

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 Belgium. Chapter XI in the Annex to the Royal Decree of 14 September 1984 establishing the nomenclature of medical benefits in connection with compulsory insurance for medical care and benefits and lifting certain temporary measures of Royal Decree No 20 of 13 May 2020 on temporary measures to combat the Covid-19 pandemic and to ensure continuity of care in compulsory insurance for medical care ('Royal Decree of 14 September 1984') refers to the term 'remote healthcare' (*zorg op afstand/soins à distance*). This is an all-encompassing term for care, covering the notions of remote consultation, tele-expertise, telemonitoring and tele-treatment, which take place without the physical presence of the patient and healthcare provider, and with the support of information and communication technologies. This definition is in line with the European Commission's Communication of 4 November 2008 on telemedicine for the benefit of patients, healthcare systems and society, which defines telemedicine as 'the provision of healthcare at a distance'.

The Royal Decree of 26 June 2022 inserted a Chapter XI into the Royal Decree of 14 September 1984 ('Royal Decree of 26 June 2022') which introduced 'remote healthcare' services into the nomenclature of the health insurance legislation, providing a basis for the reimbursement of these services and setting out conditions for the provision of such services (see Question 8, below). These services, therefore, are permitted provided that the conditions are complied with.

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

There is no specific law regulating telemedicine as such. Telemedicine is subject to compliance with the broader general regulatory framework concerning the medical profession such as:

- the Law on Healthcare Professions of 10 May 2015;
- the Health Care Quality of Practice Act of 22 April 2019;
- the Act on Hospitals and Other Care Facilities of 10 July 2008;
- the Patients' Rights Act of 22 August 2002;
- the Act of 21 August 2008 establishing and organising the eHealth platform;
- the Belgian Act of 30 July 2018 on the protection of natural persons with regard to the processing of personal data (the Belgian Data Protection Act of 30 July 2018);
- the Act of 13 December 2006 containing various provisions on health;

- Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the General Data Protection Regulation (GDPR));
- Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare; and
- Regulation(EU) 2017/745 of 5 April 2017 on Medical Devices.

Other than temporary measures under the Covid-19 pandemic (see Question 4, below), the only law specifically addressing telemedicine is the reimbursement scheme for telemedicine in Chapter XI of the Royal Decree of 14 September 1984 (see above).

In addition, in the context of the Covid-19 pandemic a number of Royal Decrees were adopted, of which the Royal Decree of 13 May 2020 on temporary measures in the fight against the Covid-19 pandemic and to ensure continuity of care in compulsory medical care insurance ('Royal Decree of 13 May 2020') is most relevant in the light of this questionnaire (see Question 4, below).

In addition, the Order of Physicians (*Orde der artsen/Ordre des médecins*) adopted deontological rules which are compiled in the **Code of Medical Deontology** (*Code van medische deontologie/Code de déontologie médicale*).

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

The key licensing bodies for telemedicine are considered to be the bodies responsible for the general licensing of physicians.

Every physician who wants to provide health services in Belgium should be registered with a Regional Council of the Order of Physicians. The Order is composed out of ten Regional Councils and one National Council. The main task of the Order of Physicians is to ensure compliance with the deontological rules and the maintenance of the honour and dignity of the medical profession and can impose disciplinary measures if a physician does not comply with these rules. Moreover, the Order of Physicians gives advice on issues related to the practice of the medical profession. The order also intervenes in conflicts between physicians. The Belgian National Council of the Order of Physicians issues general guidelines and provides advice to various authorities.

The Belgian National Institute for Health and Disability Insurance (*RIZIV/INAMI* – the NIHDI) does not qualify, strictly speaking, as a licensing body. However, it has a big practical relevance for the recognition of telemedicine in Belgium. Their main task is to make sure that everyone insured under the social security system has access to the necessary quality health care and receives reimbursement.

Furthermore, the Act of 5 September 2018 establishing the Information Security Committee, controllers must obtain a deliberation from the Information Security Committee before communicating personal data as foreseen by Article 42 section 2 of the Act of 13 December 2006 on various provisions relating to health. Based on this provision, the Information Security Committee must authorise certain communications of personal data (see Question 13 below).

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

Yes, during the Covid-19 pandemic, the Ministry of Health issued several directives to facilitate the use of telemedicine. The Royal Decree of 13 May 2020 introduced a mechanism that allowed different healthcare providers to provide care without physical contact with the patient while charging those benefits to the NIHDI.

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?

In its policy note of 2022, the Minister of Health confirmed that a regulatory framework will be provided in which telemedicine can be integrated into the Belgian health care system.

Two significant changes already took place since the pandemic.

First, in its opinion of 18 June 2022 titled 'Teleconsultations in today's healthcare landscape – Deontological rules' (the 'Opinion of 18 June 2022'), the Belgian National Council of the Order of Physicians revised its earlier opinions in which it used to regard teleconsultations as ancillary to the classic face-to-face consultations. The Belgian National Council of the Order of Physicians now expressly allows for telemedicine and set out the conditions for physicians to engage in teleconsultation.

Second, on 1 August 2022, a new framework for reimbursement of remote consultations by physicians entered into force with the Royal Decree of 26 June 2022 amending the Royal Decree of 14 September 1984 (see Question 1 above).

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

Belgian law does not provide for an exhaustive list of permitted telemedicine services. The definition of 'remote healthcare' in the Royal Decree of 14 September 1984 refers to teleconsultations, telemonitoring and tele-expertise, suggesting that these types of services are allowed. However, the list of reimbursed services currently only contains teleconsultation services (see Question 8 below).

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

The telemedicine services can be used between doctors as well as between patients and doctors. This follows from the definition of 'remote healthcare' in the Royal Decree of 14 September 1984 which refers to both tele-expertise and teleconsultations (see Question 1 above).

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 services are reimbursed through the public reimbursement system. The reimbursed services are set out in the Royal Decree of 14 September 1984. Since 1 August

2022, a general reimbursement scheme for telemedicine service provided for by physicians and physician specialists exists outside the context of the Covid-19 pandemic.

However, there are conditions attached to the reimbursement of telemedicine services. The following consultations are eligible for reimbursement:

- consultations with a physician with whom the patient already has a treatment relationship;
- consultations in the case of a referral by the physician to a physician specialist; and
- consultations in the context of an organised standby service of physicians.

A remote consultation can only take place at the patient's request and with the physician's agreement. The physician must also have access to the electronic patient file during the remote consultation.

Besides the general reimbursement scheme that entered into force in August 2022, teleconsultations held by psychiatrists, child psychiatrists and neuropaediatricians are reimbursed under a framework adopted during the Covid-19 pandemic under the Royal Decree of 13 May 2020.

Moreover, as of October 2022 reimbursement is also provided for the rehabilitation of patients before and after primary knee or hip arthroplasty by the physiotherapist where support with a mobile application is provided in addition to physical sessions.

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

There are currently no specific insurance requirements applicable to telemedicine services providers in Belgium. Accordingly, the general insurance requirements applicable to healthcare services providers in Belgium should also apply to telemedicine services providers.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practise telehealth 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).

Article 3 of the Law on Healthcare Professions of 10 May (the 'HCP law') prohibits anyone not having the relevant diploma from practicing medicine. Accordingly, only those people having the relevant diploma, can practice telehealth services.

In addition, the Royal Decree of 14 September 1984 provides for a list of healthcare professionals whose telemedicine services can benefit from reimbursement (see Question 8 above).

For the use of medical applications as such there is no regulation of which applications are permitted as such, but since January 2021 a system for the reimbursement of these medical applications has been created. To determine whether a medical app can be reimbursed, a three-step validation procedure is used. First, the app to be recognised as a CE certified medical device. The second step is a review of interoperability of the application concerned with other

mobile applications and ICT applications within healthcare and the connection to the basic eHealth platform services. Third, the app must demonstrate its added value from a socio-economic perspective.

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

In its Opinion of 18 June 2022, the Belgian National Council of the Order of Physicians determines that physicians involved in the trainings of students in medical school should highlight the use of teleconsultations in practice.

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

There is currently no information available on this topic in Belgium. There is no specific registration required apart from the registration at the Order of Physicians which is required to provide healthcare services in general (see Question 3 above).

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

A first important obligation for institutional healthcare providers relates to the eHealth platform, created by the Act of 21 August 2008, establishing and organising the eHealth platform. The eHealth platform is a Belgian public institution that provides an electronic platform where all public health stakeholders can exchange information, including personal data, in a secure and efficient manner. Article 2 of the '*User rules for access to and use of the information system of the federal government and public institutions of social welfare by enterprises and their agents of 28 September 2022*' ([weblink](#)) determines that to have access to the eHealth platform each undertaking must designate a single Main Access Manager.

Moreover, the Act of 13 December 2006 containing various provisions on health requires a prior authorisation from the Information Security Committee for communications of personal data by hospitals to third parties, as well as any communication of personal data related to health. The Information Security Committee deliberations are mandatory except when (i) the communication is between health care professionals bound by professional secrecy or (ii) if such communications are authorised by an Act or a decree or an ordinance after consulting the Data Protection Authority.

This obligation will probably be amended in the future, considering the Government plans to create a dedicated Health (Care) Data Protection Authority. The law creating this authority is expected to be adopted in 2023.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

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

There are specific requirements for platforms used to conduct video consultations. According to Article 37(3)(a) of the Annex of the Royal Decree of 14 September 1984, as amended by the Royal Decree of 26 June 2022, these platforms must meet the following conditions:

- communication is via end-to-end encryption;
- communication is not stored on the platform; and
- if the platform contains other functions in addition to the possibility of video or audio communication, including the exchange of documents, these are offered in such a way that users can comply with the applicable legal provisions.

The Information Security Committee issued a recommendation regarding good practices to be applied by remote care platforms – Deliberation No 20/098 of 7 April 2020, as amended on 24 May 2022 ('Deliberation No 20/098') – which sets out additional obligations for platforms providing remote care:

- consent of the person in need of care;
- freedom of choice of the person in need of care;
- the person in need of care is clearly informed of the critical success factors and limitations of remote consultation;
- users of the support platform use a reliable system for authenticating their identity;
- video, audio and personal data are not stored on the platform; and
- the person in need of care intentionally uses the remote consultation and is physically and mentally capable of working with the device or platform.

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

There are currently no other requirements than those applicable to telemedicine platforms as described in Question 14.

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

Article 9 of the Patients' Rights Act of 22 August 2002 determines that the patient has the right vis-à-vis the professional to have carefully maintained and securely stored electronic patient file. Article 33 of the Health Care Quality of Practice Act of 22 April 2019 determines the minimum information that should be included in the electronic patient file.

As regards the retention of the electronic patient file, Article 24 of the Code of Medical Deontology and Article 35 of the Health Care Quality of Practice Act of 22 April 2019 determine that physicians should retain the electronic patient file for a minimum period of 30 years and a maximum period of 50 years counting from the last contact with the patient.

Article 37(3)(d) of the Royal Decree of 14 September 1984, as amended by the Royal Decree of 26 June 2022, requires that the physician should have access to the electronic patient file during the remote consultation. Moreover, the physician should record the consultation in the electronic patient file, specifying that the consultation took place. The reason for the consultation, the

advice given, any adjustments to the treatment schedule and the nature of the documents delivered should also be noted in the electronic patient file.

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

Telemedicine services are currently only covered within the scope of the reimbursement rules in Belgium (see Question 2 above). These rules are adopted at national level and are applicable within the whole Belgian territory.

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

Yes, a remote consultation can only take place at the patient's request and with the physician's agreement (Article 37(3) of the Annex of the Royal Decree of 14 September 1984, as amended by the Royal Decree of 26 June 2022) (see Question 14 above).

In principle, the patient's free and informed consent is required prior to any intervention by a physician. This consent can be refused and withdrawn at any time (Article 8 Patients' Rights Act of 22 August 2002).

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

Both the Opinion of 18 June 2022 and Article 37(3)(d) of the Annex of the Royal Decree of 14 September 1984 require the existence of a prior treatment relationship between the patient and physician. The law accepts such a treatment relationship in the following cases:

- with the physician managing the global electronic patient file of the patient; or
- with the physician belonging to a registered grouping of physicians of which one member manages the global electronic patient file of the patient; and
- the physician and patient have had at least one physical consultation in the current calendar year or in at least one of the two calendar years prior to the remote consultation.

The Opinion of 18 June 2022 also list conditions of a more practical nature. Physicians should check, among other things, the identity of the patient, their choice of physician, their privacy 'on the other end of the line', their consent, and their capacity to act. The physician should also provide the patient with the necessary information, including the critical success factors and limitations of remote consultation.

DATA PRIVACY ASPECTS

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

In accordance with the GDPR and the Belgian Data Protection Act of 30 July 2018, data concerning health are considered sensitive personal data. The processing of such sensitive personal data is in principle prohibited under Article 9 GDPR. Article 9(2) GDPR sets out the

circumstances under which the processing of sensitive personal data may take place. Article 9(2)(a) GDPR refers for instance to the data subject's explicit consent to the processing of those personal data for one or more specified purposes. Furthermore, under Article 9(2)(h) GDPR, sensitive personal data may be processed for purposes of preventive or occupational medicine, medical diagnosis, the provision of health or social care or treatment. Article 9(3) GDPR foresees that the processing allowed in accordance with Article 9(2)(h) GDPR must happen under the responsibility of a professional subject to the obligation of professional secrecy.

Article 9 of the Belgian Data Protection Act of 30 July 2018 lists some complementary measures the data controller must abide by when processing genetic, biometric or health data:

- (i) the controller or, as the case may be, the processor must designate the categories of persons having access to the personal data, precisely defining their capacity in relation to the processing of the data concerned;
- (ii) this list with categories of persons having access to the data must be kept at the disposal of the competent supervisory authority; the controller must ensure that the designated persons are bound by a legal or statutory obligation, or by an equivalent contractual provision, to respect the confidentiality of the data concerned.
- (iii) The general data processing principles listed in Article 5 GDPR must be taken into account, being, lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation; integrity and confidentiality; and accountability. Deliberation No 20/098 of the Information Security Committee refers to Article 5 GDPR and underlines that personal data processed via video, audio and data communication applications or platforms used for remote consultations must be processed in a way that ensures their adequate security, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage (integrity and confidentiality), by taking appropriate technical or organisational measures.

Lastly, in its Opinion of 18 June 2022, the Belgian National Council of the Order of Physicians highlights the importance for the physician, at the start of a teleconsultation, to, among other things, verify the identity, consent and free choice of physician of the patient but also to verify the privacy of the patient 'on the other end of the line' (see Question 19 above).

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

Deliberation No 20/098 of the Information Security Committee lists minimum criteria and requirements which the video, audio and data communication applications or platforms used for remote consultations must meet (see Question 14 above).

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

No specific requirements for the transfer of information abroad apply. Account must be taken of the general rules on transfer of personal data to third countries or international organisations of Chapter V of the GDPR.

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?

There is no specific requirement regarding the registration of databases.

Regarding the recording of data in the electronic patient file, the physician must have access to the relevant electronic patient file and record the consultation as set out in Question 16 above.

In addition, Deliberation No 20/098 of the Information Security Committee provides that, in order to facilitate the provision of remote care, the healthcare provider preferably uses a software package registered with the eHealth platform and in any case records the relevant data on the provision of care in an (electronic) patient file.

LIABILITIES

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

Belgian case law generally assumes that a contractual relationship exists between the physician and the patient. A claim for compensation by the patient against the physician is therefore generally subject to the contractual liability rules. If the healthcare provider's fault does not constitute a breach of a contractual obligation but is a breach of the general duty of care or a criminal offence, the patient can bring an extra-contractual liability (tort) claim. The patient must prove there is: (i) a fault; (ii) harm; and (iii) a causal link between the fault and the harm.

In 2010, a fund has been established to compensate severe damage caused by medical accidents without liability (Belgian Act of 31 March 2010 on damage indemnification resulting from health care).

In the absence of specific regulation of liability relating to telemedicine, Belgian courts will apply the above-described general liability rules to determine liability for liability rules.

TELEMEDICINE NUMBERS AND TRENDS

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

In July 2020, the insurance institutions and the NIHDI initiated a large-scale survey which was sent to 100,000 patients. They concluded that about three out of four patients (77 per cent) are generally satisfied or very satisfied with remote consultations. Only a small minority are less satisfied (seven per cent) or not at all satisfied (four per cent) with remote consultations.

The InterMutualist Agency, an association which brings together patient data from Belgium's seven health insurance funds on a single platform, reported in a study of 2022 that in ten months, around 11 million remote consultations were billed. Remote dispensing accounted for an overall 15.1 per cent of total services provided for consultations and visits in 2020. During the first Covid-19 wave, in April 2020, there were approximately 400,000 to 500,000 remote consultations a week.

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.

Before the Covid-19 pandemic, the two main obstacles regarding telemedicine were the negative opinion of the Belgian National Council of the Order of Physicians and the lack of an existent reimbursement framework for telemedicine. These two obstacles have now been removed. This is an important step forward.

While telemedicine is now permitted, there is still no specific and comprehensive legal framework facilitating telemedicine in Belgium. The Minister of Health confirmed in its policy note of 2022, that a regulatory framework will be created in which telemedicine can be integrated into the Belgian health care system. Therefore, in the future it is expected that the core health laws in Belgium, such as the Health Care Quality of Practice Act of 22 April 2019 and the Patients' Rights Act of 22 August 2002 will be amended. Legal authors recommend that the legislator should include a more specific legal definition on telemedicine and provide clear rules on how general obligations must be translated in the context of telemedicine.