

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

Federal Law Gazette I No. 179/2004 (NR: GP XXII RV 693 AB 711 p. 90. BR: AB 7175 p. 717.)

### Amendments

Federal Law Gazette I No. 81/2013 (National Council: GP XXIV RV 2243 AB 2255 p. 200. Federal Council: AB 8961 p. 820.)

Federal Law Gazette I No. 191/2023 (NR: GP XXVII RV 2310 AB 2362 p. 243. BR: AB 11388 p. 962.)

### **Objectives and principles**

#### Section 1.

(1) In order to ensure and improve quality across the Austrian healthcare system, systematic quality work must be implemented and intensified. The work to establish, further develop, ensure and evaluate a comprehensive Austrian quality system must be carried out uniformly across the federal provinces, sectors and professions, including in particular the outpatient sector. It must take into account the principles of patient orientation and transparency and promote and ensure the quality of healthcare services in a sustainable manner, taking into account patient safety.

(2) The specifications for the quality system must in any case also comply with the requirements of target-based healthcare management in accordance with the Federal Act on partnership-based Target Management in Health Care, Federal Law Gazette I No. 81/2013, as amended, and in particular with the monitoring provided for therein. Quality work must make a significant contribution to the medium to long-term increase in the effectiveness and efficiency of the healthcare system and thus contribute to improving healthcare for the population and its long-term financial viability. In this context, the levels of structural, process and outcome quality must be taken into account in accordance with the quality system.

(3) For the purpose of ensuring the principles laid down in subsections 1 and 2, the Federal Minister of Health shall ensure that the actors involved in the Austria-wide quality system are coordinated accordingly. In addition, the Federal Minister of Health shall ensure the nationwide coordination of quality measures for the purpose of national and international comparability of health services.

(4) The data required for continuous quality work must, unless it is needed for specific purposes and objectives relating to individuals, be at least pseudonymised by means of a trust centre.

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(5) For the strategic restructuring and further development of cross-sector quality assurance and quality control in the health sector, the Federal Minister responsible for health care shall ensure appropriate coordination between the actors involved in the Austrian quality system, in particular the federal provinces and social insurance institutions.

(6) To this end, a quality council comprising members of the federal provinces, social insurance institutions and the federal government shall be established within the framework of the target management committees. The quality council shall take strategic decisions on the establishment, possible expansion and implementation of quality assurance.

### **Definitions**

Section 2. For the purposes of this federal law, the following terms shall have the following meanings:

1. 'Quality system': This refers to a federal coordination, promotion, support and monitoring system with the aim of continuously improving the quality of healthcare services.
2. 'Quality': Degree of fulfilment of the characteristics of patient-oriented, transparent, effective and efficient healthcare provision. The central concerns in this context are the optimisation of structural quality, process quality and outcome quality.
3. 'Patient orientation': In order to improve quality of life, the people affected should be at the centre of decisions and actions and be empowered to actively participate in decision-making processes.
4. 'Patient safety': This includes measures to prevent adverse events that could cause harm to the patient.
5. 'Transparency': Traceability through documentation and analysis of services and results and their systematic review; basis for continuous and systematic comparisons for quality improvement.
6. 'Effectiveness': Degree of target achievement between a set target and its realisation, whereby the target set in healthcare is ideally the maintenance or restoration of the health of citizens and patients.
7. 'Efficiency': Ratio between the input and the result of a service according to the principle of economic efficiency, taking cost containment into account.
8. 'Structural quality': The sum of material and human resources in quantitative and qualitative terms.
9. 'Process quality': Workflows and procedures that are systematised according to comprehensible and verifiable rules, correspond to the state of professional knowledge, are regularly evaluated and continuously improved.

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10. 'Outcome quality': Measurable changes in the professionally assessed state of health, quality of life and satisfaction of a patient or population group as a result of certain framework conditions and measures.
11. 'Healthcare service': Any action performed on or for a person by a member of a legally recognised healthcare profession or a legally authorised organisation that serves to promote, preserve, restore or improve physical and mental health.
12. 'Quality standards': Describable regularities or specifications regarding equipment, procedures or behaviour.
13. 'Federal quality directives': Standards issued by the Federal Minister of Health as regulation and thus made binding.
14. 'Federal quality guidelines': Standards recommended by the Federal Minister of Health as guidance.
15. 'Quality indicator': A measurable variable that is suitable for observing, comparing and evaluating the quality of healthcare services.
16. 'Reference value, reference range': A reference range is the interval within which the value of a quality indicator is defined as good or normal. A reference value is a reference range whose upper and lower limits coincide.
17. 'Basic principles of health promotion' in the context of the provision of healthcare services: Health promotion aims to enable people to exercise a high degree of self-determination over their health and to empower them to improve their health.

### **Scope**

#### Section 3.

(1) Healthcare providers, regardless of their organisational form, are required

1. to comply with the quality standards in accordance with this federal law and
2. to participate in nationwide quality assurance measures in accordance with Section 7 (2) of the Federal Law on Partnership-Based Target Management in Health Care, Federal Law Gazette I No. 81/2013, as amended.

Health services must comply with the requirements of this law and the recognised state of scientific knowledge and experience, and must be provided in a professionally appropriate quality and in a health-promoting environment.

(2) When providing healthcare services, transparency regarding structural, process and outcome quality must be guaranteed to patients upon request.

(3) The reimbursement of individual services within the public health system by social insurance institutions, the provincial health funds and the private hospital financing fund requires compliance with essential quality standards that are directly relevant to patient safety and treatment success. These include, in particular, those based on this federal law, those based on Section 7 (3) and (4) of the Federal Law on Partnership-

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Based Target Management in Health Care and in accordance with Section 117c (1) (5) of the Medical Practitioners Act 1998, Federal Law Gazette I No. 169/1998, as amended, as well as participation in measures for measuring and ensuring the quality of results in accordance with Section 7 (2) of the Federal Act on Partnership-Based Target Management in Health Care.

### **Quality standards**

#### Section 4

(1) The Federal Minister of Health may support the development of quality standards for the provision of certain health services with the involvement of the parties concerned, in particular the relevant health professions and patients.

(2) The Federal Minister of Health may recommend quality standards in connection with the provision of health services as federal quality guidelines or issue them as federal quality directives by means of a regulation, paying particular attention to the following:

1. Federal uniformity,
2. Consideration of a cross-sectoral and interprofessional approach,
3. Patient orientation,
4. Basic principles of health promotion,
5. Transparency,
6. State of the art in science and experience with regard to effectiveness and efficiency.

The federal quality standards contain specifications for one or more of the dimensions of quality work specified in Section 5 (structural, process or outcome quality). In order to implement the federal quality directives, the federal government may provide for non-binding instruments in addition to binding instruments, which may be replaced by equivalent measures if compliance with the requirements can be proven.

(3) To federal quality guidelines or federal quality directives quality indicators may be linked, their contents also constitute elements of Austrian quality reporting. When developing quality indicators, international comparability must be taken into account.

### **Dimensions of quality work**

#### Section 5.

(1) The Federal Minister of Health shall ensure that the quality requirements for the provision of health services in the sense of systematic quality work take into account structural, process and outcome quality. Structural, process and outcome quality must be in direct and balanced proportion to each other, with the development and further development of outcome quality indicators and their measurement in all

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sectors of the health care system being a priority. These requirements must also be implemented in accordance with the objectives of the target management in healthcare, taking into account existing reporting and documentation requirements as well as international developments.

(2) In the area of structural quality, the Federal Minister of Health shall develop binding structural quality criteria for the provision of healthcare services. These structural quality criteria must be complied with in the provision of healthcare services, regardless of the organisational form in which they are provided. The Federal Minister of Health shall specify the corresponding reporting requirements.

(3) In the area of process quality, the Federal Minister of Health shall develop binding requirements and ensure support by providing suitable instruments. The Federal Minister of Health shall ensure that indicators for process quality and reporting obligations for these process quality indicators are defined, among others within the framework of Austrian quality reporting.

(4) In the area of outcome quality, the Federal Minister of Health shall ensure that indicators and benchmarks for outcome quality and corresponding reporting requirements are defined, among others within the framework of Austrian quality reporting.

(5) In order to develop recommendations for the design and regular adaptation of the regulation in accordance with Section 9b, the Federal Minister responsible for health care may make use of the Federal Institute for Quality in Health Care (BIQG) in accordance with Section 9.

### **Quality reporting**

#### Section 6.

(1) With regard to the establishment, further development, safeguarding and evaluation of a comprehensive Austrian quality system, the Federal Minister of Health shall issue guidelines for the establishment of a uniform, cross-provincial, cross-professional and cross-sectoral quality reporting system. In particular, regular reports on the quality of results in the inpatient and outpatient sectors shall be prepared, beginning in 2014. The following principles shall be observed for the documentation and data reporting required in this regard:

1. Determination and collection of the data necessary to verify compliance with the requirements of this federal law;
2. Ensuring the Austria-wide collection of data relevant for monitoring the quality of the Austrian healthcare system;
3. Minimising the administrative burden of documentation and quality reporting and incorporating existing documentation as far as possible.

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(2) The Federal Minister of Health may lay down more detailed provisions regarding documentation and quality reporting by means of a regulation. These include in particular:

1. Data scope, data quality, data flow,
2. Reporting date,
3. Reporting period and
4. Determination of those obliged to provide documentation, data reporting and quality reporting.

In doing so, particular attention shall be paid to the requirements specified in subsection 1.

(3) In the interests of transparency, the Federal Minister of Health shall publish the reports on the Austrian quality system in a suitable form. He/she shall also ensure that appropriate feedback systems are set up for those obliged to provide quality reporting.

### **Support measures and incentive mechanisms**

Section 7.

The Federal Minister of Health may support the development of support measures and incentive mechanisms in the area of quality work. The Federal Minister of Health may also implement support measures and incentive mechanisms to sustainably improve or ensure the quality of health services.

### **Control**

Section 8.

(1) The Federal Minister of Health shall ensure nationwide monitoring and control in connection with securing and improving the quality of health services. This shall include at least

1. reviewing participation in Austrian quality reporting,
2. reviewing the implementation of federal quality directives,
3. evaluating the implementation or application of federal quality guidelines or the use of equivalent instruments, and
4. quality assurance of the professional practice of healthcare providers, in particular doctors, but not in the area of continuing education, with regard to the overriding interests of the general public by means of
  - a) developing and implementing quality assurance measures to improve the structural quality, processes quality and outcome quality, in particular to measure and ensure the outcome quality in the outpatient sector in accordance with Section 7 of the Federal Act on Partnership-Based Target Management in Health Care (G-ZG),

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Federal Law Gazette I No. 26/2017, last amended by Federal Law Gazette I No. 191/2023,

b) quality evaluation with the exception of self-evaluation in accordance with Section 49 (2a) of the Medical Practitioners Act 1998 (ÄrzteG 1998), Federal Law Gazette I No. 169/1998, as amended by Federal Law Gazette I No. 108/2023,

c) Quality control and

d) Maintenance of a quality control register.

The Federal Minister of Health may make use of the BIQG for this purpose.

(2) The Federal Minister of Health shall ensure that accompanying external controls are carried out on quality work in the health care system. To this end, the Federal Minister of Health and the persons, institutions and authorities appointed by him/her shall have the right to request information and reports, to inspect all documents relevant to quality work, including data quality, and, if necessary, to carry out on-site surveys, insofar as this is necessary for the performance of his/her duties. Copies of the documents inspected shall be made available free of charge to the persons, institutions and authorities inspecting them. Other obligations or rights concerning observation and control based on other legal provisions remain unaffected.

(3) The Austrian Medical Association shall implement quality assurance measures within its own sphere of activity to ensure the quality of medical practice, insofar as these are in the overriding interest of doctors (self-evaluation in accordance with Section 49 (2a) of the Medical Practitioners Act 1998), whereby it may make use of the Austrian Society for Quality Assurance & Quality Management in Medicine GmbH (ÖQMed) as an auxiliary body in the performance of its tasks.

### **Procedural principles for evaluation and control**

Section 8a.

(1) Quality assurance and quality control of healthcare providers must be carried out systematically, both in the intramural and extramural sectors. Unless a shorter interval is specified in the regulation pursuant to Sect. 9b, the BIQG shall carry out an evaluation of outpatient healthcare providers, in particular outpatient doctors, including group practices, every five years and, if necessary, with the involvement of the Evaluation Advisory Board pursuant to Sect. 9c. The BIQG shall verify the results of the self-evaluation on a random basis by visiting the medical practices and premises and locations. Irrespective of the visits to the medical practices and premises and locations initiated by the self-evaluation, the BIQG shall also carry out such visits on the basis of justified suggestions from

1. the Federal Minister responsible for health care and other authorities,
2. the Austrian Medical Association,
3. the medical associations in the federal provinces,

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4. the social insurance institutions,
5. the Federation of social insurance institutions, and
6. the representative of patient interests (specific evaluation).

(2) If a deficiency is identified during the evaluation pursuant to subsection 1, the BIQG shall request the doctor or group practice to remedy the deficiency, if necessary setting an appropriate deadline. If necessary, the rectification of deficiencies shall also be monitored by visits to the medical practices and the premises and locations of group practices in accordance with subsection 3, in particular if, in connection with the monitoring, contract termination proceedings are envisaged due to deficiencies in process and/or structural quality. If the order to remedy the deficiency is not complied with, the BIQG shall immediately file a disciplinary complaint with the disciplinary lawyer of the Austrian Medical Association. If a deficiency concerns hygiene requirements pursuant to Section 56 (1) Par.1 of the Medical Practitioners Act 1998, the BIQG shall also immediately notify the competent district administrative authority in writing.

(3) A representative of patient interests and of the social insurance may be involved in random checks, specific evaluations, checks in the course of identifying deficiencies and checks on the rectification of deficiencies, and has the right to participate in on-site inspections, visits to medical practices and the premises and locations of group practices. In the case of inspections and evaluations of outpatient doctors, ÖQMed also has the right to participate.

(4) ÖQMed must carry out a self-evaluation using subject-specific evaluation forms and electronic data transmission in accordance with the technical equipment available, and must transmit the evaluation forms and the results of the self-evaluation to the BIQG electronically in a suitable form. ÖQMed is entitled to process and store the self-evaluation forms and the results of the evaluation and inspection for transmission to the BIQG. The stored data must be deleted after 15 years.

(5) The self-evaluation forms and the results of the evaluation and control shall be entered into a quality control register by the BIQG and stored. The stored data shall be deleted after 15 years.

(6) The results of the evaluation and control shall be made available in anonymised form to the Federal Minister responsible for health care.

### **Support from the Federal Institute for Quality in Healthcare**

#### **Section 9.**

(1) A 'Federal Institute for Quality in Healthcare' shall be established. The Federal Minister of Health may make use of this 'Federal Institute for Quality in Healthcare' in the performance of his or her duties under this Act.

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(2) Taking into account federal uniformity, a cross-state, cross-sector and cross-professional approach, patient orientation, transparency, effectiveness, efficiency and international standards, this institute shall perform the following tasks in particular:

1. Participation in the development of general guidelines and principles
    - a) for the development of standards in the area of structural, process and outcome quality,
    - b) for documentation concerning quality reporting and for quality reporting,
    - c) for support measures and incentive mechanisms,
    - d) for monitoring in accordance with Section 8 (1);
  2. Reviewing, recommending and developing quality standards that can be issued by the Federal Minister of Health as regulation (federal quality directives) or recommended as guidance (federal quality guidelines);
  3. Preparing quality reports;
  4. Implementing or participating in the establishment of support measures and incentive mechanisms;
  5. Implementing or participating in the monitoring of compliance with the provisions of this Act and the ordinances or other requirements issued on the basis of this Act;
  6. Supporting the Federal Minister of Health in the nationwide coordination of quality measures for the purpose of national and international comparability of health services;
  7. Quality assurance and quality control of healthcare providers, in particular doctors, with the exception of self-evaluation in accordance with Section 49 (2a) of the Medical Practitioners Act 1998 and continuing education, with regard to the overriding interests of the general public.
- (3) The BIQG may call upon experts with the appropriate professional qualifications to perform the tasks arising from this federal law.

### **Scientific Advisory Board**

#### Section 9a.

(1) The Federal Minister responsible for health care shall establish a commission in accordance with Section 8 of the Federal Ministries Act 1986 (BMG), Federal Law Gazette No. 76/1986, as amended by Federal Law Gazette I No. 98/2022, to advise on matters of quality assurance, in any case involving representatives

1. the federal government
2. the federal provinces
3. the Federation of social insurance institutions

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4. the Austrian Health Insurance Fund
5. the Social Insurance Institution for the Self-Employed,
6. the Insurance Institution for Public Servants, Railways and Mining,
7. the Austrian Medical Association,
8. the medical universities or universities with a medical faculty, and other providers of medical training institutions in accordance with Sections 9 and 10 of the Medical Practitioners Act 1998,
9. the Professional Association of Private Hospitals and Health Resorts, and
10. the Patient Advocacy Service.

In addition to the representatives mentioned in Par. 1 to 10, representatives of other health professions and institutions may also be included, depending on the topic.

(2) The Scientific Advisory Board shall advise the BIQG and the Federal Minister responsible for health care in the performance of their statutory tasks in quality assurance in the areas of the outpatient sector, inpatient care and the interface between these two sectors.

(3) The Scientific Advisory Board shall not be prevented from meeting by the failure to appoint representatives.

(4) The chair of the Scientific Advisory Board shall be appointed by the Federal Minister responsible for health care.

(5) In the event of a tie, the chair shall have the casting vote (right of casting vote).

(6) The costs of participation of the members of the Scientific Advisory Board shall be borne by the delegating institutions themselves.

(7) The tasks of the Scientific Advisory Board pursuant to subsection 1 shall include, in particular, the formulation of recommendations for the provision of health care services

1. in the outpatient sector and

2. in hospitals, in particular in hospitals operating as independent outpatient clinics, and

3. at the interface between these two sectors with regard to the content of the quality criteria and the process of quality evaluation and quality control.

(8) The Federal Minister responsible for health care shall establish further modalities, in particular with regard to decision-making, in rules of procedure.

### **Regulation on quality assurance in health care**

#### **Section 9b.**

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(1) After consulting the Scientific Advisory Board and on the basis of its recommendation, the Federal Minister responsible for health care shall, after consulting the Federal Chamber of outpatient doctors, decree by regulation

1. the criteria to be evaluated,
2. the procedure for evaluation and control by the BIQG in accordance with the procedural principles of Section 8a, and
3. the quality control register to be maintained by the BIQG

for a period of five years. The period of validity of the regulation for the first period ends on 31 December 2027.

Section 9c.

(1) The BIQG shall establish an Evaluation Advisory Board. On the basis of the Quality Assurance Regulation (Section 9b), the Evaluation Advisory Board shall support the BIQG in the planning, implementation and practical application of evaluation and control, and, where appropriate, in the assessment of individual evaluation results. The Evaluation Advisory Board shall adopt rules of procedure to ensure the fulfilment of the tasks assigned to it.

(2) The Evaluation Advisory Board shall comprise representatives

1. of the Federal Ministry responsible for health care,
2. of the Austrian Medical Association,
3. the federal provinces, appointed by the liaison office of the federal provinces,
4. the Federation of social insurance institutions,
5. the Austrian Health Insurance Fund,
6. the Social Insurance Institution for the Self-Employed,
7. the Insurance Institution for Public Servants, Railways and Mining,
8. the Federal Institute for Quality in Healthcare ,
9. the Federal Chamber of Labour, and
10. the Professional Association of Private Hospitals and Health Resorts.

The Evaluation Advisory Board also includes an expert with experience in the field of representing patient interests. This expert is appointed by the Federal Minister responsible for health care. In addition to the representatives mentioned in Par. 1 to 10, representatives of other health professions and institutions may also be included, depending on the topic.

(3) The chair shall be determined by the Federal Minister responsible for health care.

(4) The Evaluation Advisory Board shall not be prevented from meeting by the failure to appoint a representative.

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(5) In the event of a tie, the chair shall have the casting vote (right of casting vote).

(6) The costs of participation by the members of the plenary and the evaluation committees shall be borne by the delegating institutions.

### **Penal provisions**

#### Section 10.

(1) Anyone who, in the provision of health services, contravenes a federal quality directive made binding under this Act shall, unless a criminal offence has been committed, be guilty of an administrative offence and shall be punished with an administrative fine of up to €10,000, or up to €20,000 in the event of a repeat offence.

(2) Anyone who fails to comply with the provisions on quality reporting or documentation commits an administrative offence and shall be punished with an administrative fine of up to €3,000, or up to €5,000 in the event of a repeat offence.

(3) Anyone who obstructs the control rights of the Federal Minister of Health pursuant to Section 8 (2), second and third sentences, or of the persons, institutions or authorities commissioned by him/her, commits an administrative offence and shall be punished with an administrative fine of up to €5,000, or up to €7,000 in the event of a repeat offence.

(4) The Federal Minister of Health shall be notified of any administrative offences that are punished.

### **Final provisions and provisions on entry into force**

#### Section 11.

(1) The Federal Minister of Health shall be responsible for the implementation of this Federal Act.

(2) With the exception of Section 10, this federal law shall enter into force on 1 January 2005. Section 10 shall enter into force on 1 January 2006.

(3) Sec. 1 (5) and (6), Sec. 5 (5), Sec. 8 (1) and (3), Section 8a including heading, Section 9 (2) and (3) and Sect. 9a to 9c including headings, as amended by Federal Law BGBl. I No. 191/2023, shall enter into force on 1 January 2024.