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 not specifically regulated in Bolivia. However, according to Article 41, paragraphs I and IV of the Bolivia Constitution, the State shall guarantee access to medicines to all its citizens; the right to access medicines may not be restricted by intellectual property and marketing rights; and will contemplate quality and first generation standards. Therefore, telemedicine would not be prohibited in order to fulfil the access to medical attention and to medicines.

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

- 1. Bolivian Constitution.
- 2. Law 3131 dated 8 August 2005 on the Professional Exercise of Medicine, (*Ley del Eiercicio Profesional Médico*).
- 3. Law 475 dated 30 December 2013 on the Granting of Integral Health Services of the Plurinational State of Bolivia (*Ley de Prestaciones de Servicios de salud Integral del Estado Plurinacional de Bolivia*).
- 4. Supreme Decree No 28562 of 22 December 2005, regulations to Law 3131 (*Reglamento a la Ley 3131*).

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

According to Bolivian regulations, there is no special public entity that provides any type of licence for telemedicine. However, whoever provides health services, must be a healthcare provider, whose obligation is to attend people with health requirements and said professional services are regulated by Law 3131.

According with Law 3131, article 12 (h) mentions the following: 'It is the responsibility of the healthcare professional to grant the benefits of medicine to anyone who needs them, without any distinction and without more limitations than those indicated by law.'

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

No, it wasn't authorised specifically. Law 1293 of 1 April 2020 for the Prevention, Contention and Treatment of Infections caused by Covid 19 (*ley para la prevención, contención y tratamiento de*

la infección por el coronavirus Covid-19) doesn't mention specified details about Telemedicine but, in any case, is not prohibited.

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?

It is possible that new regulations on this matter are approved due to the pandemic scenario.

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

There are no specific regulations on this matter.

7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.

There are no specific regulations on this matter.

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.

There are no specific regulations on this matter.

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

There are no specific regulations on this matter.

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).

There are no specific regulations on this matter. However, in order to practice medicine in general certain requirements must be met. According to Article 4 of Law 3131, the healthcare provider is a professional who, having carried out studies in legally recognised universities, has an Academic Diploma (*Titulo en Provision Nacional*) issued by competent authorities. In addition, Article 7 establishes that said professional must be registered in order to provide his professional services. Therefore, and there not being any restrictions to practice telemedicine, other healthcare professionals (who comply with their own requirements to practice) could offer their services through the same system.

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

There are no specific regulations on this matter.

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

There are no specific regulations on this matter.

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

There are no specific regulations on this matter.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

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

There are no specific regulations on this matter.

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

There are no specific regulations on this matter.

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

Article 10 of Law 3131 establishes that medical records must be preserved and under protection of the medical centre. Also, Supreme Decree 28562 details which documents must be incorporated in the medical records.

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

There are no specific regulations on this matter.

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

There are no specific regulations on this matter. However, for regular consultation such consent by the patient or legal representative is required.

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

N/A

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.

According to Article 4 of Law 3131, all information identified during the medical act on the health or illness of the patient, his or her treatment and all other information of a personal nature, must be kept secret, even after his death, to safeguard the dignity of the patient (medical secrecy), so all information about the patient must be conserved under said conditions that are inviolable, except for certain exceptions provided for in the Law.

Under Article 130 of the Bolivia Constitution:

'Any individual or collective person who believes that he or she is duly or illegally prevented from knowing, objecting or obtaining the elimination or rectification of the data recorded by any physical, electronic, magnetic or computer means, in public or private data files or banks, or that affects to their fundamental right to intimacy and personal or family privacy, or to your copy, image, honour and reputation, may file the Privacy Protection Action.'

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

There are no specific regulations on this matter.

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

There are no specific regulations on this matter.

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?

For the second part of the question, there are no specific regulations on this matter.

LIABILITIES

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

There are no specific regulations on this matter. However, for general practice of the medicine, the Criminal Law in Article 218 mentions four scenarios regarding the illegal exercise of the medicine:

- 1. anyone who, without professional licence or authorisation, exercises a medical, health or similar profession;
- 2. anyone who with professional licence or authorisation announces or promises the cure of diseases to fixed term or by secret or infallible means;
- 3. anyone who, with the same professional licence or authorisation, lends his name to another who does not have it, to who practices the professions referred to in subsection (1); and
- 4. anyone who performs unnecessary surgical intervention or medical treatment.

The criminal sanction is imprisonment of three months to two years, or economic sanction equivalent to between 30 and 100 working days.

TELEMEDICINE NUMBERS AND TRENDS

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

There is little public information of this matter. However, according to data from Health Ministry of Bolivia, from the beginning of the Covid-19 pandemic until the end of June 2020, about 220 thousand virtual consultations have been carried out by operators and medical specialists.

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.

The practice of Telemedicine should be regulated, and proper public policies should be approved, which include: increase and improvement of the technical equipment; training for all health professionals and support staff; increase of adjacent telemedicine industries; and search for more reliable and secure solutions considering the need to ensure data security in health.