Direct Payments for Health Care: A consultation on proposals for regulations and guidance

The Government's response

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A list of respondents and responses will be available on the Department of Health website in April 2010

Introduction

1. Piloting personal health budgets was a flagship announcement in *High Quality Care For All*. The aim is to give people more choice and control over their care, and help bring about a more personalised NHS.

2. Primary Care Trusts (PCTs) are already able to offer personal health budgets that do not involve giving money directly to individuals. The Health Act 2009 amended the National Health Service Act 2006 (the NHS Act) to provide powers to allow personal budgets in the form of a direct payment as part of the DH pilot programme.

3. Between October 2009 and January 2010, the Department of Health consulted on proposals for using the powers in the NHS Act to make regulations to enable pilot sites to use direct payments. This document describes the Government's response to that consultation.

4. The consultation asked respondents to consider four overarching questions as they read each section of our proposals:

   Question 1: Do you agree with the substance of the proposals?
   Question 2: Is the level of detail proposed for the regulations right?
   Question 3: Is the balance right between regulations and guidance? Is there anything that should be in guidance rather than regulations, or vice versa?
   Question 4: Is there anything else we should include?

5. Respondents could send free-standing comments or use a structured response form. Easy read versions of the consultation were also available.

6. The majority of respondents broadly supported our proposals to pilot direct payments, and felt that the balance of detail proposed for regulations was right for the pilot phase. There was clear support for the three principles we outlined:
   - **avoid being over-prescriptive**. The regulations should allow freedom to innovate and test different models while ensuring safeguards are in place to protect patient health and the public purse;
   - **build on the experience of social care direct payments**, and, wherever possible, include similar provision as in their regulations and guidance; and,
   - **develop guidance as well as regulations**, in order to address issues better dealt with in guidance than in regulations and take account of emerging lessons.

7. Many respondents suggested specific additions or changes to our proposals; others chose to comment on the personal health budgets programme more widely. As a result, we have modified our proposals in several areas.

8. This document describes the key points made and our response. It does not list every comment, but we have considered all the points made and will continue to consider them as the pilot programme develops.

9. In the light of the consultation, the Government laid regulations in Parliament on 29th March 2010 for the pilot phase: the National Health Service (Direct Payments) Regulations 2010[1].

Consultation process: who responded

10. We received 132 responses and we are grateful to everyone who took the time to contribute their views. The greatest number of responses came from charitable or voluntary organisations (24%) and professional and representative bodies (19%).

Breakdown of respondents:

Type of respondent	% of respondents
Charitable or voluntary organisations	24%
Professional and representative bodies	19%
Individual members of the public	14%
NHS bodies	11%
Local government	9%
User and carer groups and networks	7%
Social care and direct payment networks	5%
Regulators	5%
Independent providers	2%
Health and social care professionals	2%
Unknown	2%

11. Many contributors responded only on issues where they had particular interest or expertise.

12. Over 60% of respondents chose to provide feedback in free text, rather than use our structured questionnaire. Therefore, we have not carried out a quantitative analysis of the responses for each section, as we do not feel this would accurately reflect the range of views raised.

[1] The National Health Service (Direct Payments) Regulations 2010, S.I. 2010/1000

What people said

13. Annex A gives a detailed summary of and response to the main points raised on each section of our proposals.

Piloting direct payments

14. The vast majority of respondents were supportive of our proposals to pilot direct payments for health care. Comments included:

- Member of the public: *"Good scheme. Should give people a lot more choice".*
- Association of Directors of Adult Social Services: "*ADASS welcomes the proposed introduction of direct payments for health care" "We would urge LAs and PCTs to work together on the development of direct payments for health care".*
- Rethink (mental health charity): "*Rethink believes that personalisation of services and individual budgets could provide better outcomes for people who use mental health services".*
- Counsel and Care (national charity working with older people): *"the direct payment pilot programme, if implemented successfully, has the potential to offer older people in need of regular healthcare treatment and services greater independence, autonomy and control".*

15. However, while the majority of responses received were supportive of the principle of direct payments for health care, this was not universal. A small number of those replying were sceptical about the idea of direct payments, arguing that they would not improve patient care, would be too costly, could have significant implications for the way NHS services are delivered or were too difficult to deliver successfully.

16. Some of the more sceptical respondents included:

- Royal College of Nursing: "*supports the principle of direct payments for social care but is cautious over its application in the health care sector as the practical challenges are in reality very different".*
- UNISON: "*there are many issues that still need to be considered from a staffing point of view of direct payments for healthcare"… "whether NHS managers will have the capacity they need to implement new policies properly".*
- *British Medical Association: "have a number of overarching concerns about personal health budgets being introduced in the NHS in general, which are amplified in relation to direct payments".*

17. Even supportive respondents emphasised that there are many issues and challenges to overcome if direct payments, and personal health budgets more widely, are to be a success.

Balance between regulations and guidance

18. While not everyone did, the majority of respondents agreed with the balance between guidance and regulation as set out in the consultation document. For example:

    - The Alzheimer's Society felt that the combination of regulations and guidance "*will provide robust support to PCT pilot sites who wish to trial direct payments".*

19. A number of respondents agreed that a flexible approach was right for piloting, but wanted further consideration following the evaluation. If a decision was made to roll out direct payments nationally, they wanted more prescriptive regulations, to help ensure consistency between PCTs. There was also a request for further consultation on future proposals, following the pilots and the evaluation.

20. Many made helpful suggestions for things to include in either regulations or guidance in a number of areas of detail, such as:

    - the services which should be included or excluded;
    - budget setting;
    - care planning;
    - provision of information;
    - advice and guidance; and
    - equality of access.

Evaluating direct payments

21. There was clear support for the independent evaluation of the pilot programme, for example:

    - Royal College of General Practitioners: *"believes that the scheme needs robust assessment before it is made permanent or further expanded and we welcome the fact that an independent review will be commissioned to assess its effect".*

22. Unison suggested that the regulations give a commitment that if the pilot is not successful this will be acknowledged. The BMA went further by requesting clarity in the regulations that Parliamentary approval will be sought prior to a more widespread rollout (this is already an explicit requirement in the NHS Act[2]).

[2] See section 12C(8) of the NHS Act

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Overall approach

23. The consultation responses have reinforced the Government's belief that piloting and robust evaluation are essential. This is a complex and challenging policy, and we do not yet have answers to all the questions raised.

24. We envisage that following the pilot programme and in light of the evaluation and lessons learned, there will be a further review of the regulations and guidance, if a decision is taken to roll out personal health budgets more widely. This is likely to include a further period of public consultation.

Changes to our proposals

25. In light of the responses to the consultation, we have made a number of specific changes to our proposals for regulations. These are discussed in more detail in Annex A. There are no fundamental changes of approach, they are largely points of clarification or detail.

Section in annex A	How we have changed our proposals
1.1	Required PCTs to explain in writing the reasons for refusal if they refuse to give a direct payment to an individual who wants one (regulation 10(10)). **Rationale:** A number of respondents felt it was important that individuals who were refused a direct payment were told why.
1.1	Set out the circumstances where a child (or person with parental responsibility) could receive a direct payment (regulation 8(1) and 8(9)). **Rationale:** It was our intention to do this, but the consultation document did not make it clear.
1.2	Required PCTs to explain the reasons for refusing to include a service in the care plan on request (regulation 11(7)). **Rationale:** Respondents felt it was important for individuals to have a right to know why a particular service was turned down.
1.2	Guidance rather than regulations will be used to ensure that a direct payment will not be used to purchase primary medical services or emergency and urgent care. **Rationale:** There was concern that defining primary medical services, emergency and urgent care in regulations would risk excluding services where direct payments might be of benefit. We have not changed our policy intent but have decided to use guidance rather than regulations.

Section in annex A	How we have changed our proposals
2	Included a power allowing PCTs to select a representative to hold a direct payment on behalf of an individual who lacks capacity where there is no legal representative (deputy, donee, attorney or person with parental responsibility) (regulation 8(4)). **Rationale:** This brings our Regulations more in line with social care arrangements.
2	Included explicit reference to a "nominated person" or "representative" (who receives a direct payment on behalf of a patient) being responsible for contractual arrangements secured by a direct payment, including employment contracts (where they would be the employer), and the repayment of a direct payment, if required (regulation 8(5)(c), regulation 9(3)(a) and regulation 18(2)). **Rationale:** It was our intention to do this, but the consultation document did not make it clear.
3.1	Defined the role of the care co-ordinator (regulation 11(3)). **Rationale:** It was our intention to do this, but the consultation document did not make it clear.
3.1, 3.2, 3.3 and 3.7	Added a requirement that PCTs must advise the patient, representative or nominee of significant risks, the potential consequences of these and the means of mitigating the risks: including in relation to employment responsibilities, inadequate complaints procedures or inadequate indemnity cover (regulation 11(1)(b), 11(2)(c), (d) and (e)). **Rationale:** There were very different views on the right balance between individual choice/control and safeguarding/risks. We felt that the PCT and the individual should discuss risks (and benefits) during the care planning process.
3.1 and 8	Required the PCT to carry out a first review within three months of an individual getting a direct payment (regulation 17(2)(a)). **Rationale:** A number of respondents commented that it was important to have an early review to ensure the direct payment/care plan was working.
3.1	Specified that a care plan should include details of when and how it will be reviewed (regulation 11(4)(f)). **Rationale:** A number of respondents felt it was important to set out at the planning stage what would be included in a review and when reviews would occur.
3.1 and 14	Amended the NHS Bodies and Local Authorities Partnership Arrangements Regulations 2000[3] to allow the pooling of NHS and social care funding and enable local authorities to administer the direct payment on the PCT's behalf. (regulation 21). **Rationale:** This should help facilitate joint working between PCTs and Local Authorities.

[3] S.I. 2000/617.

Section in annex A	How we have changed our proposals
3.3	Guidance rather regulations will be used to highlight future regimes for safeguarding vulnerable groups. **Rationale:** Given the potential for future change, we have decided it would be more appropriate to discuss future safeguarding vulnerable groups regimes in guidance. The Regulations will continue to set requirements on obtaining an enhanced criminal record certificate (referred to as CRB check).
3.3 and 3.4	Made the recipient of the direct payment initially responsible for checking that their provider has the necessary registration and qualifications, and, where necessary, appropriate indemnity cover. The recipient has the option of asking the PCT to carry out these checks instead – in which case, the obligation would fall on the PCT. The PCT must also consider these issues during any review of the care plan (regulation 14(2), regulation 14(3) and regulation 17(6)(d)). **Rationale:** Our initial proposal was that checking providers should take place before a care plan was agreed. During the consultation process it became clear that this would not be practical as the care plan would need to be agreed before the arrangements could be made with providers.
3.5	Made it clear that the same bank account could be used to receive direct payments for health care, for social care direct payments, payments under the Independent Living Fund or payments to secure other relevant services for a disabled person (regulation 13(2)(a)). **Rationale:** It was our intention to allow this, but the consultation document did not make it clear.
4	Added a condition that the recipient of the direct payment would only be required to notify the PCT of changes in their (or the relevant patient's) health condition or circumstances if they consider it is reasonable to do so (regulation 14(6). **Rationale:** This addresses concerns that regulations might require patients to notify changes where this was irrelevant or inappropriate.
6 and 7	Required PCTs to reconsider a decision to withdraw or reclaim a direct payment if required to do so by the patient, nominee or representative (regulation 17(10), regulation 18(4) and regulation (20(5)). **Rationale:** It was our intention to do this, but the consultation document did not make it clear.
14	Limited the Secretary of State's power to extend the pilot period, by setting a maximum pilot length of five years (regulation 4(2)). **Rationale:** It was our intention to do this, but the consultation document did not make it clear.

26. We believe these are helpful refinements to our existing proposals. They are intended to provide greater clarity without undermining the flexibility we have tried to incorporate into the direct payment framework.

Next Steps

27. The Government has now laid regulations in Parliament using the powers introduced by the Health Act 2009. These allow direct payments in approved pilot areas. The Regulations reflect our updated proposals following consultation. They are subject to the negative resolution procedure: provided that Parliament is content, they will come into force on 1 June 2010.

28. Pilot sites will only be directed to offer direct payments if they are explicitly approved by the Department. We have put in place an authorisation process, which will provide assurance that sites have suitable governance arrangements in place to manage direct payments effectively.

29. We have undertaken to develop guidance in partnership with pilot sites and other stakeholders. Initially the guidance will focus narrowly on the core parameters of the policy. We envisage more detailed and comprehensive guidance being produced in the light of growing experience from the pilots.

30. We intend to work with pilot sites throughout the pilot period to develop and disseminate best practice. We have established a learning network for the pilot sites, to enable sites to keep in touch, raise issues and find solutions.

Annex A: Responses to the individual sections of the proposals

1. This outlines the main points raised on the details of our proposals as set out in our consultation. The sections of this annex mirror those in the consultation document. Areas where we have altered our proposals in response to consultation are marked in **bold**.

Section 1.1: Persons for whom direct payments may be made

Our original proposal: Mirroring social care regulations, our guiding principle here is for direct payments to be available to anyone who might benefit from them, if they are located in the area of a pilot PCT and they meet the criteria set out in the pilot proposal.

2. Overall, the comments received supported this proposal.

3. A number of respondents felt that the eligibility and exclusion criteria should be set out more clearly in either regulations or guidance to ensure consistency across the country. It was suggested that anyone receiving NHS continuing health care should be able to have a direct payment. Another request was for early roll out to people who have had social care direct payments. Given that pilot sites have different patient selection criteria, we do not feel it is appropriate to set national eligibility and exclusion criteria at this early stage. In the longer term, and following the pilots, the Government is interested in the idea of developing a right to a personal budget, as outlined in *The NHS Constitution – a consultation on new patient rights* and *NHS 2010-2015: From Good to Great*.

4. Similarly, if direct payments prove successful and are extended more widely, it may be sensible to have a more standardised system for offering a direct payment and deciding whether a person has the ability to manage one. However, at this stage of the pilot, we do not know enough about the conditions or circumstances in which people could benefit from direct payments, so we do not want to be too prescriptive.

5. The distinction between someone having the capacity to consent[4] to receiving a direct payment and the ability to manage one was raised several times, and we will be drawing attention to this in guidance. In many cases PCTs will already have processes in place to assess capacity.

[4] In this document, references to people "with capacity" mean those with capacity (as defined in the Mental Capacity Act 2005) to consent to receive a direct payment.

6. Other responses suggested the guidance should include detail on how to assess whether people can manage a direct payment. There is guidance on this issue in social care[5] which pilot sites may find useful. At this early stage we do not intend to issue additional guidance on this but we will consider whether this is needed as the pilots develop.

7. It was clear from the responses that people felt that if individuals were turned down for a direct payment, they should be given the reasons. **We have amended our proposals to impose this duty on PCTs**.

8. Taking this a step further, some responses felt that if someone was turned down for a direct payment, the PCT should consider using other methods of personal health budgets or other ways of personalising their care. PCTs in the pilot programme are looking at various models of personal health budget and we foresee that, once a person has been included in the pilot, the discussion with the care co-ordinator will be around which method of delivery will best suit the individual, rather than direct payments being the first or default choice.

9. There was support for enabling people with parental responsibility to hold a direct payment on their child's behalf. **The Regulations set out the circumstances where a child (or person with parental responsibility) could receive a direct payment.**

Section 1.2: Circumstances and services for which a direct payment could be made

Our original proposal:
We intend to heed the lessons learned from experiences in social care, where direct payments worked best where people had the flexibility to use their resources in a range of innovative ways, including using services and options not normally commissioned through traditional mechanisms.

The PCT will need to agree the care plan. We propose that PCTs should decide which services are suitable for funding through direct payments; allowing local flexibility is particularly important at this pilot stage.

10. A significant number of respondents wanted specific guidance or regulation on what could be included in a direct payment and what should be excluded. Work is currently underway with pilot PCTs to explore what a personal health budget could be spent on. We do not want to be too prescriptive at this early stage as knowledge in this area will develop greatly over the pilot period.

[5] *Guidance on Direct Payments: For community care, services for carers and children's services: England 2009*, p.23

11. The term “services” as used in the Regulations is defined by the National Health Service Act 2006 at section 12B(6). It includes “anything in respect of which direct payments may be made”. Direct payments may be used to secure the provision of a broad range of treatments, equipment and services that the Secretary of State is obliged to provide or arrange for under the NHS Act[6] (or which PCTs are required to provide under section 117 of the Mental Health Act 1983). We intend to explain this in the guidance as a number of respondents suggested the term was too restrictive.

12. There were a range of views on whether we should have a broad or narrow range of services that a direct payment could be used to purchase. A few felt that only services deemed suitable for the NHS to fund, such as services to which GPs currently refer patients, should be included. Others wanted a more inclusive approach, for example allowing patients the freedom to use non-traditional services, or anything that is legal and safe. This is an area where we do not have enough evidence to explicitly exclude services, and where we feel the pilots need to have the flexibility to find innovative ways to meet agreed health outcomes. Furthermore, we think that if choice is to be real for people, this should include allowing patients to purchase services that the NHS does not traditionally fund. To ensure that services will meet people’s needs, proposals will need to be considered on a case-by-case basis as part of the care planning process. **If PCTs reject a service, they will be required to give the reasoning for their decision if asked, and the person will be able to appeal though the PCT’s normal complaints procedures.**

13. Our proposal suggested using regulations to prevent a direct payment being spent on primary medical services, and a number of respondents wanted a clearer explanation of what we meant by this. There was concern that by excluding primary medical services we might risk excluding some services, such as community equipment services or district nursing services. **Therefore**, **we have decided to use guidance rather than regulations to recommend that a direct payment not be used to purchase primary medical services. For similar reasons we have decided to describe in guidance what services we intend to exclude by way of emergency or urgent care.** However, this is not a change in our policy intent to exclude both from the scope of direct payments.

[6] See section 12A(2) of the NHS Act.

Section 2: Paying direct payments to a person nominated by an individual

Our original proposal:
We set out three different circumstances where a direct payment could be paid to a third party on the patient's behalf:

- individuals with capacity to consent to receive a direct payment, but who would prefer to appoint a "nominated person" to receive and manage it on their behalf;
- people who lack capacity, where the direct payment could be paid to a "representative" on their behalf.
- people with fluctuating capacity who may have a combination of both.

14. The Regulations and consultation document address these three scenarios separately, however as many of the comments received relate to all three, they are being combined in this response.

15. Overall, there was support for allowing a nominated person to receive a direct payment on behalf of an individual with capacity, and enabling people who lack capacity or have fluctuating capacity to benefit from a direct payment.

16. A number of respondents felt that there should be guidance on how to appoint nominated persons and representatives. Our intention is for individuals with capacity to select their own nominated person, although they will need to be approved by the PCT. As there may be cases where the person may ask for the PCT's help in identifying a nominated person, we will consider the need for guidance on how to do this as the pilot programme progresses.

17. For people lacking capacity, social care guidance is already available on appointing representatives. In cases where people do not already have formal representatives, we have introduced powers allowing **PCTs to select a representative to hold a direct payment on behalf of an individual who lacks capacity.** This will enable a wider range of people without capacity to benefit from the pilot programme.

18. The consultation document lists some key roles and responsibilities of a nominated person or representative, but we did not provide an exhaustive list. One issue we did not cover but feel it is important to make clear in regulation is the contractual responsibilities of nominees and representatives. The Regulations set out that a **nominated person or representative is responsible for contractual arrangements secured by a direct payment, including employment contracts (where they would be the employer), and the repayment of a direct payment, if required.**

19. There was a difference of opinion on safeguarding checks for nominated persons. Some respondents would like all nominated persons to undergo Criminal Records Bureau (CRB) checks. Others felt that this should not be prescribed. There is likely to be a significant difference between a nominated person whom a patient has known for many years, and someone whom they do not know, who has been chosen to be a nominated person on their behalf. We have decided to require checks when the PCT is considering whether to make a direct payment to a nominated person who is not an individual living in the same household as the patient, a family member or friend involved in the provision of the patient's care. Checks will be optional when a nominated person is an individual living in the same household as the patient, a family member or friend involved in the provision of the patient's care.

20. The need for training, advice and support for people acting as nominated persons or representatives was raised by several respondents. Knowledge of employment law, book-keeping and budgeting was felt to be particularly important. We agree that these are important areas and the guidance will highlight the need to ensure that nominated persons have the right support and information.

Section 3.1: Care plans

Our original proposal:
That the person receiving care, their representative or nominated person, and the PCT would need to agree a care plan,[7] which sets out the budget, desired outcomes and how they will be met.

21. A care plan, agreed by both the person receiving care and the NHS, is at the heart of all personal health budgets, including direct payments. None of the responses we received challenged the need for a care plan. A few suggested that the term "support plan" would be better as this is the term used in social care. To ensure consistency with the Health Act 2009 and its general familiarity to healthcare professionals we have chosen to use care plan, but a number of different terms could be used. Guidance will make it clear that the information in the document is what is important, not its name.

22. A number of respondents stressed the need for the care plan to be outcome focused, with enough flexibility for individuals to choose the services that would meet their desired outcomes. Others suggested that it should take a holistic or patient centred approach. Although the Regulations specify some of the things which must be included in a care plan, we do not think it is appropriate, at this stage, to be too specific in regulations about the structure or focus of care plans or to be too prescriptive about the approach to care planning. Rather we want to allow the pilot sites to develop and test different models.

[7] Also known as a support plan, personal health plan, or a care and support plan, but for ease here referred to as a care plan

23. The role, skills and training of the care co-ordinator were raised by a number of respondents. **The Regulations provide for the care co-ordinator to: manage the assessment of the health needs of the patient for the purposes of the care plan; ensure that the patient or their representative has agreed the care plan; arrange for the monitoring/review of the direct payment and care plan; and liaise between the patient or their representative and the PCT.** The skills and training a care co-ordinator will require is an important issue, we do not yet know enough to specify what is needed in either regulations or guidance but our knowledge will grow though the pilot programme.

24. The process for agreeing care plans and resolving any differences of opinion between the individual, carer and the PCT was also identified as an area where respondents wanted guidance. Some people felt it was important to include information about involving carers, friends who provide care/support and individuals who lack capacity in the care planning process. We agree that these are important issues, and pilot sites will need to develop local procedures. However, we are not intending to issue prescriptive guidance at this stage but rather learn from the experience of pilots.

25. We recognise that giving people more control and choice over how their health needs are met, and enabling people to choose innovative or different solutions, does not come without risks. A number of respondents felt it was important that individuals and the care co-ordinator identified, discussed and considered how to manage risks as part of the care planning process. We agree, and **we have added a requirement in the Regulations to ensure that PCTs advise patients about significant risks, their potential consequences and the means of mitigating the risks**. It was also suggested that risks should not be considered in isolation but should be balanced against the benefits which might ensue. We agree but feel that it would be more useful to include information in guidance than in regulations.

26. Many respondents commented on the necessity for clarity around the frequency of care plan reviews. We agree, and **have added a requirement for a first review to take place within three months of first receiving a direct payment and at least annually after that**. **The Regulations also specify that the care plan should include details of when and how it will be reviewed**. The precise frequency will depend on clinical need and the complexity of the plan.

27. Combining health and social care wherever possible received general and widespread support. A large number of respondents encouraged the development of joint assessments, joint care planning and joint budgets. While this might not be possible or appropriate to do in all cases, PCTs have a general duty under section 82 of the NHS Act to cooperate with the Local Authorities “to secure and advance the health and

welfare of the people of England and Wales" [8]. More generally, pilot sites needed to get local authority support prior to applying to become a pilot, and many sites are already working with their local authorities to develop joined up processes. Some are considering pooled budget arrangements and how joint care plans and combined direct payments could be used. **To facilitate this further, we have amended the NHS Bodies and Local Authorities Partnership Arrangements Regulations 2000[9] to allow the pooling of NHS and social care funding and enable local authorities to administer the direct payment on the PCT's behalf.**

Section 3.2: Employment

Our original proposal:
In some circumstances, people will wish to use their direct payment to employ staff. PCTs should support them to do so, while ensuring that there are proportionate safeguards in place.

28. A number of respondents would like to see more freedom for individuals to employ family members. We have decided to take the same approach as applies in social care in our Regulations and guidance. We feel that to do differently would make things unduly complicated and potentially confusing for individuals. In order to not undermine family relationships, the Government does not believe it is appropriate, except in exceptional circumstances, for family members to be paid for care as part of an employer-employee relationship. In order to recognise the contribution of carers, the Government has put in place separate means of support for carers, and has recently announced additional help for carers to build their state pension entitlement.[10]

29. It is obviously important that people using a direct payment to employ someone should meet their legal responsibilities, and have the right information to do so. It was suggested that guidance should list all the responsibilities of an employer. We do not wish to set out a list of all a person's employment responsibilities, as this could be cumbersome. However, we have decided to **make clear in the Regulations that PCTs need to, where relevant, advise individuals or their nominated person/representative of the risks arising from their responsibilities as an employer**. PCTs will also need to signpost where to get more information and guidance. For example, this may be from a Centre for Independent Living or from information available on the Government's business link website. It will be possible for individuals to use direct payments to secure employment services to assist them with the recruitment of employees.

[9] S.I. 2000/617.
[10] http://www.direct.gov.uk/en/CaringForSomeone/MoneyMatters/DG_10012529

Section 3.3: Registration and safeguarding

Our original proposal:
The service that people purchase through a direct payment should meet all the regulatory requirements that it would need to meet if it was procured by more traditional means. Providers and staff should be vetted and checked to ensure that the services people receive are safe.

30. The need to find a balance between choice and duty of care on one hand and risk and safeguarding on the other was raised repeatedly. Respondents had very different views on where the balance should lie. In order to ensure that there is a discussion between the care co-ordinator and the individual, **we are including a requirement in the Regulations for PCTs to discuss risk management as part of the care planning process**, as mentioned above in section 3.1.

31. There was a difference of opinion on whether people providing care should be CRB checked. Some felt that there should be no requirement, that such checks and checking registrations slowed down the recruitment process or that the checks for were not appropriate for family members. However, others felt that such checks were important even when employing friends and family of vulnerable people. Some respondents went as far as suggesting that all people should be checked. We envisage that the PCT will discuss the need for such checks at appropriate times, in line with the requirements set out by the *Safeguarding Vulnerable Groups* legislation. **Guidance rather regulations will be used to highlight future safeguarding vulnerable groups regimes.** As these are likely to change in the future we felt it was more appropriate to discuss them in guidance.

32. It is clear from responses that we need to clarify in guidance that not everyone will necessarily need to be registered, or to have qualifications. Generally, people providing care which is paid for using a direct payment will need to have the same qualifications as those who provide services under traditional NHS provision. However, there may occasionally be some exceptions, if it is agreed by all parties to be the best way to meet the individual's health needs. For example, some carers are trained to carry out care (eg tracheotomy care or changing dressings) at home which would be carried out by qualified staff if they were undertaken in hospital. We do not want to prevent this, if it is in someone's best interests. Guidance will discuss this more fully.

33. Our initial proposal was that checking providers should take place before a care plan was agreed. During the consultation process it became clear that this would not be practical as the care plan would need to be agreed before the arrangements could be made with providers. We have decided that **during the pilot programme, the patient, nominee or representative will be initially responsible for checking that their provider has the necessary registration and qualifications. The patient, nominee**

or representative has the option of asking the PCT to carry out these checks instead, in which case, the obligation would fall on the PCT. The PCT must also consider these issues during any review of the care plan.

Section 3.4: Indemnity

Our original proposal:
Our intention is to help ensure that people are properly protected, with appropriate indemnity cover for the services they are receiving, while avoiding imposing undue burdens either on people receiving direct payments or PCTs.

34. The issue of indemnity cover is complex and a number of respondents suggested that more guidance was needed, particularly around what we mean by "appropriate indemnity". We would expect indemnity cover to be proportionate to the risk, and in line for the cover for similar services commissioned by the NHS.

35. Several suggestions were made regarding indemnity, including: that consideration of indemnity should be included in the risk assessment; that the outcome of the discussion should be recorded; and that PCTs should check companies' indemnity cover as the default. We agree that **discussing the risks of using providers who have inadequate indemnity cover should be included in the discussion on risks, where appropriate and this is set out in the Regulations**. For similar reasons as above we have decided that the **patient, nominee or representative will be initially responsible for checking that their provider, where necessary, has appropriate indemnity cover. The patient, nominee or representative has the option of asking the PCT to check this instead, in which case the obligation would fall on the PCT. During the first review (and future reviews as necessary) PCTs may need to ensure that the need for indemnity cover has been checked and, if necessary, is in place, when considering whether the direct payments have been effectively managed.**

36. We will be providing some guidance on indemnity. However, the issues are complex, and we anticipate the guidance will develop through the pilot period, informed by the sites' experience.

Section 3.5: Distinct and secure means of receiving a direct payment

Our original proposal:
In line with practice in social care, we propose that direct payments should be made into a "distinct and secure means" of receiving them: for example, a bank account or a pre-paid card.

37. Respondents generally supported the idea of allowing a single bank account to receive both health and social care direct payments, if someone was receiving both.

38. Although the majority of respondents agreed with, or had no comment on, the requirement for a separate bank account, not everyone agreed. It was suggested that a separate account should not be needed so long as the patient provided receipts. However, we have decided that a separate bank account should be a requirement of holding direct payments, because it would make a clear distinction between the individual's own funds and the direct payment, which remains public money given to them for their agreed healthcare needs. **We have also made it clear in the Regulations that the bank account could be used for social care direct payments, payments under the Independent Living Fund or payments to secure other relevant services for a disabled person.**

39. Opinion was divided on the merits of pre-paid cards. Some felt they would be too restrictive while others preferred them, suggesting they could reduce the risk of fraud. Early learning from the pilots using pre-paid card systems will help inform the debate as the pilot programme progresses.

Section 3.6: Frequency of payments

Our original proposal:
Regulations should provide for PCTs to have the flexibility to agree frequency of payment of a direct payment with individuals in light of their circumstances and needs.

40. There was some discussion around when a direct payment should be paid. Some felt that regulations should set out that individuals should be paid before they purchase any care or service. While we agree that this would be good practice, we feel regulations requiring this would be too restrictive. The guidance will suggest that the frequency of payment should be discussed and agreed with the individual prior to the direct payments starting, and PCTs may choose to do this as part of the care planning process. However, we also wish to allow PCTs the freedom to develop and test their own practices and procedures.

Section 3.7: Complaints

Our original proposal:
Under the NHS complaints procedures, people will have a means of complaint if something goes wrong with NHS services. However, this may not always be the case with direct payments, although there would always be a right of complaint about any decision made by the PCT. Where a provider does not have a complaints procedure, the PCT should make the implications of this clear to the individual. We do not anticipate that the Regulations will say anything about complaints.

41. A number of respondents suggested that we include a requirement for PCTs to provide information on relevant complaint procedures. Several respondents suggested that regulations should provide individuals with a means of redress if they had a complaint about any stage of the direct payment process, such as a disagreement over the care plan or the level of budget set. We envisage that guidance will advise pilots that they should ensure that their normal procedures enable people to raise concerns or make complaints at any stage of the direct payment process. All aspects of the direct payment process that directly involve an NHS body will be covered by the well-established NHS complaints procedure.

42. It was also proposed that regulations should only permit care to be provided by organisations that have robust complaints procedures in place. We do not want to be overly restrictive by preventing an individual purchasing a service because the provider does not have a complaints procedure. Instead, **the Regulations identify the lack of specific complaints procedures as a risk that may be discussed during the care planning stage**.

Section 4: Conditions that patients or payees will be required to meet

Our original proposal:
Regulations should require recipients, as a condition of receiving a direct payment, to:
provide information on their condition and expected health outcomes;
tell their PCT if their conditions or circumstances change sufficiently to require a re-assessment of their condition or their package of care;
provide a distinct and secure means of receiving a direct payment;
provide evidence of and information about their spending, through the provision of receipts or any other information as required; and
agree to ongoing review to ensure that the care plan is meeting their care needs.

43. The majority of comments suggested that the proposed duties placed on the individual appropriately balanced risks and safeguards. A few respondents felt that the regulations would be too prescriptive, or placed too many responsibilities on individuals. There was concern that people may not fully understand what was meant by the requirement to notify the PCT if their "conditions or circumstances change sufficiently to require a reassessment of their condition or package of care", and there was a concern that a lack of clarity could lead to anxiety or individuals accidentally failing to comply with the law. We recognise that there is concern about placing requirements on individuals, but we think it is important that the PCT should be made aware if a person's condition changes, as it may require changes to the care plan. Others highlighted that a change in condition would not necessarily result in a change in the care plan. In light of comments received, **we have modified the requirement so that individuals can make a judgment as to whether it is reasonable to notify the PCT if their condition**

changes substantially. We envisage that PCTs will discuss what changes in conditions should be reported and explain why.

44. Concerns were raised about the requirements around providing information on spending. Our intention is for the PCT to discuss requirements with individuals early in the process and provide them with support to ensure they can provide the necessary information. We intend to develop best practice in light of learning from the pilot programme.

Section 5: Setting the budget for direct payments

Our original proposal: Regulations would not set out how the amount of a direct payment should be calculated. As resource allocation at the level of the individual is new to the NHS, we intend to develop the policy in light of experience gained through piloting.

45. There were a large number of comments around the process for setting the budget. A number of respondents called for more guidance and transparency on how budgets will be set or a debate on the processes and principles of budget setting. Some felt that the budget set should not be more than the cost of traditionally provided services; others felt that PCTs need to base the budget on the true cost of services, not on negotiated block contracts. It was suggested that objectives should be realistic, meeting basic needs and not “gold plated”.

46. At this stage, we do not have sufficient information to issue formal guidance. However, the pilot programme delivery team are working with pilot sites to help them develop their plans, and best practice will be shared through the learning network. Thinking on the process of setting a budget will develop as the pilots progress and information emerges from the evaluation.

47. A number of respondents felt that individuals should be able to top up their direct payments for health care, in order to access more expensive or more tailored services. Examples given were specialist and more expensive equipment, such as enhanced hearing aids. However, personal health budgets must support the fundamental principle that access to NHS care is based on clinical need not ability to pay. This differs from the means-tested approach in social care. The Government has made clear that people may not top up any form of personal health budget from their own resources. They may choose to buy additional private healthcare, but this must remain separate, with clear accountability between NHS funding and private expenditure.

48. In circumstances where individuals have joint care plans across health and social care, it will need to be clear where an individual is contributing to their social care provision and where care or services are being paid for through a direct payment for health care.

49. There were differing opinions on what should happen if there is a budget underspend. Some felt that any surplus should be carried forward, that there needed to be flexibility to take account of changing needs or that there should be flexibility to reward prudent planning. Others felt that any underspend should be returned to the PCT for use in other parts of the NHS. We have suggested that there should be some flexibility in this area, depending on the size of the underspend and the circumstances; the Regulations reflect this. Currently, we do not have sufficient information to issue formal guidance, but we will be exploring this as the pilot progresses.

Section 6: Terminating direct payments

Our original proposal: Regulations will allow PCTs to stop paying direct payments. The conditions under which this may be necessary are similar to the conditions under which a social care direct payment may be stopped.

50. There were relatively few comments on this section. The majority of those received emphasised the need to ensure continuity of care if the direct payment was stopped. Some felt that this was particularly important if the patient was moving between health and social care systems, moving into hospital or moving out of the pilot area. We intend guidance to clear than when a direct payment stops, the PCT must endeavour to ensure continuity of care.

51. Although we did not make it clear in the consultation we believe it is important during the pilot period that an individual has a right to have any decision to withdraw a direct payment reconsidered. **There is a requirement for PCTs to reconsider a decision to withdraw or reclaim a direct payment, if asked to do so by the patient, nominee or representative.**

Section 7: Reclaiming direct payments

Our original proposal: Our original proposal outlined the circumstances where a PCT could reclaim a direct payment (for example, in the event of fraud or abuse, an unplanned surplus or a significant change of circumstances).

52. There were few comments on reclaiming direct payments. Suggestions included: that reclaiming money should be a last resort; that the needs of bereaved carers should be considered when considering reclaiming budgets after a patient has died; and that guidance was needed on what should be taken into account when a PCT considers whether to pursue an individual for repayment. As originally proposed, we believe that the Regulations should give PCTs a degree of discretion on whether to reclaim a direct

payment. We will include advice in guidance suggesting that PCTs carefully consider the circumstances of individuals and their families when reclaiming a direct payment.

53. As is the case when a PCT makes a decision to terminate a direct payment, there **is a requirement for PCTs to reconsider a decision to reclaim a direct payment, if asked to do by the patient, nominee or representative**

Section 8: Review and monitoring

Our original proposal: Our approach to monitoring and reviewing direct payments for health is largely the same as in social care, and is intended to help safeguard people's health and public money without being too burdensome on individuals or PCTs. We also propose to include additional provision around triggering a re-review.

54. The proposal to reflect monitoring and review practice in social care gained widespread support. Many respondents suggested that joining up of health and social care could simplify the process and benefit patients. Pilot sites will have the flexibility to develop their own monitoring processes, which could mean a single monitoring process for health and social care. We will be examining different models and sharing best practice as the pilots progress.

55. There were a number of comments on the frequency of reviews, including that they should initially be more frequent, with the first review within three months. As outlined in section 3.1, we agree that this is a sensible approach, and have made this an explicit requirement in the Regulations. We feel that the PCT and individual should discuss and agree the frequency of the review(s) and what they will involve. The Regulations require the care plan to set out the anticipated date of the first review and how it is to be carried out.

56. There were a range of views around the scope and content of monitoring and reviews. Respondents suggested that: the clinical and financial monitoring should be kept separate, that financial monitoring should occur at least quarterly, that there should be greater financial scrutiny where a nominated person or representative manages the budget to prevent misappropriation, that the review should include value for money in addition to outcomes met, and that the monitoring should examine overall outcomes rather than precise expenditure. We anticipate that what is included in a review will vary depending on the individual's condition and background. As mentioned in section 3.1 above, the PCT will be expected to discuss what will included in the reviews with the person during the care planning process, and this will be set out in the care plan.

57. A significant number of respondents suggested that, in order to not discourage people or put too great a burden on them, any review should be as light touch as possible. We

agree with the principle, but feel that the reviews will also need to be clinically appropriate and ensure that the public purse is protected. We want to allow PCTs sufficient flexibility to design and test their review systems and we intend to learn from their experiences before considering guidance.

Section 9: Requirements to provide support, information and advice

Our original proposal:
Regulations will:

- require the PCT to provide, or make arrangements for the provision of, advice, information and support, both during the development of someone's care plan, and also while they are managing the direct payment;
- allow PCTs to include the cost of purchasing support services in an individual's direct payment, if this is appropriate.

58. A very large number of responses highlighted the need for PCTs to provide information, advice and support. A number of respondents felt that the regulations should set out a minimum requirement for information, advice and support and which areas that should be covered. However, because we are at an early stage, we do not yet understand what will be needed, or how best to delivery it, and we want to leave space for pilots to innovate. Therefore we do not intend to set out minimum requirements in regulations. Instead, the Regulations require PCTs to make arrangements to ensure that people are provided with information, advice or other support. Information will be important at every stage, including before a person makes a decision about whether to have a direct payment or not, to help them make an informed choice. We will be using the pilot programme to establish and share best practice.

59. A number of respondents felt that there should also be more guidance and emphasis given to advocacy and support services. Some went further, suggesting that free independent advocacy and support should be made available to help individuals develop their own plans and negotiate with their PCT. We appreciate the potential benefit of advocacy and brokerage services, and these are among a range of potential support mechanisms we envisage that PCTs will explore.

60. There were a number of suggestions about who would be best placed to provide information, advice and support, such as user-led or third sector organisations. Some people felt that PCTs should join up with local authorities, other local support services, or national organisations such as Citizens Advice. It was suggested that the Government should provide a central website and helpline on direct payments and that information should be placed on the DirectGov website or helpline. We agree that there are a number of different delivery mechanisms and do not think that a single mechanism will be suitable for everyone. We are encouraging pilot sites to consider the mechanisms and partners who could deliver effective support in their area.

61. The need for information to be provided in an easily understood format was raised. It was suggested that PCTs should proactively provide information, and a number of respondents gave examples of topics that should be covered, such as:
    - employment issues;
    - personal experiences and case studies;
    - information and training on how to manage a budget;
    - drawbacks and what can go wrong;
    - risks and benefits;
    - how to tailor support for people with dementia;
    - how to tailor support for those with other mental health needs; and
    - one-to-one advice.

62. This is not an exhaustive list of what people felt should be included nor is it an exhaustive list of what PCTs should provide. Rather it is intended to demonstrate the extensive range of information, advice and support that PCTs will need to consider as they develop their pilots. Pilots' understanding of what is needed will develop through the programme as will examples of best practice.

63. A number of comments also highlighted the importance of tailored information for different groups, including support for deaf-blind people, people with significant communication impairments, young people, and people requiring information in other languages or specific formats. We intend to include this in guidance.

64. The Regulations allow for direct payments to include sums to buy information, advice and guidance. This provoked a range of views. Some felt that all information should be provided free, or should be provided using additional funding; some felt that the full cost of providing advice and support including brokerage should be included in the direct payment. Others believed that PCTs having contractual arrangements with those providing these services is a better approach as it enables capacity building within providers. The possible adverse effect of charging for advice that is currently provided free was also raised. This is an important area and allowing people to purchase information, advice and guidance during the pilot will allow pilots to explore different mechanisms.

Section 10: Treating direct payment services as NHS services

Our original proposal: We do not intend to use regulations to define the extent to which services provided by direct payments should be regarded as services provided by the NHS.

65. A number of respondents wanted regulations and guidance to stress that receiving a direct payment would not remove a person's right to access NHS services. Direct

payments are not intended to change existing obligations for the NHS to provide care. No-one should be denied essential treatment as a result of having a personal budget: we intend to make this clear in guidance.

Sections 11 to 14: The pilot schemes

Our original proposals in sections 11 to 14 set out the design of the direct payment pilot programme and included:

- selection of individual pilot schemes;
- purchasing care outside a PCT's geographical area;
- revoking or amending pilot schemes; and
- extending pilot schemes.

66. In May 2009, 70 sites were provisionally confirmed as pilot sites. Before being awarded full pilot status these sites must pass a progress check which includes an online self-assessment and a review of project documents. It was suggested by some that all sites who want to give a direct payment should submit extra information; others felt that all pilot sites should have automatic right to offer direct payments. The approval process for direct payments is built into the progress check and pilots will be required to answer specific questions on direct payments. All pilot sites will be eligible to apply.

67. The NHS Act gives the Secretary of State power to set and extend the pilot period. We envisage that the pilot period will run until 2012. **The Regulations give the Secretary of State power to extend the pilot length to a maximum of five years.**

68. Some respondents raised the importance of equality. One response suggested that ethnic profile of people recruited in the pilots should reflect the local population. Another suggestion was for a pilot that specifically focused on Black and Minority Ethnic populations to help identify barriers to participation and how to overcome them. It was suggested that we needed to highlight equality and diversity issues in our guidance. We agree that tackling inequalities and promoting equality in pilot sites is vital, and our guidance and support to pilots will reflect this.

69. There was also clear support for encouraging pilots to join up with social care, particularly around assessments, care planning, budget setting and regulations. Other parts of government are currently planning to pilot direct payments as a way of personalising services – for example, the work by The Office of Disability Issues (ODI) on the Right to Control[11], and the Department for Children, Schools and Families' Aiming High For Disabled Children programme[12]. Some respondents felt that links should be made between these programmes. We agree and are working with colleagues in other departments to share learning and identify some joint pilot sites.

[11] www.odi.gov.uk/right-to-control
[12] www.dcsf.gov.uk/everychildmatters/healthandwellbeing/ahdc/AHDC/

70. We are encouraging pilot sites to share learning and experiences, both positive and negative, though the web-based learning network and at focused workshops and events. The lessons learnt and the outcome of the evaluation will inform future decisions on direct payments for health care.

Section 15: Scope of the review of the pilot programme

Our original proposal: Regulations will: • define the scope of the review of a pilot scheme; • require an independent evaluation team to review the pilot programme, and publish their findings when the review was complete.

71. As outlined in the consultation document, an independent research team is in place to evaluate the personal health budgets pilot programme, including direct payments. While all pilot sites will contribute to the evaluation, the team has selected 20 sites to be studied in depth.

72. A large number of responses contained suggestions for areas that should be included in the evaluation, including:
    - employment issues and terms and conditions such as pay, pension, and health and safety;
    - whether other patients are disadvantaged by direct payment recipients having access to non-NHS services;
    - cost / benefit analysis; and
    - improved outcomes from patient and clinical perspectives.

73. While the suggestions received were largely covered within the existing specification, all suggestions have been passed on to the evaluation team.

74. There were requests for early learning to be made widely available. Information on early learning will be made available on the public facing section of the learning network, and people can register to receive regular newsletters by emailing the personal health budget team[13]. In addition, the evaluation team will be publishing five interim reports on their website[14]: the first of these will be available in summer 2010. The final report will be published in October 2012.

75. Some respondents stressed the importance of including patients in the evaluation. We agree: the evaluation will look at the experiences of both patients and carers. In

[13] Personal health budget email address: personalhealthbudgets@dh.gsi.gov.uk
[14] Personal health budget evaluation website: http://www.phbe.org.uk

addition, service users and carers are represented on the evaluation steering group, which provides the evaluation team with advice and guidance.

76. The full evaluation specification, a summary, and an easy-read version will be made available on the learning network website within the next two months. These set out the plans for the evaluation in more detail. The Regulations require the review of the pilots to examine:
    - the effect of direct payments on the health, well-being and satisfaction of patients, representatives and carers;
    - the effect on cost effectiveness of care;
    - the impact on care workers and NHS staff;
    - the extent to which direct payments produce innovation; and
    - the effects of administering and managing direct payments.

Annex B: References

Personal health budgets websites	
Pilot programme learning network	www.personalhealthbudgets.org
Department of Health website	http://www.dh.gov.uk/en/Healthcare/Highqualitycareforall/DH_090018
Personal health budget Evaluation (PHBE) website	http://www.phbe.org.uk
Policy documents	
High Quality Care For All: NHS Next Stage Review final report (DH, 2008)	http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_085825
The NHS Constitution (DH, 2009)	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093419
Improving access to medicines for NHS patients	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_089927
NHS 2010 - 2015: from good to great. Preventative, people-centred, productive	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_109876
Legislation and regulations	
The National Health Service (Direct Payments) Regulations 2010 SI 2010/1000	http://www.opsi.gov.uk and search SI number 2010/1000
Health Act 2009	http://www.opsi.gov.uk/acts/acts2009/ukpga_20090021_en_1
Mental Capacity Act 2005	http://www.opsi.gov.uk/ACTS/acts2005/ukpga_20050009_en_1
National Health Service Act 2006	http://www.opsi.gov.uk/Acts/acts2006/ukpga_20060041_en_1
Safeguarding Vulnerable Groups Act 2006	http://www.opsi.gov.uk/ACTS/acts2006/ukpga_20060047_en_1
The Community Care, Services for Carers and Children's Services (Direct Payments) (England) Regulations 2009	http://www.opsi.gov.uk/si/si2009/uksi_20091887_en_1
Mental Health Act 1983	http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_4002034
The Local Authorities, Social Services and National Health Service Complaints (England) Regulations 2009	http://www.opsi.gov.uk/si/si2009/uksi_20090309_en_1
Guidance	
Guidance on direct payments for community care, services for carers and children's services (DH, 2009)	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_104840
Independence, choice and risk: a guide to best practice in supported decision making (DH, 2007)	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074773
Transforming Community Services: Currency and Pricing Options for Community Services, (DH, 2009)	http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093008
Government advice on employing people	http://www.businesslink.gov.uk/bdotg/action/layer?r.s=tl&r.lc=en&topicId=1073858787

Annex C –Glossary

Care co-ordinator
A person who manages the assessment and care planning process where a person needs complex and/or multiple services to support them, and who takes overall responsibility for ensuring that the process is completed satisfactorily. Care co-ordinators are usually the central point of contact with the individual. Depending on the setting and services, the same or a similar role might be played by a care navigator or a case manager. The role of the "care co-ordinator" is defined in the Regulations for the purposes of the Regulations.

Care planning
A process based on an assessment of an individual's needs that involves determining the level and type of support to meet those needs, and the objectives and potential outcomes that can be achieved.

Capacity
The ability to make a decision about a particular matter at the time the decision needs to be made. "Capacity" as used in the Regulations is defined in the NHS Act by reference to the Mental Capacity Act 2005.

Care worker
A paid worker who supports a person with everyday tasks.

DirectGov website (www.direct.gov.uk)
The official UK Government website for citizens which contains a wide range of information about public services.

Direct payments
Are payments given to individuals to choose, organise and pay for the services they need. In the Regulations they have the meaning given by sections 12A to 12D of the NHS Act.

Emergency Care
Unplanned in-patient or out-patient admissions to hospital.

Guidance
Guidance is primarily designed to provide recommendations and good practice.

Integrated care
Integrated care is when both health and social care services work together to ensure that individuals get co-ordinated treatment and support.

Regulations
The National Health Service (Direct Payments) Regulations 2010, S.I. 2010/1000. The Regulations set out the formal legal requirements and powers – what a PCT, patient, representative or nominee must do, may do or must not do.

Social care
Social care refers to the 'wide range of services designed to support people to maintain their independence, enable them to play a fuller part in society, protect them in vulnerable situations and manage complex relationships' (*Our Health, Our Care, Our Say: A New Direction for Community Services* (2006), paragraph 1.29). It is provided by statutory and independent organisations and can be commissioned by a local authority's social services department on a means-tested basis, in a variety of settings.