

Charter¹

§1

Name, Legal Form and Registered Headquarters of the Foundation

In accordance with §91 SGB² V, the Federal Joint Committee (*Gemeinsamer Bundesausschuss*), an institution established under public law, establishes the private law foundation,³ with legal capacity, bearing the name

Foundation for Quality and Efficiency in Health Care

(Stiftung für Qualität und Wirtschaftlichkeit im Gesundheitswesen)

(hereinafter referred to as the "Foundation") as the governing body of the Institute with the same name pursuant to §139a (1) SGB V.

The Foundation has its registered headquarters in Berlin. The Institute has its head office in the Cologne/Bonn region until 31 December 2008, and thereafter in Berlin. It can establish a branch office in Berlin.

§2

Purpose of the Foundation

The Foundation exclusively and directly pursues charitable purposes as defined in the Section "Purposes with Tax Relief" in the Tax Code.

The aim of the Foundation is the promotion of science and academic research, as well as the promotion of the publicly funded health service. The purpose of the Foundation will be exclusively realised by the establishment and maintenance of the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und*

¹ Status: 17.07.2008. The comments in footnotes are not part of the original Charter, but have been added by IQWiG to increase understandability. Disclaimer: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

² Sozialgesetzbuch = Social Code Book (regulates the statutory health care services).

³ In the German legal system, a "private law foundation" is a non-governmental and non-profit foundation.

Wirtschaftlichkeit im Gesundheitswesen; hereinafter referred to as the "Institute") provided for in §139a SGB V, whose tasks are specified in §7.

§3

Use of Funds

The Foundation works in the public interest. It pursues no economic aims of its own. Funds of the Foundation may only be used for purposes that conform with the Charter.

§4

Bodies and Institutions of the Foundation

- (1) The bodies of the Foundation are
 1. the Federal Joint Committee for resolutions to alter the Charter and terminate the Foundation
 2. the Foundation Board
 3. the Board of Directors.

- (2) The Institute is an institution of the Foundation under scientifically independent responsible management.
Advisory committees of the Institute are:
 1. the Board of Trustees
 2. the Scientific Advisory Board.

- (3) A Financial Committee of the Foundation will be appointed, which advises the bodies of the Foundation and in particular reviews the budget and the annual account prepared by the Institute Director.

§5

Foundation Board

- (1) The Foundation Board comprises 6 representatives of the Central Federal Association of Health Insurance Funds (*Spitzenverband Bund der Krankenkassen*), together with a total of 6 members of the Board of Directors or the management of the National Association of Statutory Health Insurance Physicians (*Kassenärztliche Bundesvereinigung*), the German Federal Association of Sick Fund Dentists (*Kassenzahnärztliche Bundesvereinigung*), and the German Hospital Federation (*Deutsche Krankenhausgesellschaft*). The stipulated organisations of the service providers will agree internally on the allocation of the seats on the Foundation Board to which they are entitled. They can also agree on a representative who does not belong to their bodies. The representatives will in each case be appointed by the respective organisations. The appointment must be adjusted in accordance with the current membership of the respective Board of Directors or management. A representative according to Sentence 3 can be removed from office at any time. Appointed representatives stay in office until such time as they are replaced by newly appointed representatives. The representatives themselves can be represented by representatives authorised in writing. The Chairman of the Federal Joint Committee belongs to the Foundation Board as an advisory member without the right to vote. The Foundation Board elects a chairman and a vice-chairman for a term of 4 years from among the members entitled to vote. They fulfil these functions on an annually alternating basis.
- (2) The Foundation Board resolves on the establishment of the Institute as an institution of the Foundation. The Foundation Board appoints 4 members of the Board of Directors pursuant to §6 and discharges the Board of Directors. The Foundation Board proposes the Institute Director and his or her deputy. The Foundation Board is in addition also responsible for approving the budget of the Foundation and the Institute, including the approval of expenditure exceeding and expenditure outside the budget, the monitoring of the budget and economic management, and the adoption of the annual accounts. In the

course of this, however, the scientific and professional independence of the Institute must be safeguarded. The Foundation Board also decides on the auditor who has the obligation to examine the regularity of the management and to produce an audit report on the results in accordance with §8 (2) Foundation Act (Berlin).

The audit instruction must also encompass the maintenance of the Foundation's assets and the use in accordance with the Charter of the earnings and other payments. The Foundation Board approves the report to be produced by the Board of Directors on the fulfilment of the Foundation's purpose, and the audit report assessed by it as the annual report.

- (3) The Foundation Board passes its resolutions with a majority of the members present or represented, unless the Charter provides otherwise. The transfer of voting rights in writing is permissible. In case of a tie in the voting, the vote of the Chairman of the Foundation Board is decisive.

Resolutions on budget matters require the consent of at least 7 votes.

- (4) For a quorum to pass resolutions, the presence of the Chairman of the Foundation Board and of at least 4 representatives each from the Central Federal Association of Health Insurance Funds and from the service providers is necessary.
- (5) The meetings will be called by the Chairman of the Foundation Board at least twice a year. A meeting must be called if the Board of Directors of the Foundation or 3 members of the Foundation Board so require.
- (6) The Foundation Board can also pass a resolution in writing if all members agree to this procedure in writing. A resolution is passed with a majority of the members.

§6

Board of Directors

- (1) The Board of Directors consists of 5 members who hold office on an honorary basis. Four members are appointed by the Foundation Board for a term of 4 years, one member is appointed by the Federal Ministry of Health (representative of the Federal Ministry of Health pursuant to §139a (2), Sentence 2, SGB V). After the expiry of the term of office of the members appointed by the Foundation Board, the Board of Directors holding office continues the business until the election of the new Board of Directors. The members of the Board of Directors appointed by the Foundation Board can only be removed from office as members of the Board of Directors before the expiry of their term of office for important cause or with a vote passed by two thirds of its members. The rights of the Foundation Supervisory Authority⁴ remain unaffected. If a member of the Board of Directors appointed by the Foundation Board leaves office before the expiry of his or her term of office, the Foundation Board will elect a replacement member for the remainder of the term of office without undue delay. Until the Board of Directors is supplemented in this way, the number of members in the Board of Directors reduces by the number of persons who have left. The Institute Director belongs to the Board of Directors in a consultative capacity. The Chief Operating Officer and the Legal Advisor of the Institute have a right to make motions to the Board of Directors as well as a right to participate in and talk at the Board's meetings. Motions can be made both in meetings and within the framework of the written resolution procedure according to (3) below.

- (2) The Board of Directors deals with the current business of the Foundation and supervises the Institute Director in respect of proper management. For this purpose, it decides after consultation with the Institute Director on the necessary principles, in particular for the organisational structure of the Institute, regular reporting of the use of funds, the obligation to obtain consent

⁴ The Foundation Supervisory Authority is the Senate Department of Justice, Berlin (*Senatsverwaltung für Justiz*), which ensures that the Foundation adheres to the Charter.

for certain legal transactions exceeding a defined framework (details on this issue are regulated in the Standing Orders of the Institute), on the award of external commissions and their remuneration, as well as the conditions of employment for Institute staff. It must produce a budget at the start of each business year, and annual accounts at the end of each business year, which must in each case be prepared by the Institute Director. Expenditure exceeding or outside the budget requires its consent.

- (3) The Board of Directors meetings will be held in rotation in a way agreed amongst the members of the Board of Directors and chaired alternately. The Board of Directors passes its resolutions by majority voting unless the Charter provides otherwise. The member appointed by the Federal Ministry of Health can be represented by a representative authorised in writing. The Board of Directors can also pass a resolution in writing if all members consent to this procedure in writing.
- (4) The Board of Directors has an obligation to submit the annual report adopted pursuant to §5 (2), Sentence 8 to the Foundation Supervisory Authority. This must take place within 8 months after the end of the business year. The resolution of the Foundation Board must be attached.
- (5) In all its decisions, the Board of Directors must respect the scientific and professional independence of the Institute.

§7

The Institute

- (1) The Institute will work on issues of fundamental importance for the quality and efficiency of the services performed within the framework of the statutory health insurance (SHI) system as an independent scientific institution of the Foundation, in particular in the following areas:
 1. Search for, assessment and presentation of current scientific evidence on diagnostic and therapeutic procedures for specific diseases;

2. Preparation of scientific reports and expert opinions on quality and efficiency issues of SHI services, taking age, gender, and personal circumstances into account;
3. Appraisal of evidence-based clinical practice guidelines on the epidemiologically most important diseases;
4. Issue of recommendations on disease management programmes;
5. Assessment of the benefits and costs of drugs;
6. Provision of easily understandable information for all citizens on the quality and efficiency of health care services, as well as on the diagnostics and treatment of diseases of high epidemiological relevance.

Its task is to support the Federal Joint Committee in fulfilling its statutory duties in these areas by the submission of recommendations (§139b [4] SGB V).

- (2) The Institute Director, at the proposal of the Foundation Board, will be appointed by the Board of Directors. The latter will also produce the contract of employment. The appointment will be for a limited period of time. Re-appointment is permissible. The Institute Director must have a high scientific reputation and experience in the management of scientific and/or clinical institutions commensurate with the significance of the Institute's tasks.
- (3) In addition, the Board of Directors appoints a deputy for the Institute Director; (2) applies accordingly.
- (4) The consent of all members of the Board of Directors is required for resolutions pursuant to (2) and (3).
- (5) The Institute Director is responsible for the Institute's fulfilment of its tasks within the framework of the statutory tasks pursuant to §139a and §139b SGB V, the priorities set by the Federal Joint Committee, the budget approved by the Foundation Board and the principles decided by the Board of Directors for the organisational structure and the use of funds pursuant to §6 (2). The

Institute will establish a tendering office, in particular for the award of research commissions according to §139b (3) SGB V. The detailed procedure is regulated in a tendering directive of the Institute, which is to be decreed by the Board of Directors. The procedural regulations decided by the Federal Joint Committee on the basis of §91 (4) SGB V must be observed with as far as the involvement of the Institute is concerned. The methodological requirements regarding the scientific, cross-sector evaluation of measures to be regulated in the procedural regulations and the demands on the professional independence of external experts must be defined in close consultation with the Institute Director.

- (6) The Institute Director is responsible to the Board of Directors for the proper fulfilment of his/her tasks. He/She must prove his/her professional independence to the Board of Directors in suitable form.
- (7) The Institute Director must produce a report each year about the working processes and results of the Institute, including the bases for the decision-making process, and must forward it to the Board of Directors for publication.
- (8) Recommendations to the Federal Joint Committee and other decisions and publications stipulated by statute must be submitted to the Board of Directors for its information.
- (9) The Institute Director employs the scientific staff and other staff of the Institute in accordance with the budget and the principles passed by the Board of Directors. The Institute Director is the superior of the scientific and other staff. The Institute Director must comply with the stipulations in §139a (6) SGB V.

§8

Board of Trustees

- (1) The Board of Trustees comprises 30 members. They are appointed by organisations which the Board of Directors specifies at the suggestion of the Foundation Board in consultation with the Institute Director. Ten members must be appointed from each of the following:
 1. the bodies of self-administration of the governing organisations of the Federal Joint Committee;
 2. relevant organisations of organisations of service providers not represented in the Federal Joint Committee and of the social partners;⁵
 3. other organisations relevant to the health system, 6 of which are representatives of organisations representing the interests of patients and self-help of chronically ill and disabled persons, as well as the Federal Government Commissioner for Patients' Affairs.

- (2) The organisations required by the Board of Directors to appoint a representative will notify the name of the representative to the Foundation. He or she will be appointed by the Board of Directors. The nominating organisation can remove its representative from office at any time and propose another person, who can be appointed by the Board of Directors.

- (3) The members of the Board of Trustees receive from the Institute Director the recommendations of fundamental importance issued by the Institute to the Federal Joint Committee, and have the opportunity to submit comments in writing. They can submit comments together, in groups or individually.

- (4) Prior to issuing recommendations of the Institute on matters which directly affect the interests of patients, in particular on the provision of understandable general information on the quality and efficiency in health care, the patients'

⁵ Social partners=representatives of workers and employers.

representatives on the Board of Trustees and the Federal Government Commissioner for Patients' Affairs must be given the opportunity to submit comments within the framework of a hearing.⁶

- (5) At the invitation of the Board of Directors, the Board of Trustees meets once a year. It elects a chairman and a vice-chairman for a term of 4 years, who exchange offices at the start of the third year. In order to ensure that a quorum exists for the election of the chairman/vice-chairman of the Board of Trustees, the presence of at least 6 members from each circle of organisations specified in (1) Nos. 1 to 3, or representatives with voting rights on the basis of the transfer of voting rights pursuant to Sentence 4, is required. A written transfer of voting rights to another member within the respective organisations is permissible pursuant to (1) Nos. 1 to 3. The chairman/vice-chairman is elected if he/she receives more than half the votes cast. The election of the chairman/vice-chairman takes place in principle by a show of hands, but can take place by secret ballot upon application of at least 11 members of the Board of Trustees present or representatives entitled to vote.
- (6) The Board of Directors can issue invitations to additional meetings in consultation with the Chairman of the Board of Trustees.
- (7) If the Board of Trustees resolves its opinion pursuant to (3) in meetings, the relevant resolution is passed with the majority of the members present or members represented in their right to vote. A written transfer of voting rights to another member within the respective organisations is permissible pursuant to (1) Nos. 1 to 3. In the event of a tie in the voting, the chairman's vote is decisive. In order to have a quorum, the presence of the chairman or vice-chairman and of at least 6 members or representatives entitled to vote from each circle of organisations pursuant to (1) Nos. 1 to 3 is required.
- (8) Members of the Board of Directors, the Foundation Board and the Institute Director can participate in the meetings.

⁶ This hearing can also be conducted as a written hearing (submission of comments).

§9

Scientific Advisory Board

- (1) The members of the Scientific Advisory Board are appointed by the Board of Directors in agreement with the Institute Director. If no agreement can be reached, the Board of Directors can appoint the member with the majority of its members. The Scientific Advisory Board comprises at least 6 and not more than 12 scientists. The members of the Scientific Advisory Board are appointed for a term of 4 years. They can usually only be reappointed once.
- (2) The Scientific Advisory Board decides on a chairman and vice-chairman from amongst its members with the majority of the votes of its members.
- (3) The Foundation's Board of Directors invites the Scientific Advisory Board to meetings which are chaired by the Chairman of the Scientific Advisory Board.
- (4) The Scientific Advisory Board is intended to advise the Institute Director on fundamental issues he/she submits.

§10

Finance Committee

- (1) The Finance Committee comprises 3 representatives of the Central Federal Association of Health Insurance Funds, and one representative each from the National Association of Statutory Health Insurance Physicians, the German Federal Association of Sick Fund Dentists, and the German Hospital Federation. The representatives are appointed by the Foundation's Board of Directors upon the recommendation of the Foundation Board..
- (2) The Finance Committee advises the Foundation Board, the Foundation's Board of Directors, and the Institute Director in financial affairs. The Committee reviews the budget and the annual account prepared by the Institute Director.

§11

Minutes of the Bodies' Resolutions

A written record of the resolutions passed by the bodies of the Foundation in meetings must in each case be produced and signed by the chairman of the respective meeting. In case of voting by written procedure, the results must be verified and signed by a member of the Board of Directors.

§12

Representation of the Foundation

- (1) The Foundation is represented in and out of court in each case by 2 members of the Board of Directors elected by the Foundation Board. The Institute Director and his/her deputy, as special representatives pursuant to §30 German Civil Code within the framework of the principles resolved by the Board of Directors pursuant to §6 (2), are entitled to act independently for the Institute and in this respect represent the Foundation in and out of court.
- (2) The representative authorisation is evidenced by a certificate of representation issued by the Supervisory Authority.

§13

Raising Funds

- (1) The Federal Joint Committee makes available the funds required on the basis of the resolutions of the Foundation Board on the budget pursuant to §5 (2), Sentence 4. The financing takes place in accordance with §139c (1) SGB V. The allocation of unused funds to the assets of the Foundation requires the consent of all members of the Board of Directors. It can only be given within the framework of §58 Tax Code.

- (2) The assets of the Foundation are EUR 50 000.00. They are inalienable and must be invested in analogous application of the provisions on the investment of monies with trustee investment status; yields from the assets and any payments by third parties which are not specified as assets must only be used for the fulfilment of the purpose specified in the Charter. The acceptance of payments by third parties – with the exception of payments pursuant to (1) – requires the consent of the Board of Directors. “Outside funding contracts” require the consent of all members of the Board of Directors. If this is not obtained, the decision is taken by the Foundation Board.
- (3) No person or organisation may benefit from the assumption of administrative tasks foreign to the purposes of the Foundation or from disproportionately high remuneration.

§14

Business Year

The business year is the calendar year.

§15

State Supervision

According to §8 Foundation Act (Berlin), the members of the Board of Directors have an obligation to notify without undue delay and prove to the Supervisory Authority the respective composition of the bodies of the Foundation and the Institute Director and his/her deputy, including the distribution of the offices within the bodies (election records, deeds of appointment, declarations of acceptance and resignation, or other evidentiary documents) and to notify the address of the Foundation and the residential addresses of the members of the Board of Directors, and of the Institute Director and his or her deputy. Proof of the composition of the Federal Joint Committee is provided by a declaration of the Chairman of the Federal Joint Committee with a legitimating effect in relation to third parties.

§16

Alterations to the Charter and Liquidation

- (1) This Charter can be altered by the Federal Joint Committee with a majority of two thirds of its members.
- (2) The Foundation can only be terminated in case of a significant change in the circumstances by a resolution of the Federal Joint Committee pursuant to §91 (2) SGB V with a majority of two thirds of its members.
- (3) Resolutions pursuant to (1) and (2) require the consent of the Foundation Supervisory Authority.

§17

Accession of Assets

In case of dissolution or termination of the Foundation, or in case of cessation of the purposes subject to tax relief, the assets accrue to the Federal Joint Committee, which must use them exclusively and directly for purposes subject to tax relief as defined in §2.

Siegburg, 17.07.2008

Chairman of the Federal Joint Committee

Dr. jur. Rainer Hess