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# SPECIALISED HOSPITAL SERVICES

Principles of national planning in Denmark



**SPECIALISED HOSPITAL SERVICES – PRINCIPLES OF  
NATIONAL PLANNING IN DENMARK**

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# INTRODUCTION

Under the Danish Health Act<sup>1</sup>, the Danish Health and Medicines Authority (DHMA) is responsible for defining and allocating specialised hospital services for all publicly funded hospital services in Denmark. For each specialty (35 medical and 1 odontological) the DHMA maintains and updates a specialty guidance defining the relevant specialised hospital service within that specialty, and listing the hospitals approved for each specialized service. The totality of the 36 specialty guidance documents constitutes the national plan for specialized hospital services

The purpose of planning specialised hospital services is to ensure the quality and continuity of patient care, while at the same time allowing for efficient resource utilisation. Planning of specialised hospital services should also facilitate the necessary education and training, and should ensure the continued development of healthcare in Denmark.

When planning specialised hospital services, the DHMA strives to ensure consistent planning, coordination and collaboration between relevant parties in the Danish healthcare system, thereby assuring that specialised treatment can be provided at the national level with the necessary capacity, supply reliability and availability.

Under section 208 of the Danish Health Act, the DHMA defines requirements for specialised at regional and private hospitals, and approves individual hospitals to provide specific specialized services. Thus, the DHMA has the statutory authority to establish and discontinue specialised services and to grant and withdraw approvals for the performance of specialised services. The DHMA is responsible for performing regular reviews to ensure that the current planning of specialised hospital services is up-to-date, relevant and adequate.

Planning of specialised hospital services comprises publicly funded health services in the hospital system, and thus relates to the performance of patient treatment paid for by public funds at public and private hospitals, including private specialised hospitals, see section 79 of the Danish Health Act.

A central guiding principle of national planning of specialised hospital services is that 'practice makes perfect' – based on recognition of the relationship between healthcare experience, quality and volume at individual, unit and hospital level. Another premise is to ensure that citizens receive uniform, high-quality treatment across the country. This is ensured, for example, through planning of where and on what basis various services can be performed. If there is a conflict between delivering high-quality healthcare and delivering

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<sup>1</sup> Legal act no. 1202 of 14 November 2014, 'Sundhedsloven', in Danish only:  
<https://www.retsinformation.dk/Forms/r0710.aspx?id=152710>

health-care close to where the patient lives, the consideration of high-quality healthcare is prioritised.

Below, the general principles, requirements and recommendations for planning of specialised hospital services applicable for individual speciality guidance are described.

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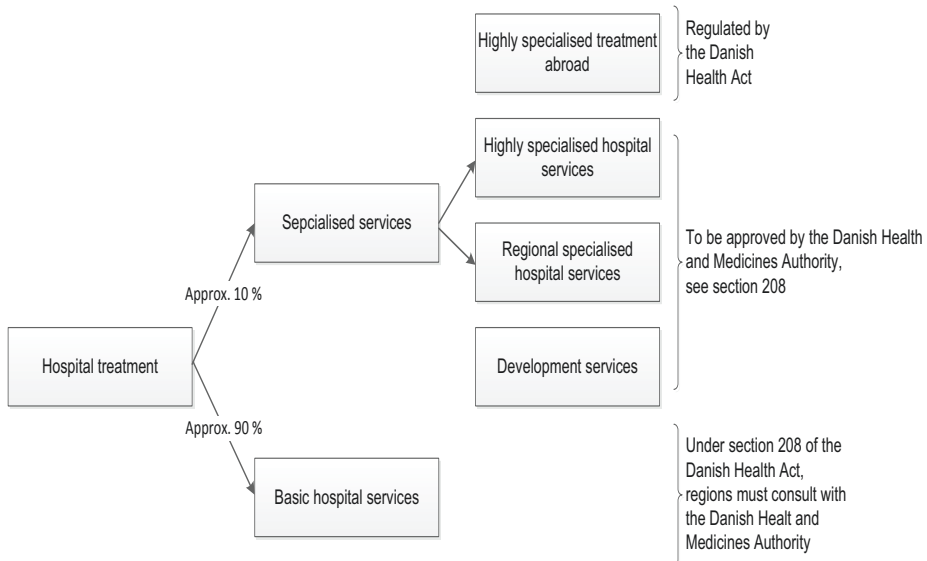
## LEVELS OF SPECIALISATION

Hospital treatment can be performed at two overall levels: main services and specialised services. The definition of specialised services is based on an assessment of the service, including the size of the patient group and the complexity and resource consumption of the service.

Specialised hospital services are secondary or tertiary referral services, and under current Danish legislation, and for the purposes of the national planning, the specialised hospitals services are categorised into two levels: regional and highly specialised hospital services. In certain circumstances, a specialised service may be defined as a developing specialised service. The allocation of specialised services under individual specialities is specified in the speciality guidelines for each speciality. The totality of the 36 speciality guidance documents constitutes the Danish national plan of specialised hospital services.

A given service may include prevention, assessment, treatment, palliation, rehabilitation and/or follow-up on a specific disease or defined group of diseases, or the service may be defined based on specified methods or techniques.

Figure 1. Overview of concepts used in planning of specialised hospital services



## **Basic hospital services**

For basic hospital services, patient care is of limited complexity, e.g. where diseases are prevalent and the services of the healthcare system are frequently required and where the resource consumption does not warrant concentration of services at specialised service.

## **Specialised service**

Tasks defined as either regional specialised hospital services or highly specialised hospital services are included in the overall category of specialised hospital services. Individual specialised services are defined in the speciality guidelines

- **Regional specialised hospital services**

Regional specialised hospital services are tasks of some complexity where the disease is relatively rare or the services of the healthcare system are rarely required and/or where the resource consumption warrants some concentration of services. A regional service is typically established in 1-3 locations in each region, depending on the patient population and local conditions of the region. If regional specialised hospital services are allocated to several hospitals in the same region, it is assumed that the hospitals performing the particular services enter into binding collaboration on, for instance, referral and guidelines for treatment. The collaboration could include clinical guidelines, quality monitoring and follow-up etc. In general, various regional specialised hospital services should be concentrated in few hospitals in the region to achieve synergies through easier collaboration opportunities and advantages of utilising emergency preparedness, common services and synergies in education and training, research and development etc.

- **Highly specialised hospital services**

Highly specialised hospital services are tasks of considerable complexity and depend on the existence of many interdisciplinary services/partners, tasks where the disease is very rare or the services of the healthcare system are required very rarely and thus require that knowledge, experience and expertise are concentrated, and/or tasks where the resource consumption is significant. The concentration in specific hospitals is designed to help generate synergies in that individual services can be supported and work with other services and specialities at the same level. This also applies to research and development, education and training where the existence of a wide variety of services provides a better foundation for establishing and developing these areas. Collaboration at the national level between hospitals approved to perform the same highly specialised hospital services is a prerequisite. A highly specialised hospital service is typically established at hospitals in 1-3 locations in Denmark.

A specialised service can be defined as a developing specialised service when its content, extent and definition remains to be clarified, and the DHMA finds that there is a particular need for close, national follow-up, for instance in terms of clarification of evidence, application, indications, professional qualifications, organisation etc. All specialities have in-process services, for instance at the research or experimental stage, and these services are not defined as development service, but should be performed in accordance with applicable rules. A developing specialised service may be placed either at the regional level or at the highly specialised level. Developing specialised service are subject to requirements in terms of, for instance, national guidelines, quality follow-up, organisation, collaboration and general follow-up. Details about developing specialised service are reviewed in chapter 7.

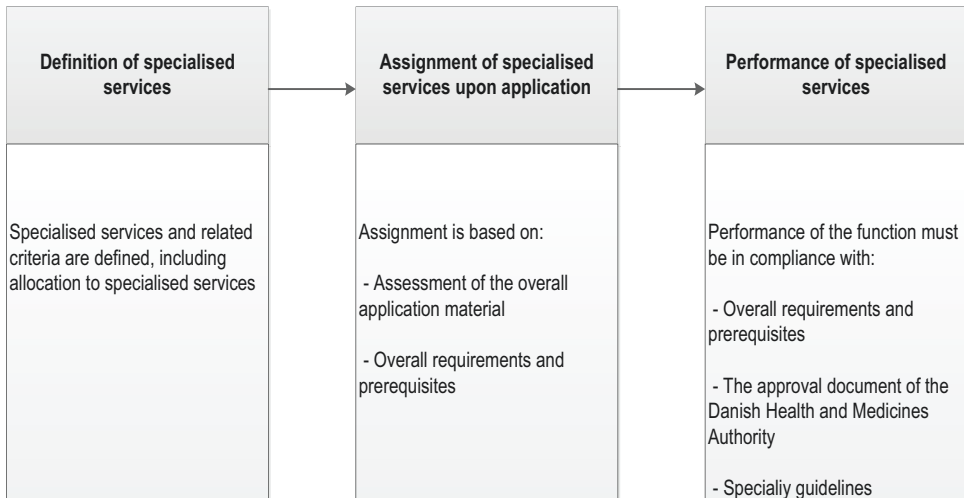


Some services are so complex, rare or resource-intensive that treatment at an adequate level cannot be established independently in Denmark. In those cases, and in respect to current legislation in Denmark, patients can be referred for highly specialised hospital services abroad. Such referrals must be provided by a nationally recognized tertiary service in the field; such recommendations being subject to approval by the DHMA, see section 89 of the Danish Health Act. Some services may possibly be performed by a Danish hospital in formal collaboration with a hospital abroad; where relevant, this will be specified in the individual speciality guidance.

# CRITERIA FOR ALLOCATION AND ASSIGNMENTS OF SPECIALISED SERVICES

Below follows a description of the criteria to be applied when a hospital service is defined as specialised and the prerequisites for assignment and approval of facilities to perform the service. The next chapter describes the overall prerequisites and requirements for the performance of specialised services. Figure 2 provides an overview of prerequisites and requirements.

Figure 2. Definition, assignment and performance



## 3.1 CRITERIA FOR SPECIALISED HOSPITAL SERVICES

The premise of planning of specialised hospital services is that 'practice makes perfect'. This means that a service should be performed only in the number of locations necessary to ensure that the required and appropriate knowledge, experience, expertise and volume are available, along with the necessary facilities to deliver high-quality performance.

The allocation of a service to a given level of specialisation is based on an overall assessment of the **complexity, occurrence and resource consumption** of the service. The more complex, rare and resource-intensive the service, the more specialised it is.

Other factors to be taken into account are national and holistic aspects of the overall Danish hospital system, as well as regional and speciality-specific differences, including capacity, development and geographical conditions.

Thus, it is a priority to ensure that a national offer is available with the necessary capacity, supply reliability and availability.

**Complexity** is assessed based on the complexity of the service, for instance technically or in terms of assessment, and the need for collaboration with other specialities/services, including multidisciplinary collaboration, as well as the need for emergency preparedness.

**Occurrence** is in most cases estimated by the incidence of disease as assessed by the annual number of new cases of one or more conditions, or as the number of specific diagnostic or therapeutic modalities offered within the respective specialised service. Where relevant, measures of prevalence can also be used. The need for experience, building of expertise, quality follow-up and development of the service is also considered. Some specialised services are so similar that specific expertise can be built that spans across these services. In these cases, the overall volume of these services may be included in the assessment of the future performance of the services.

The assessment of **resource consumption** includes considerations of socio-economic and economic conditions (for instance equipment or special medical products) and staff conditions (for instance specially qualified or specially trained staff).

Whenever possible, planning of specialised hospital services is evidence-based. Solid documentation exists for the relationship between volume and quality both at individual, unit and hospital level and for the benefit of close multidisciplinary collaboration between several specialities. However, evidence of specific organisational solutions is less well established. Thus, planning of specialised hospital services is to a large degree based on the knowledge and experience of health professionals.

The criteria of complexity, occurrence and resource consumption are not static. For instance, a specialised service may evolve to become more established, commonly known and uncomplicated. As a result, the indication area – and thus the patient population for the service – may grow, meaning that a regional service may change to become a main service. Consequently, developments may require changes and the establishment of new specialised services, and services may be reallocated from one level in the hospital service to another. These adjustments are subject to consultation with the Advisory Board for National Planning of Specialised Services (*Det Rådgivende Udvalg for Specialeplanlægning*).

### 3.2 ASSIGNMENT OF SPECIALISED SERVICES

The DHMA approves the allocation of specialised services to regional and private hospitals.

Where relevant, the DHMA will invite applications for the performance of specialised services<sup>2</sup>. Applications will usually be invited as part of the ordinary rounds of applications and only in exceptional cases outside these rounds. Based on the application material and

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<sup>2</sup> DHMA Guideline no. 9753 of 27 February 2014 on the implementation of section 208 of the Danish Health Act on planning of specialised hospital services, in Danish only, <https://www.retsinformation.dk/Forms/R0710.aspx?id=161659>

any supplementary information, the DHMA will decide which hospitals will be approved to perform specialised services.

Hospitals approved to perform a specialised service must comply with the requirements specified in the relevant speciality guidelines, the specific approval document and the requirements set out in chapter 4.

As part of a round of applications, the DHMA evaluates the overall application material submitted by the applicants. Thus, it will be possible for an applicant to be allocated a specialised service it did not previously perform. However, at the same time, specialised services will not be reallocated unnecessarily, thereby ensuring the development of qualified professional environments and the resilience of the healthcare system. If, in connection with a review of the speciality plan, it is assessed that further concentration of specialised services is required, allocating specialised services to hospitals performing other specialised services at the same level will generally be prioritised. For instance, highly specialised hospital services will be allocated primarily to hospitals performing other highly specialised services, including services related to the service in question.

In general, approvals will be granted only as part of ordinary reviews of the speciality plan based on rounds of applications, and approvals generally apply until the DHMA announces that revised speciality guidelines will come into force.

The DHMA will assign a specific specialised service on the basis of the description of this service in the speciality guidelines. When a given specialised service is assigned, the successful applicant undertakes to perform the service in question in accordance with the speciality guidelines, its application and the DHMA's approval.

In cases of doubt, the DHMA's interpretation of the service or the group of patients catered for by the specialised service or the requirements for the performance of the service will apply.

It is assumed that the region/private hospital will notify the DHMA if it no longer complies with the requirements, if the prerequisites for the approval change during the approval period or if the service is no longer performed. The DHMA should be notified as soon as possible and in any circumstances in connection with the statutory annual status reporting. If, after the assignment of specialised services, the organisation of specialised services needs to be changed, and these changes are not described in the application material, the applicant must apply for approval of the changes.

The DHMA approves private hospitals to perform specialised services to the extent that publicly funded patient treatment is involved. Private hospitals approved to perform specialised services must generally comply with all requirements placed on regional hospitals performing specialised services. This is especially the case if the private hospital offer replaces a public offer.

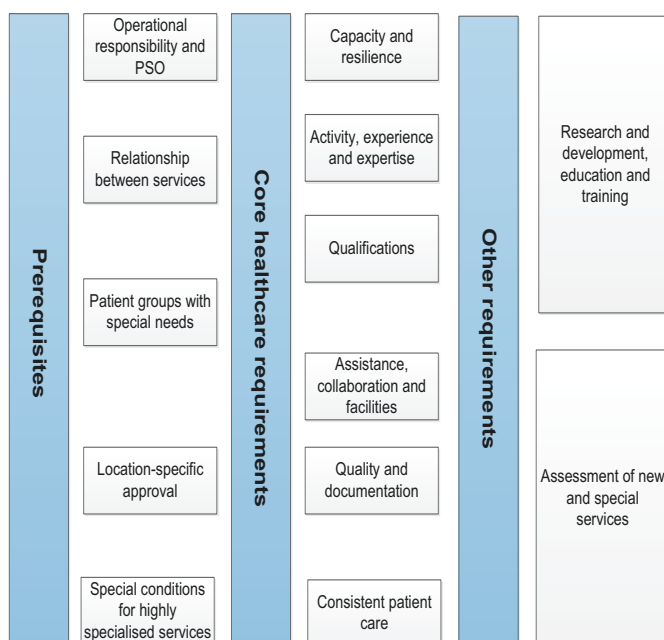
The DHMA's approval of a specialised service in a private hospital means that Danish Regions (*Danske Regioner*) may enter into agreement with the hospital on the performance of the specialised service under the provisions of the Danish Health Act on extended free choice of hospitals. Regions may also enter into other types of agreement on the performance of a specialised service with a private hospital approved to perform the specialised service. If a private hospital has been approved to perform a specialised service, but does not obtain an agreement with the regions – and thus does not receive patients for publicly funded treatment – the DHMA will withdraw the approval as it would with a public hospital that is unable to maintain the volume anticipated in its original application.

A region cannot enter into agreement on a specialised service with a private hospital not approved by the DHMA to perform the specialised service in question.

# GENERAL PREREQUISITES AND REQUIREMENTS FOR THE PERFORMANCE OF SPECIALISED SERVICES

This chapter describes the overall prerequisites and requirements for the performance of specialised services. Figure 3 provides an overview of these prerequisites and requirements.

**Figure 3. Overview of prerequisites and requirements for hospitals' performance of specialised services**



## 4.1 GENERAL PREREQUISITES FOR THE PERFORMANCE OF SPECIALISED SERVICES

### 4.1.1 Operational responsibility and public service obligation

Under section 74 of the Danish Health Act, the regional councils are responsible for the delivery of hospital services. If a region's hospitals perform a specialised service, the region thus has a public service obligation for the specialised service. The public service obligation entails an obligation to provide the specialised service 24/7/365 – also at peak times. To meet this obligation, at least three medical specialists must generally be available to perform the specific specialised service.

If a specialised service is not performed in the region, under section 209 of the Danish Health Act the regional council must enter into agreements on the utilisation of the specialised services at the hospitals of other regions or private hospitals. Thus, the region is required to refer patients for the appropriate treatment, including at the appropriate specialised service, whether or not this service is provided in the region of residence or in other regions. Under the Danish Health Act, private hospitals, in principle, have equality of status with regional hospitals, and it may therefore be necessary to specify explicit requirements for the public service obligation, for instance in terms of capacity and duration of the public service obligation, if private hospitals are approved to perform specialised services.

#### **4.1.2 Relationship between different services**

The specialities are, to varying degrees, interdependent, and the regional councils must ensure the cross-speciality relationship. The various regional specialised hospital services in a speciality must be concentrated at the same (few) hospitals to maintain the professional environment of the speciality and a relevant relationship with other specialities. When organising their regional specialised hospital services and highly specialised hospital services in the region, regional councils are also expected generally to ensure the relationship with the main service and with assisting and collaborating specialities. The regions are also expected to ensure the necessary coordination between regions.

Often, the elective and acute services of a specialised service are performed at the same location. In general, it is assumed that the acute services of a specialised service may be provided only at hospitals also providing the elective services of the service. If the elective and acute services of a specialised service are not provided at the same hospital location, a detailed description of the relationship between the services must be submitted in order for the hospital to be approved for these services. If the hospital provides only elective services of a service, it must also be specified how the hospital plans to manage acute complications.

#### **4.1.3 Patient groups with special needs**

For I selected patient groups, some tasks must be performed at a higher specialised service than otherwise required for the disease. In some cases, with particularly vulnerable patient groups, tasks that are not normally specialised services must be performed at specialised service. Special patient groups could be patients with a primary disease or disorder that is usually treated at main service, but where additional severe diseases or disorders co-occur with the primary disease or disorder (comorbidity), warranting that the task should be performed at specialised service. For these special patient groups, pregnancy or age could also warrant that a task should be performed at specialised service.

The speciality guidelines describe that, for some specialised service, maintenance treatment in a stable phase may be provided at a lower level of specialisation. Moreover, with some patients, it may be appropriate to provide maintenance treatment in a stable phase at a lower service than indicated in the speciality guidelines. This decision, including the follow-up plan for both service levels, will be made at the specialised service responsible for the service; the decision in each case will always be subject to a specific assessment.

If a patient does not want to be referred to the relevant specialised service, or if there are other weighty professional reasons for not referring or transferring the patient to the

relevant level of specialisation, the information and consent given must be specified in the patient's medical record.

It is assumed, *inter alia*, that treatment of children requiring anaesthesia is provided in accordance with the recommendations and requirements set out in the speciality guidelines for anaesthesiology and that treatment of pregnant women is provided in accordance with the recommendations and requirements set out in the speciality guidelines for gynaecology and obstetrics.

In addition to the diseases and treatments specified in the speciality guidelines, other selected patients should also be referred to a hospital providing specialised services, for instance in case of unclarified and complex conditions, particularly difficult or resource-intensive treatments or very rare conditions, even if these are not mentioned explicitly in the speciality guidelines, and/or special treatment offers are not expected to be available.

#### **4.1.4 Specialised services are approved for performance at specific, designated locations only**

The DHMA's approval of specialised services is location-specific. The location means the geographical location of the hospital, i.e. its physical location/address. Hospital locations are typically listed in 'SOR' (Register of Danish Health Organisations), under hospital classification for regional hospitals, or in 'CVR' (Central Business Register of Denmark), under the P number register for private hospitals.

A specialised service may be performed only at locations approved for the performance of the service independently or in formal collaboration at the hospital location specified. This means that the DHMA's approval of a specific specialised service applies only to the specified speciality at the specific, designated hospital and at the physical location approved by the DHMA.

#### **4.1.5 Special conditions for highly specialised services**

Due to the Danish Health Act's focus on quality, the principle that 'practice makes perfect' and the requirements for ongoing professional development, requirements especially for the performance of highly specialised services are extensive. Planning of specialised hospital services must ensure sufficient volume in the performance of a highly specialised service and ensure that the necessary special resources are available, including, for example, close collaboration with many other specialities at a highly specialised level. Moreover, planning of specialised hospital services must form the basis for utilising the experience gained in the ongoing professional development, research, education and training in the area. Thus – to an even greater extent than for the specialised level in general – it is essential for highly specialised services that public as well as private hospitals performing highly specialised services participate in professional development, research, education and training in the area, including in cross-regional collaboration to this effect. Finally, in its planning, the DHMA must ensure that the entire country has the best possible access to highly specialised services.

## **4.2 REQUIREMENTS FOR THE PERFORMANCE OF SPECIALISED SERVICES**

Below, the requirements for the performance of specialised services are reviewed. A number of core healthcare requirements are listed, all of which must be met by hospitals approved to perform specialised services; in addition, a number of other requirements are described.



### **4.2.1 Core healthcare requirements**

The same basic requirements apply to the performance of specialised services at public and private hospitals. Where private hospitals perform services on behalf of the public hospital service under an operating agreement concluded with a region or a similar authority, the private hospital must generally comply with the same requirements as the regions. If a private hospital performs a specialised service under the provisions on extended free choice of hospitals, the private hospital must comply with the core healthcare requirements for the service.

#### **Capacity and resilience**

Hospitals performing a specialised service must have the capacity and resilience required to perform the service in question. To ensure that a specialised service is available 24/7/365 and to ensure building and development of experience and a professional environment, it is generally assumed that at least three medical specialists have the specific qualifications to perform a given specialised service at a hospital in the speciality in question and at the level in question. The individual medical specialist may have specific qualifications to perform several specialised services. It is also assumed that qualifications relative to the individual specialised service are available from other relevant professional groups.

#### **Activity, experience and expertise**

In general, there is a relationship between quality, healthcare experience and expertise and volume at individual, unit and hospital level; thus, sufficient volume is an important factor in the performance of a specialised service. Hospitals performing a specialised service must have sufficient activity to achieve, maintain and develop experience in all professional groups. Moreover, there may be requirements as prerequisites for the service in terms of interdisciplinary services, emergency preparedness for both the service and other areas and the existence of other specialised services.

#### **Qualifications**

Hospitals performing a specialised service must ensure that sufficient staff, including doctors, nursing staff and other staff with the relevant and assumed specific qualifications, are available to perform the specialised service in the form of diagnostics, treatment, information, observation, nursing, rehabilitation etc. For the treatment of children, it is important to ensure that both medical specialists and nursing staff also have experience with the treatment of children and the qualifications to go along with it.

#### **Collaboration with other specialities**

If relevant, and where the expertise of other specialities is available, collaboration with other specialities is generally a prerequisite for the performance of specialised services.

In addition to this general prerequisite, the speciality guidelines specify requirements for collaboration with other specified specialities.

Interdisciplinary collaboration on the patient and more focus on the patient care process are increasingly needed. With technological advances, some treatments are becoming more complex, involving more speciality areas. In addition, there is a higher prevalence of multimorbidity than previously, due, inter alia, to the ageing population, which also increases the need for interdisciplinary collaboration.

Collaboration between specialities is important in a number of areas in daily clinical work and can take on many forms. Some specialities collaborate on specific patient groups, others on specific clinical procedures/services. Collaboration between two or more specialities may, for example, be simultaneous or serial, and in some cases joint conferences or shared clinical guidelines may be required to ensure quality and coherence in patient care efforts.

There is also an increasing tendency for medical specialists from different specialities to use the same treatment modalities and technologies, thus necessitating collaboration to ensure uniform treatment and sharing of experience. Some services are performed more appropriately if the necessary specialities are available at the same location, while other services may very well be performed in collaboration between specialities at different locations.

The speciality guidelines generally assume that a number of supporting hospital services are available at all service levels (or that access to such supporting services is available, depending on the specific specialised service). Thus – unless specific requirements exist for collaboration with these specialities in order to perform the individual specialised services – these specialities are not mentioned specifically in individual speciality guidelines:

- Radiology
- Clinical biochemistry
- Clinical immunology with blood bank services
- Clinical microbiology
- Pathological anatomy and cytology
- Clinical physiology and nuclear medicine
- Clinical pharmacology
- Paediatrics in the treatment of children
- Anaesthesiology in surgery

When intensive therapy is needed in the performance of specialised services, Intensive Level II is required as a minimum.

In general, specialised services must be performed in collaboration with other relevant specialities and, where relevant, at least at the same level of specialisation. This also means that, to the greatest possible extent, specialised services should be performed at a limited number of hospitals in Denmark with a wide range of collaborating specialities and facilities available at a relevant level of specialisation.

The speciality guidelines include the following requirements for collaboration between one or more specialities (inter-speciality collaboration):

- 1) To be performed in close collaboration with [speciality]
  - a) At the location [*To be specified explicitly if this is a requirement*]

*Explanation: Close collaboration with one or more other specialities is required. If the service must be performed at the location, this will be specified explicitly in the speciality guidelines.*

- 2) To be performed in a multidisciplinary team with [speciality/specialities]
  - a) At the location [*To be specified explicitly if this is a requirement*]

*Explanation: Multidisciplinary team collaboration with one or more other specialities is required. Collaboration is based on shared guidelines and joint conferences. If the service must be performed at the location, this will be specified explicitly in the speciality guidelines.*

- 3) To be performed in close collaboration rooted in one unit

*Explanation: Close collaboration with one or more other specialities in one unit at the same location is required. The rooting in one unit (organisational or physical) is designed to ensure a robust professional environment, joint professional development and building of sufficient experience to deliver high-quality healthcare treatment. Collaboration will typically be simultaneous where several specialities treat the patient*

*at the same time, or in relation to specialised services where the same treatment can be performed by medical specialists in one or more specialities.*

- 4) To be performed in interdisciplinary collaboration between [professional groups]

*Explanation: Interdisciplinary collaboration is required when the involvement of several different professional groups is particularly important.*

In hospitals treating elective patients only, collaboration with all of the specialities stipulated in the speciality guidelines may not be required. In those cases, a specific assessment of the individual specialised service applied for will be required.

Private hospitals, in particular, may experience cases where a collaborating speciality or a specific facility is not available in the hospital. In those cases, it should be documented in the application for specialised services how and where specifically collaboration with the speciality in question will be established.

#### **Assistance from medical specialist in own speciality**

The individual speciality guidelines specify requirements for how assistance must be available from a medical specialist from a given speciality. The assistance requirement refers to on-call time, as it is assumed that medical specialists in the speciality in question are present in the daytime on weekdays.

The specific implementation of these requirements, including work planning and staffing, will be a local management responsibility. Where the speciality guidelines specify requirements for medical specialist assistance, it is a local management responsibility to determine whether, in the specific case, this qualification requirement may be met by doctors towards the end of their speciality training for the speciality in question.

At the level of basic hospitals services, the DHMA issues recommendations. At the regional and highly specialised the requirements of the DHMA are specified for assistance from a medical specialist in the speciality in question as follows:

- 1) Immediately (usually within minutes)
- 2) Within a short period of time (usually 30 minutes depending on the specialised service)
- 3) The following day
- 4) The following weekday
- 5) Telephone advice (telephone advice also covers other types of advice where the medical specialist is not physically present at the location, including computer-mediated communication technologies).

The speciality guidelines may provide more specified requirements for the specific specialised services, for instance in terms of the qualifications of the medical specialist.

In some specialities, advice from medical specialists using modern technological solutions may be relevant. If a hospital plans to use such solutions, they may be described in the hospital's application for the performance of specialised services to the DHMA.

When hospitals treat elective patients only, the medical specialist may not in all cases be required to provide assistance at the same speed as in hospitals with acute services. In those cases, a specific assessment of the individual specialised service applied for will be required.

#### **Quality and documentation**

It is assumed that hospitals will ensure high quality in the performance of specialised services and will provide ongoing documentation of their efforts. Thus, hospitals performing specialised services must document these services. It is assumed that the hospitals report to relevant clinical quality databases and respond to local and national quality monitoring, which is a requirement for performing specialised services.

It is assumed that assessment and treatment etc. comply with national clinical guidelines where applicable. This can be seen as a prerequisite for providing generally uniform treatment for which quality follow-up can be conducted.

Regions and private hospitals are required to submit an annual status report to the DHMA on their compliance with the requirements for the performance of the specialised services assigned.

### **Consistent patient care**

Hospitals performing a specialised service are generally required to establish collaboration on patient care, for instance when, after being diagnosed at a hospital with main service, patients are referred to a hospital performing a specialised service, but also when patients are referred from the primary to the secondary sector.

## **4.2.2 Other requirements**

In addition to core healthcare requirements, hospitals performing specialised services must comply with requirements for research and development, training and education, assessment of new and special services and collaboration on dissemination of information where applicable. These requirements apply to public hospitals and private hospitals performing specific services by agreement with the public hospital service under a regional operating agreement or similar agreement. Where private hospitals perform specialised services under the provisions on extended free choice of hospitals, the private hospitals must generally comply with the core healthcare requirements specified above. Moreover, in exceptional cases, it may be necessary to demand that, although a private hospital performs a service only under the provisions on extended free choice of hospitals, it may be subject to the obligations below, for instance if private hospitals at the national level perform a substantial portion of the overall activity in the area.

### **Research and development, education and training**

Hospitals performing a specialised service must perform research and development tasks related to the service. Interdisciplinary collaboration between relevant departments/departments performing the same specialised service will be important, for instance to achieve sufficient patient volume.

Hospitals performing highly specialised services may be required to engage in research collaboration, internationally and with other hospitals performing highly specialised services.

Moreover, hospitals must participate in education and training, including continuing medical education. In this context, any consequences of the allocation of specialised services must be assessed specifically in relation to continuing medical education.

### **Assessment of new and special services**

Hospitals performing a specialised service are required – when deemed relevant – to carry out assessments/analyses and health technology assessments (HTA) before new technology and new treatments etc. for the specialised service are introduced. This applies to plans for commissioning of new technology and treatments at the specific hospital. In

this context, reference is made also to the DHMA's guidance on the introduction of new treatments in Danish healthcare<sup>3</sup>

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<sup>3</sup> 'Vejledning om indførelse af nye behandlinger i sundhedsvæsenet' (1999), in Danish only, <https://sundhedsstyrelsen.dk/Udgivelser/1999/Vejledning%20om%20indfoerelse%20af%20nye%20behandlinger%20i%20sundhedsvaesenet.aspx>

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# CONSISTENT PATIENT CARE AND INTERDISCIPLINARY COLLABORATION

The DHMA generally assumes that all hospitals will enter into relevant collaboration with other hospitals performing similar or related services within or across regions. This is essential to ensure optimal knowledge sharing, efficient resource utilisation and appropriate patient care.

Hospital departments involved in a patient care process are also assumed to engage in ongoing and appropriately coordinated collaboration – both in terms of cross-speciality collaboration in the same hospital and in terms of referral and collaboration between various levels of specialisation either within the same speciality or in another speciality.

Clear, written collaboration agreements are appropriate when it comes to the allocation of specific tasks in a patient care process. These agreements are often referred to as formal collaboration agreements. At the level of basic hospital service, regions and hospital departments are free to enter into this type of collaboration agreement. Collaboration agreements relating to or involving specialised services, on the other hand, are subject to approval by the DHMA.

Planning of specialised hospital services may involve various types of collaboration. The speciality guidelines typically specify two types of collaboration: multidisciplinary team collaboration and formal collaboration, which are reviewed below.

## **5.1 FORMAL COLLABORATION ON SPECIALISED SERVICES AND OFF-LOCATION SERVICES**

Considerations of proximity to the patient's home, patient volume, resource consumption, special organisational conditions, education and training and overall national and regional conditions, including geographical conditions, may, in some cases, warrant the establishment of formal collaboration between different units and services on specific specialised services within or across regions.

Thus, where appropriate, formal collaboration enables specialised services or parts of specialised services to be performed at a high level of quality in more hospitals than would otherwise have been the case, and may also help to quality assure services in hospitals that cannot independently meet all requirements and prerequisites, for instance, if the patient volume is too small, or training collaboration is needed to ensure necessary qualifications or follow-up and data collection.

When the DHMA approves a specialised service to be performed in formal collaboration, this means that the specialised service or parts of the specialised service (for instance parts or phases of patient care processes or limited patient groups) can be performed at the designated approved hospital location, provided that it is performed in formal collaboration with another hospital approved for independent performance of this specialised service.

The independently approved hospital may set requirements for which processes or patients that are as a minimum to be conferred with or seen by the independently approved hospital, for instance patients affected by particularly complex diseases. In some cases, the speciality guidelines will specify the patients/processes involved.

In general, the DHMA approves formal collaboration agreements on the performance of specialised services at other locations/lower service levels only if this is explicitly specified in the speciality guidelines as a possibility. However, in connection with the application process, additional formal collaboration agreements may be approved if warranted by special conditions.

Hospitals approved by the DHMA to perform specialised services or parts of specialised services in formal collaboration are required to enter into a written, binding collaboration agreement with another hospital that has been independently approved to perform the specialised service in question. This collaboration agreement will be the prerequisite for the hospital that has been approved only to perform a specialised service in formal collaboration to maintain its approval.

When a hospital that has been independently approved to perform a given specialised service enters into a formal collaboration agreement with a hospital approved only to perform the specialised service or parts of the specialised service in formal collaboration, it undertakes a number of obligations, for instance monitoring of the overall specialised service to ensure that it is performed to a satisfactory quality level and within the given framework. This can be ensured, for instance, through joint education and training, quality development and data collection.

However, it should be noted that the hospital approved to perform the service in formal collaboration is fully responsible for the quality of treatment and for ensuring compliance with the requirements and prerequisites set out in the approval document and the speciality guidelines.

The mutual responsibility and the mutual obligations should be specified in the written formal collaboration agreement.

The specific content of the formal collaboration agreement may vary depending on local conditions, but it must be within the framework specified in the relevant speciality guidelines and in the DHMA's approval documents.

The specific formal collaboration agreements on specialised services must be available and submitted for approval if requested by the DHMA. The DHMA's approval of formal collaboration is based on a specific assessment of the application, and possibly the collaboration agreement, and whether it complies with the prerequisites for the specific specialised service.

The status of the formal collaboration on specialised services is included in the annual status reports to the DHMA on the performance of specialised services.

It will be possible to perform specialised services at other hospital locations in the form of off-location services. In relation to a specialised service, an off-location service means that a treatment team from the location approved for the performance of the specialised service to a limited extent performs the service at a different location, for instance in the form of a decentralised outpatient service where the treatment team from the location approved for the performance of specialised services performs the service at a different location.

Requirements and frameworks for planned off-location services must be described in connection with the application for the performance of the service and will thus be included



in the assessment basis of the DHMA. In case of material changes in relation to this basis, the DHMA must be notified.

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## FOLLOW-UP ON THE SPECIALITY PLAN

The DHMA is responsible for following up on the applicable speciality plan to ensure that it is up-to-date, relevant and adequate. Follow-up is conducted through regular reviews of the speciality plan, annual status reports and monitoring through data extracts from the Danish National Patient Registry, regional clinical quality databases and other relevant databases.

### **Status reports**

Section 208(5) of the Danish Health Act states that regional councils and relevant private hospitals are required to submit annual status reports to the DHMA on compliance with requirements for specialised services.

The status reports are important instruments for the DHMA in its monitoring of the performance and development of specialised services. Thus, the annual reporting is key to the DHMA assessments of whether the requirements for specialised services have been met. The requirements for the performance of individual specialised services are specified in this document. The DHMA must always be notified if, contrary to expectations, the speciality plan is not complied with in accordance with the description in the initial application and the prerequisites specified in the approval.

The form of the annual status report varies depending on the DHMA's assessment of whether feedback of a general nature or more detailed reporting is required. Previously, both standard status reports and detailed status reports have thus been used.

The status reports submitted by regions and private hospitals will be assessed by the DHMA in terms of significant deviations from the assignment basis and significant deficiencies in the compliance with requirements and prerequisites. If the status reports result in considerations of changes to phrases in the speciality plan, for instance, or adjustments to the allocation of or requirements for specialised services, the DHMA will contact the hospital owner for further discussion. In case of non-compliance, a remedial plan must be specified. Based on the information submitted, the DHMA will decide on future approvals for the performance of specialised services. The conclusions of the DHMA will be discussed by the Advisory Board for National Planning of Specialised Hospital Services.

### **Monitoring**

With the new national plan of specialised hospitals services, scheduled to be effective from 2016, the annual status reports will be supplemented by monitoring of selected specialised services.

The purpose of monitoring the speciality plan is to identify:

- whether the volume of activity at locations approved for a specialised service is sufficient, including, if relevant, whether there is activity at locations not approved to perform the specialised service,
- whether the quality at the approved locations is sufficiently high.

As part of the follow-up on the performance of specialised services, the DHMA also wants an assessment of the scientific output at approved locations, especially in case of the performance of highly specialised services. However, the DHMA will not by itself conduct systematic bibliometric monitoring, but will include bibliometric data as reported by the hospitals as part of the overall annual status reporting.

In the next speciality plan, selected specialised services for each speciality will be monitored. The initial experience with monitoring of the speciality plan will be included in further considerations of expanding monitoring.

Both the clinical and the administrative side wish that monitoring should be relevant and useful, but still clear and easy to use. Existing databases and common practice for clinical recording are therefore used as the point of departure, and at the same time the aim is to monitor only selected and representative indicators for each speciality.

### **Selection of indicators**

At the meetings in connection with the review of the speciality guidelines, the individual working groups were asked to suggest a small number of relevant and possible specialised services to be monitored in the speciality in question. Thus, the DHMA has regularly included working groups to select specialised services considered relevant by the working groups to monitor. The DHMA subsequently qualified the proposals in partnership with SSI (*Statens Serum Institut*, public enterprise under the Danish Ministry of Health), the regions and RKKP (the Danish Clinical Quality Registries: A National Improvement Programme) and thus sorted the proposals received.

A number of considerations had to be included in the selection of monitoring indicators. Therefore, many specialised services have not been suitable for inclusion. One reason is that registration codes in the Danish National Patient Registry and the quality databases are often related to the actual disease and not the degree of severity of the disease. In the speciality plan, a disease is often placed at several levels, differentiated in relation to, for instance, the degree of complexity, and this is difficult to monitor unambiguously using data extracts from the Danish National Patient Registry and the quality databases. In the assessment of the DHMA, it will not be possible to monitor the entire speciality plan without creating new codes and registrations.

In connection with the selection of indicators, the DHMA has focused on fulfilling the purpose of identifying monitoring of both volume and quality.

On average, one or two specialised services in each speciality are monitored. In certain cases, it has been decided to monitor selected parts of the specialised service because it has not been possible, for data technical reasons, to unambiguously delimit the specialised service. In a few specialities, it has not been possible to find suitable specialised services to monitor.

### **Use of data**

Monitoring is based on data received from the Danish National Patient Registry and RKKP. The DHMA is aware that data may be subject to errors due to, for instance, faulty or lacking registrations. The speciality guidelines will specify how individual specialised services will be monitored in future, inter alia to avoid lack of registration. In case of problems with the data extracts, the DHMA will look into the issue.

The plan is to use data for descriptive statements that will be open to comments from regions and private hospitals. The DHMA is aware that monitoring data will need to be used with caution; especially during the initial years when the monitoring model is being tested and where, in some cases, data will be extracted on newly established specialised services and/or based on a new combination of registration codes from the Danish National Patient Registry or the clinical quality databases.

The process is expected to be that the DHMA submits data extracts for the selected indicators for each speciality in connection with the status reports. Regions and private hospitals will then be asked to comment on the data extracts, meaning that the monitoring data prepared are qualified locally.

The DHMA will use data to assess whether the relevant specialised service is performed in compliance with the speciality guidelines in terms of volume and quality. The DHMA will assess quality using the quality performance measures defined in the clinical quality databases and, in other cases, on the basis of advice from the speciality working groups that have helped to define how quality can be assessed based on extracts from the Danish National Patient Registry. If, based on data, the DHMA finds that the specialised service or the performance of the service should be adjusted, for instance by specifying new or amended requirements, by reducing or increasing the number of approved hospital locations or the like, the DHMA will assess whether the information is to be included in a future general round of applications, or whether the adjustment should be made sooner, i.e. between application rounds. If adjustment of the specialised service or the performance of the specialised service is needed, the DHMA will seek the advice of the Advisory Board for National Planning of Specialised Hospital Services.

Data will not be published, but will be subject to the rules on right of access (if requested).

#### **Further follow-up on the speciality plan**

The DHMA will regularly assess how best to follow up on the speciality plan. Thus, annual status reports may vary from year to year, and the monitoring model is also expected to be developed on an ongoing basis. The experience from the monitoring of the next speciality plan is to be used to gradually roll out more adequate monitoring of the speciality plan when the initial experience with monitoring in relation to the status reports has been gathered.

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# CRITERIA FOR ESTABLISHING AND ALLOCATING DEVELOPING SPECIALISED HOSPITAL SERVICES

All specialities and specialised services have unclarified issues and a need for new knowledge. Specialised services have a general obligation to document, develop, conduct research and educate, and these aspects are thus integral parts of the obligation to perform the service.

Some areas/services may have a particular need for clarification in relation to the future planning of specialised hospital services, and in those cases the DHMA may choose to define the service as a developing specialised hospital services, with resulting specified follow-up requirements.

## 7.1 ESTABLISHMENT OF DEVELOPMENT SERVICES

The DHMA establishes developing specialised hospital service only if a particular need exists for close national follow-up on a specialised service that remains unclarified, for instance with regard to application, indications, professional qualifications etc.

When proposals are made for the introduction of a developing specialised hospital service, specific and detailed justification must be provided, including, inter alia, a summary of issues, expected volume etc. to explain the necessity of creating a developing specialised hospital service. The justification must also explain how the issue differs from the ordinary development of treatment methods and modalities taking place in the healthcare system, but which does not necessarily imply that the service should be established as a development service.

Following consultation with the Advisory Board for National Planning of Specialised Hospital Services, the DHMA decides when the introduction of a new treatment, technology or the like is to be defined as a development service.

The following applies to developing specialised hospital services:

- that the introduction of the new service remains to be unclarified
- that close national follow-up is needed with associated regular reporting
- that, over a short span of years, clarification of the service's future ranking in planning of specialised hospital services can be expected.

Developing specialised hospital service services will be assessed regularly on the basis of the annual national status of the developing specialised hospital services, including whether and how these services may be ranked in the planning of specialised hospital services in the future. In advance, the expected time frame for the discontinuation of the developing specialised hospital services is established for the purpose of ensuring that the service must be a treatment offer and will thus be redefined as a main, regional or highly specialised service.

Furthermore, it is assumed that scientific societies, regions and private hospitals notify the DHMA if developments warrant a need for reassessment of a current development service or introduction of new developing specialised hospital services.

The process for the definition, allocation and approval of the performance of developing specialised hospital services is similar to that of other specialised services.

When a developing specialised hospital service has been allocated, a professional follow-up group for the specific service will be appointed; the relevant professional associations and the hospitals performing the service will participate in this group.

## **7.2 REQUIREMENTS FOR THE PERFORMANCE OF DEVELOPING SPECIALISED HOSPITAL SERVICESERVICE**

In general, the following requirements (to be finally defined in relation to the specific service) apply to any developing specialised hospital service:

- Appointment of a professional follow-up group
- Description of the basis of the performance of the service in a project description/protocol
- Building of experience with annual reporting to the DHMA on the status of the service
- Reporting within a well-defined time frame based on an adapted health technology assessment (HTA) approach, adjusted to developing specialised hospital services
- Other service-specific requirements.

Moreover, the performance of developing specialised hospital services must generally be in compliance with the speciality guidelines, i.e. requirements in terms of on-call conditions, collaborating specialities etc. specified at regional or highly specialised, respectively, in the speciality guidelines.

The DHMA will prepare general terms of reference (annexe 2), including composition and tasks of professional follow-up groups. The terms of reference may be adjusted to service-specific conditions, if any.

Unless the DHMA decides otherwise, the professional follow-up group must develop a protocol for the performance of the service (annexe 3), be responsible for the consistent building of experience and for providing the annual status to the DHMA

Unless the DHMA decides otherwise, the follow-up group must also prepare and submit a national report (including a mini-HTA) when the developing specialised hospital service is up for reassessment.

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# ESTABLISHMENT OF NEW SPECIALISED SERVICES AND APPLICATION FOR EXISTING SERVICES OUTSIDE APPLICATION ROUNDS

Changes to, discontinuation and establishment of (new) specialised services take place in collaboration with professional and regional representatives in connection with regular reviews of the speciality guidelines/speciality plan in connection with which it is also possible for regions and private hospitals to apply for approval to perform specialised services.

Overall, weighty reasons are required to justify establishing new specialised services and reopening application rounds for specialised services that have already been allocated. One reason is that reopening of application rounds may potentially impact the overall national performance of the specialised services affected; moreover, approved hospitals must have the possibility of long-term planning. However, in certain cases, there may be a particular need for establishing new services or reopening application rounds; therefore, the following general principles govern when it may be considered to establish new specialised services or reopen an earlier round of applications for specialised services.

## 8.1 ESTABLISHMENT OF NEW SERVICES

The following general principles apply to the decision to establish specialised services outside application rounds of planning of specialised hospital services:

- If new services are to be established outside a future general review of the speciality plan, there must be a substantial need for new services.
- If services comprise patient groups where the service needs to be concentrated/established and where, out of consideration for the patients, this cannot await a future review of the speciality plan, establishing a specialised service may be considered (for instance services that were not included in the original round of applications or services where new knowledge has been gained or new and advanced technology developed, requiring the service to be concentrated).
- A broad-based consensus on the above is required, based on declarations from the Regional Working Group for National Planning of Specialised Hospital Services (*Den Regionale Baggrundsgruppe for Specialeplanlægning*) and/or the Advisory Board for National Planning of Specialised Hospital Services.

## 8.2 APPLICATION FOR EXISTING SERVICES

The following general principles apply to applications outside ordinary rounds of applications:

- In case of capacity problems among already approved hospitals, assessing applications received for already existing specialised services may be considered.
- Substantial and weighty other arguments from an applicant may justify the assessment of applications received for already existing specialised services (for instance that, out of consideration for patients, allocation to additional locations cannot await a future review of the speciality plan, or that it would be a major obstacle to a region's continued development of its healthcare system if the establishment of a service were to await a new round of applications, and where developments in the area warrant that, in the longer term, the service can/should be rolled out to more locations).
- A broad-based consensus on the above is required, based on declarations from the Regional Working Group for National Planning of Specialised Hospital Services and/or the Advisory Board for National Planning of Specialised Hospital Services.
- If deemed sufficient, the DHMA may assess applications received without involving the Advisory Board for National Planning of Specialised Hospital Services and/or the Regional Working Group for National Planning of Specialised Hospital Services, for instance in connection with changes in the allocation of existing specialised services in a given region as a result of changes in healthcare plans etc.



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# PRINCIPLES FOR WITHDRAWAL OF APPROVALS TO PERFORM SPECIALISED SERVICES

Reassessment of approvals, including considerations of withdrawal of approvals, is conducted if the DHMA assesses that a hospital approved to perform a specialised service is no longer able to provide healthcare quality at a sufficient level.

After consultation with the Advisory Board for National Planning of Specialised Hospital Services, and based on the Danish Health Act, the DHMA has defined a number of specific principles for withdrawal of approvals to perform specialised services.

Withdrawing approvals to perform specialised services may be considered if, for instance,

- there are changes in the performance of the service, including a decrease in volume or a lower volume than expected at the time of application,
- fewer medical specialists or other necessary staff than assumed are available,
- collaborating specialities are lacking, and other conditions that could potentially lead to a decline in healthcare quality, or conditions that were prerequisites for the approval, but which are no longer met.

Annexe 4 describes the process for withdrawal of hospital approvals to perform specialised services.

The DHMA Authority may withdraw an approval to perform a specialised service following consultation with the Advisory Board for National Planning of Specialised Hospital Services if a hospital department approved to perform regional and highly specialised services no longer complies with the requirements specified in chapter 4 and specific descriptions in individual speciality guidelines.

Withdrawal of approvals to perform specialised services is made by the DHMA under the authority of section 208(4) of the Danish Health Act. See also annexe 4 for a review of the statutory basis for withdrawal of approvals.

A hospital may at any time voluntarily relinquish its approval to perform a specialised service if the hospital deems that it cannot (any longer) comply with the requirements on which the approval was based. Hospitals wishing to relinquish an approval must contact the DHMA

# ANNEXES

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- Annexe 1: Model for the content of a formal collaboration agreement
- Annexe 2: Terms of reference and professional follow-up group for development services
- Annexe 3: Template for protocol/project description of development services
- Annexe 4: Statutory basis and procedure for withdrawal of approvals to perform specialised services

# ANNEXE 1

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## TEMPLATE FOR A FORMAL COLLABORATION AGREEMENT

### **Model for the content of a formal collaboration agreement in the speciality plan**

The formal collaboration must be described in a joint collaboration agreement. If relevant to the service in question, the following aspects should be described in the formal collaboration agreement:

- Definition and delimitation of the patient group, possibly including delimitation of the parts of the patient care process covered by the collaboration agreement
- Principles for referral as well as indications for assessment and treatment
- Clinical guidelines
- Collaborating specialities in the performance of the service
- Staffing of the service at the collaborating hospital, including description of staff qualifications and experience
- On-call staff
- Healthcare collaboration between the hospitals
- Collaboration on quality assurance and development
- Education/training and exchange of staff
- Capacity and activity level for the collaborating hospitals
- Description, if relevant, of transport between hospitals in case of acute or elective transfer of patients
- Collaboration on research and development within the services in question
- Collaboration on education and training, including continuing and further education and training
- Other relevant areas of collaboration
- Evaluation, duration and time frame.

# ANNEXE 2

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## TERMS OF REFERENCE FOR A STEERING GROUP OF A DEVELOPING SPECIALISED HOSPITAL SERVICES

For each development service, a professional follow-up group is appointed to be responsible for preparing a protocol/project description, building experience, preparing national status reports and annual status reports.

### Protocol/project description

The professional follow-up group must prepare a protocol/project description, describing the issue, purpose, organisation, scope etc. of the project, including application, indication, expected effect, required professional qualifications and organisation, including any clinical guidelines.

The protocol must

- be prepared within the first four months of the appointment of the group and be updated annually by the group, unless otherwise agreed with the DHMA
- comply with the DHMA's outline for the project and cover the planning and execution of the project, including practical milestones, allocation of responsibilities and tasks etc.
- include a relevant timetable for the national report and reassessment of the status of the service as a development service
- include other requirements relevant to the service in accordance with the DHMA's approval of the service.

The protocol and the updates are subject to approval by the DHMA.

### Building of experience

The professional follow-up group is responsible for building experience and ensuring consistent/comparable building of experience at all hospitals performing the service. The group defines indicators and a plan for the building of experience.

The building of experience may, for example, be in the form of reporting of relevant and comparable data to a database publishing an annual status report. If a relevant national database exists in the area or a related area, the protocol should seek to build its reporting on this database, possibly by adding additional indicators. This is prioritised over building new databases.

Where no database exists in the area, other relevant building of experience must be ensured, for instance record audits or similar means.

### Annual status

Unless otherwise agreed, the professional follow-up group must submit an annual status report to the DHMA. The status report must include the areas specified in the protocol.

In general, the status report is a brief written report covering all hospitals performing the service.

### National report

Based on the data collected, the professional follow-up group must prepare and submit a national report to the DHMA.

The national report must comply with the DHMA's outline for the report (annexe 3). The report is subject to approval by the DHMA prior to publication.

The national report must be submitted to the DHMA within a well-defined time frame agreed with the DHMA. The report must include the requirements relevant to the service in accordance with the DHMA's approval of the service.

## **12.1 Composition of the professional follow-up group**

### Members

The professional follow-up group is composed of representatives from relevant professional associations and the hospitals etc. involved in performing the service.

In general, the relevant professional associations each appoint one or two representatives, and the hospitals etc. involved in performing the development service each appoint one member of the group. The members of the follow-up group must have the requisite insight in the area. In addition, two members from the regional management level are appointed.

When several specialities or disciplines are involved, coordination must be ensured in the appointments to ensure that all specialities are represented by at least two members and that any significant disciplines are represented in the group.

In addition, the DHMA may appoint members to the follow-up group to ensure the necessary breadth of representation. The DHMA attends the meetings of the follow-up group as required.

### Chairmanship

The professional follow-up group elects its chairman and deputy chairman from among its members. The chairman is appointed by one of the participating professional associations. The meetings of the follow-up group are chaired by the chairman. The chairman must ensure that the DHMA is, at all times, kept up to speed on the group's work and that the DHMA receives the products described in a timely manner.

The DHMA must approve the composition of the group and its chairmanship and may, in exceptional cases, choose to chair the group.

### Secretarial service and appointment of committees

The secretarial service of the professional follow-up group follows the chairman. The relevant operators are responsible, as agreed, for providing secretarial services to the group, running a database, if relevant (if a database does not already exist) and for covering other expenses in relation to the group's activities.

The follow-up group may appoint an executive committee if warranted by the size of the group to ensure the work of the group. The follow-up group may also appoint ad hoc sub-working groups and, for instance, involve other relevant persons.

The follow-up group may also involve regional competencies, for instance MTA competencies, as required.

### Frequency of meetings

The professional follow-up group determines the frequency of its meetings, but will meet at least twice a year. The frequency of meetings is expected to be three or four meetings per year after start-up and preparation of the project description.

The DHMA will hold one overall annual meeting with the chairmen of the follow-up groups to ensure follow-up and sharing of experience between the groups.

In addition, the DHMA may invite the follow-up groups to annual status meetings and ad hoc meetings as required.

### Minutes

Minutes are in the form of resolution minutes. The minutes must be submitted to the DHMA for information within one month of the meeting.

# ANNEXE 3

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## TEMPLATE FOR PROTOCOL/PROJECT DESCRIPTION OF DEVELOPMENT SERVICES

The protocol is to ensure description of the issue, purpose, underlying evidence, planning, scope etc. of the project, including in relation to application, indication, expected effect, required professional qualifications, organisation etc. This includes standardised guidelines for organisation, protection of qualifications and experience, referral and assessment of patients, processes before and during treatment, follow-up and control and quality assurance.

### **Introduction and background**

- Description of the development service and its background, including issue, purpose, prevalence and other treatment options
- Brief literature review of the evidence, Danish and international, on which the development service is based
- Assessment of the usability of the existing literature in relation to the current development service and the planned treatment regimen.

### **Guidelines for referral and treatment**

#### Material and method

- Application and indication (inclusion and exclusion criteria)
- Expected number of patients or number of procedures nationally
- Guidelines for treatment
- Expected effect
- Possible risks, side-effects or other adverse effects
- Special ethical or psychological considerations
- Other patient conditions.

#### Organisational conditions

- Necessary volume
- Qualifications, experience, education and training etc. – possibly specified for each speciality involved
- Relationship with other specialised services in the speciality/specialties
- Physical framework or equipment
- On-call conditions, if any
- Other collaborating specialities
- Collaboration with other hospitals or sectors
- Other prerequisites required to be met from start-up.

**Building of experience**

- Method of building experience, including indicators, timetable etc.
- The building of experience may be described in a separate memorandum.

**Timetable and responsibilities**

- For the tasks of the follow-up group and each department involved
- How to ensure coordination across departments/hospitals etc.
- Composition of the working group.

**Reference list**

- References



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# STATUTORY BASIS AND PROCEDURE FOR WITHDRAWAL OF APPROVALS TO PERFORM SPECIALISED SERVICES

## **Statutory basis for withdrawal of approval**

Withdrawal of approvals to perform specialised services is made by the DHMA under the authority of section 208(4) of the Danish Health Act. Here, it is stated that if a hospital department approved to perform regional and highly specialised services fails to comply with the requirements specified by the DHMA, despite being ordered to do so by the DHMA, the DHMA may withdraw the approval following consultation with the Advisory Board for National Planning of Specialised Hospital Services.

'Requirements specified' should be understood in the broad sense of the word and include requirements specified in the DHMA's speciality guidelines, memoranda, approval documents and other announcements etc. in the area. Reference is also made to the requirement stated in section 208(5) of the Danish Health Act on submission of annual status reports.

Under section 208(4) of the Danish Health Act, the decision of the DHMA may be appealed to the Minister for Health. However, unless the Minister for Health decides otherwise, the appeal will not act as a stay of execution. Thus, unless the Minister for Health decides otherwise, the DHMA Authority's decision takes effect immediately

## **DHMA's procedure for withdrawal of approval**

As far as possible, the following procedure is used for the assessment and processing of cases involving withdrawal of approvals.

1. The DHMA ascertains that a given specialised service is not performed in compliance with the requirements and prerequisites specified by the DHMA, including requirements specified in the DHMA's speciality guidelines, memoranda, approval documents and other announcements etc. in the area.
2. The DHMA contacts the approved hospital/region for consultation. Following the DHMA's assessment, in the specific case, the hospital/region may be requested to submit a report and a plan for how it will solve the problem. In this connection, the DHMA may also order the hospital/region to comply with the DHMA's requirements, as described in item 1, and state that it intends to take action to withdraw the approval to perform the specialised service if the hospital fails to comply with the DHMA's instructions within a specified time limit.
3. If the hospital in question then fails to submit a report with a description of how it intends to remedy the deviation, or the report submitted fails to adequately assure the DHMA that the hospital will comply, the DHMA may choose to take action to withdraw the approval.

4. The DHMA consults with the Advisory Board for National Planning of Specialised Hospital Services on the proposed sanction for the hospital/region and then makes its decision.
5. The hospital/region in question then has a set time period to appeal the decision and submit any new and significant information that should be known by the DHMA in its handling of the case.
6. Following renewed consultation with the Advisory Board for National Planning of Specialised Hospital Services, if required, the DHMA makes its final decision on withdrawal of the approval to perform the specialised service.
7. In case of withdrawal of approval, the hospital/region in question may choose to appeal the DHMA's decision to the Minister for Health, bearing in mind, however, that the appeal will not act as a stay of execution unless the Minister for Health decides otherwise.



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