



RESEARCH PAPER 09/48  
25 MAY 2009

# ***Health Bill [HL] (excluding tobacco provisions), Bill 97 of 2008-09***

This Research Paper has been written for the Second Reading of the Health Bill [HL], following its passage through the House of Lords, where it was introduced on 15 January 2009.

The Bill as introduced covered ten policy areas, including the sale of tobacco, which is the subject of Library Research Paper 09/49. The other topics were: The NHS Constitution, Quality Accounts, Direct Payments to patients, Innovation Prizes, Trust Special Administrators for failing NHS bodies, powers of suspension, pharmacy, adult social care complaints, and disclosure of information by Her Majesty's Revenue and Customs.

The measures covered by this paper were broadly uncontroversial during the Bill's passage through the Lords. There were nevertheless some amendments, mostly introduced by the Government in response to points made during the debates, including one which followed a defeat for the Government on a division about the NHS Constitution.

There is one new clause, relating to Foundation Trusts and their income from private patients, which was introduced as a result of a Government defeat and was not a topic covered in the original Bill.

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## Summary

The *Health Bill [HL]* was introduced into the House of Lords on 15 January 2009. It contains a wide range of measures, including measures relating to the sale of tobacco, which are the subject of a separate Research Paper.

The various measures discussed in this Paper were broadly uncontroversial. There were nevertheless a number of changes, which are listed in the first section, which provides an overview of the Bill as a whole. The changes include a new clause intended to relax the limit on the amount of income from private patients that NHS Foundation Trusts can earn. This was introduced following a division on Third Reading, on which the Government was defeated and was not a topic originally covered in the Bill.

The rest of this Paper discusses the topics in turn. In broad terms, the Bill would:

- Introduce a duty for certain health bodies to have regard to the NHS Constitution. It does not introduce the NHS Constitution itself, which was published as a separate document in January 2009.
- Require all healthcare providers working for the NHS to publish a Quality Account (as distinct from a financial account) once a year. The Bill itself does not specify what is to be contained in such an account but makes provision for regulations to do so.
- Make provision for payments to be made directly to patients, with their consent, in order to enable them to purchase health care services. The payments would, at least initially, only be made through pilot schemes. The Bill does not introduce the pilot schemes directly but makes provision for regulations to do so.
- Enable the Secretary of State to award prizes to promote innovation in the provision of health services.
- Introduce measures relating to failing health providers, including the appointment of a Trust Special Administrator to take over, for a limited period, the functions of an NHS Trust, a de-authorised NHS Foundation Trust or the provider functions of a Primary Care Trust.
- Enable the Secretary of State to suspend and temporarily replace chairs and other members of certain health bodies.
- Introduce new arrangements for entry to a Primary Care Trust's list of NHS pharmaceutical providers and other provisions relating to pharmaceutical services.
- Extend the remit of the Local Government Commission (Ombudsman) to investigate complaints about adult social care which is privately arranged or privately funded.
- Allow Her Majesty's Revenue and Customs to disclose anonymised information collected for income tax purposes relating to GPs and dentists.
- Enable exemptions to the private patient cap for NHS Foundation Trusts to be made in regulations



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# I Introduction to the Bill

## 1. Announcement

A Bill on the NHS was announced in the Government's *Draft Legislative Programme* published in May 2008.<sup>1</sup> It was then referred to as the *National Health Service Reform Bill* whose main purpose would be to take forward proposals arising from the NHS Next Stage Review led by Lord Darzi, Minister at the Department of Health.

The Bill currently before Parliament, which is called the *Health Bill*, was announced in the Queen's Speech on 3 December 2008 and was introduced into the House of Lords on 15 January 2009 by Lord Darzi.<sup>2</sup>

## 2. Content

As envisaged in the *Draft Legislative Programme*, the Bill introduces measures arising from the NHS Next Stage Review<sup>3</sup> but it also contains a number of other measures, including those relating to the sale of tobacco, which was not mentioned in the *Draft Programme*.

The Bill's provisions cover ten broad areas grouped into three parts:

Part 1, *Quality And Delivery Of NHS Services In England*, which includes measures arising out of the NHS Next Stage Review, relating to:

- The NHS Constitution
- Quality Accounts
- Direct Payments to patients
- Innovation Prizes

Part 2, *Powers In Relation To Health Bodies*, which includes measures about the performance of NHS bodies relating to:

- Trust Special Administrators (to deal with financial failure)
- Suspension of appointments (eg while an NHS board chair is being investigated)

Part 3, *Miscellaneous*, which includes measures relating to:

- Tobacco advertising, displays, and sales from vending machines
- Pharmacies
- Complaints about privately funded or arranged adult social care

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<sup>1</sup> [The Government's Draft Legislative Programme 2008/9, CM 7372](#), May 2008, page 62.

<sup>2</sup> [HL Bill 18 of 2008/9](#), January 2009. As introduced into the House of Commons in May 2009, it is [Bill 97 of 2008-09](#). There are accompanying Explanatory Notes and Impact Assessments. See, in particular: [Health Bill 18-EN 2008-09](#), and [Bill 97-EN](#) as well as [Department of Health: Impact Assessments for the Health Bill 2009](#).

<sup>3</sup> [High Quality Care For All: NHS Next Stage Review Final Report, Cm 7432](#), June 2008

- Disclosure of information by Her Majesty's Revenue and Customs

The Department of Health has dedicated a section of its website to the Bill, which includes Factsheets and other relevant information, for example steps being taken alongside the Bill to develop the policies to which it relates.<sup>4</sup>

The provisions on tobacco are covered in a separate Library Research Paper. This Paper covers all the other provisions.

### **3. Opposition Parties**

The two main opposition parties were generally in favour of the measures in the Bill discussed in this Paper (that is, excluding those on tobacco sales). Nevertheless, the Government was twice defeated on divisions, one relating to Parliamentary scrutiny of the NHS Constitution principles and the other relating to the amount of private work that NHS Foundation Trusts can do, which was not a topic originally covered in the Bill (see below).

On Second Reading in the House of Lords, Lady Barker, on behalf of the Liberal Democrats, said:

I hope that as we go through the Bill, not only do we keep in mind the long-term vision of the noble Lord, Lord Darzi, but we also ask ourselves this: will what we are doing make the NHS something that people continue to value and cherish in good times and in bad? Some parts of the Bill will help that, some may not, and on some it is unclear. Those parts which are good will have our support.<sup>5</sup>

Lord Howe, the Conservative spokesman, having described the proposals on point-of-sale displays of tobacco products as “unjustified and repressive”, concluded his Second Reading speech by saying:

As I said at the beginning, for the greater part of the Bill the Government can count on our general support: and they can count on our constructive engagement on the whole of it...<sup>6</sup>.

### **4. Changes**

Measures added to the aspects of the Bill covered in this paper during the Bill's passage through the House of Lords are outlined in the list below (leaving out minor and technical amendments). Most were introduced by the Government in response to issues that arose during the debates in the House of Lords and were generally welcomed by those who had raised them. An exception is the relaxation of the private patient cap, which was introduced on a division in which the Government was defeated.

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<sup>4</sup> [Department of Health website on the Health Bill](#)

<sup>5</sup> HL Deb 4 February 2009 c746

<sup>6</sup> HL Deb 4 February 2009 c749

- **NHS Constitution [clauses 3 (5) and 7]:** Changes to the guiding principles of the NHS Constitution will have to be set out in regulations (negative procedure) so as to create an opportunity for Parliament to scrutinise them. This and related amendments were introduced on Third Reading by the Government<sup>7</sup> following a Government defeat on a similar amendment moved by Lord Howe at the report stage.<sup>8</sup>
- **NHS Constitution [clause 3 (3 (a) (b) (c) and (d) and 6]:** Bodies representing patients, bodies representing staff, carers and local authorities must be consulted when the NHS Constitution has its 10 year review; and carers have been added to the list of people on whom the effect of the constitution must be reported.<sup>9</sup>
- **Quality Accounts [clause 9(8)]:** Premises that a provider does not control (e.g. a patient's home) and those that patients do not directly access (e.g. a pathology laboratory) are exempt from the requirement to display Quality Accounts.<sup>10</sup>
- **Delegated Powers:** The House of Lords Delegated Powers and Regulatory Reform Committee made two recommendations relating to two measures in the Bill, one relating to the provisions on Quality Accounts and one to those on Trust Administrators.<sup>11</sup> The Government introduced amendments on Report to act on the recommendations.<sup>12</sup> In brief the changes are:

In the Bill as introduced in the House of Lords, regulations to omit providers of services from the duty to publish Quality Accounts were to be subject to the affirmative procedure the first time that the Secretary of State's power to issue them was exercised. The Joint Committee did not think that this was necessary and recommended the negative procedure, which is now what the Bill specifies.

The Bill originally provided for different mechanisms to be used in relation to NHS Trusts and PCTs (Regulations and Directions respectively).<sup>13</sup> The Joint Committee recommended that they should be consistent. The Bill now specifies Directions in both cases so that Parliamentary scrutiny is not necessary.

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<sup>7</sup> HL Deb 12 May 2009 c928-943

<sup>8</sup> HL Deb 28 April 2009 c115-120. The voting figures were 122 for Lord Howe's amendment and 11 against.

<sup>9</sup> HL Deb 28 April 2009 c162-5

<sup>10</sup> HL Deb 28 April c167-170

<sup>11</sup> [House of Lords Delegated Powers & Regulatory Reform Committee, 3<sup>rd</sup> Report of Session 2008-09, HL Paper 29 of 2008-09](#) See also the Government's responses in [House of Lords Delegated Powers & Regulatory Reform Committee, 4<sup>th</sup> Report of Session 2008-09, HL paper 48 of 2008-09](#) and [Delegated Powers & Regulatory Reform Committee, 6<sup>th</sup> Report of 2008-09, 2 April 2009 HL Paper 73 of 2008-09](#) .

<sup>12</sup> HL Deb 28 April 2009 c172-3

<sup>13</sup> Where the Secretary of State specifies an additional person from whom the Trust Special Administrator(TSA) should request a written response or with whom the TSA should meet.

- **Direct Payments [clause 11: section 12B (2) (g) of the NHS Act 2006]:** Advice, information and support for recipients of Direct Payments have been added to the list of topics that regulations may cover.<sup>14</sup>
- **Direct Payments [clause 11: section 12C (5) and (6) of the NHS Act 2006]:** Provisions about the way reviews of pilot schemes are to be carried out (e.g. by an independent person) and matters that the reviews should consider (e.g. the effect on the cost or quality of care) have been added to the list of subjects on which regulations for reviews may cover.<sup>15</sup>
- **Innovation Prizes [clause 14 (2) (a)]:** The Bill now says explicitly that innovation prizes include research.<sup>16</sup>
- **Trust Special Administrators [clause 15: section 65K (2) and 65W (2)]** The Bill now says explicitly that the Secretary of State must give reasons for his decision on a report about an unsustainable NHS provider from the Trust Special Administrator.
- **Private patient cap for Foundation Trusts [clause 34]:** The Bill now includes a new clause (which applies to England only) that would enable regulations to specify that NHS Foundation Trusts could develop private services outside the current limit as long as they benefit the NHS. This was an amendment moved by Lady Meacher (Crossbencher), which had support from Conservatives and Liberal Democrats as well as Lord Warner (a former Labour Health Minister) and on which the Government was defeated by 191 votes to 133.

## 5. Extent

Most of the provisions in the Bill extend to England and Wales only. Of those extending in principle to England and Wales, most are applied to England only by definitions within the Bill, for example, all those in Part 1. Overall, the Bill contains provisions that apply to England only, to Northern Ireland only, to England and Wales, to England, Wales and Northern Ireland, and to the UK. Details are given in the relevant sections of this Research Paper and full details of the extent and application of the Bill are in its Explanatory Notes.<sup>17</sup>

## 6. Structure of this Library Research Paper

This Library Research Paper takes each of the nine non-tobacco topics in turn. Except where the debates and responses were very brief or non-existent, the first section on each topic is a short outline of the Bill's provisions; the next section explains the background and context of the provisions; and the third contains a summary of responses to the Bill, firstly during the debates in the House of Lords and secondly from other sources. **Please note** that the external responses are based on a selection

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<sup>14</sup> HL Deb 12 May 2009 c930-933

<sup>15</sup> HL Deb 12 May 2009 c930-933

<sup>16</sup> HL Deb 12 May 2009 c933-4

<sup>17</sup> [Health Bill 18- EN 2008-09, pages 11-15](#)

available to the Library at the time this paper was in preparation. As indicated, many of them relate to the Bill as it passed through the Lords. The clause references may therefore relate to earlier versions of the Bill.

## II The NHS Constitution for England

*The Bill's provisions on the constitution apply to England only. There has however, been some UK-wide action on the principles of the NHS. Paragraph 77 of the Bill's Explanatory Notes says:*

*The Constitution is for the NHS in England only. However, on 3rd July 2008, England, Scotland, Northern Ireland and Wales committed to a high-level statement declaring the principles of the NHS across the UK. This was to reaffirm that the underlying principles of the NHS across the UK remain the same, even as the way the NHS provides care may vary between the four countries, reflecting their different needs and circumstances.<sup>18</sup>*

### A. The Bill (clauses 1-7)

Clauses 1-7 of the Bill contain provisions relating to the NHS Constitution and its explanatory Handbook but do not include the Constitution or Handbook themselves. These were published as separate documents by the Department of Health in January 2009.<sup>19</sup>

**Duty to have regard to the Constitution:** The Bill requires NHS bodies to have regard to the constitution in performing NHS functions. The bodies are: Strategic Health Authorities, Primary Care Trust, NHS Trusts, Special Health authorities, NHS Foundation Trusts, the Independent Regulator of NHS Foundation Trusts (Monitor), the Care Quality Commission, plus other bodies providing NHS services under contract or by arrangement. This would include, among others, private sector providers of NHS services, GP Practices, and NHS "high street" dentists.

**Production of the NHS Constitution and its Handbook:** The Bill sets out duties of the Secretary of State in relation to the production and publication of the Constitution and Handbook, including duties to review and revise them.

In relation to the Constitution, the Secretary of State must: hold a consultation before making any revision to it; carry out a review at least once every ten years (also involving consultation), the first one being no later than 5 July 2018; and publish the constitution after any revision. The Bill lists who must be consulted. (The list was extended during the

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<sup>18</sup> [Health Bill \[hl\], Bill 92 of 2008-09 -EN.](#)

See also *Department of Health Press Notice*, "All UK Health Ministers affirm commitment to core principles of NHS" 3 July 2008:

<http://nds.coi.gov.uk/Content/Detail.asp?ReleaseID=372778&NewsAreaID=2>

<sup>19</sup> [The NHS Constitution for England, The Handbook to The NHS Constitution for England](#) , 21 January 2009

Bill's passage through the House of Lords.) The guiding principles may not be revised as a result of a 10 year review except in accordance with regulations.

In relation to the Handbook, the Secretary of State must carry out a review once every three years; must complete the first review no later than 5 July 2012; and must publish the Handbook after any revision. There is no requirement to consult.

**Report on the effect of the Constitution:** The Bill requires the Secretary of State to publish every three years, and lay before Parliament, a report about the effect of the NHS Constitution on patients, staff, carers and members of the public, the first of which must be no later than 5 July 2012.

## B. Background

### 1. Emergence of the idea

Many of the early proposals for an NHS constitution were aimed at taking the NHS "out of politics" by setting up a separate body to run the NHS on a day to day basis, possibly similar to the arrangements at the BBC or the Bank of England. This is somewhat different from the NHS Constitution that did emerge, which is primarily intended to consolidate and make explicit existing rights and responsibilities relating to the NHS.

An early example is, *New Life for Health*, the report of a group called *The Commission on the NHS* chaired by Will Hutton,<sup>20</sup> published in 2000, which contained a draft "National Health Constitution Act", which would have set out principles and provided for the execution of NHS national policy to be the responsibility of a body separate from the Department of Health.

In the same year, the NHS Alliance<sup>21</sup> report, *Implementing the Vision*, was published. The press notice that the Alliance issued about the report said that the NHS was too important to be left under direct political control:

The National Health Service is too important to be left under direct political control. Instead, says the NHS Alliance, it should be set up as an independent, non-departmental public body. The Government of the day should define - and publish - an explicit description of what services should be funded by the taxpayer and agree the cost with the NHS.

This is just one of the radical recommendations in the NHS Alliance report *Implementing the Vision*, to be published tomorrow (Friday 10 March). The report was produced by a think-tank that included GPs, nurses, managers and lay representatives - the sharp end of the Primary Care led New NHS.<sup>22</sup>

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<sup>20</sup> The commission was set up in March 1999 by the now defunct Association of Community Health Councils for England and Wales in order independently to examine the issue of the public interest, and how it is served by the system of accountability in the NHS.

<sup>21</sup> The NHS Alliance described itself on the press notice as the independent body representing Primary Care Groups and Trusts, GPs, nurses, other professionals and lay people in primary care.

<sup>22</sup> *NHS Alliance Press Notice* 9 March 2000: "End Political Control of the National Health Service" [http://www.nhsalliance.org/media.asp?display=press\\_release&press\\_release\\_id=17](http://www.nhsalliance.org/media.asp?display=press_release&press_release_id=17)

By 2006 the idea had attracted the attention of both Conservative and Labour politicians. For example, in February 2006, the *Health Service Journal* reported an exclusive interview with David Cameron headed, *Tory leader proposes Bank of England-style separation of powers to bring stability....* The article said that he was considering remoulding the NHS along the lines of the Bank of England, where an independent committee decided on interest rates. He was quoted as saying that he had asked his party's policy group on public service improvement to consider whether a similar distinction between policy-making and delivery could be made in the NHS.<sup>23</sup>

On the eve of the Labour Party conference of that year (2006), the *Guardian* reported that the Labour Party would be considering a constitution for the NHS similar to the BBC Charter<sup>24</sup> and Andy Burnham, then Minister at the Department of Health, wrote in an article in *Progress* magazine:

One way to give permanent reassurance about our enduring values without stifling local innovation may be an NHS Constitution, perhaps along the lines proposed by Will Hutton in his book *New Life for Health: The Commission on the NHS*. This would set out the values and principles we share and that are not up for debate, while providing the framework within which any changes could take place. In a similar way to the BBC Charter process, the NHS Constitution could be renewed every 10 years through a wide-ranging and inclusive debate about what we want our NHS to be in the future.

Much of the detail has to be worked out, such as whether a legal constitution would cause practical problems to the NHS. But such a package has the potential to unite the coalition that believes in the NHS.....<sup>25</sup>

In his speech to the party conference on 25 September 2006, Gordon Brown spoke generally about shifting power from the centre and separating public policy-making from the independent administration of daily business. But he did not relate this to the NHS specifically. Gordon Brown was then Chancellor of the Exchequer and had not yet been chosen as Tony Blair's successor but his speech attracted particular attention as Tony Blair had already announced that he would stand down as Prime Minister, and Gordon Brown subsequently became Prime Minister in June 2007.

## 2. The present Government's plans

The NHS Constitution for England that is the subject of the Bill currently before Parliament stems from the NHS Next Stage Review, led by Lord Darzi. The review was, announced in a statement on 4 July 2007 by Alan Johnson, Secretary of State for Health,<sup>26</sup> with terms of reference that referred to an NHS constitution:

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<sup>23</sup> *Health Service Journal*, 9 February 2006, page 6.

<sup>24</sup> "Labour unveils plans for BBC-style charter for NHS: Blair supporters lay out radical blueprint on eve of party conference, *The Guardian*, 23 September 2006.

<sup>25</sup> "An NHS constitution could help unite the coalition of support for the health service", *Progress Magazine Online*, 23 September 2006: <http://www.progressonline.org.uk/Magazine/article.asp?a=1399>

<sup>26</sup> HC Deb 4 July 2007 c961-978

... The review should consider the case for a constitution of the NHS as the basis of a sustainable and lasting settlement that meets these challenges, enhances local accountability, secures value for money and protects the fundamental values that the NHS has always embodied.....<sup>27</sup>

In a summary letter to Gordon Brown and Alan Johnson about his October 2007 interim report, Lord Darzi associated the idea of an NHS constitution with removing the NHS from the thrust of day to day politics:

....I also have come to the view that the NHS could benefit from greater distance from the day to day thrust of the political process, and believe there is merit in exploring the introduction of an NHS Constitution. I have therefore asked NHS Chief Executive, David Nicholson, to chair a national working group of experts to consider the scope, form and content that such a Constitution might take.<sup>28</sup>

The final report published on 30 June 2008, the week of the 60<sup>th</sup> anniversary of the NHS, contained a chapter on the NHS Constitution, *Secured today for future generations*, which set out the case for one. It described what an NHS Constitution would do:

- Secure the NHS for the future. The Constitution will set out clearly the enduring principles and values of the NHS, and the rights and responsibilities for patients, public and staff.
- Empower all patients and the public. Patients already have considerable legal rights in relation to the NHS, but these are scattered across different legal instruments and policies. Some are obscure; many people are not aware of all of their existing rights. The Constitution will empower all patients by summarising all existing rights in one place.
- Empower and value staff. NHS services are provided by over 1.3 million staff. Those staff are our most important resource. For the NHS Constitution to be an enduring settlement, it needs to reflect what we are offering to staff: our commitment to provide all staff with high quality jobs along with the training and support they need.
- Create a shared purpose, values and principles. As the providers, including those from the third and independent sectors are offering NHS-commissioned services. Patients expect that wherever they receive their NHS funded treatment, the same values and principles should apply. All organisations are part of an integrated system for the benefit of patients. That is why we will set out the purpose, principles and values for the NHS in the Constitution. We propose that all organisations providing NHS services are obliged by law to take account of the Constitution in their decisions and actions.
- Strengthen accountability through national standards for deliver. The NHS is held to account nationally through Parliament, even though services are delivered locally. The Constitution is an opportunity to clarify

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<sup>27</sup> [Department of Health Press Notice, Shaping health care for the next decade](#), 4 July 2007

<sup>28</sup> [Our NHS Our future: NHS next stage review - interim report](#), October 2007

and strengthen both national and local accountability. In discussions with patients, public and staff, we have received a clear message that they are committed to the NHS as a national system, paid for out of general taxation; from which they can expect certain standards of care and access. The draft NHS Constitution therefore makes clear what people can expect from the NHS no matter where they live.<sup>29</sup>

The consultation document containing the draft constitution and its accompanying draft handbook were published the same day (30 June 2008), with a closing date for the consultation of 17 October 2008. The Constitutional Advisory Forum (CAF), a group of leading figures from within the NHS and from other bodies, was asked by the Secretary of State to support the consultation process for the NHS Constitution.<sup>30</sup>

Alan Johnson's accompanying statement explained:

Our proposal is to legislate so that all NHS bodies, and independent and third sector providers of NHS services, must take account of the constitution in their decisions and in their actions. The Government will be required to renew the constitution every 10 years, involving the patients who use it, the public who fund it, and the staff who work in it. No Government will be able to erode or undo the fundamental basis of the NHS without the consent of the people's elected representatives.<sup>31</sup>

Andrew Lansley, responding for the Conservatives, said:

The Government have followed our lead in proposing an NHS constitution, but where in that is the incorporation of NHS values? Why have two of the NHS principles set out in the NHS plan – continuity in respect of those principles would help the NHS – gone missing, including the principle that the NHS will support and values its staff? If it is a real constitution, where are the definitions and duties of NHS bodies; and where is the operational autonomy and independent regulation so essential to a more autonomous and patient-centred service? A constitution needs to be more than a patients charter, important as such patients' rights are. If the NHS continues legally to be whatever the Secretary of State decides it is, the power will still live in the Department of Health, which is clearly what the Department of Health intends.<sup>32</sup>

Norman Lamb, responding for the Liberal Democrats, said:

As for the constitution, although I endorse the case for clarity on rights and responsibilities, will patients be given legally enforceable rights or is this a "motherhood and apple pie" statement of ultimately meaningless intent? What will be done, for example, to end the scandal of the mixed-sex wards that still exist in our hospitals, particularly in the mental health sector?

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<sup>29</sup> [High Quality Care For All: NHS Next Stage Review Final Report, CM 7432](#), June 2008 pages 77-78

<sup>30</sup> Its report on the NHS Constitution: [Report of the Constitutional Advisory Forum to the Secretary of State for Health](#), was published on 11 December 2008 alongside a number of related documents.

<sup>31</sup> HC Deb 30 June 2008 c593-608 (speech and responses)

<sup>32</sup> HC Deb 30 June 2008 c597-8

I am very concerned about the lack of any reference to mental health in the statement. The Secretary of State will be aware of yesterday's devastating analysis of the state of mental health services by the new president of the Royal College of Psychiatrists. The 18-week target is absolutely irrelevant to anyone with a mental health problem. Can it be right for this to continue? Is it not bizarre that patients will have a legal right to a drug to suppress their condition, but no right to the treatment that could cure them? Surely that is ridiculous.<sup>33</sup>

### 3. The NHS Constitution for England

The Constitution (12 pages) and Handbook (144 pages) were published on 21 January 2009.<sup>34</sup> The Constitution sets out in one place NHS principles, rights and responsibilities of patients and staff, as well as a number of Government pledges. It does not change the structure or governance of the NHS. The supporting Handbook explains the legal basis for these rights, describes means of redress and provides further information about NHS policy. At the same time the Government's response to the consultation<sup>35</sup> and *The Statement of NHS Accountability*, which describes the roles and responsibilities of NHS providers,<sup>36</sup> were published.

In addition to its role in relation to the NHS, the Constitution has been held up by the Government as an example of its general approach to public services:

The Government has made clear that the state's role should be to set national priorities and minimum standards, whilst providing support and a fair distribution of resources. A clear framework, established by the Government in conjunction with regulators and inspectorates, sets out the standards below which providers must not fall. In this context the Government remains committed to further raising standards and eradicating underperformance. For example, the new NHS Constitution will set out clearly what patients can expect from the NHS, including legal rights and patient pledges.<sup>37</sup>

The Government's response to the consultation<sup>38</sup> said that no fundamental alterations resulted from the consultation but the text was clarified and strengthened, for example, the distinction between rights and pledges was clarified; new rights were added (the right to receive certain vaccinations and the right to information to support choice – see below); and the Handbook was revised. Annex 1 of the document covers changes made in response to the Constitutional Advisory Forum and Annex 2 how the final NHS Constitution was changed from the original draft.<sup>39</sup>

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<sup>33</sup> HC Deb 30 June 2008 c605

<sup>34</sup> [The NHS Constitution for England](#), [The Handbook to The NHS Constitution for England](#) , 21 January 2009

<sup>35</sup> Department of Health, [The NHS Constitution: Government response to consultation](#), 21 January 2009

<sup>36</sup> [The Statement of NHS Accountability for England](#), 21 January 2009

<sup>37</sup> [House of Commons Public Administration Select Committee, From Citizen's Charter to Public Service Guarantees: Entitlements to Public Services: Government Response to the Committee's Twelfth Report of Session 2007–08, Twelfth Special Report of Session 2007–08, HC 1147](#), 17 November 2008.

<sup>38</sup> Department of Health, [The NHS Constitution: Government response to consultation](#), 21 January 2009

<sup>39</sup> Department of Health, [The NHS Constitution: Government response to consultation](#), 21 January 2009

According to Government statements, there are three new rights in the Constitution, all intended to come into effect from 1 April 2009 under separate regulations and directions; other rights listed are already enforceable under existing laws.<sup>40</sup> The three new ones are set out below, with brief notes about the way that they have been implemented.

- A right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation recommends under an NHS-provided national immunisation programme.

*This is introduced by regulations requiring the Secretary of State to make arrangements to ensure, so far as is reasonably practicable, that the recommendations of the JCVI are implemented.*<sup>41</sup>

- The right to choice: meaning that any person requiring an elective referral may choose any clinically appropriate secondary care provider for their first consultant-led outpatient appointment and has a right to information to support that choice. This right is based on existing policy and includes a new element, a right to information to support that choice. Certain areas, such as maternity services, are currently excluded but may be included in future.

*The 2008-09 policy guidance is on the Department of Health's website.*<sup>42</sup> *This has now been reinforced by legally binding Directions from the Secretary of State to Primary care Trusts (PCTs) issued on 21 January 2008. The Department of Health has also issued guidance for PCTs to help them implement the Directions.*<sup>43</sup>

- The right to expect local decisions about drugs and treatments (generally those about which NICE has not yet made a recommendation) to be made rationally following a proper consideration of the evidence.

*Directions designed to clarify Primary Care Trusts' responsibilities regarding local decision making about the funding of medicines and other treatments were issued on 12 March 2009. The NHS chief executive also sent a letter that day to SHA and PCT chief executives about the Directions and other measures being taken to support this right.*<sup>44</sup>

The Constitution itself is not in the Bill but there is a duty for NHS bodies to have regard to it (see section A above). In his speech on Second Reading of the Bill in the House of Lords, Lord Darzi explained why the Government had decided to keep the Constitution itself out of the Bill:

The Government carefully considered a number of approaches to the constitution. Options ranged from setting out detailed provisions in primary

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<sup>40</sup> See, for example, Lord Darzi's speeches on Second Reading in the House of Lords, HL Deb 4 February 2009 c672-3 and c750; [Department of Health Press Release, "First NHS constitution launched"](#), 21 January 2009; and Alan Johnson's Written Ministerial Statement, *NHS Constitution for England*, 21 January 2009 HC Deb 32WS.

<sup>41</sup> *The Health Protection (Vaccination) Regulations SI 2009/38*. Information supplied by Dr. Gavin Colthart, Science and Environment Section of the House of Commons Library.

<sup>42</sup> Guidance on the policy, [Choice at referral: guidance and supporting information for 2008/9](#), is available on the Department of Health's website.

<sup>43</sup> [The Primary Care Trusts \(Choice of Secondary Care Provider\) Directions 2009](#)

<sup>44</sup> [Directions to primary care trusts and NHS trusts concerning decisions about drugs and other treatments 2009](#) and related [Dear Colleague Letter from David Nicholson, NHS Chief Executive 21 January 2009](#).

legislation to no constitution at all. The risk of the former is a rigid legislative framework in which complex decisions about NHS care become the prerogative of the courts. The risk of the latter is a missed opportunity. The approach taken by the Government will empower patients, the public and staff without creating a “lawyers’ charter”.

## **C. Responses to the Bill’s provisions on the NHS Constitution**

When it commented on the draft version of the NHS Constitution, the Health Select Committee noted witnesses’ contradictory concerns, on the one hand, that the Constitution should not be a “lawyer’s charter”, on the other, that the Constitution would be regarded as meaningless waffle.<sup>45</sup> That dilemma can be seen in the House of Lords debates on the Bill and in the responses to the final version of the Constitution and the Bill.

Some reactions have been more extreme. For example, one author described the draft version of the Constitution as “seven parts platitude, two parts mendacity, and one part hypocrisy,”<sup>46</sup> and some, such as the BMA, expressed disappointment that it had not set up a more independent governing structure for the NHS.<sup>47</sup> But the NHS Constitution was also welcomed by many. When it was published in January 2009, the Financial Times reported that it received divergent reactions. The article added:

Some patient groups and NHS bodies warmly welcomed the constitution. Others were more sceptical.<sup>48</sup>

### **1. Debates in the House of Lords**

Neither of the two main opposition parties opposed the introduction of the NHS Constitution although they did have a number of concerns. In Committee minor, technical Government amendments were passed but otherwise there was no change. On Report, a number of Government amendments and one opposition amendment were passed, the latter on a division in which the Government was defeated. At Third Reading the latter was removed and replaced by a similar Government amendment.<sup>49</sup>

#### ***General approach of Conservatives and Liberal Democrats***

The general attitudes of the Liberal Democrats and the Conservatives were set out during the Second Reading on 4 February 2009.

Lady Barker, speaking for the Liberal Democrats, said:

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<sup>45</sup> [House of Commons Health Committee, First Report of Session 2008-09, \*NHS Next Stage Review\*, HC 53-I](#), 13 January 2009. Volume II contained the evidence.

<sup>46</sup> “The emperor’s new constitution,” by Iona Heath, *BMJ*, 4 October 2008

<sup>47</sup> See “Operational independence for the NHS”, Rhema Vaitianathan and Geraint Lewis, *BMJ* 16 August 2008 page 380-382 for a discussion about how such a set-up might work.

<sup>48</sup> “*NHS ‘constitution’ is bitter pill to swallow for critics*” *Financial Times*, 22 January 2009

<sup>49</sup> The dates of the debates on the NHS Constitution were: House of Lords Grand Committee 23 February GC 1-54 and 26 February GC 147-156; Report 28 April c111-119 and 133-136; Third Reading 12 May c928-943

I start with the constitution. The first and obvious point is that it is not a constitution; I do not know what it is, but it is not a constitution. I understand from talking to people, including some of those who worked on it, that this statement of intent, or whatever it is, should not be used by individual patients to further arguments with clinicians. Rather, it sets out the general relationship between the NHS and its patients. As such, it is an important document which tries to set out some strategic issues that have a big influence on healthcare.

For that reason, we on these Benches have two regrets: two issues are missing. The first is a statement of clear principles about the use of patient data. I do not want to rerun the arguments made by the noble Lord, Lord Turnbull, but that is an ongoing issue that has never been resolved. Patients are fearful of confidentiality being breached, and researchers are frustrated by lack of access to anonymised data. That key point should have been included. Secondly, as the Local Government Association points out, if we are to reach the stated aims of overcoming health poverty, reducing mortality and improving efficiency and delivery of care, there needs to be full co-operation between the NHS and local government. I regret that there is no requirement on the NHS fully to co-operate with local government in the document.<sup>50</sup>

Lord Howe, speaking for the Conservatives, said:

When it comes to the NHS Constitution, my reaction is little different from that of many other noble Lords: one cannot sensibly oppose it. Indeed, it was my own party that originally proposed the idea of an NHS constitution some time ago. I agree with what has been said; there is a benefit to be gained from articulating in a single document those values and principles which characterise the way in which the NHS goes about its work alongside the rights and pledges which patients of the NHS should be able to rely on. Restating all these things is by no means a sterile exercise. It serves to refresh the mission and purpose of the health service and, one hopes, underpin public trust.

On the whole, I think the constitution reads very well. There is only one small problem. If you look for the constitution or any part of it in the Bill, it is nowhere to be seen. Not even the founding principles of the NHS are included here. What is more, they will not appear before us in a formal way at any time in the future, either in regulations or in any other statutory form. With all the talk in the constitution about parliamentary accountability, that is rather regrettable. Indeed, one has the feeling in this particular context that Parliament is something of an irrelevance. When we reach Grand Committee, I think we need to challenge the Minister on that point.

The other noticeable thing about the NHS Constitution is the one mentioned by the noble Baroness, Lady Barker, in that it is not really a constitution in the accepted sense at all. One of the defining features of a constitution is that it should serve to provide clarity on issues of principle that are likely to prove contentious and to act as a point of reference when disputes or matters of definition need to be settled. Section 1 of the National Health Service Act 2006, for example, speaks of a “comprehensive health service”, and the constitution

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<sup>50</sup> HL Deb 4 February 2009 c744

itself echoes that phrase. If we look for a definition of what the word “comprehensive” should actually be taken to mean, we will be disappointed. It would have been helpful to know the extent to which people have a right to access NHS dentistry, an issue of widespread concern, but the constitution is silent on dentistry altogether.

Similarly we all remember that one of the most knotty and contentious issues of health policy in 2008 concerned NHS top-ups. In precisely what circumstances should a patient who is receiving healthcare in the private sector be denied access to the NHS? It is a question of fundamental significance but the constitution fails to answer it. The Minister will know only too well, and it has been mentioned today, that the issue of mixed-sex accommodation has been a highly charged one for more than a decade. Does the constitution take us anywhere near an understanding of what NHS patients have a right to expect in this area? It does not.

The NHS constitution seems to be a lost opportunity. Equally, some of us would have liked to see within it a clear articulation of how and to whom the powers, rights and responsibilities within the health service are allocated and distributed. Constitutions are normally a convenient vehicle for defining the broad structure of governance within an organisation, but not here. Ministers have told us, and we have to accept, that the constitution was never intended to create any new legal rights for patients. Given that, it seems a distinct pity that it has ended up ducking some of the key issues of structural definition.

I am not wholly clear why it is necessary to incorporate in statute a duty for NHS bodies and independent sector organisations to have regard to the NHS constitution. The Secretary of State already has a power of direction. Why would it not be sufficient for him to issue a Section 8 direction to health service bodies under those existing powers and to achieve the same result with independent sector providers by means of contractual obligations? Perhaps the Minister will be kind enough to tell me. If it turns out that the Government could have created that duty by another and more straightforward route, we need to ask why they did not do so. If there was another route open to them, this part of the Bill looks suspiciously like political grandstanding.

Ultimately, as noble Lords have said, the test of the constitution will be the added value that it brings to patients and staff. We owe it a fair wind, but I wonder how close we will come to being able to measure its effectiveness with any degree of precision.<sup>51</sup>

### ***Points raised during the debates***

Some of the main issues raised are outlined below (in the order in which they were first debated). The list is intended to give a flavour of the debate and not to provide a comprehensive account. Unless otherwise specified, Government amendments were successful and non-Government ones were not.

- Whether NHS core principles should be listed on the face of the Bill (amendment moved by Lord Howe): Lord Darzi’s response was that the Government had

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<sup>51</sup> HL Deb 4 February 2009 c746-8

chosen not to include any principles in the Bill itself because it did not want to create a “lawyer’s charter” or to set the principles in stone.<sup>52</sup> The issue was raised again in a different form on Report when Lord Howe moved an amendment to enable the Secretary of State to make provision for the principles in regulations. At this stage Lord Darzi argued that such provision was not necessary but the amendment was carried by 122 to 188<sup>53</sup> and, on Third Reading, the Government agreed that Parliament should be given an opportunity to scrutinise any changes to the principles. Lord Howe accepted the Government’s reformulation of his amendment<sup>54</sup> and the Bill now contains provisions requiring the Secretary of State to make regulations under the negative procedure to address any changes to the guiding principles.

- Whether the duty to “have regard” to the Constitution should be strengthened by including the Handbook as well as the Constitution (amendments moved by Lady Barker and new clause moved by Lord Howe): Lord Darzi’s response was that the Handbook was not a legal document and had a relationship to the Constitution similar to the relationship between a Bill and its Explanatory Notes. In addition, if there was an obligation to have regard to the Handbook, there would be a case for a more formal process for updating it and imposing a requirement to consult, which would make changes slow and cumbersome.<sup>55</sup> The issue was raised again on report on an amendment moved by Lord Howe.<sup>56</sup>
- Whether enforcement of the Constitution should be strengthened by requiring the Secretary of State to publish guidance on the meaning of “to have regard to” the Constitution (amendment moved by Lord Howe). Lord Darzi’s response was that this would overly prescriptive and would change the nature and spirit of the Constitution. To “have regard to” was a recognised legal term. To go further and require compliance would create the kind of lawyers’ charter that the Government wanted to avoid and would be impossible for some parts of the Constitution, for example, the principle of compassion. But this did not mean that the Department of Health would not provide the NHS with help in meeting its obligations.<sup>57</sup> The issue was raised again on report on an amendment moved by Lord Howe.<sup>58</sup>
- Whether the NHS Constitution and Handbook should be “readily available” rather than just “available” as the Bill proposed (withdrawn amendment moved by Lord Howe). Lord Darzi’s response was that these documents would be readily available but if the Committee was not convinced, he was happy to look at the matter again on Report.<sup>59</sup>

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<sup>52</sup> HL Deb 23 February 2009 GC 2-18

<sup>53</sup> HL Deb 23 February 2009 GC 115-120

<sup>54</sup> HL Deb 12 May 2009 c928-930

<sup>55</sup> HL Deb 23 February GC 18-23

<sup>56</sup> HL Deb 28 April c133-136

<sup>57</sup> HL Deb 23 February 2009 GC23-27

<sup>58</sup> HL Deb 28 April 2009 c157-162

<sup>59</sup> HL Deb 23 February 2009 GC27-31

- Whether all NHS bodies should be required to consult their local authority every year on the adequacy of their local accountability (amendment moved by Lady Barker). Lord Darzi's response was that there was already an extensive system of local accountability in the NHS.<sup>60</sup>
- Whether certain people or bodies should be consulted about the 10-year review and revisions to the Constitution (various amendments moved). Lord Darzi's response in Committee was that extra provision to cover these bodies and groups was not needed as they were implicitly covered by the Bill. But he had some sympathy with the arguments for recognising certain persons or bodies explicitly.<sup>61</sup> On report the Government introduced an amendment to mention explicitly bodies representing staff, bodies representing patients, carers and local authorities as bodies/people who would have to be consulted when the Constitution had its 10 year review. Carers were also added to the list of people on whom the effect of the constitution would have to be reported.<sup>62</sup>
- Whether the Secretary of State should be required to take into account the impact on bringing together health and social care when conducting a review of the NHS Constitution (amendment moved by Lady Barker). Lord Darzi's response was that the Bill did not specify any areas that the review should take into account over and above others and he did not believe it was appropriate to do so.<sup>63</sup>
- Whether the Secretary of State should be required to lay a copy of any revised version of the NHS Constitution before Parliament as an "Act paper" (amendment moved by Lord Howe). Lord Darzi responded that the Government would always expect to make a document of such importance available to parliamentarians, usually by placing a copy in the Library and issuing a Written Ministerial Statement. Indeed Ministers were bound by the Ministerial code to make important announcements to Parliament.<sup>64</sup>
- Whether the word "patient" should be clarified (amendment moved by Lady Barker). Lord Darzi responded that recent and potential patients, as well as current patients, were covered by the provisions to consult "members of the public" on changes to the NHS Constitution.<sup>65</sup>
- Whether the Handbook should be reviewed and reports on the effect of the Constitution should take place every 5 years instead of the 3 years proposed in the Bill (amendments moved by Lady Barker). Lord Darzi responded that in contrast with the Constitution, which was intended to be an enduring document and reviewed every 10 years, the Handbook was an explanatory guide setting out

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<sup>60</sup> HL Deb 23 February 2009 GC31-37

<sup>61</sup> HL Deb 23 February 2009 GC 37-50

<sup>62</sup> HL Deb 28 April c62-7

<sup>63</sup> HL Deb 23 February 2009 GC50-52

<sup>64</sup> HL Deb 23 February 2009 GC52-54

<sup>65</sup> HL Deb 26 February 2009 GC 147-149

current law and policies and therefore needed to be kept up to date. He also believed that the timing of the review and report on the effect of the Constitution should be aligned.<sup>66</sup>

- Whether there should be a requirement to consult on the review of the Handbook, (amendment moved by Lady Barker, taken with a similar amendment from Lord Howe). Lord Darzi responded that it would not be proportionate to require consultation on changes to the Handbook in addition to the required consultation on the Constitution although he was happy to look at the wording of the Bill.<sup>67</sup> The issue was also raised on Report (amendment moved by Lord Howe).<sup>68</sup>
- The debates on the Constitution were also used to raise a number of other issues, for example

Contaminated blood products (c136-144)

The role of specialised commissioning groups (c144-147)

Scientific research and education & training (c147-157)

## 2. Briefings on the Bill

### a. *British Medical Association Briefing for the Second Reading in the House of Lords*

**Chapter 1, Clause 1 – NHS Constitution** The BMA has been a vocal supporter of the concept of a NHS constitution. It is the BMA's belief that a clearly articulated set of values that reflect a shared consensus concerning the nature and purpose of the NHS will strengthen the public's trust in it. The BMA considers that a constitution, properly constructed, offers the means to maintain the public's confidence in the NHS and safeguard its future. Similarly, for those who work in the NHS or are entrusted with its governance, a fixed point of reference would help to strengthen their relationship with the NHS, guide behaviour and inform their stewardship of the health service. Consequently, the BMA has been welcoming of the Secretary of State for Health's recent focus on the development of a NHS constitution.

However, we are disappointed that the Constitution as now recently established does not signal a more fundamental revision of the way in which the NHS is governed. Whilst the Constitution sets out clearly what the patients and public can expect from the NHS and how accountability is expected to operate across its structure and functions, we believe that an opportunity has been missed to provide the NHS with greater freedom in order to achieve an enlarged degree of operational independence and markedly depoliticise the day-to-day running of the NHS.

**Chapter 1, Clause 2 – Duty to have regard to the NHS Constitution** The BMA would like further clarification of the 'duty to have regard to the NHS Constitution' as detailed in Clause 2. It is not clear what this duty entails and what standard or

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<sup>66</sup> HL Deb 26 February 2009 GC 149-153

<sup>67</sup> HL Deb 26 February 2009 GC153-156

uniform criteria will be used to judge whether or not relevant bodies have acted adequately in this regard.

**Chapter 1, Clause 3 – Availability, review and revision of NHS Constitution** Concerns remain with regard to the Constitution's commitment to developing a responsive and service. Past experience and evidence suggest that there exist significant failings in enabling patients, public and staff to meaningfully engage in, and influence, NHS decision-making processes. Recent examples of service re-design involving poor levels of transparency and a lack of effective consultation reinforce this view. The BMA continues to be a strong advocate of patient and public involvement as an integral and collaborative process that is essential to grow productive partnerships between patients, the public, health professionals and policy makers. Consequently, we do not believe that the NHS Constitution goes far enough in determining a framework that will better enable and safeguard local accountability, both widening and strengthening the relationship between the health services at a local level and the population(s) they serve.

With specific reference to the Health Bill, in Clause 3, subsections (3) and (5), the undertaking to ensure that a wide range of stakeholders are consulted in respect of the review and revision of the Constitution does not adequately set out the nature and scope of said consultation such that transparency and confidence in this process are assured.

**Chapter 1, Clause 4 – Availability, review and revision of Handbook** There is no provision in Clause 4 for any requirement to consult in respect of review of the Handbook and any subsequent revision. We believe this should be addressed. The BMA was pleased that routine access to patient information without consent was not included in the Handbook.

**b. *King's Fund Second Reading Briefing, House of Lords***

Although its content is largely uncontroversial as it is based on existing legislation, the Constitution is ambitious in its scope and is a potentially useful way of clarifying the NHS' purpose. However, its content will not be established in legislation and its status as a 'declaratory document' leaves it vulnerable to change with every incoming government. For it to be worth of its name, the Constitution needs to be an enduring document. However, the King's fund welcome the Department of Health's decision to set a minimum of every three years for revising the Handbook that accompanies the Constitution to take into account developments in policy.

**c. *NHS Confederation Briefing for the Second Reading in the House of Lords***

The NHS Confederation is the independent membership body for the full range of organisations that make up today's NHS. Our members include primary care trusts, NHS trusts, NHS foundation trusts, ambulance trusts and independent providers of NHS services.

We support many of the proposals contained with the Health Bill, In particular, we believe that the NHS Constitution provides a useful statement of principles which should underpin the NHS, but the real test will be to provide, in time, that it makes a difference to the experience of patients and staff.

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<sup>68</sup> HL Deb 28 April 2009 c165-7

**d. *Royal College of Nursing Briefing for the Second Reading in the House of Lords***

The RCN recognises that an NHS Constitution presents a significant and historic opportunity to refresh and enshrine the NHS model and the principles underpinning the service for the next 60 years. The RCN was pleased to be involved, alongside other health professionals and trade unions, in its shape and formulation.

*Clause 2 – Duty to have regard to NHS Constitution*

This clause ensures that those organisations that provide or commission NHS services "must have regard to the NHS Constitution". This mandatory requirement is welcomed by the RCN.

However, the RCN has concerns that there is no statutory definition of what "have regard" will be or how is it expected that commissioners, managers or staff will demonstrate this regard in practice. Furthermore there is currently no provision for sanctions for any NHS organisation which fails to "have regard" to the NHS Constitution. The RCN believes that if the NHS Constitution is to be successful then there needs to be a robust enforcement process in place for those organisations that fail, or appear to disregard the statutory requirement to "have regard" to the NHS Constitution.

The RCN fears that the lack of definition for the meaning or scope of "have regard" will cause confusion and in the worst case scenario may result in a test case in the courts in order to provide clarity of the definition. The RCN wants to avoid this by providing a statutory definition that is clear to all users of NHS services. The impact and value of the NHS Constitution may be diminished if, for example, NHS providers and commissioners simply "regarding" the principles in the constitution only to disregard them at a later stage.

The RCN believes in the principles and concept of the NHS constitution and feels that this lack of clarity and enforcement has the potential to undermine it considerably.

*Clause 3 Availability, review and revision of the NHS constitution*

*Clause 4 Availability, review and revision of the NHS Handbook*

Any changes to the NHS Constitution will be subject to consultation, but the requirements for those to be consulted do not include RCN, or any trade union or professional body. The RCN has been involved in the development of the constitution through the NHS staffside group and the Constitution Advisory Forum. The RCN would like the involvement of NHS staff in future consultation enshrined in legislation.

As it stands changes to the NHS Handbook are not subject to consultation at all. The RCN understands that the Handbook is a summary of existing legislation, but given the impact of the Handbook on staff rights it would be prudent to build in a requirement for statutory consultation to ensure staff remain committed to the value and principles of the NHS Constitution.

The RCN also has concerns that while the Secretary of State must report on how the Constitution has affected patients, staff and members of the public, with the first report due by 5 July 2012, there is nothing in the Bill about how this review is carried out, or who is involved. The RCN supports the NHS Constitution and is

keen to ensure that public consultation takes place so that there is a transparent process for the evaluation of the impact of the NHS Constitution.

**e. Unison Briefing on Health Bill House of Lord Committee Stage**

4. NHS Constitution (clauses 1 – 5)

UNISON welcomes the specific naming of staff as a statutory consultee for any changes that are made to the Constitution. However, as set out in our Second Reading briefing, it is important that employee representative organisations, including trade unions, will be specifically consulted as part of any review process. At Second Reading, the Minister, Lord Darzi, provided some assurances that such organisations would be consulted. However, we would be keen to see these assurances written into the Bill.

We would therefore urge you to support the following amendment to clause 3 of the Bill: Page 3, line 15, at end insert –

“( ) trade unions and professional organisations representing staff.”

Much of the day-to-day detail of the Constitution is covered by the accompanying Handbook which the Bill proposes will be amended at least once every three years, a timetable that UNISON supports. Whilst not wanting to make the Handbook review process too cumbersome, UNISON would like assurances that key stakeholders, including staff and patients, are involved with proposed revisions to the NHS Handbook.

### III Quality Accounts

*The Bill's provisions on Quality Accounts apply to England only. They include one of the delegated powers on which the House of Lords Delegated Powers & Regulatory Reform Committee commented.<sup>69</sup>*

#### A. The Bill (clauses 8-10)

**Quality Accounts to be published once a year:** The Bill requires all healthcare providers working for the NHS to publish a “Quality Account” once a year. The NHS bodies required to publish such a document are listed as Primary Care Trusts, NHS Trusts (in England), Special Health Authorities, and NHS Foundation Trusts. Bodies providing NHS services under contract or by arrangement (as defined in relation to the duty to have regard to the NHS Constitution) would also be included.

**Regulations to specify content:** The Bill does not itself prescribe what information is to be contained in a *Quality Account* but makes provision for Regulations to do so. It also enables regulations to be made exempting bodies from all or parts of the requirements relating to publishing a *Quality Account*.

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<sup>69</sup> See changes to the Bill listed in the Introduction to the Bill at the beginning of this paper.

**Timing and publication:** The Bill includes the following requirements: the first reporting period for a *Quality Account* is to be the 12 months beginning with 1 April 2009; producers of a *Quality Account* must correct it if the Care Quality Commission or a Strategic Health Authority notifies them of an error or omission and they must include a statement explaining the correction; the document must be sent to the Secretary of State, who may specify the form it is to take for the purpose of enabling him/her to make it available to the public; providers must make a report (relating to a period of not more than two years before the request was made) available to any person requesting a copy; and the provider must display a notice in a conspicuous place at each of the sites at which NHS services are provided stating how the most recent document may be obtained (except where the provider does not have control of the premises or patients do not access the premises). The Bill also provides that regulations may impose various related requirements - about form, accuracy, publication and paying regard to any guidance published by the Secretary of State.

## B. Background

*High Quality Care for All*<sup>70</sup> was largely devoted to the issue of quality, with the general goal that every provider of NHS services should systematically measure, analyse and improve quality. It discussed various ways that this would be achieved, including strengthening the role of patients and introducing “clinical dashboards” to help clinicians. *Quality Accounts* were mentioned in a short section on publishing information for the benefit of patients and their carers:

16. Commitments have been made over a number of years to publish information on clinical effectiveness. Too often these commitments have been held up by uncertainties about what was needed to make progress and disagreements about who should be in charge. This is unacceptable. We should be seeking to create a more transparent NHS. It may be a complex task, but we should develop acceptable methodologies and then collect and publish information so that patients and their carers can make better informed choices, clinical teams can benchmark, compare and improve their performance and commissioners and providers can agree priorities for improvement.

17. Therefore, to help make quality information available, we will require, in legislation, healthcare providers working for or on behalf of the NHS to publish their ‘Quality Accounts’ from April 2010 – just as they publish financial accounts. These will be reports to the public on the quality of services they provide in every service line – looking at safety, experience and outcomes. Easy-to-understand, comparative information will be available on the NHS Choices website at the same time. The Care Quality Commission will provide independent validation of provider and commissioner performance, using indicators of quality agreed nationally with DH, and publish an assessment of comparative performance. (page 51)

In his speech on the publication of *High Quality Care for All*, Alan Johnson, Secretary of State for Health, said:

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<sup>70</sup> *High Quality Care for All: NHS Next Stage Review Final Report, Cm 7432*, June 2008. See Introduction above.

The power of information will be provided to the public. We will legislate so that all providers of NHS services will be required by law to publish quality accounts just as they publish financial accounts, which will detail the quality of care that they provide for each and every service, and easy-to-understand comparative information will be made available online....<sup>71</sup>

A more detailed account is contained in the Department of Health's Impact Assessment for the Health Bill, which describes the way that the Government envisages the way the Quality Accounts will work. The description encompasses measures that do not require legislation and some of the references to legislative requirements are not contained in the Bill but may be contained in regulations in the future. Extracts from the Impact Assessment are reproduced below:

#### *Policy Objective*

3.1 The ultimate objective of the overall quality framework is to raise the level and consistency of the quality of NHS services. Quality Accounts contribute towards achieving this ultimate objective through the publication of information on quality. This publication will allow easy access to quality information, with the intention of encouraging patients, the public and others to demand higher quality services from the NHS. In particular, the objectives of Quality Accounts are to allow:-

- the public to hold providers to account for the quality of NHS healthcare services they provide and to demand action from providers where they believe that providers are falling short on quality;
- patients and their carers to make better informed choices;
- commissioners and providers to agree priorities for improvement;
- NHS Trust Boards and their non-NHS equivalents to ensure that they place quality at the heart of their planning and delivery processes; and
- clinical teams to benchmark and compare their performance.

3.2 Each objective of Quality Accounts as stated above is, to some extent, already fulfilled by information which is currently available to patients, clinicians and managers, and by performance management mechanisms which already apply to NHS providers. However, there are some key gaps in ways in which information is provided, and in the way NHS providers are held to account for their delivery of NHS healthcare. We have considered a range of options for filling these gaps, as detailed in section 5 below, and placing a legislative requirement on providers to publish Quality Accounts is our preferred option.

3.3 In addition, a further important intermediate objective of Quality Accounts is to allow researchers to compare the effectiveness of different interventions, care processes, management structures and other determinants of care quality.

#### *Proposals for the content, form and publication of a quality account*

4.1 Our proposals for Quality Accounts are described in the paragraphs below.

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<sup>71</sup> HL Deb 30 June 2008 c595

4.2 The management of a provider – an NHS Trust Board or equivalent – will need to produce a Quality Account which provides a true and fair view of the quality of the services they provide. They will be required to sign the Quality Account to declare that, to the best of their knowledge, the Account as a whole represents a true and fair view.

4.3 Part of the Quality Account will be specified by the Department of Health and the content will be set out in regulations. This part will focus on key Departmental priorities. The information contained in this part of the Quality Account is likely to change over time as Departmental priorities change. The Department will need to continuously ensure that this element of the Account contributes to showing a “true and fair” view of provider quality, and that individual data items as well as the national part of the Quality Account as a whole is cost-effective.

4.4 For the first few years of the operation of Quality Accounts the DH-specified part of the Account is likely to comprise:-

- information which may be required by DH under the terms of the Operating Framework (eg a report on the rates of Healthcare Associated Infections - HCAs);
- information on quality that providers supply to the Care Quality Commission for performance assessment and registration purposes;
- information on quality which may be required by Monitor, where relevant;
- any information on quality that a provider may have supplied to the Care Quality Commission on special investigations or thematic reviews;
- quality metrics or standards that a provider may need to supply to their PCT under the contract they have with that PCT, and any information they need to supply to their PCT for Commissioning for Quality and Innovation (CQUIN) purposes; and
- other information which is nationally available, such as information which is supplied to Cancer Networks and to clinical audits.

4.5 The purpose of the DH-specified part of the Account is to ensure that patients, the public, managers and clinicians have easy access to information on a provider’s performance against key Departmental priorities in a way which allows Account users to compare a provider’s year on-year performance and to compare the performance of similar types of provider.

4.6 Many NHS priorities are set at local level. If Quality Accounts only contained information on national priorities they would not be able to present local users with information which is relevant and meaningful in a local context. In addition, presenting information on national priorities alone is unlikely to enable providers to give a “true and fair” view of the quality of their services, and most providers will offer services that are not covered by national priorities.

4.7 Providers will therefore also need to supply local information in their Account. The content of this section of the Account will be for providers themselves to determine. Providers will be encouraged via Departmental guidance to use metrics developed by the Department, or developed locally, to populate this part of the Quality Account. This guidance will also note the need for providers to be aware of cost-effectiveness issues, and to encourage them to consider whether any costs arising from the presentation of any individual piece of information within their Quality Account is matched by the benefits to patients and the public.

4.8 Most providers of NHS healthcare services will, in time, face a requirement to produce a Quality Account but it is likely that primary care contractors will not need to prepare accounts until 2011/12 or possibly later.

4.9 Quality Accounts will be prepared covering a standard period April – March, and will be published according to a timetable which will be set in regulations. We would hope that publication by 30 June will be achievable, eg a Quality Account for the period 1 April 2011 – 31 March 2012 will be published by 30 June 2012. However, we will need to discuss this further with the various types of provider to ensure that it can be done in a way which minimises the burdens on providers. Providers will have to supply an electronic copy of their Account to NHS Choices by the deadline chosen for publication. Providers will also have to supply a hard copy of their Quality Account from the publication deadline onwards to anyone who requests a copy.

4.10 The duty to ensure that the Quality Accounts present a true and fair view of quality will be a legislative requirement. NHS management procedures will ensure that NHS organisations adhere to this requirement. PCTs and SHAs will be able to take action – proportionate to the transgression – to deal with any provider who fails to fulfil their obligations, either through contract management or through other powers such as those proposed as part of the NHS performance regime. In addition, if any misstatements pertain to registration requirements or, for Foundation Trusts, the terms of the Trust's authorisation, then the CQC and Monitor will be able to take appropriate action.

4.11 We think that the assurances described at 4.10 above should be sufficient to ensure that providers do not deliberately publish information that they know to be false, or publish information that has not been rigorously tested to ensure that it is reliable. Nevertheless, we recognise that independent assurance is valued by the public, and so we intend to encourage, but not to require, providers to arrange for external validation of or third party commentary on their Quality Accounts.<sup>72</sup>

The Bill's Impact Assessment also discusses benefits and risks of *Quality Accounts* and concludes that there is a lack of quantifiable evidence about the impact of publishing health care data. It says that the Government is committed to undertaking a rigorous evaluation of the impact of Quality Accounts, in the context of other policies to improve measurement of quality and outcomes, on the quality and consistency of care delivered to NHS patients.

## **C. Responses to the Bill's provisions on Quality Accounts**

### **1. Debates in the House of Lords**

In Committee no changes of substance were made but Lord Howe moved an amendment pointing out some drafting errors in clauses 7 and 8 (of the Bill as introduced into the House of Lords). These were accepted by Lord Darzi and the clauses were

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<sup>72</sup> [Department of Health, Impact Assessment for the Health Bill](#), 8 January 2009

amended. On Report the Government introduced an amendment, relating to the display of Quality Accounts, in response to points made by Lord Howe in Committee.<sup>73</sup>

### ***General Approach of the Conservative and Liberal Democrats***

An overview of the position taken by the two main opposition parties was given in the House of Lords on Second Reading.

Lady Barker, speaking for the Liberal Democrats, said:

On quality accounts, the NHS is swimming in data; it has data everywhere. It does not have a clear, purposeful system for analysing and using that data. We support the aims of the noble Lord, Lord Darzi, and we welcome the involvement of clinicians in setting quality accounts, but to ensure that the provisions are right we need a much fuller statement about the purpose of quality accounts. Then we can determine what their nature should be. We will support anything that helps the NHS to come up with verifiable data that improves its evidence base.<sup>74</sup>

Lord Howe, speaking for the Conservatives, said:

I support the Minister's wish to measure quality in the NHS and to improve outcomes. The noble Lord is eloquent on his proposals to introduce quality accounts, and I am certain that this House will want to give him the chance to put them into practice. If I have doubts about the policy, they centre around the gap that may emerge between ambition and actuality. The first requirement for quality accounts is reliable and meaningful information. The collection and presentation of that information will be no mean task....<sup>75</sup>

### ***Points raised during debates in the House of Lords***

Some of the main issues raised are outlined below (in the order in which they were first debated). The list is intended to give a flavour of the debate and not to provide a comprehensive account. Unless otherwise specified, Government amendments were successful and non-Government ones were not.

- The need for clarification about the nature of Quality Accounts (which are not defined in the Bill) was a recurring theme throughout the debates on these clauses. For example, the debate began with an amendment moved by Earl Howe (withdrawn), in which various questions were raised, in particular what audience they would be for, how they would be developed, and what data would be included. His main worry was the quantity of data needed if they were to be of real use to the different audiences. Lord Darzi explained that there was a distinction between financial accounts and *Quality Accounts*. The latter would be kept within the framework of safety, effectiveness and patient experience.<sup>76</sup>

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<sup>73</sup> The dates of the debates Quality Accounts were: House of Lords Grand Committee 26 February 2009 GC156-202; Report 28 April c167-172; Third Reading (no debate).

<sup>74</sup> HL Deb 4 February 2009c744

<sup>75</sup> HL Deb 4 February 2009 c748

<sup>76</sup> HL Deb 26 February GC 156-170

- The independence of Monitor (the regulator of NHS Foundation Trusts) in relation to Quality Accounts was raised in the debate on amendments moved by Lady Murphy. Her general concern was that the measures in the Bill might mark a return to a centralised system, from which the Government had been trying hard to move for the past 11 years. Particular concerns related to the role of Strategic Health Authorities (SHAs) and the Secretary of State.

Lord Darzi responded that there was no intention to override the existing lines of accountability to the respective regulators (Monitor for NHS Foundation Trusts and the Care Quality Commission for others) and no hidden agenda. Regulations would make clear the role of existing regulators. The sole purpose of requiring NHS Foundation Trusts to send their *Quality Accounts* to the Secretary of State was to place them on the NHS Choices website, not to hold regulators to account. The role of SHAs in correcting data was to help commissioners (the PCTs). He was willing to examine the wording in the Bill to see if it could be made clearer.<sup>77</sup>

- Auditing and validation of Quality Accounts were the subject of amendments moved by Lord Howe. He argued that there appeared to be no systematic check to ensure the accuracy of information published by a Trust in a Quality Account and suggested that a more formal audit by the Care Quality Commission and a system of accreditation, for example, with a Royal College, might be part of the solution. Lord Darzi argued that this was not necessary. Much of the data would be reported to the Care Quality Commission under existing arrangements anyway and the Commission had the power to investigate if significant new issues arose. Lord Howe raised the issue again on Report but there was no change.<sup>78</sup>
- A requirement to publish the *Quality Account* more widely was suggested in Amendments proposed by Lord Howe, to which Lord Darzi replied that discussions were under way on where to make information available other than on the NHS Choices website and that guidance would be published on this.<sup>79</sup>
- The possibility of having a dignity, compassion and respect indicator was proposed by Lady Greengross, to which Lord Darzi replied that the patient experience domain in the *Quality Account* would address such issues.<sup>80</sup>
- The possibility of *Quality Accounts* that would cover several NHS bodies together was raised in an amendment moved by Lord Patel, to which Lord Darzi replied that the purpose of *Quality Accounts*, was to make the individual provider responsible.<sup>81</sup>

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<sup>77</sup> HL Deb 26 February 2009 GC 170-179

<sup>78</sup> HL Deb 26 February 2009 GC 179-186 and 28 April 2009 c170-172

<sup>79</sup> HL Deb 26 February 2009 GC 186-90

<sup>80</sup> HL Deb 26 February 2009 GC190-192

<sup>81</sup> HL Deb 26 February 2009 GC 192-197

- On Report the Government introduced an amendment to exempt premises that the provider does not control, such as a patient's own home, and those that patients do not directly access, such as a pathology laboratory, from the requirement to display *Quality Accounts*. This was in response to a briefly debated amendment moved in Committee by Lord Howe.<sup>82</sup>
- Requiring the Secretary of State to report to Parliament about the impact of *Quality Accounts* was raised in an amendment moved by Lady Barker, to which Lord Darzi replied that although it was not in the Bill, the Government had made a commitment that the National Quality Board would publish a set of indicators at national level (not the *Quality Accounts* but something that would build on them) that would look at the progress of the NHS on a year by year basis. In addition, there would be formal academic evaluation of the policy after it had been running for three years.<sup>83</sup>

## 2. Briefings on the Bill

### a. *British Medical Association Briefing for the Second Reading in the House of Lords*

Quality accounts were announced as part of the NHS Next Stage Review in June 2008. Subject to legislation, all providers working for or on behalf of the NHS will have a duty to publish annual quality accounts from April 2010. Information based on these accounts will be available via the NHS Choices website. The Department of Health has defined quality as constituting safety, experience and clinical outcomes and has recently consulted on a set of national quality indicators for acute services (including patient-reported outcome measures/PROMs), which will be in place from April 2009.

The BMA supports the intention to gather good quality and comparable data on clinical outcomes. We do, however, have some reservations over how this data will be interpreted, used and presented. The Department of Health's proposals around quality accounts are still in development and the BMA will develop more detailed policy on this area in due course.

The Health Bill sets out that the Secretary of State will have the power to determine the form, content and timetable for publication of a quality account. The BMA would not want to see the content and form of quality accounts being subjected to such significant and continual change that it becomes impossible for progress to be tracked from one to year to another and/or for providers to keep up with what is required of them. We hope that any changes to the form and content will be subject to debate and consultation.

### b. *King's Fund*

The King's Fund's overall attitude to Quality Accounts was given in its response on 3 December 2008 to the Queen's speech announcing the Bill:

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<sup>82</sup> HL Deb 26 February GC 197-8 and HL Deb 28 April c167-8

<sup>83</sup> HL Deb 26 February 2009 GC 198-202

This will mark a new era for the NHS – for the first time in a systematic way hospitals will be held to account for the quality and outcomes of the care they provide to patients as well as whether or not they balance their books. This is good news to patients as they will be able to check on the quality of the services they are being offered from infection levels to success rates following operations. There is a long way to go before we have all the information we need but this should help us all make more informed choices and put pressure on those providing care to do better.

**c. *NHS Confederation Briefing for the Second Reading in the House of Lords***

The NHS Confederation fully supports the drive to improve quality within the NHS. Quality Accounts will be only one part of this programme. The collection of quality and outcome data will undoubtedly become a major driver for improvement. In large part, this is due to the definition and measurement being driven by clinicians for their professional accountability and self assessment purposes, rather than external performance management purposes. It is important that both clinicians and boards are engaged in the development of metrics is vital to ensure they retain credibility.

We would welcome greater clarity from the Government about the purpose of quality accounts and whether they are to be used to: increase accountability; to facilitate patient choice; or as a driver of improvement and change. Discussions about the nature of quality accounts will to some extent depend on the answer to these questions.

Regulations will set out the form of the Quality Account and the method of publication. If these regulations are to impact on points of principle, such as the level of prescription, then there should be a commitment on the face of the bill to consult all relevant parties. The bill, at present, is perhaps overly detailed on issues of logistical implementation and correction but goes in to very little detail on what will be contained in the accounts.

While it is important that there are national measures, the NHS Confederation believes that there should be minimal prescription consistent with the need to be able to compare performance between organisations. There needs to be freedom to draw a wider set of indicators that reflect local circumstances.

If the Bill is to enact the intention of the Quality Accounts set out in the Next Stage Review, they need to be locally developed as an organisation's way of describing the quality of their services and improvement plans.

The drafting of clause 6 of the Bill is unclear as to the extent to which the provisions relate to independent and third sector provision of NHS care and to commissioners of health care. We hope that ministers will provide clarity during the debate on the Bill.

In summary we believe that requirements should:

- Restrict top down national requirements to a minimum
- Use existing indicators where these are available and not require different means of measurement
- Ensure that there is no duplication and overlap between the different agencies responsible for monitoring the accounts

- Encourage the use of a wide definition of quality and encourage use of indicators that reflect local concerns and priorities.

**d. *National Pharmacy Association commentary on pharmacy provisions in the Bill***

We are concerned about the lack of detail currently available in respect of Quality Accounts and would need to see a thorough cost-benefit analysis of this proposal before we can support its application to pharmacy. We ask that the NPA and other pharmacy representative bodies are provided with a formal mechanism for contributing to the development of Quality Accounts.

**e. *Royal College of Nursing***

The overwhelming majority of care provided by the NHS is safe, but the RCN believes the ambition must continue be to drive up patients experience from a safe to a high quality service. If implemented the clauses in this chapter have the potential to contribute significantly towards achieving this ambition.

The Government's ambitious plans to strengthen the place of quality in the system also need to be matched with sufficient resources to turn this vision into a reality. There needs to be sufficient time allowed to develop the detailed content of quality accounts working closely with a wide range of stakeholders including the RCN.

The RCN believes Quality Accounts should be based on indicators and measures of quality care, patient experience and outcomes that NHS Trusts are currently developing. Quality care extends beyond a medical intervention and includes factors which are sensitive to the work of nursing staff such as reducing patient trips and falls, healthcare acquired infections and the development of pressure ulcers. Quality of care is also related to systems of care which includes, for example, ensuring that nurse staffing levels and skill mix are appropriate in relation to patient dependency. Ultimately quality accounts will support and promote patient safety.

## **IV Direct Payments to Patients**

*The Bill's provisions on Direct Payments apply to England only.*

### **A. The Bill (clauses 11-13 and schedule 1)**

Clause 11 of the Bill would insert new clauses 12A-D into the *National Health Service Act 2006*. Clause 10 amends the *Health Service Commissioners Act 1993* and clause 13 introduces schedule 1, which would introduce minor and consequential amendments into other legislation. These provisions are outlined below.

**Direct Payments to be introduced through pilot schemes only:** The Bill makes provision for payments to be made directly to patients (or a person nominated by them),

with their consent, in order to enable them to purchase health care services.<sup>84</sup> It provides for the Secretary of State to make the payments and requires them to be made only through pilot schemes.<sup>85</sup>

**Coverage, Terms and Conditions of Direct Payments:** The Bill enables Direct Payments to apply to most NHS services but also provides for Regulations about Direct Payments that could limit their application and generally set the terms and conditions on which they apply. The Bill lists various areas that the Regulations may particularly cover, for example: limiting the payments to certain groups of patients; setting out services for which they could not be used; provision for patients who lack the capacity to consent; as well as the way that they are to be calculated, monitored, audited and, where specified, repaid. Advice, information and support for patients were added to this list during the Bill's passage through the House of Lords. The Bill also provides that regulations could extend Direct Payments to services provided under section 117 of the *Mental Health Act 1983*.

**Pilot Schemes to be introduced through Regulations:** The Bill does not introduce the pilot schemes directly but makes provision for Regulations to empower the Secretary of State to do so. The Bill provides for these Regulations to be able to include provisions relating to the geographical coverage of a scheme, its duration and its revocation or amendment. It requires the Regulations to include provision for the review of a pilot scheme and for the Secretary of State, having conducted such a review, to have the power to issue regulations under the affirmative resolution procedure about the future of direct payments. S/he might, for example enable them to become generally available (by removing the requirement that they be made through pilot schemes) or bring them to an end (by repealing the relevant provisions in the Bill). Details of the way that regulations might provide for a review were added during the Bill's passage through House of Lords.

**Assistance:** The Bill enables the Secretary of State to make arrangements with organisations, including voluntary organisations, to provide assistance with Direct Payments.

**NHS Ombudsman:** The Bill extends the powers of the Health Service Ombudsman (though amendments to the *Health Service Commissioners Act 1993*) to cover providers of services under Direct Payments schemes.

## **B. Background**

### **1. What is a Direct Payment?**

"Direct Payment" is the term that is used to describe a payment made to an individual in lieu of certain statutory services. The idea is that people can use the money that they are given to buy themselves the service, or its equivalent, from a range of providers, including the independent sector. Such payments were introduced for some local

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<sup>84</sup> Clause 9 would introduce new sections 12 A-D to the *National Health Service Act 2006*.

<sup>85</sup> In practice this would be Primary Care Trusts - see the Explanatory Notes paragraph 19.

authority social services in 1997. They have been extended and reinforced in various ways since<sup>86</sup> but have not so far been provided in the NHS.

Direct Payments would be introduced into the NHS as a variant of a “Personal Health Budget”, which is itself a relatively novel idea for the NHS. A Department of Health document published in January 2009 explains what they are intended to be:

*What is a personal health budget?*

A personal health budget helps people to get the services they need to achieve their health outcomes, by letting them take as much control over how money is spent on their care as is appropriate for them.

It does not necessarily mean giving them the money itself. As described in section 3.6, personal health budgets could work in many ways, including:

- a notional budget held by the commissioner;
- a budget managed on the individual’s behalf by a third party; and
- a cash payment to the individual (a ‘healthcare direct payment’).

PCTs already have extensive powers to offer personal health budgets, either as a notional budget or held by a third party. Only the healthcare direct payment is subject to the passage of legislation in the current Health Bill.<sup>87</sup>

## 2. Development of Government Policy

In January 2006, when the Government published the *White Paper, Our Health Our Care Our Say: A New Direction for Community Services*, it rejected the idea of introducing Direct Payments and individual budgets in healthcare because this would conflict with the principle of free healthcare;

4.39 It has been suggested that we should extend the principle of individual budgets and direct payments to the NHS. We do not propose to do so, since we believe this would compromise the founding principle of the NHS that care should be free at the point of need. Social care operates on a different basis and has always included means testing and the principles of self and co-payment for services.

When *High Quality Care for All* was published in June 2008, the position had changed. Direct Payments and Personal Health Budgets for healthcare were proposed as part of a general move to increase the influence of patients over NHS resources. Direct Payments would be one variant of Personal Health Budgets, themselves only one way of improving the quality of services in the NHS, which could take several forms, some of which could be provided under existing legislation. Direct Payments to patients for healthcare (as distinct from social care), however, could not be provided under existing legislation:

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<sup>86</sup> For further information see Library Research Paper 09/09 by Manjit Gheera, [Welfare Reform Bill: Disabled People, Child Maintenance and Birth Registration](#); and also the Department of Health’s website:

[http://www.dh.gov.uk/en/SocialCare/Socialcarereform/Personalisation/Directpayments/DH\\_080273](http://www.dh.gov.uk/en/SocialCare/Socialcarereform/Personalisation/Directpayments/DH_080273)

<sup>87</sup> Department of Health, [Personal Health Budgets: First Steps](#), January 2009 page 9

39. We will increase the influence that patients have over NHS resources. For hospitals, resources already follow the choices that patients make through the Payment by Results system. We will strengthen this by reflecting quality in the payment mechanism and increasing individual control.

40. First, we will make payments to hospitals conditional on the quality of care given to patients as well as the volume....

42. Second, we will go even further in empowering individual patients. Learning from the experience in both social care and other health systems, and in response to the enthusiasm we have heard from local clinicians, we will explore the potential of personal budgets, to give individual patients greater control over the services they receive and the providers from which they receive services. Personal health budgets are likely to work for patients with fairly stable and predictable conditions, well placed to make informed choices about their treatment; for example, some of those in receipt of continuing care or with long-term conditions. With a view to national roll out, we will launch a national pilot programme in early 2009, supported by rigorous evaluation. This will enable the NHS and their local authority partners to test out a range of different models.

43. The budget itself may well be held on the patient's behalf, but we will pilot direct payments where this makes most sense for particular patients in certain circumstances. We will legislate to enable these direct payments.

44. The programme will be designed with NHS, local authority, carer and patient group partners, with clear rules. We will ensure that the programme fully supports the principles of the NHS as a comprehensive service, free at the point of use. It will be voluntary – no one will ever be forced to have a budget, and for those that choose to, there will be tailored support to meet their different needs. The programme will be underpinned by safeguards so that no one will ever be denied treatment as a result of having a personal budget, and NHS resources will be put to good use, with appropriate accountability.

*Personal Health Budgets: First Steps* was published in January 2009 and set out more details about the proposal in *High Quality Care for All*. The document asked for expressions of interest in running pilot Personal Health Budgets, with a deadline of 27 March 2009. The press notice issued at the same time said that the document was not intended to be a definitive guide or rulebook. Rather it was to encourage PCTs to take an innovative approach to personal health budgets and explore the opportunities that they offered.<sup>88</sup>

The document did set out six key principles for personal health budgets and said that they would have to align with other guidance and policies. For example, approval for treatments that the NHS would not normally fund because they were not cost effective would have to be obtained in the normal way from the PCT's exceptions committee; and they should fully meet the needs for which they were intended – they should not be used a part payment for privately funded healthcare.

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<sup>88</sup> Department of Health Press Notice, [First Steps For Personal Health Budgets](#), 28 January 2009

On additional private care (top-ups), the document added:

Personal health budgets should be compatible with the core principle that NHS care is based on clinical need, not ability to pay. The budget is there to meet the individual's agreed needs in full – not to part fund them – and people may not 'top up' their personal health budgets from their own resources. If, for any reason, a patient wanted to purchase additional care privately, this would have to take place separately, with clear accountability, in line with the Government's response to Professor Mike Richards' review of additional private drugs.<sup>89</sup>

On the question of coverage it did appear to rule out some services. For example, it said:

We currently anticipate that the vast majority of primary medical services – including visits and assessments – will also not be suitable for inclusion in a personal health budget. GPs provide a comprehensive, registration-based service, and we do not intend to change that.

The six key principles for personal health budgets and personalisation in health that the document set out were:

1. Upholding NHS values. The personalised approach must support the principles of the NHS as a comprehensive service, free at the point of use, as set out in the NHS Constitution, and should remain consistent with existing NHS policy:

- There should be clear accountability for the choices made.
- No one will ever be denied essential treatment as a result of having a personal health budget.
- Having a personal health budget does not entitle someone to more or more expensive – services, or to preferential access to NHS services.
- There should be good and appropriate use of NHS resources.

2. Quality – safety, effectiveness and experience should be central. The well being of the individual is paramount. Access to a personal health budget will be dependent on professionals and the individual agreeing a care plan that is safe and will meet agreed health and well being outcomes. There should be transparent arrangements for continued clinical oversight, proportionate to the needs of the individual and the risks associated with the care package.

3. Tackling inequalities and protecting equality. Personal health budgets and the overall movement to personalise services could be a powerful tool to address inequalities in the health service. However, local organisations need to take care that their implementation does not exacerbate inequalities or endanger equality. The decision to set up a budget for an individual must be based on their needs, irrespective of race, age, gender, disability, sexual orientation or beliefs.

4. Personal health budgets are purely voluntary. No one will ever be forced to take more control than they want, and a PCT does not have to offer an individual

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<sup>89</sup> Since Personal [Health Budgets: First Steps](#) was written, the Government has followed up its response to Mike Richards review with guidance: [Guidance on NHS patients who wish to pay for additional private care](#), Department of Health, 23 March 2009.

a particular way of managing a budget if it does not feel that that is the best way of commissioning services for that individual.

5. Making decisions as close to the individual as possible. Appropriate support should be available to help all those who might benefit from a more personal approach, particularly those least well served by existing services or access and who might benefit from managing a budget.

6. Partnership. Personalisation of healthcare embodies co production. It means individuals working in partnership with their family, carers and professionals to plan, develop and procure the services and support that are appropriate for them. As one carer said to a professional: "You may be the expert professional but I am the expert carer." It also means PCTs, local authorities and healthcare providers working together to use personal budgets so that health and social care work together as effectively as possible. (Page 23)

The first personal health budget pilots are expected to run later in 2009 and, subject to the passage of the Bill, could be extended the following year (2010) to include pilot schemes for Direct Payments.<sup>90</sup>

## **C. Responses to the Bill's provisions on Direct Payments**

### **1. Debates in the House of Lords**

There were no changes to the Bill's provisions on Direct Payments in Grand Committee or on Report but there were two Government amendments on Third Reading, which were made in response to issues raised during the earlier debates.<sup>91</sup>

#### ***General approach of the Liberal Democrats and Conservatives***

An overview of the position taken by each of the two main opposition parties was given on Second Reading on 4 February 2009.

Speaking for the Liberal Democrats, Lady Barker, said;

We support individual budgets and direct payments as a means of making services responsive to need. I welcome any initiative that will enable older people to have greater independence, that will enable people to manage pain by having a chiropractor or an osteopath treat them, and that will help people with mental health problems to get rapid access to therapies, whether or not they are provided in their area.

Direct payments are, however, very complicated. I told the noble Baroness, Lady Campbell, before she left the Chamber that I would tell the House that we need to be very clear that the use of direct payments in social care has yielded very little evidence so far. That evidence suggests that they work very well for some

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<sup>90</sup> [Department of Health Fact Sheet on the Bill](#), 12 February 2009

<sup>91</sup> The dates of the debates on Direct Payments in the House of Lords were: Grand Committee 2 March 2009 c203-256; Report 28 April 2009 c191-210 and 6 May 2009 c550-553 and Third Reading 12 May 2009 c930-3.

people, but for other people they are incredibly problematic. I am sorry to say that the noble Baroness, Lady Campbell, presented a particular view that may not be typical, and I am really worried that we see individual budgets as the answer to the NHS and all its problems when they are not, although they might be an answer for some people.

I ask noble Lords to consider that the individual budget is a market model, which is interesting; when the City is ditching market models at a hell of a rate, we are suggesting that they move into the NHS. They have been trialled in social care, which has 28,000 providers, most of which provide stand-alone services, and if the providers fail, there is no knock-on consequence for anything else at all. In social care, services are managed by eligibility criteria and people's ability to pay, and we are going to apply that to the NHS, which has a few hundred providers.

In the NHS, the distinction between acute care and community care is not clear-cut, and taking a budget from one part of the organisation could have severe knock-on consequences for another. All those services are supposed to be free at the point of delivery at the moment and are largely uncosted; yet we are going to do all that on the basis of some very thin evidence from social care. That is a huge risk. We assume that this system will work, but we must realise that this is a system in which there are more providers and more capacity than people need, so they can have a choice and there is sufficient purchasing power. Noble Lords may think that that applies to the NHS today, but I ask them to consider whether it will apply in five years' time.

The IBSEN study has shown that there are some problems. I do not want to go into them; other people have, but if we go ahead without having fully evaluated this we will be in danger of compounding inequities between different client groups. That would be extremely dangerous. I say to the Minister now that we will not let the Bill leave the House without much more rigorous requirements for review and evaluation before this is rolled out.<sup>92</sup>

Speaking for the Conservatives, Lord Howe said:

I also give broad support to the proposals on direct payments for healthcare contained in Chapter 3 of Part 1. It is extraordinary: this was a proposal that my party put forward more than three years ago. The then Secretary of State denounced us, and in the Government's White Paper of 2006 the idea was ruled out. Undeterred, we made direct payments one of the central tenets of the health policy paper that we published in 2007. I am glad that the Government have changed their mind, because the whole purpose of this proposal is to extend the control that people have over the services provided to them—particularly those people living with reasonably predictable long-term illness or disability. For them, the divide between healthcare and social care can be a source of frustration and bewilderment. Services that should be seamless are not, and costs are often shunted between the NHS and social services.

If we take people's individual needs and wishes as our starting point, instead of the traditional structures of service delivery, we can begin to break down the barriers to providing people with better care. However, we have to go about this

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<sup>92</sup> HL Deb 4 February 2009 c744-5

carefully. The Government are right to start off with pilot schemes. Much detail needs to be developed and wrinkles need to be ironed out. The questions that we will ask in Grand Committee will centre on how the Government want the scheme to work; what kinds of healthcare will fall within the scope of direct payments; how individual budgets will be calculated; and how patients will be able to make informed decisions about what services to choose. Noble Lords were right to indicate the potential pitfalls. We need to take time to identify and overcome them.<sup>93</sup>

### ***Points raised during the debates in the House of Lords***

Some of the main issues raised are outlined below (in the order in which they were first debated). The list is intended to give a flavour of the debate and not to provide a comprehensive account. Unless otherwise specified, Government amendments were successful and non-Government ones were not.

- The coverage of Direct Payments, both in relation to specific types of patient and service and, more generally, whether they would be purely voluntary, were much debated in Grand Committee and on Report.<sup>94</sup> For example, Lady Barker proposed an amendment on the rights of people with learning disabilities (GC) and Lord Howe proposed one on consent (Report). The latter led to a division with 46 votes in favour of Lord Howe's amendment and 61 against.

In response, Lord Darzi confirmed that the Government intended to allow (through Regulations) a personal representative to hold a Direct Payment on behalf of a patient who was unable to give consent. He also confirmed that Direct Payments would be purely voluntary. He did not want to specify the relevant services in legislation but envisaged that as personalisation became embedded in the NHS, it might be possible to extend Personal Health Budgets more widely. He did mention some services that were likely to be inappropriate, for example, accident and emergency or acute services and people on drug or alcohol treatment orders but in general, the Government would rely on the judgement of the local Primary Care Trust.

- The issue of advice and support for recipients of Direct Payments was raised in Committee<sup>95</sup> and on Third Reading Lord Darzi introduced an amendment to make it more explicit on the face of the Bill that the NHS should make arrangements to ensure that recipients of Direct Payments should be able to access advice, information and other support.<sup>96</sup>
- What would happen if a payment ran out and why there was a power to clawback Direct Payments were the subject of clarifying amendments in Grand Committee, to which Lord Darzi responded that where Direct Payments were offered, there would be an agreed care plan to ensure suitable services and a sufficient budget,

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<sup>93</sup> HL Deb 4 February 2009 c748-9

<sup>94</sup> HL Deb 2 March 2009 GC 203-227 and 28 April c191-210

<sup>95</sup> HL Deb 2 March 2009 GC 227-239

<sup>96</sup> HL Deb 12 May 2009 c930-3

including a contingency component. There should be no question of patients being turned away from NHS services if they needed them. There would also be arrangements for monitoring and review of both the clinical outcomes and finance. The power to recover payments was necessary in order to manage taxpayers' funds responsibly where the payment was underspent but this would be a discretionary power and there might be cases where it would be disproportionate or inappropriate to use it.<sup>97</sup>

- Whether top-ups would be allowed was the subject of another clarifying amendment in Grand Committee. (The issue of topping up was also raised in relation to continuing care – see below.) Lord Darzi responded that top-ups would not be allowed. If for any reason a patient wished to purchase additional care privately, it would have to be taken separately and with clear accountability in line with the Government's response to the Mike Richards review' but he doubted whether the issue would arise as he expected most patients to go back to their care manager and negotiate some of their extra needs.<sup>98</sup>
- Evaluation and review of the pilot schemes were discussed in Grand Committee and on Report.<sup>99</sup> On Third Reading, the Government introduced new provisions to clarify how it intended that the pilot schemes should be evaluated (e.g. by an independent person) and added matters that the reviews should consider (e.g. the effect on the cost or quality of care) to the list of subjects on which regulations for reviews might make particular provision (or provide for the pilot scheme to make provision).<sup>100</sup>
- Whether the Bill should specify that healthcare providers under Direct Payments schemes were public authorities for the purpose of section 6 of the *Human Rights Act* was a question raised by Lord Dubs during the debates on Report. Lord Darzi said that the Government considered that they were public authorities and therefore that specific provision was unnecessary, whereas Lord Dubs said that the Joint Committee on Human Rights, of which he was a member, took a different view.<sup>101</sup>
- The conditions of staff providing Direct Payments were raised in a proposed amendment from Lord Campbell-Savours. Lord Darzi argued that they were already protected by provisions in the Bill.
- NHS continuing healthcare care: This could be seen as a separate issue. It was the subject of a proposed new clause, moved by Lady Barker, which would have enabled NHS patients to “top-up” the “hotel” costs of a place in a care home (as is possible under social services legislation for people who are funded by social services). It was linked to the debate on Direct Payments by including those who might be paying for their place with a Direct Payment. Lord Darzi's response was

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<sup>97</sup> HL Deb 2 March 2009 GC 240-245

<sup>98</sup> HL Deb 2 March 2009 GC 240 -245

<sup>99</sup> HL Deb 2 March 2009 GC 245-254, HL Deb 28 April c207-210 and HL Deb 6 May 2009 c550-553

<sup>100</sup> HL Deb 12 May 2009 c930-933

<sup>101</sup> HL Deb 28 April 2009 c197-200

that personal budgets and the Direct Payments that they would be piloting might not be used as part payment for privately funded healthcare. There must be no question of creating a two-tier system where those who could afford it could buy a better standard of NHS care. However, there might be confusion about the specific issue of “hotel costs” and there might be a need to clarify the position on “the very narrow question” of “hotel” costs.<sup>102</sup>

## 2. Briefings on the Bill

### a. *British Medical Association Briefing for the Second Reading in the House of Lords*

Although the BMA will certainly look at the findings of a limited pilot ..., we have serious reservations over the introduction of personal health budgets, in particular, direct payments, as this policy seems to further establish the idea of healthcare simply as a commodity, which the BMA does not believe is in patients' best interests. It also reinforces the concept of the market in the NHS in England, at a time when there is little or no evidence for its benefits and significant evidence for its adverse effects, including encouraging fragmentation, discouraging cooperation and increasing bureaucracy and transaction costs. Furthermore, it is currently unclear how personal health budgets would work in practice and what, for example, the arrangements would be regarding the following:

- A patient's budget runs out – who is responsible and would access to a personal health budget by that patient be allowed in subsequent years?
- A patient spends less than their allocated budget – will the patient be encouraged to spend the remaining balance or will the money be returned to the NHS pot?
- Scope and calculation of the budget – how will this be determined and will the methodology differ from PCT to PCT and/or patient to patient?
- Pricing care - how will this be done for services that sit outside of existing tariffs/payment systems and will prices differ from PCT to PCT and/or between NHS and private providers?

In addition, whilst this may not be the Government's intention, personal health budgets have the potential to undermine some of the fundamental principles of the NHS were they to be introduced and rolled out more widely. For example:

- How can equity be maintained between patients with a budget and those without if personal health budgets can be spent on services not ordinarily available on the NHS?
- How can NHS resources be safeguarded if personal health budgets can be spent on services and treatments that are not proven to be clinically and cost effective?
- Will patients believe that they as an individual have an actual, financial entitlement to NHS services, undermining the principle that NHS

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<sup>102</sup> HL Deb 2 March 2009 GC254-256

resources/services are made available to patients on the basis of clinical need?

- Will an increasing emphasis on the individual through personal health budgets undermine the ability of the NHS to address the collective needs of patient populations?....

**b. *King's Fund Statement on the Health Bill, January 2009***

Direct payments offer the potential for patients to have more control over the care they receive, allowing treatment to be truly personalised. However, their use won't be straightforward. Getting the initial payment level right will be important as will deciding what restrictions to place on the kind of treatment a patient is allowed to purchase with tax payers' money, and from whom.

The pilots must be genuine with no decision to extend the scheme until all the results have been thoroughly evaluated and all the implications understood.

**c. *NHS Confederation Briefing, second Reading, House of Lords***

Putting money in the hands of patients could improve care planning and have an impact in areas such as end of life care, mental health or maternity services. The NHS Confederation found a consensus after discussions with members that urgent and emergency care and elective procedures can not be part of personal health budgets because of their variability. A piloting phase and robust evaluation will be important.

There is a growing body of evidence which suggests that health outcomes are improved when the patient is directly involved in making decisions. The ability to develop personal budgets already exists for funding that is given as a notional budget or held through a third party. The enactment is about the enabling of direct payments to patients rather than the ability to have personal budgets.

There are significant barriers that need to be overcome before the policy can be implemented and a number of questions need to be answered. For example:

Should patients be allowed to spend their personal budgets on non cost-effective treatments such as some alternative therapies?

Should individuals be allowed to top-up their care?

Should patients be allowed to invest personal budgets to be spent at a later date?

The NHS Confederation had produced a briefing on personal health budgets, Personal health budgets: The shape of things to come?, which is available on our website: [www.nhsconfed.org](http://www.nhsconfed.org)

**d. *Pharmaceutical Services Negotiating Committee Commentary***

Patients need a trusted source of unbiased advice about when to access services, and the persons able to provide such services, so that Direct Payments can be used wisely. There is an opportunity to build significantly on the services currently provided by pharmacies, by developing a support service for those with newly diagnosed long term conditions as proposed in Pharmacy in England. The development of such a holistic service through community pharmacy has the support of the dental and optical professions who also have vital roles to play.

**e. *Royal College of Nursing, 2<sup>nd</sup> Reading Briefing, House of Lords***

The RCN supports the principle of personalised budgets for social care but are cautious over its application in the health sector as the challenges can be very different. There are unanswered questions on what happens if you have a healthcare need but your personal budget has been spent; whether patients should be allowed to spend their personal budgets on less cost-effective treatments; whether people should be able to top up their care and whether personal budgets could be invested and spent at a later date. It will be absolutely critical that patients have access to relevant and reliable information to enable them to make informed choices about how to spend their personalised budget and there will also be implications for staffing capacity in terms of being able to support patients, particularly the most vulnerable, to commission and manage the services they need.

The College regard the relationship between the nurse and the patient as being critical to the delivery of quality and dignified healthcare. We also believe that the professional and personal relationship, not just personalised services, is at the heart of delivering quality and dignified healthcare.

**f. *Royal Pharmaceutical Society of Great Britain***

The RSPGC fully supports the need for more patient involvement when choosing a form of care. This is especially important in the management of long-term conditions when patients are able to take a more participative role in managing their condition. The Bill make reference to independent advisers but the Bill doesn't give further details on who would perform this role and how a patient would gain access to them. It is critical for patients to be able to have access to this information in addition to having it made available in a format that is comprehensible and which identifies what a patient should expect to see from a good service.

**g. *UNISON Briefing for Lords Committee Stage***

UNISON continues to have significant and fundamental concerns about the introduction of direct payments for health services. While we recognise and support the need for NHS services to be more responsive and able to provide more tailored support to some patients, we do not believe that direct payments will be either a long-term or a satisfactory solution. We are wholly opposed to a policy that could easily lead to means-testing, patient top-up fees for services, or greater barriers to services for those who most need them. We do not feel that this is a risk worth taking, particularly in a time of tightening economic conditions when future budgets may consider reducing spending on health services.

UNISON would argue that at this stage, direct payments are likely to be more detrimental than beneficial both for the NHS and for individual patients, and would therefore urge peers to oppose the Question that Clause 9 stand part of the Bill at Committee Stage.

During the Second Reading debate, several peers raised the issue of direct payments, and their concerns around intended safeguards. We feel that there are two issues in particular which have not been addressed, which we would urge peers to raise during Committee Stage of the Bill.

Firstly, UNISON has concerns that there is not a sufficient “safety net” in place to protect those who choose to use direct payments. Lord Darzi’s Next Stage Review final report stated that safeguards would be put in place to ensure that NHS resources would be put to good use and that no one would be denied treatment as a result of having a personal budget. There is, however, no detail of this in the Bill. If a patient exhausts their budget, the two logical possibilities are either that the patient pays to top-up their care, or the NHS is left to foot the bill. Neither of these is acceptable.....

## V Innovation Prizes

*The Bill’s provisions on innovation prizes apply to England only.*

### A. The Bill (clause 14)

The Bill enables the Secretary of State to award prizes to promote innovation (including research) in the provision of health services in England, including prizes for work done before the Bill currently before Parliament becomes law. It also enables the Secretary of State to establish a committee to advise about awarding such prizes and to pay the committee’s members.

### B. Background

The provision to create innovation prizes is the fourth of the four measures in the Bill that featured in *High Quality of Care for All*. (The other three are described above.) In a section on *Creating a pioneering NHS*, *High Quality of Care for All* described several measures that the Government proposed to take in order to foster a pioneering NHS, one of which would be the introduction of prizes for innovation:

In addition, we will create new prizes for innovations that directly benefit patients and the public. They will help foster an enterprise and innovation culture within the NHS. The prizes will be designed to engage a wide range of NHS staff and an expert panel and will be focused on tackling some of the major health challenges, such as radical breakthroughs in the prevention and treatment of lifestyle diseases. (page 56)

### C. Responses

#### 1. Debates in the House of Lords

Debates in the House of Lords on innovation prizes were short; there was no debate at all on Report. There were no amendments in Grand Committee or on Report but on Third Reading, in response to arguments made in particular by Lord Walton and Lord Patel, the Government successfully introduced an amendment to clarify that innovation prizes would include research.<sup>103</sup>

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<sup>103</sup> HL Deb 12 May 2009 c933-4

At both Second Reading on 4 February 2009 and in Grand Committee on 5 March 2009, the Liberal Democrats argued that the prizes should not be paid for out of existing budgets for research, training and education. The Conservatives expressed some scepticism about the power of such a prize to bring about change and also suggested private sponsorship but neither party opposed the proposal.

Lord Darzi responded that funding for innovation prizes would be met from the overall resource envelope allocated to the Department of Health for the implementation of the commitments in the next stage review: "As such the funding available for innovation prizes- including that for administration- is all new money and will come on stream in 2010." The Government intended to allocate a prize fund of £5million per year for three years from 2010, totalling £15 million. There would also be an allocation of £1 million towards the administration, spread over the three year period.<sup>104</sup>

## **2. Briefings on the Bill**

### **a. *BMA Briefing for Second Reading in the House of Lords***

Doctors are at the forefront of innovation in the NHS and the Government's continued commitment to encourage innovation is welcome. We would seek further clarity from the Government on its intention on possible membership of the committee the Secretary of State may establish to advise on the form and allocation of innovation prizes. Also, further detail is sought on what role the Health Innovation Council will play (if any) in relation to the proposals on innovation prizes.

### **b. *NHS Confederation Briefing for Second Reading in the House of Lords***

There is little detail in the bill about how the prizes would operate. We would welcome further clarification to the following questions: What will be the size of innovation prizes? Will prizes be awarded to individuals or organisations? Who will make up the committee and how will they be appointed? The NHS Confederation would argue that prizes should not all go exclusively to high tech innovations, but also to lower tech innovations which can make a significant improvement to healthcare in community as well as hospital settings.

### **c. *Royal College of Nursing 2nd Reading Briefing***

Nurses are often at the forefront of innovation to improve the quality of patient care. The RCN welcomes the commitment to establish innovation prizes if these are transparent, fair and genuinely raise the morale of NHS staff. However, the way in which the schemes are implemented locally will be key in terms of assessing the practical impact the prizes will have on the NHS and those that work in it.

The RCN would like to see more detail on how the prizes will be decided and would hope that any effort to reward innovation will not be divisive and damaging to staff morale as a whole.

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<sup>104</sup> HL Deb GC323 – 332

## VI Trust Special Administrators for failing NHS Bodies

*The provisions on Trust Special Administrators apply to England only.*

### A. The Bill (clauses 15-18 and schedule 2)

These clauses would introduce a completely new chapter into the *NHS Act 2006*, with 28 new clauses, a new schedule, and consequential amendments. They provide for the appointment of a Trust Special Administrator to take over, for a limited period, the functions of an NHS Trust, a de-authorised NHS Foundation Trust, or the provider functions of a Primary Care Trust.<sup>105</sup>

The clauses provide for certain procedures to be followed when a Trust Special Administrator is appointed. In relation to NHS Foundation Trusts, this would include a de-authorisation procedure, whereby they would revert to being NHS Trusts. The clauses also provide for the functions of the Trust Special Administrator, including a requirement to consult; for various time limits within which certain actions must be taken, including a time limit for the TSA's final report to the Secretary of State; and for the Secretary of State's decision about the future of the Trust, for which he must give his reasons. Where a Primary Care Trust is concerned these provisions apply only to its provider functions.

### B. Background

The measures in the Bill are intended to form part of a wider process for dealing with the poor performance of NHS organisations. They are intended to be used as a last resort when an organisation fails either for clinical or organisational reasons. They do not cover independent sector organisations working under contract to the NHS.<sup>106</sup> These points are covered in more detail below.

A hint of the measures in the Bill was contained in the Department of Health document, [Developing the NHS Performance Regime](#), published in June 2008, which set out a framework for managing NHS performance. This discussed "challenged" organisations, defined as those underperforming persistently over time and likely to require support to achieve recovery and said that there might be cases where a "challenged" organisation was failing to address persistent underperformance because of weaknesses at board level or due to poor management. The document discussed the possibility of placing such an NHS organisation "under directions":

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<sup>105</sup> Primary Care Trusts are responsible for primary care services such as GP services and dental services. In many cases they do not provide the services directly themselves but they do have certain powers to do so. NHS Trusts run hospitals and certain other services, for example, ambulance services and mental health services. Foundation Trusts were created in order to provide NHS Trusts with more freedom from central government. They also have different governance arrangements from NHS Trusts. NHS Trusts have to apply to become Foundation Trusts and have to fulfil certain criteria to be accepted. As at 1 May 2009, half of all eligible acute and mental health trusts had become NHS Foundation Trusts, bringing the total number of Foundation Trusts in England to 120. There has so far been no provision for NHS Foundation Trusts to revert to the status of NHS Trusts (although there are provisions for dissolution etc.). For more information about NHS Foundation Trusts, see, for example: [http://www.dh.gov.uk/en/Healthcare/Secondarycare/NHSfoundationtrust/DH\\_072544](http://www.dh.gov.uk/en/Healthcare/Secondarycare/NHSfoundationtrust/DH_072544)

<sup>106</sup> See the documents referred to below and Government briefings and statements on the Bill.

122. Where a 'challenged' PCT or NHS Trust fails to demonstrate recovery the NHS Chief Executive may place the organisation 'Under Directions'. [The NHS Chief Executive would be acting under delegated authority from the Secretary of State.] We are exploring options to grant similar powers to Monitor in relation to NHS Foundation Trusts to the extent this may not be already provided for in existing legislation.

123. Placing an organisation 'Under Directions' will involve action to take control of the Board (ie suspensions/removals/appointments), possibly through an Intervention Order under the National Health Service Act 2006. Such intervention is also likely to include removing the incumbent Chief Executive's Accountable Officer status and designating a new member of the Board as Accountable Officer, either on an interim or permanent basis. [Removal of the Chief Executive from the Board, or removal of Accountable Officer status, would not terminate his/her employment, which would be a matter for the new Board to resolve.] The purpose of this intervention is to ensure service continuity for a transitional period pending further management and/or organisational change and make recommendations on a sustainable solution going forward.....

In September 2008, the Government followed this up with a consultation document, about establishing "a failure regime for state-owned providers that reflects the Government's obligations to ensure service continuity and protect public assets." This was called [Consultation on a Regime for Unsustainable NHS Providers](#). It referred to new enforcement powers held by the Care Quality Commission to tackle services that failed to meet registration standards.<sup>107</sup> The document argued that the application of these powers might make it clearer that a particular provider was not sustainable. For example, it was conceivable - albeit unlikely - that the Care Quality Commission could suspend or de-register a provider in its entirety on clinical quality grounds. This raised the question - amongst others - of what would then happen to that organisation, its services and staff.

The document set out a number of proposals with the following stated objectives:

13. The purpose of the regime we are proposing for unsustainable providers is fourfold:

- to underpin the NHS performance regime by providing a backstop of what ultimately happens if all previous turnaround efforts fail. Historically, failing NHS Trusts have been dealt with in a relatively ad hoc way; the specification of this regime sends a clear signal that, in future, failing services will no longer be supported. By making explicit the rules for an unsustainable provider regime, the Government believes that it is less likely that the regime will end up being used, because the certainty it provides will reinforce the motivation to take action at an earlier stage;

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<sup>107</sup> The Care Quality Commission is the independent regulator of health and social care in England. It came into being in April 2009 and took over, with enhanced powers, the functions of several earlier bodies. Its website is: <http://www.cqc.org.uk/>

- to ensure the public receive high-quality services by supporting quality regulation. It will provide a mechanism to address some of the consequences of the possibility of far-reaching Care Quality Commission enforcement action against a particular trust that breaches registration requirements. Therefore, close co-ordination between the proposed regime and the Care Quality Commission is vital;
- to reinforce the NHS Foundation Trust regime. The unsustainable provider regime supports the Monitor intervention regime and the pipeline of NHS Trusts applying to become NHS Foundation Trusts. It provides a practical answer to the question, unresolved since the conception of NHS Foundation Trusts in 2002, of what happens when an NHS Foundation Trust fails. The Health and Social Care Act 2003 (now consolidated into the NHS Act 2006) envisaged an insolvency procedure with significant commercial aspects, but the Department has never found an appropriate way to give a workable effect to that and has never laid the relevant regulations. This regime upholds the independence of Foundation Trusts and of their regulator, Monitor, but ensures that in the event of failure, Monitor is able to make the decision to de-authorise Foundation Trusts, where it sees fit; and
- to protect patients and staff from failing services and ensure good local services for all patients and service continuity even in the event of organisational failure. This regime will support staff in providing high-quality care to patients and will help to improve staff morale.

The document also set out the principles underlying its proposals and explained why the Government did not believe that a commercial insolvency procedure, or a similar arrangement, was appropriate for the NHS:

14. Discussion of organisational failure in the NHS often takes financial failure as its principal point of reference and assumes it is both possible and desirable to transpose onto the NHS a model of insolvency that includes significant commercial elements.

15. Instead, the proposals in this document for an unsustainable NHS provider regime recognise that financial failure will only ever be one aspect of a broader set of clinical service issues. Our proposals are based on the following five principles, which govern all aspects of our thinking, and we consider essential.

#### *Essential Principles*

Principle 1 – The most Patient interests must always come first. The most important consideration is the continuity of safe and effective services.

Principle 2 - State-owned providers are part of a wider NHS system. This was made clear in the draft NHS Constitution. NHS Trusts and divested PCT providers are not free-floating, commercial organisations. Whilst NHS Foundation Trusts are authorised to be run by independent boards and are answerable to a regulator nationally boards of governors locally. They remain part of the wider NHS. As such, the assets of state-owned providers will be protected, rather than disposed of by the courts.

Principle 3 - The Secretary of State is ultimately always accountable Parliament for what happens to local NHS services. In exceptional circumstances such as dealing with failed providers, accountability to Parliament should be emphasised.

Principle 4 - The regime for unsustainable NHS providers should take into account g staff and maintaining morale within the organisation will be crucial.

Principle 5 - The regime for unsustainable NHS providers must be credible and workable - otherwise there is no value in its specification. In particular, it needs to have transparent and rules-based processes to give confidence to provider organisations, such as NHS Foundation Trusts, that it will be used consistently and not so as to interfere with their independence. Critically, these rapid processes also need to be time-bound and ensure decision-making in these exceptional circumstances.

The document then set out some detailed proposals, responses to which were published by the Department of Health in January 2009, [Response to Consultation on a regime for unsustainable NHS providers](#) when the Bill was published.

## **C. Responses to the Bill's provisions on Trust Special Administrators**

There were no changes to the Bill's provisions on Trust Special Administrators in Grand Committee other than the change made in response to the Regulatory Reform Committee (see list of changes in the introduction to this paper). On Report, in response to the debate in Grand Committee, the Government introduced amendments to require the Secretary of State to give reasons for his decision about the report and recommendations of the Trust Special Administrator.

### **1. Debates in the House of Lords**

On Second Reading on 4 February 2009, neither Lady Barker nor Lady Tonge, who spoke for the Liberal Democrats mentioned the Trust Special Administrators.

Lord Howe, speaking for the Conservatives, argued both on Second Reading and in Grand Committee on 5 March 2009 that the net effect was that all liabilities of NHS Foundation Trusts would be underwritten by the taxpayer and this was bound to have an effect on decision-making at board level as well as sending out the wrong message to the independent sector. He believed that the responsibility for implementing the failure regime for Foundation Trusts should rest with Monitor, their regulator. He regarded the provisions in the Bill as "a seriously bad wrong turning on the part of the Government".

In his response Lord Darzi argued that he did not believe that the changes would change the incentives on NHS Foundation Trusts but the Government would work with Monitor to observe the effects on Foundation Trusts' incentives and behaviour, particularly with regard to borrowing.<sup>108</sup>

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<sup>108</sup> HL Deb 5 March 2009 GC 337

Other points raised in Grand Committee by the Conservatives included:

- The independence of the Trust Special Administrator from Government
- Who has to be consulted, on what and when, including the role of staff and the Care Quality Commission.

## 2. Briefings on the Bill

### a. ***British Medical Association Briefing for the Second Reading in the House of Lords***

The Government proposes to establish a regime for unsustainable NHS bodies in order to protect patients and staff from failing services. The Secretary of State would have the power to make an order to appoint a Trust Special Administrator (TSA), who would take charge of the organisation. The Government states that a TSA is only likely to be appointed after previous performance interventions have been unsuccessful – the BMA believes that much more clarity is needed on the process to be followed before recognition is given to the appointment of a TSA. Furthermore, the BMA seeks firm assurance from the Government that the TSA will be able to carry out their functions free from political interference.

### b. ***NHS Confederation Briefing for the Second Reading in the House of Lords***

It is important that trust special administrators should get the public involved, including involving foundation trust members and governors in the consultation. It could also be argued that the Secretary of State should consult the commissioner of the service as well as the SHA, as the PCT has the responsibility for the quality of care of patients.

In relation to Primary Care Trusts, this section of the bill applies only to provider responsibilities. The bill does not include equivalent powers for PCT board's commissioning responsibilities where the performance regime also applies.

The de-authorisation process will be triggered by the regulator, Monitor. Monitor should be free to exercise judgement rather than administering a rules based approach. Monitor is an independent regulator operating within its legislative framework and therefore imposing rules would be an unacceptable interference.

Clarity is needed as to what happens to joint ventures when a de-authorised foundation trust no longer has the freedoms it had.

### c. ***Royal College of Nursing Briefing for the Second Reading in the House of Lords***

The RCN agrees that a regime is required for of exit unsustainable providers in order to provide a credible signal that failure to deliver high quality, patient responsive services will not be tolerated. However given the link between this regime and the earlier checks and balances in the regulatory framework, it is vital that these are articulated and debated. This will affect the incentives (and hence behaviours) of the management team within NHS Trusts and NHS Foundation

Trusts. It is also in the context of the available leadership in the NHS. These need to be understood before final decisions on this regime are made.

Once the scheme is implemented it should be subject to regular review and assessment; The RCN broadly agrees with the principles underpinning this regime, however quality should be also be explicitly included and patients should be involved with the process for this should be clearly set out.

Staff engagement is critical and the RCN would like to see ongoing engagement before, during and after a provider is designated as unsustainable. This is vital to minimise a negative impact upon morale and retention. This includes engagement with staff directly affected, appropriate trade unions, and SHAs given the potential impact on the local health economy.

**d. UNISON**

UNISON welcomes the measures contained within the Trust Special Administrators section of the Bill that would mean an unsustainable or “failing” foundation trust would revert to being fully a part of the NHS, rather than being allowed to become insolvent and forced to close down. We would however like to see a stronger emphasis on involving the public and staff more fully in the entire consultation process that would take place in such circumstances.

## **VII Suspension of chairs and members of NHS bodies**

### **A. The Bill (clause 19 and schedule 3), Background and Response**

*This measure applies to a range of NHS bodies, the extent of whose functions varies. For example, some operate at UK level and some in England only.*

The Clause (clause 19) on powers of suspension and its associated schedule (schedule 3) were agreed in Grand Committee on 5 March 2009 without a debate. They would enable the Secretary of State to suspend and temporarily replace chairs and other members of certain NHS and health bodies, namely: Strategic Health Authorities, Special Health Authorities, Monitor, certain standing advisory committees (eg the Joint Committee on Vaccination and Immunisation), community health councils in Wales, the Human Tissue Authority, the Health Protection Agency, the Human Fertilisation and Embryology Authority, bodies established under the Medicines Act 1968, the Alcohol Education Research Council and the Appointments Commission.

Until recently the Secretary of State only had powers to appoint and remove chairs and other non-executives of NHS bodies. S/he did not have the power to temporarily suspend someone while an investigation took place. Following the outbreak of Clostridium Difficile at Maidstone and Tunbridge Wells NHS Trust in October 2007, the Secretary of State was given powers to suspend chairs and other non-executives of PCTs and NHS Trusts. (The Secretary of State’s powers are delegated to the

Appointments Commission). Similar powers are now being extended to cover various other NHS and health bodies.<sup>109</sup>

Very few organisations commented on these provisions. Those that did (for example, the Royal College of Nursing) welcomed them.

## VIII Pharmacy

*The Bill contains two sets of provisions on pharmacy, one applying to England and the other to Wales. This paper focuses on the provisions in England but includes a brief description of the provisions relating to Wales.*

### A. The Bill (clauses 25-29 for England and 30-32 for Wales)

In relation to England, the Bill makes three broad provisions, all of which add to or amend the *NHS Act 2006*:

- **New arrangements for entry to a PCT's list of NHS pharmaceutical services providers:** This has two elements:

*Pharmaceutical Needs Assessments:* The Bill requires Primary Care Trusts to assess needs for pharmaceutical services in their area and publish a statement of this assessment. This must be done in accordance with regulations. The Bill sets out several broad areas that the regulations must cover: the information that an assessment must contain; the extent to which it must take account of likely future needs; the date by which the first assessment must be published; and the circumstances in which a Primary Care Trust must make a new assessment. The Bill also sets out areas that the regulations may cover in particular: the services to which an assessment must relate; consultation requirements; the manner in which an assessment is made; and matters to which a Primary Care Trust is to have regard.

*Granting of applications to be on the PCT's list:* The Bill introduces a requirement that Primary Care Trusts have regard to their Pharmaceutical Needs Assessment (PNA) when deciding whether to grant an application to be on their lists of pharmaceutical services providers. It creates a distinction between applications that *must* be granted because they are considered necessary and those that *may* be granted because they would secure improvements or better access, having regard not only to the Pharmaceutical Needs Assessment but also to matters prescribed in regulations. The Bill also requires Primary Care Trusts to give reasons for their decisions.

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<sup>109</sup> For background, see Investigation into outbreaks of Clostridium Difficile at Maidstone and Tunbridge Wells NHS Trusts, Healthcare Commission 2007; Removing or suspending chairs and non-executives from PCTs and NHS Trusts: Consultation on introducing powers of suspension, Department of Health, 2008; The Primary Care Trusts and National Health Service Trusts (Membership and Procedure) Amendment Regulations 2008, SI 2008/1269; Removing or suspending chairs & non-executives of Health Bodies – Consultation on introducing new powers of suspension, Department of Health 2008.

- **PCT powers to issue notices and penalties:** The Bill would insert a new chapter into the *NHS Act 2006* which would enable regulations to provide for situations where pharmacists had breached the terms of their arrangement with the Primary Care Trust. The regulations would be able to provide for Primary Care Trusts to issue notices requiring the pharmacist to take or not take the actions specified in the notice and enable a PCT to withhold all or part of any payment due to the pharmacist. The Bill would also require that such regulations include rights of appeal.
- **Enabling Primary Care Trusts to provide local pharmaceutical services themselves:** The Bill makes various amendments to the *NHS Act 2006* that would enable a Strategic Health Authority to commission a Primary Care Trust (or Trusts) to provide local pharmaceutical services. The Bill would also enable a Primary Care Trust that has been commissioned to do so by a Strategic Health Authority to provide those services, but only in prescribed circumstances. (At the moment they can only commission such services.)

The provisions in the Bill relating to Wales (amending the *NHS (Wales) Act 2006*) are different. They do not cover the first of the three provisions described above. They do introduce new powers for Local Health Boards to issue notices and penalties that could be introduced by Welsh Ministers through regulations but would cover ophthalmic services as well as pharmaceutical services. They also enable Local Health Boards to provide local pharmaceutical services themselves in prescribed circumstances (there being no equivalent of Strategic Health Authorities in Wales.)

## B. Background

At the moment regulations under the *NHS Act 2006* govern entry to a PCT's pharmaceutical list. They are known as the "control of entry" regulations and can be traced back to 1987 when the Conservative Government was concerned about increasing numbers of pharmacists.<sup>110</sup> Subject to certain exceptions, they require that a PCT only grant an application to be on its list if it is satisfied that it is necessary or desirable<sup>111</sup> to grant the application in order to secure, in the relevant neighbourhood, the adequate provision of the services, or some of the services, specified in the application (known as the "necessary or desirable test").<sup>112</sup> The legislation does not require PCTs to carry out a pharmaceutical needs assessment.

In 2003 the Office of Fair Trading published a report on pharmacies, which concluded that the control of entry regulations had reduced entry to the market and distorted business locations. It recommended that controls on entry to the pharmacy market

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<sup>110</sup> See, for example, the debate on Second Reading of the National Health Service (Amendment) Bill, HL Deb 30 July 1986 cc911-2 and also the Committee Stage on Clause 2, HL Deb 15 October 1986 c831.

<sup>111</sup> The 2006 Act uses the words "necessary or expedient". In the consultation document referred to below, the Government proposes that the wording of the regulations should be aligned although it considers that the words are interchangeable and that the meaning of the legislation would not be changed.

<sup>112</sup> The NHS (Pharmaceutical Services Regulations 2005, SI 2005/641 Regulation 12. Further details about the current system are on the Department of Health's website:

<http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Communitypharmacy/index.htm>

should be lifted.<sup>113</sup> The Government's response to the pharmacy study did not view deregulation as the best course of action and it decided to modify the entry control regulations rather than to abolish them.

In 2005 new control of entry regulations were introduced, which exempted some types of pharmacy from control of entry procedures. In summary, categories that qualify for an automatic exemption are:

- Mail order services
- Pharmacies based in large shopping developments (over 15,000 square metres gross floor space) in out of town sites
- Pharmacies that intend to open for more than 100 hours a week
- Consortia wishing to establish new one-stop Primary Care Centres.<sup>114</sup>

The Department of Health published a [White Paper](#) on the future of pharmacy in April 2008,<sup>115</sup> which included its response to the [Galbraith Review](#) and to the All-Party Pharmacy Group's report, [The Future of Pharmacy](#), both published in 2007. The White Paper was followed by a consultation document on a number of proposals for structural change, including revisions to primary legislation, [Pharmacy in England: Building on strengths – delivering the future – proposals for legislative change](#).<sup>116</sup>

Proposals in the Bill are only part of the overall strategy for pharmaceutical services. Some of the changes proposed in the White Paper would not necessarily require legislation and some of the consultation document's proposals for legislation, have not surfaced in the Bill for a variety of reasons, for example, because they have been dropped or because they would be the subject of regulations rather than primary legislation.

A proposal to change the arrangements for dispensing doctors discussed in the consultation document aroused a great deal of controversy and were eventually dropped. In response to an Oral Question from John Mann in December 2008, Phil Hope, Minister at the Department of Health announced:

My hon. Friend has been at the forefront of the campaign on the issue of dispensing by doctors..... I am aware of the strength of the responses we received on the various options for amending the criteria for dispensing by doctors. We have taken into account the views of those attending the listening events, the meetings and so on, and as a result I am pleased to announce to him that there will be no change to the current arrangements on GPs dispensing medicines to their patients.<sup>117</sup>

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<sup>113</sup> Office of Fair Trading, [The Control of Entry Regulations and Retail Pharmacy Services in the UK](#), January 2003.

<sup>114</sup> *The NHS (Pharmaceutical Services) Regulations 2005*, SI 2005/641 Regulations 13-16.

<sup>115</sup> [Pharmacy in England: Building on strengths – delivering the future](#), Cm 7341, April 2008.

<sup>116</sup> Department of Health, [Pharmacy in England: Building on strengths – delivering the future – proposals for legislative change](#), August 2008 (with a closing date for the consultation of 20 November 2008).

<sup>117</sup> HC Deb 16 December 2008 c952

The consultation document and the White Paper also contained a discussion of the exemption, currently in regulations, from the control of entry procedures for pharmacies opening for more than 100 hours a week. On 24 March 2009, Lord Darzi answered a question about this, in which he said:

...We are considering the responses to the consultation in respect of pharmacies opening at least 100 hours per week. A full report of the consultation will be published in due course. In the meantime, the current system remains in place.<sup>118</sup>

Government briefings and Explanatory Notes on the Bill explain that the provisions on notices and penalties are intended to provide PCTs with more powers than they have at present and that the provision enabling PCTs to provide pharmaceutical services themselves are primarily intended for emergency situations.

## **C. Responses to the Bill's provisions on pharmaceutical services**

There were a number of technical Government amendments both to the provisions for England and for Wales. Proposed Opposition amendments were withdrawn.

### **1. Debates in the House of Lords**

During Second Reading there was little mention of the provisions on pharmacies although Baroness Barker, speaking for the Liberal Democrats, asked the Minister to explain whether the new system would decrease the number of pharmacies.<sup>119</sup>

During the debate in Grand Committee on 11 March 2009, one of the main subjects of debate concerned dispensing doctors in rural areas.<sup>120</sup> Other than that, Lord Howe, speaking for the Conservatives, proposed that there should be pilot schemes before PCTs were required to carry out pharmaceutical needs assessments and also one relating to the demarcation between the role of PCTs and the professional regulatory body for pharmacists in relation to a pharmacist's fitness to practise.<sup>121</sup> On report issues raised included the needs of the elderly, disabled and rural areas. Lord Howe again expressed concern that the Government was formalising a procedure that was not yet fit for purpose.<sup>122</sup>

### **2. Briefings on the Bill**

#### **a. BMA Health Bill, House of Lords Second Reading**

Clause 24 – New arrangements for entry to pharmaceutical list

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<sup>118</sup> HL Deb 24 March 2009 WA118.

<sup>119</sup> HC Deb 4 February 2009 c746.

<sup>120</sup> GC 468-476

<sup>121</sup> Debates in GC are at columns GC468-490.

<sup>122</sup> HL Debate 6 May 2009 c630-634

This clause relates to Control of Entry to the pharmaceutical services market as it places a statutory duty on Primary Care Trusts (PCTs) to conduct a Pharmaceutical Needs Assessment (PNA) across its area and then commission services relating to it. Dispensing doctors<sup>1</sup> are specifically excluded because the Control of Entry test<sup>2</sup> does not apply to them as the 2005 Pharmaceutical Services Regulations apply instead. If a PCT's PNA determines that there needs to be additional pharmacy provision in its area and a pharmaceutical services contractor were to apply to open a pharmacy next door to a dispensing practice, the existing 2005 Regulations relating to how a PCT would consider an application by a pharmacy in a rural area would still apply. This would mean no change from how a PCT would operate at the moment. It is also our understanding that the Government envisages no change to the situation at present as announced by the Department of Health Minister, Phil Hope MP, in the House of Commons on 16th December 2008.

**b. *NHS Confederation , House of Lords Second Reading***

A duty to access and publish pharmaceutical needs assessments (PNAs), which are to be used as a basis for deciding market entry, fits in well with the world class commissioning work stream and allows PCTs more control around decisions on commissioning community pharmacy services. These could, however, be integrated with PCT responsibilities to publish a wider Joint Strategic Needs Assessment. NHS Employers have developed PNA guidance to help PCTs understand how they fit in with the world class commissioning framework.

The quality regime for community pharmacy, based on existing and new legislation will bring community pharmacy in line with other primary care providers. It provides a helpful lever in terms of PCTs ability to performance manage the contract.

**c. *National Pharmacy Association, Briefing for House of Lords debates***

*Pharmaceutical Needs Assessment*

Many PCTs are currently ill-equipped to manage the 'new' PNAs and their follow-through. This should be made a required focus for improvement during the World Class Commissioning assurance process.

The scope, format and broad development process for PNAs should be set out in national guidance, to underpin quality and consistency – such guidance is imminent.

The competency framework for World Class Commissioning requires that PCTs should collaborate with the 'local care pathway experts' at each stage of the commissioning cycle. It should be understood that existing local contractors fit this description and should therefore be party to the development of the needs assessment

*Entry to the pharmaceutical list*

DH has indicated that the current regime, including exemptions to market entry, will give way to PCT control of market entry, on the basis of robust pharmaceutical needs assessments (PNAs). We agree that exemptions should

be removed and replaced by a reformed process of managed entry based on mapped need.

We are concerned that no timetable has been laid out for the removal of the 100 hour exemption, which is a highly destabilizing factor of the current market entry regime, undermining the confidence of existing pharmacy contractors to invest in premises and services.

PNAs must be robust enough to give a clear description of currently unmet need and to inform appeals. To this end, they should be developed by up-skilled staff in consultation with local pharmacy contractors and regularly updated.

It should be understood that if a PNA identifies an unmet need, then there is an obligation on PCTs, under normal circumstances, to secure provision sufficient to meet that need.

Where a PNA identifies services (as distinct from needs) that the PCT is not in a position to commission at that time, this should be clearly stated.

#### *Notices and penalties*

For as long as a pharmacy remains on the pharmaceutical list, we do not accept that the withholding of payments for core services should be amongst the sanctions available to PCTs should that pharmacy not perform to accepted quality standards. This could lead to a rapid deterioration in service, having the opposite effect to that intended by the penalty. (Pharmacies' day-to-day financial outlay can not usually be deferred, so withholding payments would have an immediate and dramatic effect on cash-flow and the consequent ability to provide core services).

Contractors should have the right to have appeals heard before any sanctions are applied.

#### *LPS Schemes*

The proposal to allow a PCT to become an LPS provider would seem reasonable in genuinely emergency situations. To ensure that this amendment is used appropriately, the description of emergency situation needs to be tightly defined. A suitable candidate is found consider delivering the contract itself. The PCT should be able to demonstrate that a fair and transparent process has been undertaken

It is suggested that this power could be used in the absence of any other suitable alternative provider. We believe that there should be a requirement on the PCT to invite other contractors to apply to take on the LPS, and only if no suitable candidate is found consider delivering the contract itself. The PCT should be able to demonstrate that a fair and transparent process has been undertaken.

### **d. *Pharmaceutical Services Negotiating Committee, Briefing for debates in the House of Lords***

#### *Pharmaceutical Needs Assessments*

We are surprised that Clause 23 which sets out the additional section 128A of the NHS Act 2006 does not require the Regulations to specify the persons who must

be consulted in the course of developing a PNA. We suggest that the Local Pharmaceutical Committee and the pharmacy contractors in the PCT area must be involved in the development of a robust and meaningful PNA.

*Control of Entry test*

The introduction of the PNA based test for entry onto a PCT's list (clause 24) was first proposed in Pharmacy in England – Building on strengths – delivering the future and in the subsequent consultation, it was suggested that the exemptions from the current market entry test, for example that applying to pharmacies opening for at least 100 hours per week may no longer be needed. The Bill should have included explicit provisions on the future of the exemptions.

Under the first part of the new test, a PCT must grant an application where this offers to provide some or all the services identified in the PNA as gaps in provision. But, a PNA may also include aspirations as to the future commissioning of services, whether or not the PCT is in a position to commission them. This could lead to PCTs being obliged to grant all applications if there is even the smallest gap in commissioned or aspirational services. We believe that the obligation to grant applications should arise only where the type of service to be provided is set out in regulations and where the PCT intends to commission, but has been unable to secure that service locally.

Whilst recognising that PCTs may wish to encourage applications for inclusion in a pharmaceutical list to fill unmet need, there must be a prohibition on the PCT also demanding payment of a premium on the lease costs.

*Fixed period inclusion in the pharmaceutical list*

We believe that allowing a PCT to grant an application for inclusion in the pharmaceutical list for a fixed term would reduce commercial confidence and therefore limit the investment in developing high quality premises, services and staff.

**e. *Royal College of Nursing Second Reading in the House of Lords***

Clauses 23-25 – Reforming pharmacy

The RCN is pleased to note that community pharmacy is now being recognised by the Government as a mainstream contributor to primary care and public health. The current priority is to integrate services provided through community pharmacies into programs provided by other primary care professionals including nurses. Provided there is sufficient investment this change should be welcomed and offers the potential for community pharmacy services to become fully integrated into NHS long-term care and public health programmes.

**f. *Royal Pharmaceutical Society of Great Britain, Briefing for debates in the House of Lords***

*Clause 23, Pharmaceutical Needs Assessments*

Many PCTs have gone through the process of creating a Pharmaceutical Needs Assessment (PNA) but the translation of that PNA into a service that reflects the

pharmaceutical needs of a population has been achieved with varying levels of success.

This Clause creates a new duty for all PCTs in England with respect to their assessments of pharmaceutical needs. This will mean that PCTs are required to undertake a PNA, publish a statement of their first assessment and any subsequent revisions. Criteria will be drafted that govern how these assessments should be undertaken: statutory information to be contained within the PNA; the extent to which future considerations need to be included; publication dates of the first assessment and the circumstances governing the need for PCTs to review their assessments.

The RPSGB supports this measure but the relative success of the introduction of mandatory PNAs will be determined by how well they can be translated into delivery via effective commissioning. Evidence from pharmacists suggests that the transfer of a PNA into delivery within communities is not consistent.

*'Pharmaceutical Needs Assessments as part of world class commissioning'*

Recent guidance published by the NHS employers on 'PNAs as part of world class commissioning' indicates that PNAs can set standards for all pharmacies to aspire to. The guidance also indicates PCTs can also stipulate minimum standards for premises in their PNAs which will guide their commissioning decisions about local enhanced services.

The guidance goes on to provide that the PCT should be able undertake a number of commissioning and regulatory functions in relation to the provision of high quality pharmaceutical services for its population.

The RPSGB opinion is that this will introduce an additional level of regulation that could conflict directly with the powers of the new pharmacy regulator, the GPhC when it comes into being in 2010. A difference of opinion in interpretation of the guidelines between these two regulators will lead to confusion and potential legal claims against a PCT.

*Clause 24 New Arrangements for entry to the Pharmaceutical List*

The new clause removes an anomaly that allowed any pharmacy willing to open for 100 hours or more per week to set up at a place of its choosing. It allows a PCT to develop a service that provides pharmaceutical services where needed. Decisions made in relation to applications made under this section will be publicised to ensure clarity.

The RPSGB has some concerns in relation to this Clause in that the PNA must be the result of a robust process that involves real consultation with all relevant stakeholders, such as the Local Pharmaceutical Committee, before any such decision can be made.

*Breach of arrangements: notices and penalties*

There are new provisions concerning the ways in which PCTs can deal with contractors in breach of the terms of their contracts, for example failures of quality or performance. PCTs will have the power to issue notices requiring action by the

contractor or they may withhold all or part of any payments due to the contractor for a prescribed period.

The RPSGB has some concerns in relation to this Clause in that the criteria on which pharmacists are measured must be consistent across all English PCTs and Welsh Health Boards.

The system is described by the Government as a way to recognise good practice and eradicate bad but there is no mention of what form recognition for good practice will take.

#### *Chapter 27 Local Pharmaceutical Services (LPS) schemes*

This chapter deals with the role of PCTs to provide pharmacy services as a response to an emergency situation such as pandemic flu.

The RPSGB agrees with what is a common sense measure but cautions against this clause being enacted except in extreme circumstances where the existing network of pharmacy services is unable to deliver an acceptable service.

## **IX Adult social care by Manjit Gheera**

*The Bill's provisions on the investigation of adult social care complaints apply to England.*

### **A. The Bill**

Part 3 of the *Local Government Act 1974* established the Commission for Local Administration to investigate complaints of maladministration against public authorities. Clause 31 of the Bill would give effect to Schedule 5 of the Bill, which would insert a new Part 3A<sup>123</sup> into the *Local Government Act 1974*. New Part 3A would extend the Commission's remit to investigate complaints about adult social care which is privately arranged or privately funded. This would include complaints from people who use social care direct payments to arrange their own care. Complaints which fall within local authority remit are excluded from the new Part 3A regime as they are covered by the existing Part 3.<sup>124</sup> Schedule 5A sets out other matters which the Local Commissioner would not be able to investigate under Part 3A.<sup>125</sup>

Currently, in cases involving complaints about social services care provision, complainants are generally required to raise initial concerns with the service provider. This general expectation is preserved under the Bill. However, an individual Local Commissioner would be allowed to use his discretion in cases where it may not be reasonable to expect a provider to be given prior notice of the complaint.<sup>126</sup> The

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<sup>123</sup> Part 3A contains new sections 34A-34T

<sup>124</sup> Schedule 5A

<sup>125</sup> New section 34B

<sup>126</sup> New section 34B(6)(b)

individual user, and a person acting on the user's behalf, would be able to raise a complaint with the Commissioner.<sup>127</sup>

## B. Background

All local authority social services departments are required by law to have a complaints procedure.<sup>128</sup> Further recourse is available to the Local Government Ombudsman (LGO), officially known as Commission for Local Administration, who can examine cases of maladministration against a local authority. The LGO was established under the *Local Government Act 1974* to investigate complaints about local authority matters including:<sup>129</sup>

- housing
- planning
- education
- social care
- housing benefit
- transport and highways
- antisocial behaviour
- council tax.

The remit of the LGO does not extend to investigating complaints from individuals who have arranged their own social care contracts (either privately funded or with direct payments), estimated to be about 35% of care users.<sup>130</sup> These individuals can complain to the service provider but they do not have access to a statutory complaints procedure.

The anomalous situation for privately funded social care users raised concerns from the Joint Committee on Human Rights (JCHR) in its report on the *Human Rights of Older People in Healthcare*.<sup>131</sup> In its recommendations the JCHR stated:<sup>132</sup>

In our view, in order to ensure greater protection of an individual's human rights, an individual (or his or her relative or carer) must have a real and effective means of raising concerns with service providers and, if they are not able to deal satisfactorily with the issue, a third party to which he or she can address complaints. [...] Such mechanisms go to the very heart of ensuring that the human rights of patients and residents are respected in practice.

We were alarmed that the Minister was unable to guarantee that the new inspectorate would be able to investigate individual complaints at the appropriate point in the process. We are convinced that complaints, including those raising human rights concerns, need to be investigated by an independent third party,

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<sup>127</sup> New section 34C

<sup>128</sup> *Local Authority Social Services Complaints (England) Regulations 2006* (No.1681); *Social Services Complaints Procedure (Wales) Regulations 2005* (No.3366)

<sup>129</sup> <http://www.lgo.org.uk>

<sup>130</sup> Department of Health, *Impact Assessment for the Health Bill*, para 38

<sup>131</sup> Joint Committee on Human Rights, *Human Rights of Older People in Healthcare*, 18<sup>th</sup> report of 2006-7. HL Paper 156-I; HC 378-I

<sup>132</sup> *Ibid*, paras 243, 258

rather than by the organisation against which the complaint is made and where the older person may continue to live.<sup>133</sup>

In response to the report,<sup>134</sup> the Government acknowledged that there was problem with self-funders' options for redress and it announced that it was considering the issue.<sup>135</sup>

The issue of the lack of redress for privately funded users of social care services was also raised last year during the debates on the *Health and Social Care Bill*. In response to the proposals suggested by the JCHR, Baroness Stern tabled amendments to require the new Care Quality Commission (CQC) to consider the adequacy of health and social care complaints investigations:

As I indicated, the amendments in this group are intended to deal with problems that we identified in our study into older people in healthcare. These were that the system was inaccessible; did not meet all the complaints that residents may wish to raise, particularly where human rights were at issue; and could not deal with complaints raised by self-funders, who could complain only directly to their provider—which was difficult when they were resident in a care home—or through a contractual claim in the civil courts. The Government responded to our report, making it clear that, in their view, these amendments were not necessary because, in cases where care is commissioned by the NHS or local authorities, there will be a statutory complaints process with a further avenue of complaint to the relevant ombudsman, who is either the health ombudsman or the Local Government Ombudsman. Those whose care is privately funded will not be covered by these procedures, but the Government are considering what options should be available to them.<sup>136</sup>

The amendments were widely supported by the House, including by Baroness Greengross, who added:

On self-funders, the Minister with responsibility for care in another place has said publicly on many occasions that this is the total unintended consequence. It was never intended that self-funders should be treated in this way and not be given the help and advice that they need. I very much hope that the Government will do something about that very soon [...] At the moment, it is an absolute disaster for self-funders.<sup>137</sup>

The amendments were however withdrawn on the basis of reassurances given by the Minister for Health, Lord Darzi of Denham, that the Government were looking into the issue:

We recognise that there is an issue about the fairness of current arrangements for people who either choose to seek care independently or who do not qualify for

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<sup>133</sup> The new inspectorate referred to is the Care Quality Commission established under the *Health and Social Care Act 2008*.

<sup>134</sup> [Government Response to the Committee's Eighteenth Report of Session 2006-07, \*The Human Rights of Older People\*](#). HL paper 5; HC 72,

<sup>135</sup> *Ibid*, p19

<sup>136</sup> HL Deb 29 April 2008 GC37

<sup>137</sup> HL Deb 29 April 2008 GC43

state support and feel that their complaints have been inadequately addressed. The Government are actively considering ways in which some form of independent resolution may be achieved for those groups; I very much hope to have some answers in due course. We are also looking at options for ensuring that local complaints arrangements are as consistent as possible, whether they relate to publicly or privately funded services. So, to the extent that the final registration requirements—currently the subject of our consultation—cover this issue, the commission will already have the powers it needs to ensure that registered care providers are handling complaints properly, whatever the arrangements may be to provide that care.<sup>138</sup>

At Third Reading of the *Health and Social Care Bill* the Government confirmed the action it would be taking to rectify the anomaly between private and publicly funded social care complaints systems:

**Baroness Thornton:** I am pleased to confirm that we will take the next available legislative opportunity to extend the remit of the Local Government Ombudsman so that he or she can investigate complaints by self-funders. I know that many noble Lords have expressed concerns about this issue. I therefore trust that this proposal, which is certain to make a real difference to people who arrange and fund their own care, has the support of the House.<sup>139</sup>

## C. Debates in the House of Lords

### a. *Second reading*

The proposals for a complaints scheme for self-funding users of adult social care received unanimous support during the Second Reading debate in the House of Lords. However, although welcoming the provision, Baroness Young of Old Scone remarked:

The complaints processes and system are still pretty complex for the average user to penetrate. I do hope we can press the Minister to get a clear exposition of exactly how the wider complaints process in health and social care will work for the future and how it can be readily understood by the public, and that all those involved in the complaints process can help to promulgate information widely across the public domain.<sup>140</sup>

### b. *Committee stage*

In Committee, other than a minor drafting amendment moved by the Government, no other amendments were agreed to. The issues raised in relation to social care complaints included:

- The extent of the definition of “adult social care providers” following an amendment moved by Earl Howe.<sup>141</sup> The Minister explained that the

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<sup>138</sup> HL Deb 29 April 2008 GC46

<sup>139</sup> HL Deb 1 July 2008

<sup>140</sup> HL Deb 4 February 2008, c698

<sup>141</sup> Amendment 116

definition mirrored that in the *Health and Social Act 2008* and sought to encompass activities connected with health and social care that would be regulated by the Care Quality Commission. Accordingly, the definition would include 'the supply of staff who are to provide such care; the provision of transport or accommodation for those who require such care; and the provision of advice in respect of such care.'<sup>142</sup>

- The Commissioner's powers to determine whether an individual should be represented during an investigation. The aim of the clause is regulate the investigation procedure and to ensure that it does not become unduly bureaucratic or costly. It would also assist the Commissioner in cases where a particular representative may pose a conflict of interest or place undue pressure on a witness.<sup>143</sup>
- Whether the Commissioners should be under a duty to send a statement about an investigation to the CQC or any local authority with an interest in the matter.<sup>144</sup> Amendments to impose such a duty were tabled by Baroness Baker in order that the CQC and local authorities are kept informed of the outcomes of complaints against private providers. The Minister explained that a new section 34H(7) would give Commissioners a discretionary power to inform the CQC and local authorities of such matters in appropriate cases. The Minister added the provisions 'allow the necessary degree of flexibility for the ombudsman, enabling appropriate rather than compulsory communication.'<sup>145</sup>

### **c. Report Stage**

At Report stage two amendments were tabled by Baroness Stern to Schedule 5 and the new sections 34F and 34H, which set out the investigation procedure for Local Commissioner and the issuing of statements.<sup>146</sup> The amendments were tabled in response to concerns raised by the Joint Committee on Human Rights that social care complainants were unable to comment on representations made in response to their complaint.<sup>147</sup> The tabled amendments raised the following issues:

- Whether there should be a duty on the Commissioner to show a complainant comments made in response to a complaint and give the complainant an opportunity to comment. The Minister informed the Committee that under the current procedure for local authority complaints, the Commissioner has a discretion to reveal comments to a complainant and that not all comments on a complaint will be relevant. He informed the Committee that a parallel approach for Part 3A complaints would

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<sup>142</sup> HL Deb 11 March 2009 GC493. The amendment was withdrawn

<sup>143</sup> Amendment 117. HL Deb 11 March 2009 GC493-4. The amendment was withdrawn.

<sup>144</sup> Amendments 118 and 119

<sup>145</sup> HL Deb 11 March 2009 GC495

<sup>146</sup> Amendments 68 and 69. HL Deb 6 May 2009 c 639

<sup>147</sup> Joint Committee on Human Rights, *Legislative Scrutiny: Health Bill, Eleventh report of 2008-9*. HL Paper 69, HC 369, 15 April 2009.

‘avoid making the process bureaucratic and time-consuming’. The amendment was withdrawn.<sup>148</sup>

- Whether the requirement on the Commissioner to send a statement about an investigation to concerned persons<sup>149</sup> required strengthening to allow such persons the opportunity to comment on the statement. Under the proposed amendment the Commissioner would be required to have regard to any comments when preparing a final statement. The Minister pointed out that under the current local authority scheme the Commissioner generally allows parties to see provisional comments following an investigation. He added that the amendment would legislate for a process that already happened and would remove ‘essential flexibility’ that currently existed. The amendment was not moved.<sup>150</sup>

## **X Disclosure of information by Her Majesty’s Revenue and Customs (HMRC)**

*The Bill’s provisions on disclosure of information extend to the UK.*

### **A. The Bill, clause 35**

Clause 35 allows HMRC to disclose information collected for income tax purposes relating to GPs and dental practitioners’ earnings and expenses. The information would have to be in an anonymised form and could only be disclosed to those specified in the Bill, such as the Secretary of State, Welsh Minister and Scottish Ministers.

The Explanatory Notes to the Bill say that it has been the practice of HMRC over a number of years to assist in statistical enquiries carried out by or on behalf the Department of Health and in some cases the devolved administrations. The *Commissioner for Revenue and Customs Act 2005* prohibits officials of HMRC from disclosing information of any kind held by HMRC in connection with a function of the HMRC, subject to certain exceptions. The Bill would provide a further exception to enable HMRC to continue to participate in annual earnings and expenses exercises.

There was only a very brief debate on this during the Bill’s passage though the House of Lords and the main concern expressed was that the provision for anonymity should be adequate.<sup>151</sup>

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<sup>148</sup> HL Deb 6 May 2009 c 641

<sup>149</sup> Schedule 5/new section 34H

<sup>150</sup> HL Deb 6 May 2009 c 641

<sup>151</sup> HL Deb 17 March 2009 GC35-38

## XI Private Patient Cap and other issues

*The new clause on Foundation Trusts and income from private patients applies to England. (The other issues mentioned in this section did not become part of the Bill.)*

### A. NHS Foundation Trusts and income from private patients

The Bill now contains a new clause, clause 34, which would allow exemptions to the private patient cap for NHS Foundation Trusts to be made in regulations. The private patient cap is a limit that applies to NHS Foundation Trusts only and it applies to income that they can make from private patients. It has existed since NHS Foundation Trusts were set up under the *Health and Social Care (Community Health and Standards) Act 2003* and it is linked to the level of income that the Trust made in the year 2002-03.

This is a separate issue from other measures in the Bill but it was a much debated one and it resulted in a defeat for the Government. Lady Meacher, a Crossbench peer, introduced a probing amendment in Grand Committee, which would have removed the private patient cap and substituted a requirement for all NHS Trusts to demonstrate the benefit of private patient services to their NHS patients.<sup>152</sup> The issue was discussed again on Report on an amendment moved by Lord Howe that would have allowed Monitor, the regulator of NHS Foundation Trusts, to permit exceptions.<sup>153</sup> On Third Reading Lady Meacher moved a slightly different amendment to enable the Secretary of State to make regulations to permit exceptions to the cap. The amendment had the support of Lady Barker, Lord Warner (a former Labour Minister) and Lord Howe and it was successful on a division by a vote of 191 to 133.

Lady Thornton, speaking for the Government at each of these stages of the Bill's proceedings, argued that although the cap might be arbitrary, a broader debate about the long-term direction of the policy was necessary before a lasting solution could be found. A judicial review was currently considering what income counted towards the cap and the Government was committed to taking forward a review following the outcome of this judicial review.<sup>154</sup>

### B. Other issues

As with the private patient cap, members of the House of Lords used the passage of the Bill to raise a number of issues that were not included in the Bill. Some of these have already been mentioned, for example, the issue of contaminated blood during the debates on the NHS Constitution and the issue of top-ups for NHS continuing care during the debates on direct payments. A number were, like the private patient cap, the subject of proposed new clauses at the end of the Grand Committee debates on 17 March 2009 but, unlike, the private patient cap, none of these resulted in amendments to the Bill. They are listed below:

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<sup>152</sup> HL Deb 17 March 2009 GC 64-78;

<sup>153</sup> HL Deb 6 May 2009 c654-660

<sup>154</sup> HL Deb 12 May 2009 c940

- Organ donation GC 38-46
- Spinal injuries GC 46-61
- Tax relief on medical insurance premiums GC 61-64
- Charges for refused asylum seekers GC 79-89
- Patient transport services GC 89-90
- Contaminated blood products GC 91-97