

(Translation from German)

Excerpt from the 2005 Health Reform Act, Fed. Law Gaz. I no. 179/2004

Federal Act on the Quality of Health Services (Health Care Quality Act –*Gesundheitsqualitätsgesetz – GQG*)

Objectives and Principles

§ 1. (1) Systematic quality work is to be implemented and intensified in order to provide, secure and improve quality on a full-coverage basis within the Austrian health care system. For the purpose, a sustainable quality system is to be developed, implemented and regularly evaluated throughout Austria, founded on the principles of patient orientation, transparency, effectiveness and efficiency. The quality of health care services must in particular take patient safety into account when the services are being provided.

(2) The Federal Minister of Health and Women must ensure that the work to set up, further develop, ensure and evaluate a full-coverage Austrian quality system is done nationwide, across all provinces, sectors and professions taking into account the levels of structural, procedural and outcome quality in the sense of the quality system.

(3) For purposes of assuring that the principles established in § 1 (1) and (2) are upheld, the Federal Minister of Health and Women must ensure corresponding coordination among all the stakeholders involved in the quality system throughout Austria. Furthermore, the Federal Minister of Health and Women is responsible for ensuring nationwide coordination of quality actions for purposes of national and international comparability of health care services.

(4) Unless required for specific objectives and purposes, personal data needed for continuous quality work must be maintained using pseudonyms at a minimum.

Definitions of Terminology

§ 2. The following definitions apply to the terminology set out below in the sense of this Federal Act:

1. “Quality system:” a Federal coordinating, promoting, supporting and monitoring system for the purpose of continuously improving the quality of health care services.
2. “Quality:” the degree to which patient-oriented, transparent, effective and efficient health care service is achieved. The main concerns in this context include optimising structural, procedural and outcome quality.
3. “Patient orientation:” in the sense of improving the quality of their lives, the persons concerned should be the focus when rendering decisions and taking action; they should be given the opportunity to take part as co-producers in this process of improving the quality of their lives.
4. “Patient safety:” this term refers to measures taken to avoid adverse events which could be injurious to the patients.

5. "Transparency:" clear comprehensibility in reconstruction by documenting, analysing and systematically monitoring the services and results: the basis of continuous and systematic comparisons of improvement in quality.
6. "Effectiveness:" the degree of achievement between a targeted objective and the realisation thereof, whereby the goal set in the health care system is ideally the maintenance and/or restoration of the health of both citizens and patients alike.
7. "Efficiency:" the relationship between the input and the outcome of a service according to the principle of economy, always with a view to keeping costs down.
8. "Structural quality:" the total of material equipment and staff availability expressed in terms of quantity and quality.
9. "Procedural quality:" work sequences and procedures carried out systematically according to reconstructable and reviewable rules and according to the state of professional knowledge, regularly evaluated and continuously improved.
10. "Outcome quality:" measurable changes of a patient's or group of people's professionally estimated state of health, quality of life and patient satisfaction as the result of specific framework conditions and action.
11. "Health care service:" any act performed by a member of a legally recognised health care profession on or for a person for the purpose of promoting, maintaining, restoring or improving his/her physical or mental state of health.
12. "Quality standards:" describable regularities and/or provisions regarding equipment, procedures and comportment.
13. "Federal quality directives:" standards decreed via ordinance by the Federal Minister of Health and Women which are therefore binding.
14. "Federal quality guidelines:" standards recommended as an aid to orientation by the Federal Minister of Health and Women.
15. "Quality indicator:" a measurable value in which the quality of a health care service can be observed, compared and evaluated.
16. "Reference value, reference scope:" a reference scope is the interval within which the character of a quality indicator is defined as good or normal. A reference value is a reference scope the upper and lower limits of which coincide.
17. "Basic principles of health promotion in performing health care services:" health promotion has as its objective a process enabling people to determine and improve their own health to a high degree.

Scope of Applicability

§ 3. (1) The provisions set out in this Act are to be complied with when performing health care services, irrespective of the performer's organisational form. The health care services must conform to the provisions as based on this Act and the respective acknowledged state of scientific knowledge and experience. They must also be performed with the professionally requisite quality and in a health promoting environment.

(2) Transparency vis a vis patients regarding structural, procedural and outcome quality must be ensured upon their request when performing health care services.

Quality Standards

§ 4. (1) The Federal Minister of Health and Women can support the development of quality standards for performing specific health care services, by including the respective parties involved, in particular the relevant health care professions and the patients.

(2) In connection with performing health care services, the Federal Minister of Health and Women can recommend quality standards as Federal quality guidelines or decree ordinances on Federal quality directives, with particular attention paid to

1. nationwide uniformity,
2. consideration of an approach across all sectors and professions,
3. patient orientation,
4. basic principles of health promotion,
5. transparency,
6. current state of knowledge and experience as regards effectiveness and efficiency.

The Federal quality standards include provisions on one or more of the dimensions of quality work set out in § 5 (structural, procedural and outcome quality). To put the Federal quality directives into action, the Federation can stipulate both binding and non-binding instruments which can be replaced by other equivalent measures, provided that the requirements are provably met.

(3) Quality indicators may be coupled to Federal quality directives and Federal quality guidelines; the indicators' contents also constitute elements of Austrian quality reporting. International comparability must be kept in mind when developing quality indicators.

Dimensions of Quality Work

§ 5. (1) The Federal Minister of Health and Women must ensure that the quality provisions on performing health care services in the sense of systematic quality work take into account structural, procedural and outcome quality, whereby the development of corresponding methodical work and the reporting and documentation requirements must be kept in mind. These provisions must take international developments into consideration.

(2) In the field of structural quality, the Federal Minister of Health and Women must develop binding structural quality criteria for the performance of health care services. These criteria must be complied with when performing health care services irrespective of the organisational form in which they are performed. The Federal Minister of Health and Women is to stipulate corresponding reporting duties in this regard.

(3) In the field of procedural quality, the Federal Minister of Health and Women must work out binding requirements and provide support by making appropriate instruments available. The Federal Minister of Health and Women must ensure that indicators of procedural quality and reporting duties regarding these procedural quality indicators are stipulated, inter alia within the framework of Austrian quality reporting.

(4) In the field of outcome quality, the Federal Minister of Health and Women must ensure that indicators and reference scopes regarding outcome quality and corresponding reporting duties are stipulated, inter alia within the framework of Austrian quality reporting.

Quality Reporting

§ 6. (1) With regard to setting up, further developing, securing and evaluating a full-coverage Austrian quality system, the Federal Minister of Health and Women must issue provisions on establishing nationwide quality reporting across all provinces, sectors and professions. The requisite documentation and data reporting in this regard must be in accordance with the following principles:

1. to specify and record the data necessary in order to verify compliance with the provisions set out in this Federal Act,
2. to ensure the nationwide recording of the data relevant to monitoring the quality of the Austrian health care system,
3. to keep administrative expenditures for documenting and reporting down and to apply existing documentation to the greatest extent possible.

(2) The Federal Minister of Health and Women can issue ordinances establishing more detailed provisions concerning documentation and/or quality reporting, in particular

1. the scope, quality and flow of data,
2. times of reporting,
3. time periods for reporting and
4. establishing the parties responsible for documentation, data and quality reporting.
The provisions set out in § 6 (1) in particular are to be kept in mind.

(3) In the interest of increased transparency, the Federal Minister of Health and Women must announce the intensity of the stakeholders' participation in the Austrian quality system to the interested public in a suitable manner. The Minister of Health and Women must furthermore ensure that corresponding feedback report systems are set up for the parties participating in quality reporting.

Promotional Measures and Incentive Mechanisms

§ 7. The Federal Minister of Health and Women can support the development of promotional measures and incentive mechanisms within the framework of quality work. The Minister of Health and Women can also establish promotional measures and incentive schemes him/herself to promote sustainable improvement and assurance of the quality of health care services.

Control

§ 8. (1) In connection with securing and improving the quality of health care services, the Federal Minister of Health and Women must establish a nationwide arrangement of monitoring and controlling. The system shall comprise at a minimum

1. verifying participation in Austrian quality reporting,
2. verifying the implementation of Federal quality directives and
3. evaluating the implementation and application of Federal quality guidelines or equivalent instruments.

(2) The Federal Minister of Health and Women must ensure complementary external controls on quality work within the health care system. For these purposes, the Federal Minister of Health and Women and his/her authorized agents, organisations and authorities have the right to request information and reports, inspect all documentation relevant to quality work (including data quality), and to carry out on-site investigations if necessary to perform the duties for which he/she is responsible. The agents, organisations and authorities performing such inspections are to be provided with copies of the documentation at no charge. Other mandatory observation and controlling duties and rights based on other legal provisions are not affected thereby.

Support from the Federal Institute for Quality in the Health Care System

§ 9. (1) A Federal Institute for Quality in the Health Care System is to be set up. The Federal Minister of Health and Women can avail him/herself of the services of this Institute in the course of performing his/her duties on the basis of this Act.

(2) The Institute will be responsible for the following work in particular, taking into consideration the aspects of a nationwide uniformity, an approach across all provinces, sectors and professions, patient orientation, transparency, effectiveness and efficiency and acting in accordance with international standards:

1. participating in the preparation of general provisions and principles regarding
 - a) standard development of structural, procedural and outcome quality,
 - b) documentation and quality reporting,
 - c) promotional measures and incentive mechanisms,
 - d) performing controls as set out in § 8 (1),
2. verifying, recommending and working out quality standards which the Federal Minister of Health and Women can decree (Federal quality directives) or recommend as an aid to orientation (Federal quality guidelines),
3. preparing an annual quality report,
4. implementing and participating in setting up promotional measures and incentive mechanisms,
5. implementing and participating in controlling compliance with the provisions set out in this Act and other ordinances or provisions issued on the basis thereof,
6. supporting the Federal Minister of Health and Women in coordinating nationwide quality measures for purposes of national and international comparability of the health care services.

Penalties

§ 10. (1) Anyone who, in performing health care services, acts in contravention to Federal quality directives made binding by virtue of this Act, commits a breach of administrative regulations and is liable to an administrative penalty of up to EUR 10.000,-- and, upon repeated commissions, up to EUR 20.000,--, unless the offence is punishable in a court of law.

(2) Anyone who fails to comply with the regulations on quality reporting or on documentation commits a breach of administrative regulations and is liable to an administrative penalty of up to EUR 3.000,-- and, upon repeated commissions, up to EUR 5.000,--.

(3) Anyone obstructing the controlling rights of the Federal Minister of Health and Women, as set out in § 8 (2), second and third sentence, or those of agents, organisations or authorities authorized by the Minister of Health and Women, commits a breach of administrative regulations and is liable to an administrative penalty of up to EUR 5.000,-- and, upon repeated commissions, up to EUR 7.000,--.

(4) The Federal Minister of Health and Women is to be informed of punished breaches of administrative regulations.

Final Provisions, Entry into Force

§ 11. (1) The Federal Minister of Health and Women is responsible for enforcing this Act.

(2) With the exception of § 10, this Act enters into force on January 1, 2005. § 10 enters into force on January 1, 2006.