Government of Iceland
Ministry of Health

Health Records Act No. 55/2009,
as amended by Act No. 6/2014, 44/2014, 77/2014 and 90/2018.

If mention is made in this Act of 'the minister' or 'the ministry' without further definition, the reference intended is to the Minister of Health or to the Ministry of Health, which is responsible for the implementation of this Act. Information on the division of responsibilities between ministries according to a presidential decree may be found here.

SECTION I
Introduction.

Article 1

Purpose and scope.

The purpose of the Act is to introduce rules on health records, so that patients can be provided with the best possible health service at any time, while also ensuring protection of health data.

The Act applies to health records entered when treatment is provided here in Iceland.

In so far as not otherwise provided in this Act, the provisions of the Act on the Protection of Privacy as regards the Data Protection and the [Processing][1)] of Personal Data apply to health data and their handling.

[1)] Act No. 90/2018, Article 54.

Article 2

Patients' right to self-determination and human integrity.

In the entering and storage of health records and access to them, the patient's human integrity and right to self-determination shall be respected, taking account of the fact that health records contain sensitive personal information, and that health data are confidential.

Article 3

Definitions.

In this Act the following terms have these meanings:

1. *Patient*: A user of health service.
2. *Health service*: All forms of primary healthcare, medical care, nursing, general and specialised hospital care, transport of patients, medical-aids service, and service from healthcare practitioner within and outside healthcare facilities, provided in order to promote health, to prevent, diagnose or treat illness, and to rehabilitate patients.
3. *Treatment*: A test, procedure or other healthcare service rendered by a physician or other healthcare practitioner in order to diagnose, cure, rehabilitate, nurse or care for the patient.
4. *Health data*: Description or interpretation in writing, images, including x-rays, graphical data and video and audio recordings, containing information regarding a patient's health and his/her

treatment provided by a healthcare professional or healthcare facility, and other necessary personal data.

5. *Health records*: A collection of health data about an individual, prepared in connection with treatment, or acquired from elsewhere in connection with treatment at a healthcare institute or at the premises of a self-employed healthcare professional.
6. *Health information system*: Software used to set up, store and manage health data.
7. *Connected health information systems*: Health information systems of two or more responsible parties, interoperable in such a way that data from health records may be shared between the systems.
8. *Joint health information systems*: Joint health information systems of two or more healthcare facilities or premises of self-employed healthcare practitioners.
9. *Healthcare facility*: Institution where health service is provided.
10. *Healthcare practitioner*: Person working in health services, licensed by the Medical Director of Health to use to the professional title of a legally-recognised health profession.
11. *Premises of self-employed healthcare practitioner*: Facilities of self-employed healthcare practitioners, where health services are provided with or without Government contribution to costs.
12. *Guardian of health records*: Healthcare facility or premises of a self-employed healthcare practitioner where health records are entered. Should the health records systems of two or more healthcare facilities or premises of self-employed healthcare practitioner have been joined, *cf.* Section VI, the guardian of health records in the system is deemed to be the party on whom the healthcare facilities or premises of self-employed healthcare practitioners have agreed.
13. *Supervisor of health records*: A physician, or other healthcare practitioner if no physician is available, appointed by the guardian to supervise the entry and handling of information in health records, and to ensure that they are consistent with the provisions of this Act. A healthcare practitioner who works alone on his/her premises is deemed to be the supervisor of health records he/she enters.
14. *Quality monitoring*: The aspect of quality control which is concerned with ensuring that standards of quality for healthcare services are met.
15. *Quality development*: The aspect of quality control concerned with enhancing ability to meet quality standards.
16. *Patient's representative*. A patient's guardian or a person appointed in writing by the patient to make decisions with respect to his/her health records, or granted leave to access such records.

SECTION II
Entry of health records.

Article 4
Duty to enter health records.

A healthcare practitioner who treats a patient shall enter health records.

Health records shall be entered in electronic form as far as possible.

The guardian of the health records shall ensure that it is possible to enter health records in accord with the provisions of the Act.

A healthcare practitioner who provides treatment and enters information on that treatment in health records is always responsible for his/her entries in health records.

Article 5
Entry of health data.

Only healthcare practitioners and other staff, and students undergoing clinical/health training (internship) in healthcare sciences who have undertaken an obligation of confidentiality comparable to that of healthcare practitioners, may enter health data in health records.

Entry of especially sensitive health data, *cf.* the second paragraph of Article 13, in electronic health records is subject to the provisions of regulations issued by the Minister under Article 24.

Every entry of health data in health records shall specify the name and professional title of the person making the entry, and the time of the entry. Additions, amendments and deletions of entries of health data shall always be traceable.

Health data shall be entered immediately, or normally not more than 24 hours from the time when the data were generated.

Entry of health data shall be carried out in such a manner that the data are accessible and that written text is clear and comprehensible.

Article 6

Entries in health records.

In health records, all information necessary with respect to the patient's treatment shall be systematically entered. But in all cases, the following minimum information shall be entered, as applicable:

1. Patient's name, address, ID number, profession, marital status and next of kin.
2. Date of consultation or admission and discharge.
3. Reason for consultation or admission.
4. Aspects of health and medical history relevant to the treatment.
5. Alerts, e.g. regarding allergies.
6. Examination.
7. Description of treatments/procedure, including information on medication and opinions of consultant specialists.
8. Test results.
9. Diagnosis.
10. Outcome and plans for further treatment.

The Minister can make further provision in regulations[1)] for entry of health data in health records. Entries of electronic health records and health information systems are also subject to the provisions of regulations issued by the Minister under Article 24.

[1)] Regulation No. 722/2009. Regulation No. 451/2013, cf. 899/2023. Regulation No. 898/2023.

Article 7

Patient's rights with respect to health record entries.

A patient or his/her representative can decide, when he/she receives treatment, that health records with respect to the treatment shall not be accessible to others than the person making the entry and the supervisor of the health records, and as applicable other specified healthcare practitioners. Should it be deemed necessary with respect to treatment that other healthcare practitioners have access to the health data in question, the patient shall be informed of this, and also informed that refusal to authorise necessary access to the health record may be equivalent, under some circumstances, to refusal of treatment, *cf.* the Patients' Rights Act.

Should a patient or his/her representative be of the view that health records are wrong or misleading, his/her comment to that effect shall be entered in the health record. Should it be demonstrated that information in the health record is clearly wrong or misleading, it is permissible, with the consent of the supervisor, to correct the information in the health record of the individual, provided that it is ensured that information which could be relevant to legal disputes is not lost. Should the supervisor refuse to correct health records regarded by the patient as clearly wrong or misleading, the patient may appeal that refusal to the Medical Director of Health. Deletion of information from a patient's health record is prohibited, except by permission of the Medical Director of Health.

[Decisions of the Medical Director of Health on correction or deletion of health records are final at administrative level and may not be appealed to the Minister.][1)] Procedure is subject to the provisions of the Administrative Procedure Act.

[1)] Act No. 6/2014, Article 1.

SECTION III
Storage of health records.

Article 8

General.

Health records shall be stored securely in such a way that health data are not lost and are accessible in accord with the provisions of Section IV.

Article 9

Responsibility for storage of health records.

The guardian of health records is responsible for the storage of health records being consistent with the provisions of this Act.

Article 10

Transfer of health records.

Should a patient transfer from one primary healthcare centre to another, a copy of his/her health record shall be saved in the health records system in use at the healthcare centre to which he/she transfers.

Should the operation of a health information system cease, the health records it contains shall be transferred to the Medical Director of Health. The Medical Director of Health can decide, with the consent of the patient or his/her representative, that health records transferred to the Medical Director shall be saved in the health information system of another healthcare facility or at the premises of a self-employed healthcare practitioner, or in joint health information systems.

Article 11

Duration of storage.

Health records shall be stored in the health information system of healthcare facilities or on premises of self-employed healthcare practitioners. [With respect to the obligation to pass health records to public archives, their storage and access to them, the provisions of the Public Archives Act apply.][1)]

[1)] Act No. 77/2014, Article 50.

SECTION IV
Access to health data.

Article 12

General.

Access to health records is prohibited except under authority provided by this Act or other legislation.

Article 13

Staff access to health records.

Healthcare practitioners who are involved in a patient's treatment and require his/her health records in connection with the treatment shall have access to the patient's health records, with the restrictions arising from the provisions of this Act and rules issued on the basis of the Act. A supervisor of health records can grant other staff, and students undergoing clinical training in healthcare sciences who have undertaken an obligation of confidentiality comparable to that of healthcare practitioners and are involved in the patient's treatment, leave to access his/her health records in so far as this is necessary for their work in the patient's interest.

Access to especially sensitive health data, i.e. health data which the patient himself/herself believes should be classified as such, shall be restricted to healthcare practitioners who necessarily require access for treatment of the patient. Access to especially sensitive health data shall normally be restricted to those healthcare practitioners working within the unit or department of healthcare facilities or of the premises of self-employed healthcare practitioners where the treatment is provided. Access by other healthcare practitioners to especially sensitive health data is prohibited, except with the patient's consent. An exception may be made from the above-mentioned access restrictions if deemed necessary for the security

of healthcare practitioners. The Minister shall, in regulations issued under Article 24, make further provision for access to especially sensitive health data.

Healthcare staff's obligation of confidentiality with respect to personal information of which they become aware in their work, including health data, is subject to the provisions of the Patients' Rights Act, and other relevant legislation.

A patient or his/her representative may prohibit a specific member or specific members of staff, including students undergoing clinical training, from accessing his/her health records. Should it be deemed necessary, however, with respect to treatment, that the specified member/members of staff or students have access to the health data in question, the patient shall be informed of this, and also informed that refusal to authorise necessary access to the health record may be equivalent, under some circumstances, to refusal of treatment, *cf.* the Patients' Rights Act.

Access to health records is also subject to the provisions of regulations issued by the Minister under Article 24.

Article 14

Patient's access to his/her own health records.

A patient or his/her representative has right of access to his/her own health records in whole or in part, and to be given copies on request. Such a request shall be made to the supervisor of the health records.

In the case of health data acquired from another source than the patient himself/herself or healthcare practitioners, the consent of the source of the information shall be elicited before the record is shown to the patient. Should such a source of information on a patient be deceased, or refuse on unreasonable grounds to give consent, the Medical Director of Health may decide that the patient or his/her representative be granted access to the data in question, in whole or in part.

[Should it be deemed not in the patient's interest to gif him/her access to health record in whole or in part, or give him/her or his/her representative copy of the health record, the supervisor of the health record shall guide him/her of his/her right to refer the refusal to the Directorate of Health according to Article 15 a.][1)]

A patient is entitled to information from the supervisor of health records regarding which people have gathered information from his/her health record, *inter alia* by connection of health information systems, where and when the data were gathered, and for what purpose.

...[1)]

1) Act No. 6/2014, Article 2.

Article 15

Access to health records of a deceased person.

[For exigent reasons a supervisor of health records may grant a close relative of a deceased individual, such as the spouse, a parent or a descendant, access to the deceased's health records and give copies on request. When assessing whether access shall be granted to a health record of a deceased individual, a consideration shall be taken to the relative's interests requesting such access and to the wishes of the deceased, if they are at hand. If a supervisor of health records denies of access or copy to a deceased individual's health record, the supervisor of health records shall provide guidance of the right to appeal that refusal to the Medical Director of Health under Article 15 a.][1)]

1) Act No. 6/2014, Article 3.

[Article 15 a

The right to appeal refusal of access to a health record to the Medical Director of Health

Refusal of the supervisor of health records on patient's access to his/her own health record, in whole or in part, or refusal of a copy of a health record, may be appealed to the Medical Director of Health. The same shall apply to refusals of the supervisor of health records on granting close relative access to a health record of a deceased individual or refusal of its copy. Procedure is subject to the provisions of the Administrative Procedure Act. Decisions of the Medical Director of Health on access to health records are final at administrative level and may not be appealed to the Minister.][1)]

1) Act No. 6/2014, Article 4.

Article 16

Healthcare authorities' access to health records.

Healthcare authorities which by law receive for consideration a complaint or appeal from a patient or his/her representative with respect to treatment, are entitled to access the person's health records in the same manner as the patient himself/herself.

Provision of data from health records for the keeping of health registers and monitoring by the Medical Director of Health, including quality monitoring, is subject to the Medical Director of Health Act.

Article 17

Access to health records for quality development and monitoring.

The supervisor of health records may grant healthcare practitioners and other staff, and students undergoing clinical training in healthcare sciences who have undertaken an obligation of confidentiality comparable to that of healthcare practitioners, access to health records for purposes of quality development and quality monitoring within the relevant healthcare facility or premises of healthcare practitioners.

[Article 17 a

Access to health records for scientific studies is subject to the Act on Scientific Research in the Health Sector. A patient or his/her representative may prohibit that his/her health data are stored as identifiable in a health databank for use in scientific research and that shall be noted in his/her record.][1)]

[1)] Act No. 44/2014, Article 36.

[[Article 17 b][1)]

Access to health information system to work on processing, update and maintenance.

The supervisor of health records my grant necessary access to health information system to those employees that work on service for the computer and data system, for the purpose of work on processing, update and maintenance of the system. As far as possible, when granting such service, a test data shall be used instead of actual data. Employees shall undertake an obligation of confidentiality comparable to that of healthcare practitioners.][2)]

[1)] Act No. 44/2014, Article 36. [2)] Act No. 6/2014, Article 5.

SECTION V
Connection of health information systems.

Article 18

Authority to connect health information systems.

A supervisor of health records may grant healthcare practitioners at other healthcare facilities, or at other premises of specified healthcare practitioners which do not have access to the system, direct access to health records by connecting health information systems, if the patient has not prohibited such access, *cf.* Article 21. Those healthcare practitioners who are in direct contact with the patient with respect to treatment are authorised to gather necessary information on the patient. The same may apply, as necessary, to students undergoing clinical training in healthcare sciences who have undertaken an obligation of confidentiality comparable to that of healthcare practitioners.

The Minister can make further provision in regulations on connection of health information systems and authority for access by healthcare practitioners when such a connection is made. Security of personal data when health information systems are connected is subject to the Act on the Protection of Privacy as regards the Act on Data Protection and the [Processing][1)] of Personal Data and to the Data Protection Authority's rules on security of personal data.

[1)] Act No. 90/2018, Article 54.

Article 19

Patient's right to prohibit sharing of information on him/her by connection of health information system.

A patient or his/her representative can prohibit the sharing of data about him/her by connected health information systems. The prohibition can apply to sharing of all electronic health data on a patient stored in a specific health information system. The prohibition may also apply to specific health data in the electronic health record of a patient at a healthcare facility or the premises of a self-employed healthcare practitioner, e.g. health data stored at specific departments or units in a healthcare facility or premises, in so far as this is technically practicable for the guardian of health records in question, *cf.* regulations issued by the Minister under Article 24. The patient or his/her representative can also prohibit specified parties from gathering information on him/her by connected health information systems.

Should a patient or his/her representative prohibit sharing of his/her health data by connected health information systems in a specific instance, the healthcare practitioner responsible for the patient's treatment shall inform him/her, as applicable, that the treatment may be rendered less effective than it would otherwise be, as comprehensive information on him/her cannot be gathered. A patient's decision to prohibit connection in a specific instance shall be recorded in his/her health records.

A patient's decision to prohibit all sharing of health data under the first paragraph by connected health information systems shall be communicated to the supervisor of health records. The decision shall be submitted in writing, and confirmed by a healthcare practitioner, who also confirms, as applicable, that it has been explained to the patient that, by this decision, treatment which the patient may later require may become less effective than it would otherwise be, as it will not be possible to gather comprehensive information on the patient by connection of health information systems. The supervisor of health records is then responsible for honouring the patient's prohibition of connection of health information systems and for health data about the person in question not being accessible by connecting the system with another health information system. A patient may at any time revoke the prohibition of sharing of health data on him/her by connected health information systems. A patient's decision to revoke the prohibition shall be confirmed by two healthcare practitioners, and submitted to the supervisor of health records.

The Minister may make further provision in regulations for the patient's right to prohibit sharing of health data on him/her by connected health information systems.

SECTION VI
Joint health information systems.

Article 20

Joint health information systems.

Two or more healthcare facilities or premises of self-employed healthcare practitioners may, with the consent of the Minister, enter and store health records of patients treated by them in a joint health information system.

The Minister's consent under the first paragraph shall only be granted if a joint health information system is demonstrated to be conducive to enhancing the security of patients in their treatment. The Minister may make impose such conditions as he/she deems necessary upon his/her consent under the first paragraph, in order to ensure high quality of entry and storage of health records, and protection of health data. The Minister's consent shall also be subject to the following conditions:

1. That the conditions of the regulations issued under Article 24 on entry of electronic health records and health information systems are met.
2. That the Data Protection Authority has confirmed that security of personal data in the shared health information system is ensured in accord with the Act on the Protection of Privacy as regards the Act on Data Protection and the [Processing][1)] of Personal Data and with Data Protection Authority rules on security of personal data.

[1)] Act No. 90/2018, Article 54.

Article 21

Patient's right to restrict access to health data about him/her in a joint health information system.

A patient or his/her representative can prohibit access to health data about him/her in a joint health information system, in whole or in part, outside the healthcare facility or premises of a healthcare practitioner where the records are entered. The prohibition may also apply to health data stored in specified departments or units of a healthcare facility or premises of healthcare practitioners, in so far as that it is technically practicable, see regulations issued by the Minister under Article 24. Finally, a patient or his/her representative can prohibit specified parties from gathering information on him/her in a joint health information system.

A patient's decision under the first paragraph shall be communicated to the supervisor of health records. The decision shall be submitted in writing, and confirmed by a healthcare practitioner, who also confirms, as applicable, that it has been explained to the patient that, by this decision, treatment which the patient may later require may become less effective than it would otherwise be, as it will not be possible to gather comprehensive information on the patient. The supervisor of health records is responsible for honouring the patient's prohibition, and for health data about the person in question being accessible only in accord with his/her decision. A patient may at any time revoke the prohibition of sharing of health data on him/her in a joint health information system. A patient's decision to revoke the prohibition shall be confirmed by two healthcare practitioners, and submitted to the supervisor of health records.

SECTION VII
Various provisions.

Article 22

Monitoring.

The guardian and supervisor of health records shall actively monitor compliance with the provisions of this Act. The supervisor of health records has the right to access health records in so far as is required for monitoring purposes.

The Medical Director of Health monitors, as applicable, compliance with the provisions of this Act. The Medical Director of Health's monitoring, and measures available to him/her, are as provided in the Medical Director of Health Act.

The Data Protection Authority monitors the security and processing of personal data in health records, in accord with the provisions of the Act on the Protection of Privacy as regards the Processing of Personal Data (Data Protection Act).

Should monitoring reveal a real likelihood that the personal privacy rights of a patient have been violated, the offence shall be reported to the police. The police then handle the case under the provisions of the Criminal Procedure Act. Reporting of the matter to the police does not entail cessation of investigation, nor of the application of administrative sanctions under the Medical Director of Health Act and the Act on the Protection of Privacy as regards the Act on Data Protection and the [Processing][1)] of Personal Data, or the application of measures under the Rights and Obligations of Government Employees Act.

[1)] Act No. 90/2018, Article 54.

Article 23

Penalties.

Violations of the provisions of the Act, and regulations issued on the basis of the Act, entail fines or imprisonment for up to three years.

Article 24

Regulations.

The Minister shall make further provision in regulations[1)] on the entry of electronic health records, their storage, access to them, access controls and access restrictions in accord with the provisions of this Act. The Minister shall also provide in regulations for technical requirements and standards which health information systems, including joint health information systems, must meet. The Minister's regulations shall take account of the patient's rights under the provision of this Act with respect to entry of health records, and the right to restrict access to his/her health records. Security of personal data in health information systems is subject to the Act on the Protection of Privacy as regards the Act on Data Protection and the [Processing][2)] of Personal Data, and Data Protection Authority rules on security of personal data.

The Minister is also authorised to issue further rules on other matters concerned with the implementation of this Act.

[1)] Regulation No. 550/2015. [2)] Act No. 90/2018, Article 54.

Article 25

Entry into force.

This Act takes force immediately.

Article 26

...

Temporary provisions.

The provisions of Article 19 on the patient's right to prohibit sharing of data about him/her by connection of health information systems shall be implemented not later than 31 December 2010.

The provisions of Article 21 on the patient's right to restrict access to health data about him/her in a joint health information system shall be implemented not later than 31 December 2010.

[*This translation is published for information only.*
The original Icelandic text is published in the Law Gazette.
In case of a possible discrepancy, the original Icelandic text applies.]