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If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 134

Adopted 11 March 2014

**Regulations Regarding the Unified Electronic Information System of the Health Sector**

*Issued pursuant to*

*Section 78, Paragraph two and Section 79, Paragraph 1.1 of the Medical Treatment Law*

[*1 December 2015*]

**I. General Provisions**

1. The Regulation prescribes:

1.1. the manager of the unified electronic information system of the health sector (hereinafter – the health information system), the data to be stored in the health information system and the procedures for processing them, as well as the procedures for issuing data;

1.2. the procedures for using the authentication tools of the health information system, and also the procedures for ensuring authenticity of the procedural entries;

1.3. the operation of the National Contact Point for eHealth which ensures cross-border exchange of data between the health information system and the Contact Point for eHealth of the country of affiliation of a patient.

[*1 December 2015; 21 December 2021*]

2. The National Health Service shall be the manager of the health information system.

3. The manager of the health information system shall:

3.1. determine the following standardised procedures for the exchange of data in the health information system:

3.1.1. exchange structure standards of health care related data;

3.1.2. requirements for accessing the health information system;

3.1.3. classifiers to be used;

3.1.4. security and technical standards;

3.2. ensure the storage of medical documents existing in the health information system and accessibility thereof in the health information system:

3.2.1. for medical documents referred to in Sub-paragraphs 7.1, 7.2, 7.3, 7.4, 7.7, 7.9, 7.10, 7.11, 7.12, 7.13, 7.14, 7.15, 7.16, 7.17, 7.18, 7.19, and 7.20 of this Regulation – for 75 years after the last entry;

3.2.2. for medical documents referred to in Sub-paragraph 7.5 of this Regulation – in conformity with the time period laid down in the laws and regulations regarding procedures for the production and storage of prescription forms and procedures for writing out prescriptions;

3.2.3. for medical documents referred to in Sub-paragraph 7.6 of this Regulation – for four years after the last entry;

3.2.4. for medical documents referred to in Sub-paragraphs 7.8 and 7.21 of this Regulation – for 25 years after the last entry;

3.3. ensure that the information corrected and deleted from the health information system is stored in the archive of the health information system in conformity with the time period indicated in Sub-paragraph 3.2 of this Regulation;

3.4. ensure the inclusion of the information referred to in Paragraph 32.3 of this Regulation on the authorised persons of the patient in the health information system or the deletion of such information immediately after receipt of the submission or power of attorney referred to in Sub-paragraph 32.21 of this Regulation.

[*1 December 2015; 29 November 2016; 17 July 2018; 21 December 2021; 7 March 2023*]

3.1 The National Health Service as the institution responsible for the operation of the National Contact Point for eHealth shall be responsible that data integrity, accessibility, confidentiality, audit, and traceability are ensured in the process of cross-border exchange of patient data and:

3.11. determine the safety and technical standards for cross-border exchange of patient data;

3.12. determine the transcoding (equalisation and making of changes) and translation procedures for cross-border exchange of patient data;

3.13. determine the structuring and coding standards for cross-border exchange of patient data;

3.14. ensure semantic compatibility of the data sent and received.

[*21 December 2021; 7 March 2023*]

3.2 In order to ensure the fulfilment of the requirements referred to in Sub-paragraphs 3.12 and 3.14 of this Regulation:

3.21. the State Agency of Medicines shall equate the data which are contained in the Medicinal Product Register of Latvia and which are used in cross-border exchange of data to the terms contained in the database used for cross-border exchange of data and submit them to the National Health Service;

3.22. the Centre for Disease Prevention and Control shall equate the diagnoses included in the International Statistical Classification of Diseases and Related Health Problems 10th revision (hereinafter – ICD-10) to the terms contained in the database used for cross-border exchange of data and submit them to the National Health Service;

3.23. the Health Inspectorate shall equate the data which are contained in the Register of Medical Practitioners and Medical Treatment Support Persons and which are used in cross-border exchange of data to the terms contained in the database used for cross-border exchange and submit them to the National Health Service.

[*7 March 2023*]

3.3 If the State Agency of Medicines, the Centre for Disease Prevention and Control, or the Health Inspectorate concludes that the equalisation referred to in Paragraph 3.2 of this Regulation is not possible, they shall inform the National Health Service.

[*7 March 2023*]

4. The health information system shall ensure:

4.1. centralised processing of the data related to a person’s health referred to in this Regulation that is needed for medical treatment;

4.1.1 centralised processing of the health-related data of a person referred to in this Regulation and the electronic prescriptions written out to a person (hereinafter – the e-prescription) in order to ensure cross-border exchange of data;

4.2. processing of the data related to a person’s health referred to in this Regulation that is required for the provision of statistics and research;

4.3. writing out electronic prescriptions and circulation between a medical practitioner and pharmacist or pharmacy assistant;

4.4. issue and circulation of sick-leave certificates between a medical practitioner and competent institution implementing state policy in the field of social insurance and State social benefits;

4.5. electronic booking of a patient’s appointment by a medical practitioner;

4.6. electronic processing of referrals for receipt of a health care service;

4.7. electronic transmission of payment data on State funded health care services and medicinal products and medical devices to the payment settlement system for health care services “Management Information System” of the National Health Service;

4.8. access to the images obtained during the radiological manipulations stored in the digital archiving system of the visual diagnostics images;

4.9. centralised processing of the data referred to in this Regulation and related to the health of a person which are needed to plan, organise, carry out, and supervise vaccination in accordance with the procedures laid down in vaccination regulations;

4.10. centralised processing of the data referred to in this Regulation and related to the health of a person on gamete donation which are needed to ensure the exchange of information on the use of gamete of a gamete donor;

4.11. data processing referred to in this Regulation in relation to the will expressed by the person regarding the use of his or her body, tissues, and organs after death and the performance of pathological-anatomical examination (autopsy) in accordance with the law On the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine;

4.12. data processing referred to in this Regulation regarding a person who has been authorised by a patient to take decisions related to medical treatment instead of the patient in accordance with the Law on the Rights of Patients.

[*1 December 2015; 29 November 2016; 17 July 2018; 21 December 2021 / Sub-paragraphs 4.11 and 4.12 shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

**II. Data to be Included in the Health Information System**

5. Both generally available data and restricted access data shall be included in the health information system. Restricted access data on a patient shall be divided into master data and supplementary data.

6. The following restricted access master data on a patient shall be included in the health information system:

6.1. given name (names), surname;

6.2. personal identity number;

6.3. nationality and type of the nationality;

6.4. gender;

6.5. date of birth;

6.6. declared, registered place of residence or place of residence indicated by the person;

6.7. status of the person (active/passive);

6.8. information on the restricted capacity to act or reassessment of restricted capacity to act;

6.9. date of death;

6.9.1 cause of death;

6.10. note on adulthood;

6.11. information on the residence document received in Latvia – a residence permit, registration certificate or permanent residence certificate;

6.12. information on establishment or termination of out-of-family care, or termination thereof, suspension, withdrawal or restoration of custody rights;

6.13. contact information indicated by a person (telephone number, electronic mail address, actual residence address);

6.13.1 contact person indicated by a person (given name, surname, telephone number, electronic mail address, actual residence address);

6.14. data on the person or persons who are authorised to process data in the health information system on behalf of the patient:

6.14.1. given name (names), surname, personal identity number of parents, guardians, persons fulfilling the duties of a foster family;

6.14.2 contact information (telephone number, electronic mail address) of parents, guardians, persons fulfilling the duties of a foster family;

6.14. 3. name of the child care institution;

6.14.4. contact information (telephone number, electronic mail address) of the child care institution;

6.14.5. given name (names), surname, personal identity number, contact information (telephone number, electronic mail address) of the authorised person;

6.15. given name (names), surname, contact information (name of the medical treatment institution, address, telephone number, electronic mail address) of the family doctor;

6.16. information on the documents issued in conformity with Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems:

6.16.1. type of the document;

6.16.2. name of the issuing authority of the document;

6.16.3. identification number of the issuing authority of the document;

6.16.4. term of validity of the document;

6.16.1 data on the rights of the person to receive the State paid medical assistance minimum or health care services within the framework of the State mandatory health insurance;

6.17. health data:

6.17.1. type, form of allergies, allergen (in case of a drug allergy – also the active substance and name of the medicinal product) and the allergic reaction caused thereby, the severity level, controllability thereof, the description of its determination, the date of diagnostics of the allergy;

6.17.2. diagnosed diseases and persistent health conditions in conformity with the ICD-10 and the current classification of rare diseases (ORPHA code), the date of diagnostics thereof;

6.17.3. implants and prostheses – time and medical treatment institution of implantation, type of the implant and prosthesis, manufacturer, name, number or series;

6.17.4. disability or predictable disability – basic diagnosis, ancillary diagnosis according to the ICD-10, disability group, start and end date of disability or predictable disability, date and number of the decision of the State Medical Commission for the Assessment of Health Condition and Working Ability;

6.17.5. surgeries performed – date, name and classification code of the surgical manipulations in accordance with the current version of the Classification of Surgical Procedures with the supplement (NCSP+) of the Nordic Medico-Statistical Committee (NOMESCO);

6.17.6. diseases diagnosed during the past 12 months in accordance with the ICD-10 and prescribed and received medicinal products (name, strength, dosage, frequency of use);

6.17.7. regularly used medicinal products (name, strength, dosage, frequency of use);

6.17.8. other warnings related to the patient’s health;

6.18. data on the legal representative of a child of up to 14 years of age and the authorised person of the legal representative or the authorised person of the patient who has been authorised by the patient in accordance with the Law on the Rights of Patients to consent in his or her place to medical treatment in general or to the method to be used for medical treatment or to refuse medical treatment in general or the method to be used for medical treatment and to receive information in accordance with the Law on the Rights of Patients:

6.18.1. given name (names), surname, personal identity number, contact information (telephone number, electronic mail address) of the authorised person of the patient;

6.18.2. data referred to in Sub-paragraphs 6.14.1, 6.14.2, 6.14.3, and 6.14.4 of this Regulation regarding the legal representative of the child of up to 14 years of age;

6.18.3. given name (names), surname, personal identity number, contact information (telephone number, electronic mail address) of the legal representative of the child of up to 14 years of age;

6.19. the will expressed by the person regarding the permission or prohibition to perform pathological-anatomical examination (autopsy) after death;

6.20. the will expressed by the person regarding the use of the body, tissues, and organs after death:

6.20.1. the permission to use the following tissues for transplantation:

6.20.1.1. all tissues;

6.20.1.2. skin;

6.20.1.3. stem cells;

6.20.1.4. tendons;

6.20.1.5. bone marrow;

6.20.1.6. bones;

6.20.1.7. corneas (both);

6.20.1.8. heart valves;

6.20.1.9. cartilage;

6.20.2. the permission to use the following organs for transplantation:

6.20.2.1. all organs;

6.20.2.2. pancreas;

6.20.2.3. liver;

6.20.2.4. uterus;

6.20.2.5. kidneys (both);

6.20.2.6. lungs (both);

6.20.2.7. heart;

6.20.2.8. vascularised composite allograft;

6.20.2.9. intestines;

6.20.3. the permission to use the body:

6.20.3.1. for study and scientific purposes or research;

6.20.3.2. for making medical preparations and bioprotheses;

6.20.4. prohibition to use the tissues and organs after death for transplantation;

6.20.5. prohibition to use the body after death for the purposes referred to in Sub-paragraph 6.20.3 of this Regulation.

[*22 May 2018; 21 December 2021; 7 March 2023*]

7. The following medical documents containing restricted access supplementary data on a patient shall be included in the health information system:

7.1. an overview of outpatient examination/medical treatment of a patient (Annex 1);

7.2. referral for the receipt of an out-patient/in-patient service (Annex 2);

7.3. discharge – epicrisis (Annex 3);

7.4. sick-leave certificate (Annex 4);

7.5. electronic prescription (Annex 5);

7.6. information of the emergency medical assistance (EMA) call card (Annex 6);

7.7. description of the radiological examination (Annex 7);

7.8. an immunization card (Annex 8);

7.9. a register card of traumas, injuries and cases of poisoning (Annex 9);

7.10. a narcological patient’s register card (Annex 10);

7.11. an evaluation of the medical treatment result of a narcological patient (Annex 11);

7.12. a register card of the patient with mental and behavioural disorders (Annex 12);

7.13. a register card of the patient of diabetes mellitus (Annex 13);

7.14. a register card of the patient of tuberculosis (Annex 14);

7.15. an oncological patient’s registration card (Annex 15);

7.16. an oncological patient’s medical treatment card (Annex 16);

7.17. a registration card of the patient of occupational diseases (Annex 17);

7.18. a dynamic observation card of the patient of occupational diseases (Annex 18);

7.19. a register card of the patient with congenital abnormalities (Annex 19);

7.20. a register card for the patient of multiple sclerosis (Annex 20);

7.21. a gamete donor’s card (Annex 21).

[*1 December 2015; 29 November 2016; 17 July 2018*]

8. The following restricted access data on a user of the health information system who processes patient data in the health information system on behalf of a medical treatment institution, pharmacy, or higher education institution shall be included in the health information system:

8.1. given name (names), surname;

8.2. personal identity number;

8.3. identifier and speciality of a medical practitioner or medical treatment support person assigned by the Health Inspectorate;

8.4. pharmacist’s and pharmacy assistant’s registration number in the Register of Pharmacists and Pharmacy Assistants;

8.5. position.

[*29 November 2016; 21 December 2021 / The introductory part of the Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

9. The following restricted access data on a person who has processed data of a patient in the health information system shall be included in the health information system:

9.1. given name (names), surname, for medical practitioners and medical treatment support persons – identifier of a medical practitioner or medical treatment support person granted by the Health Inspectorate, for pharmacists and pharmacy assistants – registration number in the Register of Pharmacists and Pharmacy Assistants, speciality or position;

9.2. name of the institution, for medical treatment institutions – also the code in the Register of Medical Treatment Institutions and address;

9.3. date and time of data processing;

9.4. type of data processing.

10. The following generally available data on the health care institution shall be included in the health information system:

10.1. health care services funded from the health care State budget resources and from the resources of the recipient of a service (patient fee, co-payment), which are provided by the medical treatment institution;

10.2. health care services funded by the resources of the recipient of the service, which are provided by the medical treatment institution;

10.3. appointment times of medical practitioners;

10.4. possibility to make an appointment to receive a health care service.

**III. Procedures for the Processing and Issue of Data in the Health Information System**

11. Data shall be provided to the health information system online by:

11.1. the Office of Citizenship and Migration Affairs – the current data specified in Sub-paragraphs 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 6.11, 6.12, 6.14.1, 6.14.3, 8.1, and 8.2 of this Regulation;

11.2. the National Health Service – the current data specified in Sub-paragraphs 6.10, 6.15, 6.16, 6.16.1 and Paragraph 9 of this Regulation;

11.2.1 the Centre for Disease Prevention and Control – the data specified in Sub-paragraph 6.9.1 of this Regulation;

11.3. the State Medical Commission for the Assessment of Health Condition and Working Ability – the data specified in Sub-paragraph 6.17.4 of this Regulation and in Paragraph 20 of Annex 4 to this Regulation;

11.4. a medical treatment institution:

11.4.1. the data specified in Sub-paragraphs 6.13, 6.14.2, 6.14.4, 6.17.1, 6.17.2, 6.17.3, 6.17.5, 6.17.6, 6.17.7, 6.17.8 of this Regulation and in Annexes 1, 2, and 7 to this Regulation – immediately, but no later than within five working days, after provision of a health care service to a patient in an out-patient medical treatment institution, and within 14 days – in an in-patient medical treatment institution;

11.4.2. the data specified in Annex 3 to this Regulation immediately, but no later than within five working days, after discharging a patient from an in-patient medical treatment institution. If the results of examinations of the patient have been received after submission of the data to the health information system, the medical treatment institution shall submit the most recent data immediately, but not later than within five working days, after receipt of the results of examinations;

11.4.3. the data specified in Annex 4 to this Regulation in accordance with the laws and regulations regarding the procedures for the issuance and cancellation of sick-leave certificates;

11.4.4. the data specified in Paragraphs 1, 2, 3, 4, 5, 6, and 7 of Annex 5 to this Regulation in conformity with the laws and regulations regarding the manufacture and storage of prescription forms, and also regarding writing out and storage of prescriptions;

11.4.5. the data specified in Sub-paragraph 8.5 of this Regulation – by assigning user rights to a person who processes patient data in the health information system on behalf of the medical treatment institution;

11.4.6. the current data specified in Paragraph 10 of this Regulation – as needed;

11.4.7. the data specified in Annex 8 to this Regulation – in accordance with the procedures laid down in Sub-paragraph 11.4.1 of this Regulation if the medical treatment institution has agreed in the contract referred to in Paragraph 13 of this Regulation with the National Health Service on the processing of vaccination data in the health information system;

11.4.8. the data specified in Annex 10 to this Regulation – immediately, but no later than within 14 days, after starting a treatment episode;

11.4.9. the data specified in Annex 11 to this Regulation – immediately, but no later than within 14 days, after evaluation of the result of a treatment episode;

11.4.10. the data specified in Annexes 9, 12, 13, 14, 15, 16, 19, and 20 to this Regulation – immediately, but no later than within 14 days, after determination of a diagnosis, medical treatment, and evaluation of the course of illness;

11.4.11. the data specified in Annexes 17 and 18 to this Regulation – no later than within 60 days after determination of a diagnosis, medical treatment, and evaluation of the course of illness;

11.4.1 a medical treatment institution, which stores the images obtained as a result of the radiological manipulations in the digital archiving system of the visual diagnostics images – the images obtained as a result of the radiological manipulations immediately, but not later than within five working days, after the provision of the health care service if the medical treatment institution has agreed in the contract referred to in Paragraph 13 of this Regulation with the National Health Service for the use of the health information system on the delivery of the images obtained as a result of the radiological manipulations to the health information system;

11.5. a family doctor – the data specified in Sub-paragraphs 6.17.1, 6.17.2, 6.17.3, 6.17.5, 6.17.6, 6.17.7, and 6.17.8 of this Regulation on patients who are registered with the relevant family doctor;

11.6. a pharmacy (branch of pharmacy) – the data specified in Annexes 5 and 8 to this Regulation immediately, but not later than within three working days, after dispensing of the relevant medicinal product in conformity with the laws and regulations regarding the procedures for the production and storage of the prescription forms, and also writing out prescriptions or performing vaccination;

11.7. the State Land Service – the data of the National Address Register Information System to ensure conformity of all the addresses included in the health information system;

11.8. the Health Inspectorate – the data specified in Sub-paragraph 8.3 of and Paragraphs 21 and 22 of Annex 4 to this Regulation;

11.9. the Latvian Pharmacists Association – the data specified in Sub-paragraph 8.4 of this Regulation;

11.10. Emergency Medical Assistance Service – the data specified in Annex 6 to this Regulation;

11.11. medical treatment institutions which provide medical insemination services – the data specified in Annex 21 to this Regulation immediately after receipt of a donation and use of the donated material;

11.12. the patient – the data specified in Sub-paragraphs 6.18.1, 6.18.3, 6.19, and 6.20 of this Regulation regarding himself or herself and also the data referred to in Paragraph 32 of this Regulation;

11.13. the institutions which perform pathological-anatomical examination (autopsy) regarding taking into account of the information specified in Sub-paragraph 6.19 of this Regulation in the performance of the work;

11.14. medical treatment institutions which procure or transplant tissues and organs regarding taking into account of the information specified in Sub-paragraph 6.20 of this Regulation in the performance of the work;

11.15. a higher education institution which uses a body after death for study and scientific purposes or research regarding taking into account of the information specified in Sub-paragraphs 6.20.3 and 6.20.5 of this Regulation in the performance of the work.

[*1 December 2015; 29 November 2016; 22 August 2017; 22 May 2018; 17 July 2018; 17 December 2020; 14 December 2021; 21 December 2021; 7 March 2023*]

12. The National Health Service shall ensure access to the health information through the following types of access:

12.1. user interface of the health information system;

12.2. user interface of the State administration service portal www.latvija.lv;

12.3. information system used by a medical treatment institution or pharmacy if it is integrated in the health information system;

12.4. integrator of the State information systems.

[*7 March 2023*]

13. Restricted access data stored in the health information system on patients in the amount specified in Paragraphs 22, 23, 24, 25, 26, 27, 27.1, 27.2, 28, and 29 of this Regulation may be accessed by a pharmacy (pharmacy branch) which holds a valid licence for pharmaceutical activity, a medical treatment institution registered in the Register of Medical Treatment Institutions, a higher education institution registered in the Register of Higher Education Institutions which has received the permit issued by the State Agency of Medicines for the use of tissues or organs for the implementation of an accredited medical study programme or a professional development programme of medical practitioners and has concluded a contract with the National Health Service for the use of the health information system, stipulating the security and technical requirements for using the health information system, and the user of the health information system has authenticated himself or herself in the health information system by using:

13.1. [1 January 2023 / See Paragraph 41];

13.2. [1 January 2023 / See Paragraph 41];

13.3. qualified means of electronic identification of a person.

[*29 November 2016; 21 December 2021 / Sub-paragraph 13.3 shall be applicable from 1 January 2024. See Paragraph 42.1 of Amendments*]

13.1 In order to access the health information system, any type of access referred to in Paragraph 12 of this Regulation and authentication tools of the health information system referred to in Paragraph 13 of this Regulation shall be used. The access shall take place in accordance with the following procedures:

13.11. A user shall be authenticated in the health information system at the moment when a confirmation of the person’s identity is received from the provider of the authentication service supplier;

13.12. The health information system ensures recording of the actions taken by the authenticated users (audit trails) regarding all actions taken by the users;

13.13. the audit trails of the health information system automatically record any successful and unsuccessful attempts of the user to access the health information system, date and time when each attempt to access the system was made, and also the unique user code (personal identity number, identifier of the medical practitioner or medical treatment support person assigned by the Health Inspectorate, or a registration number of the pharmacist and a pharmacy assistant in the Register of Pharmacists and Pharmacy Assistants), and also register successful and unsuccessful requests of the Contact Point for eHealth of the country of affiliation of the patient to the National Contact Point for eHealth, date and time of requests, the unique user code of the requester, the requested data, and the data provided by the National Contact Point for eHealth.

[*1 December 2015; 29 November 2016; 21 December 2021*]

13.2 In order to guarantee authenticity of the entries made in the health information system, a controller of the health information system shall:

13.21. ensure safety of the personal data stored in the health information system;

13.22. at least once a year perform a safety inspection (audit) of the system, and based on results of the safety inspection (audit) of the system evaluate adequacy of the safety measures for the health information system;

13.23. take all the necessary measures to ensure that the health information system is used and the patient or user data is accessed only by the persons to whom such rights have been granted in accordance with this Regulation;

13.24. take all the necessary measures to protect the information entered by the authorised user from unauthorized access and maintain the technological solutions, protecting the information during the data transmission in the communication networks, including ensure:

13.24.1. authenticity of the system users;

13.24.2. integrity of the information included in the entry;

13.24.3. control of the users processing (also viewing, entering and editing) the information;

13.24.4. link between the user and processed (also viewed, entered and edited) information;

13.24.5. information regarding all attempts to illegally process the information (also access the information, enter and edit it).

[*1 December 2015*]

13.3 Cross-border exchange with patient data shall occur only to such extent which is necessary for a medical practitioner to be able to help a patient whose data have been registered in another country (hereinafter – the country of affiliation of the patient), to ensure health care in the country of medical treatment and for a pharmacist or pharmacist’s assistant to be able to ensure the processing of an e-prescription issued in the country of affiliation of the patient in order to issue medicinal products to the patient. The amount of patient data in cross-border exchange shall conform to the patient data specified in Sub-paragraphs 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.13, 6.14, 6.15, 6.17, 6.18, and 7.5 of this Regulation.

[*21 December 2021*]

13.4 The master data of a patient shall be requested from the Contact Point for eHealth of the country of affiliation of the patient according to the following procedures:

13.41. the medical practitioner shall authenticate in the health information system and perform identity check of the patient, sending a request for information to the Contact Point for eHealth of the country of affiliation of the patient via the National Contact Point for eHealth;

13.42. the National Contact Point for eHealth shall also include information on the authenticated medical practitioner, the organisation which ensures authentication of the medical practitioner, and information on the medical treatment institution in which the medical practitioner is providing health care services in the request for information referred to in Sub-paragraph 13.41 of this Regulation;

13.43. upon receipt of confirmation of the patient’s identity, the medical practitioner shall request and receive the master data of the patient via the National Contact Point for eHealth.

[*21 December 2021*]

13.5 The master data of a patient are provided to the Contact Point for eHealth of the country of medical treatment according to the following procedures:

13.51. upon receipt of a request for information from the Contact Point for eHealth of the country of medical treatment, the National Contact Point for eHealth shall, using the health information system, identify the patient according to the received personal identity number of the patient and check whether the patient has not denied access to data in accordance with Sub-paragraph 32.4 of this Regulation;

13.52. if the patient is identified and has not denied access to data, the National Contact Point for eHealth shall send the health master data of the patient to the Contact Point for eHealth of the country of medical treatment.

[*21 December 2021*]

13.6 Information from the Contact Point for eHealth of the country of affiliation of the patient on the e-prescription written out for the patient shall be requested according to the following procedures:

13.61. the pharmacist or pharmacist’s assistant shall authenticate in the health information system and perform identity check of the patient, sending a request for information to the Contact Point for eHealth of the country of affiliation of the patient via the National Contact Point for eHealth;

13.62. the National Contact Point for eHealth shall also provide information on the pharmacist or pharmacist’s assistant, the organisation which ensures authentication of the pharmacist or pharmacist’s assistant, and information on the pharmacy in the request for information referred to in Sub-paragraph 13.61 of this Regulation;

13.63. upon receipt of confirmation of the patient’s identity, the pharmacist or pharmacist’s assistant shall request and receive the e-prescriptions written out in the country of affiliation of the patient via the National Contact Point for eHealth;

13.64. the pharmacist or pharmacist’s assistant shall send information on the issuing (redemption) or revocation of issuing of e-prescriptions to the National Contact Point for eHealth. The National Contact Point for eHealth shall send information to the Contact Point for eHealth of the country of affiliation of the patient.

[*21 December 2021*]

13.7 Exchange of information between the National Contact Point for eHealth and the Contact Point for eHealth of another country on the e-prescriptions written out to and redeemed by the patient is carried out according to the following procedures:

13.71. upon receipt of a request for information from the Contact Point for eHealth of another country, the National Contact Point for eHealth shall, using the health information system, identify the patient according to the received personal identity number of the patient and check whether the patient has not denied access to data in accordance with Sub-paragraph 32.4 of this Regulation;

13.72. if the patient is identified in the health information system and he or she has not denied access to data, the National Contact Point for eHealth shall send a list of the e-prescriptions written out to the patient and available for issuing in foreign countries. Such e-prescriptions are deemed available e-prescriptions which may be issued to the patient in foreign countries at the moment of request for information;

13.73. the National Contact Point for eHealth shall receive information on the e-prescription redeemed for the particular patient, confirm receipt of information to the Contact Point for eHealth of the country which issued the medicinal products, and make a note regarding issuing of an e-prescription.

[*21 December 2021*]

14. Upon entering into the contract specified in Paragraph 13 of this Regulation for the use of the health information system with a medical treatment institution or pharmacy (pharmacy branch) which accesses the health information system in conformity with Sub-paragraph 12.3 of this Regulation, the National Health Service shall provide an obligation for the medical treatment institution or pharmacy (pharmacy branch) in the aforementioned contract to ensure that the information system used by the medical treatment institution or pharmacy (pharmacy branch), which is integrated in the health information system, does not allow massive data replication and the following general security and technical requirements are complied with:

14.1. the documents laid down in the laws are regulations regarding general security requirements for State information systems have been developed;

14.2. the information system uses software which is used to make audit records, registering data on events in the information system, in order to provide an opportunity to assess their impact on security of the information system;

14.3. information and technical resources of the information system have been determined in conformity with the laws and regulations governing the circulation and storage of electronic documents;

14.4. conformity of the compatible system and the integrator with at least the following infrastructure protection requirements for the compatible system and the integrator has been ensured:

14.4.1. compatible system and integrator infrastructure (servers, disk arrays, switches, which are related to the system servers) shall be protected against unauthorised access, thefts and intentional or unintentional damage (e.g. flood, fire);

14.4.2. the security manager of the compatible system and integrator shall be responsible for ensuring that the premises of the compatible system and integrator infrastructure are accessed only by persons who need physical access to the compatible system and integrator infrastructure for fulfilling their work duties;

14.4.3. the premises of the compatible system and integrator infrastructure shall be equipped with an alarm system (detectors, which record unauthorised opening of doors and windows), smoke and fire detectors, automated gas fire extinguishing system, or shall be provided with fire-extinguishers;

14.5. conformity of the compatible system and integrator shall been ensured with the following logical protection requirements for the compatible system and the integrator:

14.5.1. internal computer networks of the compatible system and integrator shall be separated from the internet by means of a firewall;

14.5.2. infrastructure (servers, disk arrays) of the compatible system and integrator shall be separated in a separate sub-network or by means of a firewall;

14.5.3. if the technical solution permits, anti-virus protection of the compatible system and integrator shall be ensured. Anti-virus programme database shall be updated at least once a day;

14.5.4. continuous protection against work environment safety risks of the compatible system and integrator shall be ensured by means of intrusion attempt detection and a protection system;

14.5.5. by using only encrypted connection and multi-factor authentication, remote access restriction shall be ensured for the administration of the compatible system and integrator;

14.5.6. a separate testing of improvements of the compatible system and integrator shall be organised in a test environment established for these needs, and separated from the compatible system and integrator at physical or logical level. Protection requirements of the test environment infrastructure shall comply with the provisions of Sub-paragraph 14.4 of this Regulation;

14.5.7. access to the compatible system and integrator for the purpose of administration and management functionality shall be granted only to those persons who need the information contained in the compatible system and integrator in an appropriate scope for fulfilling their work duties;

14.6. the employment contract or work description of the person serving the compatible system or integrator shall contain a condition of compliance with the confidentiality requirements in relation to the data that comes into the possession of this person in the fulfilment of his or her work duties. If the compatible system or integrator is serviced by a third party, confidentiality requirements shall be defined in the document, which establishes a legal relationship;

14.7. the person referred to in Sub-paragraph 14.6 of this Regulation before taking up his or her work duties shall certify with the signature that he or she has been acquainted with the security policy of the compatible system or integrator, security provisions of the compatible system or integrator and other documents regulating the operation of the compatible systems or integrator.

14.1 A medical treatment institution which provides services of a psychiatrist, a narcologist, a family doctor, or artificial insemination shall agree in the contract with the National Health Service referred to in Paragraph 13 of this Regulation for the use of the health information system on the processing of the data referred to in Sub-paragraphs 7.10 and 7.11 of this Regulation (applies to a narcologist or a family doctor), in Sub-paragraph 7.12 of this Regulation (applies to a psychiatrist or a family doctor), or in Sub-paragraph 7.21 of this Regulation (applies to a gynaecologist who provides medical insemination services) in the health information system.

[*17 July 2018*]

14.2 A medical treatment institution of a place of detention shall agree in the contract with the National Health Service referred to in Paragraph 13 of this Regulation for the use of the health information system on the processing of the data referred to in Sub-paragraphs 7.10, 7.11, and 7.12 of this Regulation in the health information system.

[*18 December 2018*]

14.3 A pharmacy which provides vaccination services shall agree in the contract with the National Health Service referred to in Paragraph 13 of this Regulation for the use of the health information system on the processing of the data referred to in Sub-paragraphs 6.17.1, 6.17.2, 6.17.6, 6.17.7, and 6.17.8 of and Annex 8 (in relation to a pharmacist performing vaccination) to this Regulation in the health information system.

[*14 December 2021*]

14.4 A medical treatment institution which performs pathological-anatomical examination (autopsy) shall agree in the contract with the National Health Service referred to in Paragraph 13 of this Regulation for the use of the health information system on the processing of the data referred to in Sub-paragraph 6.19 of this Regulation in the health information system.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

14.5 A medical treatment institution which has obtained the permit issued by the State Agency of Medicines for the use of tissues or organs shall agree in the contract with the National Health Service referred to in Paragraph 13 of this Regulation for the use of the health information system on the processing of the data referred to in Sub-paragraph 6.20 of this Regulation in the health information system.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

14.6 A higher education institution which has obtained the permit issued by the State Agency of Medicines for the use of tissues or organs for the implementation of an accredited medical study programme or a professional development programme of medical practitioners shall agree in the contract with the National Health Service referred to in Paragraph 13 of this Regulation for the use of the health information system on the processing of the data referred to in Sub-paragraphs 6.20.3 and 6.20.5 of this Regulation in the health information system.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

15. The National Health Service shall not conclude a contract with a medical treatment institution or pharmacy (pharmacy branch) for the use of the health information system if:

15.1. the information system of the medical treatment institution or pharmacy (pharmacy branch) does not conform to the requirements laid down in Paragraph 14 of this Regulation;

15.2. a coercive measure related to the restriction of rights in the medical or pharmaceutical field has been applied to the medical treatment institution or pharmacy (pharmacy branch), and it has not been implemented in accordance with the procedures laid down in the laws and regulations.

16. The National Health Service has the right to unilaterally terminate the contract for the use of the health information system concluded with a medical treatment institution or pharmacy (pharmacy branch) if:

16.1. the operation of the medical treatment institution has been suspended or terminated;

16.2. the license for pharmaceutical activity has been suspended or revoked;

16.3. a court judgement or an injunction of a prosecutor on the application of a coercive measure has entered into force and it is related to the restriction of rights in the medical or pharmaceutical field.

16.1 The National Health Service has the right to unilaterally terminate the contract for the use of the health information system concluded with a higher education institution if:

16.11. the status of a higher education institution has been annulled for the higher education institution;

16.12. the State Agency of Medicines has not issued the permit for the use of tissues or organs for the implementation of an accredited medical study programme or a professional development programme of medical practitioners.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

17. The head of a medical treatment institution shall, within 30 days after concluding the contract with the National Health Service, determine the user, who shall process data in the health information system on behalf of the medical treatment institution in the amount laid down in this Regulation:

17.1. the user rights for a medical practitioner shall be determined in the health information system concurrently with the following provisions:

17.1.1. a medical practitioner shall be registered in the Register of Medical Practitioners and Medical Treatment Support Persons;

17.1.2. a medical practitioner shall be engaged in medical treatment in the medical treatment institution;

17.2. the user rights for a medical treatment support person shall be determined in the health information system concurrently with the following provisions:

17.2.1. medical treatment support person shall be registered in the Register of Medical Practitioners and Medical Treatment Support Persons;

17.2.2. a medical treatment support person shall be directly involved in the provision of health care process in the medical treatment institution, and his or her official duties shall include the processing of patient data;

17.3. [22 May 2018];

17.4. the user rights for a representative of a higher education institution shall be determined in the health information system if the following conditions are concurrently in effect:

17.4.1. the person is employed in the higher education institution;

17.4.2. the person is registered in the Register of Medical Practitioners and Medical Treatment Support Persons;

17.4.3. the person is indicated in the permit issued by the State Agency of Medicines for the use of tissues or organs for the implementation of an accredited medical study programme or a professional development programme of medical practitioners.

[*21 December 2021 / Sub-paragraph 17.4 shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

17.1 The head of the medical treatment institution referred to in Paragraph 14.1 of this Regulation shall additionally grant the medical practitioner referred to in Sub-paragraph 17.1 of this Regulation – a psychiatrist, a narcologist, a family doctor or gynaecologist – the right of a user to process the data referred to in Sub-paragraphs 7.10 and 7.11 of this Regulation (applies to a narcologist or a family doctor), in Sub-paragraph 7.12 of this Regulation (applies to a psychiatrist or a family doctor) or in Sub-paragraph 7.21 of this Regulation (applies to a gynaecologist) in the health information system.

[*17 July 2018*]

17.2 The head of the medical treatment institution of the place of detention shall additionally grant the right of a user to the physician of the place of detention to process the data referred to in Sub-paragraphs 7.10, 7.11, and 7.12 of this Regulation in the health information system.

[*18 December 2018*]

17.3 The head of the medical treatment institution referred to in Paragraph 14.4 of this Regulation shall additionally grant the user rights to the medical practitioner referred to in Sub-paragraph 17.1 of this Regulation whose official duties include the performance of pathological-anatomical examination (autopsy) to process the data referred to in Sub-paragraph 6.19 of this Regulation in the health information system.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

17.4 The head of the medical treatment institution referred to in Paragraph 14.5 of this Regulation shall additionally grant the user rights to the medical practitioner referred to in Sub-paragraph 17.1 of this Regulation whose official duties include extraction or transplantation of tissues or organs to process the data referred to in Sub-paragraph 6.20 of this Regulation in the health information system.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

17.5 The head of the higher education institution referred to in Paragraph 14.6 of this Regulation shall additionally grant the user rights to the person referred to in Sub-paragraph 17.4 of this Regulation to process the data referred to in Sub-paragraphs 6.20.3 and 6.20.5 of this Regulation in the health information system.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

18. The right of a user granted to a medical practitioner or medical treatment support person shall be revoked:

18.1. by a medical treatment institution if:

18.1.1. the medical treatment institution terminates the employment relationship with the relevant person;

18.1.2. the work duties of the relevant person do not include processing of personal data anymore;

18.1.3. a security measure related to prohibition of certain occupations in the field of medical treatment has been applied to the person, and it has not been amended or repealed in accordance with the procedures laid down in the laws and regulations;

18.1.4. a criminal punishment related to the restriction of the rights in the field of medical treatment has been imposed on the person, and it has not been enforced in accordance with the procedures laid down in the laws and regulations;

18.2. By the National Health Service if:

18.2.1. the operation of a unit of a medical treatment institution has been suspended or terminated;

18.2.2. the relevant person does not process the data stored in the health information system for more than three subsequent months;

18.2.3. a medical practitioner or a medical treatment support person is excluded from the Register of Medical Practitioners and Medical Treatment Support Persons;

18.2.4. the relevant person fails to comply with the requirements of this Regulation in processing data in the health information system;

18.2.5. a security measure related to prohibition of certain occupations in the field of medical treatment has been applied to the person, and it has not been amended or repealed in accordance with the procedures laid down in the laws and regulations;

18.2.6. a criminal punishment related to the restriction of the rights in the field of medical treatment has been imposed on the person, and it has not been enforced in accordance with the procedures laid down in the laws and regulations.

[*22 May 2018*]

19. The head of a pharmacy (pharmacy branch) shall, within 30 days after conclusion of a contract with the National Health Service, determine the user who on behalf of the pharmacy (pharmacy branch) shall process data in the health information system in the amount laid down in this Regulation, by assigning the user rights to a pharmacist or pharmacy assistant if the following condition exist concurrently:

19.1. a pharmacist or pharmacy assistant shall be registered in the Register of Pharmacists and Pharmacy Assistants;

19.2. a pharmacist or pharmacy assistant shall ensure pharmaceutical care in a pharmacy or its branch.

19.1 The head of the pharmacy referred to in Paragraph 14.3 of this Regulation shall additionally grant the user rights in the health information system to the pharmacist who performs vaccination in order to process the data referred to in Sub-paragraphs 6.17.1, 6.17.2, 6.17.6, 6.17.7, and 6.17.8 of and Annex 8 to this Regulation.

[*14 December 2021*]

20. The user rights assigned to a pharmacist or pharmacy assistant shall be revoked:

20.1. by a pharmacy if:

20.1.1. it terminates the employment relationship with the relevant person;

20.1.2. a person has been imposed a security measure related to prohibition of certain occupations in the pharmaceutical field, and it has not been amended or repealed in accordance with the procedures laid down in the laws and regulations;

20.1.3. a person has been imposed a criminal punishment related to the restriction of the rights in the pharmaceutical field, and it has not been enforced in accordance with the procedures laid down in the laws and regulations;

20.2. By the National Health Service if:

20.2.1. a pharmacist or pharmacy assistant ceases to practice;

20.2.2. registration of a pharmacist or pharmacy assistant is suspended or the person is excluded from the Register of Pharmacists and Pharmacy Assistants;

20.2.3. a pharmacist or pharmacy assistant fails to comply with the requirements of this Regulation in processing data in the health information system;

20.2.4. a security measure related to prohibition of certain occupations in the pharmaceutical field has been applied to the person, and it has not been amended or repealed in accordance with the procedures laid down in the laws and regulations;

20.2.5. a criminal punishment related to the restriction of the rights in the pharmaceutical field has been imposed on the person, and it has not been enforced in accordance with the procedures laid down in the laws and regulations.

21. When processing data in the health information system:

21.1. a medical treatment institution shall have the following obligation:

21.1.1. after conclusion of the contract referred to in Paragraph 13 of this Regulation use the options available in the health information system in conformity with the specialisation of the medical treatment institution and the requirements laid down in this Regulation;

21.1.2. process electronic appointments if the medical treatment institution has agreed in the contract with the National Health Service referred to in Paragraph 13 of this Regulation for the use of the health information system on the use of electronic appointments;

21.2. a medical treatment institution has the right to:

21.2.1. cancel a sick-leave certificate issued by the medical treatment institution if an opinion of the competent institution has been received stating unjustified issue of the sick-leave certificate;

21.2.2. impose restrictions on electronic booking of an appointment by a medical practitioner if the medical institution provides the relevant service.

22. A medical practitioner, who has authenticated himself or herself in the health information system in accordance with the procedures laid down in Paragraph 12 of this Regulation, is entitled to process the restricted access data on a patient included in the health information system in the amount specified in this Regulation in order to achieve the medical treatment objectives. While processing the restricted access data on a patient included in the health information system, a medical practitioner is not entitled to correct or delete the data entered by another user of the health information system, except for the data referred to in Sub-paragraphs 6.13, 6.14.2, and 6.14.4 to this Regulation.

[*1 December 201*5]

23. A family doctor is entitled to process all the restricted access data stored in the health information system (except for the data referred to in Sub-paragraphs 6.19, 6.20, 7.10, 7.11, 7.12, and 7.21 of this Regulation if the medical practitioner has not been granted the right to process the abovementioned data in accordance with the procedures laid down in Paragraph 17.1 of this Regulation and the data referred to in Paragraph 9 of this Regulation) on his or her registered patients; however, on temporary patients only if their informed consent has been received (written confirmation of the patient for the medical practitioner to process the data on the patient stored in the health information system), except when the family doctor replaces another family doctor and has informed the National Health Service thereof.

[*29 November 2016; 17 July 2018; 21 December 2021 / Amendments to the Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

24. A medical practitioner who provides the out-patient dynamic observation of a patient is entitled, starting from the first visit of a patient to the medical practitioner until the completion of the relevant out-patient dynamic observation, and also in processing the patient’s electronic appointment for receiving a health-care service, to process all data regarding the patient stored in the health information system related to the provision of the relevant health service, except for the data referred to in Sub-paragraphs 6.19, 6.20, 7.10, 7.11, 7.12, and 7.21 of this Regulation, if the medical practitioner has not been granted the right to process the abovementioned data in accordance with the procedures referred to in Paragraphs 17.1, 17.2, 17.3, and 17.4 of this Regulation, and the data referred to in Paragraph 9 of this Regulation.

[*29 November 2016; 17 July 2018; 18 December 2018; 21 December 2021 / Amendments to the Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

25. A medical practitioner providing out-patient health care services is entitled, on the day of an out-patient visit of a patient and five working days after it, and also in processing the patient’s electronic appointment for the receipt of a health-care service, to process all data regarding the patient stored in the health information system related to the provision of the relevant health service, except for the data referred to in Sub-paragraphs 6.19, 6.20, 7.10, 7.11, 7.12, and 7.21 of this Regulation, if the medical practitioner has not been granted the right to process the abovementioned data in accordance with the procedures referred to in Paragraphs 17.1, 17.2, 17.3, and 17.4 of this Regulation, and the data referred to in Paragraph 9 of this Regulation. A medical practitioner who has issued a referral for a patient for receipt of a health care service has the right to access the data on the respective health care service at any time.

[*29 November 2016; 17 July 2018; 18 December 2018; 21 December 2021 / Amendments to the Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

26. A medical practitioner providing in-patient health care services is entitled, during the time period when the patient is in the relevant in-patient medical treatment institution and five working days after discharge from this institution, but if the results of examinations of the patient are received after his or her discharge from the in-patient medical treatment institution – no longer than five working days after receipt of the results of examinations, to process all patient data stored in the health information system related to the provision of the relevant health care service, except for the data referred to in Sub-paragraphs 6.19, 6.20, 7.10, 7.11, 7.12, and 7.21 of this Regulation, if the medical practitioner has not been granted the right to process the abovementioned data in accordance with the procedures referred to in Paragraphs 17.1, 17.2, 17.3, and 17.4of this Regulation, and the data referred to in Paragraph 9 of this Regulation.

[*29 November 2016; 22 May 2018; 17 July 2018; 18 December 2018; 21 December 2021 / Amendments to the Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

27. A medical practitioner who provides emergency medical assistance is entitled, within one day after receipt of a call or provision of assistance, to process all the patient data stored in the health information system, except for the data referred to in Sub-paragraphs 6.19, 6.20, 7.10, 7.11, 7.12, and 7.21 of this Regulation, if the medical practitioner has not been granted the right to process the abovementioned data in accordance with the procedures referred to in Paragraphs 17.1, 17.2, 17.3, and 17.4 of this Regulation, and the data referred to in Paragraph 9 of this Regulation.

[*29 November 2016; 17 July 2018; 18 December 2018; 21 December 2021 / Amendments to the Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

27.1 The medical practitioner referred to in Paragraphs 17.3 and 17.4 of this Regulation whose duties include the performance of pathological-anatomical examination (autopsy) or extraction or transplantation of tissues or organs is entitled, in accordance with the laws and regulations regarding the procedures for establishing the fact of brain death and biological death and transferral of a deceased human being for burial, to process all patient data stored in the health information system during or after establishing death of a human being, except for the data referred to in Paragraph 9 and Sub-paragraphs 7.12 and 7.21 of this Regulation.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

27.2 The person referred to in Paragraph 17.5 of this Regulation whose duties include checking of information on the will expressed by a person regarding the permission or prohibition to use the body after death for study and scientific purposes or research or for making of medical preparations and bioprotheses is entitled to process all patient data stored in the health information system, except for the data referred to in Paragraph 9 and Sub-paragraphs 7.12 and 7.21 of this Regulation.

[*21 December 2021 / Paragraph shall come into force on 1 February 2022. See Paragraph 2 of Amendments*]

28. In the health information system, a medical treatment support person is entitled to access the data specified in Sub-paragraphs 6.1, 6.2, 6.4, 6.5, and 6.6 of this Regulation, and also to process those patient data which has been entered in the health information system thereby.

[*22 May 2018*]

28.1 When processing a patient’s appointment for receiving a health care service, a medical support person – a registrar of customers and patients of a medical treatment institution – is entitled, in addition to the right referred to in Paragraph 28 of this Regulation, to process the data included in Sub-paragraphs 6.13 and 6.16.1 of this Regulation and Annex 2, Paragraphs 1, 2, 3, 4, 6, 7, 8, and 9 of this Regulation. When processing the restricted access data on a patient, a registrar of customers and patients of a medical treatment institution is not entitled to correct or delete the data entered by other user of the health information system except for those referred to in Sub-paragraph 6.13 of this Regulation.

[*22 May 2018; see Paragraph 50*]

29. When dispensing medicinal products, a pharmacist or a pharmacy assistant is entitled to process the data referred to in Annex 5 to this Regulation, ensuring fulfilment of the requirement referred to in Sub-paragraph 11.6 of this Regulation. A pharmacist or pharmacy assistant is not entitled to correct or delete the data entered by another user of the health information system.

[*1 December 2015*]

29.1 In performing vaccination, a pharmacist is entitled to process the data indicated in Sub-paragraphs 6.17.1, 6.17.2, 6.17.6, 6.17.7, and 6.17.8 of and Annex 8 to this Regulation. A pharmacist is not entitled to correct or delete the data entered in the health information system by another user of the health information system.

[*14 December 2021*]

30. The State administrative institutions referred to in Section 10, Paragraph 5.2 of the Law on the Rights of Patients are entitled to process patient data in the health information system in the amount that is needed to achieve the objective of patient data processing laid down in Section 10, Paragraph 5.2 of the Law on the Rights of Patients. While processing the restricted access data on a patient included in the health information system, the State administrative institutions are not entitled to correct or delete the data entered in the health information system by another user of the health information system.

[*1 December 2015; 29 November 2016*]

31. A patient may access the data of the health information system by authenticating himself or herself in the health information system through qualified means of electronic identification of a person. The condition referred to in this Paragraph shall not apply to prisoners.

[*29 November 2016; 18 December 2018 / Paragraph shall come into force on 1 January 2024. See Paragraph 43*]

32. A patient has the right to take the following actions in the health information system if they relate to the patient himself or herself, to a person who has authorised him or her in accordance with Sub-paragraph 6.14.5 of this Regulation, to minor children and a person under guardianship of the patient:

32.1. to access all the data stored in the health information system, with the exception of the health data access to which by the person has been denied by a doctor;

32.2. to provide online the data indicated in Sub-paragraphs 6.13, 6.13.1, 6.14.2, and 6.14.5 of this Regulation in the health information system and to edit them;

32.3. to book and cancel an appointment to a medical practitioner according to the options offered by a medical treatment institution if the medical treatment institution ensures electronic booking of an appointment by a medical practitioner;

32.4. to deny access to the data stored in the health information system in the following amount:

32.4.1. by prohibiting access for all medical treatment institutions to all data stored in the health information system;

32.4.2. by prohibiting access for all medical treatment institutions to individual data stored in the health information system;

32.4.3. by prohibiting access for individual medical treatment institutions to all or individual data stored in the health information system;

32.4.4. by prohibiting access for individual medical practitioners and medical treatment support persons to all or individual data stored in the health information system;

32.5. to register with a family doctor;

32.6. to lodge a submission for the receipt of the European Health Insurance Card;

32.7. to send to the employer the information referred to in Sub-paragraphs 33.21, 33.22, 33.25, 33.26, and 33.27 of this Regulation regarding a registered sick-leave certificate;

32.8. to refuse vaccination.

[*1 December 2015; 29 November 2016; 21 December 2021*]

32.1 The rights referred to in Sub-paragraphs 32.2, 32.3, 32.4, 32.5, 32.6, and 32.7 of this Regulation shall not apply to prisoners.

[*18 December 2018*]

32.2 A patient who does not have a possibility to access the health information system using the specified types of authentication may:

32.21. grant the right to process the data stored in the health information system to other persons instead of the patient in one of the following ways:

32.21.1. in presenting a personal identification document, submit a signed submission in printed form to the National Health Service in person which includes the information indicated in Paragraph 32.3 of this Regulation;

32.21.2. send the power of attorney which includes the information indicated in Paragraph 32.2 of this Regulation with a notarised authenticity of the signature for the right of the person to process the data stored in the health information system instead of the patient to the National Health Service via post;

32.22. revoke the right granted to another person to process the data stored in the health information system instead of the patient by submitting a submission to the National Health Service in accordance with the procedures laid down in the Law on Submissions.

[*7 March 2023*]

32.3 The given name (names), surname, and personal identity number of the person who will be entitled to process the data stored in the health information system instead of the patient and the time period for which such rights should be granted shall be indicated in the submission and power of attorney referred to in Sub-paragraph 32.21 of this Regulation.

[*7 March 2023*]

33. A patient who does not have access to the health information system in accordance with the determined types of authentication may, upon a prior agreement, become familiar with the information stored in the health information system regarding himself or herself, a person who has authorised the patient and regarding minor children of the patient, or a person under guardianship of the patient, in the presence of the family doctor of the relevant person or in the presence of a medical practitioner working in the practice of the family doctor, if the family doctor agrees to it. In such case, informed consent of the patient is required. Prisoners shall access the data of the health information system by intermediation of the medical practitioner of the place of detention under the first-come, first served system.

[*29 November 2016; 18 December 2018*]

33.1 In order to ensure information to employers in the Electronic Declaration System of the State Revenue Service on the issued sick-leave certificates for the persons who during the work disability period for which the sick-leave certificate was issued are in the status of an employee with the relevant employer, the health information system shall transfer the following information to the Electronic Declaration System of the State Revenue Service and Tax Information System at least once in 24 hours:

33.11. on the sick-leave certificates closed since the last transfer of information;

33.12. on the sick-leave certificates transferred to the information systems of the State Revenue Service which were cancelled in the health information system since the last transfer of information;

33.13. on the sick-leave certificates opened since the last transfer of information.

[*17 December 2020; 21 December 2021*]

33.2 The health information system shall transfer the following information indicated in the sick-leave certificate to the information systems of the State Revenue Service on the sick-leave certificates referred to in Paragraph 33.1 of this Regulation:

33.21. registration/identification number of the sick-leave certificate;

33.22. type of the sick-leave certificate – certificate A or certificate B;

33.23. type of the sick-leave certificate – initial or continuation;

33.24. registration number of the previous sick-leave certificate if the type of the sick-leave certificate is “continuation”;

33.25. given name, surname, personal identity number (if a personal identity number has been granted to a person in accordance with the Law on the Register of Natural Persons) of the disabled person;

33.26. cause of temporary work disability:

33.26.1. occupational disease;

33.26.2. accident at work;

33.26.3. road traffic accident;

33.26.4. other reason (not specifying the reason);

33.27. work disability period – the start and end date of the period;

33.28. first day of employment;

33.29. date from which work disability continues;

33.210. [21 December 2021];

33.211. [21 December 2021];

33.212. status of the sick-leave certificate (open, closed, cancelled), date of the status, and history of changes.

[*1 December 2015; 22 August 2017; 21 December 2021*]

33.3 The State Social Insurance Agency shall process the information included in the health information system on sick-leave certificates in accordance with the following procedures:

33.31. on the closed and also closed and cancelled sick-leave certificates B, the information which is referred to in Sub-paragraphs 1.1, 1.2, 1.4, 1.5, 1.6, 1.7, 1.8, 2.2, and 2.4 and Paragraphs 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, and 26 of Annex 4 to this Regulation;

33.32. on the opened and also opened and cancelled sick-leave certificates B and opened, closed, and cancelled sick-leave certificates A, the information which is referred to in Sub-paragraphs 1.1 and 1.2 and Paragraphs 5, 6, 8, 14, 17, 18, and 26 of Annex 4 to this Regulation.

[*4 March 2021; 21 December 2021*]

33.4 The State Labour Inspectorate shall process the information referred to in Sub-paragraph 1.1 and Paragraphs 5, 14, 17, 18, and 26 of Annex 4 to this Regulation and included in the health information system regarding the closed and cancelled sick-leave certificates B in which an accident at work has been indicated as the cause for incapacity for work.

[*29 November 2016*]

33.5 The Health Inspectorate shall process all the restricted access data stored in the health information system on patients, except for the data referred to in Sub-paragraphs 6.14.5, 6.16 and Paragraph 9 of this Regulation. The Health Inspectorate has the right to cancel an electronically issued sick-leave certificate in the health information system in accordance with the laws and regulations regarding the procedures for the issuing and cancellation of sick-leave certificates.

[*22 May 2018; 17 December 2020 / The second sentence of the Paragraph shall come into force on 1 January 2021. See Paragraph 3 of Amendments*]

**IV. Closing Provisions**

34. The Centre for Disease Prevention and Control shall provide the National Health Service with the data contained in the register of patients suffering from definite diseases, in order to ensure inclusion of such data in the health information system by 1 December 2016.

[*1 December 2015*]

35. Until 31 December 2015, the National Health Service shall include those data that are contained in the health care services payment settlement system “Management Information System” of the National Health Service in the health information system.

36. A medical treatment institution shall issue a patient in printed form the medical documents prepared in the health information system that have been referred to in Sub-paragraphs 7.3 and 7.7 until 31 December 2017 and the medical document referred to in Sub-paragraph 7.2 of this Regulation until 31 December 2018 by ensuring gradual introduction of electronic transmissions, but if such is intended to be submitted to *sabiedrība ar ierobežotu atbildību “Rīgas Austrumu klīniskā universitātes slimnīca”* [limited liability company Riga Eastern Clinical University Hospital], *valsts sabiedrība ar ierobežotu atbildību “Paula Stradiņa klīniskā universitātes slimnīca”* [State limited liability company Pauls Stradiņš Clinical University Hospital], *valsts sabiedrība ar ierobežotu atbildību “Bērnu klīniskā universitātes slimnīca”* [State limited liability company Children’s Clinical University Hospital] it shall be issued in paper form until 31 August 2018. The medical document referred to in Sub-paragraph 7.1 of this Regulation shall be issued to a patient in printed form only if it is intended for submission in another medical treatment institution, but the medical document referred to in Sub-paragraph 7.8 of this Regulation shall be issued to a patient in printed form upon a request of the person.

[*22 August 2017; 27 February 2018*]

37. From 1 July 2017, family doctors are obliged to submit online the data specified in Sub-paragraph 11.5 of this Regulation to the health information system.

[*1 December 2015*]

38. By 1 November 2016, medical treatment institutions and pharmacies shall conclude the contract referred to in Paragraph 13 of this Regulation with the National Health Service.

[*1 December 2015*]

39. Sub-paragraphs 6.14.1, 6.14.3, 32.4.3, and 32.4.4 of this Regulation shall come into force on 1 January 2016.

39.1 The fulfilment of the requirements referred to in Sub-paragraphs 6.14.1, and 6.14.3 of this Regulation in the health information system shall be ensured from 25 May 2018.

[*29 November 2016; 22 May 2018*]

39.2 [28 May 2019]

39.3 The fulfilment of the requirements referred to in Sub-paragraphs 32.4.3 and 32.4.4 of this Regulation in the health information system shall be ensured from 1 July 2023.

[*7 March 2023*]

40. The State Medical Commission for the Assessment of Health Condition and Working Ability shall submit online the data specified in Paragraph 20 of Annex 4 to this Regulation to the health information system from 1 December 2016.

[*1 December 2015*]

41. Sub-paragraphs 13.1 and 13.2 of this Regulation shall remain in force until 31 December 2022.

[*29 November 2016; 22 May 2018; 17 December 2020*]

42. Sub-paragraph 13.3 of this Regulation shall come into force on 1 January 2023.

[*29 November 2016; 22 May 2018; 17 December 2020*]

42.1 Sub-paragraph 13.3 of this Regulation shall be applicable from 1 January 2024.

[*7 March 2023*]

43. Paragraph 31 of this Regulation shall come into force on 1 January 2024. Until 31 December 2023, a patient shall access the data of the health information system by using any of the ways of authentication offered by the State administration service portal www.latvija.lv for authentication in the health information system. The condition on the authentication in the health information system through a personal means of electronic identification shall not apply to prisoners.

[*7 March 2023*]

43.1 Until 31 December 2022, a patient who does not have a possibility to access the health information system in conformity with the laid down types of authentication may:

43.11. grant the right to process the data stored in the health information system to other persons instead of the patient in one of the following ways:

43.11.1. upon presenting a personal identification document, lodge a submission to the National Health Service in person indicating the given name, surname and personal identity number of the person who will be entitled to process the data stored in the health information system instead of the patient, as well as the time period for which such right is to be granted therein;

43.11.2. send the power of attorney with a notarised authenticity of the signature for the right of the person to process the data stored in the health information system instead of the patient to the National Health Service via post;

43.12. revoke the right of other person to process the data stored in the health information system instead of the patient by lodging the relevant submission to the National Health Service.

[*22 May 2018; 21 December 2021*]

43.2 The National Health Service shall ensure inclusion of the information referred to in Sub-paragraph 43.11 of this Regulation in the health information system of the authorised person of the patient or deletion of such information within three working days after receipt of the submission referred to in Paragraph 43.1 of this Regulation or receipt of the power of attorney.

[*22 May 2018*]

43.3 If during the visit of the patient the medical document referred to in Annex 2 to this Regulation cannot be issued electronically in the health information system due to technical reasons and the patient needs the referral for the receipt of health care services as a matter of emergency, a medical treatment institution has the right to draw up the referral in paper form in accordance with the laws and regulations regarding the procedures for the record-keeping of medical documents.

[*22 May 2018*]

44. The Regulation shall come into force on 1 April 2014.

45. Medical treatment institutions have an obligation to provide online the following information to the health information system:

45.1. from 1 December 2016 – the data specified in Sub-paragraph 11.4.5 of this Regulation;

45.2. from 1 January 2018 – the data specified in Sub-paragraphs 11.4.1, 11.4.2, 11.4.3, 11.4.6, 11.4.8, 11.4.9, 11.4.10, and 11.4.11 of this Regulation, as well as the data specified in Sub-paragraph 11.4.4 of this Regulation upon prescribing medicinal products the expenses for the purchase of which are partly or completely compensated for the patient from the funds from the State budget.

[*29 November 2016; 22 August 2017*]

46. From 1 January 2018, a pharmacy (pharmacy branch) has an obligation to provide to the health information system online the data specified in Sub-paragraph 11.6 of this Regulation.

[*29 November 2016; 22 August 2017*]

47. The right to process the data specified in Sub-paragraphs 7.10, 7.11, and 7.12 of this Regulation in the health information system is granted to the family doctor from 1 September 2017.

[*29 November 2016*]

48. This Regulation shall not apply to prisoners and medical treatment institutions of places of detention until 31 December 2018.

[*22 August 2017*]

49. Processing of the data referred to in Sub-paragraph 6.16.1 of this Regulation and Paragraphs 7, 8, and 9 of Annex 2 to this Regulation in the health information system shall be ensured by the National Health Service starting from 1 January 2019.

[*22 May 2018*]

50. The medical treatment support person referred to in Paragraph 28.1 of this Regulation, i.e. a registrar of customers and patients of the medical treatment institution, shall process the data specified in Sub-paragraphs 6.13 and 6.16.1 of this Regulation and the data specified in Paragraphs 7, 8, and 9 of Annex 2 to this Regulation starting from 1 January 2019 in the health information system.

[*22 May 2018*]

51. Medical treatment institutions which are providing medical insemination services shall, by 31 December 2019, include in the health information system also the information referred to in Annex 21 of this Regulations which was at the disposal of the relevant medical treatment institutions before 1 July 2019.

[*17 July 2018*]

52. Sub-paragraph 11.8.2 of Annex 4 to this Regulation shall come into force on 1 January 2021.

[*17 December 2020*]

53. Sub-paragraph 6.18.3 of this Regulation shall come into force on 1 July 2022.

[*21 December 2021*]

54. A user of the health information system may, until 31 December 2023, authenticate in the health information system, using:

54.1. any of the ways of authentication offered by the State administration service portal https://www.latvija.lv;

54.2. means of authentication of the information system of a medical treatment institution or pharmacy (pharmacy branch) which conforms to the security and technical requirements for the use of the health information system.

[*7 March 2023*]

Prime Minister Laimdota Straujuma

Minister for Health Ingrīda Circene

**Annex 1**

Cabinet Regulation No. 134

11 March 2014

**Overview of Out-patient Examination/Medical Treatment**

1. Patient information:

1.1. personal identity number\*;

1.2. given name (names), surname;

1.3. declared, registered place of residence or place of residence indicated by the person;

1.4. contact information indicated by the person (telephone number, electronic mail address, address of the actual place of residence);

1.5. gender;

1.6. date of birth;

1.7. state.

2. Information on the performer:

2.1. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.2. name of the medical treatment institution;

2.3. address of the medical treatment institution;

2.4. given name (names), surname of the medical practitioner;

2.5. identifier of the medical practitioner granted by the Health Inspectorate;

2.6. speciality of the medical practitioner;

2.7. state of the medical practitioner.

3. Name and code of the health care service\*.

4. Classification code of the surgical manipulations in accordance with the current version of the Classification of Surgical Procedures with the supplement (NCSP+) of the Nordic Medico-Statistical Committee (NOMESCO)\*.

5. Notes\*.

6. Diagnoses\*:

6.1. code and name of diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10));

6.2. type of diagnosis.

7. Medical treatment recommendations\*.

8. Recommendations for rehabilitation\*.

9. Recommendations for work regime \*.

10. Recommendations for the social service \*.

11. Service execution date.

Note. \* To be completed by the medical treatment institution.

Minister for Health Ingrīda Circene

**Annex 2**

Cabinet Regulation No. 134

11 March 2014

**Referral for Receipt of an Out-patient/In-patient Service**

[*22 May 2018/ See Paragraphs 49 and 50 of the Regulation*]

1. Patient information:

1.1. personal identity number\*;

1.2. given name (names), surname;

1.3. declared, registered place of residence or place of residence indicated by the person;

1.4. contact information indicated by the person (telephone number, electronic mail address, address of the actual place of residence);

1.5. gender;

1.6. date of birth;

1.7. state.

2. Referrer:

2.1. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.2. name of the medical treatment institution;

2.3. address of the medical treatment institution;

2.4. given name (names), surname of the medical practitioner;

2.5. identifier of the medical practitioner granted by the Health Inspectorate;

2.6. speciality of the medical practitioner;

2.7. state of the medical practitioner.

3. Name and code of the required health care service\*.

4. Diagnoses\*:

4.1. code and name of diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10));

4.2. type of diagnosis.

5. Brief medical history\*.

6. Date of referral.

7. Note on the urgency of the necessary health care service and urgency justification\*.

8. Note or referral issued for dynamic observation\*.

9. Indication whether the health care service may be paid from the State budget resources.

Note. \* To be completed by the medical treatment institution.

Minister for Health Ingrīda Circene

**Annex 3**

Cabinet Regulation No. 134

11 March 2014

**Discharge – Epicrisis**

1. Patient information:

1.1. personal identity number;

1.2. given name (names), surname;

1.3. declared, registered place of residence or place of residence indicated by the person;

1.4. contact information indicated by the person (telephone number, electronic mail address, address of the actual place of residence);

1.5. gender;

1.6. date of birth;

1.7. workplace (name, phone).

2. Provider of the in-patient service:

2.1. code of the medical treatment institution;

2.2. name of the medical treatment institution;

2.3. legal address of the medical treatment institution;

2.4. contact information (telephone number, electronic mail address) of the medical treatment institution;

2.5. address of the branch of the medical treatment institution (if the medical treatment institution has a branch, and the patient has been registered at the branch);

2.6. contact information (telephone number, electronic mail address) of the branch of the medical treatment institution;

2.7. given name (names), surname of the medical practitioner (one or several) providing medical treatment;

2.8. identifier of the medical practitioner granted by the Health Inspectorate of the medical practitioner (one or several) providing medical treatment;

2.9. state of the medical practitioner (one or several) providing medical treatment;

2.10. given name (names), surname of the signer of the document – head of the unit;

2.11. identifier of the signer of the document – head of the unit, granted by the Health Inspectorate.

3. Family doctor of the patient:

3.1. given name (names), surname;

3.2. identifier of the medical practitioner granted by the Health Inspectorate;

3.3. state of the medical practitioner;

3.4. code of the medical treatment institution;

3.5. name of the medical treatment institution;

3.6. address of the medical treatment institution;

3.7. contact information (telephone number, electronic mail address) of the medical treatment institution.

4. Information regarding the referrer of the patient (information regarding the medical practitioner who has referred the patient to a hospital):

4.1. given name (names), surname of the medical practitioner;

4.2. identifier of the medical practitioner granted by the Health Inspectorate;

4.3. speciality of the medical practitioner;

4.4. state of the medical practitioner;

4.5. code of the medical treatment institution;

4.6. name of the medical treatment institution;

4.7. address of the medical treatment institution;

4.8. contact information (telephone number, electronic mail address) of the medical treatment institution.

5. Stay in the in-patient medical treatment institution (information containing a summary of the stages of the patient's stay in the in-patient medical treatment institution):

5.1. admittance date and time:

5.1.1. type of movement;

5.1.2. unit;

5.1.3. number of days;

5.2. discharge date.

6. Diagnosis (information on the diagnoses (upon referral, admittance, clinical, final (main, additional)), recorded in relation to the patientʼs hospitalisation in the in-patient medical treatment institution):

6.1. code and name of diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10));

6.2. type of diagnosis.

7. Objective condition.

8. Medical history.

9. Analyses (information regarding all significant analyses summarised in the form of a text).

10. Diagnostic tests (information regarding all significant tests summarised in the form of a text).

11. Medical procedures, surgeries, therapy (information regarding all procedures, surgeries and medicinal products used for therapy summarised in the form of a text):

11.1. classification code of the surgical manipulations in accordance with the current version of the Classification of Surgical Procedures with the supplement (NCSP+) of the Nordic Medico-Statistical Committee (NOMESCO);

11.2. name of the surgery;

11.3. date of the surgery.

12. Allergic reactions (information in the form of a text regarding allergies recorded at hospitalisation).

13. Information regarding the fact of vaccination (if the patient was vaccinated at hospitalisation).

14. Summary of the medical treatment of the patient (description of the course of the medical treatment of the patient, significant events, results).

15. Medical treatment recommendations and medicinal products prescribed.

16. Recommendations for rehabilitation.

17. Recommendations for work regime.

18. Recommendation for the social service.

19. Date.

Minister for Health Ingrīda Circene

**Annex 4**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Sick-leave Certificate**

1. Recipient of the sick-leave certificate:

1.1. personal identity number\*;

1.2. given name (names), surname;

1.3. gender;

1.4. date of birth;

1.5. address of the declared, registered place of residence or place of residence indicated by the person;

1.6. personal identity number of the child or ward\*;

1.7. given name (names), surname of the child or ward\*;

1.8. date of birth of the child or ward.

2. Medical treatment institution and medical practitioner who processed (including registered, closed, cancelled the sick-leave certificate, extended the sick-leave period, made notes on regime infringement) the sick-leave certificate:

2.1. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.2. name of the medical treatment institution;

2.3. address of the medical treatment institution;

2.4. given name (names), surname of the medical practitioner;

2.5. identifier of the medical practitioner granted by the Health Inspectorate.

3. Note on replacement (if a sick-leave certificate is processed by a different medical practitioner)\*.

4. Type of the sick-leave certificate issued – initial or continuation\*.

5. Type of the sick-leave certificate issued – certificate A or certificate B\*.

6. Registration (opening) of the sick-leave certificate in the health information system.

7. Justification if the date of registering the sick-leave certificate in the health information system does not coincide with the first day of the period of incapacity for work regarding which the sick-leave certificate has been issued\*.

8. Registration/identification number of the sick-leave certificate. Registration/identification number of the sick-leave certificate shall be indicated as follows:

MTI–T–GG–X, where

MTI – code of the medical treatment institution in the Register of Medical Treatment Institutions;

T – type of the sick-leave certificate (A or B);

YY – last two digits of the year;

X – serial number of the sick-leave certificate within the framework of the medical treatment institution and the year.

For example, 000111000–B–15–12345.

9. Registration/identification number of the previous sick-leave certificate (if the type of the sick-leave certificate is “Continuation”)\*.

10. The registration/identification number of the cancelled sick-leave certificate on the basis of which a new sick-leave certificate has been opened\*.

11. Cause of temporary work disability\*:

11.1. tuberculosis;

11.2. occupational disease;

11.3. accident at work;

11.4. road accident;

11.5. prenatal period;

11.6. postnatal period;

11.7. nursing of an ill child or isolation of a child during quarantine;

11.8. nursing of an ill child in a hospital;

11.8.1 nursing of a seriously ill child according to the decision of the doctor’s council;

11.8.2 nursing of a child with a fracture;

11.9. other reason (not specifying the reason).

12. [22 August 2017 / See Paragraph 3 of Amendments]

13. Notes on the violation of the regimen prescribed by a doctor or an assistant of a doctor\*:

13.1. description of the infringement;

13.2. first day of the infringement of the regime;

13.3. last day of the infringement of the regime.

14. Work disability periods (there may be several periods for one sick-leave certificate)\*:

14.1. initial date of the period;

14.2. last date of the period.

15. Notes regarding sending to another doctor\*.

16. Reason for not referring to another doctor in accordance with the laws and regulations regarding the procedures for certifying temporary work disability of a person\*.

17. Date by which the recipient of the sick-leave certificate shall return to work (it shall be indicated upon closing of the sick-leave certificate if disability does not continue)\*.

18. Date by which the work disability of the recipient of the sick-leave certificate will continue (it shall be indicated upon closing of the sick-leave certificate if disability continues)\*.

19. Notes on sending to the State Medical Commission for Expert-Examination of Health and Working Ability\*.

20. Decision of the State Medical Commission for the Assessment of Health Condition and Working Ability:

20.1. type of decision (to extend the sick-leave certificate/establish disablement);

20.2. date of the decision;

20.3. number of the decision.

20.5. date from which disability has been established.

21. Opinion of a supervisory authority on unjustified issue of a sick-leave certificate:

21.1. date of the opinion;

21.2. number of the opinion;

21.3. textual notes of the opinion;

21.4. institution issuing the opinion;

21.5. initial date of the period of cancelling of a sick-leave certificate;

21.6. last date of the period of cancelling of a sick-leave certificate.

22. Substantiation for cancelling of the sick-leave certificate\*.

23. Date when disability data were transmitted to the State Social Insurance Agency.

24. Date when disability data were transmitted to the State Revenue Service.

25. Textual notes of the sick-leave certificate\*.

26. Current status of the sick-leave certificate (open, closed, cancelled), date thereof and history of the changes to status.

Note. \* To be completed by the medical treatment institution.

**Annex 5**

Cabinet Regulation No. 134

11 March 2014

**E-prescription**

[*1 December 2015; 22 August 2017 / The new wording of Paragraph 4 shall come into force on 1 October 2017. See Paragraph 2 of Amendments*]

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number;

1.3. declared, registered place of residence or place of residence indicated by the person;

1.4. gender;

1.5. date of birth.

2. Data of the person writing-out the e-prescription:

2.1. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.2. name of the medical treatment institution;

2.3. address of the medical treatment institution;

2.4. given name (names), surname of the medical practitioner;

2.5. identifier of the medical practitioner granted by the Health Inspectorate;

2.6. speciality of the medical practitioner.

3. Main data of the e-prescription:

3.1. identification number;

3.2. prescription form series and number;

3.3. type (special prescription or ordinary prescription);

3.4. Type of E or S form;

3.5. writing out date;

3.6. term of validity;

3.7. duration of the medical treatment course (if the medicinal product is meant for a medical treatment course);

3.8. indication if the medicinal product may be substituted, and if not – a justification for such prohibition.

4. Diagnoses in accordance with the laws and regulations regarding writing out and storage of prescriptions:

4.1. code and name of diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10));

4.2. type of diagnosis.

5. Special conditions for issuing.

6. Prescribed medicinal product:

6.1. name of the medical products or active ingredient;

6.2. registration number of medicinal products;

6.3. a group of compensated medicinal products;

6.4. medicinal product form;

6.5. strength of medicinal product;

6.6. unit of measurement of the strength of medicinal product;

6.7. quantity;

6.8. unit of measurement of quantity;

6.9. payer for the compensated medicinal products;

6.10. amount of compensation.

7. Instructions for use.

8. Information regarding the medicinal product issued to a person:

8.1. code of the medicinal product;

8.2. name assigned by the manufacturer of the medicinal product and size of packaging;

8.3. serial number of the medicinal product of biological origin;

8.4. number of issued packagings of the medicinal product;

8.5. price of one packaging and the amount to be paid, taking into account the number of packagings;

8.6. division of the amount to be paid between the patient and other payer (for the medicinal products distributed within the framework of the compensation procedures);

8.7. issue date of the medicinal product;

8.8. information whether the person has been granted a status of a person in need (if the medicinal product distributed within the framework of the compensation procedures is prescribed based on a special prescription);

8.9. given name (names) of the pharmacist or pharmacy assistant and registration number in the Register of Pharmacists and Pharmacy Assistants;

8.10. name, registration code, address of the pharmacy (a branch of the pharmacy);

8.11. closing date of the prescription.

**Annex 6**

Cabinet Regulation No. 134

11 March 2014

**Information of the Emergency Medical Assistance (EMA) Call Card**

[*1 December 2015*]

1. Number of the call card.

2. Basic information:

2.1. place of the call – address;

2.2. justification (reason) for the call;

2.3. given name, surname of the patient;

2.4. date of birth of the patient;

2.5. age of the patient;

2.6. sex of the patient;

2.7. personal identity number of the patient;

2.8. contact telephone number of the patient;

2.9. call priority;

2.10. type of the call;

2.11. fulfilment status of the call;

2.12. Fulfilment result of the EMA call;

2.13. place where to the patient was delivered (name and code of the medical treatment institution);

2.14. date and time of the patientʼs delivery;

2.15. a medical practitioner (given name, surname) admitting the patient in the medical treatment institution;

2.16. date and time of the patientʼs admission in the medical treatment institution;

2.17. diagnosis in accordance with ICD-10;

2.18. comments of the diagnosis;

2.19. complications;

2.20. information to other services.

3. History of performance:

3.1. a number of the EMA team;

3.2. given name and surname of the head of the EMA team;

3.3. date and time of establishing of the patientʼs death.

4. Complaints and health history.

5. Objective condition.

6. Evaluation scales of the patient's condition.

7. Treatment.

8. Refusals.

**Annex 7**

Cabinet Regulation No. 134

11 March 2014

**Description of Radiological Examination**

[*1 December 2015*]

1. Patient information:

1.1. personal identity number\*;

1.2. given name (names), surname;

1.3. declared, registered place of residence or place of residence indicated by the person;

1.4. contact information indicated by the person (telephone number, electronic mail address, address of the actual place of residence);

1.5. gender;

1.6. date of birth;

1.7. state.

2. Information regarding the medical treatment institution and medical practitioner:

2.1. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.2. name of the medical treatment institution;

2.3. address of the medical treatment institution;

2.4. given name (names), surname of the medical practitioner;

2.5. identifier of the medical practitioner granted by the Health Inspectorate;

2.6. speciality of the medical practitioner;

2.7. state of the medical practitioner.

3. Information regarding the radiological examination\*:

3.1. name;

3.2. method of the examination;

3.3. body part;

3.4. description.

4. Conclusion (opinion)\*.

Note. \* To be completed by the medical treatment institution.

**Annex 8**

Cabinet Regulation No. 134

11 March 2014

**Immunization Card**

[*29 November 2016*]

1. Patient information:

1.1. personal identity number\*;

1.2. given name (names), surname;

1.3. declared, registered place of residence or place of residence indicated by the person;

1.4. contact information indicated by the person (telephone number, electronic mail address, address of the actual place of residence).

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. given name (names), surname of the medical practitioner.

3. Information regarding immunodeficiency\*.

4. Complications caused by vaccination (post-vaccination complications):

4.1. date and time of complication\*;

4.2. complication\*;

4.3. diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*;

4.4. data regarding vaccination after which complications have occurred\*.

5. Data regarding vaccination:

5.1. vaccination date\*;

5.2. name of the vaccine, information regarding the preparation and its administration\*;

5.3. payer\*;

5.4. notes.

6. Tuberculine test:

6.1. information regarding the preparation and its administration\*;

6.2. result\*;

6.3. date of the result\*.

7. Administration of immunoglobulin:

7.1. infectious disease (for which immunoglobulin was administered)\*;

7.2. information regarding the preparation and its administration\*;

7.3. notes\*.

8. Immunity examination:

8.1. infectious disease\*;

8.2. name of the laboratory\*;

8.3. name of the test\*;

8.4. date of the test\*;

8.5. test result\*.

9. Additional information:

9.1. information\*;

9.2. date when additional information was added.

10. Contraindications for vaccination:

10.1. information regarding the vaccine with contraindications specified\*;

10.2. description\*;

10.3. date when contraindication was specified\*;

10.4. date of contraindication\*.

11. Infectious diseases undergone:

11.1. infectious disease\*;

11.2. date of falling ill\*;

11.3. description\*.

12. Planned vaccinations:

12.1. name of the vaccine\*;

12.2. the time period from and to which vaccination should be performed\*;

12.3. number of the vaccine\*;

12.4. notes\*;

12.5. status\*.

13. Refusal of a patient to vaccinate\*:

13.1. infectious disease and vaccine;

13.2. number of the vaccine;

13.3. notes;

13.4. date of refusal.

14. Date of completion.

Note. \* To be completed by the medical treatment institution.

**Annex 9**

Cabinet Regulation No. 134

11 March 2014

**Register Card of Traumas, Injuries and Cases of Poisoning**

[*29 November 2016*]

**Basic part of the card**

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender;

1.4. nationality\*;

1.5. address of the declared, registered place of residence or place of residence indicated by the person;

1.6. code of the administrative territorial unit of the declared place of residence;

1.7. occupation\*;

1.8. citizenship\*.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the medical practitioner\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Age at the time of suffering trauma\*.

4. Information regarding pregnancy and gestational week at the time of suffering trauma\*.

5. Medical card number of the patient discharged (deceased) from a hospital or medical card number of the outpatient patient\*.

6. Date and time of arrival of the patient in the emergency assistance ward/outpatient ward of the hospital\*.

7. Date on which the patient is discharged from the medical treatment institution\*.

8. Treatment:

8.1. type of medical treatment and subsequent course of medical treatment\*;

8.2. number of days spent in a hospital\*.

9. Date when trauma/injury was acquired or poisoning happened\*.

10. Being under influence of alcohol and other psychoactive substances at the time of acquiring trauma/injury and happening of poisoning\*.

11. Place where the event occurred1\*.

12. Type of injury1\*.

13. Body part injured1\*.

14. Diagnosis:

14.1. basic diagnosis – code and name (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (hereinafter – ICD-10))\*;

14.2. ancillary diagnosis – code and name (in conformity with the ICD-10)\*.

15. Purpose:

15.1. type\*;

15.2. if intentional self-injury\*:

15.2.1. the most current risk factor1\*;

15.2.2. intentional self-injury inflicted previously\*;

15.3. if attack or violence of other kind:

15.3.1. connection of the guilty person to the victim1\*;

15.3.2. sex of the guilty person\*;

15.3.3. age of the guilty person\*;

15.3.4. reason for attack1\*.

16. Type of activity at the moment of acquiring trauma/injury or poisoning1\*.

17. A short description of acquiring trauma/injury or poisoning (for example, circumstances, causes)\*.

**Part A**

**Traumas and injuries conforming to the diagnosis codes S00.0–T35.7 of the ICD-10**

1. Basic mechanism of trauma/injury1\*.

2. Direct mechanism of trauma/injury1\*.

3. Injury as a result of a transport accident\*:

3.1. type of movement of the injured person1\*;

3.2. the role of the injured person in the transport accident1\*;

3.3. other party involved in the transport accident1\*.

4. Principal object or substance causing injury1\*.

5. Direct object or substance causing injury1\*.

6. Intermediate object or substance causing injury1\*.

7. Date of completing the card\*.

**Part B**

**Poisoning conforming to the diagnosis codes T36.0–T65.9 of the ICD-10**

1. Body mass of the patient (kg)\*.

2. Type of arrival of the patient in the medical treatment institution\*.

3. Category of the place where poisoning took place\*.

4. Name, group, quantity, and unit of measurement of the substance that caused poisoning, and active ingredient1\*.

5. Initial clinical condition\*.

6. Nature of exposure\*.

7. Length of exposure\*.

8. The way of the substance entering into the body\*.

9. Treatment\*.

10. Outcome of the poisoning at the discharge of the patient from a medical treatment institution\*.

11. Date of completing the card\*.

**Part C**

**Poisoning with pesticides conforming to the diagnosis codes T60.0–T60.9 of the ICD-10**

1. Activity at the time of poisoning\*.

2. Identity of the product:

2.1. product name\*;

2.2. concentration\*.

3. Chemical type of the substance\*.

4. Date of completing the card\*.

Notes.

1. 1 The code shall be indicated in conformity with the Injury Database Coding Manual.

2. \* To be completed by the medical treatment institution.

**Annex 10**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Narcological Patient’s Register Card**

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender;

1.4. declared, registered place of residence or place of residence indicated by the person;

1.5. code of the administrative territorial unit of the declared place of residence;

1.6. nationality\*;

1.7. date of death.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the doctor\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Education acquired:

3.1. the highest level of education acquired\*;

3.2. the number of schooling years if basic education is incomplete\*.

4. Economic activity\*.

5. Type of housing\*.

6. Composition of the household (family)\*.

7. Children (0–6 years of age):

7.1. total number\*;

7.2. the number of children who live in one household with the patient\*.

8. Children (7–17 years of age):

8.1. total number\*;

8.2. the number of children who live in one household with the patient\*.

9. Person or institution who or which has sent or recommended a visit to a narcologist (without information identifying the person)\*.

10. Diagnosis:

10.1. basic diagnosis – code and name (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*;

10.2. ancillary diagnosis – code and name (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*.

11. Date of starting the treatment episode\*.

12. Planned date of ending the treatment episode\*.

13. Result of the visit/type of the out-patient and in-patient assistance provided\*.

14. End date of the treatment episode\*.

15. Reason for ending the treatment episode\*.

16. Pathological disposition to gambling/computer games/Internet\*.

17. Type of the most often used alcoholic beverage (in the last 30 days)\*.

18. Average number of alcohol doses consumed in a day (in the last 30 days)\*.

19. Number of days when alcohol was used (in the last 30 days)\*:

19.1. number of days when 60 to 120 grams of absolute alcohol were used;

19.2. number of days when more than 120 grams of absolute alcohol were used.

20. number of points in an AUDIT\*\* test\*.

21. Age when an addictive substance (except alcohol, tobacco) was used for the first time\*.

22. Addictive substance used primarily (except alcohol, tobacco)\*.

23. Habits of using psychoactive substances (except alcohol):

23.1. the substance used\*;

23.2. the substance used is the main one – yes/no\*;

23.3. the type of use\*;

23.4. the frequency of use\*;

23.5. the age when the substance was used for the first time\*.

24. It is possible to determine the main substance\*.

25. Previously has undergone medical treatment in a long-term pharmacotherapy programme of opioids\*.

26. Experience of injections\*.

27. Joint use of injection accessories\*.

28. Age when the first injection was performed\*.

29. Performance of an HIV test (information provided by the patient)\*.

30. Performance of an HCV test (information provided by the patient)\*.

31. Date of completing the card\*.

Notes.

1. \* To be completed by the medical treatment institution.

2. \*\* AUDIT – the Alcohol Use Disorders Identification Test.

**Annex 11**

Cabinet Regulation No. 134

11 March 2014

**Evaluation of the Medical Treatment Result of a Narcological Patient**

[*29 November 2016*]

1. Patient information:

1.1. personal identity number\*;

1.2. given name (names), surname.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the doctor\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Date when the evaluation of the health condition of the patient was performed\*.

4. Habits of alcohol use:

4.1. average number of alcohol doses in a day (in the last 30 days)\*;

4.2. number of days when alcohol was used (in the last 30 days)\*;

4.3. number of points in an AUDIT\*\* test\*.

5. Habits of use of psychoactive substances (except alcohol) (in the last 30 days):

5.1. the substance used\*;

5.2. the substance used is the main one – Yes/No\*;

5.3. the type of use\*;

5.4. the frequency of use\*;

5.5. injection (in the last 30 days)\*;

5.6. joint use of injection accessories (in the last 30 days)\*.

6. Self-assessment of the health condition of the patient upon starting medical treatment and after completing the treatment episode\*.

7. Existence of occupation (existence of paid work, attendance of school) and specific place of residence upon starting medical treatment and after completing the treatment episode\*.

8. Date of completing the card\*.

Notes.

1. \* To be completed by the medical treatment institution.

2. \*\* AUDIT – the Alcohol Use Disorders Identification Test.

**Annex 12**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Register Card of the Patient with Mental and Behavioural Disorders**

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender\*;

1.4. nationality\*;

1.5. address of the declared, registered place of residence or place of residence indicated by the person;

1.6. code of the administrative territorial unit of the declared place of residence;

1.7. address of the actual place of residence\*;

1.8. code of the administrative territorial unit of the actual place of residence\*;

1.9. date of death.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the medical practitioner\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Number of the health history or out-patient medical card\*.

4. Occupation\*.

5. Characterisation of living conditions\*.

6. Composition of family\*.

7. The highest level of education acquired\*.

8. Source of means of subsistence\*.

9. Care group of the patient\*.

10. Date when the patient was included in the register (for the first time in his or her life)\*.

11. Date when the patient was repeatedly included in the register\*.

12. Disability granted for the first time due to a mental illness:

12.1. disability group\*;

12.2. year of granting the disability\*.

13. Disability granted repeatedly due to a mental illness:

13.1. disability group\*;

13.2. year of granting the disability\*.

14. Activities dangerous to the public\*.

15. Compulsory medical treatment in a medical treatment institution according to a court decision\*.

16. Person or institution who or which has sent or recommended a visit to a psychiatrist (without information identifying the person)\*.

17. Diagnoses\*:

17.1. basic diagnosis of mental disorders – code and name (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (hereinafter – ICD-10));

17.2. ancillary diagnoses of mental disorders – code and name (in conformity with the ICD-10);

17.3. other ancillary diagnoses – code and name (in conformity with the ICD-10)\*;

17.4. social ancillary diagnoses – code and name (in conformity with the ICD-10)\*.

18. Changes in the basic diagnosis of mental disorders:

18.1. basic diagnosis updated – code and name of diagnosis (in conformity with the ICD-10)\*;

18.2. basic diagnosis altered – code and name of diagnosis (in conformity with the ICD-10)\*.

19. Number of hospitalisations in the reporting year\*.

20. Treatment\*.

21. Additional information\*.

22. Date of completing the card\*.

Note. \* To be completed by the medical treatment institution.

**Annex 13**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Register Card of the Patient of Diabetes Mellitus**

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender;

1.4. declared, registered place of residence or place of residence indicated by the person;

1.5. code of the administrative territorial unit of the declared place of residence;

1.6. nationality\*;

1.7. date of death.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the medical practitioner\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Diagnosis – code and name (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*.

4. Year when diabetes was diagnosed\*.

5. Year when administration of oral hypoglycemic agents was started\*.

6. Year when insulin therapy was started\*.

7. Accomplishment of training skills\*.

8. Pregnancy in the last 12 months\*.

9. Results of clinical examinations and analyses in the last 12 months\*.

10. Complications caused by diabetes, examinations and manipulations performed in the last 12 months:

10.1. examination of eyes, manipulations performed, and retinopathy detected\*;

10.2. examination of feet, manipulations performed, and complications detected\*;

10.3. terminal kidney complications\*.

11. Cardiovascular diseases in the last 12 months\*.

12. Treatment\*.

13. Additional information\*.

14. Date of completing the card\*.

Note. \* To be completed by the medical treatment institution.

**Annex 14**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Tuberculosis Patient Form**

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender;

1.4. nationality\*;

1.5. address of the declared, registered place of residence or place of residence indicated by the person;

1.6. code of the administrative territorial unit of the declared place of residence;

1.7. address of the actual place of residence\*;

1.8. code of the administrative territorial unit of the actual place of residence\*;

1.9. occupation:

1.9.1. type\*;

1.9.2. position if the patient works at a medical treatment institution\*;

1.10. country of birth\*;

1.11. date of death;

1.12. cause of death.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the medical practitioner\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Code of the administrative territory in which the patient has been enlisted in the register\*.

4. Date when the patient was included in the register\*.

5. Group of observation\*.

6. Diagnosis:

6.1. code and name (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*;

6.2. date when the diagnosis was determined for the first time\*;

6.3. situation in which the diagnosis was discovered\*;

6.4. method by which the diagnosis was confirmed\*.

7. Risk factors\*.

8. Place and time of starting the medical treatment course\*.

9. Method of medical treatment\*.

10. Surgical treatment\*.

11. Abacillated after 2–3 months\*.

12. Medical treatment under direct supervision\*.

13. Date when the medical treatment course was evaluated\*.

14. Result of medical treatment\*.

15. Number of bed days spent in a hospital\*.

16. Date when a material for determination of sensitive detection of Mycobacterium tuberculosis\*.

17. Resistance to medicinal products\*.

18. Observation group changed\*:

18.1. type;

18.2. date when the observation group was changed\*.

19. Date when the patient was removed from the records\*.

20. Additional information.

21. Patient died from tuberculosis in the first year/first month\*.

22. Repeated course of medical treatment:

22.1. code and name of diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*;

22.2. place where medical treatment was started\*;

22.3. date when medical treatment course was started\*;

22.4. method of medical treatment\*;

22.5. surgical treatment\*;

22.6. abacillated after 2–3 months\*;

22.7. medical treatment under direct supervision\*;

22.8. date when treatment course was evaluated\*;

22.9. result of medical treatment\*;

22.10. number of bed days spent in a hospital\*.

23. Date when the card was completed\*.

Note. \* To be completed by the medical treatment institution.

**Annex 15**

Cabinet Regulation No. 134

11 March 2014

**Oncological Patient’s Registration Form**

[*29 November 2016*]

1. Patient information:

1.1. personal identity number\*;

1.2. given name (names), surname;

1.3. gender;

1.4. declared, registered place of residence or place of residence indicated by the person;

1.5. code of the administrative territorial unit of the declared place of residence;

1.6. nationality.

2. Medical treatment institution and medical practitioner who completed the medical document:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the doctor\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Diagnosis:

3.1. date when the diagnosis was determined\*;

3.2. code and name of diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*;

3.3. name and code of the rare disease according the Orphanet classification of rare diseases\*;

3.4. way of discovering the diagnosis\*;

3.5. method by which the diagnosis was justified\*;

3.6. method by which the diagnosis was confirmed\*;

3.7. localisation of the tumour for paired organs, anatomical parts\*.

4. Morphology and code of the tumour in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10)\*.

5. Risk factors\*.

6. Reasons for late diagnosis\*.

7. Stage of the disease\*.

8. Classification of the tumour according to clinical classifications:

8.1. tNM classification\*;

8.2. FIGO classification1\*;

8.3. Breslow method\*;

8.4. Gleason method\*;

8.5. French-American-British (FAB) classification;

8.6. stages of chronic myeloid leukemia;

8.7. level of anaplasia for malignant tumours of the central nervous system.

9. Distant metastasis\*:

9.1. date of diagnosing;

9.2. localisation.

10. Additional information\*.

11. Date of completing the card\*.

Notes.

1. 1Classification of the International Federation of Obstetricians and Gynaecologists.

2. \* To be completed by the medical treatment institution.

**Annex 16**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Oncological Patient’s Medical Treatment Card**

1. Patient information:

1.1. personal identity number\*;

1.2. given name (names), surname;

1.3. gender;

1.4. declared, registered place of residence or place of residence indicated by the person;

1.5. code of the administrative territorial unit of the declared place of residence;

1.6. nationality\*;

1.7. date of death;

1.8. unknown cause of death.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the doctor\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Diagnosis\*:

3.1. code and name of diagnosis (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*;

3.2. localisation of the tumour for paired organs, anatomical parts.

4. Surgical treatment:

4.1. type of surgical treatment\*;

4.2. name and code of the surgery according to the NCSP+ classification1\*;

4.3. date of the surgery\*.

5. Radiation therapy:

5.1. the start and end date of radiation therapy\*;

5.2. type of radiation therapy\*.

6. Chemotherapy:

6.1. the start and end date of chemotherapy\*;

6.2. general names of the medicinal products of the chemotherapy course\*;

6.3. number of chemotherapy courses\*;

6.4. type of chemotherapy\*.

7. Endocrine therapy:

7.1. the start and end date of endocrine therapy\*;

7.2. general name of the medicinal products\*;

7.3. type of endocrine therapy\*.

8. Immunotherapy:

8.1. the start and end date of immunotherapy\*;

8.2. general name of the medicinal products\*.

9. Targeted therapy:

9.1. the start and end date of targeted therapy\*;

9.2. general name of the medicinal products\*;

9.3. number of the courses received\*.

10. Date when 131J therapy was received\*.

11. Peripheral blood stem cell transplantation:

11.1. autologous transplantation date\*;

11.2. allogeneic transplantation date\*;

11.3. allogeneic transplantation donor (without indicating data identifying the person)\*.

12. Date when symptomatic therapy was started\*.

13. Course of the disease:

13.1. date of diagnosing disease progression\*;

13.2. date of diagnosing local relapse\*;

13.3. date of diagnosing distant metastasis\*;

13.4. localisation and code of distant metastasis according to the TNM classification\*;

13.5. date of diagnosing disease remission\*.

14. Subsequent medical treatment/observation of the patient\*.

15. Additional information\*.

16. Date of completing the card\*.

Notes.

1. 1 Current version of the Classification of Surgical Procedures with the supplement (NCSP+) of the Nordic Medico-Statistical Committee (NOMESCO).

2. \* To be completed by the medical treatment institution.

**Annex 17**

Cabinet Regulation No. 134

11 March 2014

**Registration Form of the Patient of Occupational Diseases**

[*29 November 2016*]

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender;

1.4. nationality\*;

1.5. address of the declared, registered place of residence or place of residence indicated by the person;

1.6. code of the administrative territorial unit of the declared place of residence.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the medical practitioner\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Referrer:

3.1. name of the medical treatment institution\*;

3.2. code of the medical treatment institution in the Register of Medical Treatment Institutions\*;

3.3. given name (names), surname of the medical practitioner\*;

3.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

4. Date when the occupational disease was diagnosed for the first time\*.

5. Number of the registration card of the patient of occupational diseases\*.

6. Number of the report sent to the State Labour Inspectorate\*.

7. Diagnoses of occupational diseases (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*.

8. Name of the work place in which the patient came into contact with the harmful work factor\*.

9. Length of employment:

9.1. total length of employment\*;

9.2. length of employment in the harmful profession\*.

10. Profession during exposure to the causing factor of the occupational disease\*.

11. Economic activity during exposure to the causing factor of the occupational disease in conformity with NACE Rev. 2. (Statistical classification of economic activities, revision 2)\*.

12. Year when the occupational disease was recognised for the first time\*.

13. Level of seriousness of the disease during recognition of the occupational disease for the first time\*.

14. Classification of occupational diseases and their causing factors in accordance with the laws and regulations governing examination and recording of occupational diseases:

14.1. occupational disease\*;

14.2. diagnosis of the occupational disease determined by the causing factor of the occupational disease (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10))\*;

14.3. causing factor of occupational diseases\*;

14.4. category of the use of the causing factor of occupational diseases\*;

14.5. actual concentration or level of the harmful occupational factor\*;

14.6. actual concentration or level of the harmful occupational factor exceeds the norm\*.

15. Date of completing the card\*.

Note. \* To be completed by the medical treatment institution.

**Annex 18**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Dynamic Observation Card of the Patient of Occupational Diseases**

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender;

1.4. nationality\*;

1.5. address of the declared, registered place of residence or place of residence indicated by the person;

1.6. code of the administrative territorial unit of the declared place of residence.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the medical practitioner\*;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

3. Referrer:

3.1. name of the medical treatment institution\*;

3.2. code of the medical treatment institution in the Register of Medical Treatment Institutions\*;

3.3. given name (names), surname of the medical practitioner\*;

3.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

4. Date of the visit to the doctor\*.

5. Number of the registration card of the patient of occupational diseases\*.

6. Disability\*:

6.1. date when disability due to an occupational disease was granted\*;

6.2. diagnosis of the occupational disease (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (hereinafter – ICD-10))\*;

6.3. diagnosis of the general disease (in conformity with ICD-10)\*;

6.4. disability group\*;

6.5. percentage of the loss of the capacity for work\*;

6.6. cause of death (cause of death in conformity with ICD-10)\*;

6.7. date when death occurred;

6.8. relation of death to the occupational disease\*.

7. Diseases undergone in the reporting year\*:

7.1. diagnosis (in conformity with ICD-10)\*;

7.2. first-time or chronic illness\*;

7.3. number of days of incapacity for work\*;

7.4. medical treatment in a hospital without rehabilitation\*;

7.5. medical treatment in a rehabilitation institution\*.

8. Diagnoses of diseases detected in mandatory health examinations (in conformity with ICD-10)\*.

9. Diagnoses of chronic diseases until beginning employment in harmful work (in conformity with ICD-10)\*.

10. Classification of occupational diseases and their causing factors in accordance with the laws and regulations governing examination and recording of occupational diseases\*:

10.1. occupational disease\*;

10.2. diagnosis of the occupational disease determined by the causing factor of the occupation disease (in conformity with ICD-10)\*;

10.3. causing factor of occupational diseases\*;

10.4. category of use of the causing factor of occupational diseases\*.

11. Date of completing the card\*.

Note. \* To be completed by the medical treatment institution.

**Annex 19**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Register Card of the Patient with Congenital Abnormalities**

1. Medical treatment institution and medical practitioner:

1.1. name of the medical treatment institution;

1.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

1.3. given name (names), surname of the medical practitioner\*;

1.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

2. Number of the health history or out-patient medical card\*.

I. Child

3. Patient information:

3.1. personal identity number\*;

3.2. date when the patient was born\*;

3.3. given name (names), surname;

3.4. gender;

3.5. address of the declared, registered place of residence or place of residence indicated by the person;

3.6. code of the administrative territorial unit of the declared place of residence;

3.7. address of the actual place of residence\*;

3.8. code of the administrative territorial unit of the actual place of residence\*.

4. Born alive/stillborn\*.

5. Type of assisted fertilisation\*.

6. Information regarding pregnancy\*.

7. Information regarding giving birth:

7.1. which birth\*;

7.2. pregnancy week of birth\*;

7.3. body weight\*;

7.4. body length\*.

8. Date when death of the child occurred.

9. Life expectancy exceeding one week\*.

10. Diagnosis determined while being alive/dead\*.

11. Diagnoses:

11.1. basic diagnosis\*:

11.1.1. date of determination\*;

11.1.2. name and code (in conformity with the current International Statistical Classification of Diseases and Related Health Problems, 10th revision (hereinafter – ICD-10))\*;

11.1.3. name and code of the rare disease (name and orphan code in conformity with the Orphanet classification of rare diseases)\*;

11.2. ancillary diagnoses (congenital abnormalities) (in conformity with ICD-10)\*;

11.3. anatomical/pathological diagnosis (in conformity with ICD-10)\*.

12. Time period of determination of the diagnosis\*.

13. Prenatal diagnostics:

13.1. ultrasound:

13.1.1. pregnancy week in which it was performed\*;

13.1.2. result\*;

13.1.3. diagnosis (in conformity with ICD-10)\*;

13.2. chorionic villus sampling:

13.2.1. pregnancy week in which it was performed\*;

13.2.2. result\*;

13.2.3. diagnosis (in conformity with ICD-10)\*;

13.3. amniocentesis:

13.3.1. pregnancy week in which it was performed\*;

13.3.2. result\*;

13.3.3. diagnosis (in conformity with ICD-10)\*;

13.4. other examinations (including biochemical, combined, and other risks)\*:

13.4.1. pregnancy week in which it was performed\*;

13.4.2. result\*;

13.4.3. diagnosis (in conformity with ICD-10)\*;

13.4.4. additional information regarding the examination\*.

14. Type of the disease\*.

15. Genetic type of the disease\*.

16. Monogenic disease code in conformity with the McKusick classifier\*.

17. Characterisation of the karyotype\*.

II. Mother

18. Given name (names), surname.

19. Personal identity number\*.

20. Age\*.

21. Declared, registered place of residence or place of residence indicated by the person.

22. Code of the administrative territorial unit of the declared place of residence.

23. Address of the actual place of residence\*.

24. Code of the administrative territorial unit of the actual place of residence\*.

25. How long has she been living at the declared or actual place of residence (full years)\*.

26. Address of the previous place of residence\*.

27. Nationality\*.

28. Profession in the first trimester of pregnancy\*.

29. Harmfulness at work\*.

30. Harmful habits\*.

31. Reproduction history\*:

31.1. total number of pregnancies\*;

31.2. number of children born live\*;

31.3. number of stillborn children\*;

31.4. number of dead children\*;

31.5. number of miscarriages and missed abortions\*;

31.6. number of legal abortions\*;

31.7. number of medical abortions\*.

32. Diagnoses of chronic diseases before pregnancy (congenital abnormalities) (in conformity with ICD-10)\*.

33. Diseases during pregnancy\*:

33.1. week of pregnancy\*;

33.2. diagnosis (in conformity with ICD-10)\*.

34. Harmful factors during pregnancy (week of pregnancy shall be indicated for each factor)\*:

34.1. irradiation\*;

34.2. use of medicinal products\*;

34.3. other factors\*.

35. Administration of folic acid\*.

III. Father

36. Given name (names), surname.

37. Personal identity number\*.

38. Age\*.

39. Nationality\*.

40. Profession\*.

41. Harmfulness at work\*.

42. Harmful habits\*.

43. Chronic diseases (in conformity with ICD-10)\*.

IV. Family

44. Marriage between relatives\*.

45. Previous children with congenital abnormalities:

45.1. gender\*;

45.2. year of birth\*;

45.3. diagnosis (in conformity with ICD-10)\*.

46. Congenital abnormalities from the mother’s family (name and code of diagnosis in conformity with ICD-10)\*.

47. Congenital abnormalities from the father’s family (name and code of diagnosis in conformity with ICD-10)\*.

48. Date of completing the card\*.

Note. \* To be completed by the medical treatment institution.

**Annex 20**

Cabinet Regulation No. 134

11 March 2014

[*7 March 2023*]

**Multiple Sclerosis Patient Form**

I. Basic information

1. Patient information:

1.1. given name (names), surname;

1.2. personal identity number\*;

1.3. gender;

1.4. nationality\*;

1.5. address of the declared, registered place of residence or place of residence indicated by the person;

1.6. unit of the administrative territorial unit of the declared place of residence;

1.7. address of the actual place of residence\*;

1.8. unit of the administrative territorial unit of the actual place of residence\*;

1.9. occupation\*;

1.10. disability\*;

1.11. date of death.

2. Medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. given name (names), surname of the medical practitioner;

2.4. identifier of the medical practitioner granted by the Health Inspectorate\*.

II. Family anamnesis

3. Chronic illnesses diagnosed for the mother (name and code of diagnosis in conformity with ICD-10)\*.

4. Chronic illnesses diagnosed for the father (name and code of diagnosis in conformity with ICD-10)\*.

5. Chronic illnesses diagnosed for brothers, sisters (name and code of diagnosis in conformity with ICD-10)\*.

6. Chronic illnesses diagnosed for children (name and code of diagnosis in conformity with ICD-10)\*.

7. Cases of falling ill with multiple sclerosis in the family:

7.1. for the mother\*;

7.2. for the father\*;

7.3. for brothers, sisters\*;

7.4. for children\*.

III. Anamnesis of life

8. Vaccination performed:

8.1. against tuberculosis\*;

8.2. against diphtheria, whooping cough, tetanus\*;

8.3. year when last vaccination against encephalitis was performed\*;

8.4. year when last vaccination against diphtheria was performed\*;

8.5. other vaccination\*;

8.6. reason if vaccination has not been performed\*.

9. Name of the infectious disease undergone.

10. Endocrine diseases – code and name of diagnosis (in conformity with ICD-10)\*.

11. Gynaecological anamnesis:

11.1. gynaecological diseases – code and name of diagnosis (in conformity with ICD-10)\*;

11.2. age when period began\*;

11.3. age when menopause set it\*;

11.4. gynaecological surgeries and year when they were performed\*;

11.5. childbirth:

11.5.1. type\*;

11.5.2. year\*;

11.6. abortion:

11.6.1. number\*;

11.6.2. year in which it was performed\*.

IV. Anamnesis of multiple sclerosis

12. Expression of the first clinical symptoms:

12.1. characterisation\*;

12.2. initial date\*.

13. Clinical symptoms of the second exacerbation:

13.1. characterisation\*;

13.2. initial date\*.

14. Actual place of residence (town) during falling ill with multiple sclerosis\*.

15. Clinical symptoms of the last exacerbation:

15.1. characterisation\*;

15.2. initial date\*.

V. Dynamics of neurological functional disorders

(In paragraphs 16, 17, 18, 19, 20, 21, 22, 23, and 24 – year when the indicted symptoms were temporary and/or permanent)

16. Visual impairments\*.

17. Impairments in the functioning of the brain stem\*.

18. Sensitivity impairments\*.

19. Impairments in the functioning of intestines and urinary bladder\*.

20. Movement impairments\*.

21. Impairments in coordination of movement\*.

22. Impairments in the functioning of the higher nervous system\*.

23. Impairments of sexual functions\*.

24. Impairments of the vegetative system\*.

25. Diagnosis:

25.1. code and name (in conformity with ICD-10)\*;

25.2. date when diagnosis was determined\*.

VI. Information regarding the last visit

26. Complaints during the last visit:

26.1. visual impairments\*;

26.2. impairments in the functioning of the brain stem\*;

26.3. sensitivity impairments\*;

26.4. impairments in the functioning of intestines and urinary bladder\*;

26.5. movement impairments\*;

26.6. movement and coordination impairments\*;

26.7. impairments in the functioning of the central nervous system\*;

26.8. impairments of sexual functions\*;

26.9. impairments of the vegetative system\*.

27. Evaluation of the neurological condition according to the Kurtzke scale of impairments of neurological functions.

28. Evaluation of the expanded functional neurological condition according to the Kurtzke scale of impairments of neurological functions\*.

29. Course of the illness\*.

30. Form of the illness\*.

31. Stage of the illness\*.

32. Confirmation of diagnosis of multiple sclerosis by magnetic resonance imaging\*.

33. Date when magnetic resonance imaging was performed\*.

34. Accounting group and year when the patient was included in the relevant group\*.

35. Immunological findings:

35.1. conclusion\*;

35.2. date when analyses were performed\*.

36. Date when the card was completed\*.

Note. \* To be completed by the medical treatment institution.

**Annex 21**

Cabinet Regulation No. 134

11 March 2014

**Gamete Donor Card**

[*17 July 2018; 17 December 2020*]

1. The donor:

1.1. given name (names), surname;

1.2. personal identity number;

1.3. date of birth;

1.4. gender.

2. Information regarding the medical treatment institution and medical practitioner:

2.1. name of the medical treatment institution;

2.2. code of the medical treatment institution in the Register of Medical Treatment Institutions;

2.3. address of the medical treatment institution;

2.4. given name (names), surname of the medical practitioner;

2.5. identifier of the medical practitioner granted by the Health Inspectorate;

2.6. speciality of the medical practitioner.

3. Information regarding a donation:

3.1. the unique donor material code;

3.2. the donation date (-s);

3.3. the material status.

4. Information regarding the result of medically assisted insemination:

4.1. the unique donor material code;

4.2. the date (-s) of use of the donated material;

4.3. the result(s) of artificial insemination procedure;

4.4. the date of embryo transfer (ET) or frozen embryo transfer (FET);

4.5. the result of pregnancy.

5. The status of a donor in Latvia:

5.1. active;

5.2. partly blocked (the donor material has been used for three times);

5.3. partly blocked (three pregnancies have set in of the donor material);

5.4. locked irreversibly (children have born in three pregnancies);

5.5. blocked irreversibly (descendant (child, foetus) with congenital anomaly or genetic disease – indicate ICD-10 and ORPHA codes);

5.6. blocked irreversibly (due to the health condition);

5.7. partly blocked (suspended for the period of research).

6. Notes.