

TELECONSULTATION SERVICES FOR THE MOBILE WORKFORCE.

CONSIDERATIONS AND GUIDELINES FOR THE PROVISION OF GLOBAL SERVICES IN COMPLIANCE WITH REGULATIONS AND BEST PRACTICE CLINICAL STANDARDS OF CARE

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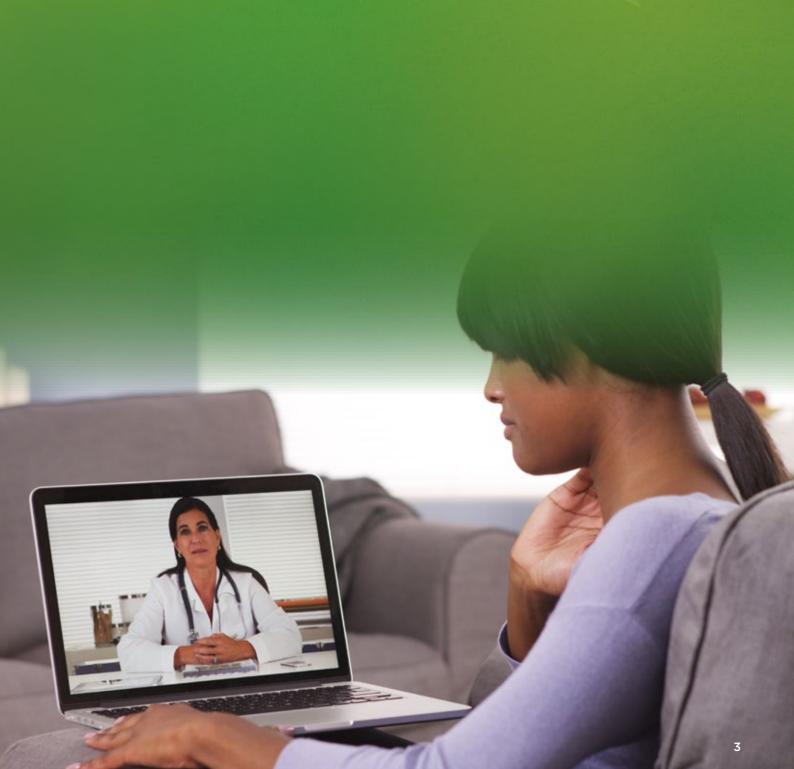
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Foreword

Across the globe, people have become increasingly comfortable purchasing goods and services online, including banking, finance, and e-commerce. Healthcare is no exception, and the world will see notable growth in international and trans-border telemedical services, particularly as new technologies allow physicians to deliver on-demand care quickly and affordably. Organisations using teleconsultation services worldwide should embrace these opportunities, but must also take the time to understand and assess applicable medical

licensure and best medical practice requirements that teleconsultation providers need to adhere to. Doing so will not only maintain legal compliance, but will help ensure employees receive the optimal standard of medical care aligned with their local healthcare infrastructure and environmental health risks, in a manner linguistically and culturally familiar to each individual patient. This will constitute the gold standard of global teleconsultation services.



INTRODUCTION

Telehealth, the provision of healthcare at a distance using communications technology is rapidly becoming an established model of domestic healthcare delivery in many markets around the world.



TeleConsultation, a category of telehealth, describes the clinical practice of medicine directly between physician and patient, typically using video conferencing. In 2018, it is estimated that 96% of large companies in the USA offer teleconsultation services to their staff. As the workforce becomes increasingly mobile, millennial and connected, the question emerges on how best practice can be applied to global teleconsultation services when utilized to support business travellers and expatriates.

This paper seeks to address the key considerations and unique challenges that arise in the delivery of a global teleconsultation capability. This includes legal and regulatory compliance across multiple international jurisdictions, as well as an appreciation of different cultural and clinical care demands. In a global teleconsultation model, physicians must follow the law of their single "home" country and that of the country where their patient is situated at the time of consultation. Just as teleconsultation requires its own tailored clinical and operational approaches, so too does it carry its own unique legal requirements.

Within this context, this paper explores the key legal and clinical care issues in international teleconsultation arrangements: medical licensure and standard of care. This is with reference particularly to the globally mobile workforce and an organisation's Duty of Care to its employees.

Definition of Telehealth

In general, telehealth is the delivery of healthcare services through technology where the physician is in one location and the patient is in a different location. It is not a medical specialty, but rather a tool – a technological conduit – through which medical care is provided. Moreover, telehealth is not a single technology or even a discrete set of related technologies. It is, rather, a large and heterogeneous collection of clinical practices, technologies, and organisational arrangements. It can be applied to numerous business models and service lines, and therefore can vastly span across a multitude of strategic objectives and clinical initiatives.

However, for simplicity and brevity, this article focuses on one type of telehealth service: direct-to-patient. These services are sometimes referred to as direct to consumer telemedicine services or "teleconsultations / teleconsults." Under this model, the physician delivers clinical services directly to the patient, often by interactive audio-video, but also interactive audio or asynchronous telemedical technologies. Teleconsultation services have been growing in use in a domestic context, but are now increasingly being offered in a transnational context to employees who travel, international staff, or for families vacationing abroad on holiday.

I. TELECONSULTATION AND LICENSING

It is widely understood and accepted that, in order to practice medicine, an individual must have a license to do so. Regarding teleconsultation services, most jurisdictions hold that licensing rules and medical practice laws are based not on the location of the physician, but rather on the location of the patient at the time of the teleconsultation.

This means, for example, a physician licensed in the United Kingdom and providing teleconsultation services to a patient located in Chicago, Illinois, USA must hold a license issued by the Illinois state medical board (or otherwise meet a licensure exception under Illinois law).

The rationale behind this position is that medical boards and ministries of health have the right (indeed, the obligation) to protect the people located in their jurisdiction. Requiring the physician to be licensed in the patient's jurisdiction affords the local medical regulating authority suitable oversight over standards of practice. This includes ensuring that the medical professionals providing teleconsultation services to patients in their jurisdiction are appropriately qualified, credentialed, and adhere to best practice clinical pathways.

In addition, licensure requirements give patients and local authorities a clear avenue for recourse should they be injured or wish to pursue a medical malpractice or negligence complaint against the treating physician. Importantly, this licensure also applies to the ability of a physician to be able to prescribe, and have fulfilled, medicine in a certain jurisdiction.

This patient-location-law approach is consistent with how jurisdictions are developing their laws on other internet-based services and e-commerce. For example, the new General Data Protection Regulation (GDPR) applies to companies that target patients residing in the EU, even if the company itself is located outside the EU.

The requirements for teleconsultation licensure vary from country-to-country, and differing local medical practice standards can present additional obstacles for physicians looking to practice across jurisdictions and organisations providing these services to customers and clients.



LEGAL REVIEW

A legal review of selected countries across the globe reveals trends and patterns regarding medical licensing and teleconsultation services.

Australia

Australia has published guidance expressly stating that physicians practicing telemedicine (i.e., delivering inter-jurisdictional technology-based patient consultations) on patients located in Australia must be registered with Australia's Medical Board regardless of where the physician is located.2

(*) Canada

Of the thirteen provinces and territories in Canada, most (including Quebec and Alberta) hold that the location of the patient governs the licensure requirements of the physician. Although some (including Ontario) extend limited reciprocity allowing a physician licensed in one Canadian jurisdiction to provide services via telemedicine to patients located in a different Canadian jurisdiction.3

France

One of the first EU countries to implement a specific legal framework for telemedicine, France requires a physician delivering medical services via telemedicine to be duly licensed to practice medicine in France.4

Mexico

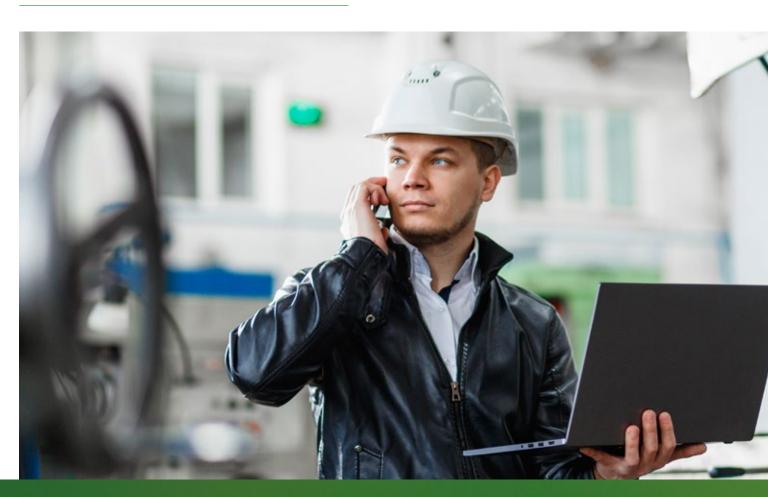
In Mexico, despite its lack of extensive telemedicinespecific regulations, a person delivering medical services to patients located in Mexico must be licensed (obtain a cédula professional) from the Ministry of Health's licensure offices.5

New Zealand

New Zealand is aligned with Australia. The New Zealand Medical Council guidance states, "if you provide care to New Zealand-based patients via telemedicine, the Council holds the view that you are practicing medicine within New Zealand and you should therefore be registered with the Council."6 The guidance applies to doctors registered in New Zealand and practicing telemedicine in New Zealand and/or overseas; as well as doctors who are overseas and provide health services through telemedicine to patients in New Zealand. Consistent with the idea that the location of the patient is what governs medical licensure requirements, if a doctor is physically located in New Zealand but only provides telemedicine services to patients who are located in another country, that doctor is not required to be registered with the New Zealand Medical Council.7

People's Republic of China (PRC)

The People's Republic of China (PRC) has issued rules on both medical licensing and telemedicine.8 A thorough reading of the published authorities makes clear that China regulators expect any person offering direct to patient medical services must be duly authorized to practice medicine in PRC. In addition, new China regulations impose additional requirements for online therapy, virtual care services, and prescribing via telemedicine.9



Philippines

The Philippines' Medical Act of 1959 does not explicitly address teleconsultation, but clearly requires a license to practice medicine, an activity broadly defined to include anyone "who shall, for compensation, fee, salary or reward in any form, paid to him directly or through another, or even without the same, physical examine any person, and diagnose, treat, operate or prescribe any remedy for any human disease, injury, deformity, physical, mental or physical condition or any ailment, real or imaginary, regardless of the nature of the remedy or treatment administered, prescribed or recommended."10 Because telemedical technology is simply a tool through which a physician can practice medicine, it logically follows that a person "engaged in the practice of medicine" with patients located in the Philippines must, himself or herself, be licensed in the Philippines to practice medicine.

Singapore

The telemedicine guidance in Singapore expressly requires that a physician "delivering telemedicine services from or within Singapore"11 must be duly registered and licensed in Singapore. Singapore's Ministry of Health offers a "regulatory sandbox" programme (the Licensing Experimentation and Adaptation Programme or LEAP), through which telemedicine providers can deploy experimental pilot programs under the supervision of the Ministry until Singapore implements a final set of telemedicine laws.¹²



United Kingdom

While the United Kingdom's medical laws do not expressly address telemedicine, its General Medical Council does require that doctors practicing medicine in the UK must be registered with a license to practice therein.¹³ The implication and inference is that a person delivering medical services to a patient located in the UK - whether teleconsultation or otherwise - must be licensed to practice medicine in the UK.



United States

The United States has arguably the most extensive and well-developed set of laws and regulations governing telemedicine. Each of the 50 states in the United States has laws or rules that require, expressly or implicitly, that the location of the patient at the time of the medical consult governs licensure.

A physician delivering medical services via telemedicine must be licensed to practice medicine in the state where the patient is located. If the patient is located in Florida, the doctor must be licensed to practice medicine in Florida, regardless of where the doctor is physically located and regardless of what other jurisdictions the doctor is licensed.¹⁴ The same holds true for California¹⁵, Texas¹⁶, New York¹⁷ and other individual jurisdictions within the United States.



Peer to Peer Consultation

Some jurisdictions offer limited exceptions to medical licensure, the most notable of which is when two physicians consult with each other regarding a medical question (often referred to as "curbside consults" or peer-to-peer consultations). In these circumstances, the foreign physician typically must be licensed in the jurisdiction where they are located, and the local physician must be licensed in the jurisdiction where they and the patient are located. The local physician is held responsible for maintaining the physician-patient relationship, while the foreign physician's services are only for secondary consultation purposes.

However, the scope of the peer-to-peer consultation exemption varies greatly between countries or states. Some allow it only for free consults or informal questions between doctors, and others only allow infrequent or occasional consults. More important, the power of telemedicine technologies to easily reach across geographic borders means that, "regardless of whether a local license is required or not, cooperation and collaboration between countries and regulators (which effectively have a national reach at most) becomes vital in ensuring that technology is safely used in providing medical care."18

II. TELECONSULTATION AND THE STANDARD OF CARE

Fundamental to the practice of medicine, whether in-person or via teleconsultation, is to meet the standard of care and deliver high-quality services.

To this end, physicians should adhere to the same standard of care in teleconsultation settings as they would when delivering care in-person. Thus, labs, diagnostic tests, medical histories, and any other information required to be obtained in the in-person setting should be obtained when delivering care via teleconsultation. Additionally, the ability to prescribe medication, or refer to inpatient or specialist care, can be important to meeting the standard of care.

The term "standard of care" is typically defined as the level and type of care a reasonably competent and skilled healthcare professional would deliver to a patient under similar circumstances. In addition to governmental medical boards and ministries of health holding physicians accountable for meeting the standard of care, departures from the standard of care can form the basis for medical malpractice or negligence claims. Understanding the standard of care in the context of teleconsultation is critical for physicians using this technology in their practice.

There are several key considerations in delivering the optimal standard and continuity of clinical care that favour the conduct of teleconsultation by in-country physicians in contrast to physicians providing cross-border teleconsultations.

This includes the depth of knowledge of the local healthcare system and environmental health risks (which vary widely across the globe) to ensure diagnostic advice and treatment recommendations are provided in full consideration of the local healthcare context.

For example, the scope of medical practice of a physician seeing patients in New York regarding tropical diseases such as malaria or Dengue Fever will be very limited compared to a physician managing patients in Singapore. Considerations in the differential diagnosis and clinical approach for a patient presenting with a fever in New York may be substantively different to a patient in Singapore. These considerations can be compounded for teleconsultations without diagnostic testing or in-person examinations.

In addition, the capability to facilitate local healthcare beyond the teleconsultation, including diagnostics and referrals to local medical facilities or specialists, can be significantly limited for a physician in another country compared to a local physician. Typically, a locally-licensed physician is able to write specialist referrals which comply with local guidelines and which will be recognized by the local specialists.





This is also applicable to ordering diagnostic tests (e.g. imaging, blood tests) and extends to the understanding of access to local healthcare, the differentiation between public versus private healthcare systems, and the implications to the patient of the cost and payment for local medical care.

The ability of a local physician to follow-up and monitor the patient's care, provide ongoing medical assistance, and ensure medical reports arising from teleconsultation are collated and available to local primary care and specialist providers, can be easier than when attempted by a physician in another country. This is also impacted by the physician being able to proficiently communicate as a medical professional in the local language.

For example, physicians in the UK or US may have significant challenges in liaising with healthcare professionals and administrators in a Chinese state hospital without substantive fluency in Mandarin. A provider desiring to build a robust global teleconsultation service should factor these considerations and needs when developing its platform and service functionality.

The conduct of teleconsultation in delivering optimal standard of clinical care also extends to the integral component of medication prescription and dispensing. Selecting and prescribing the most appropriate medication consequent to the teleconsultation requires broad knowledge and familiarity of local medication availability, brand names and accessibility, including differentiation between prescription and controlled medications.

These vary widely across countries (and indeed within countries in many locations) and the local knowledge of a physician familiar with the country is highly advantageous. In addition, in most advanced regulated medical jurisdictions, the authority to legally prescribe medication requires the prescribing physician to be licensed in the local jurisdiction of the patient. Beyond prescribing, the ability of the physician undertaking the teleconsultation to facilitate the dispensing of the prescribed medication at local suitable pharmacies (and with appropriate safe delivery of this medication) is again the domain of local physicians versus physicians based in other countries. As aforementioned, this is also impacted by the need of fluency in the local language.

CASE STUDIES

An example of a global teleconsultation capability can be illustrated via recent cases managed by International SOS:

University Student Studying Abroad

An American university student was studying abroad in the United Kingdom, and fell ill with a sinus infection. Seeking help, he contacted the International SOS Assistance Centre in Philadelphia, USA.

The coordinating nurse at International SOS conducted an initial assessment and determined that the medical condition of the patient made them suitable for teleconsultation. The coordinating nurse proceeded to triage the patient to teleconsultation after identifying no primary care providers were immediately available for an in-person consultation (since it was a Sunday afternoon), and the nearest hospital was both 15 minutes away and not the preferred clinical setting for the student's condition.

The International SOS operations team immediately scheduled an appointment with a local UK GMC registered teleconsultation provider in the UK, who was credentialed and contracted as part of International SOS' global provider network. The student participated in the video-based teleconsultation at the agreed scheduled time, using an International SOS provided mobile app on their iPhone, with an encrypted video connection to the local provider.

After reviewing the student's condition on the video call, the local provider determined the need to remotely prescribe antibiotics, and sent the prescription electronically to a nearby pharmacy, only a short walk from the student's location. The student collected the medication minutes after the conclusion of the teleconsultation, and began the course of treatment.

International SOS followed up regularly with the patient and the sinus infection successfully resolved over the following several days.

International SOS managed the payment and related medical reporting to the student's university, working in compliance with UK and USA data security laws.

International Business Traveller

A French business traveller was in the USA for an eight day business trip, with a full schedule of meetings and travel to several cities in California and New York. Upon arrival in the USA he realised that he had forgotten his prescription medication (Levothyroxine) used to manage his chronic thyroid condition.

The business traveller contacted the International SOS Assistance Centre in Paris, seeking help in obtaining a replacement of this medication. The Paris medical team determined teleconsultation was an appropriate option, considering both the clinical situation and the travel schedule of the individual.

The International SOS operations team scheduled a teleconsultation with a California licensed physician, who was credentialed and contracted as part of International SOS' global provider network – at a time that avoided disruption to the business travellers' planned meeting schedule.

The teleconsultation was completed successfully, and a prescription transmitted electronically to a pharmacy adjacent to the individual's hotel in San Francisco. The business traveller was able to continue to adhere to their thyroid treatment plan, and complete their planned travel in the USA without incident.



III. GLOBAL BEST PRACTICES

Regardless of jurisdiction, the following best practices are nearly universal, and are recommended for any global teleconsultation service.



Physicians delivering teleconsultation services should be appropriately licensed in the patient location, and working in compliance with local health regulations.



Physicians should be permitted to prescribe remotely to the patient (when clinically required), with a detailed prescribing regulations.



Patients should be told the benefits and risks of services delivered via teleconsultation, and give their consent to



Personal health information related to the teleconsultation should be managed in accordance with relevant local data protection regulations.



The organisation providing, or coordinating, the teleconsultation services should be certified to appropriate quality management standards, such as ISO/TS 13131 Telehealth Services.



The standard of care should be the same whether the patient is seen in-person, through teleconsultation, or other methods of electronically enabled health care.



If the physician cannot competently and confidently diagnose or treat the patient via teleconsultation, the physician should refer the patient to an in-person examination before rendering a diagnosis or prescribing therapeutic treatment.



The undertaking of a teleconsultation should not be considered in isolation, and should include the capability of facilitating the patient's necessary medical care and assistance requirements post-teleconsultation.



The physician should be fluent in the local language at the patient location, to ensure appropriate documentation and referral pathways when necessary.

END NOTES

- https://www.businessgrouphealth.org/news/nbgh-news/press-releases/press-release-details/?ID=334)
 See Medical Board of Australia, Inter-Jurisdictional Technology Based Patient Consultations (Aug 15, 2013).
- 2013).

 See Mui, Jospe, Foster, Telemedicine: Making Delivery of Health Care Services Across Borders More Accessible to Canadians (Mar 16, 2016); see also, e.g., College of Physicians and Surgeons of British Columbia, Professional Standards and Guidelines: Telemedicine (Mar 2015); College of Physicians & Surgeons of Alberta, Administration of Practice: Telemedicine (Mar 2015); College des Médecins du Québec, Le Médecin, la Telemedicine (Parendicine) (Jun 5, 2014); Collège des Médecins du Québec, Le Médecin, la Telemedicine et les Technologies de l'Information et de la Communication (Feb 2015); College of Physicians and Surgeons of Ontario, Policy Statement #3-14; Telemedicine (Dec 2014). See Europe Economics, Regulatory Approaches to Telemedicine (Aug. 5, 2018) at Sec. 4.1. (citing Article 78 of Law 2009-879); see also Code de la Santé Publique, Art. L. 4111-1, 4112-7; Art. R. 6316-6.7.

- 5 See Mexico General Health Law (Le General de Salud), Arts. 28 bis. & 81.6 See Medical Council of New Zealand, Statement on Telehealth (Jun 2016) at Sec. 5.
- See Rule 14 of PRC Law on Medical Practitioners; see also National Health and Family Planning Commission (NFHPC), Notice on Reinforcing the Administration of Telemedicine (1999); NFHPC,

- Opinions on Promoting Telemedicine Service of Medical Institutions (2014); State Council General Office, Opinions on Promoting the Development of the Internet Plus Healthcare Action Plan (2018) Telemedicine Service Management Specification), Internet Hospital Management Measures, and Internet Diagnosis and Treatment Management Measures (pub. Sep 14, 2018) 10 Philippines Medical Act of 1959, Art. III, § 10.
- 11 Singapore National Telemedicine Guidelines at \$ 2.3 (Jan. 2015); see also Philippines' Medical Registration Act, Ch. 174, P. 3, \$ 13 (Dec. 31, 2014).
- 12 https://www.moh.gov.sg/content/moh_web/home/our_healthcare_system/RegulatorySandbox.html 13 See UK General Medical Council, A Guide to the Medical Register: Unregistered Medical Practice also United Kingdom's Medical Act 1983, Ch. 54, P. I, § 2.
- 14 Fla. Admin. Code Ann. r. 64B8-9.0141. 15 Cal. Bus. & Prof. Code § 2290.5(6).

- 17 New York Education Law, Art. 131 Sec. 6522 et seq. 18 Europe Economics, Regulatory Approaches to Telemedicine (Aug. 5, 2018) at Sec. 4.4.1.

ABOUT INTERNATIONAL SOS FOUNDATION

Established in 2011, the International SOS Foundation — Ambassadors for Duty of Care www.internationalsosfoundation.org- has the goal of improving the safety, security, health and welfare of people working abroad or on remote assignments through the study, understanding and mitigation of potential risks. The escalation of globalisation has enabled more individuals to work across borders and in unfamiliar environments; exposure to risks which can impact personal health, security and safety increases along with travel.

The Foundation is a registered charity and was started with a grant from International SOS. It is a fully independent, non-profit organisation. For more information on Duty of Care and the International SOS Foundation, please visit internationalsosfoundation.org

ABOUT THE INTERNATIONAL SOCIETY FOR TELEMEDICINE & EHEALTH

The International Society for Telemedicine & eHealth (ISfTeH), is a nongovernmental and not-for-profit society that services primarily as the umbrella association for national Telemedicine and eHealth organization. Geopolitically neutral and democratic, the ISfTeh exists to facilitate the international dissemination of knowledge in Telemedicine and eHealth and to provide access to recognized experts in the field worldwide. The main activities of the society are promotion and support of Telemedicine and eHealth activities worldwide, assisting the start-up of new national organizations and supporting developing countries in the fields of Telemedicine and eHealth.

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