Commissioning Policies and Individual Funding[1]

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Introduction

1. This paper addresses two significant aspects of commissioning decisions: the policies which decision-makers must have in place, and also issues relating to individual funding. It however does not address the requirement for various NHS bodies to make 'arrangements' in relation public engagement (which is a type of policy). After considering individual funding, it turns to the related topic of direct payments and personal health budgets.

Commissioning Policies

Policies and Public Law: a Brief Overview

2. Policies are an aid to decision-making: they can speed up the decision-making process, provide a greater predictability of outcomes to applicants and other interested parties, and increase the consistency of decision-making. They can however be a trap: if they are applied too rigidly, then the court may find that the decision-maker has unlawfully fettered their discretion: ***British Oxygen Co Ltd v Minister of Technology*** [1971] AC 610.

3. There is no general requirement under the common law to create a policy, although failure to do so may in certain circumstances be irrational: ***R v North West Lancashire Health Authority, ex p A*** [2000] 1 WLR 977, 991. However, statute may require a decision-maker to create, and publish, a policy on a particular topic

4. The correct interpretation of a policy, especially where it forms part of a statutory scheme, is likely to be a matter for the court. It is not sufficient that a decision-maker reaches a reasonable interpretation of its own policy: it must reach the legally correct interpretation of

[1] David Lock QC's website GP Law (www.gplaw.co.uk) is an excellent resource in relation to commissioning, at Chapter 5. Alistair Mills assisted with a draft of this paper.

that policy (see, in the planning context, ***Tesco Stores Ltd v Dundee City Council*** [2012] PTSR 983).

5. An applicable policy is a relevant consideration. A failure by a decision-maker to consider its policy is likely to render the decision unlawful. Whilst a decision-maker cannot be fettered by a policy and therefore must keep its ears open to any application which may be made, if a decision-maker wishes to depart from an applicable policy, it will generally have to give good reasons for doing so.

6. A public body may not have a secret policy which is different in terms to its published policy: ***R (Lumba and Mighty) v Secretary of State for the Home Department*** [2012] 1 AC 245.

Annual Commissioning Plans

7. The National Health Service Act 2006 imposes a requirement upon Clinical Commissioning Groups to have an annual commissioning plan. Section 14Z11 of the National Health Service Act 2006 provides:

> *(a) 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.*
> *(b) 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.*
> *(c) The plan must, in particular, explain how the group proposes to discharge its duties under—*
> *(a) sections 14R,[2] 14T[3] and 14Z2,[4] and*
> *(b) sections 223H to 223J.[5]*
> *(d) The clinical commissioning group must publish the plan.*
> *(e) The clinical commissioning group must give a copy of the plan to the Board before the date specified by the Board in a direction.*
> *(f) The clinical commissioning group must give a copy of the plan to each relevant Health and Wellbeing Board.*

[2] The duty as to improvement in quality of services.

[3] Duties as to reducing inequalities.

[4] Public involvement and consultation

[5] Financial duties of clinical commissioning groups: expenditure, use of resources, and additional controls on resource use.

(g) 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.

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

(i) 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.

8. The upshot of this section is that a CCG must create, and publish, a commissioning plan for each financial year. By doing so, the CCG will have to focus its mind upon the approach it will take to decision-making. The policy may also require it to be upfront about funding restrictions under which it is operating, and that difficult decisions will have to be taken. The creation of a commissioning plan will mean that the scope for *ad hoc* decision-making is reduced.

9. The CCG is, of course, not bound by its commissioning plan. However, it will have to explain any failure to comply with it.

10. The Commissioning Plan will set the framework for funding decisions. Section 14Q of the National Health Service Act 2006 imposes a duty upon CCGs to exercise their duties effectively, efficiently and economically. CCGs are also under a duty to ensure that their expenditure does not exceed their income: s.223H of the 2006 Act. Therefore, the decision as to what measures to fund from year to year is likely to be a matter of a decision concerning the cost-effectiveness of that treatment as compared to other measures.

11. The various measures which a CCG may fund are not easily commensurable. Some measures seek to prevent disease, and others seek to cure it. Some treatments do not seek to cure diseases, but merely to treat the effects of their symptoms or to slow a decline in a patient's condition.

12. In order to assist with the relative merits of various proposals, NICE has produced a scheme entitled the Quality Adjusted Life Year. Quality-Adjusted Life Years (QALYS) are defined in NICE's Glossary:[6]

[6] https://www.nice.org.uk/glossary?letter=q

A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.
QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality of life score (on a zero to 1 scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.

13. The QALYS method is to determine how may QALYs are provided by a particular method, and then determine how much the method costs per QALY.

14. Simply because a service has been funded previously does not mean that, according to a QALYS assessment, it continues to deserve funding in subsequent years. The decisions as to what services to commission must be made, and expressed in the Annual Commissioning Plan.

15. The Annual Commissioning Plan must also be informed by the joint strategic health needs assessment,[7] produced by the local authority (a County Council in a two-tier system) pursuant to section 116 of the Local Government and Public Involvement in Health Act 2007:

    (a) An assessment of relevant needs must be prepared in relation to the area of each responsible local authority.
    (b) A further assessment of relevant needs in relation to the area of a responsible local authority–
        (a) must be prepared if the Secretary of State so directs; and
        (b) may be prepared at any time.
    (c) A direction under subsection (2)(a) may be revoked.
    (d) 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.
    (e) The responsible local authority must publish each assessment of relevant needs prepared under this section in relation to its area.
    (f) 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.
    (g) 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

[7] Local Government and Public Involvement in Health Act 2007, s.116B(1).

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.

(h) In preparing an assessment under this section, the responsible local authority and each of its partner clinical commissioning groups must–

(a) co-operate with one another;

(b) have regard to any guidance issued by the Secretary of State;

(ba) involve the Local Healthwatch organisation for the area of the responsible local authority;

(bb) involve the people who live or work in that area; and

(c) if the responsible local authority is a county council, each relevant district council.

(8A) In preparing an assessment under this section, the responsible local authority or a partner clinical commissioning group may consult any person it thinks appropriate.

(i) In this section-

"partner clinical commissioning group", in relation to a responsible local authority, means any clinical commissioning group whose area coincides with or falls wholly or partly within the area of the authority;

"relevant district council" means–

(a) in relation to a responsible local authority, any district council which is a partner authority of it; and

(b) in relation to [a partner clinical commissioning group of a responsible local authority, any district council which is a partner authority of the responsible local authority and whose district falls wholly or partly within the area of the clinical commissioning group.

CCG Commissioning Policies

16. Regulation 35(1) of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 provides:

A relevant body must—

(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.

17. Commissioning Policies will set out the precise details of services to be commissioned pursuant to the Annual Commissioning Plan. The policies will set the agreed care pathways

and define clinical criteria which set out which patients are entitled to NHs funded healthcare for each medical condition.

18. According to general principles of public law, if a patient does not fall within the categories to be funded according to the policy, a CCG cannot for this reason alone refuse a request for treatment. The CCG must be alive to any arguments the patient may make as to why (s)he should still be provided with care. However, the policy will be the starting-point. Conversely, if the patient falls within a class which policy indicates will benefit from a particular service, then this does not guarantee that the service will be provided, but it does considerably increase the prospect that (s)he will benefit from the service.

19. Where a CCG refuses to provide a particular treatment, in line with policy, then it must give reasons for that decision. Regulation 35(2) of the Responsibilities and Standing Rules 2012 provides:

> *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.*

20. The content of the duty to give reasons is relatively modest: although they must be intelligible and must be adequate, reasons can be briefly stated (***South Bucks DC v Porter (No 2)***) [2004] 1 WLR 1953.

21. The consequence of a failure to give proper reasons may be to render the underlying decision unlawful, or it may be that the court requires only that the decision-maker give proper reasons.

Exception Policies

22. Policies can be more or less detailed. A more detailed policy will tend to be very prescriptive about which individual benefit from a particular service. A less detailed policy will leave more matters to be determined by a decision-maker in the exercise of their discretion.

23. CCGs frequently develop what might be thought of as an oxymoron: exception policies. Such individuals may be entitled to services, even though other patients presenting with the same symptoms may not be provided with this service. Put another way, exception policies discriminate between patients on a basis other than the presenting medical condition

24. Needless to say, there is a risk of challenges by other disappointed patients, aggrieved on the basis that they have not been provided with a service. Such policies should therefore be drafted very carefully. There are however two examples of exception policies having been developed:
    (a) Where an NHS patient has been provided with a particular treatment pursuant to a commissioning decision relating to one area, and then that individual moves to the jurisdiction of a different commissioner, which does not normally provide that treatment.
    (b) Where an individual has taken part in an NHS-sponsored clinical trial of a new drug or treatment, and has shown a capacity to benefit from the treatment. This is however controversial,[8] and CCGs should continue to provide a trialled treatment only when agreement to fund this was given before the trial began.

Individual Funding Decisions

25. It may be inequitable not to provide a form of treatment to a particular individual, when it would not be available to the population at large. For instance, a condition may be treatable using two drugs, A and B. The cost of drug B is ten times that of A. Therefore, the policy is to fund drug A only, and not to fund treatment by drug B. However, if a particular patient cannot tolerate drug A (for instance, due to allergy or genetic condition), then this may justify the commissioning of drug B in her case. In these circumstances, there should be a decision-making mechanism available to allow the commissioner to decide whether to fund.

26. Most funding requests will be determined according to a CCG's policy. However, there is a particular class of request which, as a matter of law, must be determined according to the

[8] If the result of a trial is that a particular service, drug or treatment should not be rolled out, then continuing that service, drug or treatment with those who have undergone the trial should be unnecessary. There is however an argument based on the Medicines for Human Use (Clinical Trials) Regulations 2004 that the protocol for a trial must describe appropriate arrangements for post-trial provisions.

CCG's set process. Regulation 34(2)(b) of the Responsibilities and Standing Rules Regulation 2012 requires a CCG 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."*

27. A NICE recommendation is relevant, since if a relevant aspect of NICE's Technology Appraisal Guidance requires a particular form of treatment, then Regulation 7(6) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 provides that a CCG must comply with a TAG recommendation.

28. Issues of NICE TAGs aside, there are three main situations in which an individual funding request may arise:
    1) The CCG has made decision not to routinely fund the intervention in question.
    2) The CCGs does fund the intervention in question, but there are specified clinical criteria as a gateway to the CCG's decision to fund it, and the individual cannot meet those criteria.
    3) The CCG has no policy governing whether an individual should benefit from the intervention or not.

29. Individual Funding Requests arose in ***R (Condliff) v North Staffordshire PCT*** [2011] EWHC (Admin) and [2011] EWCA Civ 910. The High Court rejected a challenge based on Article 8 ECHR to an Individual Funding Request policy which provided that social factors will not be taken into account. This decision was upheld on appeal by the Court of Appeal.

30. Individual Funding Request which deal with situations 1) and 2) above will generally have an exceptionality test: they will require an individual to demonstrate why they should be entitled to a service which policy indicates should be denied to an individual in those circumstances. The Court of Appeal held at para. 19 of ***Condliff***:

> *"No complaint is made about the policy that IFRs were intended to be only for exceptional cases. The argument is about the criteria set for determining exceptionality. This has been a difficult subject for PCTs generally because it raises problematic ethical and practical questions in deciding, as between patients competing for limited resources, which circumstances should be taken into account as potentially exceptional."*

31. By contrast, in situation 3), there should be no exceptionality test. This is because the CCG would not be making an exception from its policy: there simply is no policy covering the situation. Rather, the CCG should simply apply s.3 of the 2006 Act in terms of meeting the "reasonable requirements of the persons for whom it has responsibility".

32. In ***Condliff***, the Court of Appeal referred favourably to a paper produced by the NHS Federation, entitled *Priority Setting: Managing Individual Funding Requests*.[9] At paras 20-22 and 24 of the Judgment, the Court of Appeal quoted *Priority Setting*:

"20. The introduction to the paper states:

> *"Commissioning by its very nature focuses on the larger scale. As a result, it cannot be undertaken in a way that meets all needs of all patients in any one clinical group or address the specific needs of patients with less common conditions. Therefore, PCTs will always need an individual funding request (IFR) process to consider making additional NHS funds available for the atypical or uncommon patient. Decision-making is compounded by the fact that legitimate demands for health care will always exceed PCT budgets. There have always been individuals whose need for health care has not been met by the NHS and this will inevitably continue in the future. Indeed, unmet need is an unfortunate feature of all health care systems. So, how should a PCT decide which individual patients should have their requests for special consideration funded? These are some of the most difficult decisions a PCT will have to face."*

21. Under the heading "What approach should PCTs take to individual funding requests?" the author suggests:

> *"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?'"*

22. The author offers the following example of a policy on exceptionality, which she suggests represents the approach gaining most popularity among PCTs:

> *"The PCT does not offer treatment to a named individual that would not be offered to all patients with equal clinical need. In making a case for special consideration, it needs to be demonstrated that the patient is significantly different to the general population of patients with the condition in question; and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition."*

24. Under the heading "What does the law have to say in relation to what is considered material to IFR decisions? the author states:

> *"The law relating to priority setting is not at all clear about the factors that PCTs should use and what they can rule out. There are a number of cases which have gone before the courts that suggest social factors may be taken into account, even though there may be good rational and ethical arguments against their consideration. Greater certainty can only be achieved through further litigation that addresses these issues. The courts can only consider the arguments that are put before them. Poorly argued cases may set uncomfortable precedents."*

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9 http://nhsconfed.org/~/media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf

33. The Court of Appeal ultimately concluded that it was not contrary to Article 8 for the commissioner to have an Individual Funding Request policy which permitted consideration exclusively of clinical factors, and did not permit social factors to be taken into account. Indeed, Article 8 was not even engaged by the decision (para. 52).

34. Despite the terms of *Priority Setting*, it is acceptable to leave the concept of "exceptional clinical circumstances" undefined. In ***R (AC) v Berkshire West Primary Care Trust*** [2011] EWCA Civ 247, Hooper LJ held:

> *"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)"*

35. *Priority Setting* has a helpful section on 'One-off decisions':

> *"...in some situations the principle of exceptionality cannot readily be applied. For some IFRs there is simply no reference point: the patient does not come from a sizeable group of patients (often they may be unique) nor is there much evidence about the treatment in question and there may never be. In these instances, the IFR panel has to assess only whether the patient is likely to benefit from the treatment and the priority to be given to the patient. Namely, it is treated as a 'service development for 1'. Under these circumstances, in addition to questions about priority and value for money, the following need to be asked:*
> - *What is the nature of the condition?*
> - *What is the nature of the treatment?*
> - *What is the evidence that this treatment might work in this situation? Is there biological plausibility that this treatment might work?*
>
> *The majority of these can be dealt with through the IFR process alone. However, occasionally the financial commitment is so large the decision needs to be referred to the PCT board. A decision to fund a treatment that costs £300,000 per patient per annum is probably not one the IFR panel alone can make."*

36. By way of guidelines for IFR policies, these generally provide that NHS funding should be available outside of established policies only 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 is able to demonstrate exceptional clinical circumstances;

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

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

(e) 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.

37. Given the fact that the essence of the IFR regime is flexibility, and there are difficult clinical judgments to be made, a challenge to the rationality of a funding decision is unlikely to succeed. Successful claimants are likely to need to demonstrate some flaw in the decision-making process.

In Year Service Developments

38. The starting-point for a commissioning decision is the Annual Commissioning Plan. However, medical research and technology is constantly developing, and so there may be critical developments during the lifetime of the plan.

39. Whether a particular service or treatment should be funded will depend in large part upon its clinical effectiveness and cost effective. If it is not demonstrated to be clinically effective, then a treatment or service is unlikely to be an acceptable use of NHS funds (unless perhaps as part of a trial).

40. Even if a treatment is demonstrated to be clinically effective, then it will often be difficult to justify expenditure upon it during the course of an Annual Commissioning Plan, as the annual budget of the CCG will already have been fully committed. Getting a treatment funded on this basis therefore faces an uphill battle: usually it will require reserves to be available, or funds to be released from elsewhere in the budget, which is likely to be controversial. However, if a treatment is exceptionally clinically and cost effective, then the commissioner should consider funding it even before the new Annual Commissioning Plan.

41. A CCG should therefore set a policy to deal with funding of in-year service developments. Such policies usually make provision for and 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.

42. A decision as to whether to fund an in-year service development is not non-justiciable, but as a high-level funding decision, it will take very cogent evidence to persuade a court that a decision is unreasonable.

Personal Health Budgets

43. Related to the question of individual funding requests is the issue of personal health budgets. These are dealt with in the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.

44. A personal health budget is defined in Regulation 32A as:

> *"an amount of money—*
> *(a) which is identified by a relevant body [being a CCG or NHS England] as appropriate for the purpose of securing the provision to a person of all or part of a relevant health service; and*
> *(b) the application of which is planned and agreed between the relevant body and the eligible person or their representative"*

45. A "relevant health service" is Continuing Care for Children, or NHS Continuing Healthcare. Continuing Care for Children is defined as:

> *"that part of a package of care which is arranged and funded by a relevant body for a person aged 17 or under to meet needs which have arisen as a result of disability, accident or illness"*

46. NHS Continuing Healthcare is defined as:

> *"A package of care arranged and funded solely by the health service in England for a person aged 18 or over to meet physical or mental health needs which have arisen as a result of disability, accident or illness"*

Essentially, these groups of people are those with long term, difficult health needs.

47. NHS England has produced helpful guidance on personal health budgets.[10] This stresses that:
    a) The institution of a personal health budget does not mean that a patient will have more spent on him – this is not provision of 'new money';
    b) Rather, a personal health budget channels money which would have been spent, allowing it to be spent more flexibly;
    c) It gives patients increased choice, control and flexibility.

48. Formerly, eligible patients were given the right to ask for a personal health budget. Now, such patients are entitled to have a personal health budget. Regulation 32B(4) provides:

> *"Where a request is made by or on behalf of an eligible person for a personal health budget, a relevant body must grant that request, save to the extent that it is not appropriate to secure provision of all or any part of the relevant health service by that means in the circumstances of the eligible person's case."*

49. The upshot of this is that:
    a) If a request is made, it must be granted;
    b) Save to the extent that such a request is not appropriate;
    c) It may be appropriate to have a personal health budget for part of a patient's care;
    d) NHS England's Guidance states (para. 5.1) that CCGs should strive to include as much of the budget as possible into a person's personal health budget.

50. Therefore, if the commissioner considers it necessary for a patient to have Continuing Care for Children or NHS Continuing Care, then that patient has the 'right to have' a personal health budget. However, even if a patient falls outside this definition (and therefore does not have the right to a personal health budget), a commissioner still retains a discretion as to whether to grant an individual a personal health budget.

51. The ability for a commissioner to provide a personal health budget where an individual falls outside the scope of NHS Continuing Care/Continuing Care for Children would be beneficial in

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10 http://www.personalhealthbudgets.england.nhs.uk/_library/Resources/Personalhealthbudgets/2014/Personal_health_budgets_right_to_have_guidance.pdf

circumstances where a patient has a fluctuating condition, such that she sometimes is eligible for NHS Continuing Care, and sometimes not. This would have the result that, whilst ineligible for NHS Continuing Care, the individual would not have a right to a personal health budget. But it would be practically and administratively unfortunate were a patient in these circumstances to lose the benefit of a personal health budget whenever her condition fluctuated for the better. NHS England's Guidance makes it clear that a discretionary personal health budget may be suitable in these circumstances.

52. Commissioners are under further duties: they must publicise and promote the availability of personal health budgets to eligible persons and their representatives. Likewise, they must provide information, advice and support to those who are deciding whether to request a personal health budget.

53. The current legislative framework constitutes a sea-change from even relatively recent law. In ***R (Harrison) v Secretary of State for Health*** [2009] EWHC 574 (Admin), Silber J held that Primary Care Trusts had no power to make direct payments to patients. In ***Harrison***, it was held that 'services' did not include the provision of money. Commissioners therefore did not have the *vires* to make direct payments to patients.

54. A 'right to have' a personal health budget is not absolute (Regulation 32B(4)). NHS England's Guidance (7.1) indicates that in 'exceptional circumstances' it may be 'impractical or inappropriate' to employ a personal health budget, even when a patient falls within the scope of the 'right to have' a personal health budget. Examples of where personal health budgets may be inappropriate may arise due to the specialist clinical care required, or where the use of a personal health budget would not constitute value for money (to the NHS). However, NHS England's Guidance suggests that the pilot studies were encouraging, to the effect that personal health budgets will generally be able to be provided.

55. Where the commissioner decides that although a patient who has requested a personal health budget and falls within the 'right to have' a personal health budget, such a personal health budget should not be given, then the commissioner must give reasons for the refusal (Regulation32B(7)). The patient or his representative may require a review of the decision, and can provide evidence or information (Regulation 32B(8)). On a review, the commissioner should provide its decision in writing, with reasons (Regulation 32B(9)). However, there is no

obligation upon a commissioner to review its decision more than once in a six-month period (Regulation 32B(10)).

56. NHS England's Guidance provides the following 'good practice timeframe for a request of a reconsideration:

    - *Acknowledge receipt of the request in writing within 10 working days. This acknowledgement should include details of how the review will be conducted and timeframes for when it should be completed; and*
    - *Any final decision should be sent in writing within 28 working days of acknowledgement of the original request. There may be instances where a complex situation requires a longer timeframe for reconsideration and response. In these instances individuals should be kept informed of progress.*
    - *Once this review is complete CCGs should inform the individual and/or his or her representative or its decision in writing, setting out the reasons for its decision. If a person and/or his or her representative is not satisfied they can pursue the matter via the local NHS complaints processes.*

57. However, the Guidance also stresses that, even if a request for a personal health budget is turned down, then the CCG should still attempt to "work in partnership" with the patient (or the patient's representative) to ensure that their views are considered and taken into account.

58. There are different mechanisms by which a personal health budget may take effect:
    - Direct payments to the patient;
    - 'Notional budgets'
    - Payments to an appointed person.

59. Most care is needed with direct payments, since they have the greatest potential for abuse. They are subject to individual regulations: the National Health Service (Direct Payments) Regulations 2013.

60. Regulation 3 of the Direct Payments Regulations provides that a direct payment can be made to anyone for whose benefit anything may or must be provided or arranged by a health body under the 2006 Act, or (in the case of a CCG or NHS England), under any other enactment, where the person consents to the making of a direct payment. The general power to make direct payments is therefore broad.

61. In making such a decision, the commissioner must have regard to (Regulation 3(2)):

(a) Whether making a payment is appropriate for a person with that person's condition;

(b) The impact of that condition on that person's life; and

(c) Whether a direct payment represents value for money.

62. In the case of children and adults lacking capacity, representatives can consent to the making of direct payments. However, those representatives must (Regulations 4 and 5):

(a) Agree to act on the patient's behalf in relation to the direct payment;

(b) Act in the best interests of the patient when securing the provision of services in respect of which the direct payment is made;

(c) Be responsible as a principal on the contracts (therefore the representative is fully party to the contract; not simply acting as an agent for the patient);

(d) Use the direct payment in accordance with the care plan; and

(e) Comply with the Direct Payment Regulations.

63. Regulation 7 of the Direct Payment Regulations provides that, in deciding whether to make a direct payment, the commissioner may consult various persons, including:

(a) Anyone identified by the patient;

(b) The patient's carer(s);

(c) Any independent mental capacity advocate or independent mental health advocate;

(d) Any health care professional or other professional person who provides health services to the patient,

(e) Any local authority social care team responsible for the patient.

64. Where the payment is to be made to a patient directly, then the patient must consent to the making of the direct payment. Where the patient lacks capacity, Regulation 7(3) provides that the patient may nevertheless be a consultee. Regulation 7(5) provides that the commissioner may in particular take into account whether a patient who lacks capacity has, during a period of capacity, expressed a wish to benefit from direct payments; the beliefs and values which would be likely to influent the patient's decision as to whether or not to consent to receive a direct payment if the patient had capacity; and any other factors which the patient would be likely to consider.

65. If payment is proposed to a nominee, then Regulation 7(7) provides that the commissioner must be satisfied that the nominee is capable of managing the payment, and the nominee

must be required to apply for an enhanced criminal record certificate (unless living in the same household as the patient).

66. If a commissioner refuses to make a direct payment, then it must:
    (a) Inform the patient and any representative;
    (b) Give reasons for the decision;
    (c) Give a right to request reconsideration (including the provision of evidence and information);
    (d) Give the decision on reconsideration in writing.

67. However, a commissioner may not be required to give more than one reconsideration in a 6-month period.

68. The commissioner must make arrangements for a patient, representative or nominee to obtain information, advice or other support in connection with the making of direct payments (Regulation 9(1)). This may go so far as it include provision for payroll, training, sickness cover or other employment related services to assist a patient, representative or nominee where an employee provides services secured by direct payments for the patient (Regulation 9(2)(h)). Alternatively, a charity may provide assistance and support to those receiving Direct Payments.[11]

69. Whilst there is no prohibition in the legislation, NHS England's Guidance suggests caution in relation to direct payments being made for residential care. It states at Section 8:

> *"Where a request for a direct payment for healthcare is made for a person living in a residential setting the CCG must be certain that providing care in this way adds value to the person's overall care. Generally, direct payments should not be used to pay for care and support services being commissioned by the NHS that a person will continue to access in the same way whether they have a personal health budget or not. In such instances, where no additional choice or flexibility has been achieved by giving someone a personal health budget, then allocating a direct payment only adds an additional financial step and layer of bureaucracy into the commissioning of the care. CCGs need to be clear that the use of a direct payment in such settings is cost effective and is a sensible way to provide care to meet or improve the individual's agreed outcomes."*

[11] The National Development Teach for Inclusion's paper 'Personal Health Budgets: Including people with learning disabilities' refers to a charity called Enham, which took responsibility for legal and tax affairs, payroll and insurance.

70. Prior to the making of a direct payment, the commissioner must prepare a care plan (Regulation 8(1)). This is at the core of the concept of direct payments. Essentially, the commissioner must decide what services are to be commissioned: it is then over to the patient, representative or nominee to work out how this is to be accomplished. The commissioner must be satisfied that the health needs in the care plan can be met by the service in the care plan, and that the direct payments will be sufficient for the full cost of each of the services in the care plan.

71. The commissioner must also inform the patient, representative or nominee of the risks which may arise from the making of direct payments, in particular including:
    (a) Risks to the patient's health;
    (b) The medical or surgical risk from the procurement of particular services;
    (c) The risks arising from employment relationships;
    (d) The risks of using a provider which lacks or has insufficient complaints procedures;
    (e) The risks of using a provider which has insufficient insurance cover;
    (f) The risks that monies may go missing, be misused or subject to fraud.

72. There must be an individual at the health body, who is the point of contact, known as the care co-ordinator (Regulation 8(3)). This can be a key relationship in ensuring the success of direct payments under a personal health budget.

73. The content of care plans is set out in Regulation 8(4):

    A health body must in the care plan specify—
    (a) the health needs to be met by services secured by means of direct payments, and the health outcomes intended to be achieved through the provision of the services;
    (b) the services to be secured by means of direct payments that the health body considers necessary to meet the health needs of the patient;
    (c) the amount to be paid by way direct payments, and the intervals at which monies are to be paid;
    (d) the name of the person who is the care co-ordinator in respect of the patient;
    (e) who is to be responsible for monitoring each health condition of the patient in respect of which direct payments may be made;
    (f) the anticipated date of the first review mentioned in regulation 14(2)(a) (monitoring and review of direct payments) and how it is intended to be carried out; and
    (g) the period of notice that is to apply if, following a review under regulation 14(2)(a), a health body decides to reduce the amount of the direct payments or to stop making the direct payments.

74. It is particularly important to ensure that payments which are made do not get out of step with what is legally due: there is a power for the commissioner to seek repayment, which could cause hardship to patients who do not take care.

75. Certain payments are excluded from direct payments (Regulation 8(5)):
    - Primary medical services (GP services are not covered by personal health budgets);
    - Prescriptions, etc.;
    - Planned surgical procedures;
    - Vaccination, immunisation or screening;
    - National Child Measurement Programme;
    - NHS Health Check;
    - Alcohol or tobacco;
    - Gambling services or facilities;
    - Repayment of a debt other than in respect of a service specified in a care plan.

76. These reflect the fact that personal health budgets are not designed to provide a patient with 'new money'. They also seek to avoid abuse.

77. There are limits on using direct payments to employ family members. It is possible to use direct payments for services from an individual living in the same household, a family member, or friend, only if the health body is satisfied that this is necessary to meet satisfactorily a patient's need for the service, or promote the welfare of a patient who is a child.

78. Regulation 10 sets out rules relating to the bank accounts into which the direct payments are paid. For instance, the bank account must be accessible only by named persons.

79. There are conditions on use upon direct payments. The flexibility inherent in direct payments must be subjected to a corresponding level of control. These conditions provide that:
    - The payment must be used only to procure the services in the care plan;
    - They payment must be used to secure the provision of the whole of the services in the care plan;
    - The patient/representative/nominee may need to make enquiries of a proposed provider, but can require a health body to do that;
    - If reasonable to do so, the commissioner must be informed in a change in the patient's condition;

- The commissioner may prevent the direct payment being used to obtain services from a particular person.

80. A decision regarding a personal health budget is not made for all time. The needs of patients may change. There is therefore a duty imposed under Regulation 14 for the commissioner to monitor the making of direct payments. There must be at least one review within the first three months of direct payments. Thereafter, reviews must be held at intervals of not more than 12 months. Where the commissioner is notified or becomes aware that the state of health of a patient has changed significantly, the health body must consider whether to make a review. A review may lead, for instance, to a change in the care plan.

81. Regulation 15 provides that direct payments may need to be repaid in certain circumstances:
    - If the care plan or the patient's circumstances have changed substantially;
    - If a substantial proportion of the payments have not been used to secure services in the care plan and have accumulated;
    - If direct payments have been used other than as in the care plan;
    - In case of theft/fraud/another offence in connection with the care plan;
    - In case of the death of the patient.

    Such payments can be recovered as a civil debt (Regulation 16). However, notice of repayment must be given, and it is possible to obtain a single review of the decision.

82. Likewise, direct payments can be stopped in certain circumstances:
    - Withdrawal of consent by the patient (if he has capacity) or representative;
    - The person for whom a payment is made is no longer a patient;
    - The representative or nominee is deemed unsuitable;
    - The nominee does not agree to receive payments, or the nomination is withdrawn;
    - Direct payments have been used otherwise than for services in the care plan;
    - Theft/fraud/another offence may have occurred in connection with payments;
    - The commissioner considers that health needs cannot be, or are not being met by services secured by direct payments;
    - The patient has died.

    Again, notice of repayment must be given, and it is possible to obtain a single review of the decision.

83. The Schedule to the Direct Payments Regulations sets out certain people who are excluded from direct payments. The list includes a person subject to a drug rehabilitation requirement, or an alcohol treatment requirement. The list also includes a person released on licence from prison.

84. One of the major difficulties with direct payments is ensuring clinical governance with a non-professional 'commissioner' of services. In order to reduce the risk of problems, a patient would be well-advised to make close use of the commissioner's care co-ordinator, and to be aware of the charitable assistance which may be available.