REGULATION IN THE TELEHEALTHCARE SECTOR IN RUSSIA: LEGAL DEVELOPMENTS

The Federal Law No. 242-FZ dated 29 July 2017 amended certain legislative acts of the Russian Federation on the use of information technologies in the area of health care developed within the framework of the priority project 'Improving Processes of Health Care Organisation Based on the Introduction of Information Technologies' (hereinafter - the 'E-Healthcare').

The principal provisions concerning provisions of medial aid with the use of telehealthcare technologies are included in Federal Law No. 323-FZ, dated 21 November 2011 'On the Fundamentals of Health Care of Citizens in the Russian Federation' (hereinafter - the 'Healthcare Law').

Features of Medial Aid Using Telehealthcare Technologies

Telehealthcare technologies are defined as information technologies that provide:

- remote interaction medical employees between each other, with patients and(or) their legal representatives;
- identification and authentication of those persons;
- documenting the actions they take when holding consulations, consultations, and remote medical supervision of the patient's health.

When holding consultations with the use of telehealthcare technologies, the consulting physician can correct the previously prescribed treatment, provided that the diagnosis is established by him or her and the treatment is prescribed at the face-to-face attendance (examination, consultation). Thus, telehealthcare technologies cannot be used to make a diagnosis of a patient and prescribe the respective treatment.

To identify and authenticate participants of remote interaction in the healthcare delivery using telehealthcare technologies, a unified identification and authentication system will be used.

The procedure for healthcare organisation and delivery with the use of telehealthcare technologies will be established by the competent federal executive authority. Such care shall also be provided in accordance with the procedures for the healthcare delivery and on the basis of healthcare standards.

Besides, when using telehealthcare technologies for the healthcare delivery, the requirements established by legislation in the area of personal data and medical secrecy shall be observed.

E-Document Flow in the Medial Aid Provision

Documenting the information on the medial aid to a patient using telehealthcare technologies, including making entries into the patient's medical documents, will be performed using a strengthened qualified electronic signature (hereinafter - the 'SQES') by a healthcare professional.

An informed voluntary consent to medical intervention or refusal of medical intervention can be made in the form of an e-document signed by a citizen or his/her legal representative using the SQES or a simple electronic signature through the unified identification and authentication system, as well as by a healthcare professional using the SQES.

A patient or his/her legal representative may receive medical documents (copies thereof) and extracts therefrom, including in e-form, on request sent, inter alia, in e-form.

Medical reports, certificates, prescriptions for medicines and medical products with the consent of a patient or his/her legal representative can be issued in the e-form with the use of the medical officer's SQES in the procedure established by the competent federal executive authority.

Amendments that provide for the option of making prescriptions for medicines in the e-form signed by the authorised healthcare professional (consulting physician or paramedic, midwife, which are entrusted with the functions of the consulting physician and the corresponding medical organisation) upon the consent of a patient of a representative thereof are also made in the Federal Law No. 3-FZ dated 8 January 1998 'On Narcotic Drugs and Psychotropic Substances' and Federal Law No. 61-FZ dated 12 April 2010 'On Circulation of Medicines'.

Thereat, the patient's right to choose the form of the prescription is not limited. Upon the patient's request, a paper original of the prescription with a doctor's signature and a certificate on the availability of the prescribed medicine in the attached pharmacy can still be issued directly at the doctor's office.

Unified State Information System in the Healthcare Sector

The competent federal executive authority shall create, develop and operate a unified state information system in the healthcare sector to ensure access of citizens to healthcare services in electronic form, as well as the interaction of health information systems (hereinafter - the 'Unified System').

The Unified System will provide the opportunity to render medical aid in e-form through a unified portal of state and municipal services, the list of which shall be approved by the Government of the Russian Federation.

The Unified System will include, inter alia:

- information contained in federal healthcare information systems, federal databases and federal healthcare registers;
- information on medical organisations (except for medical organisations subordinate to the federal executive authorities, in which military service or equivalent service is provide by federal law);
- information on persons engaged in medical activities;
- information depersonalised in the established procedure on persons under medical treatment, as well as persons, who are undergoing medical expertise, medical examinations and medical certification;
- information on medical records that cannot be used to determine the health status of a citizen, as well as information about a medical organisation, which created and store the medical records;
- classifiers, reference books and other normative and reference information in the healthcare sector, the list of which and procedure for conducting and using thereof shall be determined by the competent federal executive authority.

The information will be entered into the Unified System and accessed by the competent executive authorities (federal and of constituent entities of the Russian Federation), local self-government authorities, non-budgetary funds, medical and pharmaceutical organisations, organisations that are operators of other information systems designed to collect, store, process and provide information related to the activities of medical organisations and services they provide (hereinafter -

the 'other information systems'). Citizens will also be able to access the information contained in the Unified System.

Other information systems will be connected to:

- the Unified System by the competent federal executive authority;
- the unified system of identification and authentication - by the federal executive government authority, which exercises the functions on the development and implementation of state policy and legal regulation in the area of information technology.

The practical application of the above legislative developments, therefore, will be based on the by-laws that shall be adopted by the Government of the Russian Federation and other competent authorities.

Medical and pharmaceutical organisations will need to adopt relevant internal documents regulating, inter alia, the procedure for processing and circulation of e-documents in the course of medical aid provision and in selling medicines upon prescriptions given in e-form, respectively, as well as the necessary organisational and technical measures, in particular, to provide for obtaining of SQES for their healthcare professionals.

The amendments enter into force on 1 January 2018, except for certain provisions, which have another (later) commencement date.

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Best Regards,

GRATA International Law Firm (Moscow)

Corporate and Commercial Law Department

What we do:

- development of local regulatory acts (internal documents), including regulations on e-documents flow, protection of proprietary information and commercial secrets, personal data processing;
- legal support in obtaining an electronic digital signature;
- advising and legal support in participating in public procurement;
- advising on legal compliance of advertising and marketing materials and activities.

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