

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, but there is not a legal definition.

The Health Ministry defines it as the 'provision of remote health services, to achieve the sanitary objectives of promote, prevent diagnose, treat, rehabilitate and take care of the end of life.' (<https://portalsaluddigital.minsal.cl/telemedicina-sincronica>).

There are some instructions issued by public entities such as the Health Superintendency and the National Health Fund (FONASA per its name in Spanish) that contain some definitions of teleconsultation. Both definitions are not the same, but we can tell that they are conformed by three main elements:

- the medical action consists in a consultation that is made distantly;
- the consultation is performed between a physician and a patient that have different geographic location; and
- the consultation is performed using IT and telecommunication, which allows the physician and the patient to interact simultaneously.

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

Even when there is not specific regulation for telemedicine, there are some laws and decrees that apply to any kind of healthcare actions, whether they are in person or remote. The main ones regarding this topic are the following:

- Law No 20,584 that regulates the rights and duties held by the people in relation with their health care actions. ('Law No 28,584');
- Supreme Decree No 41, 2012, of the Ministry of Health, that approves the regulation regarding medical records ('Decree No 41');
- Law No 19,628, about private life protection. ('Law No 19,628') is also applicable as information of patients are treated under telemedicine;
- Also, there is some regulation, that regulates specifically some aspects of telemedicine, especially the ones regarding mandatory health insurance.
- Resolution No 277 from 2011, issued by the Ministry of Health, regarding public mandatory health insurance, FONASA. ('Resolution No 277'); and
- Circular IF/No 77, from 25 July 2008, issued by the Health Superintendency, regarding private health insurance. ('Circular IF/No 77').

Currently, there is a decree that regulates specifically telemedicine, that is already approved by the General Comptroller of the Republic, which means that it is ready to be published and thus to become mandatory, but the Ministry of Health, which is the authority that has to publish it, hasn't done it yet. We do not know with certainty when or if it is going to be published, as its publication is not mandatory. This decree is the Decree No 6, issued on 16 April 2021, by the Health Ministry (in the following referred as the 'Pending Decree').

The Pending Decree, even when it is not yet in force, can give us hints on what are the issues that will be regulated when a new specific regulation becomes in force. The Pending Decree regulates matters such as the IT requirements, tools and standards that should be met, data privacy requirements, the process to record information security's incidents, rights and duties of patients' subject of telemedicine consultations, and medical records specificities.

Also, it is important to bear in mind that currently there are two Bills of Law being discussed in the Parliament that can have an impact in the regulation of telemedicine. One of them is the Bill of Law about telemedicine (Bill No 13,375-11), and the other one is about data protection (Bill No 11,144-07). Provided their approval by the Parliament, it will be necessary to issue new regulations and the practice of telemedicine will have to adjust to these new requirements. We can't affirm when or if those Bills of Law will pass through the Parliament and thus become a Law, nor which areas will be regulated and how. Nevertheless, it is important to keep tracking of those projects.

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

Currently, there are no official licensing bodies for telemedicine. In general, telemedicine can be performed freely by anyone who wants to perform it, as long they comply with the general regulation set forth to perform healthcare actions on their area of expertise.

Nevertheless, and only for insurance coverage purposes, FONASA which is the fund that finances public healthcare, have to approve the platforms used to perform teleconsultation, in order for those consultations to be financed by FONASA.

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

Yes, it was, not only authorised but also promoted, so healthy people avoid visiting emergency rooms and hospitals whose efforts were focused on patients with Covid-19.

During the pandemic, the Ministry of Health and related entities issued some regulations that helped to facilitate the use of telemedicine. Specifically, they issued regulations that permitted mandatory health insurers to finance telemedicine consultations.

In general, all the regulations about the topic were issued after March 2020, which was the month when Covid-19 hit Chile.

It is important to consider that even when some regulations have become permanent, there are some other regulations about telemedicine that are linked to the Sanitary Alerts issued due to Covid-19 pandemic. The Sanitary Alerts are still in force until December 2022 and will probably be extended.

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

Yes, as we explain previously, there are some regulations that can become mandatory. Two of them are the Bills of Law about telemedicine, on one hand, and data protection on the other. In addition, there is the Pending Decree, that was developed during the pandemic and is ready to become mandatory if the Ministry of Health decides to publish it.

Even if the Ministry of Health decides not to publish the Pending Decree, so it doesn't become mandatory, there are strong motives to think that the Ministry of Health will issue a new one. This relies on the fact that telemedicine is an increasing trend and is considered in the National Health Strategy. Furthermore, it is important to note that if the Bill of Law about telemedicine is approved, the regulatory landscape on the topic will vary because it will have to adapt to the new regulation, which is one of the reasons why the Government has not yet published the Pending Decree – because they want to adapt it to the potential new legal regulation.

We cannot say with certainty when, or if, the Bills of Law about telemedicine protection will be approved.

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

As there is no specific regulation, all kinds of teleservices are permitted, in the sense that they are not prohibited.

Nevertheless, FONASA will only finance the telemedicine services listed in Resolution No 277. Also, regarding FONASA's funding, there are some services that in order to be able to be rendered remotely should also be rendered in person. This does not apply to all kind of teleconsultations. In the private sector, the list of services that are covered by ISAPRES is contained in Circular IF/No 77.

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

Anyone can use it; it is not relevant if it is doctor-doctor or patient-doctor. The important thing is that the professional rendering the telemedicine service should be allowed to perform their profession or activity.

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.

Telemedicine is being used by all the actors in the health system. The public system uses it to provide services in isolated locations, or in cities where there is lack of physicians.

The funding model for telemedicine is the same one that applies to in person medical services. They are financed whether by FONASA or ISAPRE, depending on if the patient is registered under the public fund or the private one. Both FONASA and ISAPRE are the institutions that provide the mandatory health insurance, being one the public insurance and the other the private one. That difference doesn't relate with the institution that delivers the service, both FONASA and ISAPRE¹ affiliates can go to public or private institutions, the difference will be the coverage percentage.

¹ The private system is composed of health insurance companies, which are referred to as ISAPREs (Instituciones de Salud Previsional).

Nevertheless, both funding institutions have some limitations regarding telemedicine service. Thus, only some specific healthcare consultations are eligible to be founded. In FONASA's case, those consultations are listed in Resolution No 277. In ISAPRE's case, those consultations are listed in Circular IF/No 77.

It is important to bear in mind that FONASA only covers telemedicine services if they were rendered through one of the platforms previously approved by FONASA. These approved platforms can be found here:

www.fonasa.cl/sites/Satellite?c=Page&cid=1520002749112&pagename=Fonasa2019%2FFP%2FF2_ContentidoDerecha.

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

Currently there are not insurance requirements applicable to telemedicine services providers.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practise 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).

Any healthcare professional can practice telemedicine as long as they are authorised to render the same service in person and provided that they respect the specific regulation applicable to their area of expertise.

The Pending Decree confirms this in the sense that it allows that professionals and technicians can carry out health actions, as long as they are the ones corresponding to their competencies, accordingly to the legal regulation.

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

No, their professional or technical training in their specific area is enough. There are no mandatory special trainings regarding telemedicine.

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

In general, there is no need of a special registration regarding telemedicine services. The regular registration is enough and does not have special requirements for telemedicine services. Is important to mention that in Chile all physicians must be registered in the Registry of Individual Providers of Health, kept by the Health Superintendency.

In addition, and as explained previously, for the teleconsultation to be financed by FONASA, the healthcare professional should use one of the platforms previously approved by FONASA.

<p>13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.</p>
<p>Only in the case that the teleconsultation is financed by FONASA it has to be rendered through one of the platforms previously approved by FONASA.</p> <p>On this point, it is important to keep in mind that FONASA covers approximately the 77 per cent of the people receiving healthcare in the country.</p>
<p>REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES</p>
<p>14. Are there specific requirements applicable to the telemedicine platform?</p>
<p>No. However, if the Pending Decree becomes mandatory, there will be some technical requirement to meet.</p> <p>Also, and as explained above, FONASA establishes some mandatory requisites that should be met so the teleconsultation can be eligible to be financed by them. The requisite is to provide the service through one of the platforms previously approved by FONASA. (See question 8 above.)</p>
<p>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</p>
<p>No, there are no mandatory special requirements regarding electronic equipment and internet speed.</p>
<p>16. Does the legislation provide for specific rules concerning patients' medical records?</p>
<p>There is applicable legislation and regulation with regard to medical records that should be met notwithstanding the means in which the health attention is rendered. There are no specific rules for telemedicine services. This regulation is contained in Law No 20,584 and in Decree No 41.</p> <p>Nevertheless, if the Pending Decree becomes mandatory, after each teleconsultation a report of the teleconsultation should be given to the patient. This regulation is new and it is not applicable to in-person consultations.</p>
<p>17. Are there geographic location requirements applicable to the provision of telemedicine services?</p>
<p>No, there are not.</p> <p>However, the Pending Decree establishes that the service rendered from abroad will be considered as rendered in Chile for all legal purposes. As well, it establishes that healthcare professionals should be authorised to practice in Chile.</p>
<p>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</p>

Yes, but that is not a new regulation or specific to telemedicine. Healthcare professionals must always get the patient consent before any kind of services. This regulation is established in Law No 20,584 and it is mandatory to any kind of healthcare services, regardless the way in which the service is performed. Also, Law No 19,628 states that for the processing of sensitive data, the consent of the data subject is mandatory, when there is no legal basis for the processing.

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

It is important to keep in mind that, currently, the Chilean legal framework doesn't consider specific regulation applicable to telemedicine. Nevertheless, and as explained, there are some regulations that can become mandatory. These regulations are the Pending Decree and the Bills of Law about telemedicine and data protection. Provided that any of those Bills of Law gets approved, or the Pending Decree gets published, new requirements can arise and thus become mandatory. It is possible to think that even if the Pending Decree never gets published (therefore, not mandatory) another regulation will consider these aspects.

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, there are. According to Law No 20,584 medical records are considered as sensitive data, and as such its handling should comply with the regulation set in Law No 19,628. Nevertheless, Law No 19,628 only establishes a higher standard for the processing of sensitive data, in the sense that this kind of data can only be handled if the law authorises it, if the owner consents, or if such data is necessary to determinate or grant a health benefit. The standard for safeguarding sensitive data will increase once the personal data bill becomes law.

Also, it is important to note that medical records have their own regulation contained in the Decree No 41. This decree establishes the requirements that electronic medical records should meet, regulating things such as security backups, access requirements and the characteristics of electronic medical records, among others. Nevertheless, this regulation is mandatory independently if the attention is rendered in person or remotely.

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

There is no specific regulation at this point but, eventually, if the Pending Decree becomes mandatory, it will establish some specific criteria.

It is important to note that there is a Bill of Law currently being discussed in the Parliament that will update the regulation about data protection, raising the standards, so once such Bill of Law becomes a law, the regulation will change.

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

There is no specific regulation to the telehealth area. It should meet the same standards considered for any transference of sensitive data. Thus, it has to comply with the standards set

by Law No 19,628, which does not provide specific requirements for the transfer of information abroad.
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?
<p>There is no specific regulation regarding private database registration regarding patients' medical records. Law No 19,628 only regulates the registration of public databases.</p> <p>In relation to the recording of data in the patient medical records, regardless of whether the medical attention is rendered remotely or in person, the health professional should register the relevant information in the patient's medical record.</p>
LIABILITIES
24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.
<p>As there is no specific regulation regarding telemedicine, professionals and institutions involved in telemedicine practices are subject to the same liabilities as those carrying out in- person healthcare actions.</p> <p>Obviously, there are issues that are specific to telemedicine but as there are not yet specific regulations, any breach will be ruled accordingly with the same regulations that would apply to an in-person consultation.</p> <p>It is important to note that regarding healthcare liability in Chile, before starting a judicial process there is mandatory mediation process that should be completed previously.</p>
TELEMEDICINE NUMBERS AND TRENDS
25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?
<p>Yes, the Ministry of Health have some information regarding the telemedicine services rendered in the public sector. This information can be found here: https://portalsaluddigital.minsal.cl.</p> <p>Regarding the private sector there is no updated official information. The published information can be found here: https://www.supersalud.gob.cl/prensa/672/w3-article-19740.html.</p>
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.
<p>Telemedicine in Chile is not systematically regulated. The existent regulation does not take care of all of the potential issues that can arise while performing this kind of healthcare service. As telemedicine is a new and increasing trend, some efforts have been made to regulate it, but still there is a lot to do.</p>

The number of telemedicine services is expected to increase and, therefore, increasing regulation on the area. As there is not yet specific regulation on the topic, it will be necessary to approve one that can handle all the different specific aspects of this kind of service.

As explained, there are two important bills of law being discussed in the Chilean Parliament whose approval will impact directly on the telemedicine regulation. The first bill of law is the one that will regulate telemedicine itself; and the second one is about data protection that will set higher standards for those responsible of processing sensitive data. On approval of both laws, there will be new regulation that it will be necessary to meet.

These regulations will probably set a new standard to be met by healthcare providers, so they will have to equip their practices and infrastructure to meet the new requisites. As both regulations are currently being discussed, we cannot tell yet whether they regulations will be approved.

Some important aspects that should be regulated are (among others): the data protection standards; security standards; the integration among medical records; interoperability of the platforms; and increasing the coverage of mandatory insurances.