

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?
<p>Nicaraguan legislation does not include any provision that sets forth the permissibility or prohibition of telemedicine. Nicaraguan laws do not recognise nor regulate telemedicine practice.</p> <p>However, in practice, and taking into consideration the definition of telemedicine by the World Health Organization, there is certain precedent related to the exercise of telemedicine by public and private healthcare providers.</p> <p>Such precedents are recorded on local media news, and include among others: (1) the use of technology devices (eg, smart tablets) between physicians for patients' case consultation;¹ (2) use of text messages in distant rural areas to report and request remote guidance to treat health incidents;² (3) enabling a telephone line to be reached by individuals suffering Covid-19 symptoms to receive diagnosis and guidance for treatment by public healthcare providers; (4) use of a digital platform and devices to provide medical services by the means of³ telemedicine.⁴</p>
2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.
<p>There is no legal framework regarding telemedicine in Nicaragua. The legal framework and standard provisions for medical practice are applicable to telemedicine practice.</p> <p>Medical practice is mainly regulated in the General Health Act⁵ and the Regulation of the General Health Act.⁶ It is also regulated by different laws, and administrative resolutions, rules and manuals issued by the Ministry of Health (Ministerio de Salud or 'MINSA').</p>
3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.
<p>There are no key licensing bodies for telemedicine. The key licensing body for the healthcare system in general terms is MINSA.</p> <p>MINSA regulates the exercise of medical practice, healthcare services and the registration of healthcare professionals. Furthermore, MINSA is entitled to design, update and execute the provision of healthcare services.</p>
4. Was telemedicine authorised during the Covid-19 pandemic?
<p>During the Covid-19 pandemic, there was no, and as of today there is no, legal instrument that</p>

¹ See www.el19digital.com/articulos/ver/titulo:128097-minsa-entrega-tabletas-para-el-fortalecimiento-de-la-telemedicina-en-nicaragua (published in Spanish) accessed 16 May 2023.

² See www.el19digital.com/articulos/ver/titulo:27873- (published in Spanish) accessed 16 May 2023.

³ See www.vostv.com.ni/empresas/13996-hospital-vivian-pellas-lanza-plataforma-para-atenc/#:~:text=La%20telemedicina%20en%20tiempos%20de,evitar%20el%20contagio%20del%20coronavirus (published in Spanish) accessed 16 May 2023.

⁴ See www.vostv.com.ni/nacionales/13669-la-telemedicina-metodo-que-utilizan-medicos-para-n/ (published in Spanish) accessed 16 May 2023.

⁵ See [http://legislacion.asamblea.gob.ni/Normaweb.nsf/\(\\$All\)/FF82EA58EC7C712E062570A1005810E1?OpenDocument](http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/FF82EA58EC7C712E062570A1005810E1?OpenDocument) (available in Spanish) accessed 16 May 2023.

⁶ See [http://legislacion.asamblea.gob.ni/Normaweb.nsf/\(\\$All\)/0F963CAE75EBD5DC0625715A005C0DC9](http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/0F963CAE75EBD5DC0625715A005C0DC9) (available in Spanish) accessed 16 May 2023.

sets forth the permissibility or prohibition of telemedicine. Nonetheless, during the Covid-19 pandemic, different healthcare providers started providing healthcare services by the means of telemedicine.
5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?
There is no evidence (eg, bills, administrative resolutions and official communications) that may lead to the presumption that telemedicine will be regulated in the immediate future. There is also no change taking place within the regulation in the post-pandemic scenario that deals with telemedicine.
6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis and telesurgery)?
Because no regulation is in place that specifically deals with telemedicine, it is not possible to provide an exhaustive list of the types of teleservices that are allowed or not allowed. In practice, private and public healthcare providers are providing teleconsultations.
7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.
Because no regulation is in place that specifically deals with telemedicine, it is not possible to provide an exhaustive list of persons authorised to use telemedicine. In practice, doctor-doctor and doctor-patient consultations have occurred.
8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.
There is no funding model for telemedicine and it is not included in social security insurance coverage. To the best of our knowledge, healthcare facilities under the social security regime do not provide healthcare services by the means of telemedicine.
9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.
There is no regulation that sets forth insurance requirements applicable to telemedicine service providers. In practice, some insurance providers do allow telemedicine as a covered consultation.
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 and alternative health therapy providers).
Because no regulation is in place that specifically deals with telemedicine, it is not possible to provide an exhaustive list of professionals that are allowed or not allowed to provide remote health services. In practice, other professionals, such as nurses, psychologists and nutritionists, are indeed providing remote consultation.
11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?
Nicaraguan legislation does not contemplate, as an obligation, any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services.
12. Is there any registration requirement applicable to physicians that provide

telemedicine services?
There is no registration requirement applicable to physicians that provide telemedicine services. However, physicians must hold a professional medical degree and must register according to the National Authority for Sanitary Regulation, which depends on MINSA, ⁷ to practise medicine in Nicaragua.
13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.
There are no special licenses or mandatory authorisations for institutional healthcare providers to engage in telemedicine services.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
No, there are no specific requirements applicable to telemedicine platforms.
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
No, there is no requirement regarding electronic equipment and internet speed for telemedicine services.
16. Does legislation provide for specific rules concerning patients' medical records?
Legislation does not provide specific rules for telemedicine concerning patients' medical records. Legislation does provide standard rules concerning patients' medical records. Nicaraguan laws enforce rules by which healthcare providers must keep confidential and register, among others, the procedures, treatments and interventions performed to the patient. <i>Further information related to these rules is described in the DATA PRIVACY ASPECTS section.</i>
17. Are there geographic location requirements applicable to the provision of telemedicine services?
There are no geographic location requirements applicable to the provision of telemedicine services. Please bear in mind that only healthcare professionals duly registered with MINSA are allowed to practise medicine in Nicaragua.
18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?
Nicaraguan laws do not contemplate consent provisions related to the practice of telemedicine. The provision of telemedicine services is voluntary and optional for patients. Within patients' rights, the General Health Act does include being properly informed about their treatment process. Furthermore, it establishes that healthcare providers must request patients' consent if they will be subject to experimental procedures or diagnosis. ⁸
19. Is there any other important requirement that should be highlighted?
Healthcare providers are obliged to report to MINSA the healthcare services that are provided by the practitioner. Despite that, Nicaraguan legislation does not regulate the exercise of

⁷ Art 57 of the General Health Act.

⁸ Art 8, items 4 and 7, of the General Health Act.

telemedicine. If telemedicine services are rendered, healthcare providers may consider reporting the provision of said services to MINSA.⁹

If healthcare providers deliver telemedicine services, they must exercise such services within their professional scope and capacities; standard provisions and legislation for medical practice should be provisionally considered by healthcare providers to provide telemedicine services.

DATA PRIVACY ASPECTS

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

Yes, data privacy matters should be considered for the exploitation of telemedicine.

Based on Nicaraguan law, patients' records must be preserved as confidential and in secrecy.

The General Health Act sets forth that patients' information must be confidential and healthcare providers must ensure that information remains confidential. Furthermore, MINSA has issued a rule and a manual to manage medical records and files from patients,¹⁰ which also emphasises and outlines the methods used to preserve the confidentiality of patients' information.

Likewise, the Nicaraguan Data Privacy Act protects information related to the health conditions of individuals, classifying information such as sensitive personal data,¹¹ which can only be disclosed with the patient's consent, by an express law of social interest or by court order. Information provided by patients must be used only for the means for which it was acquired.¹² Healthcare professionals as recipients of patients' information must comply with security and confidentiality measures for the protection of information.

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

The protection of patient's information – for standard medical practice – is regulated in a rule for the management of medical records and a manual for the management of medical records issued by MINSA in June 2013.¹³ The rule outlines, among others, the following obligations:

- healthcare providers must storage the patient's medical records;
- healthcare providers must have a designated area for the storage of medical records;
- the minimum term of storage is at least five years from the date of the last consultation received; after that, the healthcare provider must store the medical records for five additional years as an inactive record; and
- specifics that must be satisfied for medical records and their storage.

Medical records can be stored using electronic means; however, healthcare providers still have the obligation to keep physical medical records.

Moreover, rules established in the Data Privacy Act must be also followed by healthcare providers, which include, among others, the following:

- request express consent of the patient to collect/store his/her information;
- strictly hold professional secrets regarding the patient's information;
- execute security measures and adequate protection of the patient's information; and
- use information for the specific, explicit and lawful purposes for which they were

⁹ Title 9, c 2, Rule of the General Health Act.

¹⁰ Rule for the management of medical records and manual for the management of medical records issued by MINSA in June 2013.

¹¹ Art 3, g of the Nicaraguan Data Privacy Act.

¹² Art 9 of the Nicaraguan Data Privacy Act.

¹³ The file can be found using the following link as 'N – 004 Norma para el manejo de expediente clínico y Manual para el manejo del Expediente Clínico (Segunda Edición)' www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Normas-Protocolos-y-Manuales/Normas-2013/ accessed 16 May 2023.

<p>authorised at the time of collection.</p> <p>Please bear in mind that current legislation does not regulate specific criteria and requirements for the protection of patient's information derived from telemedicine services.</p>
<p>22. Does the applicable regulation provide for requirements for the transfer of information abroad?</p>
<p>The Data Privacy Act prohibits the exchange of a patient's information abroad. Such a prohibition is not applicable for the purpose of an epidemiological investigation for states' parties of international treaties ratified by Nicaragua.</p>
<p>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>
<p>Based on the Data Privacy Act, healthcare providers, as recipients of sensitive information, are a data controller. Data controllers are obliged to register with the Data Protection Department, under the Ministry of Finance and Public Credit. The Data Protection Department is the regulatory entity in charge of the registration of data files, as well as the entity that controls the correct application of law. However, as of today, the Data Protection Department has not been agreed.</p>
<p>LIABILITIES</p>
<p>24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.</p>
<p>There are no provisions that specifically rule the liability of healthcare professionals and institutions involved in telemedicine practices.</p> <p>Standard liability provisions for healthcare professionals and institutions are applicable to the exercise of telemedicine. Healthcare facilities' managers and healthcare facilities (owners) are jointly liable (civil and administrative) for any misconduct caused by medical staff of the institution.¹⁴ Healthcare professionals are solely liable for criminal charges that may arise within the exercise of their professions, as set forth in the crimes described in the Nicaraguan Criminal Code.</p>
<p>TELEMEDICINE NUMBERS AND TRENDS</p>
<p>25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?</p>
<p>Currently, there is no public disclosed information concerning the use and acceptance of telemedicine in Nicaragua.</p>
<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>
<p>As of today, telemedicine is not regulated within Nicaraguan legislation; thus, telemedicine practice might be considered as a non-reliable method by some patients.</p> <p>Despite the absence of the proper regulation of telemedicine, Nicaraguan healthcare providers are currently providing healthcare services by the means of telemedicine. The pertinent authorities should promptly issue proper legal instruments to outline, among others, the scope, medical fields, methods, criteria and requirements for the exercise of telemedicine.</p>

¹⁴ Art 68 of the General Health Act.

Healthcare providers and the pertinent authorities may consider ensuring that the platforms or methods used to carry out telemedicine services are secure and that they do not give rise to risks for the health condition of patients and their information.