

MINISTRY OF HEALTH AND SOCIAL WELFARE

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Pursuant to Article 5, paragraph 4 and Article 34a, paragraph 3 of the Health Care Act (Official Gazette 150/2008, 71/2010, 139/2010, 22/2011 and 84 / 2011) the Minister of Health and Social Welfare brings

REGULATIONS

ON CONDITIONS, ORGANIZATION AND METHOD OF COMPLETING TELEMEDICINE

Article 1.

This Ordinance lays down the conditions, the organization, the way of telemedicine and the conditions for obtaining the authorization for the operation of the telemedicine center.

Article 2

Certain terms within the meaning of this Ordinance have the following meaning:

Telemedicine is the provision of remote health services through the use of information and communication technologies. Telemedicine activities include consultative health services, preventive healthcare activities, diagnostic and therapeutic procedures based on information available through the information and communication system and exchange of information with a view to continuous professional training of healthcare workers.

Telemedicine Center is the place of receiving and / or providing telemedicine services.

Telemedicine services are health services in telemedicine.

Telekonzultant is a doctor of medicine specialist who provides telemedicine service.

A search engineer is a doctor or a healthcare worker looking for a telemedicine service.

The recipient of the service is the patient for whom the service is requested.

The holder of the telemedicine center's authorization is a legal or natural person who concludes a contract with an institute performing compulsory health insurance or other legal entities conducting voluntary health insurance on the basis of the telemedicine center's authorization for the work of the Croatian Telemedicine Institute (hereinafter: the Office). Authorized providers of telemedicine center work can be healthcare institutions, healthcare companies and private healthcare workers.

The insurer is a bureaus competent for compulsory health insurance and other legal persons who carry out the activity of voluntary health insurance.

Article 3

The telemedicine center can be:

- telemedicine access center,

- telemedicine specialist center.

Telemedicine Access Center is the place of receiving telemedicine services.

Telemedicine specialist center is the place of receiving and providing telemedicine services according to specialties.

Telemedicine center can be stationary and mobile.

Article 4

Telemedicine services are divided according to the type and manner of performance.

The types of telemedicine services are:

- Regular,
- urgent,
- Supervisory.

Regular telemedicine services are telemedicine services provided at the request of the service provider in the telemedicine specialist centers at the agreed date.

Emergency telemedicine services are telemedicine services provided at the request of telemedicine service providers in emergency and life-threatening situations.

Supervised telemedicine services are telemedicine services for monitoring the health status of the recipient of the service.

According to the way of performing telemedicine services are:

- with direct interaction of participants,
- without the direct interaction of participants.

Telemedicine services with direct interaction of participants require direct (real-time) communication between the service seeker, the recipient of the service and the telekonzultant.

Telemedicine services without the direct interaction of participants do not require direct (real-time) communication between the service seeker, the recipient of the service and the telekonzultant.

Article 5

Health institutions, health workers, healthcare companies and private healthcare providers performing telemedicine in the Republic of Croatia must have a telemedicine center license issued by the Institute and must be included in the telemedicine centers network.

Article 6

The telemedicine service provided by the telekonzultant on the basis of the request of the service provider is considered a specialist-conscientious service.

The search engineer can use simple invasive diagnostic and therapeutic procedures based on the instruction and supervision of telekonzultant.

Article 7

The network of telemedicine centers (hereinafter: the network) is issued by the minister responsible for health (hereinafter: the Minister) at the proposal of the Institute.

The network consists of a basic network of telemedicine centers and an extended network of telemedicine centers.

Article 8

The basic network of telemedicine centers is a network ensuring equal access to health care services throughout the Republic of Croatia.

The basic network of telemedicine centers is defined for the territory of the Republic of Croatia, for the territories of the units of regional self-government, ie for the areas of local self-government units. The basic network contains a list of telemedicine centers for primary, secondary and tertiary health care, a minimal number of healthcare workers at each telemedicine center, telemedicine center type, and telemedicine center medical field.

The basic network of telemedicine centers consists of health institutions founded by the Republic of Croatia, a unit of regional self-government or local self-government units.

The measurements for determining the basic network of telemedicine centers are: total number of inhabitants of the Republic of Croatia, total number of health insured persons, demographic characteristics of the population, population health status, social structure of population, geographical distribution and distance of health institutions in terms of population density, gravity population, geographical characteristics specific areas, traffic connectivity, availability of technical resources, availability of health resources, environmental impact on population health and economic opportunities.

The insurer in the basic network of telemedicine centers is the institute responsible for obligatory health insurance.

Telemedicine Centers for Telemedicine Centers within Telemedicine Centers Network make telemedicine services contract with the compulsory health insurance institution.

Article 9

An extended network of telemedicine centers is a network of healthcare institutions, healthcare companies, and private healthcare providers performing telemedicine.

The legal or natural person referred to in paragraph 1 of this Article for performing telemedicine activities shall submit to the Institute a request for issuance of a telemedicine center authorization, which, amongst other things, shall include a list of medical fields for which telemedicine services are planned for obtaining a certificate of compliance with minimum working conditions telemedicine centers.

Measures for determining the extended network of telemedicine centers and the prescribed form for issuing approvals for the operation of the telemedicine center are determined by the Institute and published on the Institute's web site.

Authorized providers of telemedicine specialist centers within the extended network of telemedicine centers can not sign an agreement for telemedicine services with the mandatory health insurance institution.

Article 10

The Institute will propose networking for those healthcare institutions, healthcare companies and private healthcare workers who receive a certificate from the Institute on compliance with the minimum requirements for telemedicine center work.

Article 11

Health institutions, healthcare companies, and private healthcare providers performing telemedicine activities included in the Network must obtain approval for the operation of telemedicine centers within 60 days of publishing the Narodne novine.

Article 12

The equipment and information and communication infrastructure necessary for working in the basic network of telemedicine centers shall be provided by the ministry responsible for health care (hereinafter: the Ministry). Equipment and information and communication infrastructure are procured through public procurement in

accordance with the technical and operational / functional characteristics determined by the Department.

The equipment and information and communication infrastructure for the operation of telemedicine centers in the extended network of telemedicine centers are provided by health institutions, healthcare companies and private healthcare providers performing telemedicine.

The equipment and information and communication infrastructure referred to in paragraph 1 of this Article may be used only for the purpose of providing telemedicine services within the basic telemedicine centers.

By way of derogation from paragraph 3 of this Article, the Minister may, on a proposal from the Office, authorize the use of equipment and information and communication infrastructure for other purposes.

Article 13

A health care institution, a healthcare company or a private healthcare worker with a telemedicine center-based healthcare provider who is involved in the Network, as a contractor, contracts a telemedicine service with an insurer.

The contract referred to in paragraph 1 of this Article shall be concluded for a period of one year. The contract includes a list of telemedicine services and the cost of services.

The contract referred to in paragraph 1 of this Article may be terminated even before the expiration of the time referred to in paragraph 2 of this Article if one of the Contracting Parties fails to fulfill the terms of the contract or if it so requests to the Office for a breach of the provisions of this Ordinance. If there are no changed circumstances, the contract is extended for one year.

Article 14

The telemedicine center's licensing provider is committed to providing a sufficient number of healthcare providers to provide telemedicine services in working hours, for emergency telemedicine services and in emergency care.

To provide and / or receive telemedicine services, healthcare workers may be assigned a special monthly fee that is part of the salary, whose height is determined by the contract of the holder of the telemedicine center's approval and the healthcare worker.

Article 15

Responsibility for telemedicine services provided to the recipients of the service, and according to the instructions of telekonzultant, carries the service seeker and telekonzultant solidarno.

A service seeker who has received telecommunication finds and instructions may not sign them or act in such a way that the recipient of the service can understand that the service provider has provided the service. The telekonzultant signs the instructions and instructions.

At the request of the recipient of the service the service provider is obliged to give him a written notice of how and by whom the service was provided.

Article 16

Telemedicine instructions and finds provided by teleconferencing companies are obliged to submit to the service provider written:

- no later than 4 pm the next working day for regular telemedicine services without the direct interaction of the participants,
- no later than 30 minutes after providing telemedicine services if the service is requested at full-time telemedicine center for regular telemedicine services with the direct interaction of participants,
- no later than two working days in the event of a complex case or the need for extensive computer image processing and mutual consultation of a doctor of medicine, a specialist for regular services without the direct interaction of the participant,

- no later than 10 minutes after the delivery of emergency telemedicine services with the direct interaction of the participants,
- no later than 15 minutes after emergency telemedicine services are provided without the direct interaction of the participants,
- no later than 60 minutes after emergency telemedicine services are provided without the direct interaction of participants in a complex case or the need for comprehensive computer image processing and mutual consultation of a doctor of medicine specialist.

The form of instructions and findings referred to in paragraph 1 of this Article shall be prescribed by the Office.

The instructions and findings referred to in paragraph 1 of this Article shall be delivered by telefax or electronically certified by electronic signature in accordance with special regulations governing the area of electronic signature.

Article 17

During telemedicine services and telemedicine services telemedicine centers may include teleconference, service seekers and recipients of services.

With the recipient of the service who is not aware of it, has a severe mental disability or is a minor, the telemedicine center may also be the legal representative or custodian of the service recipient.

Exceptionally, the written consent of the recipient of the service or the legal representative or the custodian of the recipient of the service at the telemedicine center may be accompanied by healthcare workers and the personal accompaniment of the recipient of the service specified in the consent.

The form of written consent referred to in paragraph 3 of this Article shall be prescribed by the Office.

Article 18

Recording audio and video recordings while providing and receiving telemedicine services is only permitted with the written consent of the recipient of the service.

For a recipient of a non-conscious service, has a severe mental disability or is underage, the written consent from paragraph 1 of this Article is provided by the legal representative or the receiver of the service.

The written consent referred to in paragraph 1 of this Article must contain the reason for the recording, the type of footage and the purpose for which the footage will be used.

The form of written consent referred to in paragraph 3 of this Article shall be prescribed by the Office.

Article 19

Costs of consumables used to provide telemedicine services are borne by contractors who are obliged to take care of the availability of supplies for uninterrupted operation of the telemedicine center.

Article 20

Supervision over the work of telemedicine centers as well as over the work of healthcare providers performing telemedicine activities is carried out by the Institute.

Article 21

A legal or natural person residing in the Republic of Croatia and providing a telemedicine service to a recipient of services outside the territory of the Republic of Croatia is subject to the application of the Republic of Croatia's regulations relating to technical and security conditions, confidentiality and data security, the manner of conducting medical documentation and the quality of telemedicine services necessary minimum quality assurance provided by this Ordinance and other general acts of the Institute and in accordance with other applicable regulations of the Republic of Croatia.

A legal or natural person referred to in paragraph 1 of this Article must have a permit for the operation of the telemedicine center and shall fully comply with all the rules of the profession applicable in the Republic of Croatia.

A legal or natural person referred to in paragraph 1 of this Article must be insured against the insurance contract with the insurance company in the country where the service provider is located and shall be responsible for the quality of the telemedicine service provided.

Article 22

A legal or natural person outside the territory of the Republic of Croatia and provides a telemedicine service to the recipient of the service in the Republic of Croatia shall be subject to the provisions of this Ordinance relating to technical and security conditions, confidentiality and data security, the manner of conducting medical documentation and the quality of telemedicine services with the necessary by ensuring the minimum quality of service provided by this Ordinance and other general acts of the Institute and in accordance with other applicable regulations of the Republic of Croatia.

The legal or natural person referred to in paragraph 1 of this Article must meet the following conditions:

- have authorization for the independent work of a doctor of medicine in the country from which the telemedicine service is provided,
- have authorization to perform telemedicine activities in accordance with the regulations of the state in which the legal or natural person providing the telemedicine service is located,
- must be insured against the insurance contract with the insurance company in the Republic of Croatia.

The legal or natural person referred to in paragraph 1 of this Article shall be responsible for the quality of the provided telemedicine services and shall, in the case of dispute, agree to the jurisdiction of the Republic of Croatia.

At the request of the recipient of the service the service provider is obliged to give written notice of how and from whom the service is provided with all the data referred to in paragraph 2 of this Article.

Article 23

The application for the approval of the telemedicine center (hereinafter: the request) shall be submitted on a prescribed form in writing to the Office.

The application must contain:

- general information about the applicant (name, headquarters, address, OIB, responsible person, code, activity),
- the network for which the request is submitted (extended),
- a list of the medical profession for which telemedicine services are provided / received,
- type of telemedicine center (telemedicine access center or telemedicine specialist center),
- types of telemedicine services (emergency, regular and / or supervisory),
- type of request:
- a new telemedicine center,
- extension of the telemedicine center (in the event of a change in the scope of the provision of services or the number of healthcare workers, the number of valid telemedicine center authorization)
- renewal of the telemedicine center's authorization (the number of the previous telemedicine center authorization must be entered).

Article 24

Please provide the following documentation with your request:

- the Ministry's decision on meeting the conditions regarding space, workers and medical-technical equipment,
- extract from the register of the Commercial Court from which the data on the name, headquarters and activities of the trading company are visible (the activity of the trading company must be a health activity), not older than 6 months until the date of submission of the application,
- proof of availability of a business space where telemedicine can be performed (evidence of ownership or use right),
- a conviction, not older than three months, that no criminal proceedings are conducted against a responsible person in a legal person,
- Evidence of paid fees for the procedure for issuing the authorization for the operation of the telemedicine center,
- a certificate and technical documentation for software support, medical diagnostic equipment, computer and communication equipment and infrastructure, and other equipment.

Article 25

The form of the application form is available on the SITE web site.

The request shall be kept for five years from the date of submission of the request to the Office.

Article 26

Incomplete and inaccurate claims will be returned to the claimant to the supplement or correction. The deadline for correction or correction is 15 days. If the applicant fails to rectify the deficiencies within that period, the claim will be rejected.

Article 27

Based on the requests received, the Institute, in cooperation with the applicant, determines the fulfillment of conditions regarding the technical possibilities, correctness and security of the information system, program support, medical diagnostic equipment, computer and information-communication equipment and infrastructure, other equipment and space provided for the telemedicine center .

Article 28

The Telemedicine Center must meet the following conditions:

1. Must be made of solid materials in accordance with special legal regulations,
2. It shall not be subject to any contamination or noise above the permitted values in accordance with special legal regulations,
3. must have access to persons who are using auxiliary means of transport or wheelchairs,
4. In a room with insufficient ventilation it is necessary to provide artificial ventilation in accordance with the relevant legislation,
5. The room must have a permanently solved issue of heating sources that must comply with technical and ecological standards in accordance with the relevant legislation,
6. Must be airy and constructed so that it can be efficiently and quickly ventilated,
7. must be sound insulated in such a way that the sound does not extend beyond the room, sound insulation (at least 40dB),

8. Must comply with all prescribed municipal and sanitary conditions of water supply and drainage of sanitary and other waste water, electricity supply, connections and gas pipelines and other installations as well as fire protection,
9. Must be illuminated by artificial hot light source 450 - 550 Lux,
10. Must have adaptive blinds or light-tight curtains on the windows,
11. Doors, walls and ceilings must be flat and smooth surfaces that are frequent and thoroughly cleaned in accordance with applicable regulations,
12. The color of the walls must be non-reflecting pigment,
13. can not be used for residential purposes or for other purposes,
14. flammable substances and chemicals must be stored in the original packaging in a closed area or in a separate closet in accordance with the relevant regulations,
15. Must have at least one connection to connect to the information-communication infrastructure,
16. Must have at least one telephone connection,
17. Must have at least four connectors to connect to the 220 V, 50 Hz,
18. all power supply connections must be connected to the aggregate of the facility,
19. On the door of the premises, within 8 days of issuance of the approval, the telemedicine center mark plate should be highlighted,
20. must be located close to the main area of the patient's disposal with the possibility of unobstructed access and entrance of the movable bed or worn with the patient in the room,
21. Size of at least 12 m² and its length or width shall not be less than 3 m,
22. the height of the room must be at least 260 cm,
23. it is necessary to ensure the disposal of medical and other waste in closed and properly labeled containers that must be regularly discharged,
24. Doors shall be at least 90 cm wide,
25. windows must be designed in such a way as to ensure room and window clearances,
26. flooring rooms must be designed in such a way that they can be quickly and easily cleaned, maintained and disinfected,
27. Must have a wash basin with hot and cold water and liquid soap and disposable towels or hand dryer,
28. Must have a metal keychain wardrobe, a doctor's desk and information technology equipment, a doctor's chair, a patient's chair stool, a wardrobe hanger, a patient bed, a parasol, an instrument cabinet, an instrument table, a gloves disposable.

Article 29

The premises of the mobile telemedicine center must comply with all regulations relating to emergency medical services and special conditions for mobile telemedicine centers prescribed by the Institute, and are located on the Internet site of the Institute.

Article 30

Information-communication and computer equipment telemedicine center must have a European certificate (CE).

Each telemedicine center must have:

1. Continuous power supply to ensure minimum autonomy of all components of 30 minutes,
2. computer with peripheral devices required for operation,
3. information and communication devices for data transmission and protection.

Article 31

Information and communication equipment and computer equipment and telemedicine infrastructure must meet the following conditions:

- a computer network used to perform telemedicine is a private computer network without access to other computer networks and the Internet,
- it is possible to connect the network information and communication infrastructure to other networks in order to exchange patient data. Connectivity must be performed through a firewall that filters traffic at least to destination IP addresses and ports,
- access to database data via any interface may only be made by an authorized person,
- computer equipment manufacturers and service providers should not have access to patient data, this data may only be accessed by the data owner (patient) to that authorized person,
- The information system must be implemented with the data security of the data on at least two spatially remote locations,
- Backing up the information system is performed on a regular basis on a daily basis,
- The backup of the information system backup is performed once every month in a way that a fully functional information system is restored from the backup,
- In audio or audio-video conferencing, the delay in sound and image may not exceed 150 ms,
- The delay in data in the network communication infrastructure must not exceed 50 ms.

Article 32

Medical products used in telemedicine must comply with essential requirements in accordance with special regulations.

Article 33

The Department determines the fulfillment of prescribed conditions regarding the information system, program support, medical diagnostic equipment, computer and information-communication equipment and infrastructure, other equipment and facilities for telemedicine centers.

Article 34

If the determination of the fulfillment of the conditions referred to in Articles 28 and 31 of this Ordinance is found to be defective, the Office shall order the applicant to rectify the deficiencies.

If the applicant does not correct the deficiencies within a certain time, the claim will be rejected.

Article 35

Approval for the operation of the telemedicine center (hereinafter: approval) is granted for a period of four years.

The Office shall issue an approval based on the decision referred to in Article 33 of this Ordinance after the applicant has been included in the Network.

Article 36

The layout and content of the approval is prescribed by the Office and is published on the Institute's Intranet page.

Approval must contain the following information:

1. ordinal number,
2. telemedicine center code,
3. the name, the OIB and the applicant's headquarters,
4. Date and place of issue,
5. validity of the authorization,
6. type of telemedicine center,
7. type of telemedicine services (emergency, regular and / or supervisory),
8. signature and stamp of the responsible person of the Institute.

Article 37

Approval for the basic network of telemedicine centers is issued in three copies, one of which belongs to the holder of the authorization, one compulsory health insurer and one Institute.

Approval for an extended telemedicine center network is issued in two copies, one of which belongs to the approval holder, and one to the Department.

Approvals are kept for at least 5 years from the date of issue.

Article 38

Approval is renewed every four years.

In order to renew the authorization, the holder of the authorization is obliged to apply to the Office.

Article 39

The records of issued and seized licenses are kept by the Office.

Article 40

The Department shall withhold Telemedicine Center approval if:

- the conditions for termination of the contract of insurer and contractor arise,
- the conditions for the conclusion of the contract of insurer and contractor are not ensured,
- the conditions for telemedicine center work are not ensured,
- health workers do not comply with prescribed guidelines on telemedicine services published on the Internet site of the Institute,
- telemedicine services abuses.

Article 41

If the telemedicine center is deprived of approval, the equipment provided by the Ministry returns to the Ministry.

Article 42

The use of telemedicine in mass accidents, crisis situations and defense of the Republic of Croatia must be carried out in accordance with this Ordinance, unless otherwise regulated by a special regulation.

Article 43

For the award and renewal of the name of the Ministry's reference center for any field of medical profession in telemedicine, the prior opinion of the Institute shall be obtained.

Article 44

All telemedicine centers are obliged to comply with the guidelines regarding equipment, space, quality assurance and procedures for certain areas of the medical profession in telemedicine.

The guidelines referred to in paragraph 1 of this Article shall be issued by the Institute and shall be available on the Internet site of the Office.

Article 45

The Agency's Board of Governors shall publish the list of services provided by the Department for the procedure of issuing approvals.

Telemedicine centers within the main network of telemedicine centers are exempted from payment of fees for the procedure of issuing approval for the operation of the telemedicine center.

Article 46

On the date of entry into force of this Ordinance, the Ordinance on Conditions, Organization and Mode of Telemedicine (Official Gazette 89/2009) shall cease to be valid.

Article 47

This Ordinance shall enter into force on the eighth day after its publication in the Official Gazette.

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