CONTENTS

Clauses 212 to 215 agreed to, one with an amendment.
Schedule 14, as amended, agreed to.
Clause 216 agreed to.
Schedule 15 agreed to.
Clauses 217 to 233 agreed to, some with amendments.
Schedule 16, as amended, agreed to.
Adjourned till Thursday 31 March at Nine o'clock.
Members who wish to have copies of the Official Report of Proceedings in General Committees sent to them are requested to give notice to that effect at the Vote Office.

No proofs can be supplied. Corrigenda slips may be published with Bound Volume editions. Corrigenda that Members suggest should be clearly marked in a copy of the report—not telephoned—and must be received in the Editor’s Room, House of Commons,

not later than

Saturday 2 April 2011

STRICT ADHERENCE TO THIS ARRANGEMENT WILL GREATLY FACILITATE THE PROMPT PUBLICATION OF THE BOUND VOLUMES OF PROCEEDINGS IN GENERAL COMMITTEES
The Committee consisted of the following Members:

**Chairs:** † Mr Jim Hood, Mr Mike Hancock, Mr Roger Gale, Dr William McCrea

† Abrahams, Debbie (*Oldham East and Saddleworth*) (Lab)
† Barron, Mr Kevin (*Rother Valley*) (Lab)
† Blenkinsop, Tom (*Middlesbrough South and East Cleveland*) (Lab)
† Brine, Mr Steve (*Winchester*) (Con)
† Burns, Mr Simon (*Minister of State, Department of Health*)
† Burstow, Paul (*Minister of State, Department of Health*)
† Byles, Dan (*North Warwickshire*) (Con)
† Crabb, Stephen (*Preseli Pembrokeshire*) (Con)
† de Bois, Nick (*Enfield North*) (Con)
† James, Margot (*Stourbridge*) (Con)
† Kendall, Liz (*Leicester West*) (Lab)
† Lefroy, Jeremy (*Stafford*) (Con)
† Morgan, Nicky (*Loughborough*) (Con)
† Morris, Grahame M. (*Easington*) (Lab)
† Poulter, Dr Daniel (*Central Suffolk and North Ipswich*) (Con)
† Pugh, John (*Southport*) (LD)
† Shannon, Jim (*Strangford*) (DUP)
† Smith, Owen (*Pontypridd*) (Lab)
† Soubry, Anna (*Broxtowe*) (Con)
† Sturdy, Julian (*York Outer*) (Con)
† Thornberry, Emily (*Islington South and Finsbury*) (Lab)
† Turner, Karl (*Kingston upon Hull East*) (Lab)
† Twigg, Derek (*Halton*) (Lab)
† Wilson, Phil (*Sedgefield*) (Lab)

Chris Stanton, Mark Etherton, Committee Clerks

† attended the Committee
Public Bill Committee

Tuesday 29 March 2011

(Afternoon)

[Mr Jim Hood in the Chair]

Health and Social Care Bill

Clause 212

Establishment of voluntary registers

4 pm

Question (this day) again proposed, That the clause, as amended, stand part of the Bill.

The Minister of State, Department of Health (Paul Burstow): Before we broke for other business, we were discussing some important matters on the Government’s overall approach to the regulation of health and social care professionals and workers, and when it is appropriate to extend regulation to new groups.

We have made it clear that we will not rule out compulsory statutory regulation for any part of the work force when there is a compelling case for it on the basis of a public safety risk and when assured voluntary registers are not considered sufficient to manage the risk. It is important, however, that the costs and benefits of regulation are fully assessed and that a clear case can be made that compulsory statutory registration is proportionate before it is introduced.

Hon. Members, and the hon. Member for Islington South and Finsbury in particular, have expressed the view that social care workers should be subject to compulsory statutory regulation. I do not want to belittle the very real concerns she has raised about the poor quality of care in some parts—I emphasise that—of the care sector. Nor do I wish to dwell unnecessarily on the past, but I remind the Committee that in 2005 the previous Administration committed to regulating 250,000 home care workers and a further 500,000 residential care workers. By 2007, however, it became increasingly clear that the commitment to registering the entire work force had not been fully thought through and was not being implemented. The Government then clarified that their intention was to regulate home care, or domiciliary care, workers in the first instance.

Until July 2009, work was undertaken to enable a voluntary register for home care workers to be opened by the General Social Care Council by 2010. In 2009, however, the General Social Care Council discovered a backlog in its handling of conduct cases, and work on opening a register of home care workers was postponed until Ministers were confident that the General Social Care Council could deliver its existing functions.

That is effectively where we found things when we came into office. As the Committee knows, that backlog led to the commissioning of the report by the Council for Healthcare Regulatory Excellence, which has been mentioned several times in debates on this part of the Bill.

It is our view that voluntary registration should be encouraged for the adult social care work force. We will explore the scope for the Health and Care Professions Council to establish a voluntary register of social care workers in England by 2013. Although regulation of the health and social care work force is sometimes necessary, under the previous Administration there was a tendency for compulsory blanket statutory regulation of the health and social care work force in England to be seen as the first resort, rather than the last, in deciding how best to assure appropriate standards of care.

If all the previous Administration’s commitments to extend regulation to new groups of workers had been delivered, an additional 1.3 million workers, many of whom are in relatively low-paid support roles, would be obliged by law to pay registration fees to continue to pursue their livelihoods. It is our view that the assured voluntary route is a better route, and, more than that, we need to strengthen local responsibility for managing problems effectively and promptly.

The Government’s view is that there is a key role for employers and providers in ensuring high standards of service. That role must rest with local service providers. As the previous Government demonstrated, it is simply not possible effectively to manage the whole system from the centre.

The Government are clear that regulation of individual workers is not always the proportionate response given the wider safeguards in the system. Children’s services providers, for example, are regulated by Ofsted. Many providers of health and social care services in England must register with the Care Quality Commission and meet a set of 16 essential safety and quality requirements. People working in health and social care in England also fall within the scope of the vetting and barring system. In the NHS there are specific obligations on employers to undertake a range of pre-employment checks on workers, and primary care providers are subject to a range of statutory checks by virtue of the National Health Service (Performers Lists) Regulations 2004.

There is clearly a need to ensure that providers are held to account for the quality of the work force and that swift and effective action is taken by the Care Quality Commission when there is a breach of its standards. For those reasons, we seek a more proportionate approach that will enable a system of assured voluntary registration to be developed for unregulated workers, with the CHRE being the national accrediting body for registers of health care workers throughout the UK who are currently not regulated by statute, and for social care workers in England.

Our view is that a system of assured voluntary professional registration should be considered in the first instance as an alternative to statutory intervention to drive up the quality of service provision, and that full statutory regulation should be a last resort. However, we recognise that in exceptional cases assured voluntary professional registration will be considered insufficient to mitigate against the level of presenting risk; if the extension of compulsory statutory regulation is necessary, it will be taken forward by the Government.
At present, there is no external quality assurance to enable existing holders of voluntary registers to demonstrate that they set and enforce professional standards effectively. The Government therefore intend to establish the CHRE—under the Bill, it will be renamed the Professional Standards Authority for Health and Social Care—as the national accrediting body for voluntary registers for health care workers for the UK and for social care workers in England.

It is our intention that the authority will set standards against which the governance, procedures, registration criteria and performance of voluntary registers can be judged, to establish whether they are sufficient to provide assurance to the public and employers about the training, skills and conduct of their registrants. Through assured voluntary registration, we seek to improve service users’ experience of the system by driving up the quality of the work force. We will also ensure that voluntary registration systems accredited by the authority make appropriate links to the wider regulatory system and include appropriate policies on professional indemnity and safeguarding—including, when appropriate, procedures for making referrals to the Independent Safeguarding Authority, or Disclosure Scotland, if individuals are deemed to pose a risk to the public.

For all those reasons, I hope that I have reassured the Committee and that I have persuaded the hon. Member for Islington South and Finsbury that the clause should stand part. Indeed, I urge my colleagues to ensure that it does.

Emily Thornberry (Islington South and Finsbury) (Lab): I have listened carefully to the Minister, and I am not reassured. I still do not understand why Scotland and Northern Ireland should move towards a mandatory system of registration and why we are not learning from experience of the system by driving up the quality of the work force. We will also ensure that voluntary registration systems accredited by the authority make appropriate links to the wider regulatory system and include appropriate policies on professional indemnity and safeguarding—including, when appropriate, procedures for making referrals to the Independent Safeguarding Authority, or Disclosure Scotland, if individuals are deemed to pose a risk to the public.

For all those reasons, I hope that I have reassured the Committee and that I have persuaded the hon. Member for Islington South and Finsbury that the clause should stand part. Indeed, I urge my colleagues to ensure that it does.

Emily Thornberry (Islington South and Finsbury) (Lab): I have listened carefully to the Minister, and I am not reassured. I still do not understand why Scotland and Northern Ireland should move towards a mandatory system of registration and why we are not learning from Wales. I found the Minister’s response extraordinarily complacent. I wish to put the clause to a vote.

Question put, That the clause, as amended, stand part of the Bill.

The Committee divided: Ayes 13, Noes 10.

Division No. 93]

AYES

Brine, Mr Steve
Burns, rh Mr Simon
Bristow, Paul
Byles, Dan
Crabb, Stephen
de Sois, Nick
James, Margot

Lefroy, Jeremy
Morgan, Nicky
Poulter, Dr Daniel
Pugh, John
Soubry, Anna
Sturdy, Julian

NOES

Abrahams, Debbie
Barron, rh Mr Kevin
Blenkinsop, Tom
Kendall, Liz
Morris, Grahame M. (Easington)

Smith, Owen
Thornberry, Emily
Turner, Karl
Tivig, Derek
Wilson, Phil

Question accordingly agreed to.

Clause 212, as amended, ordered to stand part of the Bill.

Clause 213 and 214 ordered to stand part of the Bill.
stated that £10 million would be saved every year as a result of rolling up into one adjudication body the adjudication hitherto conducted by the GMC, the General Optical Council and the relevant bodies for pharmacy and nursing. It thought that a united body would save £10 million, which was the cost of the initial set-up. Is the Minister convinced that the financial argument makes sense?

More importantly, OHPA's submission concluded that, had it gone ahead and been maintained by the Government, it would have addressed the legitimate “public concern and lack of legal soundness inherent in a system where the disciplinary body bringing the proceedings is also responsible for judicial decision-making”.

Is the Minister entirely certain and content that allowing the GMC to make adjudications on its members is the appropriate way forward? The GMC has submitted evidence to the Committee in which it supports the Government's decision to scrap OHPA. Having already said that OHPA was not a good idea, such evidence should not be a great surprise to us. In its evidence it says that it has addressed the problem by introducing a degree of separation between the investigation and adjudication stages.

4.15 pm

John Pugh (Southport) (LD): The hon. Gentleman is making a good case of sorts, but will he not recognise three points? First, some adjudication bodies are also disciplinary bodies. Secondly, the GMC has made substantial attempts to change itself with increased lay representation. Thirdly, and this is an empirical point, there are more cases and evidence of the GMC doing that—in other words, more people have been up before the GMC and treated fairly severely than hitherto. Some progress has been made, so the Government's case that reforms are in place now and that the Shipman case could not easily be repeated is relatively valid is it not?

Owen Smith: I do not dispute that the GMC has clearly addressed the matter and was addressing it before OHPA was established. It may be accurate to say that the GMC is able to do this. It is certainly true that other bodies regulate themselves and prosecute their members in the event of their transgressing. However, the key point is that the Shipman inquiry did point to this as a key weakness in the adjudication and regulation of the medical fraternity in this country. We all remember the Shipman case—it was a particularly awful chapter in the history of medicine in this country. When Lady Justice Smith came to the previous Government with a firm recommendation that the split was a prerequisite of having an efficient and effective safeguard for patient interests and efficient policing of the medical fraternity, it was a pretty brave leap. To describe that in just six or eight lines of a Bill with 300 clauses probably does not pay due deference and respect to the magnitude of the issue.

Paul Burstow: I am grateful to the hon. Gentleman for giving us the opportunity to debate the clause and me the chance to address his concern that no impact assessment was done on the measure. An impact assessment was done but it was separate from the main one—

Owen Smith: I did not say that.

Paul Burstow: I will reread Hansard and I apologise to him if it turns out that he did not say that. My understanding of what he said is that no separate impact assessment was done and that there was a single line reference, which was a saving, in the main impact assessment.

Owen Smith: For this Bill.

The Chair: Order. The rule of the game in this Committee is that the person who is on their feet is speaking and the other Members are listening. If any Member wants to intervene, they can do so, but they cannot have a conversation over the Committee.

Owen Smith: May I intervene?

Paul Burstow: I give way to the hon. Gentleman.

Owen Smith: I am grateful to you, Mr Hood, and to the Minister for allowing me to intervene. What I said was that in the impact assessment for the Bill, there is no mention of the measure, save for the line in the table. An impact assessment was conducted as part of the Government's consultation and subsequent report, but it, as I suggested, did not reflect the volume of savings that might have resulted from the introduction of the measure.

Paul Burstow: We have established that an impact assessment was done for the Bill, in which there is a passing reference; there is then a 23-page impact assessment that deals solely with the issue, which is available on the Department of Health website. I commend other hon. Members to read it—the hon. Gentleman has clearly made such a study of it. I will try to answer his questions and offer him the assurances that he seeks.

In presenting his concern, the one thing that the hon. Gentleman has overlooked is a change the Bill makes that provides for a new responsibility for the Council for Healthcare Regulatory Excellence, whose name and some of whose functions we are changing. We touched on one of its new functions this morning, when we discussed social care and fitness to practise. The council in its new role will have the function of also being able to refer cases to the High Court if it believes that the decision made by a regulatory body after a fitness-to-practise hearing was unduly lenient. That provides an important new safeguard in the system that is independent of the individual regulator. It is not true to suggest, as the hon. Gentleman did, that the removal by the Bill of a body that has never been set up—OHPA was in the process of being established when we came into office—in some way weakens the arrangements.

Owen Smith: Does the Minister not accept that there is a fundamental difference between a body that is separate from the GMC, and which conducts the adjudication and judges the cases that are brought before it, and another council that may, post hoc, review a decision taken by the GMC and refer it to a higher court?
Paul Burstow: They are different but I think they achieve an important purpose, which is the safeguard that the hon. Gentleman seeks. They ensure that a matter is not solely in the purview of the regulator and that there is another opportunity to look at it. If there are serious concerns, the Council for Healthcare Regulatory Excellence can refer it to the courts.

I need to make a quick correction. I said that this was a new provision in the Bill. In fact, it is an existing power—the safeguard is already there, which we think is important in terms of understanding the arrangements.

The Office of the Health Professions Adjudicator has never been operationally activated. It was established in law in January 2010 and it was not expected to take over its duties from the GMC until April this year. The functions that OHPA was expected to perform will therefore remain with the GMC, the General Optical Council and other regulatory bodies. However, as my hon. Friend the Member for Southport said, there has been quite a significant change in the way that those organisations configure themselves, the involvement of lay members, and so on.

To the question about the legitimate public interest and patient safety, and whether doctors protect doctors and perhaps not the public interest, the answer is clearly no. There is no evidence to suggest that the current GMC-led adjudication arrangements do not properly protect the public. The Council for Healthcare Regulatory Excellence reviews all decisions made by the GMC adjudication panels to assess that, and if it feels there was undue leniency, it can refer the matter, as I said.

Dr Daniel Poulter (Central Suffolk and North Ipswich) (Con): Does the Minister agree that aside from the important strengthening of the lay representation on the GMC, there is also a requirement now for two doctors to sign the forms before someone can be cremated? That allows either doctor to refer to a coroner, which is an important safeguard against one of them behaving inappropriately.

Paul Burstow: I am grateful to my hon. Friend for highlighting that change, which came out of the Shipman inquiry. It is an important safeguard to have in the system.

The hon. Gentleman also asked about the consultation. It is worth bearing in mind that the Government consulted on options for the office to continue in its current form, for changes to be made to it, or for it to be abolished. The responses to that consultation show that 45% of people said yes to abolition, 35% said no, 4% were unsure, 3% did not answer the question and 13% had no clear preference. Governments have make a judgment based on consultation results; we took the view that, on balance, the decision, with the safeguards that I have mentioned, was the right one to take.

The hon. Gentleman suggested that the measure might be being driven by an agenda of short-term savings. I can assure him that that is not the reason: neither I nor the Government would have accepted that as the rationale for making the change. However, the Government are committed to spending taxpayers' money well and wisely. Setting up the Office of the Health Professions Adjudicator would have cost between £10 million and £16 million to replicate functions already undertaken by the GMC. We took the view that that was not proportionate.

Derek Twigg (Halton) (Lab): Could the Minister give us a further breakdown of those respondents who were in favour of abolition?

Paul Burstow: The figure I quoted was 45%.

Derek Twigg: Of what did that figure comprise?

Paul Burstow: I shall make sure the hon. Gentleman receives a note containing that information in due course. That is probably the best thing to do, rather than try to rattle off each organisation that responded and state whether they said yes or no.

I was about to deal with worry expressed by the hon. Member for Pontypridd about patient safety and adjudication decisions, and whether they are, for example, compliant with the Human Rights Act 1998. There is no evidence to suggest that the system of adjudication operated by the GMC and other regulators is not compliant with the Human Rights Act, and case law confirms that the system of adjudication and fitness-to-practise arrangements used by health regulators, which includes a right of appeal to the High Court, does not breach that duty.

Mr Kevin Barron (Rother Valley) (Lab): As the Minister might know, I spent nine years as a lay member of the General Medical Council and was involved in both of the governance changes that got it into a shape where there is practically equality in lay membership of the council itself and, indeed, of fitness-to-practise committees. The GMC is not arguing against the change on adjudication except in one area—members of council were in the House at a reception yesterday, and I talked to them. In the area in question, the council took its foot off the pedal. There is a need to change the law to enable it to take action sooner, particularly on doctors who have been convicted of serious offences, but who still have to be heard under current legislation. The law will have to be changed to allow that. Is the Minister willing to meet the General Medical Council and to discuss in some detail the changes that will be needed, if it is to retain that responsibility?

Paul Burstow: Yes, absolutely. That goes without saying, but I am grateful for the opportunity to put it on the record that I or other Ministers will be only too happy to have those discussions to make sure that the system, as we believe it will be, is fit for purpose and offers all the assurances that members of the Committee have been seeking.

With that, unless the hon. Member for Pontypridd, who looks as though he wants to get up again to conclude the debate, I urge that the clause stands part of the Bill. However, I hope that the arrangements made for the Council on Healthcare Regulatory Excellence and the other changes we propose, guided by the consultations, provide the assurances that he seeks.

Owen Smith: I listened carefully to what the Minister said. He said that cost did not drive the decision, but I urge him and other hon. Members to read the Government’s consultation response, which places front and centre the principal rationale for the change as the savings that could be derived and then goes on to refer to the submissions made by various others.
Secondly, what is proposed is not the same as having an independent adjudicator separate from the regulator and the investigating body, as was proposed by Dame Janet Smith, now Lady Justice Smith. That is a very different scenario and governance structure, and I do not believe that what is proposed under the Bill does anything than return us to the status quo ante, albeit perhaps with a slightly changed GMC. The basic point about the requisite safeguards not necessarily being in place if the GMC is acting as judge, jury and prosecutor therefore remains.

Finally, on reading the impact assessment and the Government’s response, I was surprised to find that the submissions made by the individuals and institutions that responded were not published. They were summarised in one page. I therefore ask the Minister to offer us greater reassurance than is provided by detailing who was in favour and who was not. He should publish the submissions, so that we can read in detail who exactly thought the measure was a good idea. After Shipman, Opposition Members do not think that what the Government propose is a good idea.

Paul Burstow: I shall certainly look into publication. I know that in some consultations participants are asked whether they do or do not wish to have their responses published. Without checking, I do not know the position for certain.

On the question of the GMC acting as judge, jury and prosecutor, the council is looking at how it can enhance the independence of its adjudication and the efficiency of its processes—the processes that it currently operates. It is looking to see how it can go further. The GMC proposes to establish a tribunal-style model of hearings, which will be overseen by a separately appointed president. The objective is a robust, fair and effective system of adjudication for doctors, so the policy question is whether the objective can be achieved without a separate body undertaking adjudication. We think that it can be, which is why we set that case out in the impact assessment.

4.30 pm

Regarding the question about full consultation, a summary of responses was published on the website. It can be, which is why we set that case out in the impact assessment.

Question put, That the clause stand part of the Bill.

The Committee divided: Ayes 13, Noes 10.

AYES

Brine, Mr Steve
Burns, Mr Simon
Burstow, Paul
Byles, Dan
Crabb, Stephen
de Bois, Nick
James, Margot

Lefroy, Jeremy
Morgan, Nicky
Poulter, Dr Daniel
Pugh, John
Soubry, Anna
Sturdy, Julian

NOES

Abrahams, Debbie
Barron, Mr Kevin
Blenkinsop, Tom

Kendall, Liz
Morris, Grahame M. (Easington)
Smith, Owen

Schedule 14

PART 7: CONSEQUENTIAL AMENDMENTS AND SAVINGS

Amendments made: 594, in schedule 14, page 318, line 35, leave out paragraph 47.

Amendment 595, in schedule 14, page 321, line 37, at end insert—

‘( ) Omit paragraph 26(a) of Schedule 10 to the Health and Social Care Act 2008 (which provides for the inclusion of a reference to the Council for Healthcare Regulatory Excellence in the National Assembly for Wales (Disqualification) Order 2006, which has itself been revoked).’.

Amendment 596, page 322, in schedule 14, line 8, leave out paragraph (d).

Amendment 597, page 322, in schedule 14, line 15, leave out paragraph (b).

Amendment 598, page 322, in schedule 14, line 15, at end insert—

‘( ) Omit paragraph 26(b) of Schedule 10 to the Health and Social Care Act 2008 (which inserts a reference to the OHPA in the National Assembly for Wales (Disqualification) Order 2006, which has itself been revoked).’.—(Paul Burstow.)

Schedule 14, as amended, agreed to.
Clause 216 ordered to stand part of the Bill.
Schedule 15 agreed to.

Clause 217

GENERAL DUTIES

Liz Kendall (Leicester West) (Lab): I beg to move amendment 665, in clause 217, page 189, line 16, leave out ‘desirability of promoting’ and insert ‘Commissioning Board’s duty to promote’.

Part 8 sets out the Government’s proposed changes to NICE—the National Institute for Health and Care Excellence, as it will be known—which give rise to a huge number of concerns. The fundamental reason why NICE was established was to take decisions on which drugs should or should not be available on the NHS. That responsibility will transfer to general practitioners.

There is a huge range of concerns about that, which I shall discuss on clause stand part.

Clause 217 sets out NICE’s general duties. Subsection (1)(c) specifies that one such duty is “the desirability of promoting innovation”.

Hon. Members may remember our discussions a mere few weeks ago—it may seem longer—about the NHS commissioning board arrangements in part 1, which give the board a clear duty to promote innovation. Under new section 13H of the National Health Service Act 2006, inserted by clause 19:

“The Board must, in the exercise of its functions, promote innovation in the provision of health services”.

Amendment 665 seeks to give NICE a stronger and clearer role in promoting innovation by giving it an essential duty to support the board in its role to do so.
I want the Minister to set out, because it is not entirely clear in the Bill, how NICE will promote innovation as part of its work in two key areas: first, in the production of its quality standards, in which it will set out the very best quality across health and social care; and secondly, in assessing new drugs and technology under the Government’s new value-based pricing?

Nicky Morgan (Loughborough) (Con): I shall speak briefly about what the hon. Lady mentioned—the desirability of promoting innovation. I shall illustrate my point with an example from my constituency.

I recently visited a company called Dialog Devices, which is based at Loughborough university. It has developed a machine called a Padd, which ensures a non-invasive assessment of peripheral arterial disease to prevent heart disease and stroke. I am not asking the Minister to comment specifically on that; we have all realised during the course of our discussions that commenting on specific examples is not a good use of our time. However, the point that the company made was that the NHS is not only a provider, as we have discussed over a number of weeks, but a promoter of innovation—and it is, in fact, a consumer. If we want the NHS to achieve savings as part of the Nicholson challenge, embracing new medical technology and innovation will play an important part.

The chief executive of Dialog Devices told me that if the NHS does not invest in new and innovative products, its products go to the United States, where research programmes and money are available. Although the company has recently been given money to start clinical trials, it does not have any money for marketing and going out to GPs to talk to them about new products.

The reason why I have a problem with the hon. Lady’s amendment is that innovation needs to run right the way through the NHS. It is not for only the board or NICE; it should be for all levels, including GPs, who will look to link more closely the price of a medicine to the value that it offers—taking into account aspects of the new architecture put in place by the Bill, to contribute in many ways to driving an agenda that promotes the greater use of innovation within public health, social care and the health service. Quality standards will be reviewed by NICE at regular intervals to take new developments and innovations into account. Again, that clearly links across. In terms of promoting innovation and assessing new drugs, with value-based pricing we will look to link more closely the price of a medicine to the value that it offers—taking into account aspects of the value, including therapeutic innovation and improvement.

I think there is agreement on the aim of driving innovation within the NHS, but there are concerns. Member for Leicester West is concerned about how the provision is formulated in respect of NICE. Although the intention is clear, the wording of the amendment would not have the desired effect. I will try to explain why and reassure the hon. Lady about what I think is our shared purpose. The amendment appears to be based on a misreading of the Bill, which I am sure was not the intention, and I believe the issue has been raised previously by the Association of British Healthcare Industries. I will take this opportunity to clarify the situation and offer some assurances.

Clause 217 does not place a duty on NICE to consider whether innovation is desirable. Instead, it does something a lot stronger and places an explicit duty on NICE to have regard to the promotion of innovation, which is itself established as desirable, when carrying out its work. If the amendment were accepted, it would have the unintended consequence of restricting NICE’s duty in relation to innovation and the scope of the NHS commissioning board’s duty to promote innovation. NICE’s remit, as set out in the Bill, is broader than just NHS services. The Bill retains the remit that NICE was originally given in 2005 for public health, and extends its remit further to cover social care. Public health and social care would not normally be the responsibility of the NHS commissioning board, and it would be excluded from the duty if the legislation were constructed in that way.

Grahame M. Morris (Easington) (Lab): Will the Minister clarify the point about the desirability of innovation and restricting the role of NICE? Is it envisaged that NICE would advise pharmaceutical companies, for example, on some issues? Would that be a potential conflict of interest?

Paul Burstow: The hon. Gentleman seeks to lead me down a tempting path, but if I go down it I will probably find myself in the hall of mirrors into which the Opposition regularly try to take us. I am not going to do that as it would probably be outside the scope of the clause.

Let me reassure the hon. Gentleman that the clause places an explicit duty on NICE to have regard to the promotion of innovation, which is established as desirable when carrying out its work. It is necessarily constructed in that way so as to include the full range of its remit, which comprises social care, health care and public health. The amendment would have the undesirable effect of narrowing that remit to the health system and excluding everything else. It would have a strange effect, which I hope I have explained to the satisfaction of members of the Committee.

It is our intention for NICE, along with other parts of the new architecture put in place by the Bill, to contribute in many ways to driving an agenda that promotes the greater use of innovation within public health, social care and the health service. Quality standards will be reviewed by NICE at regular intervals to take new developments and innovations into account. Again, that clearly links across. In terms of promoting innovation and assessing new drugs, with value-based pricing we will look to link more closely the price of a medicine to the value that it offers—taking into account aspects of the value, including therapeutic innovation and improvement.

I hope I have been able to reassure the hon. Member for Leicester West and persuade her that the amendment would not achieve what she wants. As currently drafted, the clause goes where she wants it to go, so I hope she will withdraw the amendment.
Liz Kendall: I will respond to the Minister’s points, particularly the last point about value-based pricing that will specifically take into account the degree to which a new drug is considered to be innovative; in other words, a premium will be applied in some way if a drug is particularly innovative. I definitely do not want to stray outside the scope of the amendment, but one of the reasons why I tabled it was to probe how much value-based pricing will seek to promote innovation.

All I would say is that if more is paid for a drug because it is innovative, that will have a cost effect elsewhere; in other words, if more is paid for some drugs because they are seen to be particularly innovative, they meet previously unmet needs or they have wider societal benefits, it will cut a bit of the cake away from care elsewhere. These are not cost-free decisions. When one pays more for particular drugs, trade-offs will need to be made. I believe that innovation is important, but it has to be weighed against other issues, as I am sure the Minister knows.

Paul Burstow: Innovation can also lead to a more efficient use of resources. It is not a black and white issue, but a judgment in each case.

Liz Kendall: I absolutely agree with that, but, as I shall come on to say in a little while, these are very difficult issues. We have one pot of money, and balancing the different objectives is a huge challenge. This was a probing amendment to try to assess the degree to which NICE will promote innovation. On that point, I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

4.45 pm

Question proposed, That the clause stand part of the Bill.

John Pugh: The clause is about the general duties of NICE, which have been an issue of appreciable public interest. I read it with some interest, hoping that the legislation would say what the general duties of NICE were. I read it several times, turned the book upside down, read it backwards and so on, but the clause does not actually do that. For once, the explanatory note is slightly more helpful. It states:

“This clause describes the matters that NICE must have regard to in developing its products”—

“products” is a strange word—and then gives a list of its current products, which include

“guidance on new and existing medicines,”

which is, of course, the familiar role of NICE, and other new roles that it has taken on such as

“guidance on treating and caring for people with specific diseases…and guidance on preventing ill health.”

We can add to that public health and other things as well.

I have two concerns that I hope the Minister will succeed in allaying. The first is about mission creep. I brought this up with the chairman of NICE at a meeting organised by an all-party group the other day. NICE started off, fundamentally, as an organisation for examining drugs on a value-for-money basis. Then it branched further afield into physical and psychological therapies and now will take on social care, public health and who knows what else.

That raises a competence issue, because those of us who know anything at all about the NICE drug approval process will know that it sets a high standard of rigour—I have attended meetings at which NICE has actually been doing its stuff in committee—and has been very impressive. The process has often been slow, but it has been rigorous. Around the table are not only people who are expert on the drug but expert practitioners in the field and also patients who provide input. That led to a slightly bogus, quasi-mathematical process where things such as qualys—quality adjusted life years—were analysed. When a thing had enough qualys, the drug was considered to be value for money.

I was always a bit sceptical about that as a device for ensuring that a drug was suitable for widespread use in the NHS, but it has to be said that the process was diligent. There were all sorts of flaws: it was often slow, it was contentious at times, and it did not really differentiate between drugs that were universally of benefit to all patients with a condition, and drugs—such as Aricept, for example—which sometimes worked for some patients but not for others. So there were critics, and I am sure that every MP in the previous Parliament at some time or other would have written to their primary care trust about some judgment of NICE simply because a patient in their constituency had raised an issue about the non-availability of a particular drug.

However, with all its flaws, it has to be said that the people who were doing that specific job were clearly the best people one could pick to do it, even though they could not do it to everyone’s satisfaction. That was reflected in the fact that NICE, in that role, became internationally respected. Many people looked to the NICE model as the kind of thing that they should adopt in their own country.

When I use the expression “mission creep”, my concern is that NICE might go the same way as the Audit Commission. At one time, the Audit Commission had a good reputation as a decent set of accountants and bean counters, who told local authorities when they were going to over-spend. Then it started to branch into social care, talking about how local authorities should be politically run—all that kind of thing, as well.

To some extent, the Audit Commission devalued its currency, because it was clearly commenting on areas where it was not expert. It is clearly not the intention of the Government to have a body that cannot comment as an expert body; to perform its range of functions, that body is going to need a heck of a lot of experts. There will be other experts in the field doing similar jobs who will have a view that may differ, and therefore its authority may be questioned. Will the Minister assure me that we are not going in that direction?

My specific questions take us back to the fundamental gatekeeper role of NICE. Essentially, what was not approved by NICE, what did not pass the various quality tests, the NHS did not have to fund. It could choose to fund; individual PCTs certainly did fund things that were not NICE-approved. However, there was the function of a NICE judgment.

A NICE judgment meant that no person could go to their PCT with the absolute assurance that the PCT would regard that as the appropriate value-for-money
therapy for their ailment. When deciding whether an individual patient should get a drug—maybe because the patient had seen on the internet that the drug might be good for them or the pharmacist had persuaded them that the drug was the magic bullet to solve their problem—there was some good reason to say, “You can’t have this particular drug, or it would be inadvisable to have it.” That may not have been an overwhelming reason; it may have been contested.

**Grahame M. Morris:** On that specific point of assessment of treatments, was the whole rationale of the establishment of NICE not to address the issue of the postcode lottery—drugs and therapies being available in one part of the country and not another? Will these changes not turn the clock back and make that situation more likely?

**John Pugh:** It did not altogether address the issue of the postcode lottery. In my own area, people came to see me saying that a drug was available in west Lancashire that was not available in Sefton, or that homeopathy was available in Liverpool and paid for, but not in Sefton. The postcode lottery still occurred but NICE tried to construct a set of principles for value-for-money treatments for particular ailments.

I am not sure whether we have completely eliminated that in the legislation. I am not clear about it, which is why I seek clarification. The absence of that makes the whole business of rationing care a little more difficult. If NICE is not doing it by saying, “This drug might have some effect but is simply not value for money within the NHS”, who will do it?

Presumably, doctors will have to do it, and make a decision themselves. Doctors have to face the patient in the surgery and say, “Actually, although you think this will work well, I do not think that we are prepared to fund it locally. We are not saying it has no effect; we are saying it does not represent value for money. It may have a minimal effect in its quality impact, as it used to be described.”

**Paul Burstow:** We come later to amendment 670, an Opposition amendment to clause 221, where that issue will be debated. I suspect that the issue around the general powers is not where this is most appropriately dealt with. I want to ensure that I give a full response to my hon. Friend’s concerns.

**The Chair:** Order. I will decide what is in order in the stand part debate.

**John Pugh:** We are talking about the general duties of NICE, so we may as well have the debate now, as I am seven eighths of the way through what I have to say. I do not think people would want me to repeat the same points. If doctors are making the decisions, the critical question we need to get straight is, “If my doctor will not give it to me, but I know that it is appropriate medicine for my ailment, can I join another practice and get it?” Can everybody do that when they are turned down by their doctor? If so, the implications for the NHS drugs budget are horrific. If that is not the case, presumably we are going to adopt a model in which if I go to see a doctor anywhere, but my consortium will not pay for the drug, I simply do not get it, in which case my consortium again determines what I do or do not get. It is very important that that principle is made clear, because the scenario in which people can shop around for doctors in order to get the drugs that they want would have very damaging effects, if only on the health service budget.

Finally, Monitor’s role, if it is not to be a gatekeeper, is to offer quality standards. What concerns me is whether a quality standard can bring in value-for-money issues. In other words, a quality standard can say that such and such an ailment is best treated in this way, and the quality way to treat it is to use such and such a drug or therapy, rather than another that is simply a more expensive way of doing the same thing. If Monitor’s quality standards can involve the same value-for-money judgments as did its previous judgments, we are back in familiar territory, but if they do not, we are in the scenario, I think, in which people can shop around for whatever medicine they want.

**Liz Kendall:** I intended to bring up under a later clause some of the points that the hon. Gentleman has made, but as we are in it, we might as well go for it, if those are the appropriate parliamentary terms.

**The Chair:** Order. The hon. Lady should not take it upon herself to “go for it”, unless it is within the stand part debate on clause 217. I ask her to address her comments to the stand part debate on clause 217 and not to “go for it” by discussing anything that we might deal with in the future.

**Liz Kendall:** I beg the Chair’s forgiveness for my possibly unparliamentary language. The hon. Member for Southport has discussed the general duties of NICE, so I feel that this is the appropriate place to discuss those issues. As he said, NICE was originally set up to take on the very tricky problem that health care systems have faced throughout the western developed world—with new and ever-more expensive drugs coming on-stream, how do we decide what is paid for out of, in our case, the public purse?

NICE is widely respected across the world for the work that it does. People might not necessarily think that if they read only certain newspapers or if they just accept the view that certain Ministers have expressed about the failures of the system. Of course improvements can be made, but other countries look to NICE and follow NICE. It was one of the previous Government’s great achievements. Much praise is due to my right hon. Friend the Member for Holborn and St Pancras (Frank Dobson), who took that step forward. He thought that it was a difficult thing to do, but he took a very bold step in launching NICE, of which I am very proud.

NICE’s role changes and its general duties change as a result of the Bill, but as I am sure that hon. Members will appreciate, the same issue remains—how do we decide which drugs should be paid for out of the public purse? The Bill changes which makes the decision. It goes from being the responsibility of a national body to being the responsibility of general practitioners and general practitioners commissioning consortia or whatever they are going to be called if amendments are introduced.
A number of organisations have raised serious concerns about the likely consequences of the change, and I would like to go through them, because I believe that hon. Members may be facing hard questions from their constituents as the process moves forward and we need to be aware of what they may be. I shall begin by quoting NICE’s response to the Government’s consultation on replacing the current system for setting prices in the NHS with a new value-based pricing system.

NICE explicitly warns that that could increase the postcode lottery, and says:

“The tight fiscal environment in which the NHS will be operating over at least the next 4 years, together with the proposed arrangements for commissioning NHS services, will tend to increase rather than reduce the challenge of achieving consistent access to new treatments. We believe that there is a risk that patients and health professionals who want to use drugs made available under the new arrangements may find it difficult to do so unless the new arrangements retain powerful, national reference points.”

I just want to state those three key national things that NICE believes need to be in place, because simply changing the way in which a drug is valued or the price that is set on a drug does not automatically ensure access or uptake of that drug. That will be up to the commissioning consortia based on their available resources.

I am sure that Ministers would not say this, but sometimes it is suggested that a new way of pricing drugs will automatically lead to their uptake. That is not the case. It is not the view of NICE and it is not the view of many pharmaceutical companies.

What NICE says is that clear steps have to be taken at a national level to try to ensure that there is as small a postcode lottery as possible. The first step is a clear recommendation through NICE conducting a technology appraisal, which I think is what the hon. Member for Southport must have been sitting through.

Julian Sturdy (York Outer) (Con): Does the hon. Lady not accept that under the current system we are suffering postcode lotteries with PCTs?

Liz Kendall: There are variations, but more GP consortia will, as NICE says, make the situation far worse. If the hon. Gentleman will bear with me, I shall go on to explain why that situation is likely to get worse. It is not just NICE that says that; the BMA, the Royal College of General Practitioners and patient groups also have concerns. The current system is not perfect, but my concern is that the new system will make matters worse.

NICE believes that there should be a clear recommendation about that drug. Secondly, there must be what is called a funding direction. In other words, there must be a direction from NHS organisations—in this case, GP commissioning consortia—that indicates that the drug needs to be funded. Thirdly, NICE states that the NHS constitution gives a clear right for patients to have access to drugs recommended by NICE. I mention that because I have some concerns that that right may not be as strong as it should be.

Grahame M. Morris: Does my hon. Friend agree that although it is a prime duty of NICE to control costs, which is absolutely vital, it is also the role of NICE to counter-balance the powerful influences of the large pharmaceutical companies? Perhaps the GP consortia will be far less able and equipped to stand up to them.

Liz Kendall: My hon. Friend makes a point I was about to come on to about GPs’ very real concerns. I shall quote Dr Clare Gerada from the Royal College of General Practitioners. In her interview with The Guardian on 10 November—I am sure Ministers will remember it—she raised real concerns that GPs will “be exposed to lobbying by patients, patient groups and the pharma industry…At worst, the negative impact for GPs could be patients lobbying outside their front door, saying, ‘You’ve got a nice BMW car but you will not allow me to have this cytotoxic drug that will give me three more months of life’.”

That is a fair point. She says that making GPs “the new rationers” could ruin trust between doctors and patients. In another interview that she gave to Pulse magazine on 15 November she praises NICE’s role:

“NICE protects us. I am absolutely convinced it needs to be strengthened, not reduced. I am long enough in the tooth as a GP to have worked pre NICE. I know what postcode lotteries are about and I’m very concerned”.

Jeremy Lefroy (Stafford) (Con): The hon. Lady makes the point that GPs are rationers, and I think that that argument has some merit, but does she not also agree that GPs have in effect been gatekeepers to the NHS almost since its inception? They therefore have some experience of that.

Liz Kendall: To an extent, that is true. However, the hon. Gentleman will learn, either from his own constituents or from reading the newspapers, that there are questions about whether very expensive drugs should be made available. We must not forget that some GP consortia may cover very few patients—we have had this debate already. Just two or three patients with a need for very expensive drugs could push them into debt, and they will have to grapple with those issues. NICE provided some protection against that, but it could be faced locally a great deal. I think that these concerns are of a different order; they are very difficult, and I am concerned about how GPs will deal with them.

Some pharmaceutical companies welcome what they think value-based pricing might mean, but others have said something different. Richard Barker, the director general of the Association of the British Pharmaceutical Industry, says that value-based pricing should not be seen as some kind of magic bullet. On its own, negotiating a new value-based price will not necessarily improve access to new drugs and medicines. He is also concerned about returning to a postcode pricing system as each individual consortium will be free to make the decision about whether they have those drugs.

Perhaps I should ask the Minister about that. The Government have been exploring how to move forward on this by using the cancer drugs fund. They have explicitly recognised that it will take time to implement the value-based pricing system—I believe it will not be in place until 2014—and in the meantime they will set up a cancer drugs fund to provide access for the pressing and challenging issue of drugs for cancer patients. The Government say that “the Cancer Drugs Fund is a key part of our wider plans to improve access to effective medicines.”
I have looked at how the fund is working in different regions. Hon. Members will know that at the moment it is being run at the regional level by strategic health authorities. I have struggled to get all the information together, and because I do not have that I will make no firm conclusions about how the system is running, but I will say that there are wide variations in how many oncology products are on the priority lists of strategic health authorities.

For example, NHS South Central has eight products on its priority list for funding from the cancer drugs fund, compared with 24 on the list for NHS North West. It is also using very different criteria to determine whether those drugs should be put on the list. If that is not done nationally there will be variations. In the cancer drugs fund, there are significant variations in the numbers and the criteria used. If that is already happening, what do we think is likely to happen when GP commissioning consortia make those decisions? I am doing my best with limited resources to establish why different criteria have been developed in different regions, why different numbers of drugs are included and how the different processes work. I hope that clear evidence and analysis will be presented to the House before the different processes work. I hope that clear evidence and analysis will be presented to the House before the different processes work. I hope that clear evidence and analysis will be presented to the House before the different processes work. I hope that clear evidence and analysis will be presented to the House before the different processes work. I hope that clear evidence and analysis will be presented to the House before the different processes work. I hope that clear evidence and analysis will be presented to the House before the different processes work. I hope that clear evidence and analysis will be presented to the House before the different processes work.

Margot James (Stourbridge) (Con): I am concerned that an impression is being created that GPs will be left to interpret NICE guidance and get on with decision making in front of an individual patient. From my reading of the Bill, I do not think that that is the case. A GP will operate within the whole construct of a duty of quality that surrounds him or her via the outcomes framework. GPs and their commissioning groups must operate with a close regard to NICE advice and guidance. That advice and guidance will be much more far-reaching now that it goes beyond the evaluation of individual drugs. It will be a whole outcomes framework by disease and the various other interventions mentioned in the Bill.

Liz Kendall: GPs must still decide whether to spend £80,000 on a drug for the patient in front of them. It does not change the difficulty of the decision. Nobody knows how the new value-based pricing system will work. The consultation has just closed. The new system is supposed to consider not only whether an individual will benefit clinically from the drug but whether wider society will benefit and whether the drug, technology or treatment fulfils unmet need. Those are broad and nebulous concepts that have not yet been pinned down. We are not sure how all of it will work, pharmaceutical companies are not sure how it will work and NICE is not sure how it will work.

Will NICE have a role in determining the value-based pricing system? We think that it will have a role in assessing drugs under the new system, but will it have a role in drawing that up? I say to the hon. Lady that the drug companies will not suddenly and miraculously start making complicated gene-based drugs cheaper as a result. GPs, not NICE, will have to make the decisions. I freely admit that when NICE has made decisions, not all PCTs have taken them up, but that is about money, and simply wishing it away will not work.

In conclusion, I would like the Minister to answer some questions in his response. First, it seems to me that NICE has two roles. One involves producing quality standards, which we know will cover not only the NHS and public health but, for the first time, social care. That could cover a huge range of different treatments and services, and will involve consulting many more organisations.

NICE’s second function will relate to the value-based pricing system. It will at least assess drugs under the system, and will possibly help to develop the system in the first place. As I said, that will be a complicated process—even more complex than NICE’s current focus on quality-adjusted life years. We must remember that NICE’s funding is being cut by 30%. That relates to the point made by the hon. Member for Southport about mission creep. NICE has a huge number of jobs and tasks to do. I am sure that it would never let its standards slip, as it holds those standards dear, but it has a big and complicated task.

John Pugh: The hon. Lady mentioned a postcode lottery. I may have misunderstood the legislation, but one benefit of NICE rules is that no PCT at the moment can refuse to deliver a treatment that NICE recommends. There is a possibility of that happening with the Bill, because if we change the function of NICE there will not be approved standards in the same sense. That must produce a more uneven picture in terms of health outcomes.

5.15 pm

Liz Kendall: I agree. That is my concern, and we will come to amendments on that. The requirement on health and social care bodies to deliver and implement the quality standards or implement the advice and guidance is weaker. Amendment 670 covers that. The requirements are far too weak, which we will discuss later. With that, I thank you, Mr Hood, for your patience.

Debbie Abrahams (Oldham East and Saddleworth) (Lab): Some points I wanted to raise have been mentioned already but my other points follow on neatly from what has been said.

Subsection (1)(a) mentions “benefits and costs” in the general NICE duties. I would like the Minister’s reassurance that cost-benefit analysis will not be the only method used. Given the reduction in resources to NICE and, obviously, the breadth of work that has been added to it, as my hon. Friend mentioned, there might be a tendency to use quicker, less engaging processes. One of the real exceptions to how NICE undertakes its work is the quality and robustness of the range of evidence that it uses. As has been mentioned, it is well respected across international health systems.

I know how seductive numbers are and, over the past few years, there has been a tendency to try to look at and pin down evidence in quantitative form. I think that is a weakness. There are benefits to including social care in NICE’s remit, but there is a caveat in that it must use a broad range of methodologies to determine the effectiveness of different interventions.

Owen Smith: I have said this on other clauses to the Bill, but in this clause and the other clauses that relate
to NICE there is a dearth of detail about what NICE will do. The clause repeatedly stipulates that most things will be sorted out in regulations. [Interruption.] The Minister shakes his head and looks exasperated, but I do not see how he could demur from that conclusion, because it says repeatedly in this clause and others that matters will be in the regulations. I do not think that it is illegitimate for the clauses to say that, because clearly NICE’s role is changing quite significantly. The reason for that change is the introduction of value-based pricing.

We have a consultation on that, and it is entirely proper that the Government consider what comes out of the value-based pricing proposals before they determine how the final function and form of NICE will look.

The assumption in the value-based pricing proposals is very significant for NICE, because it will shift from being a body that provides independent advice to the NHS at arm’s length from the pharmaceutical companies on the nature and cost efficacy of a given medicine to being a price-setting body. That is the big change in play under value-based pricing. NICE will effectively be determining what it thinks the price ought to be for a medicine in this country, as opposed to the current situation, whereby a company sets the price and NICE suggests whether it is value for money, and therefore whether the NHS ought to pay it. That change raises many questions, which are relevant to the clause, about the general duties.

First, NICE has not previously done that sort of job. It has done the analysis to determine whether it thinks a medicine is cost-effective; it has certainly not then set a price. That is a very different skill set from the roles that NICE currently has. It has not engaged in price negotiation with the companies, which we assume, because it is not clear in the Bill, will be the next step. So, will the Minister clarify whether the value-based pricing system works? If NICE determines what it thinks the price ought to be, will it go on to negotiate the price or will it be a price-setting body. That is an open question.

My second point, far more importantly, is about the PCTs and the crucial role that they have played in the NICE process. The issue is twofold and it speaks in many respects to some of the matters that the hon. Member for Southport raised. One is that, under the current system, it is the PCTs that effectively, through their pharmaceutical committees, make decisions on medicines that are not NICE-approved, for which there is no guidance, and they make the decision as to whether that medicine is going to be made available to local patients. [Interruption.] I am obviously speaking to myself. I do not know why I am bothering.

The Chair: Order. The Chairman is listening, and I hope the rest of the Committee. I am delighted to see that the Minister is feeling better than he was this morning.

Owen Smith: As am I, Mr Hood. I am delighted to see that he is looking considerably improved.

The Chair: [Interruption.]

The Minister of State, Department of Health (Mr Simon Burns): Oh, thank you.

Owen Smith: He had a good lunch, I hope.

PCTs that are being abolished are clearly playing an important role in determining which medicines that were not NICE-approved would be funded and therefore that local GPs could prescribe. The second crucial role that they increasingly provided on behalf of the NHS was engaging in the single technology assessment and multiple technology assessments, offering advice and guidance to NICE on clinical practice, either in trials or post-licensing of medicines being used in the NHS. There is a question about who in the NHS will in future be able to provide that guidance to NICE, because PCTs have built up that expertise and it has effectively been managers and clinicians with managerial responsibility in PCTs who have done it. In the new system it may be that somebody is designated with that task in GP consortia, but that is not clear in the Bill and therefore I think that that is an open question.

The third question, which comes on to the substance of the comments made by the hon. Member for Southport, concerns whether the legislation makes it clear that the current process whereby the NHS is mandated to provide funding for NICE-approved medicines within three months of their launch will continue. That is the current mechanism that we have to drive from the centre the take-up of cost-effective, innovative medicines. It is not clear whether the Bill will continue the status quo. It says that it may do that under regulations, but I would be grateful if the Minister clarified whether that will continue. If it does not continue, presumably there is a risk that the postcode lottery will expand.

Even if the status quo does continue in respect of medicines that are not NICE-approved and where therefore there is local decision making, there is still an obvious risk that, in a more disaggregated, more autonomous NHS, there will be more postcode prescription, or more divergence in decisions. My hon. Friend the Member for Leicester West made that point in respect of the cancer drugs fund. That is the evidence that we need to suggest that that might be a danger under the new system.

If the status quo does apply and subsequently the regulations state that funding is mandatory—it will be provided by GP consortia in future, I presume—how do we square that with competition law? Will there not be problems whereby providers of alternative medicines feel that they ought to have been given a different crack of the whip when NICE made the assessment of their medicine versus another medicine? Some clinicians may feel that NICE has made the wrong decision. It opens up NICE decisions to judicial review under competition law and other legislation.

My final and most important point is about Wales. Wales is not mentioned in this part of the Bill. Scotland has a different system—it has the Scottish Medicines Consortium—for assessing medicines, and Wales has the All Wales Medicines Strategy Group. The reality, however, is that the AWSMG is a much less well-resourced and much smaller body, which is unable to provide the enormously powerful service that NICE does in assessing all medicines. If NICE guidance does not have a mandatory effect across the board, or if there is less NICE guidance,
because it is tied up with price negotiation, the AWSMG will have to pick up the tab and try to do that role for Wales. I will be interested to hear the Minister’s comments on that in particular.

Jeremy Lefroy: Subsection (1)(a) mentions “the broad balance between the benefits and costs”, and my question relates particularly to medicines where the benefits may be long term, but the costs may be immediate and high. That will become particularly important with drugs that are targeted at the progressive diseases of ageing, which will—I hope and pray—be coming on to the market over the next few years. We may see high up-front costs, which may create problems for drugs budgets, but long-term benefits.

Liz Kendall: Does the hon. Gentleman agree that it is not only what we would call traditional drugs that have long-term benefits? The vast majority of drug development is going towards new genetic and biotechnology-based drugs. One of the problems with traditional drugs is that they are the same for everybody. The genetically based, biotech drugs can help individuals to benefit, because of their genetic predisposition. That is the whole thrust of drug policy. For many of those drugs, the benefits may not be seen for many years, because they will be trying to prevent genetic predispositions from coming forward.

Jeremy Lefroy: The hon. Lady makes a good point, and those drugs, along with drugs targeted at ageing, are precisely the kind that I had in mind. Indeed, there was a good initiative under the previous Government on the financing of vaccines internationally, whereby money was effectively provided for vaccinations up front, so that children would be protected from the ravages of disease, and they would gain throughout their whole life. The cost of that was borne not in one year, but over several.

Liz Kendall: One of the issues that pharmaceutical companies and others have raised about the value-based pricing proposal is that they are not clear whether it covers vaccines. The hon. Gentleman makes an apt point in relation to not only other countries, but this country. They are not clear as to whether vaccines will be included under that system.

Jeremy Lefroy: I thank the hon. Lady for that intervention, but I just want to ask the Minister whether these things are being considered and whether there will be finance mechanisms that enable the up-front costs to be spread over several years to ensure that people can accrue such benefits, rather than the costs being borne in a single year and refused, because of the adverse consequences on budgets.

5.30 pm

Paul Burstow: The debate has been useful, if only because it has allowed a number of misconceptions and misunderstandings to be dispelled—and quite a few were rehearsed by the Committee today.

As hon. Members said, NICE is recognised as the international leader in the evaluation of drugs and health technologies. It will continue to have an important role in that context, including assessing the incremental therapeutic benefits of new medicines. We will implement our plans for value-based drug prices in 2014. I want to say more about that, so I shall take no interventions while answering the various questions that have been asked, although I am sure that hon. Members will be tempted.

The arrangements to be put in place from 2014 will ensure that NHS patients have consistent access to effective medicines wherever in England they live. That is one of our key objectives in designing the new value-based pricing system. We are considering further what specific arrangements should be put in place from 2014, when value-based pricing is implemented in the light of responses to the consultation.

Some of the comments on the consultation that the hon. Member for Leicester West shared with the Committee gave the impression that the Government had set up an Aunt Sally in the value-based pricing system, and that the comments were about specific proposals. Of course, the consultation made a big contribution to the early stages of an ongoing design process. We would expect that process to continue to engage with the stakeholders, many of whom have already contributed their questions, their concerns and their suggestions.

The Bill makes no specific provision for value-based pricing, not least because the policy detail is still under development following the recent consultation. If it appears that further legislation is required to implement the final arrangements for value-based pricing before 2014, we will have to consider the matter separately. That should not be taken to mean that we believe that it will be necessary; it simply means that we need to keep the option open, and that I am being as straightforward with the Committee as possible at this stage.

My hon. Friend the Member for Southport posed a question about mission creep, a subject that was touched upon by several hon. Members. General concern was expressed about whether it was appropriate and how it could be stopped. It is worth noting that reference was made to an inadequacy of detail about NICE in the Bill. We ought to consider the relevant pages of past legislation to see what detail they gave about NICE. For the benefit of the Committee, I am holding up some pages that make clear how much detail was included in previous legislation. That demonstrates that there is a difference in the level of detail: we have provided considerable detail in a number of the clauses that we shall be debating over the next few hours.

Nicky Morgan: For the benefit of Hansard, perhaps I can clarify that the Minister held up some blank pages; there was nothing on them and no detail.

Paul Burstow: Those who follow our proceedings may have missed that nuance, but I am grateful to my hon. Friend for pointing it out.

This is the first time that NICE has been placed on a statutory footing. It is important to mark the fact and to note that the Government are prepared to establish it on that basis. I would like to develop my points a little further before—

Liz Kendall: Will the Minister give way?
Paul Burstow: In a second, and before I finish this point.

It means that the underpinning legislation is now open to far greater parliamentary scrutiny. NICE's scope was increased to cover public health in 2005, but that would now require a change to primary legislation. My hon. Friend the Member for Southport seeks the opportunity for Members to scrutinise and to ask whether an extension of the remit is appropriate. He did that during his remarks. We have placed all that detail in the Bill for the first time, which means that further primary legislation would be required to make other changes to the remit.

I welcome the comments of the hon. Member for Leicester West on the social care remit extension. The change has been widely welcomed by the social care sector and beyond. We have had a running theme during our consideration of these clauses on the necessity of greater integration and collaboration across health and social care. That was very much the thinking that drove us to the conclusion that the remit should be extended in this way.

The hon. Member for Leicester West also asked about clause 217(1)(a), and whether there was a risk that it could lead to a narrowing of the types of tools used to assess costs and benefits. Again, that is a perfectly fair question, and I assure her that, no, that is not the intention of the wording in the clause. We intend to ensure that a wide range of tools is used. In respect of the social care remit in particular, there is much discussion with the sector about how we draw on various expertise, particularly with regard to quality standards.

I have covered the point about the level of detail.

Mr Barron: Is not the lack of detail in past legislation because NICE is a special health authority, and not the non-departmental public body that the Bill will create?

Paul Burstow: The answer is yes. I struggle to understand the point, because it is a special health authority and at the stroke of a pen, the Secretary of State could abolish it at his discretion. The Bill puts the body into statute—[Interruption.]

The Chair: Order. I know that it is getting late in the day, but hon. Members should calm down a bit.

Paul Burstow: I will try to calm down, Mr Hood; I am sorry. The Bill puts NICE's future beyond doubt, and if there were a desire to change it, that could be challenged. I will give way to the hon. Lady who has been warring at me for some time.

Liz Kendall: Not warring, and never warring. I am disappointed, but perhaps not surprised that the Minister attempted a cheap conjuror's trick of holding up pieces of blank paper. I hope that he will acknowledge that in 2005 the then Secretary of State issued clear directions to the National Institute for Health and Clinical Excellence. If the hon. Member for Loughborough will look, I can point her to plenty of criteria, functions and issues that NICE must take into account. Opposition Members are raising serious issues, and I hope that the Minister will respond in a serious manner.

Paul Burstow: If the hon. Lady thinks that putting something in the Bill is not a serious matter, and that we should not draw attention to the fact that directions that are not subject to parliamentary scrutiny are a lower level of accountability than we are introducing, she is mistaken. Those who follow our proceedings might take note that she dismisses that so casually.

I shall try to deal with some other points. The hon. Member for Pontypridd asked about competition law. Monitor's role applies only to services and not drugs, so his concern is not relevant. We have discussed that, and I urge him to reread some of our extensive discussions last week—they are a good read—when my right hon. Friend and fellow Minister was dealing with those matters.

On drugs funding, there has been and is a huge misunderstanding. Mandatory funding for certain drugs will apply to consortia in the same way as to PCTs. I want to be clear about that. Mandatory funding of certain drugs will apply to consortia in the same way as to PCTs. The hon. Gentleman asked what part of the Bill is relevant to that. It is clause 221, and we will discuss the matter further when we come to it. It provides a regulation-making power that we intend to use to give exactly the same effect as the directions in respect of money in the existing system.

Grahame M. Morris: Will the Minister give way?

Owen Smith: Will the Minister give way?

Paul Burstow: In a moment. We need to update the underpinning directions, but the effect will be the same. I draw hon. Members' attention to the fact that the specific part of clause 221 subsection (8)(a).

Owen Smith: I do not want to fall foul of you, Mr Hood, but the clause to which the Minister refers, clause 221(8)(a), is preceded by—

The Chair: Order. The Minister said that he would comment on that when we came to it. I hope that the hon. Gentleman will not take that as an invitation to comment on it before then.

Owen Smith: I am grateful to you, Mr Hood. Of course, I bow to your judgment. In that case, my question is this. The Minister says that current mandatory funding procedures will apply to certain drugs in future. Given that NICE will not be doing its job of approving medicines in the same way, to which drugs will they apply?

Paul Burstow: If we are talking about the pre-2014 world prior to value-based pricing, we intend for the present policy position to continue. Consortia will be under the same obligations as PCTs in respect of paying for drugs recommended by NICE. I hope that I have put that point on the record as clearly as possible. When we get to clause 221, where we should deal with the issue—I hope that you will agree, Mr Hood—I will be happy to return with further clarification.

A common misunderstanding is that NICE has the power to ban the use of drugs in the NHS. The suggestion that that role will be removed is based on that misunderstanding of the true position. Far from banning drugs, NICE takes into account all the latest clinical evidence and published guidance on how a drug can
best be used in the NHS to improve patient outcomes and make best use of NHS resources. NHS bodies act in the light of that advice and normally make funds available for health care interventions recommended by NICE.

Given NICE’s expertise, it will continue to play an important role in any new system. We have just concluded the consultation on that new system, and the Committee has been a useful extension of that consultation. Members have aired numerous concerns that we must take into account. It would also be helpful if hon. Members cared to suggest further solutions. I am sure that they will, as we proceed with the design of the change in prices.

Grahame M. Morris: Notwithstanding the outcome of the consultation on the new value-based system for the pricing of branded medicines, does the Minister rule out ministerial involvement in the pricing of individual drugs and the directions issued to GP consortia?

Paul Burstow: I will not do that at this point. It is another path leading down to a certain place and I will not go down it, for the simple reason that we have just concluded a consultation, we are properly considering it and I do not want to pre-empt it and our judgments on it. That is what the hon. Gentleman is inviting me to do, but that would be wrong.

On the question about how value-based pricing will operate and whether it will operate at a local or a national level, that is another area in which misconceptions and misunderstandings have run wild. We did not state that in the recent consultation. We are considering the responses and how the system might best operate to meet our objectives, but we have not said specifically whether it will be local or national. We have asked questions and are in the early stages of design.

Our priority, as I said, is to give NHS patients better access to effective and innovative medicines. We intend to do so by reforming how companies are paid for NHS medicines and moving to a system of value-based pricing when the current pharmaceutical price regulation scheme expires at the end of 2013. The current system of drug pricing has provided stability over time, but it does not promote innovation or access to the extent that we are seeking. We need a much closer link between the price that the NHS pays for medicine and the value that it delivers.

On questions about other aspects, we want the arrangements to be in place from 2014 to ensure that NHS patients have consistent access to effective medicines. We are considering further specific arrangements that should be in place from 2014. That is the purpose of the consultation.

I have also been asked whether NICE will have a role in price setting. NICE will have an important role in any new system; that is the clear, unequivocal point. However, we have only recently finished the consultation, and the details of how value-based pricing will operate is still being considered and worked through. We will continue to hold discussions with NICE, the industry and other interested parties as we take forward the design of the new system.

It has been suggested that NICE’s role is changing in a way adverse to the patient’s interests. Absolutely not—value-based pricing will be in place from 2014.

The Bill makes no provision for value-based pricing. As we develop the policy, we will consider whether any further legislation is necessary.

My hon. Friend the Member for Stafford asked about expensive drugs, and their up-front costs and long-term benefits. The answer is yes, as happens now.

I have saved the best for last—NICE in Wales. NICE is an England-only body, but Wales will have access to NICE products and may also contract independently with NICE for Wales-specific products. That is a devolved matter for Wales, which will be able to use the expertise of NICE, because it is well respected, under those contracting arrangements.

5.45 pm

Owen Smith: I am grateful for that clarification. The Minister is entirely accurate in his description of the situation in legislation, but in the real world the All Wales Medicines Strategy Group and the NHS in Wales rely greatly on taking NICE guidance and applying and assessing it. In a world post value-based pricing, will NICE still provide that guidance or will its role be restricted to price setting and, in that case, will there be less NICE guidance in the public domain for the AWMSG to take advantage of?

Paul Burstow: I do not believe that there is any reason to suppose that that will be the outcome of the changes to value-based pricing. With that and my other answers, I hope I have reassured the Committee that the clause, which deals with the general purposes of NICE, should stand part of the Bill.

Liz Kendall: I am grateful to the Minister for his reply. I do not think that he addressed one point that was raised by my right hon. Friend the Member for Rother Valley, but I am sorry if I missed it. Who will undertake the price negotiation—NICE or the Department of Health?

Paul Burstow: I refer the hon. Lady to the answer that I have already given. We are at the point in the consultation process where we have just received the responses, and we will consider and deliberate on them before we move to the next stage.

Question put and agreed to.

Clause 217 accordingly ordered to stand part of the Bill.

Clause 218

QUALITY STANDARDS

Liz Kendall: I beg to move amendment 666, in clause 218, page 189, line 33, after ‘(c)’ insert ‘adult and children’s’.

The clause sets out more detail about the quality standards that NICE produces. I want to say again that it is a good idea formally to bring together health and social care services within NICE’s remit. Hon. Members will know that NICE has already begun to do that through some of its existing quality standards. It has looked at public health, health care and social care, and at how all the different bits of the system need to work
together. It has produced some excellent quality standards. One that I have read all the way through is on obesity. It looks at everything that needs to be done to tackle that problem, which is very welcome.

The amendment seeks to clarify whether NICE's remit on social care will include children's as well as adult social care. The explanatory notes to the Bill suggest that its remit will cover both areas, because it refers to the Secretary of State's being able to commission quality standards alongside the Secretary of State for Education. However, NICE has certainly raised with me the issue of whether children's social care will come within its remit.

I want to ask about a point raised in a previous debate by the Minister, who said that discussions are going on with relevant bodies. What discussions has he had with local authorities or the Local Government Association about the new role for NICE in its covering quality standards and social care as well as health? Will local councils be required to implement NICE quality standards? Have the Government conducted an impact assessment on the implications of that for council budgets?

Let me give an example. I am pretty sure that if NICE had a quality standard for the various aspects of adult social care, it would say that the best quality care would seek to prevent adults, and older people in particular, from having deteriorating health. That might require some social care support—perhaps visits from supporters and carers. We know that many councils are raising the threshold for the support that they provide because of funding squeezes.

Councils are facing substantial cuts to their budgets because of the Government's determination to eliminate the deficit within four years—they are facing 26% or 27% cuts, which are being frontloaded. As I am sure hon. Members are aware, many councils are raising their thresholds for support. So it is important to be clear whether the Minister has conducted any kind of impact assessment relating to the effect on council budgets. Has the Minister had any discussions with Ofsted about the issue? If NICE is setting quality standards for children's social care, will Ofsted be required to inspect services and councils to ensure that they are delivering and implementing those quality standards?

The other point that I want to raise is about the Social Care Institute for Excellence. Hon. Members know that NICE was initially set up for the health service and SCIE was set up for social care. Now that NICE is taking on the function of setting out the highest possible quality standards, will SCIE continue? Or will it instead be brought into NICE? Will NICE commission its quality standards from SCIE? Will the quality standards have the same rigour as those developed by NICE? I know it does some excellent work, but I would appreciate the Minister's answers to all those questions. I am sure that hon. Members will have other questions, too.

Paul Burstow: Amendment 666 would make it explicit that NICE's remit in preparing quality standards will include both adults' and children's social care. There is no difference between the two sides of the Committee on the issue, but the amendment is unnecessary. The definition of social care used in relation to NICE, which is set out in clause 217(3), already covers adults' and children's social care services. Furthermore, not making a distinction between the two enables NICE to consider issues relevant to the transition from childhood through adolescence and into adulthood. That is an area of public policy that has much scope for improvement in practice.

The hon. Lady also referred to the funding pressures on local authorities. I draw the Committee's attention to the work recently published by the King's Fund, which looked at the social care funding challenge. The King's Fund made two conclusions. The funding gap by 2014 will be £1 billion, but—this is an important "but"—that funding gap arises only if one does not take into account the efficiency savings within local authorities.

Once efficiencies are taken into account, the King's Fund concluded that there will be no funding gap on the basis of the resource decisions made specifically and explicitly in support of social care, both through the funding that the Department of Health is making available via the NHS to social services departments and the funding that has gone into the formula grant and will continue to go into the formula grant during the spending review period. Local authorities are making choices about the services that they are choosing to protect, but it is not true that the Government have not provided a settlement to support social care, if that is what local authorities choose to do.

The hon. Lady asked about discussions with the LGA. In the end, that is a matter for NICE. I have had discussions about the principles of the Bill, particularly this opportunity to drive more integration. I have spoken to colleagues at the LGA, and they have indicated their support of the broad direction of travel.

However, the detail of how NICE takes forward its remit is clearly not a matter for Ministers; it is for NICE to have those discussions. It will also continue to have close working relationships with SCIE, which does some very important work, as the hon. Lady rightly says, and they are making different choices about the services that they are choosing to protect, but it is not true that the Government have not provided a settlement to support social care, if that is what local authorities choose to do.

The hon. Member for Leicester West also asked about Ofsted and inspections. I want to make it absolutely clear that, as will be the case with the Care Quality Commission—I say that so the question does not get asked in a moment—Ofsted will not be bound to inspect against quality standards. Local authorities will not have a specific statutory duty in respect of quality standards, and nor will consortia.

In respect of the NHS, the NHS commissioning board will produce commissioning guidance based on the quality standards, but it will be a matter for local authorities to make decisions about the social care services that they commission as independent, locally elected bodies. For the first time we will bring together, in a clear, creditable and accredited way, a set of standards that have been put together by the profession and the sector and which can be drawn on by commissioners as they commission social care services. I hope that that has answered the hon. Lady's questions. The amendment is unnecessary, and I hope that she will withdraw it.
Liz Kendall: The Minister claims that the quality standards that NICE will set for social care will have some sort of force behind them because consortia will be required to deliver them. Under later amendments, I will explain why I do not think that is necessarily the case, but I suggest to him that it is quite amazing he has not spoken to local councils and the LGA specifically about NICE's new role setting quality standards in social care.

Paul Burstow: The proposal was contained in the White Paper last July and was the subject of consultation, to which we had extensive responses; and there has been ongoing dialogue with local government about the transition of a host of the changes that the Bill produces. Those discussions have taken place.

Liz Kendall: That sounded slightly different from the Minister's original reply. I am not sure that local councils across the land are aware that NICE will set the quality standards for social care, so I strongly urge the Minister and other hon. Members to have that discussion. I know that my local council has been very focused on the new health and well-being boards and what public health money will come over, but there is no point in having a quality standard that joins up health and social care if neither party is committed or able to implement it. More detailed discussion is needed. If the Minister has had specific discussions on that subject, I am pleased to hear it, but I urge other hon. Members to engage in such discussions, because I am not sure that a huge number of councils are aware of the change.

I am grateful for the Minister's clarification that the definition of social care in the Bill does indeed include children's social care. I am sure that NICE will be glad to be heard that. It raised that question with me, so I am very pleased by that provision. I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Liz Kendall: I beg to move amendment 664, in clause 218, page 189, line 35, after 'preparing', insert 'or revising'.

The Chair: With this is will be convenient to discuss the following:

Amendment 667, in clause 218, page 189, line 35, after 'consult', insert 'and involve'.

Amendment 668, in clause 218, page 189, line 35, after 'public', insert 'and health and social care professionals as appropriate.'.

Amendment 669, in clause 218, page 190, line 11, leave out

'such persons as it considers appropriate'

and insert 'all relevant persons'.

6 pm

Liz Kendall: Am I required to speak to the amendments in order, Mr Hood, or may I hop about?

The Chair: This is the hon. Lady's own group of amendments and she can do what she likes.

Liz Kendall: Marvellous—liberating the Opposition Front Bench. That is much appreciated, Mr Hood.

The amendments are designed to strengthen the requirements on NICE to consult and involve the public, health and social care professionals and all relevant bodies both when it draws up and when it revises its guidance. Existing legislation does not provide a strong or broad enough outline of how NICE should involve and consult various bodies.

Amendment 667 would require NICE not only to consult the public, but to involve them in decisions. I want to say a little about NICE's citizens council, which I hope will continue in NICE's new role. There is no mention of it in previous legislation and there is none in the Bill, but I want to say something about why I think the citizens council plays such an important role. I use it as an example to show what we mean by not just consulting and asking the public, but genuinely involving them in decisions.

Hon. Members may be aware that the citizens council was set up in 2002 to ensure that NICE hears not only from patients, patient groups and their carers, but from ordinary members of the public who fund the NHS. An extremely innovative body, it comprises 30 ordinary members of the public who are broadly representative of the UK as a whole. The council meets twice a year for three days at a time, when it takes evidence and seeks to come to decisions and make recommendations on often very challenging matters. For example, the council has looked at the definition of quality adjusted life years, which encompasses not only the extra years a patient would get from taking a particular drug, but how healthy the patient would be and how free from disability, and the severity of illness that remains. The council has also looked at the circumstances in which NICE should recommend interventions where the cost per QALY is above the stated £20,000 to £30,000 per year.

I am a long-standing and passionate supporter of involving the public in more meaningful ways. I was involved in the first citizens juries established in this country, and the citizens council came out of that work, which is about saying that the public, given enough time and information, can make serious and difficult judgments. The amendment aims to ensure that NICE not only asks patients and patient groups what they think, but genuinely involves the public in very difficult decisions.

Amendment 668 would require NICE to consult and involve not only the public, but health and social care professionals, as appropriate. The reason why is obvious: NICE needs to consult a range of professionals in producing its guidelines. I am sure that it would probably do that anyway, but the amendment would make that clear.

Amendment 669 would replace the duty of NICE to consult with the duty to consult "all relevant persons". Again, it seeks to strengthen the requirement on NICE. As NICE said in its response to the consultation on value-based pricing, it needs to consult patients, providers, manufacturers and commissioners. The amendment would put that requirement for broad consultation in the Bill.

Finally, amendment 664 would add a requirement for NICE to consult all those groups and bodies not only when it is preparing guidance, but when it is revising it.
As we know, the guidance that NICE publishes sometimes has to change, and it is important that NICE involves and consults people in that case.

I am not a soothsayer, but I predict that the Minister will say that the amendments are unnecessary, that that is what NICE would seek to do and that Labour never provided any detail about NICE when we were in government.

Jim Shannon (Strangford) (DUP): NICE is a reputable organisation that has the confidence of the general public. Does the hon. Lady think that the proposed changes will ensure that that will continue?

Liz Kendall: I thank the hon. Gentleman for his intervention. That is precisely why the amendments have been tabled. During a tight funding period for the NHS, when huge efficiency savings have to be made and when overall funding for the NHS is going to be reduced over the next couple of years—

Mr Burns: Wrong.

Liz Kendall: If we take the change in inflation that is in the Budget, that is correct.

The Chair: Order. I am now listening to chuntering from Members on both Front Benches.

Liz Kendall: Thank you, Mr Hood. I think it is vital that NICE retains the support of patients, the public and health and social care professionals, which is why I have tabled the amendments.

Paul Burstow: I shall try not to use all the lines that the hon. Lady predicted I would utter, but I should say again that we share the intentions behind the amendments. The question is how we achieve them, and I hope to be able to reassure her.

NICE’S reputation rests in large part on the open and transparent processes that it adopts in developing its products. That is a key part of what people appreciate about how it operates. In its current form, NICE actively promotes the involvement of patients, carers and the public in its work through its patient and public involvement programme. The hon. Lady has described the work that the citizens council does. Whether that continues is up to NICE; the only thing that will change under the Bill is that NICE moves from being a creature of the Secretary of State as a special health authority to being a creature of statute, thus protected by the fact that it will require parliamentary scrutiny to change in the future. It will not change the key personalities and people involved in that organisation, so it is highly unlikely that its change in status will suddenly make it reconsider the things that it thinks are working well now. If NICE thinks that citizens councils are working well now, nothing in the Bill will change its ability to continue to run that operation in the future.

Debbie Abrahams: I applaud everything the Minister says, but I cannot see how the circle may be squared of NICE maintaining the types of methods and tools that we applaud and recognise as robust while its work load doubles and it has a 30% reduction in the budget. I do not see how it can be done.

Paul Burstow: As the hon. Lady knows, the reality is that right across the public sector, we have to make some tough decisions about resources. Although I would be only too pleased to do so, I will not rehearse the reasons why the present Government find themselves in that position. That is probably for another day.

Debbie Abrahams rose—

Paul Burstow: Let me come to the substantive point, which is that, in our view, the resources we are providing to NICE will allow it to develop its new role over the next few years and continue to do the valuable work that it does now. That is the judgment that we have made based on the resource envelope that we have provided.

Earlier, references were made to NICE expressing concern about the drafting of a particular clause. Although it is very helpful to have that feedback via the hon. Member for Leicester West, NICE can pick up the phone and speak to the Department directly, and does so regularly. We have a good, healthy working relationship with NICE.

I draw attention to the work done to date on developing the published quality standards. There is a wide range of publication partners drawn from a broad spectrum of stakeholders, including clinical and patient, professional and lay, and managers and front-line staff. Because we are putting NICE on to a statutory footing for the first time and moving away from the special health authority approach, we do not want anything that NICE does in the future to detract from its excellent track record, and we have reinforced that point in the Bill. NICE will have a specific requirement to consult the public in preparing quality standards.

Rather than improving or increasing the level of public involvement, I fear that the amendments would merely burden NICE with additional tasks that add uncertainty and little value to the extensive engagement that the hon. Lady partly described and that is part of the way that NICE operates. NICE’s open and transparent approach means that when a review of quality standards proposes significant changes, consultation will be an expected part of the process. I hope that that reassures the hon. Lady. If she feels that she cannot, I urge my colleagues to resist it.

Liz Kendall: I think that facing a 30% budget cut will mean that NICE has to look very seriously at what it does. NICE does not know what role it will have under value-based pricing, because the Minister is still chewing over—sorry, considering—the responses to the consultation. If NICE is required in statute to set those quality standards, whatever role it has, I am worried that among the first things to go will be bodies such as the citizens council, because it costs money and takes time to genuinely involve and engage members of the public. I personally believe that the council represents money well spent.

I think that the Minister is right—I believe that NICE will involve and engage members of the public, because, as the hon. Member for Strangford said, it wants to have that authority. However, I want on the record the Opposition’s concern that innovative forms of public engagement, such as the citizens council, will...
be one of the first things to go when an organisation is faced with a one-third cut in its budget combined with a possible doubling of its work load. Despite that, I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

The Chair: I have been asked for a five-minute suspension, so the Committee will be suspended until 6.20 pm.

6.14 pm
Sitting suspended.

6.20 pm
On resuming—

Amendments made: 599, in clause 218, page 190, line 33, after ‘section’, insert ‘7A or’.

Amendment 600, in clause 218, page 190, line 35, leave out from first ‘of’ to ‘Schedule’ in line 36 and insert—

(a) the Secretary of State under section 2A or 2B of, or paragraph 7C, 8 or 12 of Schedule 1 to, that Act, or

(b) a local authority under section 2B or 111 of, or paragraphs 1 to 7B or 13 of.---(Paul Burstow.)

Question proposed, That the clause, as amended, stand part of the Bill.

Mr Barron: I have a couple of questions for the Minister about clause 218. We were told during our first sitting that 150 quality standards would be produced within five years and that NICE now has about three or five ready to publish. That looks like a very difficult task against the backdrop of the 30% cut in budget, but I have no doubt that we have debate another day.

More importantly, I want to ask the Minister how he thinks quality standards will affect health care delivery in this country. In that first sitting, a number of Members asked Sir David Nicholson what he believed would happen. He said that 150 quality standards will be developed and continued:

“That will then be translated by the commissioning board into local commissioning guidelines. It will all be translated into a national framework contract for providers. In that way—” Official Report, Health and Social Care Public Bill Committee, 9 February 2011; c. 15; Q30.

The hon. Member for Stourbridge mentioned that earlier this afternoon.

What will the likely effect of that be? NICE, as an organisation, has been issuing both statutory and non-statutory mechanisms for a number of years now; sadly, however, even when NICE has recommended good practice it has been up to PCTs how to interpret that, or not interpret it as the case may be. It has always been difficult for NICE to spread best practice throughout the NHS. It seems to me that “quality standards” are about doing exactly that, and that was what Sir David Nicholson was referring to in his evidence.

Subsection (5)(a) says:

“A quality standard (and any revised standard)...must be endorsed by the relevant commissioner.”

As I understand it, in effect, that provision means that organisations will have to deliver to the quality standards, which will be published. NICE will have to build up a library of different patient pathways and what the relevant quality standard should be. What are the implications of putting that in the Bill? I will not go into any great detail, but the Minister will know that bringing competition and competition law into the national health care system will result in lawyers interpreting whether or not local commissioners have ensured that they commission on the basis of the quality standard for their area. That is my question to the Minister: what are the implications of putting that in the Bill, given the great changes accompanying the introduction of competition? Will the quality standard be the one thing that people will look at to see whether commissioners are doing the right thing or not?

We were told—I assume that it is in this clause but I cannot pick it out—is that NICE will also lay down quality standards for providers, both public sector and independent. Those providers would have to look at the quality standards when providing a service. That might be a good thing, but something is absent from clause 218 or any other. First, competition was going to be based on price. Then we were told that it would be based on quality. Nowhere in any evidence or on the face of the Bill does it say that Monitor will have to consider the quality standards, although we are led to believe that it will be the one organisation that will ensure quality throughout the national health service.

It seems a great absence, if that is the case. I know that it was a late conversion for Monitor to consider competition based on quality rather than price. I suspect that we will debate that further in the House during the next few months, but I would like to know why Monitor is absent. Am I just misreading the clause? Will Monitor be given the quality standards to ensure that when it comes to competition policy, everybody will meet the quality standards laid down by NICE?

Debbie Abrahams: I rise to reiterate my concern about the scope of the work that NICE will be required to undertake using the existing robust mechanisms, tools and procedures, but with fewer resources. In addition, clause 218(10)(b) relates to quality standards for the provision of public health. I would like to understand the scope of the services covered. It would be incredibly regressive to consider only services such as smoking cessation and other lifestyle-related interventions. Currently, NICE undertakes effectiveness reviews of a range of different public services. If anything, given the new approach to public health and health inequalities set out in the Bill, that range should expand, not contract.

I note the concerns expressed by the Association of Directors of Public Health, particularly about what the provision will mean for reducing inequalities, as we have discussed. We must be mindful of the Bill’s broad and different impacts on inequalities. Will the provision cover the three domains of public health that we know of, or will it be limited, as I fear it will?

Liz Kendall: My points follow on from both my hon. Friends, starting with that of my hon. Friend the Member for Oldham East and Saddleworth. One issue raised with me relates to whether the Bill will remove or supersede some of the directions issued to NICE in 2005, which was the piece of paper that I waved earlier.

The directions contain some useful and specific points about NICE’s functions relating to public health. For the record, they are the “Directions and Consolidating
[Liz Kendall]

Directions to the National Institute for Health and Clinical Excellence 2005”, and they say that NICE should
“develop, maintain and disseminate an evidence base for effective public health action on health improvement and the reduction of inequalities in health”
and
“provide guidance on the development and setting of standards for public health and health promotion programmes and practice and support their implementation”.
Crucially, they also say that NICE should
“provide guidance on the means for improving the capability and capacity of organisations, systems and the wider public health workforce to deliver health improvement and reduce inequalities in health”.
That is quite a detailed description of the different levels on which NICE must work if it is to deliver high quality standards. My first question is: will the Bill remove the 2005 directions, or will they remain? Secondly, will the Minister explain how NICE will work with Public Health England? There is no reference to that and it is very unclear how that will work in practice.

6.30 pm
My right hon. Friend the Member for Rother Valley asked about the general strategy for improving quality and how NICE works with other bits of the system. I want to highlight two issues and ask the Minister to provide a response. The NHS commissioning board is obviously setting the outcomes that the service is supposed to achieve. I assume that the NICE quality standards will demonstrate how those outcomes will end up being delivered, because there is little point in setting an outcome if there are no means by which it can be achieved. I understand—perhaps the Minister can clarify this—that discussions are going on with NICE about whether it will have a role in determining what a reasonable outcome is. We might have an outcome of everyone living perfect, happy lives, but there would be no point in that. We have to know that the outcome we are setting as an objective can be achieved. Will NICE have a role in determining the NHS commissioning board’s outcomes?

How will NICE work with Monitor? As the Minister will know, Labour Members do not have great faith that Monitor will improve quality for patients and the public across England. As far as I can see—I may be wrong—there is no reference to how NICE will work with Monitor in doing that. For example, will Monitor be required to take NICE’s quality standards into consideration when making its recommendations on promoting competition? Clause 221 states that regulations may require specified health bodies to take into consideration NICE’s quality standards. Does that include Monitor? Why was there nothing in the provisions on Monitor’s role about its working with NICE? If the Minister explains that and provides some clarity on it, I am sure that others will be overjoyed as I.

Paul Burstow: I shall try to spread some joy in the answers I give to the Committee. Let me start with the point about competition. It is important to remind the Committee again that the clauses on Monitor make it clear that Monitor’s principal role is to protect and promote the interests of patients. The Bill goes on to indicate the ways in which it might do that. Those are the means; the purpose is very clear. All too often, we state over its purpose and move immediately on to various concerns—often unreal and that will not be realised—rehearsed by Opposition Members.

The right hon. Member for Rother Valley asked about the requirements to implement quality standards. Under their duty to promote quality, the Secretary of State and the NHS commissioning board will have to have regard to quality standards in undertaking their functions. The Committee has already discussed in some detail the meaning of “have regard to”, but it is worth saying that the term is not meaningless; indeed, it has a very specific set of legal meanings. We are not talking about a tick-box exercise; there is a rigorous process of considering the matter that has to be had regard to. The courts have said that that duty must be exercised with real rigour and an open mind. The commissioning consortia must have regard to the guidance produced by the NHS commissioning board, which will draw on the quality standards in developing its guidance.

On whether Monitor has to follow the quality standards, the standards are implemented through the commissioning system, not through the board and consortia. Monitor must have regard to the desirability of securing quality improvement. That is covered in clause 54, which usefully addresses the hon. Lady’s question as well.

On quality standards and public health, the scope will be as broad as the Secretary of State or the board requests. NICE will not have to make a distinction between health, social care and public health. That will enable a much more integrated approach of the sort that hon. Members have raised concerns about, which the Bill drives forward significantly.

The right hon. Member for Rother Valley expressed concern about subsection (5)(a), and how we interpret “endorse”. There is a misunderstanding of what that is about, which is partly answered by subsection (10), which talks about the relevant commissioner. It means the commissioner of the quality standard, which in this case might be the board or the Secretary of State. The commissioner will have to confirm that it is content for the standard to be published. Subsection (5) refers not to the commissioning activity within the NHS, but to the commissioning of the standard, and in that sense it has nothing to do with competition.

An overarching concern articulated in several of our debates today is the level of resource that is available to NICE, and the suggestion that there is to be a 30% cut. Let me make it clear that we have not announced a 30% cut for NICE. That is speculation that has developed in the Committee over the past few hours. The planning assumption for NICE is a 10% to 11% reduction for 2011-12, which is consistent with other arm’s length bodies. The 30% figure refers to the arm’s length body sector as a whole. I hope that that reassures hon. Members that much more resource will be available to
NICE than has been suggested. I am sure that the joy that the hon. Member for Leicester West sought has now been disbursed.

**Liz Kendall:** I am not overjoyed. I do not understand how the Minister can suggest that an 11% cut this year will give NICE more money than it thought it would have. On the origin of the 30% figure, it is hardly surprising when the Government have said that arm’s length bodies will face a 30% cut. In the first year NICE is facing an 11% cut, and there are two or three more years ahead of the spending review period, so it is not unlikely that it would face such a cut. It is important to have that on the record.

The Minister did not answer my questions about whether the directions that were issued in 2005 remain in force for NICE or whether the Bill supersedes them. The directions set out a detailed approach to what the Opposition consider to be public health, which is acting on a societal level as well as on community and individual levels.

**Paul Burstow:** I suspect the hon. Lady is about to ask about the relationship with Public Health England, as well. The answer is that Public Health England is part of the Department of State functions; the Department is accountable to the Secretary of State. We have discussed that already. The relationship will therefore be the same as any relationship that NICE has with the Department of Health. Regarding the 2005 directions—I wish I could read the handwriting on my note, which comes as a big shock as my own handwriting is very bad—the Bill provides for the re-establishment of NICE with the functions that are specified in the Bill. I will make sure that there is more clarity about the directions, but our intention is that we do not lose anything that is necessary during the transition from special health authority to statutory body.

**Liz Kendall:** I am grateful to the Minister for his comments. I urge him to look closely at the directions, because they are a good outline of what it would take to improve the quality of public health services for individual professionals, for organisations and for the system as a whole.

**Question put and agreed to.**

Clause 218, as amended, accordingly ordered to stand part of the Bill.

Clauses 219 and 220 ordered to stand part of the Bill.

**Clause 221**

**ADVICE, GUIDANCE, INFORMATION AND RECOMMENDATIONS**

**Liz Kendall:** I beg to move amendment 670, in clause 221, page 192, line 18, leave out ‘may’ and insert ‘will’.

The amendment relates to the point raised by hon. Members during the discussion on clause 70 and concerns whether commissioning bodies will be required to implement the NICE guidance. That was one of the key issues raised. Clause 221(8) states that the regulations “may” make provision to require health and social care organisations to have regard to NICE advice or guidance, and “may” make provision for bodies to comply with NICE recommendations. As the Minister will be aware, I do not want a debate about “have regard to.” This debate is about the wording that states that regulations “may” require specified health or social care bodies to have regard to guidance and comply with it.

The amendment would change the wording to state that the regulations “will” make provision to require bodies to comply with the NICE guidance. It is a small change, but it would have a big impact. Labour Members are concerned that there could be a watering down of the rights of patients and the clear requirement on commissioning bodies to comply with the NICE guidance. That could have a knock-on effect that would undermine the right of patients, as set out in the NHS constitution, which states:

“...you have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.”

If the Government believe that the Bill will not change anything and that GP commissioning consortia will still be required to implement the NICE guidelines—there are big debates about whether they will be able to afford to do that within the budget—the amendment would make that clear.

**Owen Smith:** As my hon. Friend said, some of these points have been addressed to a certain extent in an earlier debate. Nevertheless, if the Minister could provide any clarifications, that would help the Committee. Those clarifications relate to the future world in which we have the changes to NICE and where value-based pricing applies. I anticipate the Minister saying that we do not know exactly how value-based pricing is going to work, and therefore he cannot address that point, but I will ask him to delve into those realms to some extent. The point is relevant because in a world with value-based pricing, however it works, there is a crucial question about the connection between NICE’s guidance, price setting and the GP consortia. The Minister needs to address that issue and offer some clarity in relation to the issue touched on in subsection (8) about the mandatory funding, or otherwise.

The Minister said earlier that value-based pricing could apply or be relevant nationally or locally, which delves into the future. Can he clarify that point?

6.45 pm

**Paul Burstow:** I urge the hon. Gentleman to read the record. I said that we had not formed a view on whether it would be national or local, but he is implying that a view had been formed. I want to ensure that this is clear.

**Owen Smith:** I think I was clear, but I phrased it differently. I said that the Minister implied that value-based pricing could apply locally or nationally, which is pretty much the same as saying that he had not decided whether it would apply locally or nationally.

My point is simple: it cannot possibly be right to suggest that value-based pricing could apply locally, because that would suggest that individual GP consortia would negotiate value-based prices with pharmaceutical companies. I do not imagine that the Minister thinks that would be a sensible situation. Such a lack of clarity
on that speaks volumes about how it is very unclear at the moment how value-based pricing will work and how it will relate to NICE's job and GPs' decisions to fund medicines. That takes us to a second hypothetical but entirely relevant point.

Let us remember what happens now. If NICE reviews a medicine and deems it cost-effective, it is mandatory for the NHS to fund it, and, effectively, PCTs have to provide funding. The Minister implied in an earlier answer that that will still pertain under the new system and that certain types of medicine—the ones that NICE accepts are value for money or for which the company agrees to the price point set by NICE, I presume—will be mandatorily funded. However, I asked him to reflect on what happens now when a medicine is not approved by NICE and is still, as the Minister mentioned, put on the market in the UK. That is where PCTs come in and, either through exceptional case funding or through the pharmaceutical committees in the PCT, make local, ad-hoc decisions on whether to fund a patient in their locale to receive that medicine. That situation will not go away.

If a company chooses not to agree to the price point set by NICE and releases the medicine to the market anyway, somebody in the system at a local level will decide whether to make that medicine available. In the new system, I assume that will be the GP consortia. That leads me to the specific question: does the Minister imagine that, under the terms of the Bill, GP consortia will have similar methods, through pharmaceutical committees of their own, of making those decisions? Will the consortia apply things such as the exceptional case funding mechanisms with which we are familiar? If that is the case, is he convinced that they will have the relevant expertise? Given that they will be doing a hell of a lot under this new system as far as I can see, will they have the time? Is there not a risk that some will do it well and some will do it badly, so it will be less uniform than the system now and the postcode lottery will be expanded?

**John Pugh:** I understand the amendment would change the wording from “may” to “will”. Clearly, “will” is more prescriptive. My point relates to the remarks that were made on mission creep. Where all NICE is recommending is that a particular drug be made available, I think that Ministers can reasonably gauge the effect of requiring any specified health body to make it available. It is different where NICE is doing something more complex, such as laying out a pathway of care. I was looking at the pathway of care quality standards for strokes recently, and Members can look at it themselves if they so wish. A complex chain is expected to be in place with regard to how things are dealt with in the first phase, in the acute setting and after the stroke patient has been seen to, and with regard to how recovery is aided. Regulations to require people to implement that will be a very tough judgment call for a Minister to make to some extent, because he must be assured that all organisations are capable of implementing it. That takes us back in a sense to the debate about “have regard to”. If Ministers are simply asking various commissioning bodies to take it on board that that is where they should be heading and that that is the sort of thing they should be looking to prescribe, that is fine.

**Liz Kendall:** If the requirement was on GPs to implement NICE guidance on drugs, would the hon. Gentleman be more in favour of it than if it were about a whole pathway and quality of care?

**John Pugh:** I am not sure that my views on which would be favourable or not are really the point. The point I am trying to make is that, if we are asking people to have regard to guidance and the guidance is “supply a drug” we know what we are asking for and we know the system’s capacity to deliver it, subject to funding and so on. Quality standards in stroke care are an ideal, which is replicated in only part of the country. To replicate them right across the country would involve a number of complex adjustments to health systems.

**Grahame M. Morris:** Is not the nub of the issue whether NICE is being reduced to a body that issues advice rather than clear direction in relation to drugs?

**John Pugh:** That is precisely the point I am trying to make. A prudent Government might prefer to put in “may” rather than “will” because some things are easier to direct than others.

**Paul Burstow:** This is a bit of a rerun of our earlier debate, but it is important to make it absolutely clear where we are with regard to the NHS constitution right to NICE-recommended drugs. The Government fully recognise the importance of consistent access to clinical and cost-effective treatments. Subject to the successful passage of this Bill, we intend to use the regulation-making power in this clause to replicate the effects of the existing funding direction.

The NHS commissioning board, the commissioning consortia and, in the short term, primary care trusts would therefore be required to make funding available for drugs that NICE has recommended in its technology appraisals. My hon. Friend the Member for Southport took an intervention from the hon. Member for Easington who suggested that NICE directs. NICE does not direct. It produces technology appraisals on a whole range of other products. It does not have the power to direct the NHS to do anything. That power sits with the Secretary of State under the current arrangements. What we are saying is that through the regulation-making power that this clause will provide, we intend to give effect in exactly the same way as now with regards to technology appraisals and ensuring that consortia and PCTs fund on that basis.

**John Pugh:** For absolute clarity on that point, in future when NICE no longer does its value-for-money assessments and gives its imprimatur to particular drugs, the Minister used the expression mandatory and said that certain drugs will be mandatory. Does that imply that if a drug is graded mandatory—clearly some will not be so graded—it will have to be provided by a PCT if the consultant or the GP thinks that a patient should get it?

**Paul Burstow:** First, I shall restate what I said. I do not think that I used the word “mandatory”, but I used some other words that were probably equally strong. I said that the NHS commissioning board, commissioning
consortia and, in the short term, the primary care trusts would therefore be required to make funding available for drugs that NICE has recommended in its technology appraisals. We will replicate the funding direction that currently exists that gives effect to the current policy that underpins the NHS constitution right to NICE-recommended drugs. That is what we will do.

My hon. Friend went on to explore how other guidance that is produced around care pathways might be interpreted. They are not subject to quite the same set of directions as applies to technology appraisals. I will also say that, when it comes to quality standards, which we have discussed at some length today, the NHS commissioning board will have to have regard to them. That is not a duty that can be lightly dismissed. It is an important one in terms of the law. The commissioning board will use that in producing its commissioning guidance for consortia, which in turn have to take that into account by having regard to it. It is not just a tick-box exercise.

Owen Smith: I am grateful for the clarification that the Minister has offered. It is now clear that the mandatory funding comes with the direction from the Secretary of State. Effectively, just as PCTs are obliged to fund NICE-approved medicines, GP consortia will be obliged in the same way. My question is therefore who will do the budgetary planning in this new system in advance of anticipated approval or otherwise by NICE of new medicines? That is currently an extraordinarily difficult, time-consuming and expensive process, undertaken by budgetary controllers in PCTs, who look ahead in collaboration with NICE and plan. Who will do that in the future?

Paul Burstow: I am grateful for the question. Because the hon. Gentleman is describing a hugely complicated process, I will write to him on that point, along with a description of the arrangements with exceptions committees, so that we are clear and so that all members of the Committee benefit from that exchange.

I want to return to the amendment, and say something about the impact it would have, were it to be passed by the Committee. It would mean that regulations made under any regulation-making power in this clause would have to make provision under subsection (8). That is unnecessarily bureaucratic. Subsection (8), as it is currently framed, allows such regulations to be made where they serve a policy purpose. To be required to make regulations, which may simply state that there is no specific requirement for compliance, would introduce unnecessary complication. That would be the consequence of the amendment.

The hon. Gentleman brought us back to value-based pricing, on which we have spent some time. It is not provided for in the Bill. We are at the early stages of developing policy on that. None the less, he invited me to fast-forward to a point where we have a clear policy and answer questions on that. I will resist the temptation of fast-forwarding to the conclusion, when we are paying due respect to the results of the consultation and giving it proper consideration. I am sure that there will be ample opportunity for parliamentary scrutiny as that policy develops and is implemented.

John Pugh: One final point, before the Minister closes on the clause. He has talked about a policy imperative for making provision in some cases, but not in others. Presumably quality standards will exist in nearly every case. Would that not run the risk that when people looked at quality standards that were not the subject of regulation, commissioners would sit loose on those and be less attentive to them, or regard them as second-class objectives?

Paul Burstow: No. I think my hon. Friend is misreading how the clauses in this part of the Bill sit together. There are specific clauses earlier in the Bill that deal with the duties on consortia to have regard to the commissioning guidance produced by the NHS commissioning board and the duties on the NHS commissioning board to have regard to the quality standards that are produced. There are no ifs, buts or maybes. There is no additional regulation that has to be issued to say that this one is okay and should be taken into account. There is, however, the issue of the relevant commissioner of the quality standard deciding whether it should be published. Having commissioned it, they make that judgment at that point. There is certainly no issue on a second-class form of quality standard, which does not have the imprint of a regulation that says it should be taken into account. They all have to be taken into account once they are published.

Jim Shannon: The hon. Gentleman will appreciate that NICE is looked upon as a sheriff of the health service—overseeing it and keeping control of it. Does he accept that the coalition Government have an enormous task to convince the general public that everything will be as it was and that there are guarantees in place? I accept the changes and why the Government are doing it, but I am not convinced that the general public are convinced by what the Government are trying to do, or by the safeguards.

Paul Burstow: That is the purpose of our deliberations and of the opportunity that hon. Members have given me through the amendments to set out, on the record, our intention to fully honour the NHS constitution requirements on NICE-recommended drugs. I have described today how we intend to give effect to that. With that, I urge the hon. Lady to consider withdrawing her amendment.

7 pm

Liz Kendall: I am glad that the Minister has announced that regulations will be issued that require commissioning consortia to pay for NICE drugs. That is important because it has not been clear before, and I am sure that Members will look forward to tweeting the news when they leave the Committee. I hope that we will be able to rely on the Minister’s commitment to that, and we look forward to seeing it happen.

Labour Members still have very real concerns, and I just want to pick up the point about the Bill not setting out value-based pricing—that is still being discussed. The problem is that the Bill changes NICE’s role, but Government policy on value-based pricing still has not been ultimately figured out—it is still being worked through.

I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Amendments made: 601, in clause 221, page 192, line 21, leave out ‘and’.
Amendment 602, in clause 221, page 192, line 31, after ‘any’, insert ‘public’.

Amendment 603, in clause 221, page 192, line 40, at end insert—

“"public body" means a body or other person whose functions—
(a) are of a public nature, or
(b) include functions of that nature, but, in the latter case, the body or person is a public body to the extent only of those functions;".—[Paul Burstow].

Question put, That the clause, as amended, stand part of the Bill.

The Committee divided: Ayes 12, Noes 10.

Division No. 95]

AYES
Brine, Mr Steve
Burns, rh Mr Simon
Burstow, Paul
Byles, Dan
Crabb, Stephen
de Bois, Nick

Lefroy, Jeremy
Morgan, Nicky
Pouler, Dr Daniel
Pugh, John
Soupby, Anna
Sturdy, Julian

NOES
Abrahams, Debbie
Blenkinsop, Tom
Kendall, Liz
Morris, Grahame M. (Easington)
Shannon, Jim

Smith, Owen
Thornberry, Emily
Turner, Karl
Tigg, Derek
Wilson, Phil

Question accordingly agreed to.

Clause 221, as amended, ordered to stand part of the Bill.

Clause 222

NICE RECOMMENDATIONS: APPEALS

Question proposed, That the clause stand part of the Bill.

Derek Twigg: We are concerned that the clause does not set out much detail of the appeals procedure. We all know that this is a particularly significant aspect of the Bill in relation to NICE, because NICE has so many important recommendations to make. Some of those recommendations are controversial and some less so, but they can all have a massive impact on treatment, drugs and services. It is important, therefore, that we have a chance to discuss the issue.

Unfortunately, there are only two lines of explanatory notes, and they basically say what we already know from reading the Bill. That is a classic example of there being no detail in the Bill on areas vital to our decision making. It is all very well to say what we did and did not do, but the fact is that the Government were told that they were rushing the Bill and that many areas were not covered. This is another example of that happening.

The Bill refers to

“(a) the types of recommendations in relation to which an appeal may be brought,
(b) the persons who may bring an appeal,
(c) the grounds on which an appeal may be brought, and
(d) the persons by whom an appeal is to be heard.”

Those are significant areas. It would have been useful to have some information so that we could make a decision on the clause. I do not know how the Minister will respond and we will obviously wait for that.

We have already discussed how NICE is expanding its role in social care. An important point is made in paragraph E37 on page 119 of the impact assessment about the benefits of the policy justifying the costs:

“The total budget spent on social care, and which NICE’s guidance might be expected to influence, is £16 billion.”

That is a massive figure by anybody’s estimation. Yet the number of appeals that may take place in relation not just to this current responsibility but to social care may be more or less than under the current system. I just do not know. It would be useful to get some detail about what the process will involve.

There is no mention of the process by which an appeal is to be heard, only the persons by whom it is to be heard. We have no idea who that may be. We also have no idea what Monitor’s role or influence will be here. What will the national commissioning board’s role be here? There is an awful lot that we do not know. The impact of NICE’s recommendations is profound for many people yet we have no detail at all. We come back to the old phrase that regulations “may make provision” about appeals against the recommendations made by NICE. Will that be by affirmative resolution by the House? I do not know what the problem is. It is a reasonable question to ask about an important matter. Does the Minister have any time scale in mind for when the House will first get a chance to see the details here, and is there anything else he can tell us that will enable us to consider the clause?

Paul Burstow: The reason my face showed some surprise was that the hon. Gentleman’s argument seems to rest on a desire for detail. He is right that we should have as much detail as possible and that is what we have tried to provide throughout the passage of the Bill both in our responses to points made by hon. Members and in the letters that we have provided. I find it odd that he is so interested in detail when he refers to what happened in the past.

The detail that was set out in the direction that currently gives effect to the work of NICE on appeal arrangements runs to four lines. It says:

“The Secretary of State directs the Institute to make arrangements for holding appeals, on the application of persons aggrieved by recommendations made by the Institute under paragraph 2(9)(a), on the grounds that the Institute has failed to act fairly, has exceeded its powers or has formulated guidance which cannot reasonably be justified.”

That is what it currently says. The clause therefore contains more detail than the hon. Gentleman’s Government set out in their direction. The difference between a direction and the proposals in the Bill is that they are before a Committee of the House and can be amended and debated. A direction cannot.

On so many counts the Bill demonstrates a change of view between the previous Government and this Government. We believe first that we should put more detail in legislation and secondly that we should make it

[完]
more accountable to Parliament. Those are big differences which those who follow our proceedings might wish to take into account.

**Derek Twigg:** Will the Minister give way?

**Paul Burstow:** In a moment. I want to make sure that I have answered the hon. Gentleman’s questions. He has asked some questions and he should get some answers. He asked what procedure will be used in respect of regulations. It will be the negative procedure, and it will be in time for the implementation of the Bill in April 2012.

As for pace, we published a White Paper in July and a Command Paper in December, and the Bill was published in January. The Bill sets out in far greater detail how the different parts of the NHS will relate to one another before that. I hope that my colleagues will allow the clause to stand part of the Bill. As NICE takes forward its work, it will build on existing practices, and we see no particular reason for that to change. I am sure that the hon. Gentleman’s questions will be answered.

**Derek Twigg:** It is a bit rich for the Minister to suggest that these few lines in the Bill are somewhat better than what we produced. However, it is rather academic. The Government talk about making regulations, but that lack of detail is typical of the Bill, with regulations being made under the affirmative resolution procedure. The question is what those regulations will do. Again, I received hardly any answers to my questions. We accept that there has to be an appeals procedure, but we expected a little more detail about what the Government propose.

*Question put and agreed to.*

Clause 222 accordingly ordered to stand part of the Bill.

**Clause 223**

**Training**

*Amendment made: 604, in clause 223, page 193, line 24, after ‘provision’, insert ‘, or the facilitation of the provision.’—(Paul Burstow.)*

Clause 223, as amended, ordered to stand part of the Bill.

**Clause 224**

**Advisory services**

**Derek Twigg:** I beg to move amendment 671, in clause 224, page 193, line 34, leave out subsections (2), (3) and (4). The amendment seeks to ensure that NICE cannot impose blanket charges for advice currently offered free to users. The amendment is necessary because the clause provides that NICE can charge for advice on anything connected with health care, public health or social care. Although we understand that that is to be further defined in much-awaited regulations, it is not clear. We are concerned that the definition of health care in subsection (4) is broad and seems to relate to a wide range of conditions. We seek clarification from the Minister.

**Paul Burstow:** I can be very clear that the clause is not about enabling NICE to charge end users or drug companies for its main guidance, advice or information products such as technology appraisals. NICE does not charge for those, and there is no intention that it should. However, NICE can already charge for some services, subject to direction from Ministers. I believe that it is right and necessary that it should continue to do so in specific cases, subject to regulation.

The clause provides that regulations may permit NICE to provide advisory services in relation to health care, public health or social care to any body or organisation within or outside the United Kingdom. In its existing form, NICE offers two such advisory services that may come under the scope of the clause. They are the scientific advisory service and NICE International.

NICE officers a scientific advice service to companies with drugs or technologies in development who want to ensure that information requirements for health technology assessment are addressed through the research that the company undertakes as part of the drug development. That is an entirely optional service, which was introduced in response to demand from pharmaceutical companies. It is widely accepted that it is reasonable for NICE to charge those companies that decide to take advantage of the service. NICE’s advice may be useful to companies in meeting the needs of health technology assessment systems internationally, not just in this country.

Through NICE International, NICE in its existing form also shares its extensive experience of evidence-based decision making with foreign Governments and other bodies operating outside the UK. It has been active as far afield as Asia and south America. Again, NICE currently charges for such activity, as it is not right that such costs should be covered by the UK taxpayer.

7.15 pm

**Grahame M. Morris:** Will the Minister clarify a point that he raised in the debates on some of the earlier clauses? The Minister has said that European competition law will apply only to services, but what the Minister has just said clearly demonstrates that NICE’s sphere of operation is in the provision of services. So NICE could be subject to European competition law in the particular areas that the Minister has just identified.

**Paul Burstow:** That was a good try and a demonstration of how to weave a point that has nothing to do with this part of the Bill into this part of the Bill. I am afraid that, despite his use of a crowbar, the hon. Gentleman will not get me to go down that path and daily with him on competition yet again.

Subsections (2) and (3) make provision for NICE to charge for such work on the basis it sees fit, whether that be on a cost recovery or commercial basis. NICE does not directly charge end users for most of the services it provides, such as technology appraisals and quality standards. We have no intention that it should begin to do so, and regulations made under clause 224 would not in any event be able to make provision for
[Paul Burstow]

charging on functions that NICE is given under other clauses, including clause 221.

Any provision for NICE to charge will be set out in regulations, which, before the hon. Member for Halton asks, will be subject to the negative procedure. That is a more robust process than the current arrangements, which rely only on ministerial directions. Ministerial directions do not even require the signature of a Minister, let alone any form of parliamentary scrutiny.

I do not understand why Opposition Members are so keen to remove subsection (4), because it merely gives a definition of “health care”. Elsewhere in this part there are definitions of “social care” and “public health”. A definition of “health care” is needed to give meaning to the provisions in this clause. I note that the amendment proposes no alternative definition, so I confess to being puzzled by its intention.

I believe that NICE, as re-established, should be able to continue to provide advice of the kind I have set out. There is no justification for the Department of Health or the NHS commissioning board meeting the cost of advice provided by NICE to third parties, so to continue with such work NICE needs to be able to charge for it.

Grahame M. Morris: The amendment would address a potential conflict of interest. If NICE was privately advising drug manufacturing companies and separately making recommendations on their products, such as whether purchasing them was in the public interest, surely that would be a clear conflict of interest. Why do it? Why should the Department not meet the cost?

Paul Burstow: Let me deal first with the conflict of interest allegation. There is no conflict of interest. The service does not offer guidance on securing a positive recommendation. It ensures that drug companies can consider the requirements of NICE’s appraisal process at every stage of drug development and may design clinical trials accordingly. It is comparable to the service offered by the Medicines and Healthcare Products Regulatory Agency to pharmaceutical companies on seeking a market authorisation. So the hon. Gentleman is trying to suggest something that is not the case, has never been the case and certainly will not be the case when the Bill is enacted.

To address the hon. Gentleman’s obsession with competition law, I should say that Monitor has a role only on services. Monitor does not have a role on drugs, so as I have said several times today, it does not apply in this situation.

Derek Twigg: I disagree with the Minister’s interpretation of the amendment, but one of the reasons for moving it was to get more information on the record, which will be examined both on Report and elsewhere later during the Bill's passage. We will examine in detail what the Minister has said, because, as my hon. Friend for Easington has said, there are some serious concerns about the implications. As I understand it, the Minister said that there will be no extension of the ability of NICE to charge.

Paul Burstow indicated assent.

Derek Twigg: The Minister is nodding, so I assume that is correct. The issue will be examined, so I beg to ask leave to withdraw the amendment.

Amendment, by leave, withdrawn.

Question proposed, That the clause stand part of the Bill.

Debbie Abrahams: I did not intervene early enough when the Minister was speaking.

The Chair: Order. The Member who moved the amendment has said he is not pursuing it, and has already withdrawn it. If the hon. Lady wants to oppose that, it will have to be put to a vote. Do you want that? The Member who moved the amendment withdrew it.

Debbie Abrahams: I wanted to speak to the clause.

The Chair: My apologies.

Debbie Abrahams: I wanted clarification about the cost of the charging aspect of NICE. Will it be cost-neutral or profit-making? Is a business plan associated with the provision? Can the Minister elaborate on whether costs only are being covered, or is the intention to have a profit-making commercial arm of NICE?

Paul Burstow: In the debate that we have just had on the amendment, I indicated that the regulations could cover whether the basis would be commercial or cost recovery. That is the case at the moment. I can supply the hon. Lady with the details of what currently happens and of what will happen as a result of the Bill. She will see that there is no difference, but she will also have some information about the level of income currently generated by NICE’s activities.

Question put and agreed to.

Clauses 224 accordingly ordered to stand part of the Bill.

Clauses 225 to 232 ordered to stand part of the Bill.

Clause 233

Consequential provision

Paul Burstow: I beg to move amendment 605, in clause 233, page 196, line 5, at end insert—

'(2) A statement of standards prepared and published by the Institute before commencement is to be treated on and after commencement as if it were a quality standard—

(a) prepared and published by NICE in accordance with section 218,

(b) endorsed under subsection (5) of that section, and

(c) in respect of which the transitional commissioner is the relevant commissioner for the purposes of that section.

(3) Subsections (4) to (6) apply to a case where before commencement—

(a) the Secretary of State has referred a matter to the Institute for the purpose of preparing and publishing a statement of standards, but

(b) the Institute has not published the statement.'
The referral by the Secretary of State to the Institute of the matter is to be treated on and after commencement as if it were a direction given to NICE by the transitional commissioner for the preparation of a quality standard in relation to that matter under section 218(1); and the transitional commissioner is to be treated as the relevant commissioner for the purposes of that section.

Anything done by the Institute before commencement in relation to the matter is to be treated on and after commencement as having been done by NICE in pursuance of the direction.

Consultation undertaken by the Institute before commencement in relation to the matter is to be treated on and after commencement as if it were consultation by NICE under section 218(3) in relation to the preparation of the quality standard.

A procedure established by the Institute before commencement for the preparation of statements of standards is to be treated on and after commencement as if it were a procedure established by NICE in accordance with section 218(7) for the preparation of quality standards.

For the purposes of this section “the transitional commissioner” is the Secretary of State; but the Secretary of State, after consulting the Board, may direct that in relation to a particular statement of standards or matter the transitional commissioner is—

(a) the Board, or
(b) both the Secretary of State and the Board.

In this section—

“commencement” means the commencement of section 218;

“the Institute” means the Special Health Authority known as the National Institute for Health and Clinical Excellence;

“statement of standards” means a document containing advice to the Secretary of State in relation to the quality of the provision of health care prepared and published by the Institute pursuant to the directions given to the Institute by the Secretary of State on 27 July 2009.

Briefly, the amendment means that any quality standard that is published or in development prior to the commencement of the new section on quality standards would have an equivalent status to any quality standard that is prepared or published thereafter.

Amendment 605 agreed to.

Clause 233, as amended, ordered to stand part of the Bill.

Schedule 16

PART 8: CONSEQUENTIAL AMENDMENTS

Amendment made: 606, in schedule 16, page 331, line 7, at end insert—

‘National Assembly for Wales (Disqualification) Order 2010 (S.I. 2010/2969)

In Part 1 of the Schedule to the National Assembly for Wales (Disqualification) Order 2010 (bodies of which the members are disqualified), at the appropriate place insert—“National Institute for Health and Care Excellence.”. . .—(Paul Burstow.)

Schedule 16, as amended, agreed to.

Ordered, That further consideration be now adjourned.

—(Stephen Crabb.)

7.25 pm

Adjourned till Thursday 31 March at Nine o’clock.