Principles for priority setting in health care

Summary of a white paper on priority setting in the Norwegian health care sector

Norwegian Ministry
of Health and Care Services

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PREFACE

In June 2016, the Government presented a white paper (Meld. St. 34 (2015–2016)) to Parliament, proposing a set of principles for priority setting in the Norwegian health care sector. Parliament approved the white paper in November 2016. The approved principles for priority setting will guide decisions on allocation of resources in the Norwegian health care sector.

Oslo, January 2017.
Norwegian Ministry of Health and Care Services

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INTRODUCTION

Why is it necessary to set priorities for medical treatment? After all, such priorities imply that some people will get treatment before others, while others may get no treatment at all. Is this really necessary? Why is it not possible to offer everyone the medical assistance they desire? It is one of the fundamental challenges of the health care services that the possibilities and wishes for treatment exceed the available resources to provide it. Thus, there is no question of whether we need to set priorities, because there is a prioritisation process taking place whether we choose it or not. But we can decide which principles should be applied as a basis for these prioritisation decisions. Without such principles in place, priority setting in health care will become more random, patients with identical needs will receive different levels of treatment, and it will become more difficult to promote legitimacy for difficult decisions.

In the Government's view it is essential to clarify principles, roles and responsibilities in this area, and to reinforce this with support from the Storting (Norwegian parliament). Otherwise it will not be possible to provide a system for priority setting in health care that is economically and politically sustainable and that is consistent with the underlying value base of the Norwegian health care services.

THE NEED TO SET PRIORITIES

The key priority-setting challenges in the Norwegian health care services can be divided into three main groups. The first involves the gap between society's overall resources to implement interventions and what is medically feasible. The potential inherent in emerging medical technology will always be greater than the resources that the health care services have available. It will never be possible to expand allocations enough to resolve this. This gap is the result of forces such as demographics, morbidity among the population and patient expectations, which are only to a limited degree steered or influenced by policy. In 2015, the Government presented a white paper (Meld. St. 11 (2015–2016)) containing the National Health and Hospital Plan (2016–2019) which includes, among other things, projections for population growth in Norway and the ramifications of this for resource needs in the specialist health care services in the period up to 2030. The second relates to the design of the health care services themselves, for example in connection with the organisation of the services or the status of the various professions, which may have unintended effects on the distribution of health care services among the various patient groups. And the third revolves around the external framework conditions, such as regulations or international market conditions, that may have an impact on the distribution of resources within the health care services.

These are complicated issues encompassing some factors that can be influenced through political decisions and some that cannot. The mosaic of challenges facing the health care services illustrates the need for an effective and just system for priority setting. Without such a system, we run a greater risk of making decisions that create an imbalance between resources and opportunities, and of distributing health care among patients in a manner that is at odds with the prioritisation principles we seek for our national health care services.

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BACKGROUND AND HISTORY

Systematic efforts relating to prioritisation issues in the Norwegian health care services go back many years. In the past 30 years, five government commissions were appointed to evaluate principles for priority setting in the health care sector: the Lønning I Commission (1987), the Lønning II Commission (1997), the Grund Commission (1997), the Norheim Commission (2014), and the Magnussen Working Group (2015). In Official Norwegian Report 1997:18 *Prioritering på ny* [Priority setting revisited], the Lønning II Commission recommended that priority setting in the Norwegian health care services should be based on three criteria: severity, expected benefit and cost-effectiveness. Parallel to this, in Official Norwegian Report 1997:7 *Piller, prioritering og politikk* [Pills, priorities and policy], the Grund Commission recommended reimbursement of costs for medications to treat serious diseases when such medicines are proven to be beneficial and cost-effective. "Benefit" and "cost-effectiveness" were directed towards the objective of achieving the best possible health in relation to available resources, while "severity" was directed towards the objective of providing medical assistance to those in greatest need of it.

The Lønning II Commission's proposal defining the three priority-setting criteria – severity, expected benefit and cost-effectiveness – was approved by the Storting in its deliberations on St.meld. nr. 26 (1999–2000) *Om verdiar for den norske helsetenesta* [Report No. 26 (1999–2000) to the Storting on values for the Norwegian health care services] and has since then formed the foundation for priority setting in health care in Norway. These criteria are reflected in the Norwegian Patients' Rights Act. The recommendations of the Grund Commission resulted in, among other things, the introduction of Section 14 into the Norwegian Act on Medicinal Products, which regulates medicines funded under the Norwegian National Insurance Scheme. The same priority-setting criteria are employed by the National System for Managed

Introduction of New Health Technologies within the Specialist Health Care Services, which was established in 2013 and takes decisions regarding funding of medicines and technologies for use in Norwegian hospitals.[1]

Although the recommendations of the Lønning Commissions have received widespread acceptance in the Norwegian national health debate, a number of questions have subsequently been raised. How is severity to be defined in concrete terms in different situations, what is the actual threshold for how much we are willing to pay for medications or other methods and technologies, and have any other criteria or considerations emerged that are more relevant now than in 1997? In the wake of the debate on costly cancer medicines in spring 2013, and knowing that additional new costly medicines and treatment methods would certainly appear in the years ahead, the Stoltenberg II Government decided to appoint an official commission – the Norheim Commission – to evaluate the current set of criteria for priority setting in health care. In Official Norwegian Report 2014:12 Åpent og rettferdig – prioriteringer i helsetjenesten [Open and fair – priority setting in the health care services], the Norheim Commission proposed three revised criteria for priority setting in health care in Norway:

- The health-benefit criterion: the priority of an intervention increases in keeping with the expected health benefit.

- The resource criterion: the fewer resources an intervention requires, the greater the priority of this intervention.

- The health-loss criterion: the priority of an intervention increases in keeping with the expected health loss from birth of the individual/individuals who will be experiencing the health benefits.

The recommendations of the Norheim Commission can be seen as an effort to hone the recommendations of the Lønning II Commission into something more precise. An important exception here is the Norheim Commission's proposed health-loss criterion. The Norheim Commission also proposed explicit cost thresholds for prioritising interventions. The report received support from various actors, but the health-loss criterion was broadly criticised and reactions to the proposed explicit thresholds were mixed. In June 2015, the Solberg Government chose to set aside the health-loss criterion and appointed an expert group – the Magnussen Working Group – to determine how to assess severity of illness in priority setting in the health

1 An English-language description of the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services may be found at: https://nyemetoder.no/english.

care services. The working group presented its recommendations in the report *På ramme alvor – alvorlighet og prioritering* [In all seriousness – severity and priority setting] in November 2015.[2] The working group's recommendations garnered broad-based support when the report was circulated for consultation. The group's proposed severity criterion and the Government's proposed principles for priority setting in the Norwegian health care sector are discussed in greater detail in Chapters 5 and 6.

2 A summary of the report is available in English: www.regjeringen.no/contentassets/d5da48ca5d1a4b128c72fc5daa3b4fd8/summary_the_magnussen_report_on_severity.pdf

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MAIN FOCUS OF THE WHITE PAPER

An important aspect of this white paper is to describe the relationship between the values underlying the Norwegian health care services and the principles and instruments for priority setting. Practical priority setting in health care entails distributing the services' resources to certain areas and interventions rather than others. Sound and just prioritisation requires a set of instruments, such as decision-making systems, rules, and normative clinical guidelines and instructions. To ensure that the instruments are applied consistently, they must be based on a set of principles for priority setting. Priority-setting principles ensure equal access to treatment across patient groups and decision-making levels in the health care services. These principles must be based on values that have widespread legitimacy among the population at large and among health care personnel. It is the principles for priority setting that render the values of the Norwegian health care services concrete.

The values underlying the principles for priority setting in the Norwegian health care sector are rooted in the following fundamental view: Each individual has an inviolable intrinsic value regardless of gender, religion, socioeconomic status, level of functionality, relationship status, place of residence or ethnic background. The population must have equal access to health care services. Similar cases must be treated in the same way. Equitable distribution also entails that society must be willing to give higher priority to those with the greatest need for health care services. At the same time, this must be viewed together with what will promote the greatest possible health among the population over time. Furthermore, the health care services are part of a comprehensive social insurance scheme for the population, and residents must receive equal services according to need, regardless of personal finances, social status, age, gender, health status earlier in life, etc. Health care personnel have an obligation to help individual patients to the best of their ability and at the same time to be responsible for health care in an overall perspective. Priority setting in health

care must be practiced in a manner that safeguards the relationship between health workers and the patient, both the known patient being treated at the time and the next patient who will need medical assistance. Steps must be taken to preserve patient dignity. All patients who need nursing and care must receive it even if the health care services cannot provide effective treatment.

The principles for priority setting in health care in Norway must be formulated to harmonise with this value framework. At the same time, the Government emphasises that these values must be reflected not only in the principles for priority setting, but also in the related decision-making processes. When assessing these processes, openness and user involvement will be of key importance.

The Government further seeks to draw attention to the relationship between participation in working life and health. As a general rule, participation in working life enhances the quality of life and health of the individual. Working may help to prevent mental health problems by offering a framework for daily routines and activities, a chance to socialise, opportunities for mastery, increased meaning of life, and providing income and a sense of belonging. Use of resources in the health care services also helps to promote good health among the population and enhance the opportunity for the individual to participate in working life and society at large throughout his or her lifetime. When assessing the benefit of an intervention for an individual patient, it may be relevant to include the positive aspects of working life for the patient's quality of life. However, the economic value of the work that will be performed when a patient returns to his or her job is not to be included in prioritisation considerations in the Norwegian health care services. Every human being has an inherent worth regardless of what he or she can be said to deserve or what he or she carries out in working life.

In the view of the Government, the principles for priority setting are relevant for all levels of the Norwegian health care services. However, there is some variation in the degree to which they have been incorporated into the regulatory framework, into professional decision support tools or serve as more general ethical guidelines. There are also differences in how these principles can be rendered more concrete at different levels, including the degree to which the exercise of discretion will be called for. At the clinical level, there may be a need for different discretionary assessments when meeting the individual patient than in decision-making based on a health technology assessment (HTA) in connection with the introduction of new methods and technologies. In the discussion of the principles for priority setting, this white paper distinguishes between different types of decision-making:

- Decision-making at the clinical level;
- Decision-making at the group level;
- Decision-making at the administrative level;
- Decision-making at the political level.

The clinical level is where health care personnel meet the individual patient and decision-making typically involves situations in which interventions are targeted towards individuals. Interventions can be implemented quickly, the decision-maker knows the individual in question and the decision-maker may possess extensive information about this individual. This information may include, for example, knowledge about the individual's gender, age, use of medicines, history of illness and clinical findings. In addition, the decision-maker often has information about the preferences, wishes and social or family situation of the patient in question. User involvement is an important consideration in decision-making at the clinical level. Decision-making is also influenced by the fact that health care personnel often have a limited choice of options due to existing capacity.

Decision-making at the group level primarily concerns decisions taken within national decision-making systems, i.e. decisions taken by the Decision Forum of the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services and decisions taken by the Norwegian Medicines Agency regarding inclusion of medicines in the reimbursement scheme. However, decisions regarding the funding of new medicines under the National Insurance Scheme are taken by the Storting as well, when the expected costs exceed a defined minimum threshold. Decision-making at the group level is normally characterised by different factors from decision-making at the clinical level. These decisions revolve around how to prioritise between certain patient groups or diseases in society. As a general rule, the decision-maker does not know the individuals affected by the decision. Prioritisation decisions at the group level are often based on total and average values for a patient group as a whole. These may include, for example, average costs of treatment for the group or information about the expected benefit for the group. However, each patient group will be heterogeneous, for example with regard to the way each individual in the group will respond to the treatment. Decision-makers often have limited information about such variation. When a decision is made to establish a treatment option for a patient group, all patients who fulfil the medical criteria and conditions will normally be offered this treatment.

Administrative decisions regarding distribution of resources are prioritisation decisions taken by managers and boards at various levels of the specialist health care services, municipal health and care services and the national health administration. Decisions may encompass day-to-day activities, budget distribution and investments that may affect the treatment options available to various

patient groups. These decisions typically share the same characteristics as those described in the paragraph above on decision-making at the group level.

Political decisions on distribution of resources are primarily manifested in budget-related and legislative decisions taken by the Storting and decisions taken by municipal councils as well as through the Minister of Health and Care Services' steering documents for the regional health authorities. Political decisions will per definition involve finding a cohesive balance between many different considerations.

Current principles for priority setting, including priority-setting criteria, have primarily been targeted towards priority setting in the specialist health care services, for funding of medicines under the National Insurance Scheme and for interaction between general practitioners and the specialist health care services. The Government will therefore appoint a public commission to examine priority-setting issues in the municipal health and care services and determine whether and how the principles for priority setting proposed in this white paper can be applied in the municipal health and care services. Thus, the principles for priority setting discussed in the white paper are mainly of relevance for the specialist health care services, for funding of medicines under the National Insurance and for interaction between general practitioners and the specialist health care services.

The three priority-setting criteria proposed in this white paper represent on the whole a further refinement of the current criteria and are consistent with the proposals by the Norheim Commission and the Magnussen Working Group, which received wide support when circulated for consultation. Other proposed criteria will also be discussed along with the Norheim Commission's and the Magnussen Working Group's proposed systems for weighing criteria and cost thresholds, cf. Chapters 7–9. Together, these proposals comprise the principles for priority setting that are to apply in the Norwegian health care services. A key message conveyed in this white paper is that the principles must address relevant considerations and they must be viewed together in an overall perspective. At the same time, a clear distinction is made between the principles and frameworks to be decided by the Storting and the decisions that should be left to the decision-makers in the health care services.

The white paper presents a brief outline on how the proposed principles for priority setting should be followed up with the use of various instruments, including professional decision support tools and the regulatory framework. Special focus is placed on the systems for funding and evaluation of medicines used in the public health care system in Norway and proposed adjustments to these, as well as on the principles for patient user-payment schemes.

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OVERALL PRINCIPLES FOR PRIORITY SETTING

The Government will base priority setting in the health care sector on the principles described below. These principles will apply to the specialist health care services, funding of medicines under the National Insurance Scheme and interaction between general practitioners and the specialist health care services. The principles are discussed in greater detail in Chapter 6 and in Chapters 8–10.

Main criteria for priority setting:

- Interventions in the health care services are assessed on the basis of three priority-setting criteria: the benefit criterion, the resource criterion and the severity criterion. Two forms of the benefit criterion and the severity criterion have been provided: a textual description for use at the clinical level and a quantitative form for use in health technology assessments (HTAs) at the group level.

The criteria for use at the clinical level:

- The benefit criterion: The priority of an intervention increases in keeping with the expected benefit of the intervention. The expected benefit of an intervention is assessed on the basis of whether there is knowledge-based practice that indicates that the medical intervention will extend the patient's life and/or enhance the patient's quality of life by increasing the likelihood of:
  - survival or reduced loss of function;
  - improvement of physical or mental function;
  - reduction of pain, physical or mental distress.

- The resource criterion: The fewer resources an intervention requires, the greater the priority of this intervention.

- The severity criterion: The priority of an intervention increases in keeping with the severity of the condition. The severity of the condition is to be assessed on the basis of:
  - risk of death or loss of function;
  - the degree of loss of physical and mental function;
  - pain, physical or mental distress.

  The present situation, the duration and the future loss of life years are all of significance for determining the degree of severity. The more urgent the need to start the medical intervention, the higher the degree of severity.

Quantification of the criteria for use in HTAs at the group level:

- Benefit is to be measured in healthy life years.

- Severity is to be quantified by measuring the number of healthy life years lost as a result of not making the treatment under assessment available, i.e. absolute shortfall.

- In connection with assessments of preventive measures, severity is to be calculated based on those individuals who would have developed the disease if the measure had not been introduced.

- In keeping with current practice, a quality-adjusted life year (QALY) is to be used as a measure of a healthy life year.

A definition of the benefits and resource use to be emphasised in prioritisation decisions:

- Health improvements for family members may in relevant cases be included in the calculation of benefit.

- The impact of a medical intervention on the patient's future productivity is not to be given weight.

- All relevant resource use in the health care services is to be given consideration in so far as this is possible.

- In HTAs at the group level, consideration is to be given to the impact of interventions in the specialist health care services on resource use in the primary health and care services.

- Consideration is to be given to the amount of time used by the patient in connection with a medical intervention.

- The impact of a medical intervention on the patient's future use of public services and receipt of benefits/ pensions is not to be given weight.

Balancing the criteria at the group level:

- The priority-setting criteria are to be assessed and weighed against one another. The more severe the condition or the more extensive the benefit of the intervention, the more

acceptable higher resource use will be. Conversely, giving priority to conditions with low severity and interventions with limited benefit can only be justified if resource use is low.

- The Norheim Commission's and the Magnussen Working Group's estimated opportunity cost is to be used as the basis for priority setting at the group level, i.e. NOK 275 000 per healthy life year.

- An intervention is to be assessed against the opportunity cost of that intervention, i.e. the benefit to other patients that could have been realised with the same resources. In keeping with current practice, a cost-effectiveness ratio is to be calculated and assessed against the opportunity cost.

- The cost-effectiveness ratio is to be weighted with the severity of the condition. In order to be financed by the public health care services, the intervention must provide more benefit per Norwegian krone, adjusted for severity, than the resources it displaces. Extremely severe conditions may be given a high weight, moderately severe conditions a moderate weight and conditions with low severity a low weight. The more severe the condition, the higher the cost-effectiveness ratio that will be accepted. Current practice is a reasonable expression of how society weights high severity in decision-making at the group level.

- As a basis for prioritisation decisions at the group level, an HTA is to be performed in keeping with the principles for priority setting.

- In connection with HTAs, discretionary assessments are to be included in the overall assessment of interventions. This applies in particular to assessments of:
  - Quality and uncertainty associated with documentation. Provided that all other factors are essentially equal, great uncertainty in connection with documentation and calculation methods will result in lower priority.
  - Overall budget ramifications of an intervention.

- When assessing interventions targeted towards small patient groups with a severe condition where it is difficult to perform controlled outcome studies, a less stringent requirement for documentation may be acceptable.

- When assessing interventions targeted towards very small patient groups with an extremely severe condition, such as children with congenital genetic diseases, where there is often a lack of good documentation of the benefit of an intervention, higher resource use than for other interventions may be acceptable.

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FURTHER DETAILS ON THE MAIN CRITERIA FOR PRIORITY SETTING

The benefit criterion

Many different assessments of benefit take place in the Norwegian health care services each day. Health care personnel assess whether a treatment will be beneficial for a patient, the patient assesses the treatment options proposed by a physician to find the one he or she considers most promising, and hospitals assess the benefit of investing in new equipment. The benefit criterion appears in a legal context in two main ways. First, expected benefit is to be weighted when allocating the right to necessary medical assistance in the specialist health care services. Second, benefit is to be weighted when determining whether medicines should be pre-approved for reimbursement under the National Insurance Scheme. Correspondingly, when assessing a technology, the Decision Forum in the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services gives decisive weight to the benefit of that technology.

The benefit criterion proposed by the Lønning II Commission and the health-benefit criterion proposed by the Norheim Commission are essentially identical. Both commissions were of the opinion that the priority of an intervention should increase in keeping with its expected benefit. The Government shares this view. In this white paper, the benefit criterion is presented in two forms: a textual description for use in prioritisation decisions at the clinical level and a quantitative form for use in HTAs and prioritisation decisions at the group level (public funding of medicines and technologies), cf. Chapter 5. The two forms of the benefit criterion have equal status, but will have different application areas.

Quantification of the benefit criterion requires that health improvements can be summed up in a measureable unit that makes it possible to compare benefit across patient groups and interventions. The Government supports the Norheim Commission's recommen-

dation that "healthy life years", in keeping with current practice, should continue to be used as a unit of measure for benefit in calculations that form the basis for decisions regarding interventions at the group level. This concept accommodates both changes in health-related quality of life and changes in life expectancy resulting from an intervention.

A natural point of departure for measuring benefit in HTAs is to give all healthy life years the same weight. It is difficult to identify other principles for weighting that have the same legitimacy. The Government views it as justifiable to use this as a basis for measuring benefit at the group level. However, in HTAs future health is discounted, so healthy life years that will be gained well into the future have a lower present value than those gained in the near future. In line with current practice, the discount rate will remain at 4 per cent. A minimum value for expected benefit will not be used when prioritising interventions at the group level. Indirect benefit in the form of health improvements for family members may, in relevant cases, be included in the calculation of benefit. In the HTAs that form the basis for decision-making by the Norwegian Medicines Agency and the Decision Forum of the National System for Managed Introduction of New Health Technologies, quality-adjusted life years (QALYs) are used as a quantifiable measure of healthy life years.

The resource criterion

Consistent with the Norheim Commission's recommendation, the Government proposes the following resource criterion: *The fewer resources an intervention requires, the greater the priority of this intervention.* The resources used to treat someone could potentially be used to treat someone else. Interventions that improve the health of certain patients will therefore entail lost opportunities for improving the health of others. Optimal use of resources is a prerequisite for achieving effective, fair priority setting. The resource criterion should not be applied on its own, but together with the other two main criteria. Prioritising an intervention that will use more resources than another might be the right thing to do in cases where that intervention generates more benefit or is targeted towards individuals with more severe conditions. It must also be understood that the resource criterion is to be applied per patient or intervention. Low overall resource use because a patient group is small will not be sufficient for giving priority to an intervention on the basis of this criterion.

The proposed criterion does not entail any significant change to current practice, but aids in clarifying the role of the individual priority-setting criteria. The Lønning II Commission did not propose a separate criterion for resource use, recommending instead that cost and effect be assessed together in a common cost-effectiveness criterion. The commission did, however, propose a separate benefit criterion, which was to be understood as estimating the value of

the clinical outcome. This has contributed to somewhat imprecise use of concepts, in the Norwegian regulatory framework among other places. The regulations on priority setting in the health care services state, among other things, that a patient must be expected to derive benefit from a medical intervention in order to have the right to necessary medical assistance in the specialist health care services, but that there must be a reasonable relationship between the estimated costs and the effect of the intervention. In the view of the Government, the various measures of effect, benefit and health improvements should be included under the benefit criterion, while resource use should be included under the resource criterion. The Norheim Commission's separation of resource use and benefit (health benefit) into two criteria helps to clarify this.

In addition, both the Lønning Commissions and the Norheim Commission recommended distinguishing between assessments of resource use at the clinical level and resource use at the group level when setting priorities. At the clinical level, available resources are often clearly delineated and well defined; however, for practical reasons an individual physician cannot map and calculate all resource use within and outside of the health care services in connection with the treatment of an individual patient. For assessments at the group level, on the other hand, mapping of all relevant resource use will be appropriate. The Norheim Commission and the Magnussen Working Group recommended that resource use is compared with the benefit of an intervention in a cost-effectiveness ratio in HTAs at the group level. The Government supports this recommendation. This will give decision-makers the opportunity to choose interventions based on an overall assessment of the resources required by and benefit of the interventions.

Many different resources may be needed in connection with the implementation of a medical intervention: buildings, ambulance services, ICT systems, medicines and technical medical equipment. Not least, competent health care personnel are essential for nearly all interventions in the health care services. Prioritisation decisions should give consideration to all relevant resource use in the health care services in so far as this is possible. In this context the health care services refer to both the specialist health care services and the municipal health and care services. Interventions in the specialist health care services may increase or reduce resource use in the municipal health and care services. The impact of interventions in the specialist health care services on resource use in the municipal health and care services is currently taken into consideration in HTAs at the group level. The Government recommends continuing this practice. The Government also believes that the time used by patients in connection with a medical intervention is of relevance for prioritisation decisions at the group level. In general, the quality of life must be

assumed to be higher for patients undergoing less time-consuming treatments. However, the impact of a medical intervention on the patient's future productivity or future use of public services and receipt of benefits/pensions must not be given weight when taking prioritisation decisions, cf. the discussion in Chapter 4.

The severity criterion

In Norwegian priority setting traditions, it has long been recognised that the severity of illness is significant as a criterion for prioritisation. The more urgent the need to start the medical intervention and the greater the health losses the patient will experience without treatment, the greater the willingness has been to give priority to a patient. At the same time, questions have been raised about how to adequately define severity, not least in HTAs at the group level, and about whether severity exerts any influence on the willingness to pay for a medicine or a treatment method.

In a legal context, severity is manifested in the Norwegian health care sector in the prioritisation of patients through assessment of their right to necessary medical assistance in the specialist health care services and in the assessment of applications for pre-approved reimbursement of medicines under the National Insurance Scheme. The regulations on priority setting in the health care services state that when prioritising patients, weight must be given to shortfall in terms of life expectancy and quality of life if the medical intervention is postponed. According to the regulations, in order for a medicine to be placed on the list for pre-approved reimbursement under the National Insurance, the medicine must be used to treat a serious illness or risk factors that will in all likelihood lead to or exacerbate a serious illness. However, no concrete definition is given for how to quantify severity in HTAs at the group level.

The Norheim Commission proposed measuring severity with a health loss criterion. In June 2015, the Solberg Government set aside this recommendation and assigned the Magnussen Working Group the task of determining how to assess severity of illness in practical priority setting. The working group concluded that severity is relevant for priority setting at both the clinical level and the group level, but recommended presenting the severity criterion in two forms: a broad textual description for use in clinical practice, and a targeted operationalised form for use in quantifying severity in HTAs at the group level. The working group proposed quantifying severity in assessments at the group level by measuring the number of healthy life years that would be lost if the treatment was not made available, i.e. absolute shortfall. In addition, the group stressed that the application of the severity criterion must be supplemented by discretionary assessments both at the clinical level and in analyses at the group level. There was broad-based support

from the consultative bodies for the working group's concrete proposal for the severity criterion. The Government gives its support to this proposal, cf. Chapter 5. At the same time, however, the Government wishes to emphasise that in connection with HTAs, discretionary assessments must be part of an overall assessment of interventions at the group level. Further details on the Magnussen Working Group's discussion on how to quantify severity may be found in the box below.

THE MAGNUSSEN WORKING GROUP'S DISCUSSION ON HOW TO QUANTIFY SEVERITY

The Magnussen Working Group considered four alternatives for quantifying severity at the group level. In each alternative, the degree of severity of a condition was measured based on a comparison of a new intervention and the treatment options currently available. In its consideration of these alternatives, the working group attached particular importance to:

Absolute shortfall from birth

Absolute shortfall from birth entails an assessment of the patient group's loss of quality of life and life expectancy in comparison with normative figures for the population as a whole. The Norheim Commission proposed a norm of 80 healthy life years. According to the Magnussen Working Group, using the patient group's expected absolute shortfall from birth as the basis for priority setting implies using the health care services in a project in which the objective is that all individuals should be able to experience an equal number of healthy life years over the course of their lifetime. This is because higher priority is given to those who have lost the most healthy life years earlier in life, in addition to those who are expected to experience a higher loss of healthy life years in the future. According to the working group, loss of health prior to the onset of a disease represents a phase of life that belongs to the past and does not increase the severity of the present health situation. In the view of the working group, severity must thus be linked to future health outcomes related to a given disease, i.e. the health impacts of not making a new form of treatment available.

The number of remaining healthy life years – prognosis

Prognosis is based on the evolution of the patient's condition and captures the present health situation as well as the development and duration of the disease. The working group defined prognosis as remaining life expectancy and quality of life as measured in healthy life years. In the case of chronic conditions, the number of remaining healthy life years will necessarily be higher the younger the patients are. Prognosis does not, however, take into account future loss of healthy life years. This implies that patient groups that live longer with a disease will have a better prognosis than those suffering

from the disease for a shorter period. The working group concluded that *prognosis* alone does not adequately capture the relevant aspects of the term severity.

Future loss of healthy life years – shortfall

Future loss of healthy life years compares the life expectancy and quality of life for a patient group with the average expected remaining healthy life years and quality of life for the population as a whole. According to the working group, future loss of healthy life years plays a significant role in the assessment of severity and is a measure that captures the present health situation, the illness duration and future loss of healthy life years. The working group discussed in detail whether the future loss of healthy life years should be measured as proportional shortfall or absolute shortfall. Absolute shortfall expresses the number of healthy life years lost by a patient group as a result of a disease as compared with the average expected healthy life years for the population of the same age. Proportional shortfall expresses the proportion of anticipated life expectancy and quality of life lost by a patient group as compared with the average anticipated life expectancy and quality of life for the population of the same age.

Proportional shortfall differs from absolute shortfall in two ways. Proportional shortfall does not take into account when during life a chronic condition occurs, and it will assess a temporary loss of healthy life years as more serious for older patients than for younger patients. Both of these elements led the working group to prefer absolute shortfall as a better measure of severity. In addition, in the context of proportional shortfall, a small loss of healthy life years late in life may be considered as equally serious as a large loss early in life because the small losses may comprise an equivalent *proportion* of expected remaining healthy life years. In the opinion of the working group, it is more serious to lose 20 of 40 remaining healthy life years than to lose one of two remaining healthy life years.

Thus, the working group concluded that absolute shortfall incorporates to a greater degree than the other measures the key features of what characterises a condition as severe. Furthermore, the group recommended that future loss of healthy life years should be calculated based on the anticipated life expectancy of the patient group in question, not on normative figures on average expected healthy life years for the population as a whole.

Some of the consultative bodies were critical to the Magnussen Working Group's proposed quantification of severity, stating that it indirectly gave too much weight to age, since future loss of healthy life years is influenced by the age of the patient group at the time of treatment. The Government disagrees with this objection. It is more serious to develop a chronic disease earlier in life than later in life because the individual will live longer with the disease. Correspondingly, those who die of disease early in life will lose more healthy life years than those who die of disease later in life. The majority of the

consultative bodies support the working group's conclusions. It is also important to underline that assessments about whether to introduce a method or a medicine at the group level are linked to the average values of the group. When the decision is made to introduce a method or technology, elderly patients will be given the same priority as younger patients with the same disease. At the same time, clinicians must consider which specific patients in the relevant patient group should be offered a given treatment based on clinical guidelines for the condition in question and their clinical discretion.

The Government would also like to point out that examples involving young and elderly patients in discussions on priority setting can sometimes give a misleading picture of the distribution of the health care services' resources among age groups. Independent of the choice of priority-setting criteria, a large share of the health care services' resources will be used to treat elderly patients as needs increase and disease occurs more frequently with age.

The Norheim Commission and the Magnussen Working Group also discussed assessment of severity in connection with preventive measures and in cases of comorbidity. Both the commission and the working group concluded that assessment of severity should be included in group-level decision-making on preventive measures in the health care services. In many cases, however, preventive measures are targeted towards healthy individuals with the aim of reducing their risk of becoming seriously ill in the future. Thus, these individuals will not be seriously ill at the point in time a preventive measure is implemented, and their risk of becoming seriously ill in the future may be reduced as a result of the measure. The respective proposals of the Norheim Commission and the Magnussen Working Group involve linking calculations of severity to the disease to be prevented, measured from the time this disease occurs. In addition, the working group proposed that comorbidity should have an impact on the degree of severity if the co-occurring diseases/disorders are related to the condition towards which a preventive measure is targeted.

The Government supports the Norheim Commission's and the Magnussen Working Group's approach to severity and preventive measures. When considering preventive measures, severity should in general be calculated for those who would have developed the disease had the measure not been introduced. Furthermore, the Government supports the Magnussen Working Group's approach to integrating comorbidity considerations into assessments of severity. The Government acknowledges, however, that there may be methodological challenges to achieving this in practice and will therefore launch an effort to revise the instructions and guidelines for HTAs subsequent to the Storting's deliberations on this white paper.

7

OTHER CRITERIA

The terms of reference for the Norheim Commission referred to the three main criteria proposed by the Lønning II Commission, and asked the commission to evaluate whether other criteria should also be included in the basis for priority setting. Other criteria, such as age and rarity, have been discussed in Norwegian and international literature. Some of the considerations relating to potential additional criteria will already have been wholly or partially addressed in the main priority-setting criteria proposed here. This white paper looks at the most important other criteria that have been discussed. It is the Government's view, in keeping with the Norheim Commission's recommendation and current practice, that none of these criteria should have an independent role as criteria for prioritisation in the Norwegian health care sector. The arguments relating to the criteria age, rarity and end-of-life care are outlined in brief below. In addition to these, the white paper also discusses the criteria lack of intervention alternatives, contribution to innovation, and individuals' responsibility for their own health.

Age has never been used as a designated criterion for priority setting in health care in Norway. Current priority-setting instructions state explicitly that age in itself is not to be used as a basis for prioritisation when assessing the right to necessary medical assistance in the specialist health care services. Although age is not a formal priority-setting criterion, it may nevertheless be given weight when health care personnel assess patients. Among other things, age is an important factor in diagnostics and treatment because it indicates the patient's risk of developing various conditions, the expected severity of a disease and the extent of the benefit the treatment is expected to have. Pneumonia and influenza, for example, are often much more serious for the very young and the very old.

Although age does not have an independent role in priority setting in the health care services, it may thus nevertheless correlate with the priority-setting criteria. As mentioned above, the

expected benefit of an intervention may be dependent on the risk of illness or deterioration within the patient group, which often has a correlation with age. With regard to chronic conditions, the benefit of an intervention with lasting effect measured as healthy life years will also increase the younger the patient group is, assuming that all other factors are essentially equal. Severity measured as absolute shortfall will in many cases be greatest for diseases affecting younger age groups. It is more serious to develop a chronic condition earlier in life than later in life, and those who die of illness early in life lose more healthy life years than those who die of illness late in life. The Magnussen Working Group pointed out that this is not an indication of a deprioritisation of elderly patients. Rather, it implies that society considers diseases depriving patients of many future healthy life years as more severe than diseases depriving patients of fewer future healthy life years. The majority of the consultative bodies that provided input to the working group's report support this view. The Government shares it as well.

There is no single, widely accepted definition for rare diseases/diagnoses/conditions, but the term is used in connection with diseases with very low prevalence in the population. Rare diseases are often accompanied by multiple challenges for the individual and his or her family members as well as for health policy development. There may be limited incentives for the pharmaceutical industry to develop medications for such diseases because market potential is small. In the event a medicine is developed, it is often very expensive because development costs can only be distributed among a few patients. Furthermore, there may be greater uncertainty about the figures from clinical studies where the number of participating patients is low. The fact that a disease is rare also means that expertise among health care professionals is often limited to a few individuals. For patients and their family members, a rare disease may entail trying out a variety of methods with little or limited effect until, when possible, a diagnosis is reached for which there are treatment options.

The Government believes that the three main criteria will for the most part address relevant considerations relating to rare diseases in prioritisation decisions. Rare diseases with a high degree of severity for which relevant treatment will be of good benefit to patients viewed in relation to resource use, will be given priority. Non-severe rare diseases should not necessarily be given priority over severe conditions that affect many people. The Government therefore supports the Norheim Commission's conclusion that there is no basis for introducing rarity as an independent priority-setting criterion. The Government would also like to point out that challenges relating to the rarity of a condition must primarily be solved with measures targeting these challenges

directly, such as measures relating to competence-building for health care personnel, organisation of the health care services, and Nordic and other international research cooperation.

There is, however, one factor typically associated with small patient groups that may be relevant for priority setting. This is related to uncertainty surrounding documentation of the benefit of a treatment because it may be difficult to perform controlled outcome studies on small patient groups. Thus, when assessing interventions targeted towards small patient groups with a severe condition, it should be possible to stipulate a less stringent requirement for documentation of benefit.

Furthermore, it is the Government's view that when assessing interventions targeted towards very small patient groups with an extremely severe condition, such as children with congenital genetic diseases, where there is often lack of documentation of the benefit of an intervention, higher resource use than for other interventions may be acceptable. This is discussed in greater detail in Chapter 11.

End-of-life care may be administered during the terminal stage of a long-term disease or to elderly patients whose life is naturally ebbing away as a result of the gradual failure of key organs. A central question is whether there are any ethical considerations of particular relevance for prioritisation in connection with end-of-life care. The Norheim Commission discussed this question, but did not propose a separate criterion. The commission pointed out that, as a general rule, the issue at the end of life is not to consider curative treatment alternatives, but rather to provide proper care and effective palliative treatment options. The Magnussen Working Group stated that it would not recommend the introduction of a designated end-of-life criterion. Treatment of patients with short life expectancy is already given high priority under the proposed severity criterion and giving this even higher priority would displace more cost-effective treatments for other groups.

The Government supports the Magnussen Working Group's and the Norheim Commission's recommendation not to introduce a separate priority-setting criterion for end-of-life care. Patients with few years to live are already prioritised under the severity criterion. If prioritisation assessments were to give weight to the fact that a treatment is being administered in the final phase of life, an end-of-life intervention with low expected benefit could end up being given priority over a treatment with high expected benefit simply because the treatment is being administered at the end of life, even though the degree of severity is the same. This could ultimately reduce the number of healthy life years that the use of the health care services' resources could yield.

As the Norheim Commission pointed out, end-of-life care does not usually entail assessment of curative treatment alternatives, but rather ensuring proper care and effective palliative treatment options. The health care services must always seek to preserve patient dignity and provide good nursing, support and pain alleviation as part of end-of-life care.

8

BALANCING THE PRIORITY-SETTING CRITERIA

The main priority-setting criteria proposed in this white paper are each discussed separately in Chapter 6. In agreement with the Lønning II Commission and the Norheim Commission, the Government recommends that the priority-setting criteria must be assessed together as well as weighed in relation to one another. The more severe the condition or the greater the benefit of the intervention, the higher the resource use that can be accepted. Conversely, giving priority to conditions with low severity and interventions with limited benefit can only be justified if resource use is low. The Government agrees with the commissions' view that it is legitimate for high priority measured by multiple criteria to entail increased overall priority.

The way in which the criteria are currently balanced in relation to one another in practice in the Norwegian health care services varies depending on the decision-making level. When assessing the right to necessary medical assistance in the specialist health care services, there must be a reasonable relationship between the estimated costs and the expected benefit. Patients granted the right to necessary medical assistance are then given a deadline for start-up of the intervention based on the degree of severity. In national decision-making systems at the group level, decisions generally involve approving or rejecting the introduction of new technology and methods. In practice, calculations of costs and benefit are put together in a cost-effectiveness ratio, which is then viewed in context with the degree of severity of the condition. At the same time, there is currently no clear specification of how much weight should be given to the degree of severity in decision-making at the group level in the Norwegian health care services, nor is there an explicit, fixed norm for what is considered cost-effective.

The recommendations of both the Lønning II Commission and the Norheim Commission were imprecise, albeit in different ways, with regard to the impact of differences in the decision-making level on the application of and balance between the criteria. The Lønning II Commission did not clearly define how the criteria were to be applied together in decision-making at the group level, whereas the Norheim Commission was very clear on this point. The Norheim Commission, on the other hand, was criticised for not adequately delineating the frameworks for decision-making at the clinical level versus the group level. In accordance with the Magnussen Working Group's recommendation, the Government believes it is important to distinguish between the various levels of decision-making when describing how to weight the criteria, particularly between the clinical level, where decisions are targeted towards individual patients, and the group level, where decisions are targeted towards patient groups. The Government also shares the commissions' view that application of the criteria must be supplemented by discretionary assessments at both the clinical and the group levels. Furthermore, to ensure that decision-makers attach importance to factors that are consistent with the main criteria, it is important to provide effective instruments to guide the decision-makers, such as clinical guidelines and instructions.

Overall assessment at the clinical level

At the clinical level, the priority-setting criteria generally support decisions to determine whether the patient should receive medical assistance, what type of medical assistance the patient should receive and how long the patient can wait before treatment is administered. The Government distinguishes between four types of situations in which prioritisation assessments are made at the clinical level: prioritisation in connection with emergency care, assessments of the right to necessary medical assistance in the specialist health care services, assessments throughout a patient pathway, and assessments made by a general practitioner in his or her meeting with the patient.

- Prioritisation in connection with emergency care: No formal assessment of the right to necessary medical assistance is made when a patient has an acute need for care. According to Section 2-1 b, Paragraph 1 of the Patients' Rights Act, all patients are entitled to emergency care. Thus, the specialist health care services have the obligation to provide medical assistance when there is an urgent need for care. What constitutes an urgent need for care must be determined based on responsible medical discretion on a case-by-case basis. It is primarily the clinician's professional discretion that is decisive here. In general, emergency care situations involve an acute need for examination and treatment, among

other things to restore and/or maintain vital life functions, to prevent and or/limit severe loss of functionality as a result of injury or disease, and/or to provide adequate relief of short-term pain. In many situations, however, capacity limitations will make it necessary to prioritise between different patients on the basis of the degree of urgency and severity. It may be necessary to consider whether an intervention will be of sufficient effect to justify the use of resources it requires.

- Assessments of the right to necessary medical assistance in the specialist health care services: In cases where the need for treatment is not acute and a patient's referral to the specialist health care services is being considered, the patient is to be given the right to necessary medical assistance if a clinical assessment indicates that the patient in question does have a need for specialist health care. According to Section 2-1 b, Paragraph 2 of the Patients' Rights Act, all patients are entitled to necessary medical assistance in the specialist health care services. Inherent in this is the expectation that there is a reasonable relationship between the costs of an examination or treatment and the expected improvement in patient health the intervention can be expected to yield. Patients are to be prioritised based on a clinical assessment of the degree of severity and urgency. Priority-setting guidelines have been drawn up to offer practical assistance in determining whether a patient who has been referred to the specialist health care services has the right to necessary medical assistance.

- Assessments throughout a patient pathway: After a patient has been granted the right to necessary medical assistance, the clinicians will make ongoing assessments of the patient's need for examination, treatment and follow-up based on their medical discretion. Assessments of severity, benefit and resource-use considerations will be of relevance for prioritisation assessments throughout a patient pathway. It is particularly important to be aware of this in cases where the right to necessary medical assistance has been granted in the form of examination and testing. Once the type of treatment needed by the patient is determined, it must be provided within an acceptable time frame. The criteria are not, however, applied in a correspondingly formalised process as when assessing the right to necessary medical assistance in the specialist health care services. The criteria will be reflected in various decision-support tools, such as national clinical guidelines and instructions, and may thus influence prioritisation assessments through this.

- Assessments in connection with the general practitioner's meeting with the patient: General practitioners

represent the first line of the health care services and must thus be in close proximity and accessible to the patients. According to Section 21 of the Regulation relating to a Municipal Regular GP Scheme, general practitioners must prioritise the individuals registered on their list based on a concrete medical assessment of the degree of urgency and severity. It is natural that general practitioners also assess whether the expected benefit of further diagnostics, such as X-rays or blood tests, and/or referral to the specialist health care services is reasonable in relation to the expected resource use. An instruction has been drawn up to assist physicians in referring patients to the specialist health care services.

The priority-setting criteria proposed in this white paper do not entail any significant change to the current application of priority-setting criteria in clinical situations. In general, the more severe the condition or the greater the benefit of the intervention, the higher the resource use that will be accepted. Giving priority to conditions with low severity and interventions with limited benefit can only be justified if resource use is low. Except for assessment of the right to necessary medical assistance, it may be unclear to health care personnel how to consider the priority-setting criteria together overall in different situations in an everyday clinical framework. In that framework, prioritisation of resource use will involve access to services with limited capacity, such as radiological examinations, surgical operations, beds in the intensive care unit and, not least, the time and attention of health workers. A lack of clarity surrounding the application of the criteria can lead to uncertainty and differing practices, thus making it difficult to achieve equal treatment for all patients.

In the Government's view, there are at least two ways in which clinicians can be supported when facing prioritisation decisions in the clinic. First, professional decision support tools may be of help. The decision support tools must be reviewed to ensure that they are designed in conformance with the principles for priority setting proposed in this white paper, cf. the discussion in Chapter 12. Second, general instructions on how to assess the priority-setting criteria as a unified whole in a clinical setting may also be helpful.

Clinical personnel deal with resource limitations on a day-to-day basis, including their own time. Decisions regarding treatment methods and pathways must be taken within the framework of these limitations and in light of the clinicians' responsibility to all of their patients. Decisions must be taken in accordance with clinical guidelines, medical discretion and the requirement for responsible conduct. The priority-setting criteria should therefore be discussed and reviewed in relevant fora in clinics/hospitals to

ensure that they are internalised and integrated into clinicians' assessments. It is the responsibility of the management to ensure that such discussions take place. When reviewing the criteria, it will be natural to explore how they are actually applied in practice, whether practice varies among clinicians within the same unit and whether there is any need to adapt the practice. How is the expected benefit and resource use of an intervention to be compared with other possible interventions for the same patient or with the use of the same intervention and the same resources for other relevant patients? How does one incorporate severity in concrete terms into such decisions? This type of approach to the application of the criteria in an everyday clinical setting may be a valuable guide for clinicians. The Norwegian Directorate of Health, in collaboration with clinical specialists, will draw up a framework for discussion on how to view and balance the priority-setting criteria in an overall perspective in the clinic, cf. Chapter 12.

The role to be played by other considerations in the clinical setting will depend on the specific clinical context. The Government recommends continuing current practice as described in the instructions for priority setting (item 5.11): Various attributes of the patient – gender, ethnic background, previous health damaging behaviour, work capacity (productivity), worldview, sexual orientation and social status – are not of relevance to assessments of the patient's rights (cf. page 5 in the Lønning II Commission's report). The preservation of dignity will remain an important consideration in assessments at the clinical level as well. Nor is it unreasonable to give weight to considerations related to the patient's family members, primarily in cases where the patient has responsibility for caregiving tasks for others. Health care personnel may often find themselves in a situation in which they cannot offer a patient any more medical treatment, either because the patient is terminally ill or because the patient has a chronic condition for which there are no effective treatment alternatives. In such situations, it must be possible for these personnel to provide relief and comfort, even though the time they use could have been used to treat other patients. This is consistent with current practice in providing medical assistance.

Balancing the criteria at the group level

A key issue in connection with priority setting is determining what an intervention would displace. The Lønning II Commission, the Norheim Commission and the Magnussen Working Group all have as their basis that priority setting in the health care services must distribute a budget that is for the most part fixed and that interventions at the group level must be assessed against the intervention's opportunity cost, i.e. the benefit to other patients that could have been realised with the same resources. In accordance with current practice, they

proposed calculating a cost-effectiveness ratio and assessing this against the opportunity cost. This principle received wide support in the consultation on both the Norheim Commission's report and the Magnussen Working Group's report. The Government agrees with this view. The terms willingness to pay and opportunity cost are described in greater detail in the box below.

WILLINGNESS TO PAY AND OPPORTUNITY COST

A key issue in connection with priority setting is determining what an intervention would displace. How do we know whether one relevant intervention is more valuable for society than another? The Lønning II Commission, the Norheim Commission and the Magnussen Working Group all concluded that in the health care services it is the opportunity cost of an intervention that is the relevant value for comparison, i.e. how much benefit an intervention will displace per Norwegian krone when resources are used for that intervention rather than for others.

An alternative to using the opportunity cost is to use studies of the population's willingness to pay for a new intervention. However, because the population does not have an overview of the interventions that would be displaced if a new intervention were to be introduced, it would be difficult to say anything definitive about the willingness to pay for a specific intervention. Alternatively, the Storting could address the issue. The Storting, however, would face the same lack of information as the population, as it would not know the benefit that could potentially be lost when a new intervention is introduced. In other words, using willingness to pay as a basis for comparison for a new intervention, instead of the opportunity cost, would mean that new interventions would be introduced without knowledge of whether these will generate more or less benefit for the same resources. This type of decision-making system would result in random results that would be hard to reconcile with the prioritisation thinking based on priority-setting criteria and the principle of equal access to health care for all.

In countries where the health care services are organised as a market and the residents themselves determine how much they wish to pay for various health care services, the individual's willingness and ability to pay will decide who receives medical assistance. This type of organisation is neither relevant nor desirable in the Norwegian context.

Public measures outside the health care services may also have an impact on the population's life and health, such as measures to reduce traffic accidents. It would not be relevant to employ an estimated opportunity cost designated for the health care services in connection with these measures. It is therefore common practice to use willingness-to-pay studies to assess the value of life and health outside the health care services. In these studies, individuals are asked – before the occurrence of potential accidents – about their willingness to pay to reduce the risk of accident.

With regard to decision-making at the group level, the commissions and the working group proposed weighting the cost-effectiveness ratio with the degree of severity. In order for an intervention to be introduced, it must generate more benefit per Norwegian krone, adjusted for severity, than it displaces. This means that in assessments of a new intervention involving a higher degree of severity than other interventions, less weight will be given than would normally be the case to lost benefit for other patient groups when resources are transferred to the new intervention. Considerations relating to severity will thus result in less total benefit (fewer healthy life years) from available resources, but the healthy life years will be distributed more equitably based on the degree of severity. Thus, it is not only the total number of healthy life years that the health care services' resources can yield that is of significance, but also how these years are distributed. This principle, too, received broad support when the Norheim Commission's and Magnussen Working Group's reports were circulated for consultation. The Government agrees with this assessment. Extremely severe conditions may be given a high weight, moderately severe conditions a moderate weight and conditions with low severity a low weight. The more severe the condition, the higher the cost-effectiveness ratio that will be accepted. In the Government's view, current practice in the Norwegian health care services is a reasonable expression of how society weights high severity in decision-making at the group level.

Both the Norheim Commission and the Magnussen Working Group proposed an opportunity cost of NOK 275 000 per healthy life year. More information on estimated opportunity cost may be found in the box below. Although there is significant uncertainty concerning this proposed figure, the Government supports the commission's and the working group's assertion that it is a reasonable estimate for opportunity cost in the Norwegian health care services. Thus, if a new intervention costs less than NOK 275 000 per healthy life year, it should as a general rule be introduced.

ESTIMATED OPPORTUNITY COST

When a new intervention is introduced in the health care services within a fixed resource framework, other interventions will be supplanted and have to be phased out. It is possible to estimate the average number of healthy life years lost in other segments of the health care services when resources are transferred to the new interventions. Based on this, it is possible to calculate the amount a new intervention will displace on average, measured in Norwegian kroner per healthy life year. In their 2013 study, Professor of Health Economics Karl Claxton and his colleagues estimated the opportunity cost for the National Health Service (NHS) in England as approximately GBP 13 000 per healthy life year.

One potential objection to the proposals to employ an estimated opportunity cost as a basis for comparison may be that the health care services are funded in part under the National Insurance Scheme (reimbursement of pre-approved medicines, reimbursement scheme for regular general practitioners, selected specialists covered by the specialist reimbursement scheme, laboratory and X-ray fees) and in part within the budgets of the regional health authorities. If the same criteria are to apply across the entire scope of the health care services, the Government believes that the principle of a common estimated opportunity cost should be employed throughout. It would deviate from the principle of equal access if the authorities were, for example, to prioritise medicines funded under the National Insurance differently from medicines funded within the budgets of the regional health authorities.

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THRESHOLDS

How much are we willing to spend on a new medication or treatment method? This is one of the most difficult questions for health care politicians to answer and one of the most difficult decisions for managers in the health care services to make. However, it is the Government's view that the Storting already answers this question indirectly. The Storting decides how much of society's resources are to be allocated to the health care services, while giving residents the statutory right to equal access to these services. In the event that the health care services were, for example, to abruptly choose to use a significantly larger proportion of available resources on costly methods or technologies, this would not be in accordance with the statutory requirement to ensure equal access to health care services across patient groups. Thus, as a logical extension, the introduction of new methods and technologies must be assessed against the opportunity cost – as well as weighted with the degree of severity, cf. the discussion in Chapter 8.

It could be argued that the Storting should set explicit cost thresholds in connection with the introduction of new methods and technologies in Norway. There are no such thresholds in Norwegian health care today. Furthermore, there has been ongoing discussion in the public debate and in academic circles about whether such thresholds are necessary. Both the Norheim Commission and the Magnussen Working Group recommended the introduction of explicit thresholds. The proposed solutions received a varying degree of support in the consultation.

Meanwhile, the Magnussen Working Group pointed out that it could be seen as unwise to base decisions that will have a tremendous impact on many people on a mathematical formula alone. The working group therefore suggested supplementing its proposed threshold with discretionary assessments. The group pointed to preservation of dignity, uncertainty regarding the cost and/or effect of the intervention, and the overall

budget impact of the intervention as examples of modifying factors to be included in such assessments.

In the Government's opinion there are three factors in particular that indicate that neither the Storting nor the Ministry of Health and Care Services should set explicit thresholds. First, health economic calculations and HTAs of interventions at the group level should not automatically result in decisions. In connection with HTAs, discretionary assessments are to be included in the overall assessment of interventions at the group level, cf. Chapter 10. This is of particular relevance in connection with assessment of quality and uncertainty regarding documentation as well as the overall budget impact of an intervention. The significance of these factors may vary from intervention to intervention and should be assessed as an integrated whole by those with decision-making authority, i.e. the Decision Forum, the Norwegian Medicines Agency or the Storting in cases where the costs of a medicine exceed the defined minimum threshold.

Second, maximum thresholds set by the Storting or the ministry may in certain cases help to reduce prices through negotiations with suppliers, while in other cases they may cause suppliers to drive their prices up to reach the cost ceiling considered acceptable. In England, where such thresholds have been employed over a longer period of time, there are indications that manufacturers of new technology price their products in the vicinity of the fixed ceiling.

Third, it will be difficult for the Storting to stipulate principles for priority setting, total budgets and fixed thresholds without these three factors coming into conflict with one another. If the Storting approves the principles for prioritisation proposed in this white paper, continues to increase health care budgets at the same rate, but, for example, sets explicit cost thresholds that are significantly higher than the costs per healthy life year that the Decision Forum and the Norwegian Medicines Agency deem acceptable for the introduction of new methods and technologies, this will lead to extensive reprioritisation within the health care services. This reprioritisation will almost inevitably contradict the principles for priority setting the Storting itself has approved. It is the view of the Government, therefore, that the Storting should adopt the priority-setting principles and the overall resource frameworks for the health care services. Within this framework of resources and principles, it should be left to those with the responsibility for prioritisation at the group level, i.e. the Norwegian Medicines Agency and the Decision Forum, to take their decisions based on assessment of the opportunity cost of introducing a new intervention. Furthermore, the Storting and the Government must fulfil their responsibility and back the decisions taken by the decision-makers in the health care services.

This will also require that the Norwegian Medicines Agency and the Decision Forum reach a common understanding of the opportunity cost of an intervention and the weighting of the degree of severity of an appurtenant condition. In this process, the Government recommends employing the thinking behind the Norheim Commission's and the Magnussen Working Group's proposal for how to weight the severity criterion as a point of departure. A brief description of the working group's proposal may be found in the box below. HTAs should not, however, be interpreted or employed in a manner that automatically allows for the introduction of new interventions that lie below a certain threshold per healthy life year gained.

THE MAGNUSSEN WORKING GROUP'S PROPOSED COST THRESHOLDS AND WEIGHTING OF SEVERITY

The Magnussen Working Group recommended weighting cost ceilings with the degree of severity measured as absolute shortfall in HTAs at the group level. The working group proposed that diseases or conditions where the expected absolute shortfall is less than four healthy life years should be given lowest priority, while diseases or conditions where the expected absolute shortfall is more than 20 healthy life years should be given highest priority. The group proposed that the minimum cost threshold should correspond to the average opportunity cost in the health care services, which has been estimated at NOK 275 000, and that the maximum cost threshold for the highest priority diseases/conditions should be three times higher, i.e. NOK 825 000. The group proposed six severity classes. It emphasised that such thresholds were only to be used in decision-making on interventions at the group level.

It is the Government's view the proposals in this chapter do not entail any significant change to the practice followed by the Norwegian Medicines Agency and the Decision Forum in recent years. They do, however, entail that cost-effectiveness calculations must be supplemented with calculations of severity. In keeping with the findings of the Magnussen Working Group and the Norheim Commission, the Government agrees that extremely severe conditions may be given a high weight, moderately severe conditions a moderate weight and conditions with low severity a low weight. It may therefore be the case that methods or technologies targeted towards less or moderately severe conditions must in the future be priced lower than previously in order to be introduced into the health care services. It is also the Government's view that the practice followed by the Norwegian Medicines Agency and the Decision Forum up to the present is a reasonable expression of how society weights high

severity in decisions regarding the introduction of methods and medicines at the group level. The Government therefore sets as the framework that access to methods/technologies and medicines targeted towards extremely severe conditions will be approximately what it is today, given these proposals.

DISCRETIONARY ASSESSMENTS

Health technology assessments (HTAs) of interventions at the group level must be supported by discretionary assessments in an overall evaluation of the intervention. This is particularly the case for assessing quality and uncertainty regarding documentation and the overall budget impact of introducing an intervention.

Considerations relating to quality and uncertainty regarding documentation should be taken into account in prioritisation decisions at the group level. Provided that all other factors are essentially equal, the greater the uncertainty associated with documentation and calculation methods the lower the resulting priority. This is in accordance with the recommendations of the Lønning II Commission, the Norheim Commission and the Magnussen Working Group.

One exception here concerns the assessment of interventions targeted towards small patient groups with a severe condition. These patient groups may often be too small to conduct traditional controlled outcome studies. This makes it difficult to perform HTAs corresponding to those for interventions targeted towards larger patient groups. The Government is therefore of the opinion that a less stringent requirement for documentation may be acceptable for interventions targeted towards small patient groups with a severe condition where it would be difficult to conduct controlled outcome studies.

An underlying principle must be that interventions at the group level in the health care services are to be assessed against the opportunity cost of the intervention, i.e. the benefit to other patients that could have been realised with the same resources. If a single intervention requires a very high level of resources, however, the opportunity cost will be higher than that normally used as a basis for comparison, as the intervention will displace more benefit per Norwegian krone than other interventions.

The Magnussen Working Group identified this problem and proposed that the overall budget impact of an intervention should be incorporated into an overall discretionary assessment of the intervention. The working group justified this by pointing out that if the budget impacts are large enough, not only will the existing, least cost-effective interventions be displaced but there will also be a risk of supplanting more cost-effective interventions. The consultative bodies supported this view, and the Government agrees as well. If consideration is not given to the overall budget impact of an intervention, the benefit of the intervention could potentially be less than that of the interventions that were displaced. This would result in fewer healthy life years for the health care services' resources than could otherwise be achieved. The relationship between opportunity cost and cost-effectiveness ratio is described in the box below.

RELATIONSHIP BETWEEN OPPORTUNITY COST AND COST-EFFECTIVENESS RATIO

The opportunity cost of an intervention is the benefit of the best alternative use of the resources required by the intervention, in other words the benefit to other patients that could have been realised with the same resources. The opportunity cost can therefore be expressed as lost benefit per Norwegian krone. HTAs, on the other hand, are often summed up in a cost-effectiveness ratio. This expresses the amount of resources required to obtain an extra healthy life year and is measured as the cost per healthy life year or krone per unit of benefit. The opposite of a higher opportunity cost, i.e. higher displaced benefit per krone, is therefore a lower cost-effectiveness ratio, i.e. fewer kroner per unit of benefit. To compare the cost-effectiveness ratio of an intervention with its opportunity cost, the opportunity cost must be expressed as the cost per unit of benefit.

The Norheim Commission referred to the opportunity cost as the average cost per healthy life year gained in the health care services with *marginal changes* to the health care budget. The activities and treatment options that will be reduced (or increased) with a marginal reduction (or increase) in the health care budget will be the sum of numerous decisions taken by health care personnel and managers at various levels. These may include decisions to downscale established treatment options, to increase the waiting period for patients, or to phase out services of least benefit to patients. Thus, the opportunity cost is not to be understood as a value specifically linked to decision-making within the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services. The opportunity cost is an expression of the average impact of the entire range of decisions measured in benefit per krone, which can then be calculated as krone per healthy life year.

In cases of more extensive budget changes, for example in connection with the introduction of interventions with a major budget impact, the health care services must take a number of decisions regarding the volume of treatment options and the phasing out of various treatments. The greater the budget impact, the greater the benefit per krone associated with the services for which resources could have alternatively been used. This implies that the opportunity cost will be higher and the average cost-effectiveness ratio *lower*. If the overall budget impact of an intervention was not given consideration, the benefit of the intervention would be less than the benefit of the interventions that were displaced. Consequently, the use of the health care services' resources would yield fewer healthy life years than would have otherwise been achieved.

One example of an intervention with potentially major budget ramifications is described in *Prop. 83 L (2015–2016) Endringer i legemiddelloven (refusjonskontrakter og rabatter)* [Proposition No. 83 L (2015–2016) to the Storting on amendments to the Norwegian Act on Medicinal Products (reimbursement contracts and discounts)], which was presented to the Storting in March 2016 and concerns the use of new cholesterol-lowering medications (statins) (page 7):

- "The current maximum price is approximately NOK 70 000 per patient per year. Treatment is expected to be lifelong and the number of patients needing this type of treatment will be high. This is an example of a group of effective medications for a large patient group that may have a major budget impact. If 10 000 patients receive this treatment, the cost of the medications will amount to NOK 700 million annually. If the number of patients increases to 100 000, which corresponds to one-fifth of all patients taking statins, this will have a budget impact of NOK 7 billion. If these new medicines are introduced and the state pays the maximum price, the medicines will displace far more cost-effective treatments."

Not only will the opportunity cost be higher when the budget impact is sizeable, there may also be practical challenges related to introducing interventions with a budget impact of those dimensions. In cases where an intervention absorbs a large share of the annual growth in the regional health authorities' budgets, it will be difficult in practical terms to apply the intervention across the entire relevant patient group. It may be difficult in the short and medium term to retrain health care personnel and reassign infrastructure and technical medical equipment from other applications to the intervention in question. By way of example, it takes approximately nine years to train a medical specialist. Moreover, the introduction of the intervention may entail such large cuts to treatment options for other patient groups over a short period of time that it will

undermine the legitimacy of the decision.

At the same time, it can be unreasonable to permanently limit a treatment to segments of a patient group when it will be of greater benefit viewed in relation to resource use and severity than other interventions in the health care services. In such cases, structured forms for introducing the treatment may be called for, in which segments of a patient group receive the offer of treatment before others, for example by stipulating conditions for treatment, and then treatment is extended to larger segments of the patient group at a pace aligned with the capacity of the health care services. It is the Government's view that such conditions should be designed in conformance with the principles for priority setting; for example, the treatment should first be offered to the patients who are the most seriously ill and/or who will derive the most benefit.

One possible argument in connection with budget ramifications may be that the alternative cost for an intervention with minor budget impact will be lower than for other interventions and thus a higher cost-effectiveness ratio may be acceptable for that intervention. The Government points out, however, that the best estimate for opportunity cost is precisely linked to marginal changes in the health care budget. The Government agrees with the Norheim Commission's recommendation that these types of interventions must be assessed on the basis of the three main criteria, i.e. the benefit criterion, the resource criterion and the severity criterion. Interventions targeted towards small patient groups with a high degree of severity and which have high expected benefit that justifies high costs will be prioritised on an equal footing with comparable interventions targeted towards larger patient groups. The move towards more personalised treatment may lead to very high total resource use for the individualised interventions. If a higher cost-effectiveness ratio is accepted for such interventions, the sum of these may as a whole displace other interventions with lower cost-effectiveness ratios.

CHANGES IN THE AREA OF MEDICINES

The Government's national medicines policy was presented in Meld. St. 28 (2014–2015) *Legemiddelmeldingen – Riktig bruk – bedre helse* [Report No. 28 (2014–2015) to the Storting, White paper on medicinal products – Correct use – better health]. The white paper sets out four objectives for medicines policy: to provide high quality in medicine-based treatment; to keep the price of medicines as low as possible; to ensure equal and rapid access to effective medicines; to promote research and innovation. The Storting supports these objectives, cf. Recommendation 151 S (2015–2016). The Storting also agrees with the Government's view that any changes to the rules for individual reimbursement for medication under the National Insurance Scheme must take place in the context of a broader review of priority setting in the health care sector and should therefore be addressed in this white paper.

Medicines are one of the pillars of the modern health care services, and proper use of medication can lead to major treatment benefits for patients. However, many medications are costly and it can be difficult to introduce new drugs within the resources available for the public health care services. Systems to evaluate funding of medicines within the public health care system have been put in place to ensure sound prioritisation practices. For the most part, new medicines are evaluated on the basis of existing priority-setting criteria before they are approved for use in hospitals or for National Insurance funding via the reimbursement scheme for pre-approved medicines. This is a means of ensuring that medicine-based treatment is of good quality and that resources for medication in the public health care system are used responsibly. Effective priority-setting systems also facilitate negotiations on price. The principles for including medicines as pre-approved for reimbursement and for determining introduction of medicines for use in the specialist health care services are essentially the same. These principles must be adapted in keeping with the proposals set out in this white paper.

There is also a scheme under which patients may seek individual reimbursement from the National Insurance for medicines that are not on the reimbursement list, including for off-label use outside the approved indication, as well as for medicines that have not been granted marketing authorisation. At present, no HTAs or assessments of severity or cost-effectiveness are required under this scheme. The hospitals also make medications available to patients as part of experimental treatment. Experimental treatments are characterised by a lack of, or inadequate, documentation of benefit and cost-effectiveness.

The existing structures generally ensure systematic evaluation of medicines funded within the public health care system. However, there are certain problems that make it difficult to realise medicines policy objectives and follow the principles for priority setting. First, the funding of alternative medications for the same condition from different sources, i.e. the National Insurance Scheme and the budgets of the regional health authorities respectively, may influence physicians' choice of medication, and in the worst case decrease the quality of treatment. Second, the scheme for individual reimbursement and the contribution scheme for medications that are not on the reimbursement list have several shortcomings:

- When HTAs are not performed, it is difficult to ascertain whether the quality of a medicine-based treatment is good enough in relation to both resource use and other treatments.

- The design of these schemes leaves it somewhat up to chance which medicines can be covered for different patients. This is difficult to reconcile with the objective of equal access to medication.

- When neither cost-effectiveness nor severity has been assessed, there is no basis for evaluating whether the price level is reasonable. This may undermine the state's negotiating position with the pharmaceutical industry and lead to unreasonably high prices.

It is the view of the Government that responsibility for funding a medicine should primarily follow the responsibility for treatment. The criteria for dividing funding responsibilities between the National Insurance Scheme and the regional health authorities have not been clearly enough defined. The Government will therefore draw up more detailed criteria for how to assign responsibility for funding new medications that come onto the market, so that this can be clarified as early as possible and at the latest by when the medication is granted market authorisation in Norway. This will give the regional health authorities more responsibility for funding medicines than has currently been the case. The new responsibility must be taken into

account when determining the budgets for the regional health authorities; otherwise the proposed re-defined funding responsibility could gradually lead to reduced capacity to provide regional health care services compared to a continuation of the division of responsibility used today. The transfer of funding responsibility for more medications should therefore be implemented gradually.

Currently, all new medicines to be funded by the regional health authorities undergo an HTA. The Government proposes that all new medicines to be funded under the National Insurance should undergo an HTA based on the same priority-setting principles before they can be introduced for use. In the case of most of the medications funded under the individual reimbursement scheme and the contribution scheme, neither the benefit of nor the resources used have been assessed. The same is the case for medicines to treat contagious diseases. Thus, there is no guarantee that the medications funded under these schemes adhere to the medicines policy objective of equal and rapid access to effective medicines. Furthermore, there has been no basis for determining whether the price level for these medications is reasonable or not. The proposal to subject all new medications to an HTA entails that more medications can be pre-approved for reimbursement, provided that the principles for priority setting are met. In addition, the authorities may be able to achieve lower prices through bid processes and negotiations. The Government sees it as important to ensure that the shortest possible time elapses from the date when a medicine receives marketing authorisation to the performance of an HTA. Measures are already underway to achieve this. It should be noted that the individual reimbursement scheme will be continued for medicines that are currently funded, with certain adjustments in keeping with the proposed principles for priority setting.

In the Government's view, higher resource use than is normal compared to other interventions can under special circumstances be accepted for interventions related to treatment of very small patient groups with extremely severe conditions, assuming that all other factors are essentially equal. It is not the rarity of a condition itself, but rather certain factors that are typically associated with various conditions affecting only a small number of patients that are of relevance when making this assessment. There may be a weaker incentive for the pharmaceutical industry to develop medications when the patient group for absorbing development costs is small, and in the event a medicine is developed, it will often be very expensive. Furthermore, small patient groups make it more difficult to obtain good documentation of the benefit of a treatment. Thus, the Government proposes that higher resource use than for other

interventions may be acceptable when assessing interventions targeted towards very small patient groups with an extremely severe condition, such as children with congenital genetic diseases, where there is often a lack of good documentation of the benefit of an intervention. A formal framework for such exceptions should be approved by the Storting in connection with this white paper and be incorporated into the basis for funding of new medicines under the National Insurance and new methods and technologies in the specialist health care services.

The legitimacy and sustainability of such a scheme will rest on two key prerequisites. First, a less stringent requirement for documentation of the benefit of the interventions means there must be greater focus on monitoring to document the benefit of the treatment. Methods and technologies funded under such a scheme must be required to implement procedures to further document efficacy and any associated risk, among other things. This documentation may be used as a basis for re-evaluating the medicines funded under the scheme once a certain amount of time has passed. In addition, it is important to stress that although a lower level of documentation may be acceptable in these cases, an HTA must still be performed and serve as the basis for the decision. Second, to retain its legitimacy, a scheme such as this must truly be limited to what is actually defined as a very small patient group with a very severe condition. If this group is defined too broadly, it will undermine the objectives of equitable and fair priority setting. This delimitation must be distinguished from the definition of rare diseases, which has been designated for other purposes. The Government assumes that only a very limited number of medicines and methods/technologies will be funded under such a scheme. The framework must be discussed in more detail in relation to stricter requirements for monitoring to document the benefit of the treatment, a re-evaluation system and a mechanism to counteract undesired adaptation on the part of the pharmaceutical industry, among other things.

Together, the proposals will make it easier to achieve more equal and more rapid access to effective medicines, as well as satisfy objectives relating to high quality and low prices of pharmaceuticals.

Adaptation of existing systems subsequent to the Storting's deliberations on this white paper will primarily apply to new medications that have come onto the market. Based on the proposals in this white paper and the Storting's deliberations, the Government will draw up a proposal for changes to the rules for the reimbursement scheme, including pre-approved reimbursement and individual reimbursement, and circulate this for consultation. The Government

will give further consideration to whether the contribution scheme for medications should be discontinued. The contribution scheme will be assessed in connection with the review of the rules for the reimbursement scheme.

In cases where the hospitals have responsibility for funding a new medicine, the completed HTA will be submitted to the Decision Forum as a basis for decision-making within the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services. In cases where the funding responsibility lies with the National Insurance Scheme, the Norwegian Medicines Agency can add new medicines to the list for pre-approved reimbursement provided that the HTA indicates that the medicine satisfies the principles for priority setting for its indication and that the costs do not exceed the defined minimum threshold. When the costs do exceed this threshold, the Storting must decide whether to include the medicine in the reimbursement scheme.

When the Norwegian Medicines Agency processes applications for pre-approved reimbursement, the increase in costs for the National Insurance Scheme is calculated on the basis of the estimated reimbursement costs for the medicine five years after the date of approval of the application, minus the estimated costs for individual reimbursement and competing medicines for the same target group. The proposal that all medications funded under the National Insurance must undergo an HTA and be subject to cost control entails that the Storting will have to deal with a much larger number of reimbursement cases than today if the current minimum threshold is maintained. This will make it difficult to achieve the policy objective of rapid access to effective medicines. Thus, it will be necessary to raise the minimum threshold to be able to implement the proposed changes to the funding schemes under the National Insurance Scheme without this in practice preventing rapid access to effective medicines. This will also ensure better cost control for the National Insurance. Raising the threshold will make it easier in future to carry out HTAs on medicines that would currently be funded under the individual reimbursement scheme, and thus to include these in the reimbursement scheme without requiring the approval of the Storting. The Government proposes raising the minimum threshold to NOK 100 million.

Proposals for new funding mechanisms for medications have come from several different quarters, including a proposal to establish a designated financing fund and one for a mechanism for preliminary financing in the interim before a decision is taken by the Decision Forum. According to the Government, a national fund for financing medications would exempt medicines from being subject to the same principles for priority setting as

all other patient treatment. If medicine-based treatment is to be evaluated on the basis of the same priority-setting principles as other patient treatments, the Government sees no reason why medicines should be funded separately. On the contrary, this could pose an obstacle to equal access to health care across patient groups. In addition, such a funding mechanism could undermine the authorities' position in negotiations with the pharmaceutical industry and lead to higher prices. This would reduce the number of healthy life years that the use of the health care services' resources could yield. The same reasoning applies to the idea of a mechanism for preliminary funding for medicines undergoing an HTA. If the door is opened wide to allow individual patients or groups of patients to use treatments that have not been evaluated based on the principles for priority setting proposed in this white paper, it will compromise the objective of equal treatment. Special funding in the interim before an HTA is completed and a decision is taken could weaken industry incentives to compile and submit documentation and correspondingly diminish the authorities' potential to negotiate on price. In the Government's view, a temporary funding mechanism could therefore work against its purpose.

The Government proposes the implementation of the following measures in the area of medicines:

- Consider transferring funding responsibility for individual medicines or groups of medicines from the National Insurance to the regional health authorities in support of the premise that funding responsibility should follow treatment responsibility.

- Establish a system for clarifying funding responsibility between the National Insurance and the regional health authorities before a medicine receives marketing authorisation.

- Revise the rules for medicines funded under the National Insurance Scheme in accordance with the proposed principles for priority setting and the Storting's deliberations on this white paper.

- Introduce the requirement that HTAs must be performed for all new medications being evaluated for public funding based on the proposed principles for priority setting and the Storting's deliberations on this white paper. This proposal requires changing the defined minimum threshold.

- Ensure, by means of corporate governance, that the regional health authorities revise the principles that form the basis for introduction of new

medications in the specialist health care services, in accordance with the proposed principles for priority setting and the Storting's deliberations on this white paper.

- Consider whether the contribution scheme for medicines should be discontinued.

- Facilitate discount agreements between pharmaceutical companies and the state for medications funded under the National Insurance, cf. Prop. 83 L (2015–2016) *Endringer i legemiddelloven* [Proposition No. 83 L (2015–2016) to the Storting on amendments to the Norwegian Act on Medicinal Products].

- Raise the minimum threshold to NOK 100 million. This will be proposed as part of the ordinary budget processes.

- Continue the current scheme for individual reimbursement for medicines that are already receiving funding, with some adjustments based on the proposed principles for priority setting. Severity will be introduced as a fundamental criterion, and reimbursement will no longer be given solely on the basis that the disease is rare. Furthermore, it may be relevant to perform HTAs on certain medicines that are currently funded under the individual reimbursement scheme. All patients who have already been formally granted reimbursement will continue to receive this, regardless of the proposed changes.

- Establish a scheme under which higher resource use than normal is acceptable when assessing interventions targeted towards very small patient groups with an extremely severe condition, such as children with congenital genetic diseases, where there is often inadequate documentation of benefit. The framework for such a scheme will be discussed in greater detail, with particular focus on introducing more stringent requirements for monitoring to obtain documentation of the benefit of a treatment, a re-evaluation system and mechanisms for counteracting undesirable adaptations on the part of the pharmaceutical industry, among other things.

12

POLICY INSTRUMENTS TO SUPPORT PRIORITY SETTING

If they are to promote the desired priorities, relevant policy instruments at the various levels must incorporate the proposed principles for priority setting. This white paper announces a number of development efforts to ensure that the instruments used in priority setting conform with the principles proposed here.

At the clinical level, the regulations on priority setting in the health care services and other types of professional decision support tools comprise key instruments for prioritisation processes. There will be a need to revise the language of these regulations in light of the Storting's deliberations on this white paper. The Norheim Commission pointed out that few of the existing national clinical guidelines are clearly and directly justified with reference to the priority-setting criteria. At the same time, the commission pointed out that clinical guidelines and instructions are key tools for promoting knowledge-based priority setting. The commission stated that the development of clinical guidelines should incorporate information related to the three priority-setting criteria, and that recommendations for which patients should receive what type of medical intervention should openly refer to these criteria. The Government by and large agrees with the commission's assessment. Effective prioritisation requires good decision support. It is the Government's view that national clinical guidelines should be aligned with the principles for priority setting proposed in this white paper. In the formulation of each guideline, an explicit assessment of benefit, resource use and severity should form the basis for recommended interventions to the greatest extent possible.

Subsequent to the Storting's deliberations on this white paper, the Government will draw up a proposal for changes to the rules for medicines

funded under the National Insurance and will circulate this for review. The regional health authorities will be required to make necessary revisions to the principles for introduction of new methods and technologies in the specialist health care services. The Norwegian Medicines Agency and the regional health authorities must collaborate closely on interpreting and implementing the principles for priority setting. Government agencies and services must revise their instructions for health economics analyses and HTAs to ensure that these are based on the same principles and are updated in keeping with the proposals in this white paper.

Managers at different levels of the health care services and the national health administration take decisions that have consequences for prioritisation. Such decisions may involve, among other things, day-to-day activities, budget distributions, the scope and volume of education, and investments that may directly or indirectly affect the treatment options available to various patient groups. Decision-making at the administrative level needs to include consequence assessment based on the principles for priority setting to a greater extent than is the case today. The regional health authorities will assess how to give emphasis to the principles for priority setting in the design of regional and local development plans. It is assumed that the content of educational programmes in the health sciences reflects the principles for priority setting. The regional health authorities must ensure that leadership training offered in the various segments of the health care services clearly emphasises the need for management personnel to align their activities with the principles for priority setting.

The funding schemes for the health care services comprise a key instrument for implementing health care policy. These schemes are primarily intended to enable the regional health authorities to ensure that the populations of their respective regions are offered the necessary health and care services. Furthermore, activity-based funding, particularly in the specialist health care services, is designed to ensure that activities are carried out cost-effectively. In the Government's view, these funding schemes are poorly suited as instruments for steering priorities. In the funding scheme based on diagnosis-related groups (DRG), the activity-based income for a given intervention reflects the average cost of implementing that intervention or comparable interventions. This encourages efficiency, without distorting priorities. This does not mean that existing funding schemes do not have ramifications for prioritisation. Nor is it possible to establish funding schemes that will be entirely neutral in this regard. Nevertheless, the design of the existing activity-based funding schemes provides a reasonable balance between achieving cost-effectiveness and ensuring

neutrality in relation to priority setting. The principles for priority setting proposed in this white paper will not in themselves necessitate any changes in the funding schemes.

The Storting, the Government and the municipal councils take decisions that have major consequences for prioritisation, such as distribution of budget funds and approval of rules and regulations, among other things. Although decisions taken by political bodies involve balancing many different considerations in an overall perspective, the aim is still to obtain the best informed basis for decision-making to ensure effective and fair distribution, as set out in the national Instructions for Official Studies and Reports. Analyses of measures to be decided in political arenas, based on the principles for priority setting among other things, can help to shed better light on the potential consequences of decisions, identify any conflicting objectives and clarify any other critical considerations.

The Storting is the only body that can and should prioritise between the health and care services and other societal tasks at the national level. The selection of methods and technologies to introduce for use is primarily a task for professionals in the field. It is the regional health authorities, which have the overall responsibility for patient treatment, that take these decisions in the specialist health care services. However, establishing the principles underlying these decisions and their accompanying budgets remains a political responsibility. It would be difficult to adhere to the objectives of equal access to and fairness in health care without employing a set of common principles for priority setting. This is precisely why the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services was established. Instead of individuals in the health care services taking difficult decisions on their own regarding the use of new methods and technologies, a single joint decision is now reached based on known principles, which ensures equal treatment and consistency.

The Government will implement the following measures to support priority setting:

- Make necessary revisions to the regulations on priority setting in the health care services, the guidelines on priority setting and the guideline on referral based on the principles for priority setting proposed in this white paper.

- Make sure that national clinical guidelines are designed in conformance with the principles for priority setting proposed in this white paper. When formulating each guideline, an explicit assessment of benefit, resource use and severity should form the basis for recommended interventions to the greatest extent possible.

- Determine the impact of the principles for priority setting proposed in this white paper on ongoing efforts to develop normative products and the processes related to this.

- Ask the Norwegian Directorate of Health, in collaboration with clinical specialists, to draw up a framework for discussion on how to view and balance the priority-setting criteria in an overall perspective in the clinic.

- Revise the instructions and guidelines for health economics analyses and HTAs to ensure that they are based on and updated in keeping with the principles for priority setting proposed in this white paper.

- Follow up development activities under the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services.

- Ask the regional health authorities to discuss how to give emphasis to the principles for priority setting in the design of regional and local development plans.

- Ensure that educational programmes in the health sciences reflect the principles for priority setting.

- Ask the regional health authorities to ensure that leadership training offered in the various segments of the health care services clearly emphasises the need for management personnel to align their activities with the principles for priority setting.

- Appoint a commission to evaluate priority setting in the municipal health and care services.

- Evaluate the role of the National Council for Priority Setting in Health Care based on the follow-up of this white paper and the input from the commission evaluating priority setting in the municipal health and care services.

13

USER PAYMENT

The underlying premise of the Norwegian health and care services is that the services should be provided to residents free of charge. Nevertheless, there is a small patient co-payment for certain types of services – this is set out in a number of regulations. The question of whether patient user-payment schemes should be employed as a tool for supporting priority setting was discussed by the Norheim Commission and the Lønning Commissions. The Government does not propose any significant changes to this framework in this white paper, cf. also the Government's Political Platform. Nevertheless, consideration must be given to several new issues relating to user payment which have emerged in recent years:

- To what degree should the health care services assist patients who are undergoing treatment with medications or equipment that are not offered within the publicly funded health care services, but which the patient has obtained using personal funds? Is such a practice part of the provision of equal treatment within a universally funded public health care system?

- To what degree should patients have the opportunity to pay for a higher standard of health care than that provided by the publicly funded health care services? Would such a practice lead to an internal division of the publicly funded health care system into two levels?

- Should patient co-payments be adjusted on a scale according to the level of priority of the intervention, as proposed by the Norheim Commission? Is it possible to reconcile such a system with the need for individual assessments?

- Should an exemption for value added tax be given for the purchase of medications that are not available within the publicly funded health care system? Should changes in health-related costs in the income accounts

of the national fiscal budget be treated differently than health-related costs in the expenditure accounts?

Treatment with patient-purchased medication that is not offered within the public system

In 2015, the media covered a case in which Haukeland University Hospital refused to treat a cancer patient with a medication she had purchased herself but which the regional health authorities had decided was not to be offered within the publicly funded health care services. According to the Norwegian Medical Association, the hospital had a legal obligation to assist the patient by administering the medication.

It will deviate from the principle of equal access and lead to a gradual erosion of the universally designed health care system if patients with identical treatment needs but variable capacity to purchase medicines privately are given different access to publicly funded medical treatment. Those who are responsible for providing the health care services, i.e. the regional health authorities, must determine the types of treatment options to be made available. The Government would therefore like to clarify that patients are not entitled to assistance with a medical intervention other than those provided by the specialist health care services, even if they pay for it themselves, and emphasises that hospitals are not to administer such treatments. This will entail changes to the current legal framework.

Possibility to pay for a higher standard of medical care than the one offered

Another problem related to user payment arises in cases where the publicly funded health care services offer a standard treatment, but the patient desires a more expensive alternative. One example is a patient who will be undergoing cataract surgery and wishes to have multifocal lenses to correct for both nearsightedness and farsightedness. The public health care services only cover a lens that corrects for one of these. The patient would like the most expensive lenses and is willing to pay the difference between the cost of the multifocal lenses and the cost of the standard lenses. Another example is a patient who has been approved to receive an insulin pump. However, the patient would like another, more costly insulin pump than the standard one offered. In reality, these examples deal with the upgrading of a treatment option to which the patient is entitled by the patient paying the difference of the additional cost of the more expensive alternative. This differs from the example in the section above in which the regional health authorities have decided that a specific medicine is not to be offered within the publicly funded health care system.

There are arguments that weigh in favour of allowing this type of user payment in certain cases. The issue at the core is the standard of treatment and not the access to treatment. Such a

practice would therefore be easier to justify in relation to the objective of equal access to health care than the practice described in the section above. It could also counteract a bifurcation of the health care system into two levels if those with the ability to pay for a higher standard of treatment procure it from a private supplier. On the other hand, allowing user payments may lead to a division of the publicly funded health care system into two levels as well. Patients with the same needs will receive the same treatment at the same hospital, but the patient's ability to pay will determine the standard of the treatment. Moreover, this may provide public hospitals with an unfortunate incentive to offer the cheaper standard solutions than they would otherwise have done because they expect patients to choose to pay the difference for a higher standard.

In light of this, the Government believes that great caution must be employed when opening the door to user payment, also in cases that involve upgrades in areas which are relatively uncontroversial. There may be some situations, for instance in connection with various technical aids, where it will not be particularly problematic if patients pay for an upgrade. The Government wishes to examine ways of limiting potential schemes for user payments to ensure that these do not infringe on the principle of equal treatment of patients and generate undesirable adaptation in the public health care services.

Should there be a graduated scale for user payment based on priority?

The Norheim Commission proposed introducing higher patient co-payments for interventions that can be expected to provide very few health benefits in relation to resource use and that are targeted towards conditions with little loss of health. The commission further proposed reducing or eliminating patient charges for interventions that can expected to provide significant benefits in relation to resource use and that are targeted towards conditions with significant loss of health. The Government agrees that user-payment schemes can in principle be used as an instrument for priority setting. Currently, for example, patients are required to partially or fully cover the cost of non-medically indicated sterilisation of women, sterilisation of men, assisted reproduction, and dental implant surgery to replace lost teeth as a result of marginal periodontitis.

Although patient co-payments for these services are well justified, it is difficult to group together services funded by the public health care system based on priority. Introducing a graduated user-payment scale based on, for example, the degree of severity will require a system for verifying the medical decisions taken. This will be problematic because the same diagnosis can have a differing degree of severity based on an individual assessment. For this reason, cases may arise in which different

medical discretion can lead to divergent assessment of patients with identical needs. A user-payment scale can therefore have a different impact in relatively similar cases. This will undermine the objective of equal treatment and give the system little legitimacy. Therefore, the Government does not recommend the systematic use of patient co-payments as an instrument for priority setting. However, the Government does point out that it in the future it may still be relevant to require patients to partially or fully cover the costs of certain services, such as is the case for sterilisation today.

Exemption for value added tax in connection with private purchase of medications

A value added tax of 25 per cent is currently imposed on all prescription and over-the-counter medications sold in Norway. It has been argued that individual patients who have paid out of pocket for medicines that the regional health authorities have rejected for inclusion within the specialist health care services should be qualified for exemption for value added tax. In the view of the Government, however, this would break with the principles for priority setting and funding of the health care services. The Storting allocates funds to the regional health authorities, and the regional health authorities must decide which treatment methods to introduce for use within the confines of their budget. If the government authorities wish to expand the budgets of the hospitals, this should take place directly through an increase in the allocations to the health care services, not indirectly through tax exemptions in connection with private purchase of medications. The latter would not adhere to the objective of equal access to medicines across individual patients and patient groups, and could, in the Government's opinion, ultimately reduce the number of healthy life years that the use of the health care services' resources could yield.

14

TRANSPARENCY AND PRIORITY SETTING

Priority setting in health care entails distributing the services' resources to certain areas and interventions rather than others, or giving certain patients more rapid access to treatment than others. Prioritisation decisions may therefore be seen as controversial. In the Government's view, it is important that patients whose intervention has been given lower priority than others find the decision-making process to be reasonable, even if they would have preferred another outcome. Decisions taken in the health care services must be well justified, so that those who are affected understand the reasoning behind them. Open processes that are presented in a manner that is easily understood and that involve patients and users will strengthen the legitimacy of the decisions taken.

Norway has a long tradition of transparency in decision-making processes related to priority setting. This is particularly evident in the priority-setting situations in which structured decision-making systems are in place, such as for assessment of the right to necessary medical assistance in the specialist health care services, decision-making within the National System for Managed Introduction of New Health Technologies, and decisions regarding reimbursement for medicines under the National Insurance. In the Government's view, these processes are adequately transparent, in terms of both the underlying principles for the decisions and the organisation of the evaluation and decision-making processes. There is likely greater transparency in these processes in Norway than in most other countries.

The Government sees a need to enhance the transparency of priority setting in two arenas in particular. First, the Storting must take a more decisive stance than is currently the case on the principles that are to form the basis for priority setting in the health care sector. The Storting is responsible for approving the principles and systems on which health care personnel and managers in the health care services can base their

prioritisation decisions. This white paper is an invitation to the Storting to do precisely this. Second, it is important to integrate assessments based on the principles for priority setting into the basis for decision-making at the administrative level more widely than is done today, cf. Chapter 12.

In certain situations, there may be a price to pay for openness, and the advantages and disadvantages of transparency must be weighed. This is particularly relevant in light of developments in the pharmaceutical market, especially as regards the issue of non-public discounts. There is a trend in the pharmaceutical industry towards setting exorbitant list prices for certain new medications but being willing to negotiate on discounts and other conditions with the caveat that the official list prices stay the same. One of the industry's motives may be to prevent information on discounted prices from being spread between countries, and thus from being used by other countries in their price negotiations.

The advantage of transparency relating to costs and prices is that all involved actors are aware of the basis for assessment and decisions relating to the introduction of new medicines and technologies, and that this transparency facilitates equitable health care services. This ensures the democratic legitimacy of the decisions. Openness also allows actors to determine on their own whether treatment is equal or not. The disadvantage of transparency is that the buyers, i.e. the hospitals and the authorities, could miss out on substantial discounts. High costs of new medicines or medical equipment may result in the products not being introduced or that less priority is given to other segments of the health care services in favour of the new products.

The Government believes that, ideally, there should be openness about discounts, but this will require coordination at the European level. The Government is therefore participating actively in several initiatives at both the Nordic and the European levels to expand cooperation in the area of medicines. In the Government's opinion, the disadvantages of a specific Norwegian transparency requirement in pharmaceutical pricing far outweigh the advantages. At the same time, effective, transparent processes for priority setting are essential to give decisions involving undisclosed prices legitimacy among the population. Decisions regarding the introduction of new medicines and technologies must be taken after a thorough assessment of the benefit for the patient group, the amount of resources required for implementing the method/technology and the severity of the condition. The decision-making basis must be openly accessible to all in so far as this is possible.

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USER INVOLVEMENT AND PRIORITY SETTING

A fundamental principle in the health care services is that patients and users have the right to participate in the implementation of health and care services. It is the patients themselves, based on the advice of and information from competent health care personnel, who are in the best position to assess the consequences of the various treatment options or to refuse treatment. Moreover, substantial weight is to be given to patient and user views when designing the services offered. The Government stresses that involving and training patients, users and their family members in mastering a life with illness and in helping to develop the health care services is of great importance. User involvement at all levels will help to increase the legitimacy of and acceptance for the prioritisation processes. User involvement does not, however, mean that the treatment provider no longer has medical responsibility, and patients are not free to choose a treatment method if health care professionals believe that another treatment is more suitable or reasonable.

Tools for shared decision-making between patients and health care personnel are an essential component of user involvement at the clinical level. With the help of these tools, patients and health care personnel work together to take decisions regarding examination and testing, treatment and follow-up to the degree and in the manner the patient desires. Good information about the efficacy and side-effects of treatments provides a basis for informed decisions and is important for giving patients ownership of their treatment. The patient receives support to assess the alternatives based on the best available knowledge about efficacy, advantages and disadvantages and to explore his or her own values and preferences. The aim is to agree on and choose the alternative that best harmonises with the patient's personal

preferences. The Government will continue efforts to further develop and implement effective tools for shared decision-making at the clinical level and to publish these on the web site www.helsenorge.no.

There is extensive user involvement at the group level as well as the clinical level. At the group level it is generally user organisations for the specific disease that safeguard user interests and can help to develop effective services based on experience and user competency. User involvement at this level entails users who contribute experience-based knowledge, creating the best possible knowledge base for the actors who will be designing the services. User involvement at the overall level should aim to ensure that all user groups are heard, preventing stronger user organisations and groups from receiving a greater share of the resources to the detriment of weaker groups.

GLOSSARY

Absolute shortfall

Absolute shortfall is a quantitative measure of the severity of a disease. Absolute shortfall expresses the number of healthy life years lost by a patient group as a result of a disease, given the current treatment, as compared with the average expected healthy life years for the population of the same age.

Cost-effectiveness ratio

The cost-effectiveness ratio expresses the relationship between the resources used and the expected benefit of an intervention. In health technology assessments (HTAs) of interventions at the group level in the health care services, the cost-effectiveness ratio is expressed in Norwegian kroner per quality-adjusted life year (QALY).

Criteria for priority setting

Interventions in the health care services are assessed on the basis of three priority-setting criteria: the benefit criterion, the resource criterion and the severity criterion. Two forms of the benefit criterion and the severity criterion have been provided: a textual description for use at the clinical level and a quantitative form for use in HTAs at the group level. These three criteria for priority setting comprise part of the overall principles for priority setting.

Decision Forum

The Decision Forum in the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services is comprised of the four Chief Executive Officers (CEOs) of the four regional health authorities. In addition, a representative of the health regions' user committees and a representative of the Norwegian Directorate of Health participate as observers. The regional health authorities have delegated the authority for determining which medicines and technologies are to be introduced in the specialist health care services to the Decision Forum.

Decision support tools

Decision support tools for health care personnel and patients help to promote a common understanding and shared practice. Examples of professional decision support tools in the health care services include national clinical guidelines and instructions, tools for shared decision-making between patients and health care personnel, and clinical ethics committees. Principles for priority setting may be established by means of these tools.

Decision-making at the administrative level

Administrative decisions regarding distribution of resources are decisions taken by managers and boards at various levels of the specialist health care services, municipal health and care services and the national health administration. Decisions may encompass day-to-day activities, distribution of a limited budget and

investments that may have an impact on the treatment options available to various patient groups.

Decision-making at the clinical level

These decisions are taken in the individual patient's meeting with the health care services. Decision-making at the clinical level generally concerns determining whether the patient should receive medical assistance, what type of medical assistance the patient should receive and how long the patient can wait before treatment is administered. Decision-making at the clinical level typically involves situations in which interventions are targeted toward individuals, interventions can be implemented quickly, the decision-maker knows the individual in question and the decision-maker may possess extensive information about this individual.

Decision-making at the group level

Decision-making at the group level primarily concerns decisions taken within national decision-making systems, i.e. decisions taken by the Decision Forum of the National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services and decisions taken by the Norwegian Medicines Agency regarding inclusion of medicines in the reimbursement scheme. Decision-making at the group level is often based on total and average values for a patient group.

Decision-making at the political level

Political decisions on distribution of resources are primarily manifested in budget-related and legislative decisions taken by the Storting (Norwegian parliament) and decisions taken by municipal councils as well as through the Minister of Health and Care Services' steering documents for the regional health authorities.

General practitioner

All municipalities are responsible for providing a Regular General Practitioner Scheme, and all persons residing in a Norwegian municipality have the right to a regular general practitioner. Most general practitioners are self-employed physicians who have a contract with the municipality. General practitioners represent the first line of the health care services. For conditions requiring specialised treatments patients receive a referral from the municipal health care services, most often from their general practitioner.

Health economics

Health economics is a field within the discipline of economics that deals with, among other things, how to make optimal use of the resources in the health care services. Economic analyses of incentives in the health care services and evaluation of interventions in the health care services from an economic perspective are key areas of focus.

Health technology assessments

A health technology assessment (HTA) is a systematic assessment of the documentation of the efficacy, safety and cost-effectiveness of methods for prevention, diagnosis, treatment, rehabilitation or the organisation of the health care services. Severity is also assessed. An HTA may bring to light multiple consequences of decisions taken by assessing economic, ethical, social, organisational and/or legal consequences. Documentation that forms the basis for the assessment may comprise primary studies, systematic reviews and health economic evaluations.

Healthy life years

A healthy life year corresponds to a life year with good health, i.e. an entire life year without reduced quality of life. Healthy life years are used as a measure of the benefit of an intervention or the severity of a condition. The term is used to capture changes in life expectancy and changes in health-related quality of life.

Municipal health and care services

The municipalities have the primary responsibility for providing necessary health and care services to all persons residing in their municipality regardless of age and diagnosis, including a Regular General Practitioner Scheme. The state is responsible for ensuring equal framework conditions for all municipalities through the introduction of relevant rules and financial frameworks.

National System for Managed Introduction of New Health Technologies within the Specialist Health Care Services

A national system for introducing new medicines and technologies has been established in the specialist health care services. Decisions regarding the medicines and technologies to be funded within the budgets of the regional health authorities are a component of their responsibility to ensure that the population of that region is offered the necessary health and care services. The four regional health authorities have established a Decision Forum consisting of their four CEOs. Decisions regarding the introduction of new medicines and technologies in the regional health authorities are taken on the basis of consensus between the four CEOs.

Opportunity cost

The opportunity cost of an intervention in the health care services is the benefit to other patients that could have been realised with the same resources.

Overall principles for priority setting

The overall principles for priority setting encompass the three criteria for priority setting for use at the clinical level and in HTAs at the group level, the principles for weighing these criteria for use in HTAs at the group level, and a definition of the benefits and resource use to be emphasised in prioritisation decisions.

Quality-adjusted life years (QALYs)

A measure of healthy life years.

Regional health authorities

Norway is divided into four health regions. Each of these regions has a regional health authority that is responsible for providing specialist health care services to the population of that region. The state is the owner of the regional health authorities. In addition to owning hospitals, the regional health authorities perform tasks related to research, education, and information and training targeted towards patients and their family members. The regional health authorities carry out their assigned tasks via the hospitals they own or through services provided by private actors.

Specialist health care services

The state and the municipalities are responsible for providing health care services to the population of Norway. The distribution of responsibility between the regional health authorities and the municipalities is related to the extent of specialisation of the services, among other things. The four regional health authorities are responsible for ensuring that the population in their region has access to necessary specialist health care services. The specialist health care services encompass somatic and psychiatric hospitals, outpatient clinics and treatment centres, training and rehabilitation institutions, institutions for specialised interdisciplinary treatment of alcohol and drug abuse, pre-hospital services, specialists in private practice, and laboratory and X-ray services. For conditions requiring specialised treatments patients receive a referral from the municipal health care services, most often from their general practitioner.

Published by:
Norwegian Ministry of Health and Care Services

Public institutions may order additional copies from:
Norwegian Government Security and Service Organisation
E-mail: publikasjonsbestilling@dss.dep.no
Internet: www.publikasjoner.dep.no
Telephone: + 47 222 40 000

Publication number: I-1176 E
Design: Kord
Print: Norwegian Government Security and Service Organisation
02/2017 – Impression 50