Commissioning NHS Services

The abbreviations used in this chapter are:

ACO	Accountable Care Organisation
CCGs	Clinical Commissioning Groups
HWB	Health and Wellbeing Board
IFR	Individual Funding Request.
JHWS	Joint Health and Wellbeing Strategy.
JSNA	Joint Strategic Needs Assessments
NHS England	National Health Service Commissioning Board
STP	Sustainability and Transformation Partnership
NHS Act	National Health Service Act 2006
2012 Act	Health and Social Care Act 2012
2012 Regulations	National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012
NICE Regulations	National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013

Contents of this chapter:

1 What is NHS commissioning?

1.1 NHS organisations have been separated into commissioners, providers and regulators since 1993 although some organisations combine roles as commissioners and regulators or commissioners and providers. This chapter explores what is meant in law by "NHS commissioning" and seeks to explain how commissioning decisions are taken[1].

1.2 There are many definitions of the word "commissioning". The NHS Improvements Website previously described commissioning as the achievement of high quality and value-for-money services for the NHS. It states:

> "Commissioning is a cycle of activities that includes assessing the needs of a population; analysing 'gaps'; setting priorities and developing commissioning strategies; influencing the market to best secure services and monitoring and evaluating outcomes. In other words, it involves buying in services from a range of health service providers (including GPs, dentists, community pharmacists, NHS and private hospitals, and voluntary sector organisations) to meet the health needs of local people, and monitoring how well they are being delivered. Commissioning is an on-going process that applies to all services, whether they are provided by the local authority, NHS, other public agencies, or by the independent sector"

1.3 The main NHS commissioners are the National Health Service Commissioning Board ("**NHS England**") and local clinical commissioning groups ("**CCGs**"). Please see the chapter on the "Responsible Commissioner" for an explanation as to which NHS services are commissioned

[1] There is a good guide to the practical issues around commissioning and good practice at https://www.england.nhs.uk/wp-content/uploads/2014/03/serv-trans-guide.pdf

by NHS England and CCGs for particular services. The output of the commissioning process is usually a legal contract (or an NHS contract) under which the NHS commissioner enters into an enforceable arrangement with a provider of NHS services under which the provider agrees to provide defined categories of medical treatment to NHS patients as part of "the health service". The health services is used as a term throughout the National Health Service Act 2006 ("**the NHS Act**") to mean the collection of services which is known as the NHS. However, as the above definition makes clear, the placing of contracts with a provider is thus the final act of the commissioning process. The placing of the commissioning contract is just one step in a long sequence of events that ought to take place before the decision is made by a CCG or NHS England that the NHS ought to provide a specific service to NHS patients at a specific location. Placing the contract does not complete the commissioning process. Commissioning is a continuing process because, after the contract has been placed, the commissioner is responsible for monitoring the performance of the contract and considering whether the services should be renewed, extended, cut back or terminated in the next contracting year.

1.4 Hence commissioning process is thus complex. This chapter describes some of the legal challenges which arise in the commissioning process. It also contains an outline as to how NHS bodies are able to make lawful commissioning decisions. The model will not be followed by every NHS commissioner in every case, but the steps which are set out below are the essential building blocks of a lawful commissioning process. It does not explore the question as to whether the commissioning produces benefits to the NHS which exceeds the costs of the commissioning process (where there are deeply held views for and against but an absence of clear evidence to prove the case either way) or whether commissioning has any future if the NHS moves to an Accountable Care Organisation ("**ACO**") model which effectively transfers commissioning from CCGs to provider organisations.

1.5 Commissioning presents particular challenges for all doctors and healthcare staff. The vast majority of medical training and professional medical practice is focused on the one to one relationship between a doctor and his or her patient. Commissioning is different because it is about population medicine, and is rarely about individual patients. Problems in commissioning regularly arise because the demand for clinically effective healthcare treatment for individual patients (suffering from both common and rare medical conditions) vastly exceeds the ability of the NHS to fund such treatment. NHS bodies have a finite

budgets and this means that difficult choices have to be made about how services are organised and structured and, in the end, which drugs and other treatments can and cannot be provided to patients suffering from both common and rare conditions. Once it is recognised that choices have to be made as to which treatments the NHS can afford to provide to patients, it is a legal necessity that the process of making those policy choices should be transparent and rational. Hence, in practice the difficult commissioning decisions are where the NHS commissioner is saying "No" to a treatment. Saying "Yes the NHS will fund your treatment" is straightforward. Saying "No" leaves a patient (and usually a proposed treating clinician) without the treatment that both clinician and the patient believes is necessary. Negative decisions lead to legal challenges and often leads to an intense focus of the decision making process which led up to the negative decision.

1.6 The proper approach to be taken by an NHS commissioner was set out in the evidence in *R (Condliff) v North Staffordshire Primary Care Trust* [2011] EWCA Civ 910[2] and reproduced by Toulson LJ in his judgment as follows:

> "13. The PCT is under a legal duty to break even and our Chief Executive is the Accountable Officer responsible for ensuring that this requirement is met. This means that the PCT needs to consider carefully the costs of treatments and the benefits that a treatment delivers before we can agree to commission it. For the PCT, the decision to commission a particular type of treatment is not just a question of whether a medical treatment is clinically effective. If a treatment were not clinically effective, we would not commission it. However if a treatment is clinically effective, we would only commission the treatment if we could afford to do so. Our duty to break even means we need to judge whether clinically effective treatments are (a) a cost effective use of the limited resources available to the PCT and (b) affordable. As we have a fully committed and finite budget, the duty to break even means that if we commission additional services for any patient group where these are not funded at the moment, we need to pay for this by disinvestment in other services for other patient groups.
>
> …

[2] See http://www.bailii.org/ew/cases/EWCA/Civ/2011/910.html

42. Each year the PCT undertakes a prioritisation process whereby the budget of the PCT for the present year is examined and plans are made for the treatments to be commissioned in the following financial year. As part of that process, the PCT considers the pressures that are likely to be placed on its services and budgets, the NICE (National Institute for Health and Clinical Excellence) Technology Appraisal Guidance that is likely to be published and thereby attract mandatory funding, and any other matters that are likely to affect the PCT budget. After ranking the competing demands on its financial resources in order of importance, the PCT reaches a conclusion about which treatments and interventions it will and will not fund in the coming financial year…

43. The PCT has adopted an Ethical Framework…These principles stand behind the PCT's decision making processes, especially those relating to our commissioning activities. The principles emphasise that decisions should be made on the evidence, should be non-discriminatory, should take into account that our budget can only be spent once and should result in the PCT maximising the welfare of our patient population within the resources available. Every decision we make to fund one treatment means that we are effectively taking a decision not to fund another treatment. As a result, the 3 components of the Ethical Framework – effectiveness, equity and patient choice – must be carefully balanced. Although patient choice is important, it may not outweigh the other relevant factors…

44. Our local prioritisation process involves evaluating healthcare interventions in order to decide what investments should be made with limited resources. It is a fundamental part of the commissioning business cycle"

1.7 Once a policy decision has been made as to which treatments will be funded by an NHS commissioner and which will not be funded, the court has no role to approve or disapprove of the choices made by the NHS commissioner. Lord Bingham said in *R v Cambridge Health Authority ex parte B* [1995] 1 WLR 898[3]:

"I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it costs, particularly when a life was potentially at stake. It would however, in my view,

[3] See http://www.bailii.org/ew/cases/EWCA/Civ/1995/49.html

> be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet.... Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this authority can be fairly criticised for not advancing before the court."

1.8 It is not the role of the court to second-guess such decisions. Its role is generally limited to seeing that the decision-making is within the law. See *R (AC)* v *Berkshire West Primary Care Trust & Anor* [2011] EWCA Civ 247[4] per Hooper LJ at para. 56.

1.9 Successful judicial challenges to commissioning decisions such as *R (S (a child)) v NHS England* [2016] EWHC 1395 (Admin) are almost always focused on the way in which decisions were made and involve a detailed analysis of the records made by the decision maker. Hence the primary challenge for NHS commissioners is how to say "No" in a legally defensible manner. It follows that following a proper process to reach commissioning decisions is an essential part of lawful commissioning. Following a proper process will not necessarily lead to NHS commissioners making the right decisions. However failing to follow a proper process will leave any decisions open to legal challenge and thus, if they are challenged, will prevent the commissioners from giving effect to their decisions.

1.10 At the level of an individual patient, a positive outcome of commissioning process is that a decision to approve funding for a patient to be provided with NHS funded treatment. Patients are almost always unaware of the legal decision making processes that exist behind decisions taken by doctors to provide them with treatment. Hence, for example, a patient attends the GP to ask about pain in a hip. The GP considers that the patient may need a hip replacement operation and refers the patient to a consultant at the local hospital. The patient is seen by the consultant who then books the patient in for an operation and, hopefully within the 18 week target, the patient has a completed operation. However, unseen to the patient, each of these decisions is underpinned by a complex series of commissioning decisions and contracts.

[4] See http://www.bailii.org/ew/cases/EWCA/Civ/2011/247.html

1.11 The GP is entitled to make a referral to the hospital because (a) the CCG (of which the GP's practice is a member) has an acute services contract with the hospital and (b) the GP is a delegated decision maker on behalf of the CCG under that contract. The consultant can see the patient as an out-patient and then perform the operation because a commissioning decision has been taken that hip replacement operations should be funded as part of NHS funded care for patients referred by a GP under the contract. Once the operation is completed the episode of care will be coded and reported and, in due course, the hospital trust will be paid a national tariff fee for the activity.

1.12 Any decision to provide services to an NHS patient ought to be made by an NHS commissioners based on only one of 4 routes, namely:

a) As a result of contract made by an NHS commissioner to fulfil a statutory duty under the NHS Act;

b) By applying the terms of an approved CCG or NHS England commissioning policy (funding through a "**a Commissioning Policy Decision**");

c) By making a decision that a patient is within a recognised exception to a CCG or NHS England commissioning policy PCT (funding through an "**Exception Policy Decision**"); or

d) By making an individual funding decision outside of CCG or NHS England existing commissioning policies ("**An Individual Funding Request ("IFR") policy Decision"**).

1.13 Detailed of each of these routes is set out below. However in the above example, the patient was able to see her GP because NHS England placed a primary care commissioning contract with the GP practice. That funded the primary care service and hence the GP practice was able to run its business of providing NHS services to patients. The GP was able to refer the patient to the local hospital because the CCG had an acute services contract with the hospital Trust, and that contract defined hip replacement operations as one of the services that the Trust could provide to patients as part of NHS funded services.

2 Commissioning and the duty to promote a comprehensive health service

2.1 Section 1 of the NHS Act 2006 imposes a duty on the Secretary of State to continue the promotion of "a comprehensive health service". Section 1H imposes this duty concurrently on NHS England. However this does not impose any duty on the NHS to provide a comprehensive health service[5]. Section 1 of the NHS Act has comparatively little legal effect because it is difficult to imagine any set of circumstances in which a decision could be challenged on the grounds that the Secretary of State had breached his or her section 1 duty. There has been no court case concerning reorganisation of NHS services or access to NHS funded medical a treatment which (and there have been many) which, as far as the author is aware, has successfully criticised the Secretary of State or any other NHS body for failing to discharge the section 1 duty. The Court of Appeal in *R (on the application of YA) v Secretary of State for Health* [2009] EWCA Civ 225[6] noted that the Secretary of State has a duty to continue the promotion in England of a comprehensive health service. The court then said:

> "His duty under section 3 is subject to the qualification that his obligation is limited to providing the services identified to the extent that he considers that they are necessary to meet all reasonable requirements. He does not automatically have to meet all the requirements and in certain circumstances he can exercise his judgment and legitimately decline to provide them. In exercising that judgment he is entitled to take into account the resources available to him and the demands on those resources"

2.2 It is therefore clear that the Secretary of State does not have a statutory duty to deliver a comprehensive health service. NHS commissioners are required to remain focused on the fact that the Secretary of State has a duty to promote the delivering of a comprehensive health service. That target remains the ultimate aim of the NHS even if that is largely unachievable in practice.

3 Commissioning and the effect of the NHS Constitution

3.1 All NHS bodies, including CCGs, are required to "have regard to the NHS Constitution": see section 2 of the Health Act 2009. The duty to "have regard" to the NHS Constitution during

[5] See Chapter 1 for an explanation of this duty.
[6] See http://www.bailii.org/ew/cases/EWCA/Civ/2009/225.html

a decision making process means that the CCG is obliged to understand the terms of the NHS Constitution and act in accordance with the principles set out in that document unless it has a very good reason to depart from those principles[7]. The relevant part of the NHS Constitution on commissioning provides:

> "The NHS commits to make decisions in a clear and transparent way, so that patients and the public can understand how services are planned and delivered."

3.2 Hence, throughout the commissioning process, there is a need for CCGs to act in a clear and transparent way, and to ensure that they can defend their reasoning at all times within the commissioning decision making process. It also ties in to the central importance of public participation in the commissioning process which is considered at chapter 11 below.

4 The 5 stage process to lawful commissioning decision making by a CCG

4.1 Commissioning decisions by CCGs referable to an individual patient are required to be typically at the end of a 4 stage decision making process is imposed by the statutory schemes under which NHS bodies are required to operate. Whilst every stage of the commissioning process is not undertaken every year (because decisions referable to many treatment areas are rolled over from year to year), elements of the 4 stage process should be present each year as part of any lawful commissioning process. The 4 main stages within the decision making process for those commissioning NHS care, and thus carrying the responsibility for managing NHS budgets, are as follows:

a) A **Joint Strategic Needs Assessment**;

b) A **Joint Health and Wellbeing Strategy**;

c) An **Annual CCG Commissioning Plan;**

d) **Commissioning policies** for individual medical conditions which flow from the Annual Commissioning Plan; and

[7] For more details on the effect of the "have regard" duty, please see paragraph 6.3.

e) Agreeing policies concerning where **Exceptions** will be made to policies, how **In-Year Service Developments** will be managed and adopting a policy for **Individual Funding Requests**.

4.2 Thus the "arrangements" that the CCG is obliged to have in place in order to discharge its legal duties ought to describe the processes that the CCG will follow to go through each of the above processes, and thus allow patients to understand the decision making process which leads up to a final decision on whether the treatment they are requesting will or will not be routinely funded under a commissioning policy. It should also describe whether funding could be secured through **Exception Policies** and how the CCG **Individual Funding Request** process will operate.

4.3 Getting through the above procedures requires those involved in the difficult business of priority setting. In conducting this exercise it is important for commissioners to bear in mind that it is potentially lawful for a CCG or NHS England to adopt a policy which provides that provides the NHS will not fund medically appropriate treatment even if this has the capacity to benefit a group of patients. Commissioning involves making tough (and sometimes near impossible) choices. NHS commissioners are entitled to decide that their substantial but nonetheless limited financial resources should be used to fund other treatments for one group of patients in preference to another group. That will inevitably leave disappointed patients and clinicians where clinically effective medical interventions are decided not to have a sufficient priority to justify funding. These decisions will, almost inevitably, come under intense public scrutiny. It is thus essential that they are taken in a transparent and lawful manner The primary duty on NHS commissioners is therefore for take these decisions in a rational way by following a lawful procedure. That procedure needs to ensure that the CCG or NHS England complies with all of its legal duties.

4.4 There are a large number of people who have either a legitimate or a commercial interest (and sometimes both) of having a say within the commissioning process. These include:

a) Patients (whose rights to be involved in decision making are discussed elsewhere);
b) The board members of a CCG;
c) GPs who are not members of a CCG board;
d) Provider NHS Trusts;
e) Other providers of healthcare services to the NHS;

f) Universities and other providers of training for clinical staff;

g) Persons who are engaged in clinical research which may be affected by CCG decisions;

h) Clinicians;

i) Locally elected politicians (both MPs and local councillors; and

j) Drug companies and other organisations that supply goods and services to the NHS.

4.5 A key part of a lawful decision making process is recognising the right of everyone who has a proper interest in the outcome of the commissioning process to have their say during the process. The CCG will remain the final decision maker but many of the above have the right to have an input into the process and to have their views properly considered by the CCG before final decisions are made. The commissioning process thus involves a series of complex challenges which GPs need to surmount in order to be confident that CCG decisions are legally robust.

5 The legal duties on CCGs and NHS England in the commissioning process

5.1 Before considering the details of each of the steps that a CCG (and to a lesser extent NHS England) is required to follow in a lawful commissioning process, it is necessary to examine some of the overarching legal duties imposed on CCGs and NHS England throughout the commissioning process. Regulations 34 to 36 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations") impose a series of duties on NHS commissioning bodies governing the way in which commissioning decisions are required to be taken. The effects of these Regulations was partially summarised by Mr Justice Jay in *R (Rose) v Thanet Clinical Commissioning Group* [2014] EWHC 1182 (Admin) at §26 to §27 as follows:

> "26. In my judgment, and insofar as is relevant to this case, there are three express regulatory obligations on the CCG and two implied ones. The express obligations are (i) to have in place arrangements and general policies for deciding whether to make available for persons particular health care interventions, (ii) to provide or make available its reasons for any general policy not to fund a particular intervention, and (iii) to include within its decision-making framework arrangements for dealing with specific requests by a person for funding in circumstances where there is no NICE-driven duty to make available the intervention at issue and the CCG's general policy is not to fund. Put in these terms it may be seen that express obligation (iii) is addressed to the

determination of exceptional cases. It is to be noted that Regulation 34(1) refers to "persons" and Regulation 34(2) to "a person", underlining the distinction between general policies and special cases.

27. As for the CCG's implied obligations imposed by force of public law and/or the true construction of the regulatory scheme, the first is that the duty to have regard to NICE recommendations made under Regulation 5 must bear on the formulation of its general policies (see (i) above) rather than its exceptional policies (see (ii)). This flows from the structure of the regulatory scheme but I will be amplifying this point subsequently. The second implied obligation, and it flows from the first, is that the duty to give reasons for any general policy not to fund a particular intervention must encompass the giving of a reasoned explanation of why a NICE recommendation made under Regulation 5 is not being followed"

5.2 Regulation 34(1) of the 2012 Regulations imposes a legal obligation on every CCG and NHS England to have "*arrangements for making decisions and adopting policies on whether a particular health care intervention is to be made available for persons for whom the relevant body has responsibility*". This legal duty means that each CCG and NHS England have a legal duty to set up transparent processes which explain how that body will go about making decisions in its annual commissioning round, who will be consulted, who will take the decisions and how these will be translated into contracts with its providers.

5.3 The wording of the legal duty is to "*make arrangements*". This form of words is used in many other places in the NHS Act and in other legislation which imposes statutory duties on public bodies. The nature of the duty to make arrangements gives a considerable amount of discretion to CCGs and NHS England. Subject to other legal constraints (some of which are described below), CCGs and NHS England are able to decide for themselves what decision making processes they should adopt. However, once the CCG or NHS England has put its "arrangements" in place, the public body comes under a public law legal duty to follow its own procedures when making commissioning decisions.

5.4 Some guidance about the meaning of a duty to make "arrangements" was given by Underhill J in the first instance decision of *R (Nash) v Barnet London Borough Council (Capita plc and*

others, interested parties [2013] EWHC 1067 (Admin)[8]. The case was only a permission decision and so is of limited weight but it is a full judgment by a distinguished judge (now in the Court of Appeal) and was subsequently upheld by the Court of Appeal. The Judge was concerned with a duty to make arrangements to secure best value under local government legislation. The Judge said at paragraph 70:

> ".. the reference to 'making arrangements' would make it clear that the duty was concerned with intentions rather than outcome. It may also be that the draftsman wanted to emphasise the need to build the fulfilment of the best value duty into authorities' plans and procedures. Or perhaps it is just circumlocution. But, whatever the explanation, the important point for present purposes is what the arrangements are aimed at, namely securing improvements in the *way* in which authorities perform their functions"

5.5 Thus the legal duty under is to ensure that the way in which a CCG of NHS England makes commissioning decisions and/or adopts commissioning policies is clearly described. The published "arrangements" need to describe the commissioning processes that the NHS commissioner will follow from its initial assessment of needs through to final contracting decisions. In *Tandy v East Sussex CC* [1998] A.C. 714 Mummery LJ emphasised the width of the discretion on a public body which had a duty to make arrangements (in that case about the education of children with special educational needs). He said:

> "In the interests of fairness, consistency and administrative efficiency a local education authority is entitled to formulate a policy setting norms, standards and criteria to be applied in the consideration of the circumstances of individual children. Such a policy is lawful if it promotes the specified statutory purpose and is sufficiently flexible not to fetter the decision-making process in individual cases. Further, once a policy has been formulated, it is permissible (and advisable) to review it from time to time in the light of experience and of changing circumstances"

5.6 The importance of NHS commissioners having clear policies which guide decision making where decisions are made to fund some areas of treatment and not to fund others has been

[8] See http://www.bailii.org/ew/cases/EWHC/Admin/2013/1067.html

recognised by the courts long before the 2012 Regulations came into effect. In *North West Lancashire Health Authority v A & Ors* [1999] EWCA Civ 2022[9] where Auld LJ said:

> ".. it is an unhappy but unavoidable feature of state funded health care that Regional Health Authorities have to establish certain priorities in funding different treatments from their finite resources. It is natural that each Authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each Authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. **It makes sense to have a policy for the purpose - indeed, it might well be irrational not to have one …"**

5.7 The overall purpose of the arrangements required by Regulation 34 of the 2012 Regulations must be to describe the processes that the CCG will follow to make commissioning decisions so that those affected by those decisions[10] know what processes the NHS commissioner will take and when decisions will be made. Speaking in the House of Lords in *Tandy* case Lord Browne-Wilkinson said at page 747:

> "The duty is to make arrangements for what constitutes suitable education for each child. That duty will not be fulfilled unless the arrangements do in fact provide suitable education for each child"

Thus the arrangements made by each CCG and NHS England will only comply with the terms of the statutory duty if they describe a proper system for decision making and explain how policies will be adopted.

5.8 Regulation 35(1) of the 2012 Regulations imposes a duty on each CCG and NHS England to give reasons for its decisions in favour or against funding any particular healthcare intervention. It provides:

> "(1) A relevant body must—

[9] See http://www.bailii.org/ew/cases/EWCA/Civ/1999/2022.html

[10] I.e. Those interested include patients, medical lobby groups, pharmaceutical companies and clinicians who wish to provide the treatment as part of NHS funded care.

(a) publish on its website a written statement of its reasons for any general policy it has on whether a particular healthcare intervention is to be made available for persons for whom it has responsibility; or

(b) where it has not published such a statement, provide a written statement of the reasons for any such policy when any person makes a written request for such a statement.

(2) Where a relevant body—

(a) makes a decision to refuse a request for the funding of a health care intervention for a person; and

(b) its general policy is not to fund that intervention,

the relevant body must provide that person with the reasons for that decision in writing"

5.9 These are potentially onerous responsibilities because they require the NHS commissioners to formulate reasons as to why it funds or declines to fund a particular healthcare intervention. There is a considerable amount of caselaw on the duty to give reasons which is beyond the scope of this guide. However the general principle is that reasons was explained by Lord Brown in *South Bucks DC v Porter (No2)* [2004] 1 WLR 1953[11] as follows:

"The reasons for a decision must be intelligible and they must be adequate. They must enable the reader to understand why the matter was decided as it was and what conclusions were reached on the "principal important controversial issues", disclosing how any issue of law or fact was resolved. Reasons can be briefly stated, the degree of particularity required depending entirely on the nature of the issues falling for decision. The reasoning must not give rise to a substantial doubt as to whether the decision-maker erred in law, for example by misunderstanding some relevant policy or some other important matter or by failing to reach a rational decision on relevant grounds.

[11] See http://www.bailii.org/uk/cases/UKHL/2004/33.html

But such adverse inference will not readily be drawn. The reasons need refer only to the main issues in the dispute, not to every material consideration"

5.10 If the CCG or NHS England fails to give proper reasons for a decision then the decision itself may be unlawful because it will not be clear whether the CCG has properly understood the statutory function that it was undertaking: see *R (on the application of Ermakov) v Westminster* [1995] EWCA Civ 42[12]. There are however occasions on which an NHS body is entitled to give supplementary detail to support initially inadequate reasons and may then, as a whole, be held to have acted lawfully.

5.11 Once a CCG or NHS England has resolved how it is going to make commissioning decisions and adopt commissioning policies, Regulation 36 of the 2012 Regulations provides that the NHS body must publicise those arrangements. It provides :

"Each relevant body[13] must compile information in writing describing the arrangements it has made pursuant to the requirements in regulation 34 and must ensure that that information is—

(a) published on the website of the relevant body; and

(b) available to inspect at the head or main office of the relevant body"

5.12 Thus the "arrangements" that each CCG and NHS England are required to have in place must be set out on its website. It is thus probably unlawful for a CCG or NHS England to make commissioning decisions in accordance with procedures which are not publicised. There are vast differences between the extent to which both CCGs and NHS England comply or fail to comply with these statutory obligations. NHS and some CCGs are excellent and provide a clear guide to members of the public about how decisions affecting them will be taken. Others fail to provide any proper guidance to show how they make decisions. It goes without saying that those CCGs who fail to publish details of their decision making processes are leaving themselves open to legal challenges.

[12] See http://www.bailii.org/ew/cases/EWCA/Civ/1995/42.html

[13] Relevant bodies under the 2012 Regulations are CCGs and NHS England: see Regulation 2.

6 The additional legal duties imposed on CCGs relevant to the commissioning process

6.1 The Health and Social Care Act 2012, which created CCGs, imposed a series of legal duties on the new NHS commissioning bodies. These are in general, target duties which are required to guide and focus the CCG's decision making processes. The general legal duties imposed on CCGs are:

a) A duty to act with a view to securing that health services are provided in a way which promotes the NHS Constitution: see section 14P of the NHS Act;

b) A duty to exercise the CCG functions effectively, efficiently and economically: see section 14Q of the NHS Act;

c) A duty to exercise CCG functions with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness: see section 14R(1) of the NHS Act;

d) A duty to act with a view to securing continuous improvement in the outcomes that are achieved from the provision of the services: see section 14R(2) of the NHS Act. "Relevant outcomes" for these purposes means outcomes which show—

(a) the effectiveness of the services,
(b) the safety of the services, and
(c) the quality of the experience undergone by patients

e) A duty to regard to any guidance published by NHS England on the discharge of their commissioning functions (see section 14Z8 of the NHS Act);

f) A duty to assist NHS England in NHS England's duty to secure that there is continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness and continuous improvement in the outcomes that are achieved from the provision of the services: see section 14S of the NHS Act;

g) A duty to have regard to the need to—

(a) reduce inequalities between patients with respect to their ability to access health services, and

(b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services: (see section 14T of the NHS Act).

h) A duty to promote the involvement of patients, and their carers and representatives (if any), in decisions which relate to—

(a) the prevention or diagnosis of illness in the patients, or

(b) their care or treatment (see section 14U(1) of the NHS Act);

i) A duty to have regard to guidance published by NHS England concerning the duty to involve patients in decision making under section 14U(1) of the NHS Act (see section 14U(3) of the NHS Act);

j) A duty to act with a view to enabling patients to make choices with respect to aspects of health services provided to them (see section 14V of the NHS Act)[14];

k) A duty to promote innovation in the provision of health services (including innovation in the arrangements made for their provision) (See section 14X of the NHS Act);

l) A duty to promote research on matters relevant to the health service and the use in the health service of evidence obtained from research (see section 14Y of the NHS Act);

m) A duty to promote education and training for persons who are employed, or who are considering becoming employed, in an activity which involves or is connected with the provision of services as part of the health service in England (see a combination of section 1F(1) and section 14Y of the NHS Act); and

n) A duty to promote integration between the services that the CCG commissions and other health and social care services (see sections 14Z1 of the NHS Act).

[14] For more details on patient choice rights, see the chapter on patient choice issues.

6.2 Each of these duties are legal obligations which are concerned with the way in which commissioning functions are undertaken and which impose duties on the CCG to have regard to particular factors when commissioning decisions are taken. They do not impose any requirement on CCG to make specific commissioning decisions (such as commissioning a specific service or keeping a specific hospital open). They are concerned with ensuring that CCG take into account defined factors when making these decisions. It is difficult to describe precisely what each of these duties mean in practice in any particular circumstances because the relevance of each factor will depend on the circumstances of each commissioning decision.

6.3 However, they are largely described as being duties to "have regard" to specified factors. In *R (The Pharmaceutical Services Negotiating Committee & Anor) v Secretary of State for Health* [2017] EWHC 1147 (Admin)[15] Collins J emphasised the scope and importance of a public body which was under a "have regard" duty. He said at §48:

> "I am equally wholly unpersauded that there is in reality any material difference between the obligations to have regard and to have due regard. Merely to have regard in the sense that the existence of the statutory requirements is recognised is never likely to suffice, albeit much will turn on the nature of the matters to which regard must be had. In s.1C it is a specific need to reduce inequalities so that the defendant is obliged to show that that need is recognised and that what is proposed does not in his view at the very least cause an increase in such inequalities. All that 'due' adds in my view is a specific recognition that the effect of the decision on the specified matters must be properly taken into account. It could indeed be argued that 'due' does not strengthen but rather weakens in that it recognises that there may be circumstances in which regard is not needed. But it seems to me in any event that the argument was a barren one having regard to the nature of the obligation in s.1C"

6.4 If there is no difference between the duty to "have regard" and the duty to "have due regard", the following general guidance about the duty to have due regard is relevant to NHS decision makers. The meaning of the "due regard duty under the Equality Act 2010 was expressed as follows by Aitkens LJ in *R (Brown) v Secretary of State for Work and Pensions*

[15] See http://www.bailii.org/ew/cases/EWHC/Admin/2017/1147.html Permission has been given for this case to go to the Court of Appeal.

[2008] EWHC 3158 (Admin)[16] and, translated into the wording of the duties on a CCG, means that CCG decision makers must take the following steps:

a) Decision makers in a CCG must be made aware of each of the legal duties which are relevant when they are taking decisions. A CCG is likely to be in difficulties in asserting that it has followed its legal obligations in making commissioning decisions if those who have made the decisions were not aware of each one of the legal duties set out above;

b) The mind of the decision maker must be focused on each of the above duties at some relevant point during the commissioning decision making processes. Decision makers must have a "*conscious approach and state of mind*" which is focused upon the legal obligation when they are taking commissioning decisions;

c) Each legal duty must be exercised in substance, with rigour and with an open mind;

d) The duties are non–delegable duties. They bind which ever individual is delegated to take decisions on behalf of a CCG;

e) The duties are continuing duties throughout the commissioning process;

f) It is good practice for those exercising public functions in public authorities to keep an adequate record showing that they had actually considered their duties and pondered relevant questions. Proper record-keeping encourages transparency and will discipline those carrying out the relevant function. Further it will, in practice, be difficult if not impossible to show that the CCG has had regard to statutory factors if the records of the decision making process make no reference to those factors.

6.5 There is a specific legal duty to seek public health advice. Interestingly, despite the myriad of legal duties on a CCG, there is no duty to seek legal advice. In undertaking commissioning duties, there is a legal duty on a CCG to seek external advice in specific areas. The wording of the duty in section 14W of the NHS Act to seek public health advice is as follows:

[16] See http://www.bailii.org/ew/cases/EWHC/Admin/2008/3158.html

"Each clinical commissioning group must obtain advice appropriate for enabling it effectively to discharge its functions from persons who (taken together) have a broad range of professional expertise in—

(a) the prevention, diagnosis or treatment of illness, and

(b) the protection or improvement of public health"

6.6 The reference to the requirement to seek advice from a "broad range of professional expertise" inevitably means that the CCG is required to seek advice from more than one person before taking any key decision. The CCG almost certainly will not discharge this duty of it only relies on the expertise of its own GP professionals because these individuals are potential decision makers. NHS England has a power (but not a duty) to publish advice on how the CCG should seek advice in order to discharge this duty. No guidance has yet been published by NHS England about how they recommend CCGs exercise this statutory duty.

6.7 Unlike some of the target duties set out above, the duty to seek advice is clear. A CCG will act unlawfully if it fails to seek appropriate advice within the commissioning processes. There is no specific obligation in the NHS Act to require the CCG to publish the advice that it receives. However the advice would not be covered by legal professional privilege because it is not legal advice. It is therefore difficult to see any exemption under the Freedom of Information Act 2000 which the CCG could rely on refuse to publish any advice that it has received.

7 The role of Health and Wellbeing Boards in NHS commissioning decisions

7.1 The first stage to any commissioning process is for a statutory provider of NHS or community care services to gain an understanding the needs of the population which the public body serves. These functions are required to be carried out by the Health and Wellbeing Board ("**HWB**"), acting on behalf of both the CCGs operating within a local authority area and the local social services authority. HWBs, as joint NHS and local authority committees, were created by section 194 of the Health and Social Care Act 2012 ("**the 2012 Act**"). Section 194(2) of the 2012 Act provides that the HMW must include the following persons:

"The Health and Wellbeing Board is to consist of—

(a) subject to subsection (4), at least one councillor of the local authority, nominated in accordance with subsection (3),

(b) the director of adult social services for the local authority,

(c) the director of children's services for the local authority,

(d) the director of public health for the local authority,

(e) a representative of the Local Healthwatch organisation for the area of the local authority,

(f) a representative of each relevant clinical commissioning group, and

(g) such other persons, or representatives of such other persons, as the local authority thinks appropriate"

7.2 The primary functions of the Health and Wellbeing Boards ("**HWBs**") are set out in section 195 which provides:

"(1) A Health and Wellbeing Board must, for the purpose of advancing the health and wellbeing of the people in its area, encourage persons who arrange for the provision of any health or social care services in that area to work in an integrated manner.

(2) A Health and Wellbeing Board must, in particular, provide such advice, assistance or other support as it thinks appropriate for the purpose of encouraging the making of arrangements under section 75 of the National Health Service Act 2006 in connection with the provision of such services.

(3) A Health and Wellbeing Board may encourage persons who arrange for the provision of any health-related services in its area to work closely with the Health and Wellbeing Board.

(4) A Health and Wellbeing Board may encourage persons who arrange for the provision of any health or social care services in its area and persons who arrange for the provision of any health-related services in its area to work closely together.

(5) Any reference in this section to the area of a Health and Wellbeing Board is a reference to the area of the local authority that established it.

(6) In this section—

"the health service" has the same meaning as in the National Health Service Act 2006;

"health services" means services that are provided as part of the health service in England;

"health-related services" means services that may have an effect on the health of individuals but are not health services or social care services;

"social care services" means services that are provided in pursuance of the social services functions of local authorities (within the meaning of the Local Authority Social Services Act 1970)"

7.3 Section 196(1) of the 2012 Act provides that the functions of preparing the joint strategic needs assessment ("**JSNA**") and the joint health and wellbeing strategy ("**JHWS**") under the Local Government and Public Involvement in Health Act 2007 are to be discharged by the HWB as follows:

"The functions of a local authority and its partner clinical commissioning groups under sections 116 and 116A of the Local Government and Public Involvement in Health Act 2007 ("the 2007 Act") are to be exercised by the Health and Wellbeing Board established by the local authority"

7.4 HWBs have considerable powers to require CCGs and NHS England to provide them with information. Their powers to require the provision of information are set out in section 199 of the 2012 Act which provides:

> "(1) A Health and Wellbeing Board may, for the purpose of enabling or assisting it to perform its functions, request any of the following persons to supply it with such information as may be specified in the request—
>
> (a) the local authority that established the Health and Wellbeing Board;
>
> (b) any person who is represented on the Health and Wellbeing Board by virtue of section 194(2)(e) to (g) or (8);
>
> (c) any person who is a member of a Health and Wellbeing Board by virtue of section 194(2)(g) or (8) but is not acting as a representative.
>
> (2) A person who is requested to supply information under subsection (1) must comply with the request.
>
> (3) Information supplied to a Health and Wellbeing Board under this section may be used by the Board only for the purpose of enabling or assisting it to perform its functions.
>
> (4) Information requested under subsection (1) must be information that relates to—
>
> (a) a function of the person to whom the request is made, or
>
> (b) a person in respect of whom a function is exercisable by that person"

7.5 Further details of the functioning of HWBs are set out in the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013[17].

[17] See http://www.legislation.gov.uk/uksi/2013/218/contents/made

8 Joint Strategic Needs Assessments

8.1 Each year the NHS has an established pattern of services but, with a changing and in particular substantial immigration and an ageing society, the footprint of existing services may not properly match the needs of the local population. There is a tendency in the NHS (as in all public services) to continue to fund any existing services that are serving a need for those services rather than examining whether the existing services are the best use of limited resources to meet population needs. However continuing to fund existing services inevitably consumes resources and leaves little if any money for the expansion of other services that have seen increased demand or the development of new services to meet gaps in provision. The purposes of the JSNA is to create an objective assessment for the overall need for statutory health and social care services of the local population and thus ensure that planning is informed by a proper evidence base. This process should, to some extent, combat the inevitable tendency to continue to fund services as "business as usual". The statutory scheme imposes a series of steps that CCGs, working through the HWB, are required to take each year, in co-operation with their local authority colleagues, to assess needs and thus inform decisions whether the pattern of existing statutory services best meets the local needs and, if not, to make appropriate changes.

8.2 The commissioning process should start with the development of a JSNA which is carried out by the HWB on behalf of both the CCGs operating in a local authority area and the local authority. The duty to carry out a JSNA is set out in section 116(1) of the Local Government and Public Involvement in Health Act 2007 which provides:

> "(1) An assessment of relevant needs must be prepared in relation to the area of each responsible local authority"

8.3 Section 116(4) then provides:

> "It is for—
>
> (a) the responsible local authority, and
>
> (b) each of its partner clinical commissioning groups,

to prepare any assessment of relevant needs under this section in relation to the area of the responsible local authority"

8.4 The term "relevant needs" within the JSNA is widely defined by sections 116(6) and (7) which provide:

"(6) For the purposes of this section, there is a relevant need in relation to so much of the area of a responsible local authority as falls within the area of a partner clinical commissioning group if there appears to the responsible local authority and the partner clinical commissioning group to be a need or to be likely to be a need to which subsection (7) applies.

(7) This subsection applies to a need—

(a) which—

(i) is capable of being met to a significant extent by the exercise by the responsible local authority of any of its functions; and

(ii) could also be met, or could otherwise be affected, to a significant extent by the exercise by [the partner clinical commissioning group or the National Health Service Commissioning Board] of any of its functions; or

(b) which—

(i) is capable of being met to a significant extent by the exercise by [the partner clinical commissioning group or the National Health Service Commissioning Board] of any of its functions; and

(ii) could also be met, or could otherwise be affected, to a significant extent by the exercise by the responsible local authority of any of its functions"

8.5 Hence, each CCG is required, working through the HWB, on an annual basis to work with the local authority to carry out an assessment of all of the actual and potential needs in the local authority area for NHS or social care services. The identification of a "need" as part of an assessment does not impose any direct legal obligation on either the NHS body or the local authority to provide a service to meet that need. The primary purpose of the assessment is to inform the priority setting decision making process which is undertaken by both the NHS and by local authorities so as to ensure that the NHS and social services authorities are fully aware of the range of needs in their area and can thus make the best use of the resources available to them to fulfil as many of those needs as possible.

8.6 The local authority is under a specific duty to publish the joint strategic health needs assessment: see section 116(5) of the 2007 Act.

8.7 The Department of Health has published non-statutory "best practice" Guidance concerning these functions in March 2013[18]. This explains the purpose of these documents as follows:

> "The purpose of JSNAs and JHWSs is to improve the health and wellbeing of the local community and reduce inequalities for all ages. They are not an end in themselves, but a continuous process of strategic assessment and planning – the core aim is to develop local evidence-based priorities for commissioning which will improve the public's health and reduce inequalities. Their outputs, in the form of evidence and the analysis of needs, and agreed priorities, will be used to help to determine what actions local authorities, the local NHS and other partners need to take to meet health and social care needs, and to address the wider determinants that impact on health and wellbeing"

8.8 The Guidance explains the purpose of the JSNA as follows:

> "JSNAs are assessments of the current and future health and social care needs of the local community. – these are needs that could be met by the local authority, CCGs, or the NHS CB. JSNAs are produced by health and wellbeing boards, and are unique to each local area. The policy intention is for health and wellbeing boards to also consider wider factors that impact on their communities' health and wellbeing, and local assets

[18] See https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/277012/Statutory-Guidance-on-Joint-Strategic-Needs-Assessments-and-Joint-Health-and-Wellbeing-Strategies-March-20131.pdf

that can help to improve outcomes and reduce inequalities. Local areas are free to undertake JSNAs in a way best suited to their local circumstances – there is no template or format that must be used and no mandatory data set to be included.

A range of quantitative and qualitative evidence should be used in JSNAs. There are a number of data sources and tools that health and wellbeing boards may find useful for obtaining quantitative data. Qualitative information can be gained via a number of avenues, including but not limited to views collected by the local Healthwatch organisation or by local voluntary sector organisations, feedback given to local providers by service users; and views fed in as part of community participation within the JSNA and JHWS process.

JSNAs can also be informed by more detailed local needs assessments such as at a district or ward level; looking at specific groups (such as those likely to have poor health outcomes); or on wider issues that affect health such as employment, crime, community safety, transport, planning or housing. Evidence of service outcomes collected where possible from local commissioners, providers or service users could also inform JSNAs. Boards will need to ensure that staff supporting JSNAs have easy access to the evidence they need to undertake any analysis they needed to support the board's decisions"

8.9 The JSNA thus ought to be a key document for the local all NHS and social services bodies.

9 Joint Health and Wellbeing Strategies

9.1 Once the joint strategic health needs assessment has been undertaken, the next step for the local authority and the CCGs to work together through the HWB to produce a Joint Health and Wellbeing Strategy ("JHWS"). The legal duty on the HWB to produce a JHWS is in section 116A of the 2007 Act which provides:

"(1) This section applies where an assessment of relevant needs is prepared under section 116 by a responsible local authority and each of its partner clinical commissioning groups.

(2) The responsible local authority and each of its partner clinical commissioning groups must prepare a strategy for meeting the needs included in the assessment by the exercise of functions of the authority, the National Health Service Commissioning Board or the clinical commissioning groups ("a joint health and wellbeing strategy").

(3) In preparing a strategy under this section, the responsible local authority and each of its partner clinical commissioning groups must, in particular, consider the extent to which the needs could be met more effectively by the making of arrangements under section 75 of the National Health Service Act 2006 (rather than in any other way).

(4) In preparing a strategy under this section, the responsible local authority and each of its partner clinical commissioning groups must have regard to—

(a) the mandate published by the Secretary of State under section 13A of the National Health Service Act 2006, and

(b) any guidance issued by the Secretary of State.

(5) In preparing a strategy under this section, the responsible local authority and each of its partner clinical commissioning groups must—

(a) involve the Local Healthwatch organisation for the area of the responsible local authority, and

(b) involve the people who live or work in that area.

(6) The responsible local authority must publish each strategy prepared by it under this section.

(7) The responsible local authority and each of its partner clinical commissioning groups may include in the strategy a statement of their views on how arrangements for the provision of health-related services in the area of the local authority could be more closely integrated with arrangements for the provision of health services and social care services in that area.

(8) In this section and section 116B—

(a) "partner clinical commissioning group", in relation to a responsible local authority, has the same meaning as in section 116, and

(b) "health services", "health-related services" and "social care services" have the same meaning as in section 195 of the Health and Social Care Act 2012"

9.2 These provisions provide that CCGs are required to work with the relevant local authority (which in a 2 tier local authority areas is the County Council) to prepare a joint strategic health and wellbeing strategy which describes how the NHS and local authority are planning to meet the needs of the local population for NHS and community care services. Each CCG is required to have regard to the Mandate published by the Secretary of State under section 13A of the NHS Act and to any guidance published by the Secretary of State.

9.3 The HWB has a duty under section 116A(5) to involve the Local Healthwatch organisation and to involve the "*the people who live or work in the area*" in the preparation of that strategy. That is not a consultation duty but a duty to "involve" local people in planning for NHS and community care services.

9.4 The Guidance explains what the JHWS should contain as follows:

"JHWSs are strategies for meeting the needs identified in JSNAs. As with JSNAs, they are produced by health and wellbeing boards, are unique to each local area, and there is no Statutory Guidance on Joint Strategic Needs Assessments and Joint Health and Wellbeing Strategies mandated standard format. In preparing JHWSs, health and wellbeing boards must have regard to the Secretary of State's mandate to the NHS CB which sets out the Government's priorities for the NHS.

They should explain what priorities the health and wellbeing board has set in order to tackle the needs identified in their JSNAs. Again, it would not be appropriate to specify or dictate issues which should be prioritised. This is not about taking action on everything at once, but about setting a small number of key strategic priorities for action, that will make a real impact on people's lives. JHWSs should translate JSNA findings into clear outcomes the board wants to achieve, which will inform local

commissioning – leading to locally led initiatives that meet those outcomes and address the needs"

9.5 The Guidance explains that there is no requirement on NHS bodies and local authorities to rewrite these documents from scratch every year. It provides:

> "JSNAs and JHWSs are continuous processes, and are an integral part of CCG and local authority commissioning cycles. Health and wellbeing boards will need to decide for themselves when to update or refresh JSNAs and JHWSs or undertake a fresh process to ensure that they are able to inform local commissioning plans over time. They do not need to be undertaken from scratch every year; however boards will need to assure themselves that their evidence-based priorities are up to date to inform the relevant local commissioning plans. To be transparent and enable wide participation, boards should be clear with their partners and the community what their timing cycles are and when outputs will be published"

9.6 There would be no benefit in undertaking the considerable amount of work needed to produce a proper JSNA and then an JHWS if the output of this work did not influence commissioning decisions by local authorities, CCGs and NHS England. Section 116B of the 2007 Act (as amended by the 2012 Act) provides that, in exercising any functions, both a CCG and NHS England are required to "have regard" to the JSNA and the JHWS. The section provides:

> "(1) A responsible local authority and each of its partner clinical commissioning groups must, in exercising any functions, have regard to—
>
> (a) any assessment of relevant needs prepared by the responsible local authority and each of its partner clinical commissioning groups under section 116 which is relevant to the exercise of the functions, and
>
> (b) any joint health and wellbeing strategy prepared by them under section 116A which is so relevant.

(2) The National Health Service Commissioning Board must, in exercising any functions in arranging for the provision of health services in relation to the area of a responsible local authority, have regard to—

(a) any assessment of relevant needs prepared by the responsible local authority and each of its partner clinical commissioning groups under section 116 which is relevant to the exercise of the functions, and

(b) any joint health and wellbeing strategy prepared by them under section 116A which is so relevant.

9.7 The duty to "have regard" to a plan or set or assessment is a term of art in public law statutes[19]. In this context, it probably has the following general consequences:

a) Decision makers in a CCG and in NHS England must be made aware of any relevant JSNA and JHWS when making commissioning decisions. A CCG cannot assert that it has followed its legal obligation to have regard to the joint strategic health needs assessment in making commissioning decisions if those who made the decisions were not aware of the relevant recommendations in the assessment document. In practice this means that relevant decision makers must be focused on the recommendations of the joint strategic health needs assessment during the commissioning processes. Decision makers must have a "conscious approach and state of mind" which is focused upon this particular legal obligation when they are taking commissioning decisions;

b) The duty to have regard to the JSNA and JHWS means that the audit trail must show that the conclusions of these documents have been considered in substance, with rigour and with an open mind when the CCG are taking commissioning decisions;

c) The duty is non–delegable. It rests on the key decision makers within the CCG or NHS England and cannot be discharged if the relevant "regard" is given lower down in the organisations but not reported up to the key decision makers;

d) The duty to have regard to the JSNA and the JHWS is a continuing duty which is engaged throughout the commissioning process;

[19] See paragraph 6.3 for details of the caselaw on have regard duties.

e) It is good practice for both a CCG and NHS England to keep an adequate record showing that they had actually considered these documents and pondered the relevant questions raised by them as part of any decision-making process. Proper record-keeping encourages transparency and will discipline those carrying out the relevant function.

9.8 However, the "have regard" duty imposes a procedural obligation on NHS bodies but does not mandate a particular outcome. Neither the CCG nor NHS England is bound to adopt each and every one of the priorities identified in either the JSNA or the JHWS. If either NHS body has good reasons to do so, it can depart from the collective views about the priorities for services set out in the JSNA and the JHWS. However, in order to ensure that it is acting lawfully, a CCG or NHS England would be required to demonstrate that it had carefully considered the recommendations of the JSNA and the JHWS and had identified precise reasons why it was taking a different course.

10 The CCG Annual Commissioning Plan

10.1 The provisions of the 2012 Act imposed a statutory obligation on CCGs are required to consult key stakeholders about their annual commissioning plans and then publish a plan saying how they propose to exercise their functions in the coming financial year. This is an area of considerable legal risk for CCGs because NHS England Guidance appears to have largely forgotten about this legal duty and to require that CCG plans are absorbed within the wider plans of Sustainability and Transformation Partnerships ("**STPs**"). Whilst the STP process may be an entirely laudable, it is entirely non-statutory. Accordingly, notwithstanding the Guidance from NHS England which has elevated the STP planning process above almost all other aspects of NHS planning, CCGs and NHS England need to take care to ensure that it does not take the place of the statutory planning processes which are set out in the 2012 Act. The statutory processes may well have been found to be less than perfect, but the 2012 Act is an Act of Parliament and public bodies have a legal duty to comply with the provisions of the 2012 Act (at least until Parliament is called on to repeal the relevant parts of the 2012 Act).

10.2 The duty to publish an annual commissioning plan is set out in section 14Z11 of the NHS Act which provides:

"**14Z11 Commissioning plan**

(1) Before the start of each relevant period, a clinical commissioning group must prepare a plan setting out how it proposes to exercise its functions in that period.

(2) In subsection (1), "relevant period", in relation to a clinical commissioning group, means—

(a) the period which—

(i) begins on such day during the first financial year of the group as the Board may direct, and

(ii) ends at the end of that financial year, and

(b) each subsequent financial year.

(3) The plan must, in particular, explain how the group proposes to discharge its duties under—

(a) sections 14R, 14T and 14Z2, and

(b) sections 223H to 223J.

(4) The clinical commissioning group must publish the plan.

(5) The clinical commissioning group must give a copy of the plan to the Board before the date specified by the Board in a direction.

(6) The clinical commissioning group must give a copy of the plan to each relevant Health and Wellbeing Board.

(7) The Board may publish guidance for clinical commissioning groups on the discharge of their functions by virtue of this section and sections 14Z12 and 14Z13.

(8) A clinical commissioning group must have regard to any guidance published by the Board under subsection (7).

(9) In this Chapter, "relevant Health and Wellbeing Board", in relation to a clinical commissioning group, means a Health and Wellbeing Board established by a local authority whose area coincides with, or includes the whole or any part of, the area of the group"

10.3 The purpose of the annual commissioning plan is to set out how the CCG "proposes to exercise its functions" in the coming financial year. A CCG has powers under section 14Z12 to revise its annual commissioning plan if it wishes to make any significant changes to the exercise of its functions within a financial year. This power is set out in section 14Z12 which provides:

"(1) A clinical commissioning group may revise a plan published by it under section 14Z11.

(2) If the clinical commissioning group revises the plan in a way which it considers to be significant—

(a) the group must publish the revised plan, and

(b) subsections (5) and (6) of section 14Z11 apply in relation to the revised plan as they apply in relation to the original plan.

(3) If the clinical commissioning group revises the plan in any other way, the group must—

(a) publish a document setting out the changes it has made to the plan, and

(b) give a copy of the document to the Board and each relevant Health and Wellbeing Board"

10.4 The CCG is required to follow a specific consultation statutory process prior to publishing the annual commissioning plan. This includes duty to consult the public. The full details of the statutory process which each CCG is required to follow a set out in section 14Z13 of the NHS Act which provides:

> **"**14Z13 Consultation about commissioning plans
>
> (1) This section applies where a clinical commissioning group is—
>
> (a) preparing a plan under section 14Z11, or
>
> (b) revising a plan under section 14Z12 in a way which it considers to be significant.
>
> (2) The clinical commissioning group must consult individuals for whom it has responsibility for the purposes of section 3.
>
> (3) The clinical commissioning group must involve each relevant Health and Wellbeing Board in preparing or revising the plan.
>
> (4) The clinical commissioning group must, in particular—
>
> (a) give each relevant Health and Wellbeing Board a draft of the plan or (as the case may be) the plan as revised, and
>
> (b) consult each such Board on whether the draft takes proper account of each joint health and wellbeing strategy published by it which relates to the period (or any part of the period) to which the plan relates.
>
> (5) Where a Health and Wellbeing Board is consulted under subsection (4)(b), the Health and Wellbeing Board must give the clinical commissioning group its opinion on the matter mentioned in that subsection.
>
> (6) Where a Health and Wellbeing Board is consulted under subsection (4)(b)—

(a) it may also give the Board its opinion on the matter mentioned in that subsection, and

(b) if it does so, it must give the clinical commissioning group a copy of its opinion.

(7) If a clinical commissioning group revises or further revises a draft after it has been given to each relevant Health and Wellbeing Board under subsection (4), subsections (4) to (6) apply in relation to the revised draft as they apply in relation to the original draft.

(8) A clinical commissioning group must include in a plan published under section 14Z11(4) or 14Z12(2)—

(a) a summary of the views expressed by individuals consulted under subsection (2),

(b) an explanation of how the group took account of those views, and

(c) a statement of the final opinion of each relevant Health and Wellbeing Board consulted in relation to the plan under subsection (4).

(9) In this section, "joint health and wellbeing strategy" means a strategy under section 116A of the Local Government and Public Involvement in Health Act 2007 which is prepared and published by a Health and Wellbeing Board by virtue of section 196 of the Health and Social Care Act 2012"

10.5 Section 14Z14 of the NHS Act provides a power (but not a duty) for the HWB to provide NHS England with an opinion as to whether a CCG annual commissioning plan takes proper account of the JHWS published by the HWB. This is a power which enables the HWB to express its disagreement with the priorities identified by the CCG and would lay the ground for a legal challenge that, in making commissioning decisions, the CCG has failed to comply with its duty to have regard to the JHWS. A CCG may, of course, seek to defend that challenge by producing evidence that the CCG has properly had regard to the JHWS but, for defensible reasons, has come to a different view on the priorities for the local NHS.

10.6 The NHS England "Operational Planning and Contracting Guidance 2017-2019"[20] makes no mention of the duties on CCGs to produce annual commissioning plans. In place of the statutory planning process, it requires joint plans between commissioners and providers to be submitted to NHS England for approval. This is a completely non-statutory process and NHS England have no clear statutory powers to require any CCG to engage in these procedures. This is the planning process which NHS England is enforcing currently seeing to impose on CCGs, under the umbrella of the STP process. However, NHS England has no power to permit CCGs to ignore their legal obligations to consult with the public about their annual commissioning plan. A CCG which fails to produce an annual commissioning plan will be acting unlawfully in the absence of a recommendation in the NHS Operational Planning and Contracting Guidance document will be no defence. Further, any major commissioning decision which is taken without the CCG having annual commissioning plan which describes the decision and has been the subject of prior public consultation could be the subject of a Judicial Review challenge.

11 The development of CCG Commissioning Policies

11.1 Once the CCG **annual commissioning plan** has been agreed, the precise details of the services that are to be commissioned for each patient group or specialised service need to be formulated in **commissioning policies**, which must also be informed by the joint strategic health needs assessment**.** These policies set out agreed care pathways and define clinical criteria which set out which patients are entitled to NHS funded healthcare for each medical condition. Once a policy has been agreed, patients are entitled to expect that the CCG will routinely agree to fund the medical treatment set out in the policy patients who fulfil for the stated clinical criteria. Patients whose clinical criteria are outside the scope of a policy will not be routinely funded for NHS care, even if the medical treatment has the potential to benefit an individual patient. However, there is always the possibility of the CCG making an individual decision to depart from its own policy.

11.2 CCGs and NHS England have a duty to publicise their commissioning policies on their website: see Regulation 35(1) of the 2012 Regulations (see paragraph 5.8 above). Thus, for example, patients are entitled to know what approach a CCG takes to funding IVF treatment

[20] See https://www.england.nhs.uk/wp-content/uploads/2016/09/NHS-operational-planning-guidance-201617-201819.pdf

and can thus know when they are and are not likely to be eligible for NHS funded IVF treatment.

12 Exception Policies and pick-up funding for clinical trials

12.1 Commissioning policies define what care will be funded by the NHS for defined cohorts of patients. However there are always a minority of patients whose circumstances do not precisely fit the general pattern and thus are entitled to be treated separately from other patients. CCGs routinely develop **exception policies** to apply to such patients**.** The essence of an exception policy is that a patient who comes within the policy will be provided with NHS funding to support a medical treatment even though the other patients with the same clinical presentation are denied funding for the same treatment.

12.2 The formulation of exception policies is problematic but they are used to over situations where the NHS has decided that particular circumstances justify making a different decision for one group of patients in comparison to other patients with a like condition. The CCG needs to formulate the justification for exception policies very carefully in order to avoid challenges by other patients who are denied the relevant treatment.

12.3 The following are examples of areas where exception policies have been developed:

a) Funding can be agreed for patients who have taken part in an NHS sponsored clinical trial of a new drug or medical treatment and have shown a capacity to benefit from the treatment. Thus such patients will continue to funded to receive the treatment after the trial has finished even if funding would not be made available to a new patient in the same clinical circumstances; and

b) To continue NHS funded medical treatment which has been commenced by another NHS commissioner and now falls to the CCG as a result of the patient moving from one CCG area where a treatment is funded to an area where it is not routinely funded.

12.4 The limitations on funding for trial pick-up costs is a hugely contentious area. NHS commissioners can come under considerable pressure from patients, clinicians and drug companies to continue to fund the treatment after the trial has been completed. However the policy position adopted by most NHS commissioners is that funding will only be provided

to support successful treatment if an agreement to fund was obtained before the trial began. Funding for trial pick up costs should be rarely (if ever) agreed by NHS commissioners where funding has not been agreed in advance of the trial because it ought to be unnecessary. Every clinical trial is required by the Medicines for Human Use (Clinical Trials) Regulations 2004[21] to operate in accordance the Helsinki Declaration[22] published by the World Medical Association. The requirement to identify a source of funding to allow the treatment to continue for patients who have a capacity to benefit is part of the present version of the Helsinki Declaration. It provides:

> "In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions"

12.5 There is an argument that the version of the Helsinki Declaration referred to in the Regulations does not include this wording. However, the spirit of the Regulations is that the Helsinki Declaration should be followed and thus Medical Ethics Committees ought only to give approval for a clinical the trial if those running the proposed trial have identified the source of funding for post-trial treatment for successful patients at the outset.

13 The Duties on CCGs and NHS England to commission treatments identified in NICE Technology Appraisal Recommendations and Highly Specialised Technology Recommendations

13.1 Regulation 34 of the 2012 Regulations provides that the arrangements that the CCG has in place for making commissioning decisions must ensure that the CCG funds Technology Assessment Guidance published by the National Institute for Health and Care Excellence[23] ("**NICE**"). The Labour government of 1997 to 2001 recognised the tension between local decision making and post code prescribing. Its solution was to create the National Institute for Clinical Excellence, later renamed as the National Institute for Health and Care Excellence by section 232 of the 2012 Act.

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[21] See http://www.legislation.gov.uk/uksi/2004/1031/contents/made for the original form of the Regulations. This version will not necessarily incorporate amendments made after the Regulations were made.
[22] See https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
[23] See https://www.nice.org.uk/

13.2 NICE's function is to evaluate specific medical interventions and make "recommendations" to the NHS and local authorities about the intervention under consideration. NICE describes its own functions as follows:

> "NICE guidance supports healthcare professionals and others to make sure that the care they provide is of the best possible quality and offers the best value for money.
>
> We provide independent, authoritative and evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health, reducing inequalities and variation

Hence NICE to produce guidance which recognises that NHS services should be investing in the delivery of services that are both clinically effective and cost-effective.

13.3 NHS commissioners can thus divide the guidance that NICE produces broadly into 2 types:

a) Technology Appraisal Recommendations ("TARs"); and

b) All other NICE Guidance.

13.4 The TAR process is used to assess the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but also include procedures, devices and diagnostic agents. NICE suggests that its intention is to attempt to ensure that "*all NHS patients have equitable access to the most clinically - and cost-effective treatments that are available*". However that ambition would only be achieved if all medical treatments had been subject to binding NICE Guidance. In fact only a tiny proportion of the medical delivered by the NHS is set out in binding NICE Guidance and so this ambition is still a very long way from being achieved.

13.5 In 2003 the Secretary of State converted NICE TAR process which "recommended" NHS commissioners fund a particular treatment for a particular patient group into a legal obligation by issuing directions to require primary care trusts to fund interventions in accordance with the relevant NICE TAR. The directions required the PCT to allocate funding for recommended treatment for patients within the cohort described in the TAR within 90 days of the publication of the final TAR (unless the Secretary of State exempted the TAR from

the scheme). There were a few exemptions but in the vast majority of cases a decision from NICE by-passed any prioritisation process because it effectively top sliced an NHS commissioner's budget by requiring funds to be made available for a particular treatment for a particular group of patients.

13.6 The Health and Social Care Act 2012 abolished PCTs and replaced them with clinical commissioning groups. One key difference between PCTs and CCGs was that the Secretary of State was not given power by the 2012 Act to issue directions to CCGs. The omission of the power for the Secretary of State to give directions to CCGs was not an error. The then Secretary of State, Andrew Lansley, thought that the role of the Secretary of State was to set the strategic framework for the NHS and then allow local decision making to operate to run the NHS at a local level without being impeded by Whitehall. It followed that CCGs were deliberately not included in the list of bodies to whom the Secretary of State could give directions in section 8 of the NHS Act. One effect of this policy was that from April 2013, the legal requirement on local NHS commissioners to fund medical treatments set out in NICE TAGs could therefore not be enforced through directions.

13.7 The new mechanism to reduce Post Code Prescribing in the NHS is section 237 of the 2012 Act. This allows the Secretary of State to make Regulations which replicate the former system which was enforced by Directions. The relevant Regulations are the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 ("**the NICE Regulations**"). Regulation 7 of the NICE Regulations provides:

> "NICE may make a technology appraisal recommendation—
>
> (a) in relation to a health technology identified in a direction given by the Secretary of State;
>
> (b) that recommends that relevant health bodies provide funding within a specified period to ensure that the health technology be made available for the purposes of treatment of patients"

13.8 Regulation 7(6) of the NICE Regulations then provides that a CCG must comply with a technology appraisal recommendation. CCGs must also provide funding to support patients who could benefit from TARs which were included in Directions to PCTs which were made

prior to 1 April 2013 (see Regulations 34 and 34 of the 2012 Regulations). Every TAR contains clinical indicators which describe the patients who NICE considers should be permitted to benefit from a clinical intervention. The legal right to access NHS funded treatment described in a TAR only applies to patients who satisfy the clinical indicators in the TAR. Thus the legally enforceable rights given by this statutory scheme do not apply to the a patient who suffers from the condition described in a TAR and who may be able to benefit from the described clinical intervention if the patient's clinical indicators fall outside those set out in the TAR.

13.9 Regulation 8 of the NICE Regulations produces a similar system for NICE to produce binding highly specialised technology recommendations which are required to be funded by NHS England.

13.10 The remaining Guidance produced by NICE is hugely useful for CCGs in assessing whether a particular medical intervention or care pathway provides clinically effective and/or cost effective medical treatment. However, other than TAGs, there is no absolute legal requirement on CCGs to follow guidance issued by NICE. Some NICE guidance is routinely followed by virtually all CCGs but other guidance is departed from by many CCGs throughout the country. Hence, for example, NICE Guidance 156 recommends that CCGs should fund up to 3 cycles of In-Vitro Fertilisation for infertile women up to the age of 42. There are relatively few CCGs which fund IVF to that extent.

13.11 Even though CCGs do not have an absolute legal obligation to implement CCG Guidance, they have a legal obligation to look at the guidance, understand what it is recommending and to consider whether to implement it. This was explained by Dyson J in *R (on the application of Fisher) v North Derbyshire Health Authority* [1997] EWHC Admin 675 who said:

> "If the Circular provided no more than guidance, albeit in strong terms, then the only duty placed upon health authorities was to take it into account in the discharge of their functions. They would be susceptible to challenge only on *Wednesbury* principles if they failed to consider the Circular, or they misconstrued or misapplied it whether deliberately or negligently: see *Grandsden & Co Ltd and another -v- Secretary of State and Another* (1985) 54 P&CR 86, 93 – 94"

13.12 A CCG will act thus unlawfully if it does not consider relevant NICE guidance (or potentially other relevant guidance which it would be unlawful to fail to consider) when making a commissioning policy decision or if the CCG misunderstands the guidance or misapplies it. In contrast the CCG will be acting lawfully if it considers relevant guidance as part of a decision making process but makes the decision not to follow the guidance for a good reason. Allocating the medical treatment a lower level of priority than suggested by NICE is a potentially good reason. See for example *R (Condliff) v North Staffordshire Primary Care Trust [2011] EWHC 872 (Admin)* and the same case in the Court of Appeal. In order to ensure that the CCG can show that it has acted lawfully it is preferable if the document trail leading up to the commissioning decision shows on the face of the relevant documents that the relevant NICE Guideline has been properly considered.

14 Individual Funding Requests

14.1 It is inevitable that, from time to time, patients and the clinicians treating them will seek NHS funding for medical treatment where there is no established commissioner policy which provides that a particular treatment will be funded. The vast majority of NHS patients will be provided with wholly adequate medical treatment in accordance existing commissioning policies. However, where there is no commissioning policy which approves the funding for the treatment to be provided as part of NHS funded care or the patient's clinical circumstances fall outside a commissioning policy, an NHS commissioner needs to make an individual decision as to whether to fund the requested treatment outside or to decline to do so. Regulation 34(2)(b) of the 2012 Regulations requires every CCG and NHS England to have:

> "arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention"

14.2 Thus both CCGs and NHS England must have an Individual Funding Request ("IFR") policy which explains how decisions can be made by that body in cases where the general approach of the CCG or NHS England is not to fund a particular drug or other treatment generally or outside a defined patient population. Patients generally seek NHS funding for medical treatment outside existing commissioning policies in the following circumstances:

a) The NHS commissioner has a policy which describes the treatment available for a particular medical condition, including the treatment in question, but the patient's clinical indicators fall outside the circumstances where the NHS is prepared to fund the treatment which the patient and his or her treating clinician is requesting; or

b) The NHS commissioner has a policy which describes the treatment available for a particular medical condition but the policy does not provide to NHS funding to be provided for the particular drug or other medical treatment which the patient and his or her treating clinician is requesting; or

c) The patient presents with a medical condition for which the NHS commissioner has no particular policy or which does not fall within a category of conditions for which the NHS commissioner has a policy and thus there is no policy to guide the decision maker as to whether the patient should or should not be funded for have treatment in question.

14.3 IFR policies vary from one NHS commissioner to another but they generally provide that, for the first 2 categories set out above, NHS funding should only be provided for drugs or other medical treatments which lie outside established policies where:

a) That patient can show that the application is supported by an NHS referring clinician. If the patient does not have a clinician who is prepared to provide the treatment for the patient then the CCG should not entertain the application because the NHS does not generally fund medical treatment which is not recommended by clinicians;

b) The patient, supported by his or her clinician, can show that the requested treatment is likely to be clinically effective;

c) The patient, supported by his or her clinician, can show that the requested treatment is likely to be cost effective;

d) The circumstances are such that there are not likely to be other patients in a clinically similar situation. If there are other patients then the CCG should respond to the request by devising a policy and/or considering the request as an "in year service

development" but should not process the request as an IFR case (unless the case has a degree of urgency); and

e) If all of the above tests are met, the patient is able to demonstrate that he or she has exceptional clinical circumstances.

14.4 The underlying assumption in the above cases is that the NHS commissioner has made a policy decision about what it is reasonable for the NHS to fund for a particular category of patients and thus is generally entitled to rely on its policy to make a negative decision. Hence, for example, patients who have a particular form of cancer will be entitled to treatment in accordance with protocols agreed between an oncologists and the CCG, and incorporated into an acute service contract. If a new, expensive but potentially life-extending cancer drug emerges, there will be an understandable desire by oncologists to have the benefit of this drug for their patients and, amongst patients, an understandable desire to be treated with the drug. However the issues for the NHS commissioner are different where the commissioner has no policy because there is no-prior decision about what it is reasonable for the NHS to provide to this particular category of patients. Thus a requirement under an IFR policy for a patient to have to demonstrate exceptional clinical circumstances in the third category of cases would unlawfully set the bar too high. The question is such cases ought to be whether the patient has a "reasonable requirement" for the requested treatment, and that would only engage the questions as to whether there was evidence that the treatment was both clinically effective and was cost effective (and possibly whether it was affordable in the case of a particularly expensive treatment).

14.5 The NHS Confederation has produced an excellent guide to the IFR process for the first 2 categories set out above. That Guide[24] was specifically approved by the Court of Appeal in the *R (Condliff) v North Staffordshire Primary Care Trust [2011] EWCA Civ 910*. Commenting on the requirement to show exceptional clinical circumstances, the Court approved a statement in the NHS Confederation Guide saying:

[24] See http://www.nhsconfed.org/~/media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf

"Exceptionality is essentially an equity issue that is best expressed by the question: “On what grounds can the PCT justify funding this patient when others from the same patient group are not being funded?”"

14.6 The reason that NHS bodies have traditionally operated an IFR process is that, within a patient group with the same disease, there may be patients with individual clinical situations which are so unusual that a decision to deny funding to a patient is inequitable. The patient may, for example, have a genetic condition which means that the patient cannot tolerate the treatment which is usually provided to patients with that medical condition. If another treatment is available, even if it is more expensive, then it would be justifiable to refuse access to the treatment for the majority but it may be equitable to permit the exceptional patient to have that more expensive treatment.

14.7 It is almost impossible to define what is meant by “exceptional clinical circumstances”. Some policies ask the decision maker to consider whether the patients is significantly clinically different to the group of patients in question at the same stage of the progression of the condition. The Courts have said that it is permissible (and perhaps preferable) to leave the term undefined. In *R (AC) v Berkshire West Primary Care Trust & Anor* [2011] EWCA Civ 247[25] Lord Justice Hooper said:

“The use of the phrase "exceptional circumstances" tells the decision maker that the number of persons who will succeed under the proviso is expected to be a small minority. It does not otherwise provide a helpful legal test for the decision maker (see *Huang v. Secretary of State for the Home Department* [2007] 2 AC 167 paragraph 20)”

14.8 However “exceptional” does not mean “unique” and the IFR policy will be operated in an unlawful way if, in practice, no one can ever secure funding for a treatment. In *R (S (a child)) v NHS England* [2016] EWHC 1395 (Admin) Collins J said at §12:

“The [*NHS England*] policy[26] considers what is meant by exceptionality. I do not propose to burden this judgment with the four pages which deal with this. I shall summarise. It

[25] See http://www.bailii.org/ew/cases/EWCA/Civ/2011/247.html
[26] NHS England is working under an “interim” policy which is at https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/cp-03.pdf

starts by stating that 'very few patients have clinical circumstances which are exceptional so as to justify funding for that patient which is not available for other patients'. Thus the approach to exceptionality must be to require considerably more than a failure of usual treatment. But it must be borne in mind that exceptional is not the same as unique and that there should not be an approach that denies that any but an extreme case is regarded as exceptional. In its ordinary meaning, exceptional can mean no more than a case which does not meet what is normal"

14.9 The IFR process is not intended to be an appeal on the merits of an individual case. Funding for a medical treatment that is requested by both a clinician and a patient can almost always be justified on an individual basis. The IFR process exists to preserve a measure of flexibility so as to balance the duties that the NHS has to each NHS patients with the need to ensure the equitable distribution of NHS resources in the competition between patients for scares resources. Whilst the individual clinical circumstances of each patient are, of course, unique, only very few patients are likely to be able to show that they genuinely have exceptional clinical circumstances. It follows that challenges to decisions of IFR Panels are almost always based on an attack on the decision making process adopted by the IFR Panel rather than a challenge to the reasonableness of the decision.

14.10 The assessment as to whether a patient demonstrates exceptional clinical circumstances is a decision for the NHS commissioner, not the referring clinician. The NHS commissioner is required to consider any opinion expressed by the referring clinician but is not obliged to accept any opinion on clinical exceptionality. Despite the way in which Mr Justice Collins approached the issues in *R (S (a child)) v NHS England,* the real issue is often whether a decision by an NHS commissioner that a patient is not exceptional can be described as either irrational or a decision that has been reached without having paid proper regard to the evidence submitted by the treating team.

14.11 The largest area of risk for CCGs in the IFR process is probably showing that they have discharged all of the general duties imposed on them by the NHS Act (as described at paragraph 5 above) when making an IFR decision. Most IFR policies make only the most general references to, for example, the need to promote patient choice or the need to tackle health inequalities, when making IFR decisions.

15 In year service developments

15.1 During the lifetime of the **annual commissioning plan** there can be new unanticipated developments in the form of new drugs or medical treatments which emerge as options for CCG funding during the year. If there is insufficient evidence that a new treatment is clinically effective then it is highly likely that the new treatment will not be supported with CCG funds (unless it is funded as an experimental treatment). However, the fact that there is evidence that a new treatment is likely to be clinically effective should not, of itself, be sufficient to justify funding because the annual CCG budget for commissioning healthcare will be fully committed. In contrast there will be the occasional new treatment which is so stunningly good (i.e. It is highly clinically effective and cost effective) that a responsible commissioner ought to fund it straightaway rather than waiting for the treatment to compete for funding in the next annual plan, and thus not being funded until the following April.

15.2 Each CCG therefore needs to have a policy which sets out how it will respond to requests for **funding for in-year service developments**. Policies usually provide that any such applications need to go through an in-year prioritisation process to determine:

a) the evidence base to support a case that the treatment is likely to be clinically effective;

b) the evidence base to support a case that the treatment is likely to be cost effective;

c) what level of relative priority should be applied to the new proposed treatment in comparison to the other treatments that are already funded; and

d) what services should cease to be funded (i.e. decommissioned) in order to redirect funding to any new investment area that has been viewed as a high priority.

15.3 The assessment of new treatments therefore is a process of re-evaluating the overall priorities for a new service. Even if a new service is considered an important priority, the service development still has to compete with other potential investments from other services in the annual commissioning process. Occasionally a treatment may be considered so important that it should be funded immediately (**an in-year service**

development). Usually can only be done if reserves are available or if funding can be released from elsewhere to fund the investment.

15.4 Difficult issues can arise where clinicians seek to introduce funding for a new treatment by a series of IFR applications and thus, in effect, create a precedent for funding for a new intervention. The clinician's perspective is that the CCG does not have a policy to fund or not to fund the drug and accordingly the IFR process is only mechanism to secure funding for an individual patient. However the perspective of the NHS commissioner is, of course, wholly different. The commissioner will say that the IFR process is not intended to permit a creeping extension of the range of services the NHS is prepared to fund outside of the annual prioritisation process. The In-Year Service Development Policy is there to square this circle by allowing genuinely innovative treatments to be considered outside the annual prioritisation process but also ensuring that the IFR process is not used to secure funding for medical treatments that failed to achieve funding through the annual prioritisation process.

16 Patient and public involvement in commissioning decision making

16.1 A CCG is required to consult the public about its annual commissioning plan. That is a formal duty of consultation which is separate from the general duties on all NHS bodies to involve the patients and the public in their decision-making. There will be a separate chapter on the legal issues around public engagement in decision-making. However, both CCGs and NHS England are subject to wide-ranging duties of public involvement in making commissioning decisions.

16.2 A significant commissioning decision which was taken without any elements of public involvement will almost certainly leave the NHS commissioner to a legal challenge.