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NEW CODE ON PEOPLE'S HEALTH AND HEALTHCARE SYSTEM OF THE REPUBLIC OF KAZAKHSTAN

IMPORTANT!

On 7 July 2020, the Kazakhstan President signed the new <u>Code</u> on People's Health and Healthcare System (the "Code") and the accompanying <u>Law</u> on Introduction of Amendments into Certain Legislative Acts of the Republic of Kazakhstan on Healthcare Issues, which will enter into legal force starting from 19 July 2020 (except for certain provisions, which will be put into effect later).

Besides the issues of broadening of powers of the Ministry of Health for the period of introducing the state of emergency and powers of the Chief State Sanitary Doctors on *introduction of restrictive measures and quarantine, mandatory vaccination, donation and anatomical gift, differentiated approach to medical malpractice, parameters of determining night time in the context of noise prohibition, equation of electronic consumption systems to tobacco products* and some other issues broadly discussed by people, business may be interested in other novelties, including, but not limited to, the following legislative amendments.

Advertising

Among other things, the Code expressly prohibits advertising of:

- prescription medicines in mass media;
- services provided by persons who have no certificate of specialist in the healthcare sphere, including by foreign specialists.

At the same time, in addition to mass media and healthcare organizations, the Code <u>legalized electronic information resources</u> as the source for advertising of services, medicines and medical products.

Digital Healthcare

The Code introduced the conceptual framework of digital healthcare:

- mobile healthcare (use of mobile devices, including mobile phones, palmtop computers, medical devices and other appliances for healthcare purposes);
- *tele-healthcare* (remote medical services);
- personal medical data (information on health status of an individual or the services provided to him/her recorded on electronic, paper or other tangible media) and other.

Healthcare subjects must **ensure the transfer of data** to the National Electronic Health Passport and electronic information resources of the authorized agency, and personal medical data may be transferred to third parties only subject to consent of an individual. It is not allowed to connect electronic information resources containing personal medical data of individuals to telecommunication networks connecting them to other databases without consents of individuals when using personal medical data pertaining to their private life, except for the cases associated with donation of blood and its components, organs (parts thereof) and/or tissues (parts thereof), and requests of law-enforcement, special governmental agencies for submission of information constituting a medical secrecy in the form of an electronic document concerning registration of persons with psychological and behavior disorders (diseases) associated with the consumption of psychoactive substances.

Circulation

- Along with the paper form of prescriptions, Kazakhstan also secured electronic form on a legislative level.
- The law-maker provides for a possibility to apply advanced therapy medicines in the concept of exclusion from the standard procedure for admission of a medicine to the market. The procedure for such application and the list of medical organizations entitled to treat under **Hospital exemption** is determined by an authorized agency.
- The law-maker also sets out the concept of "co-payment" in a more specific manner. From now on, co-payment means the payment of difference in the cost of medicines, medical products and the established maximum price for their compensation in the framework of the guaranteed volume of free medical aid and/or in the system of mandatory social medical insurance at outpatient level taken out on a voluntary basis.

Price Formation

Similarly to the rules in effect prior to the introduction of the Code, Kazakhstan established **state regulation of prices** in the framework of the guaranteed volume of free medical aid and/or in system of mandatory social medical insurance. Nonetheless, the following provisions were added to requirements in the price formation area:

- maximum retail price cannot be approved without observing the summarized wholesale and retail mark-up to the manufacturer's maximum price;
- wholesale trade in medicines without establishing the maximum prices for medicines according to trade names is not allowed.

Promotion Ethics

The Code duplicates the previously introduced legislative **prohibition on promotion** of medicines and medical products by the representatives of their manufacturers and/or distributors in medical organizations and educational organizations in the healthcare sphere. The exception still covers the promotion in the framework of daily medical conferences and at research-to-practice conferences and/or special-purpose

workshops. The Code introduced the concept of a **"daily medical conference,"** which means a scheduled meeting of a medical organization to summarize the results for the past day, discuss and analyze medical cases, and to inform the collective about new progress of medical science and clinical practice.

HR Issues

Among the requirements to medical and pharmaceutical employees there appeared an obligation to be registered with the National Accounting System for HR Resources in the Healthcare Sphere. Furthermore, in addition to accreditation and attestation of specialists in the healthcare sphere, the Code introduced a requirement on certification, without which specialists will not be admitted to clinical or pharmaceutical practice.

Liability

- The Code introduced the term "medical incident," where unexpected complications occurred as a result of the treatment and the adverse outcome is absolutely connected with the human body specifics. Criminal liability for medical malpractice was cancelled; medical negligence still entails a criminal sanction.
- There are new administrative fines for smoking in a car in the presence of children and for the sale of tobacco products (including electronic cigarettes, tobacco heating systems and hookahs) to persons under the age of 21.
- The law-maker adjusted the elements of the "disturbance" administrative violation subject to changes in the night time on business days from 10:00 PM to 9:00 AM; on weekends from 11:00 PM to 10:00 AM.

Should you have any additional questions in connection with this Legal Update, we would be happy to provide more detailed information.

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