speed for the telemedicine services.

### 16. Does the legislation provide for specific rules concerning patients' medical records?

Privacy laws and health records legislation apply to telehealth. Please see Question 20 below.

## 17. Are there geographic location requirements applicable to the provision of telemedicine services?

There are no longer any geographic location requirements applicable to the provision of telemedicine services.

<sup>4</sup> www.ahpra.gov.au/Resources/Telehealth-guidance-for-practitioners.aspx.

## 18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?

Consent to medical treatment is generally required (except in the case of an emergency where consent cannot be obtained and there is no indication that treatment cannot be provided), but nothing specific to telehealth.

Health information can only be collected by lawful and fair means, and generally only with the patient's (express or implied) consent and where the information is reasonably necessary for providing a health service to that patient.

### 19. Is there any other important requirement that should be highlighted?

As noted for Question 7 above, to be eligible for GP telehealth services which are subsidised by the Commonwealth Government, patients must have had a face-to-face consultation with their GP or another GP in the same practice in the 12 months before the telehealth service.

#### **DATA PRIVACY ASPECTS**

# 20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.

Yes, telemedicine services are subject to privacy and surveillance laws.

In Australia, the regulation of 'health information' is governed by legislation at both a state/territory and federal level.

The Privacy Act 1988 (Cth) ('Privacy Act') applies to federal government agencies and the private sector. The Privacy Act contains 13 Australian Privacy Principles (APPs).

The APPs govern standards, rights, and obligations around:

- (a) the collection, use and disclosure of personal information;
- (b) an organisation's governance and accountability;
- (c) integrity and correction of personal information; and
- (d) the rights of individuals to access their personal information.

In some states and territories, state and territory legislation apply to healthcare providers in the private sector, in addition to the Privacy Act, for example, the Health Records and Information Privacy Act 2002 (NSW).

Requirements relating to data collection and use of private health data include:

From the Privacy Act 1988 (Cth):

### Interpretation

Personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

- (a) whether the information or opinion is true or not; and
- (b) whether the information or opinion is recorded in a material form or not.

### Meaning of health information

The following information is health information:

(a) information or an opinion about:

- (b) the health, including an illness, disability, or injury, (at any time) of an individual; or
- (c) an individual's expressed wishes about the future provision of health services to the individual; or
- (d) a health service provided, or to be provided, to an individual;
- (e) that is also personal information;
- (f) other personal information collected to provide, or in providing, a health service to an individual.

### Meaning of health service

An activity performed in relation to an individual is a health service if the activity is intended or claimed (expressly or otherwise) by the individual or the person performing it:

- (a) to assess, maintain or improve the individual's health; or
- (b) where the individual's health cannot be maintained or improved—to manage the individual's health; or
- (c) to diagnose the individual's illness, disability, or injury; or
- (d) to treat the individual's illness, disability or injury or suspected illness, disability, or injury; or
- (e) to record the individual's health for the purposes of assessing, maintaining, improving, or managing the individual's health.

The 13 APPs govern the way in which personal information is to be collected, used, disclosed, and stored.

State/territory privacy laws may also apply. For example, the Health Records and Information Privacy Act 2002 (NSW) (HRIP Act) applies to organisations that are health service providers or that collect, hold, or use health information. The HRIP Act contains 15 Health Privacy Principles (HPPs), which impose similar obligations to the APPs.

# 21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?

Yes, as discussed above, the security systems must comply with the APPs to protect the patient's information.

Telemedicine providers must manage personal information in an open and transparent way, by having an up-to-date APP privacy policy (APP 1).

Further, telemedicine providers must take reasonable steps to protect personal information it holds from:

- 1. misuse, interface, and loss; and
- 2. unauthorised access, modification, and disclosure.

Telemedicine providers must also destroy or de-identify personal information it no longer requires (unless otherwise required to retain it by law) (APP 11).

## 22. Does the applicable regulation provide for requirements for the transfer of information abroad?

Yes, any cross-border transfers of information must comply with the Privacy Act. Telemedicine providers must impose contractual obligations on the overseas recipient of the information to

comply with Australian privacy laws, or otherwise gain appropriate informed consent from data subjects that their personal information may be sent overseas without the protection of Australian privacy laws or ensure that the overseas laws are commensurate with Australian laws (APP 8).<sup>5</sup>

23. Is there any registration of databases requirement that companies must observe?

Are there requirements regarding the recording of data in the patient's medical records?

Based on our review, there are no specific requirements for companies that provide data storage for telemedicine services beyond the current regulatory frameworks that apply, including privacy and surveillance laws.

#### **LIABILITIES**

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

Medical negligence laws apply to healthcare professionals and institutions involved in telemedicine practices.

The standard of care expected of health care professionals in most Australian jurisdictions is now expressed in statute. For example, section 50 of the Civil Liability Act 2002 (NSW) exemplifies the general approach:

Standard of care for professionals

- A person practising a profession (a professional) does not incur a liability in negligence
  arising from the provision of a professional service if it is established that the professional
  acted in a manner that (at the time the service was provided) was widely accepted in
  Australia by peer professional opinion as competent professional practice.
- 2. However, peer professional opinion cannot be relied on for the purposes of this section if the court considers that the opinion is irrational.
- 3. The fact that there are differing peer professional opinions widely accepted in Australia concerning a matter does not prevent any one or more (or all) of those opinions being relied on for the purposes of this section.
- 4. Peer professional opinion does not have to be universally accepted to be considered widely accepted.

The equivalent provisions in other jurisdictions include:

- (a) Wrongs Act 1958 (Vic) s 59;
- (b) Civil Liability Act 2003 (Qld) s 22;
- (c) Civil Liability Act 1936 (SA) s 41; and
- (d) Civil Liability Act 2002 (Tas) s 22.

There are also penalties under the Health Insurance Act 1973 (Cth) for inappropriate Medicare claims, including claims against the telehealth MBS item numbers:

128A False statements relating to Medicare benefits, etc.

<sup>5</sup> www.oaic.gov.au/privacy/australian-privacy-principles-guidelines/chapter-8-app-8-cross-border-disclosure-of-personal-information.

- 1. A person shall not make, or authorise the making of, a statement (whether oral or in writing) that is:
  - (a) false or misleading in a material particular; and
  - (b) capable of being used in connection with a claim for a benefit or payment under this Act.

Penalty: 20 penalty units.

#### **TELEMEDICINE NUMBERS AND TRENDS**

# 25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

According to a media release published by the Australian Government in April 2020, more than 4.3 million health and medical services were delivered to a total of more than three million patients through the telehealth items introduced by the Australian Government for the Covid-19 pandemic.<sup>6</sup>

An Australian Bureau of Statistics survey conducted in 2020–21 found that the following people were more likely to access telehealth services:

- (a) those with a long-term health condition than those without a long-term health condition (40.1 per cent compared to 16.5 per cent);
- (b) those aged 65\_74 years than those aged 15\_24 years (35.8 per cent compared to 21.4 per cent)
- (c) females than males (35.0 per cent compared to 22.2 per cent)
- (d) those living in inner regional areas and major cities than those living in outer regional, remote, or very remote areas (30.4 per cent and 29.1 per cent compared to 22.9 per cent).<sup>7</sup>
- 26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

Current identified issues regarding telehealth in Australia include:

- (a) lack of technological infrastructure;
- (b) limitations to performing physical examination; and
- (c) concerns regarding privacy and confidentiality.

The Royal Australian College of General Practitioners has noted that tailored GP training and sustainable funding models are necessary to ensure that telehealth is used 'optimally and equitably' in Australia.<sup>8</sup>

<sup>6</sup> www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/australians-embrace-telehealth-to-save-lives-duringcovid-19

<sup>7</sup> www.abs.gov.au/statistics/health/health-services/patient-experiences/2020-21#experience-of-telehealth-services.

<sup>8</sup> www1.racgp.org.au/ajgp/2022/august/telehealth-for-australian-general-practice#:~:text=Lack%20of%20technological%20infrastructure%20and%20privacy%20concerns%20are%20barriers%20to,is%20used%20optimally%20and%20equitably.