



**[Medical Director of Health and Public Health Act]¹⁾, No. 41/2007,
as amended by Act No. 12/2008, 112/2008, 162/2010, 28/2011, 126/2011, 44/2014, 45/2014,
92/2016, 47/2018, 90/2018, 153/2018, 145/2019, 99/2020 and 43/2022.**

¹⁾ Act No. 28/2011, Article 11.

Where 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

[Objectives, appointment of Medical Director of Health, definitions and role.]¹⁾

¹⁾ Act No. 28/2011, Article 5.

Article 1

[Objective.

The objective of this Act is to promote the health of the people of Iceland, *inter alia* through more active public health activities and by ensuring the quality of health services, and conduce to public health work and health services being grounded in the best knowledge and experience at all times.]¹⁾

¹⁾ Act No. 28/2011, Article 1.

Article 2

[Directorate of Health.

A Directorate of Health shall operate under the authority of the [Minister].¹⁾ The Minister shall appoint a Medical Director of Health for a term of five years, having received the findings of the committee under Article 9 of the Health Service Act. He/she shall have a specialist medical qualification, knowledge in the field of public health and extensive experience or education in the field of administration.

The Medical Director of Health is responsible for the agency he/she heads operating in accord with law, government directives and the terms of its commission. The Medical Director of Health appoints the staff of the Directorate.]²⁾

¹⁾ Act No. 126/2011, Article 452. ²⁾ Act No. 28/2011, Article 2.

Article 3

Definitions.

In this Act following words shall have these meanings:

- [1. *Public health work:* Maintenance and enhancement of the health, wellbeing and conditions of the nation and individual social groups, through health promotion, preventive measures, and health services.]¹⁾

- [2.]¹⁾ *Health service*: All forms of primary healthcare, medical care, nursing, general and specialised hospital care, transport of patients, medical-aids service, and service from health personnel within and outside healthcare facilities, provided in order to promote health, to prevent, diagnose or treat illness, or to rehabilitate patients.
- [3.]¹⁾ *Healthcare practitioner*: Person working in health services, licensed by [the Medical Director of Health]²⁾ to use to the professional title of a legally-recognised health profession.
- [4.]¹⁾ *Healthcare facility*: An institution where health service is provided.
- [5.]¹⁾ *Premises of self-employed healthcare practitioner*: Facilities of self-employed healthcare practitioners, where health services are provided with or without State contribution to costs.

¹⁾ Act No. 28/2011, Article 3. ²⁾ Act No. 12/2008, Article 2.

Article 4

[Principal roles of the Medical Director of Health.

The role of the Medical Director of Health is *inter alia* as follows:

- a. to provide advice and information on matters within the sphere of the Directorate to the Minister and other authorities, healthcare practitioners and the public,
- b. to undertake preventive and health-promoting tasks,
- c. to promote public-health work in collaboration with other parties involved in the field, and to lend support to education in the public-health field,
- d. to work for quality development,
- e. to monitor health services and healthcare practitioners,
- f. to monitor prescriptions, and observe and promote reasonable use of medicinal products by the people of Iceland,
- [g. to monitor activities of biobanks and acquire health data in accordance with Biobanks and Health Databanks Act],¹⁾
- [h]¹⁾ to issue licences to individuals who meet the criteria of legislation and regulations to use professional titles of authorised health professions,
- [i]¹⁾ to conduce to training of healthcare practitioners being consistent with the standards of the health service at all times,
- [j]¹⁾ to deal with complaints from the public regarding health services,
- [k]¹⁾ to be responsible for the implementation of infectious-disease control measures, *cf.* the Act on Health Security and Communicable Diseases,
- [l]¹⁾ to gather and process data on health and health services,
- [m]¹⁾ regularly to evaluate the results of public health activities in view of stated objectives,
- [n]¹⁾ to promote research in the spheres of the Directorate's work,
- [o]¹⁾ to perform other tasks assigned to him/her by law, by government directives or by decision of the Minister.

The Minister may make further provision for the tasks of the Medical Director in Regulations.

The Medical Director of Health may also make agreements with university agencies and other agencies on collaboration in the fields of research, teaching and services relating to the sphere of the Directorate.]²⁾

[The Directorate of Health is authorised to process personal data, including sensitive personal data about health and medicine use of individuals, for the purpose of monitoring quality and safety of health service, medicinal product prescription and promote rational use of medications by the people of Iceland, as well as to fulfil other statutory obligations according to this Act under the conditions of the Act on Data Protection and the Processing of Personal Data.]²⁾³⁾

¹⁾ Act No. 45/2014, Article 22. ²⁾ Act No. 99/2020, Article 5. ³⁾ Act No. 28/2011, Article 4.

**[SECTION I A.
Expert Councils and Public Health Fund.]¹⁾**

¹⁾ Act No. 28/2011, Article 6.

[Article 4 a

Expert Councils.

The Medical Director of Health shall appoint expert councils for the principal areas handled by the Directorate, including prevention of alcohol and drug abuse and tobacco control, comprising experts and representatives of agencies and organisations in the relevant field. The expert councils shall provide advice to the Medical Director of Health.

The Medical Director of Health issues rules on the appointment of expert councils, and these rules are subject to approval by the Minister.]¹⁾

¹⁾ Act No. 28/2011, Article 6.

[Article 4 b

Public Health Fund.

[The role of the Public Health Fund is to support public health work that is in accord with the objectives of this Act, *cf.* Article 1, whether within the Directorate or outside it. The Minister makes allocations from the Public Health Fund, having received proposals from the Fund's board and in accord with regulation by the Minister as provided in the fourth paragraph.

The Minister appoints the board of the Public Health Fund. The Fund's board comprises three people; one nominated by the Directorate Health, one nominated by the School of Health Sciences at the University of Iceland and a chair, appointed by the Minister. Alternates shall be appointed in the same way.]¹⁾

[Annual allocation to the Public Health Fund shall be decided with appropriation on grounds of allocation of funds in each Budget.]²⁾

The Minister shall make further provision in regulations³⁾ for allocations from the Public Health Fund. The regulations shall include specification of criteria for allocation of grants to projects in specific fields, e.g. preventive and public-health activities. Criteria shall also be specified for allocations from the Fund to projects and activities in the relevant field within the Directorate.]⁴⁾

¹⁾ Act No. 92/2016, Article 1. ²⁾ Act No. 47/2018, Article 12. ³⁾ Regulation No. 1260/2011, *cf.* 1323/2016. ⁴⁾ Act No. 28/2011, Article 6.

SECTION II

[Monitoring of health services.]¹⁾

¹⁾ Act No. 28/2011, Article 9.

Article 5

Directives, guidance and advice.

The Medical Director of Health may give healthcare facilities and healthcare practitioners general professional directives on work procedures, measures and responses of various nature, with which they must comply. Such directives shall be submitted to the Minister for confirmation, and made public.¹⁾

[The Medical Director of Health may issue instructions to healthcare practitioners, healthcare institutions and those involved in public-health work, including instructions conducive to approaches and resolution of problems which are consistent with the best knowledge at the time. Instructions shall be promulgated to healthcare practitioners and to those who are involved in public-health work, and shall be accessible to the public.]²⁾

The Medical Director of Health may make known to the public advice and counsel on matters concerned with health and the health service.

¹⁾ Adv. No. 585/2020. Adv. No. 702/2020. Adv. No. 798/2021. ²⁾ Act No. 28/2011, Article 7.

Article 6

Professional standards for operation of health services.

The Minister shall, having received proposals from the Medical Director of Health and after consultation with the relevant health professions, make provision in regulations¹⁾ for the minimum professional standards to apply to operation of health services in individual fields. The regulations shall be based upon knowledge and circumstances at any time, and shall be regularly revised. The regulations shall specify *inter alia* minimum standards of manning, accommodation, facilities and equipment or operation of health service.

Those who intend to commence operation of a health service, including the State or a local government, shall notify the Medical Director of Health of the planned operation. The notification shall be accompanied by adequate information on the operation, such as the type of health service, personnel, equipment and premises. The Medical Director of Health can request further information, and carry out an assessment of the prospective operation, if he/she deems necessary. By the same token the Medical Director of Health shall be notified if major changes are made to manning, equipment, operations and services of operators. Should operation of a health service cease, this shall be notified to the Medical Director of Health.

The Medical Director of Health confirms whether the prospective operation of a health service meets professional standards and other conditions of health legislation. The same applies when the Minister [or Health Insurance Administration]²⁾ renews contracts with healthcare facilities. Operations in the field of health services may not be commenced unless the Medical Director of Health has given confirmation. The Medical Director of Health may impose stricter requirements if deemed necessary due to the nature of the operations in question. Confirmation from the Medical Director of Health is also required for major changes under the first paragraph.

Should the Medical Director of Health refuse to grant confirmation under the second paragraph, the refusal may be appealed to the Minister. The same applies to a decision of the Medical Director of Health to impose stricter requirements under the second paragraph. However, in the case of a health service which the State intends to operate, the Minister always has the power to rule on whether legal requirements and professional standards are met.

[The Medical Director of Health maintains a register of health service operators and is authorised to publish information from the register for the purpose of ensuring quality and safety in health service. The Medical Director of Health shall notify the Minister and Health Insurance Administration of all changes to the register.]³⁾

A fee may be charged for an assessment by the Medical Director of Health under the first paragraph and for his/her confirmation that professional standards are met under the second paragraph, as further provided in Regulations⁴⁾ by the Minister.

¹⁾ Regulation No. 786/2007. Regulation No. 1130/2021, cf. 704/2020 and 1519/20202. ²⁾ Act No. 112/2008, Article 64. ³⁾ Act No. 99/2020, Article 6. ⁴⁾ Regulation No. 226/2016.

Article 7

Monitoring of health service.

The Medical Director of Health shall regularly monitor compliance of health services provided in Iceland with professional standards and the provisions of health legislation at any time. The Medical Director of Health has authority to demand from healthcare practitioners, healthcare facilities and others who provide health services information and data he/she deems necessary in order to perform his/her monitoring role, and they must comply with such a demand. The Medical Director of Health shall have ready access to healthcare facilities and the premises of self-employed healthcare practitioners for monitoring purposes under this Act.

Should the Medical Director of Health deem a health service not to meet the professional standards under Article 6 or other requirements of health legislation, he/she shall instruct the operator of the service to make improvements. Should the operator not comply with such instructions, the Medical Director of

Health must report on the matter to the Minister, and submit proposals on measures. The Minister may then decide to halt the operation, either temporarily pending rectification, or permanently.

The Minister may make further provision in regulations¹⁾ for the practice of monitoring by the Medical Director of Health.

¹⁾ Regulation No. 786/2007.

Article 8

Reports and health registers.

The Medical Director of Health shall, in accord with regulations¹⁾ issued by the Minister, organise and maintain national registers on health, diseases, accidents, prescriptions, births, and the work and performance of the health service. The purpose of the registers is to gather information on health and the health service, to monitor the service, to ensure its quality and assess its success, and also to use the registers in planning for quality development in the health service and in scientific research. The Medical Director shall also, in consultation with the Ministry, process data from the health registers for use in planning, policy formation and other tasks of the Ministry, and publish health reports. The data in the Medical Director's registers shall not be personally identifiable, but see the second paragraph, except with the consent of the person involved.

In the following registers organised by the Medical Director of Health, information on patients' names, identity numbers, and other personal identifying features may be recorded without the consent of the patient:

1. Register of births
2. Register of cardiovascular disease
3. Register of neurological diseases
4. Register of cancer patients
5. Register of accidents
6. Register of admissions to healthcare facilities
7. Healthcare centres' contact register
8. Self-employed specialist physicians' contact register
9. Diabetes register.
- [10. Register of causes of death.]²⁾
- [11. Register of dementia diseases.]³⁾

[The Medical Director of Health has the authority to take into safekeeping disease databanks which were established before the enactment of data protection legislation. The handling of data from such databanks shall be subject to authorisation by the Data Protection Authority and the National Bioethics Committee.]²⁾

In the Medical Director's registers under the second paragraph, personal identifying features shall be encrypted. The Ministry shall make further provision in regulations,¹⁾ after receiving the recommendations of the Data Protection Authority, regarding the personal and health data which may be entered in the registers and their encryption, and the circumstances in which they may be decoded.

The Medical Director of Health is responsible for the registers he/she organises.

Healthcare facilities, healthcare practitioners and others who provide health services shall provide the Medical Director of Health with the information he/she requires in order to maintain the health registers under the first and second paragraphs. The Medical Director of Health gives healthcare facilities, healthcare practitioners and others who provide health service directives on minimum data recording for these purposes, and how registration of data and their submission to the Directorate is to be carried out. The Medical Director's directives shall be submitted to the Minister for confirmation, and made public. Other bodies which are under the aegis of [the Ministry]⁴⁾ and gather data in the field of health, such as the Medicines Control Agency [and the Health Insurance Administration],²⁾ shall also provide the Medical Director of Health with access to the data gathered in their work, which are necessary in order to maintain health registers under the first and second paragraphs, or in order to carry out monitoring under this Act. [The same applies to the Social Insurance Administration.]⁵⁾ These bodies shall consult with the Medical

Director of Health regarding the gathering and recording of such data and submission of it to the Medical Director of Health. Data under this provision shall be provided to the Medical Director of Health free of charge.

[The Medical Director of Health can, with the Minister's consent, assign healthcare facilities and self-employed healthcare practitioners, or other parties, to handle and be responsible for certain registers organised by the Medical Director under the first and second paragraphs. A written agreement shall be made on such registers, specifying *inter alia* the keeper of the register, rules of procedure and security standards, content, processing, right of disposal, use and promulgation of information, duration of the agreement, and revision. The responsible person must inform the Medical Director of Health of all matters concerning maintenance of the register when requested, and provide the Medical Director with all data he/she requires with respect to his/her mandated role. Such data shall be provided to the Medical Director of Health free of charge.]⁶⁾

The Medical Director of Health may charge a fee for processing and delivery of data from health registers, in accord with regulations⁷⁾ issued by the Minister.

[Access to personally-identifiable data from health registers under the second paragraph for scientific research purposes is subject to the provisions of the first paragraph of Article 27 of the Act on Scientific Research in the Health Sector.]⁶⁾

Gathering and handling of data under this provision shall be in accord with the provisions of the Act on Data Protection and [the Processing]⁸⁾ of Personal Data, and shall meet the criteria of the Data Protection Authority for security of personal data in records in the health sector.

The Minister can make further provisions in regulations¹⁾ for the form and processing of health registers, promulgation of data, and publication of health reports.

[The Medical Director of Health shall, in accordance with this Act and the regulation issued by the Minister, organise and maintain a central treatment-related health register at a national level in connection with cancer screenings, which is called a screening register. The purpose of the register is to promote coordinated and targeted implementation and follow-up of cancer screenings and to increase the quality and safety of health service. The Minister may, in a regulation, stipulate in more detail the personally identifiable data that may be collected and stored, security measures and the rights of the registered individuals.]⁹⁾

¹⁾ Regulation No. 548/2008. ²⁾ Act No. 28/2011, Article 8. ³⁾ Act No. 145/2019, Article 1. ⁴⁾ Act No. 162/2010, Article 78. ⁵⁾ Act No. 12/2008, Article 4. ⁶⁾ Act No. 44/2014, Article 36. ⁷⁾ Regulation No. 226/2016, cf. 573/2017. ⁸⁾ Act No. 90/2018, Article 54. ⁹⁾ Act No. 43/2022, Article 1.

Article 9

Recording of unforeseen incidents.

Healthcare facilities, self-employed healthcare practitioners and others who provide health services shall maintain a register of unforeseen incidents, for the purpose of finding explanations for them and seeking ways of ensuring that they do not recur. An unforeseen incident is defined as an accident, error, negligence or other incident which has harmed or could have harmed a patient.

Healthcare practitioners who are involved, their professional superiors and other staff of the healthcare facility, as applicable, must record all unforeseen incidents under the first paragraph.

Healthcare facilities, self-employed healthcare practitioners and others who provide healthcare service shall regularly submit to the Medical Director of Health a summary of all unforeseen incidents under the first paragraph, as further determined by the Medical Director of Health.

The Minister may make further provision in regulations for the recording of unforeseen incidents.

Article 10

Mandated reporting.

Healthcare facilities, self-employed healthcare practitioners and others who provide healthcare services must notify the Medical Director of Health without delay of any unforeseen incident which has caused or could have caused serious harm to a patient, such as death or grave disablement. The patient shall also be informed of the unforeseen incident without unnecessary delay, and his/her closest relatives where applicable.

The Medical Director of Health shall investigate such cases in order to find an explanation for them and to ensure as far as possible that they do not recur. The Medical Director of Health shall be provided with the information and documents he/she deems necessary in the investigation of the case. The Medical Director of Health shall have ready access to healthcare facilities and premises of self-employed healthcare practitioners for the purposes of investigation.

Should an unforeseen death occur at a healthcare facility or other place where healthcare service is provided, which is regarded as probably attributable to error, negligence or a mishap in treatment or preventive measures with respect to an illness, in addition to the notification to the Medical Director of Health this shall be reported to the police, in accord with the provisions of the Act on Death Certificates, Autopsies, etc.

The Medical Director of Health shall maintain a constantly-updated register of unforeseen incidents under Article 9.

The Medical Director of Health shall send the Minister an annual summary of unforeseen incidents, findings of investigations, and results of cases.

The Minister may make further provisions in Regulations for mandated reporting, response, investigation of cases, the Medical Director's register of unforeseen incidents and the publication of such data.

Article 11

Quality development plan.

The Medical Director of Health makes a plan for quality development within the health service, which shall be submitted to the Minister for confirmation. The quality development plan shall aim to enhance the quality and security of health services, and be conducive to its development.

Healthcare facilities and healthcare practitioners shall in the making of quality plans take account of the Medical Director's confirmed quality development plan.

The Medical Director of Health assesses quality and performance within the health service with respect to yardsticks laid down by the Minister in Regulations.¹⁾ Comparable findings of quality and performance assessment shall be published in health reports under Article 8.

¹⁾ Regulation No. 1148/2008, cf. 615/2017.

Article 12

Complaints to the Medical Director of Health.

The Medical Director of Health must handle matters concerning interaction between the public and providers of health services, and provide guidance to those who consult him/her on matters of the health service.

A formal complaint may be made to the Medical Director of Health with respect to alleged negligence or error in provision of health service. Users of health services may also make a formal complaint to the Medical Director of Health if they feel that healthcare staff have behaved inappropriately in provision of health service.

Complaints shall be in writing, and shall clearly state the cause of the complaint.

A complaint shall be made to the Medical Director of Health without unnecessary delay. Should more than ten years have passed since the event on which the complaint is based, the Medical Director of Health should dismiss the complaint, unless special circumstances justify in his/her judgement that the complaint be considered.

The Medical Director of Health shall normally elicit an opinion from a disinterested specialist or specialists in a case of alleged negligence or error in diagnosis or treatment. The specialists in question, and the Medical Director of Health himself/herself, should call the patient for examination if special cause so requires. The procedure of complaints is otherwise subject to the provisions of the Public Administration Act as may be applicable. At the conclusion of the procedure the Medical Director of Health gives a written opinion. The Medical Director of Health shall in his/her opinion specify the cause of the complaint, the facts of the case, and the grounds for his/her findings. A general conclusion shall be stated at the end of the written opinion.

Handling of a case by the Medical Director of Health under this provision may be appealed to the Minister.

SECTION III **Monitoring of healthcare practitioners.**

Article 13

Monitoring of healthcare practitioners by the Medical Director of Health.

The Medical Director of Health monitors the work of healthcare practitioners, and monitors their compliance with the provisions of health legislation and of other legislation, and government directives as appropriate.

The Medical Director of Health may require a healthcare practitioner to undergo specialist examination if he/she deems necessary, in order to ascertain whether he/she is fit to perform his/her work. Should a healthcare practitioner be suspected of being under the influence of alcohol or other substances at work, the Medical Director of Health may require him/her to undergo immediate tests to ascertain whether this is so.

Article 14

Reprimand.

Should the Medical Director of Health become aware that a healthcare practitioner neglects his/her professional duties, exceeds his/her professional boundaries, or violates the provisions of health legislation, the Medical Director shall give the healthcare practitioner a directive on rectification, or reprimand him/her, according to the circumstances. Should the healthcare practitioner not comply with the Medical Director's directive, provided without reprimand, the Medical Director shall reprimand him/her.

The issue of a reprimand shall comply with the provisions of the Public Administration Act. The reprimand shall be in writing and cite grounds, and shall invariably be issued with respect to a specified event or events. A reprimand shall be issued without unnecessary delay. ...¹⁾

A decision of the Medical Director of Health to issue a reprimand may be appealed to the Minister.

¹⁾ Act No. 12/2008, Article 5.

Article 15

Revocation of licence.

[Should a reprimand from the Medical Director of Health under Article 14 prove ineffective, he/she may decide that the licence of the person in question be revoked, permanently or temporarily.]¹⁾

[The Medical Director of Health can revoke the licence of a healthcare practitioner without prior reprimand]¹⁾ if the person in question is deemed incapable of performing his/her duties in an acceptable manner, for instance due to grave mental problems, mental or physical illness, use of drugs or other substances, abuse of alcohol or lack of professional competence. The same applies in the case of a healthcare practitioner grossly violating his/her professional duties, for instance by issuing wrong or misleading medical certificates, giving a physician's report without examination of the case, issuing wrong or misleading invoices, violating his/her duty of confidentiality, or by gross negligence in his/her work, or other conduct contrary to law.

If the circumstances exist to justify revocation of a licence, [the Medical Director of Health may]¹⁾ restrict the person's licence temporarily. The nature of the restrictions shall be specified, and also their duration and the nature of monitoring.

Procedures in decision-making on revocation or restriction of licences are subject to the provisions of the Public Administration Act.

However, if there is strong evidence to suggest that the criteria for revocation of a licence are met, and that a delay in revocation could entail risk to patients, the Medical Director of Health may revoke the licence of a healthcare practitioner with immediate effect, until a final decision under the first and second paragraphs has been reached. ...¹⁾ Should [the Medical Director of Health]¹⁾ not have made a final decision on revocation of the licence under the first paragraph within three months, the provisional revocation is rescinded.

[The decision of the Medical Director of Health to revoke or restrict a licence may be appealed to the Minister.]¹⁾

Should a healthcare practitioner base his/her right to practise in Iceland on a licence issued in another country, his/her right to practise in Iceland is revoked if his/her licence is revoked in that country.

The right of a healthcare practitioner to practise is revoked if he/she is declared legally incompetent, or if he/she no longer meets the criteria which applied when the right to practise was granted.

[The Directorate of Health is authorised to publish information on the name, date of birth, year of birth and work permit of health workers, including restrictions on work permits of health workers, in order to ensure the safety and quality of health service.]²⁾

¹⁾ Act No. 12/2008, Article 6. ²⁾ Act No. 99/2020, Article 7.

Article 16

Surrender of licence.

A healthcare practitioner can surrender his/her licence by written notification to [the Medical Director of Health].¹⁾ This does not preclude a reprimand under Article 14 where appropriate, nor formal revocation of licence under Article 15, in the case of professional misconduct which may entail revocation.

¹⁾ Act No. 12/2008, Article 7.

Article 17

Re-granting of licence.

[The Medical Director of Health may]¹⁾ grant a licence anew to a healthcare practitioner whose licence has been revoked, or who has surrendered his/her licence, provided that the person in question has demonstrated that he/she meets the criteria of law for re-granting of the licence, and that the reasons which led to the revocation or surrender of the licence no longer apply. [The Medical Director of Health]¹⁾ may determine that the new licence shall be granted on a provisional or restricted basis, *cf.* Article 15.

¹⁾ Act No. 12/2008, Article 8.

SECTION IV

Prescriptions of medicinal, products.

Article 18

Monitoring of prescriptions of medicinal products.

The Medical Director of Health monitors prescriptions for medicinal products in general, and observes developments in use of medicinal products.

The Medical Director of Health shall especially monitor physicians' and dentists' prescriptions for addictive drugs, including their prescriptions for addictive drugs for their own use. The Medical Director of Health shall consult with the Medicines Control Agency with respect to the practice of monitoring of prescriptions for medicinal products. The Medicines Control Agency shall notify the Medical Director of Health if it believes that it has probable cause for special monitoring of prescriptions for a drug, and

especially addictive drugs. The Medical Director's access to data in the pharmaceutical database with respect to monitoring of prescriptions is subject to the provisions of the Pharmaceuticals Act.

Article 19

Revocation of right to prescribe medicinal products.

[Should a physician, dentist, nurse or midwife be found to have prescribed medications in violation of law or government instructions, or in a manner deemed inappropriate, the Medical Director of Health shall reprimand him/her. Should a reprimand from the Medical Director of Health under Article 14 prove ineffective, the Director may decide to revoke his/her licence to prescribe medications, of all kind or in specific categories, if revocation of the licence under Article 15 is not deemed warranted.]¹⁾

The procedure in decision-making on revocation of the right to prescribe medications of any kind or in specific categories is subject to the provisions of the Public Administration Act.

If there is strong evidence to suggest that the criteria for revocation of the right to prescribe are met, and that a delay in revocation could entail risk to patients, the Medical Director of Health may, however, revoke the licence of [physician, dentist, nurse or midwife]¹⁾ with immediate effect, until a final decision under the first paragraph ...²⁾ has been reached. Should [the Medical Director of Health]²⁾ not have made a decision to revoke the right to prescribe under the first paragraph within three months, the provisional revocation is rescinded.

[The decision of the Medical Director of Health to revoke the right to prescribe medicinal products may be appealed to the Minister.]²⁾

¹⁾ Act No. 153/2018, Article 3. ²⁾ Act No. 12/2008, Article 9.

Article 20

Re-granting of right to prescribe.

[The Medical Director of Health may]¹⁾ reverse the revocation under Article 19 of the right to prescribe medications of all kinds or in specific categories, if the person in question has demonstrated that the reasons which led to the revocation no longer apply.

¹⁾ Act No. 12/2008, Article 10.

SECTION V

Various provisions.

Article 21

Notification.

Revocation, surrender or restriction of a professional licence, and revocation of the right to prescribe, and the re-granting of these rights, *cf.* Articles 15-17 and 19 and 20, shall be notified to ...¹⁾ [the Health Insurance Administration],²⁾ the Medicines Control Agency, the employer and others who may be concerned, and also to those States which Iceland is obliged under international law to notify.

¹⁾ Act No. 12/2008, Article 11. ²⁾ Act No. 112/2008, Article 64.

Article 22

Regulations.

[The Minister shall issue a regulation¹⁾ on further implementation of this Act, i.a. which personal data may be processed and which specific measures should be taken to protect fundamental rights and interest of the registered person.]²⁾

¹⁾ Regulation No. 426/1997, *cf.* 886/2013. Regulation No. 1188/2008. Regulation No. 312/2015, *cf.* 386/2015. ²⁾ Act No. 99/2020, Article 8.

Article 23

Entry into force.

This Act takes effect on 1 September 2007.

Article 24

...

[Temporary Provisions.

I.

All positions at the Public Health Institute shall be abolished from 1 May 2011. Staff of the Public Health Institute shall be offered positions at the Directorate of Health from the same time. The provisions of Article 7, Act No. 70/1996 do not apply to appointments under this provision.]¹⁾

¹⁾ *Act No. 28/2011, Article 10.*

[II.

From 1 May 2011 the Directorate of Health takes over the assets of the Public Health Institute and its rights and obligations with regard to the implementation of legislation within the sphere of the Institute at that time.]¹⁾

¹⁾ *Act No. 28/2011, Article 10.*

*[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.]*