

Regulation for approval of hospitals, use of the term university hospital, and national services within the specialist health service

(unofficial translation)

Legal Basis: Decreed by the Ministry of Health and Care Services on 17 December 2010 pursuant to the Act of 2 July 1999 No. 61 relating to the specialist health service etc. (the Specialist Health Service Act), § 2-1a fifth paragraph, § 2-3 No. 1 and § 4-1 second and fourth paragraph.

Section 1. Scope

§ 1-1. *Scope*

The present Regulation apply to the approval of hospitals, approval of the use of the term university hospital and approval of national services within the Norwegian specialist health service.

Section 2. Approval of Hospitals

§ 2-1. *Requirements for approval*

Establishment of hospitals must be approved by the Ministry of Health and Care Services before health services may be provided, cf. the Specialist Health Service Act § 4-1.

Hospitals covered by the doctor distribution scheme, cf. the Specialist Health Service Act § 4-2, shall apply for new approval in the case of construction, reconstruction or expansion of hospitals where the construction work is estimated to total NOK 500 million or more. Application for approval is also necessary in the case of a change in hospital operations which will have significant consequences for the services provided by other regional health authorities.

Private hospitals covered by the second paragraph, but which do not receive operating subsidies from a regional health authority or the government, shall apply for new approval in the case of changes which involve an expansion of services to include new medical fields.

Private hospitals not covered by the Specialist Health Service Act § 4-2 regarding distribution of doctors shall apply for new approval in the case of operational changes which involve an expansion of services to include new medical fields or an increase in the number of beds by more than 40% or by more than 10 beds in relation to the previously approved number of beds. The creation of more than three new positions over two years in total for radiographers or medical specialists within medical laboratory fields or radiology shall be submitted to the Ministry for consideration as to whether this creation represents a significant change which requires new approval.

Changes in approved hospitals under the provisions of the second, third and fourth paragraphs shall not be implemented until approval has been granted.

Hospitals which were approved prior to these Regulations coming into force shall still be considered as approved.

§ 2-2. *Application Requirements*

A programme of the hospital's main functions shall be attached to an application for approval under § 2-1, second paragraph.

§ 2-3. *The right to revoke approval*

Approval may be revoked if the operations are not conducted in a justifiable manner. In the case of a breach of conditions related to the approval, the approval may be revoked if this is in accordance with the general legal administrative requirements for reversal.

§ 2-4. *Requirements for hospitals with medical laboratory or X-ray facilities*

Medical laboratory facilities implies the medical activities of analysis and diagnosis of samples and the provision of examinations and treatment which require specialist expertise in the relevant medical laboratory field. Medical X-ray facilities implies medical activity which provides patients with examination, diagnosis, and treatment which require specialist expertise in medical radiology.

Hospitals with medical laboratory or X-ray facilities shall provide advice and guidance to the applicant regarding the benefit of various surveys and the participation in population surveys initiated by the central health authorities.

State-funded hospitals with medical laboratory and X-ray facilities shall also participate in preventive work and pass opinion on matters of hygiene or infectious diseases at the request of local or central health authorities.

§ 2-5. *Directives*

The Ministry may direct individual hospitals included in the doctor distribution scheme, cf. the Specialist Health Service Act § 4-2, to have or discontinue one or more of the services mentioned in § 4-2 of the Regulation.

Section 3. Approval of the Use of the Term University Hospital

§ 3-1. *Requirements for approval*

The regional health authority must apply to the Ministry of Health and Care Services for approval to use the term university hospital for a hospital trust and/or a hospital.

In the case of organisational changes of great significance for the use of the term university hospital, new approval must be sought.

§ 3-2. *Requirements for obtaining approval to use the term university hospital*

The following conditions must be fulfilled to obtain approval to use the term university hospital:

The hospital trust and/or the hospital must collaborate with one or more universities with degree courses for medicine and other health professionals in the following ways:

1. It makes a significant contribution in research-based education in medicine and other health disciplines
2. Students have most of their practical and theoretical education at the hospital
3. It makes a significant contribution to the PhD course in most clinical studies in medicine and other health disciplines
4. Biomedical and health-related basic research and translational and clinical research in most clinical disciplines can be documented
5. Wide-ranging research activity of high international standard can be documented

§ 3-3. *Assessment and recommendation by the liaison body and the Ministry of Education and Research*

The liaison body established between the regional health authority and the university or universities shall assess applications for approval to use the term university hospital. The assessment shall be based on the requirements as defined in § 3-2.

The case shall be sent to the Ministry of Education and Research for evaluation before the Ministry of Health and Care Services makes a final decision.

Section 4. Approval of National Services within the Specialist Health Services

§ 4-1. *Approval and termination of national services*

The regional health authorities shall apply to the Ministry of Health and Care services for approval of national services.

The Ministry may decide to terminate approved national services if one or more conditions that formed the basis for approval is no longer satisfied or if there is no longer a need to maintain the national service.

§ 4-2. *National and multi-regional treatment services*

A national treatment service shall be established by only one health authority in the country.

A multi-regional treatment service shall be established by only two health authorities.

§ 4-3. *Requirements for approval of national and multi-regional treatment services*

In order to be approved as a national or multi-regional treatment service, the centralisation of the treatment must be considered to provide:

- Additional health-related benefits in terms of improved prognosis and quality of life.
- Improved quality and competence.

- Improved national cost-effectiveness.

The evaluation shall emphasise competence and infrastructure.

§ 4-4. *Responsibilities of national and multi-regional treatment services*

National and multi-regional treatment services have the following responsibilities:

- To provide health care to all patients needing the relevant highly specialised treatment.
- To monitor and communicate treatment outcomes.
- To participate in research and the establishment of research networks.
- To contribute to relevant teaching.
- To ensure the provision of guidance and the dissemination of knowledge and competence to the health services, other service providers and clients.
- To implement measures to ensure equal access to national and multi-regional treatment services.
- To contribute to the implementation of national guidelines and evidence-based practice.
- To establish professional reference groups.
- To report annually to the Ministry or the body designated by the Ministry.

§ 4-5. *Requirements for approval as a national competence service*

In order to be approved as a national competence service, the centralisation of competence building within a certain field must be considered to provide:

- Improved quality in a holistic course of treatment within reasonable time.
- Increased national competence.
- Improved national cost-effectiveness.

The evaluation shall emphasise competence and infrastructure.

§ 4-6. *Responsibilities of national competence services*

National competence services have the following responsibilities within their field:

- To build and disseminate competence.
- To monitor and communicate treatment outcomes.
- To participate in research and the establishment of research networks.
- To contribute to relevant teaching.
- To ensure the provision of guidance and the dissemination of knowledge and competence to the health services, other service providers and clients.
- To implement measures to ensure equal access to national competence services.
- To contribute to the implementation of national guidelines and evidence-based practice.

- To establish professional reference groups.
- To report annually to the Ministry or the body designated by the Ministry.

Section 5. Commencement

§ 5-1. *Commencement*

These Regulations come into force on 1 January 2011.

This repeals the regulations of 18 December 2001 No. 1539 regarding approval of hospitals, national functions and national medical competence centre functions at hospitals.
