

(Translation from German)

Commentary on the Health Care Quality Act [Gesundheitsqualitätsgesetz]

Introductory page to the Health Care Quality Act

Problem:

1. At the present time, there is neither a pan-Austrian quality system nor is quality work including all provinces in the health care system. Provisions on quality and/or quality assurance in the health care system are isolated and scattered throughout the most widely varying legal statutes.

2. Although providing health care services for the person concerned can involve greater or lesser risk, at the present time the provisions on the quality to be maintained when performing these services are scarcely transparent.

Objective:

1. To intensify quality work and implement a quality system including all provinces and across all sectors to improve and assure quality within the health care system.

2. To make it possible to bind the provision of health care services to compliance with Federal quality standards.

Content:

1. Developing, implementing and continuously developing a nationwide Austrian quality system based on the principles of patient orientation, transparency, effectiveness and efficiency.

2. Making compliance with specific provisions mandatory when performing health care services to improve and assure quality within the health care system.

Otherwise:

Maintaining the current situation can result in the mid-to-long term in the impossibility of sustaining quality on a high level in the Austrian health care system; on the other hand, the eventuality cannot be ruled out that the quality level in the provinces and/or various sectors of the health care system will drift apart.

Effects on employment and the Austrian economic situation:

The desired intensification of quality work and creation of a “Federal Institute for Quality in the Health Care System” can have a positive effect on employment.

Financial effects:

Attention is drawn to the financial commentary

Relation to the European Union legal statutes:

According to Art. 152 of the EC Treaty, the European Union has no competence as regards the organisation and provision of health care services. Thus, it is not competent under the title of “public health” to give provisions on quality in health facilities and services. On the

other hand, the European Union does indeed influence the health care systems under the title of other areas of competence (e.g. in connection with the domestic market). Thus, for instance, there are binding EU norms on quality standards for pharmaceuticals, medicinal products, blood and blood products, as well as on mutual recognition of professional diplomas in health care professions. The developments must be taken into consideration when redesigning the present Act in future.

Peculiarities of the legislative procedure:

None.

Commentary on the Health Care Quality Act

General Section

Main aspects of the draft:

The present draft Act is intended to assure high-quality, effective, efficient, freely accessible and consistent health care in Austria. Accordingly, a quality system is to be introduced for the Austrian health care system which is nationwide across all sectors and which increases efficiency. Nationwide quality projects have been initiated and advancing nationwide since the early 1990s. Many of these activities came about in response to health care policy requirements at the time; they include projects on the topics of quality reporting, patient safety and avoiding adverse events, structural quality criteria, optimising the use of antibiotics and the use of blood components, patient orientation, interface management, hygiene, outcome quality and quality assurance in microbiological diagnosis. A number of experts in the branch supported these projects and guided them with their scientific knowledge. The contents and results of these projects and actions contribute to developing rules uniform nationwide, including all professions and across all sectors towards developing and realising full-coverage quality reporting for the entire country.

Furthermore, the government programme provides that quality assurance and standards are legally regulated on the Federal level to assure a uniform nationwide framework.

Corresponding to the provisions and actions described above, the present draft Act bindingly prescribes the implementation of a nationwide Austrian quality system and compliance with quality provisions in performing health care services.

A legal link is required in order to develop in a structured manner the manifold topics of quality taken up in the past years. The link should secure an overall strategic procedure on the one hand and, on the other, direct the approach of voluntarily participating in quality activities more strongly in the direction of mandatory quality work. This draft of a Federal Act on the quality of health care services will secure the new framework conditions. It indicates the fundamental (coordinating) duties the Federation will perform to create a nationwide quality system in the Austrian health care system and to secure the quality of health care services. The draft Act is a rational addition to the provisions already extant regarding quality. At present, about 50 Federal norms contain provisions relating to quality; they regard mandatory documentation, the quality of pharmaceuticals and medicinal

products, the quality of training and practising health care professions, patients' rights and quality work in the hospital sector.

The Act's key points concern provisions on quality in performing health care services and the appurtenant development of standards, the structural, procedural and outcome quality as dimensions of quality work and of an entire quality system, quality reporting, promotional measures and incentive mechanisms in quality work. Furthermore, it regulates that the Federal Minister can avail him/herself of scientific input with the assurance of corresponding resources in performing his/her duties.

Financial effects:

1. Funding will be needed to develop, implement and evaluate a nationwide Austrian quality system. Nothing conclusive can be said on the amount of funding required since, on the Federation's part, future quality standards made binding are already a reality and are functioning in some areas whereas, in other areas, they still need putting into action. It will be necessary regarding many areas of quality not yet extensively processed to work out new fields of activity, which will require additional material and personnel expenditures. Fundamentally, it should be emphasised that the approaches in the individual provinces and/or sectors differ widely in their scope. According to tendency, though, we can assume that, in the course of initial implementation, more funding will be needed than for the ongoing further developments and that actions to improve quality will lower costs in the mid-to-long term.

2. The funding required in connection with documentation and quality reporting cannot be determined until the details have been established via ordinance. Some requirements can already be managed on the basis of existing data and information systems with relatively little material and personnel expenditure. A nationwide project is currently underway within the framework of which the costs of expedient documentation and quality reporting are to be determined, among other things. At all events, these costs are to be kept as low as possible, e.g. by including existing documentation and/or data.

3. Only slight expenses are initially reckoned with in this area, since specific means of promotional measures and incentive mechanisms have yet to be developed.

4. As shown in a study by the SOLVE Consulting Company on hospitals financed by provincial funds, the costs incurred through putting into action the structure-quality criteria already in force today lie within acceptable limits.

5. Costs of approx. two million euros are estimated in the set-up phase, based on what is known to date and in connection with the Federal Institute for Quality in the Health Care System. The costs of full operation depend on the future focus of the work (e.g. standards, incentive mechanisms, monitoring, etc.). The estimated costs in this area are among the lowest in comparison to similar quality-developing organisations in other EU countries.

Basis for competence:

The present draft is based on Art. 10 Par. 1 Fig. 12 of the Federal Constitution Act [*Bundes-Verfassungsgesetz*] (health care system). According to long-standing judicature of the Constitutional Court of Justice, this circumstance of competence comprises “measures to avert risks for the populace’s general state of health (board of health) – unless a typical variety of such risk is being combated for a specific competence matter alone” (comp. *Sammlung der Erkenntnisse und wichtigsten Beschlüsse des Verfassungsgerichtshofes* [“Collection of Findings and Most Important Rulings of the Constitutional Court of Justice“], 3650, 4609, 782, 8035).

According to H. Mayer, this covers

- general protection of human health and life from injury through ionising radiation or
- combating infectious diseases (recovery, healing, payments to the ill, protection of other persons), including, for example, the AIDS Act, the Venereal Diseases Act and the Tuberculosis Act.

This draft Federal Act creates the basis for establishing quality standards in providing health care services, i.e. the medicinal, therapeutic and nursing care of patients, including quality standards for nursing procedures. These quality standards are to link exclusively to the respective health care service and apply irrespective of the person providing them and/or within which organisational form they are provided.

Article 5b (quality assurance), adopted in 1993 into the Hospital and Health-Cure Institutes Act [*Krankenanstalten- und Kuranstaltengesetz*] contains fundamental legal organisational provisions exclusively, corresponding to the competence matter of “convalescent and nursing institutes” in accordance with Art. 12 of the Federal Constitution Act. Thus, according to Par. 1, for example, the provincial legislature must instruct the organisations responsible for hospitals to undertake measures to secure quality within the organisation’s framework. Furthermore, Par. 4 regulates that every hospital with inpatient facilities must set up a quality-assurance committee. By contrast, the present draft tends neither toward prescribing a specific quality system for the health care service providers, nor toward exerting influence on their internal organisation. The intention is rather to assure the maintenance of the same specific level of quality throughout Austria in providing health care services.

It would be conceivable, for instance, to perform an MR test within the framework of quality standards for providing specific medical services in the sense of “state of the art.” This standard can be met either by the service providers keeping an MR machine themselves or by ensuring that the machine is available in another manner, such as by making contractual arrangements for the purpose. Thus, prescribing this standard on the basis of the present draft Act entails no interference in the service providers’ internal organisation.

In the sense of the Constitutional Court of Justice finding dated December 10, 1959 (“Collection of Findings and Most Important Rulings of the Constitutional Court of Justice“, 3650), risks pertaining to the populace’s general state of health are to be allocated to the

“health care system” matter if they are not a variety of the risks typically belonging to other administrative matters. Fundamentally, every health care service involves greater or lesser risk for the party being treated, irrespective of the person providing them and/or within which organisational form they are provided. The state of health of persons asking about a health care service has generally suffered detriment in any case already. Therefore, there is great public interest in preventing to the extent possible further detriment to these persons’ state of health by stipulating corresponding quality standards.

Thus, the objective of the present draft is to avert risks for the populace’s general state of health in connection with providing health care services, irrespective of who provides them and where. It is therefore not a variety of risk typical for other administrative matters.

Special section

Re § 1 (objectives and principles)

The traditional and usual manner of looking at service providers in the health care system is oriented toward their membership in certain institutions and/or their sources of financing. However, this manner of observation precludes the patients from being the focus of the considerations. It is much more important from the viewpoint of quality work to ensure health care during the progress of an illness in a manner across all sectors. Furthermore, the traditional borderlines and definitions of tasks among health care facilities will increasingly vanish in the future health care system. Essentially, the traditional care-structures today are the individual medical practice and the hospital. Introducing group practices and increased efforts to outsource hospital services into the extramural area are already indications now that, in the future, a large variety of differing organisational health care forms will exist side by side. Therefore, we need to create nationwide standards for providing services, irrespective of the organisational form in which they are provided.

The example of decubitus is useful to make this manner of observation clearer. Decubitus is a trophic irritation of the tissues (cutaneous and subcutaneous tissues in particular) caused by bedsores, for example. It can occur in many health care facilities – hospitals and nursing homes, for instance – and in the established sector as well (physicians, home nursing). Maintaining standards can prevent the occurrence of decubitus and/or assure its treatment on a uniform level. Therefore, it makes sense to develop and make compulsory quality standards in this area which will apply nationwide.

Diabetes is another example underlining the necessity of introducing nationwide standards. Diabetes is widespread throughout the populace; it numbers among the chronic diseases and, along with its secondary diseases, is one of the most cost-intensive. Efficient interface management (perhaps in the form of disease/case management) is absolutely necessary in order to assure successful treatment and avoid secondary diseases, as well as to promote patients’ self-responsibility and thus keep costs within acceptable limits. But this is precisely lacking in the Austrian health care system, since quality-assured cooperation among health care providers is often not clarified, meaning that unnecessary and expensive ruptures in the treatment chain result for the patients. Quality standards applicable nationwide need to be developed and made binding in order to rectify these defects.

Re § 2 (Definitions of terminology)

Analysing the scientific definitions of quality traceable in the literature on the basis of fundamental characteristics, we can identify the following elements: quality regards the relation between (defined) ideals of a service and the actual realisation thereof. The service under consideration can be a product, a service, a process or a system. In the context of a health care system, the objective (ideal) to strive for can only be the promotion and preservation of the citizens' and patients' quality of life and the restoration of their health. Quality work in the health care system is not a one-time thing; it must be performed continuously. Based on the results of regular evaluations, the necessary steps must be taken and their sustainable effectiveness reviewed. Expressed in other words, quality work is defined as the ability to provide the right health care service at the right time and the right place, and to review it continuously.

The term "nationwide Austrian quality system" circumscribes a fundamental Federal system of coordination, support, promotion and control of quality work in the health care system. No specific "systemic quality management system/model" is bindingly introduced within the framework of the nationwide Austrian quality system. This is intended to support the health care providers' flexibility in their quality work on the one hand and, on the other, to prevent hindrances in connection with the further development of quality management systems/models, and to allow unobstructed competition as well. We should assume that continuously developing and bindingly applying Federal quality directives and Federal quality guidelines in the Austrian health care system will lead to harmonisation of the quality strategies and models within a realistic period of time. International developments must be kept in mind at all times.

In the course of carrying out his/her nationwide work, it will be the duty of the Federal Minister of Health and Women to be attentive that existing nationwide quality activities are integrated into the future further development of the overall strategy in a manner which is sensible and sparing in the use of resources. The Federal Minister of Health and Women must ensure that corresponding arrangements are made among the participants in the Austrian quality system in order to safeguard the principles firmly set out in Art 1. In this context, the term "participant" particularly includes the financiers, the service providers and the patients.

Within the context of the present draft Act, quality in the health care system is defined in the narrower sense as the ability of the health care service providers to structure their services in a manner which is patient-oriented, transparent, effective and efficient. Patient safety must be kept in mind when providing health care services.

Patient orientation (in the sense of maximising the quality of life) means that the respective persons concerned are the focal point in decision-making and actions and that they are given the opportunity to participate actively (co-producer role) in the process. This is based on the appreciation that quality can only be achieved if all the professions and specialist areas work together.

Patient security encompasses every action taken to avoid adverse events within the framework of providing health care services. In this context, commissions, omissions, and incidents entailing harm to patients can be interpreted as adverse events.

Transparency refers to analysing and documenting services and results in a visible and reconstructable manner and systematically reviewing them as a basis for continuous and systematic comparisons and quality improvement.

Effectiveness is defined as the degree of achieving an objective between a set goal and its realisation. As mentioned above, the sole objective of health care is to maintain fully the citizens' and patients' quality of life and to restore their health. Although this objective will be achieved to a varying extent from case to case, we should still not lose sight of the ideal.

In general, efficiency involves the relation between the input and the outcome of a service. The objective of the principle of economy is to provide a service as efficiently as possible in terms of an optimal relation between performance and result, whereby either the maximality principle (input held constant, outcome maximised) or the minimality principle (outcome held constant, input minimised) can be applied. Economical efficiency is an essential but not exclusive objective in the health care system. In juxtaposition with the efficiency principle, all the other applicable principles of quality work must be taken equally into account. Scientific instruments such as Health Technology Assessment (HTA) and Evidence-Based Medicine (EBM), as well as increased use of health-economic evaluation methods (e.g. cost-benefit analyses, cost-effectiveness analyses, cost-utility analyses, data development analyses) can provide substantial support as regards effective and efficient health care.

Structural, procedural and outcome quality – the three dimensions of quality according to Donabedian – form the basis for a system of rules on which improvement develops.

Structural quality is defined as both material and personal framework conditions (qualitative and quantitative characteristics) within which health care services are provided.

Procedural quality comprises the method of performing medical, therapeutic and nursing services on the one hand and, on the other, it takes the entire course of treatment into consideration. The parameters of procedural quality include

- access to care,
- availment of medicinal/therapeutic/nursing services (suitability),
- technical quality of diagnostic, therapeutic and nursing services,
- factors involving personnel (interaction, cooperation).

Outcome quality as a product of structural and procedural quality is also defined in the health care system as the degree of achieving the professionally estimated result of a health care service, taking into consideration the patient's subjective satisfaction and the quality of life the service has provided.

The draft Act regulates that health care services should be provided in an environment which promotes health and that quality standards should be developed taking into

consideration the basic principles of health promotion. The basic principles of promoting health have already been defined in the 1986 WHO Ottawa Charter; we quote:

“Health promotion is the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental and social well-being, an individual or group must be able to identify and to realize aspirations, to satisfy needs, and to change or cope with the environment. Health is, therefore, seen as a resource for everyday life, not the objective of living. Health is a positive concept emphasizing social and personal resources, as well as physical capacities.”

Realising the Ottawa Charter’s central idea of self-determination is suggested in the health care system according to current interpretation both as concerns integrating patients into the treatment processes and the workers into the structuring of work procedures, as well as cooperation among health care sectors. Health-promotion projects have been underway for several years now which integrate the providers of health care services (e.g. the Austrian Network of Health-Promoting Hospitals and the Health Promotion in Primary Health Care: General Practice & Community Pharmacy Project). Findings and experience gained in these projects, among others, should be adopted in a meaningful manner as part of the strategy for implementing a nationwide Austrian quality system.

From the viewpoint of provisions uniform nationwide on quality, a guarantee must be provided that a quality strategy including all provinces, professional groups and across all sectors will be pursued as an essential instrument of control within the Austrian health care system. This is the only way of assuring that the populace will be provided with extensively equal services of extensively equal quality.

In this context, “nationwide” means that provisions must be applicable throughout Austria and thus apply to all the provinces in one and the same manner. “Including all provinces” means that, within the framework of implementing and promoting quality work, the provinces should meaningfully cooperate in areas where synergic effects can be fostered.

“Across all sectors” means that that the provisions fundamentally apply to all providers of services, irrespective of their organisational form. In other words, it must be assured that the quality of health care services is equally high, no matter where and in which form they are provided.

“Across all professions” means that the individual professional groups contribute in a cooperative manner to ensuring the desired level of quality.

Re § 3 (Scope of applicability)

The scope of the present Act’s applicability extends to all health care services, irrespective of the service providers’ organisational form to the extent that the health care service concerned is one performed for human beings by one of the health care professions defined on the basis of Art. 10 Par. 1 Fig. 12 of the Federal Constitution Act. Accordingly, the provisions set out in this Act do not cover trade professions and health care services performed by persons not correspondingly trained, within their families or as a type of

neighbourly assistance. As regards nursing, the framework of this Act includes activities falling within the competence of the Federation and not regulated in other statutes.

Re §§ 4 and 5 (Quality standards, dimensions of quality work)

In order to assure a level of health care quality which is constant throughout Austria and across all sectors, the competent Federal Minister may decree quality standards either in the form of ordinances on Federal quality directives or recommend them as assistance in the form of Federal quality guidelines.

This procedure assures that a system will be implemented in Austria in which Federally acknowledged quality standards can be developed, maintained and made available to the public, whereby either the Federal Minister of Health and Women or cooperating stakeholders may develop and maintain such quality standards. Should stakeholders wish to convert their quality standards to Federal quality standards, they will be obliged to take part in acknowledgement proceedings to be organised at a future date, within the framework of which a quality standard's compatibility with the strategy of a full-coverage Austrian quality system (in the sense of the factors set out in Art. 4 Par. 2) will be examined and in which responsibilities regarding maintaining and further developing the quality standard must be established.

The relevant stakeholders (patients, professional groups, specialist associations, legal entities, financiers, etc.) are to be integrated in a suitable manner into the process of working out the quality standards indicated. This will not only ensure additional knowledge and experience; it will also encourage the users' acceptance thereof. Apart from the aforementioned general principles on quality work (patient orientation, transparency, effectiveness and efficiency), special attention should also be paid when developing standards to effecting a smooth transition among the individual health care fields.

The Federal quality standards (i.e. Federal quality directives and Federal quality guidelines) will take a different form depending on the field of specialty. Both detailed provisions and generally formulated ones are conceivable, depending on the subject area concerned. Moreover, basic provisions on developing quality standards are also a possibility (guidelines for developing directives and guidelines). For the purpose, for example, the Federation will also avail itself of the results of quality projects already implemented and take into consideration the Council of Europe's work on the topic of "Developing a System for Working Out Guidelines for Optimal Medical Practice".

The Federal quality standards (i.e. directives and guidelines) may include provisions necessary with respect to personal and material requirements, procedures, conduct and results. Moreover, the Federal quality standards may be coupled with indicators the substance of which should also be integrated into Austrian quality reporting.

In developing the quality provisions, the traditional breakdown according to Donabedian into structural, procedural and outcome quality has proved to be effective in particular because the terms are introduced into professional circles and are accepted. The breakdown has already found its way into legal standards on the Federal level. In the sense of continuously developing further extant and introduced work methods, the systematic

scheme indicated is retained and developed into a quality system by way of continuous improvement. Development of rules and principles uniform nationwide should be based on the tried and true. The essential activities already underway and the Federation's activities planned for the future are presented below.

Federal rules regarding structural quality:

Structural quality criteria for the hospitals sector were developed in the past years. In consideration of the necessity to create standards for all fields of providing service (irrespective of the institution), structural quality criteria are to be adapted in future from the perspective of application extending to cross all sectors and, in the mid-term, all health care service providers are to be bound over to them.

Federal rules on procedural quality:

In the area of procedural quality, the Federation has initiated a series of projects, some of them concerning interface management, patient orientation, strategies regarding antibiotics, optimising the use of blood components, hygiene, patient safety and palliative care. The results of these projects – which will appear in particular in the form of best-practice instruments – will serve as a basis for building on extant foundations and to provide and implement rules uniform nationwide and across all sectors in the area of procedural quality. Apart from other leading work, there is also the option of creating binding requirements by decreeing ordinances. In addition, sample instruments can be provided to improve procedural quality continuously. Evidence will need to be provided of the manner in which the requirements are met within the framework of providing health care services.

Federal rules on outcome quality:

As of several years ago, the Federation has already initiated activities concerning outcome quality (e.g. the Quality Indicator Project, Outcome Quality in Hospitals). Outcome quality cannot be considered without the influence of structural and procedural quality; at the same time, it is the aspect most difficult to subsume and measure. The Federation's efforts focus primarily on promoting the structural use of economic methods in the area of outcome quality and on guaranteeing increased transparency as regards compliance with the corresponding Federal rules. For this reason, the instrument of Austrian quality reporting will also serve to assure development across all sectors, compulsoriness, and the application as experienced of outcome indicators and reference sizes. Further initiatives and extant work in the area of outcome quality should be integrated in a meaningful way into the overall strategy.

The foregoing expositions regarding development of standards and the dimensions of structural, procedural and outcome quality clearly show that, by virtue of this draft of a Federal act on the quality of health care services, the cornerstone should initially be laid to conceive and realise strategic development of standards and maintenance in Austria. It is evident that the process of developing nationwide quality standards and rules in the area of structural, procedural and outcome quality, as well as continuous improvement in the coming years within the framework of an overall strategy and a priority concept extending over many years must be planned and realised over the long term.

Based on the results of Federal quality projects currently underway and/or already completed, the following Federal quality standards and indicators could be conceivable on the following topics:

- quality reporting
- strategies concerning antibiotics
- hygiene and nosocomial infections
- investigating and analysing patient satisfaction in a manner uniform throughout Austria.

In addition, special attention will also be given to certain topic areas, among them: further development of quality components within the framework of planning services to be offered: meaningful further development of work on structural criteria, simultaneously integrating elements of procedural and outcome quality. However, these activities within the framework of planning services to be offered must fit into the overall concept of a nationwide Austrian quality system and be adapted to align with other relevant activities.

Pushing forward quality aspects in interface management:

Interface management in the Austrian health care system must be improved in order to ensure efficient and effective, patient-oriented care. Structured solution approaches can be developed by using the methods and instruments of quality work in this area. Core processes of intra- and extramural provision of services such as patient referral, admission, discharge and takeover are of particular importance in this connection. The approach by way of the Disease/Case/Care Management Programme also seems justifiable, whereby the following aspects should be taken into consideration at all events:

- patients and their relatives as co-producers of their own health
- use of EBM-supported guidelines
- corresponding information and documentation systems
- meaningful coordination and arrangements among various health care service providers irrespective of their organisational affiliation.

The Disease/Case/Care Management Programme is particularly useful in connection with chronic diseases such as diabetes, chronic obstructive pulmonary disease, allergies, strokes and malignant carcinomas.

Patient safety:

This field comprises all measures to prevent undesirable results within the framework of providing health care services. According to international studies, the rate of undesirable results within the framework of providing health care services lies at 4 – 16%, depending on definition and delimitation. Undesirable results can be interpreted in this context to include acts, omissions or occurrences to a patient's detriment.

Primary efforts will focus on supporting the development of a culture of dealing with errors within the framework of providing health care services. Conceivable approaches in this

connection include promoting the establishment of a corresponding culture, reporting and feedback systems (monitoring and reporting), training concepts and a continuous assessment of health care service providers.

Quality standards in training for health care professions:

Developing and consolidating quality standards for health care professions is of particular importance in connection with implementing a nationwide Austrian quality system. The corresponding provisions on training regularly establish such standards.

Re § 6 (Quality Reporting)

The Federation considers that following progress as regards the set-up and further development of a full-coverage Austrian quality system is one of its duties. For the purpose, nationwide Austrian quality reporting is to be established with the objective of preparing an annual, comprehensive quality report. The system is to be designed as a flexible instrument to be further developed on a continuous basis and which is to serve as the foundation for identifying improvement potentials and for comprehensive planning within the Austrian health care system. Uniform rules on documentation are required in order to achieve the goal of uniform quality reporting. They should be derived to the extent possible from extant documentation obligations and/or use available data, to keep (additional) expenditures as low as possible. Delimitation to existing reports (e.g. health reports) must be assured.

Within the scope of their spheres of activities, the stakeholders in the Austrian health care system should contribute in accordance with further developing the Austrian quality reports toward full-coverage, nationwide Austrian quality reporting and should provide the requisite documentation.

All levels should be included, especially

- the health care service providers
- the administrative organisations
- the provinces
- the treasuries
- the social insurance commission
- the professional representatives
- the health agencies on the provincial level.

The first Austrian quality report is currently being realised as a pilot project within the framework of a nationwide quality project involving representative of the provinces, the social insurance commission, patients' advocacies and the Austrian Medical Association, among others. The practical feasibility of jointly worked out report requirements is being tested within a defined circle of participants. The instruments to be deployed are to be improved and/or further developed on the basis of this work. Furthermore, additional participants from the group of health care service providers are to be successively integrated into the work.

For the sake of increased transparency, the Federal Minister of Health and Women must ensure that corresponding feedback systems are set up for the parties obligated to submit reports. In addition, he/she must announce to the interested public in a suitable form the intensity of the participation of the stakeholders in the Austrian quality system.

Re § 7 (Promotional measures and incentive mechanisms)

Assurance and improvement of quality in the health care system cannot be achieved by imposing obligations, rules and sanctions alone. Therefore, apart from the rules and/or sanctions, promotional measures and incentive systems should be developed and implemented in order to encourage the various stakeholders to strive for quality assurance and improvement on their own initiatives above and beyond the obligatory rules.

At all events, it seems essential to disseminate knowledge and promote the use of quality-work instruments and methods, for example by supporting corresponding scientific work and regular informative events.

Moreover, it could be conceivable to publicly award a prize (“Quality Oscar”) to stakeholders for special achievements in the field of quality assurance and/or improvement, as well as honouring health care service providers who have brought their achievements to a particularly high level while complying with the specific rules.

At the same time, increased transparency vis-à-vis the interested groups of experts and the public should serve to relay positive examples of quality work in the health care system to a large, interested audience.

Re § 8 (Control)

The Federal Minister of Health and Women must ensure a nationwide system of observation and control in connection with assuring and improving the quality of health care services. The system must include monitoring participation in Austrian quality reporting and the implementation of Federal quality directives and evaluating the implementation and/or application of Federal quality guidelines and/or equivalent instruments. The Federal Minister of Health and Women must ensure that parallel external controls of quality work in the health care system are carried out. For the purpose, the Federal Minister of Health and Women and/or his/her commissioned agents are entitled to request information and reports, to inspect all documentation relevant to quality assurance (including data quality) and, if necessary, to conduct on-site investigations. These entitlements apply to the extent necessary to perform their duties. Other rights and obligations on the basis of other legal provisions concerning observation and control remain unaffected thereby.

Re § 9 (Support from the Federal Institute for Quality in the Health Care System)

Since the duties for which the Federal Minister of Health and Women is responsible cannot be carried out in their entirety by the Federal Ministry of Health and Women due to the lack of resources, the Federal Minister may also avail him/herself of the services of a Federal Institute for Quality in the Health Care System to fulfil his/her duties. The duties of this

Federal institute functioning in the field of quality in the health care system would include in particular

- participating in preparing general rules and principles on developing standards of structural, procedural and outcome quality and analysing improvements, including a priority concept and an award procedure to and for documenting quality reporting, for promotional measures, incentive mechanisms and control,
- reviewing, recommending and working out quality standards which the Federal Minister of Health and Women may bindingly decree (Federal quality directives) or recommend as an aid to orientation (Federal quality guidelines),
- preparing an annual quality report,
- implementing and/or participating in the establishment of promotional measures and incentive mechanisms, and
- implementing and/or participating in monitoring compliance with the provisions set out in this Act and ordinances or other rules decreed on the basis of this Act.

Along with simultaneously integrating already extant, sensible quality activities, this Federal Institute for Quality in the Health Care System should set up committees of experts in order to exploit as much knowledge and experience as possible for its work and to ensure requisite acceptance. Furthermore, patients should also be systematically integrated. Setting up and/or using already extant information platforms could also be conceivable, to promote the dissemination of knowledge of quality instruments and methods.

Since procedure is also to be made on the principle of the most efficient and effective use of funds in connection with the Federal Institute for Quality in the Health Care System as well, the question of whether an already extant facility could be entrusted with duties to be performed should initially be looked into. However, in such a case, corresponding staff (number and qualification) and technical-organisational equipment would have to be provided.

Notwithstanding the duties the Federal Institute for Quality in the Health Care System will perform in future in the area of quality work, assurance must be provided that

- the Federal Minister of Health and Women can resort to the Federal Institute at all times,
- the Federal Minister of Health and Women performs his/her coordinating function when important decisions are being made (in particular regarding the participants in the nationwide Austrian quality system and the integration of experts), and that the interdisciplinary aspect – in the health care professions especially (doctors, nursing professions, other health care professions) – and other professional groups involved (health care law specialists and health care economists) is correspondingly taken into account when hiring personnel.

Developments in other EU member states regarding institutions for quality

By the 1990s, health care system quality had become topical in all the EU member states. In the absence of explicit EU harmonisation competence, however, the individual states went very different ways in designing their health care quality policies. Some of the states focused

on external control and accreditation measures, whereas others turned to research and support in the form of standards, guidelines and directive, while still others emphasised internal quality-improvement measures and information support. The legal rules on quality and institutions for quality for providing services within the health care system therefore differ widely as well. There is scarcely a member state today which can get along without specially created institutions for quality. By order of the Department, studies were commissioned in 1999 and 2002 to provide an overview of the institutions extant in other EU countries. The following information was provided among the results:

EU member state	Name of institution	Commentary
France	ANAES (Agence National d'Accréditation et d'Evaluation en Santé)	Work focuses on drawing up directives and standards, accrediting health care institutions. 1999 budget: € 20 M 1999 personnel: 150 employees
Finland	STAKES (National Research and Development Centre for Welfare and Health)	Work focuses on research and development, non-binding standards, implementation and benchmarking projects, evidence-supported medicine. 1997 budget: € 32 M 1997 personnel: 374 employees
Netherlands	LCZK (National Centre for the Coordination of the Policy on Quality of Health Care)	Work focuses on information, networking, consultation. 1999: € 50,000 1999 personnel: 2 employees
	CBO (Dutch Institute for Quality Improvement)	Work focuses on developing guidelines, inspection programmes, developing methods, economic and organisational support in introducing quality programmes, training.
	NIAZ (Netherlands Institute for Accreditation of Hospitals)	Work focuses on implementing accreditations.
	HKZ (Centre for the Harmonisation of quality review in health care)	Work focuses on developing certification routines for the health care and social services sector.
Great Britain	NICE (National Institute for Clinical Excellence)	Work focuses on developing and administrating standards. Reporting 1999 budget: approx. £ 10 M
	CHI (Commission for Health Improvement)	Work focuses on Quality inspections, consulting functions, reporting. 2000 budget: approx. £ 25.5 M
	NPSA (National Patient Safety Agency)	Work focuses on setting up a reporting system on medical errors,

		preventive consulting.
Germany	DIMDI (German Institute for Medical Documentation and Information)	Authority subordinate to the Federal Ministry of Health for providing up-to-date information from the entire biological sciences sector Work focuses on developing and administrating databases, developing and administrating database-supported information, publishing official classifications, cooperating in the development and administration of standards and methods together with AWMF, BQS, AQS, KTQ, ÄZQ.
	AWMF (Syndicate of Scientific Medical Specialty Companies)	Work focuses on preparing and administrating guidelines, standards and indicators.
	Federal Commission for Quality Assurance and BQS (Federal Office of Quality Assurance)	Union of all relevant stakeholders in the health care system Central consultation and resolution committee for quality assurance in the inpatient sector Work focuses on developing quality assurance procedures, benchmarking between and within hospitals.
	AQS (Syndicate for Quality Assurance)	Work focuses on developing and recommending guidelines for quality assurance, particularly at the interfaces between inpatient and outpatient care.
	KTQ (Syndicate for Transparency and Quality in Hospitals)	Work focuses on certifying and quality reporting in hospitals.
	ÄZQ (Medical Central Office for Quality Assurance)	Work focuses on providing a central consulting office for Federal medical associations and Federal associations of doctors participating in the health insurance system.

Re § 11 (Final Provisions, Entry into Force)

With the exception of the provision on penalties, this Act enters into force per January 1, 2005. In the first year, essentially, the Federal Institute for Quality in the Health Care System must be set up and, thereafter, principles and rules must be developed and the various stakeholders involved be given time to adapt to the new conditions; therefore, sanctioning from the beginning onward does not seem expedient.