RESEARCH PAPER 99/39
8 APRIL 1999

The *Health Bill* [HL]

Bill 77 of 1998-99

Three White Papers on the NHS were published in December 1997 and January 1998: *The New NHS* (England), *Designed to care* (Scotland) and *NHS Wales: putting patients first*. All three are discussed in Research Paper 98/15.

The *Health Bill* [HL] seeks to implement those aspects of the White Papers which require legislation, in particular the abolition of GP fundholding, the establishment of Primary Care Trusts, the creation of a Commission for Health Improvement and improvements in the way the NHS and local authorities are able to work together. The Bill also makes provision for a number of other Government policies relating to the health service: new measures for dealing with fraud, reform of the way in which prices and profits on medicines are controlled, and provision for the legislation governing the regulation of health professionals to be amended in future by statutory instruments. This Paper discusses the main issues raised by the Bill, together with other aspects of the White Papers, in particular the development of Primary Care Groups and the creation of the National Institute for Clinical Excellence.

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Summary of main points

In December 1997 and January 1998, the Government published three White Papers on the NHS: *The new NHS: modern dependable* for England, *Designed to care for Scotland* and *NHS Wales: putting the patient first.* These set out the Government's vision on how the "internal market" in the NHS, which had been created by the *National Health Service and Community Care Act 1990*, should be replaced. The White Papers are discussed in more detail in Research Paper 98/15, but the main points are outlined below.

GP fundholding will be abolished, to be replaced by groups of GPs and other health professionals working together in Primary Care Groups (PCGs). These groups will be subcommittees of Health Authorities and will be able to operate either at level 1, where their main role will be to advise the Health Authority, or level 2 where they will have a devolved budget and be responsible for commissioning secondary (ie hospital and community) services from their local NHS trusts. The Health Authority, however, will remain accountable for how the budget is spent. 481 PCGs "went live" in England on 1 April 1999.

In time, these PCGs may evolve into Primary Care Trusts (PCTs), which will be freestanding bodies like NHS trusts, with responsibility for their own budgets and staff. Level 3 PCTs will have a similar remit to level 2 PCGs except for their independent status: they will be responsible for providing GP services, commissioning secondary services and handling their own budgets. Level 4 PCTs, on the other hand, (which may come about as a result of mergers with local NHS trusts providing community services) will be able not only to commission but also to provide secondary services. A level 4 PCT, therefore, might be responsible for providing district nursing services or health visiting services to all the patients within its area, rather than commissioning such services from a separate body. The aim is to bring GP and community services closer together, to create a more "seamless" service for the patient.

Local Health Groups in Wales will have a similar remit to PCGs in England, but will remain subcommittees of the Health Authority, rather than developing into freestanding bodies. The position in Scotland is different again. GPs will work together in Local Health Care Co-operatives, within the overall umbrella of a Primary Care Trust. Scottish PCTs will not be involved in commissioning secondary services (this responsibility will remain with the Health Board), but they will have more wide-ranging powers than in England in connection with the other "family health services", that is dentistry services, pharmaceutical services and optical services.

The *Health Bill* [HL] will formally abolish GP fundholding, and create a new statutory framework for PCTs in England and Wales. PCTs in Scotland have already been set up under existing legislation, but their powers will be extended by the Bill.

Health Authorities have been given a more strategic role by the White Papers, as much of the day-to-day commissioning decisions will be taken over by PCGs and LHGs. They have been

required to develop "health improvement programmes", outlining both how local health services and the health of the local population could be improved. While Health Authorities have been working on these programmes for some time, the *Health Bill* will give them statutory force. One of the aims of the concept of "health improvement programmes" is to involve organisations outside the NHS in working to improve health. The *Health Bill* will impose on NHS bodies and on local authorities a duty to work co-operatively with each other, and also makes it easier for them to operate joint budgets or delegate functions to each other.

Quality issues formed an important part of the White Papers, with the creation of the National Institute of Clinical Excellence (NICE) and the Commission for Health Improvement in England and Wales. NICE has now been launched, and this Paper includes a summary of how it will appraise new drugs and methods of treatment in order to recommend how these new "interventions" should be used in the NHS. The Commission for Health Improvement, which will carry out a rolling programme of inspections of NHS trusts and PCTs, will be established when the Bill is enacted. Other initiatives to improve the quality of NHS care include "clinical governance" which requires all NHS bodies to implement quality assurance systems. NHS trusts and PCTs will have a statutory "duty of quality" with the aim of ensuring that issues of quality play as large a part in boardroom discussions as financial issues.

The Bill also includes some major provisions which were not part of the White Papers. Following concerns that the current need to use primary legislation to amend the regulatory machinery of the healthcare professions was holding up improvements, the Government has proposed that it should take "Henry VIII" powers to amend the regulatory statutes by statutory instrument. Considerable opposition was expressed as the Bill went through the House of Lords, and as a result, a number of extra safeguards have been built in to reassure the professions that the principle of self-regulation will remain.

Finally, the Government has used the opportunity provided by the *Health Bill* to reform the way in which prices and profits on medicines are controlled when supplied to the NHS. The Bill provides for measures to ensure compliance with a voluntary, negotiated pharmaceutical price regulation scheme, and also creates powers to control the maximum price charged for any health service medicine, and to make a statutory scheme to limit prices and profits of manufacturers or suppliers of health service medicines.

CONTENTS

I Introduction

The Government's plans for reforming the NHS and dismantling the "internal market" created by the *National Health Service and Community Care Act 1990* were set out in a series of White Papers covering England, Scotland and Wales in December 1997 and January 1998.[1] The proposals contained in these Papers were discussed in Library Research Paper 98/15, *The NHS White Papers.* This Paper will concentrate on those aspects of the White Papers which require legislation and hence are covered by the *Health Bill* [HL].[2] Reference will also be made to aspects of the White Papers which do not require legislation where major developments have taken place since the publication of Research Paper 98/15.

While the three White Papers differed significantly in some respects, some features were common to all: the creation of a new administrative and financial structure to replace the "internal market" of purchasers and providers; the subsequent abolition of GP fundholding; closer working between different parts of the NHS and between the NHS and local authorities; and the strong emphasis on measures to improve the quality of healthcare provided by the NHS. A separate, if related, issue, that of the regulation of the healthcare professions, has generated considerable comment since the publication of the Papers and forms a significant part of the Bill. Other issues covered by the Bill include financing arrangements for NHS trusts, reform of the way in which prices and profits on medicines are controlled, and the treatment of fraud. Below, the background to each of these issues is discussed in turn, followed by a summary of the Bill's provisions and the responses from interested parties.

II NHS structures

A. Primary care groups

The English White Paper proposed the abolition of the "internal market" in the NHS (in which Health Authorities and GP fundholders acted as "purchasers" and NHS trusts as "providers") by creating "Primary Care Groups" made up of both local GPs and other health professionals such as practice or community nurses. Initially these Primary Care Groups, or PCGs, could act simply as advisory bodies to the Health Authority, which would retain responsibility for agreeing contracts with NHS trusts. In time, however, PCGs would be expected to move on through a series of stages, firstly becoming "level 2" PCGs, taking over budgetary responsibility from the Health Authority for commissioning hospital and community services (although the Health Authority would remain legally responsible for the budget), and then becoming a free-standing "Primary Care Trust" or PCT. A "level 3" PCT would have similar responsibilities to a level 2 PCG, but would be

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1 Cm 3807, Cm 3811 & Cm 3841 respectively

2 Bill 77 1998-99

legally responsible for its budget, while a "level 4" PCT would not only take on responsibility for providing general medical services and commissioning secondary services but would also take over the *provision* of some community services such as district nursing.

Primary legislation is needed for abolishing the fundholding scheme as a whole (although it has effectively been reduced to a "rump" scheme from 1 April 1999 through secondary legislation[3]) and for creating a legal framework for Primary Care Trusts. The development of PCGs, however, has not required legislation, as legally they count as committees of Health Authorities. PCGs formally came into being on 1 April 1999, after operating for some months as "shadow" organisations.

Since the White Paper, a series of circulars has been issued by the NHS Executive giving much more detail on the development of primary care groups: *Implementing "The new NHS" and "Our healthier nation"*[4] was issued on 25 February 1998, *Establishing primary care groups*[5] on 9 April 1998, *Developing primary care groups*[6] on 13 August 1998, *Guidance on Health Authority and primary care group allocations*[7] on 2 October 1998 *PCG remuneration*[8] on 28 October 1998, *Primary care groups: delivering the agenda*[9] on 7 December 1998, *Governing arrangements for primary care groups*[10] on 8 December 1998 and *NHS management costs*[11] on 19 February 1999. Below are listed some of the main points:

- Groups should be established round a "natural geographical community" of around 100,000 population, taking account of social services structures. Neither Health Authorities, nor groups of like-minded GPs, should try to impose a unilateral decision; all stake-holders (including Local Medical Committees, other health professionals, local NHS trusts and the public) should be properly involved. 481 Primary Care Groups have now been established in England, due to "go live" on 1 April 1999.[12]

- GP fundholders could apply for a fast-track change of status, from individual fundholding status to GP commissioning status, before 30 June 1998, if they wished to free up time and resources to concentrate on PCG involvement.

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3 The *National Health Service (Fund-Holding Practices) Amendment Regulations*, SI 1999/261 & the *National Health Service (Fund-Holding Practices) (Scotland) Amendment Regulations*, SI 1999/365
4 Dept of Health circular HSC 1998/21
5 Dept of Health circular HSC 1998/65
6 Dept of Health circular HSC 1998/139
7 Dept of Health circular HSC 1998/171
8 Dept of Health circular HSC 1998/190
9 Dept of Health circular HSC 1998/228
10 Dept of Health circular HSC 1998/230
11 Dept of Health circular HSC 1999/41
12 HC Deb 2 February 1999 c 709

- From 1999/2000, Health Authorities and PCGs will be allocated a single management cost "envelope", averaging around £3 per head of population in addition to current HA management costs. HAs and PCGs will have to agree how this will be divided between them. While reductions in management costs in 1997/98 and 1998/99 have saved an estimated £240 million, the Government has promised that there will be no targets for further net reductions in Health Authority management costs over the next three years.

- On the question of the "governance" of PCGs, each board should have 4-7 GPs (elected by local GPs), 1-2 community or practice nurses (either elected by local nurses or appointed by the Health Authority), 1 social service officer nominee (nominated by local Social Services Authority members), 1 lay member (nominated by the Health Authority), 1 Health Authority non-executive member and 1 primary care group chief officer (as ex-officio member).

- Dentists, optometrists and pharmacists have not been given a formal role, such as a compulsory member of the PCG board; however, they should be consulted both on the health needs of the local population generally, and on the potential impact of any changes.

- The board of a PCG will be accountable, as a committee of the Health Authority, to the chief executive of the Health Authority, with the chief officer of the primary care group being the formal "responsible officer" for the delegated budget. The extent to which the Health Authority devolves its budget and responsibility will be a matter for local agreement between groups and their responsible Health Authority.

- Chairs of PCGs will receive allowances of between £11,445 and £15,125 per year, depending on the size of the group and whether the group has "level one" (advisory) or level 2 (delegated budget holder) status. Board members will receive £2,700 per year if their PCG is at level 1 or £4,000 if it is at level 2, recognising that members of level 2 boards will have financial responsibilities in a way that members of level 1 boards do not.

- As PCGs prepare for "going live" in April 1999, it is emphasised that PCGs should be free to decide how much responsibility they will initially take on. Health Authorities should facilitate this process through, for example, providing specialist financial advice and human resources input. Health Authorities are also required to be "robust" in managing priorities during the transitional phase by, for example, ensuring PCGs have sound financial frameworks in place and "agreeing shared approaches" with PCGs to ensure that national priorities and targets (such as waiting list targets) are met.

- PCG functions from April 1999 will include a responsibility to improve the health of their communities, develop primary and community health services in their area, improving both the quality of those services and the integration of services, and to

advise on, or take on the commissioning of, secondary services for patients within their area.

- The importance of education and training, and of implementing "clinical governance" to ensure that the quality of care is audited and improved, is particularly emphasised.

- PCGs are required to develop "primary care investment plans" with costed plans covering three year investment cycles; the first such plans were expected in draft form in January 1999.

- On the sensitive issue of how GP fundholder savings should be used once former fundholders are members of PCGs, it is proposed that ideally former fundholders and the PCG as a whole will come to an agreement over how savings should be spent and incorporate this into the investment plan. Where this is not possible, former fundholding practices will be guaranteed 25% of the savings they have made.

- Financial allocations for 1999/2000 have been made by the Department of Health to Health Authorities based on "recurrent baselines" (ie previous years' funding) and "weighted capitation targets" (ie the Authority's "fair share" based on the national resource allocation formula). This mirrors the policy over the last decade, whereby Health Authorities are gradually brought closer to their target allocations without involving the major redistributions of funding which an instant shift from historical funding to formula funding would have caused. The major difference this year is that the funding for hospital and community services, prescribing and GP infrastructure will form one unified budget, rather than three separate funding streams. The same allocation process should be applied by HAs to PCGs, so that both "historical activity" and "fair shares" based on the national formula will determine budgets. Following concerns from GPs, the Government has also guaranteed that the GP infrastructure funding will be ringfenced within the unified budget to guarantee a "floor" beneath which funding for GP premises, computers and staff cannot be reduced.

- Finally, guidance was issued in February 1999 on the governance of primary care *trusts*.[13] PCTs will have a board with a lay majority, mirroring current arrangements for NHS trust board, but will also have a trust "executive" with a majority of clinical members, described as the "engine room" of the PCT. At level 3, the executive will be similar to PCG boards with up to 7 GP members, 2 nurses and a professional with public health or health promotion knowledge as well as the chief executive, finance director and social services officer. At level 4, where the PCT will take on the role of providing some secondary services, as well as commissioning them, the clinical membership of the executive will be drawn from a broader base: it is envisaged that up to 10 clinicians would be involved with GP involvement "balanced" by nurses and

[13] Letter from Health Minister John Denham, 19 February 1999

"other community and public health professionals" such as members of the professions allied to medicine.

- The February letter from John Denham also gave indications as to how PCGs will evolve into PCTs, with Health Authorities, PCGs and community NHS trusts all being able to trigger the process of consultation. It is emphasised that progression to trust status will be "locally-driven" and that it is the Government "assumption" that the support of the relevant PCG would be required.

Responses from the healthcare professions and others to the way PCGs and PCTs are evolving is discussed below in Part VIII.

B. Wales

The Welsh White Paper proposed the creation of "local health groups" (LHGs), which are broadly the equivalent of Primary Care Groups in England. However, there is no proposal that LHGs should ultimately gain free-standing status in the same way that Primary Care Groups are expected to develop into Primary Care Trusts. Instead they will remain committees of the Welsh Health Authorities, influencing Health Authorities' commissioning of secondary services and later taking on some direct commissioning decisions, but without taking over formal legal or financial responsibility. There will be a total of 22 LHGs in Wales, covering areas roughly co-terminous with local authorities.[14]

Guidance on establishing LHGs in Wales was issued by the Welsh Office in October 1998.[15] This emphasised that LHGs must be "vehicles for decision-making, not just maintaining the status quo" and that they would have major contributions to make in three main areas: the development of Health Improvement Programmes, developing clinical governance in primary healthcare and "informing" the commissioning of hospital and community services. All LHGs will start at level one (advisory) status, but from April 2000 will be able to develop to level 2 status and take on direct responsibility for commissioning agreed local services.

Management boards will be in the form of an "executive committee" of a chair (usually a GP), another GP, one representative each from the Health Authority and local authority and the "responsible officer" (an official employed by the Health Authority specifically to work in the LHG). In addition to this executive committee, the Board will include up to a further four GPs, a pharmacist, a dentist and an optometrist working in the community, two representatives of nursing, midwifery or health visiting, a second HA representative, a representative of local voluntary organisation, a lay representative and a second local authority representative.

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14 HC Deb 9 February 1999 c 162W

15 Welsh Office, *Establishing local health groups,* October 1998

Health Authorities will receive "unified budget" allocations from the Welsh Office (in future the Welsh Assembly) in the same way as in England, and the same formula will be used for allocations to LHGs as to Health Authorities. Initially, the allocations made to LHGs will mainly cover prescribing, GP infrastructure (the latter ring-fenced in the same way as England) and a primary care development fund for promoting service innovation (also ring-fenced). As LHGs develop to level 2 status, however, the allocations will include funds for commissioning services. As LHGs will remain technically sub-committees of Health Authorities, even at level 2, the formal "accountable officer", responsible for proper accounting, will be the HA chief executive. However, annual performance agreements will be agreed between HAs and LHGs to ensure that LHGs remain accountable.

C. Scotland

The position in Scotland is different again. From April 1999, voluntary networks of GPs in the form of "local health care co-operatives" will come together with other primary and community services such as community hospitals and mental health services, to form "primary care trusts" (PCTs). However, these trusts will not have a role in commissioning hospital services from "acute" NHS trusts; this will remain the responsibility of the Health Board. As in England and Scotland, Health Boards will receive unified funding allocations based on a weighted capitation formula, bringing GP prescribing costs, GP infrastructure and funding for hospital and community services together into one income stream. PCTs, similarly, will receive weighted unified budgets covering GP prescribing and community services. Within PCTs, local health care co-operatives may choose to hold their own share of the budget if they wish, but cash will be administered by the trust which will retain formal accountability for the budget. Another feature unique to Scotland is the creation of "joint investment funds" (JIFs), to be established by each Board to support changes in the way care is delivered (for example where services are shifting from hospitals to more community-based settings). PCTs will be allocated their share of the JIF, which may be delegated further to health care co-operatives if the co-operative wishes.

Considerable concern was expressed in the health press during 1998 and early 1999 that no detailed guidance, like that issued in England, was provided in Scotland as health care co-operatives were developing.[16] However, in February a circular was finally issued although it emphasised that the proposals had been clearly outlined in the White Paper and that there is a great deal of flexibility for co-operatives to develop in accordance with local needs.[17] The circular included the following guidance:

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16 eg "GPs will boycott reforms unless confusion ends, GP leader warns", *BMA News Review*, 16 January 1999 p 13

17 Scottish Office circular MEL 1999/13, 8 February 1999

- there is no "single model" of how local health care co-operatives (LHCCs) should develop. This will depend on geography, local patterns of service and the extent to which GPs and other primary care clinicians are already involved in collaborative working;
- the precise scope and functions of LHCCs will depend on the wishes of the member practices and the PCT;
- there is no blue-print for the management of LHCCs, but it is important that all those affected should feel involved and engaged.
- Membership of a LHCC will not affect the independent contractor status of GPs. Practice staff and nurses will continue to be employed by the practice, while community nurses and professions allied to medicine (such as physiotherapists or chiropodists) will be employed by the PCT;
- Where new staff are appointed to support the work of LHCCs, their appointment must be agreed both by the LHCC and the PCT. They will be accountable on a day to day basis to the "clinical leaders" of the LHCC;
- GPs who are "actively involved" in the management of LHCCs should be remunerated at a rate of £77 per session, the rate currently paid to GPs acting as clinical assessors for the NHS complaints procedure;
- the resources to be allocated from PCTs to LHCCs should be agreed between them, depending on the range of functions being carried out by the LHCC and the area's "fair share" on the basis of need.

III Quality of care

The White Papers set out four measures to improve the quality of clinical care:

- The English and Welsh papers promised a "National Institute for Clinical Excellence" (NICE) to draw together information on the effectiveness of both existing and new medical interventions (including, for example, both new drugs and new surgical methods), while Scotland is developing a "Health Technology Assessment Centre" to assess new treatments and provide advice on their use.

- A second new body, the Commission for Health Improvement (again covering England and Wales), would police the quality of care in individual NHS trusts while the Clinical Standards Board would perform a similar function for Scotland.

- All NHS trusts are to be given a new statutory "duty of quality", with the aim of forcing quality issues on to boardroom agendas by putting the same emphasis on quality as on the financial duties already imposed on trusts by the *National Health Service and Community Care Act 1990*. This will be part of a general programme of "clinical governance" under which all NHS bodies are required to put quality assurance systems in place.

- Finally, a programme of "National Service Frameworks", specifying the kind and level of services which patients are entitled to expect are promised in England and Wales, with publication of the first two frameworks, on mental health and coronary heart disease, due in spring 1999.

Since the publication of the White Papers, legislation has also been promised to make it easier to amend the statutes regulating the healthcare professions, against a background of concern that current provisions do not provide adequate protection to the public.

A. National Institute for Clinical Excellence

The National Institute for Clinical Excellence, or NICE, was first promised in the White Paper *The new NHS: modern, dependable*[18] in December 1997. Since then, two further consultation papers, giving much more detail of how the Government envisages NICE working, have been produced: *A first class service: quality in the new NHS* in July 1998 and *Faster access to modern treatment: how NICE appraisal will work* in February 1999. The consultation period on the latter document finished on 19 March 1999 and the Institute was formally "launched" on 31 March.[19]

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18 Cm 3807, December 1997

19 Dept of Health press notice 99/193, 31 March 1999

The general aim of NICE is to "promote clinical and cost-effectiveness through guidance and audit"[20] and the Secretary of State for Health has laid particular emphasis on the intention that NICE's work should "help end the unacceptable geographical variations in care that have grown up in recent years".[21] NICE's work will be part of a general drive to raise clinical standards and ensure that they are evenly applied across the country. The Department of Health identifies six stages of this process:

- identifying new health interventions and examining current practice to identify unjustifiable variations in existing procedures;
- undertaking research to assess both the clinical effectiveness and the cost effectiveness of health interventions;
- appraising this research and producing guidance for the NHS;
- disseminating this guidance;
- implementing it at local level;
- monitoring its impact and keeping it under review.[22]

NICE will be responsible for the third and fourth stages of this process: creating and implementing guidance on the effectiveness of health interventions. It will also be required to participate in the sixth stage: monitoring and reviewing the effect of the guidance.

The functions NICE will carry out are not entirely new: a number of bodies both inside and outside the NHS currently review research and issue recommendations on best treatment for particular conditions (for example the *Effective Health Care* bulletins issued by the NHS Centre for Reviews and Dissemination at the University of York, which are funded by the NHS). However, one of the reasons why the Government believes that NICE is necessary is that there is no single body providing advice for health professionals: there may be a plethora of guidelines (not necessarily consistent) on one intervention and nothing on others. The aims of NICE are threefold: to bring together all this work in the NHS so that duplication is avoided and there is one clear focal point for health professionals to seek advice; to give the guidance greater authority; and to bring the issue of *cost*-effectiveness into the equation. This last point is particularly emphasised in the Regulatory Impact Assessment issued in February 1999.[23] This specifically refers to the "Secretary of State's responsibility under the NHS Acts to seek to promote the greatest health benefit within available resources" and to "the risks that patients will suffer harm either because of use of inappropriate treatments or because NHS resources have been diverted into ineffective treatments".

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[20] Dept of Health, *A first class service*, 1 July 1998, p 13
[21] Dept of Health press notice 99/66, 3 February 1999
[22] Dept of Health, *A first class service*, 1 July 1998, p 15
[23] Dept of Health, *Appraisal of healthcare interventions by the National Institute of Clinical Excellence: regulatory impact and compliance cost assessment*, 1999

NICE will also include under its umbrella the four "National Confidential Enquiries" (into perioperative deaths, stillbirths and deaths in infancy, maternal deaths and suicide and homicide by people with mental illness) which currently review clinical performance. At present participation in these enquiries is voluntary, but it is proposed that in future all hospitals will be compelled to participate. Recommendations resulting from the Enquiries' consideration of clinical performance will be fed into NICE's guidelines.

1. The appraisal process

The second consultation paper, *Faster access to modern treatment: how NICE appraisal will work,* sets out the Department of Health's proposals on how NICE should identify appropriate interventions and appraise them, together with an idea of the possible timescale.

- The Centre for Horizon Scanning of the University of Birmingham and the National Prescribing Centre will have a permanent remit to "scan the horizon" for new developments in medicine and produce "vignettes" describing new developments, including their area of application, their possible benefits and their likely impact on NHS resources.

- The Department of Health, in association with its Standing Advisory Committees and other expert advice, will use these vignettes to create a standing short-list of possible interventions for appraisal. When considering which interventions to appraise, the Department will consult with the companies sponsoring the research, the Association of the British Pharmaceutical Industry, the NHS and with patient and professional groups. Interventions are likely to be considered between 2 and 6 years before their likely launch date, when they are close to final clinical trials. Where there is no sponsoring company, the Department will consider whether any research should be commissioned through the NHS R&D programme.

- Once an intervention has been provisionally selected for appraisal, this decision will be reviewed on an annual basis, with a final decision taken within around 12 months of the expected launch date. During this period, the sponsoring company will liaise with the NICE secretariat over the form of clinical trials. It is envisaged that initially between 20 and 30 new interventions will be selected for appraisal each year.

- NICE will then be formally requested to carry out an appraisal. The sponsoring company will be required to submit evidence, generally no later than 4 months before the expected launch date, and patient groups will be invited to make comments by the same deadline. If there is no sponsoring company, NICE will request the Department of Health to commission an assessment, for example from university-based research groups.

- This evidence will be appraised by a multi-professional group within NICE, based on the papers submitted by the sponsoring company (or external research where no

sponsoring company) and patient groups. Factors which will guide the appraisal process include the robustness of the company's assessment of the effectiveness of the new intervention; the cost-effectiveness of the new intervention, compared with other possible uses of NHS resources; whether there are particular subgroups of patients for whom the intervention would be particularly effective; whether use of the intervention should be subject to conditions (for example for prescription by specialists only rather than by GPs); and whether further research is desirable.

- NICE's draft recommendations are likely to be in one of three forms: (A) recommended as clinically cost-effective for use in the NHS (possibly only for specific patient sub-groups); (B) recommended only for use in clinical trials in order to answer further questions on cost-effectiveness or targeting; or (C) not recommended for routine use. Sponsoring companies and patient groups will have the opportunity to comment on the draft recommendations before they are issued in final form.

- Where new information on costs or benefits becomes available, the sponsoring company will be able to request a re-appraisal. The NICE secretariat will also be able to initiate a reappraisal if it decides that this is necessary.

- The final guidance will be disseminated directly from NICE to the NHS. Only occasionally will additional management guidance be issued by the Department of Health or the Welsh Office (Welsh Assembly).

- Over a period of years, the Department of Health will also initiate a "catch-up programme" of appraisals of the most significant interventions currently in use in the NHS. In particular, interventions may be selected for appraisal if there are wide variations in their use within the NHS at present. When responding to a debate on multiple sclerosis in February 1999, for example, the Health Minister, John Hutton, stated that the Department was "minded to refer beta-interferon to the NICE as one of its priority tasks,"[24] reflecting the considerable degree of public concern there has been over the variable availability of this relatively new and expensive MS drug.

- As well as issuing around 20-30 sets of recommendations on specific interventions, NICE will also draw together existing best practice on treatment for particular conditions in the form of "clinical guidelines". According to the press notice launching *Faster access to modern treatment*, it is expected that NICE will produce between 10 and 15 sets of guidelines each year.[25]

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[24] HC Deb 15 February 1999 c 710

[25] Dept of Health press notice 99/66, 3 February 1999

2. The structure of NICE

The *National Institute for Clinical Excellence (Establishment and Constitution) Order 1999*,[26] which was laid on 3 February 1999 and came into force on 26 February 1999, establishes NICE as a "Special Health Authority", under section 11 of the *National Health Service Act 1977*. As such, NICE will have a duty to comply with any Directions made by the Secretary of State,[27] and Regulation 3 states that "the Institute shall perform such functions in connection with the promotion of clinical excellence in the health service as the Secretary of State may direct". The Establishment Order also spells out the membership of NICE: it will have a chair, seven non-executive members and four executive members (Regulation 4). These last four will include the Chief Officer, the Chief Finance Officer and the Clinical Director. Further details as to the membership and procedures of NICE are found in the *National Institute for Clinical Excellence Regulations 1999*,[28] which were laid on the 5 February 1999 and also came into force on 26 February. The chair and non-executive members will be appointed by the Secretary of State, and in fact the chair-designate was announced on 13 November 1998, as Sir Michael Rawlins, then Chair of the Committee on Safety of Medicines.[29]

Regulation 9 creates two committees within NICE: a Partners' Council to advise NICE and an appraisal committee to carry out the day to day work of appraising new interventions. NICE is also empowered to establish further committees. The Regulations require that the chair of NICE also be the chair of the Partners' Council and that the Secretary of State approve appointments to the Council, but make no other specifications as to membership of either the Council or the appraisal committee. However, *A first-class service* suggests that the Partners' Council "will be formed of representatives of all the key stakeholder groups (patients and carers, the health professions - including the professional Royal Colleges, academics, NHS service interests and the pharmaceutical and other health care industries). The Council, which will be appointed by the Secretary of State for Health, will review NICE's annual progress report and contribute to the development of the work programme commissioned by the Department of Health".[30]

Similarly, *Faster access to modern treatment* gives further details on the possible composition of the appraisal committee. It is suggested that the committee should consist of a chair who is a respected clinician, 2 medical practitioners, a nursing generalist, a public health physician, a clinician with expertise in medical statistics or epidemiology, a health economist, a health policy academic, 3 NHS managers, 2 representatives of patient or carer groups, (for pharmaceutical interventions only) a clinical pharmacologist and a clinical pharmacist and (for surgical and medical device interventions only) a surgeon and

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26 SI 1999/220

27 section 13 of the *National Health Service Act 1977*

28 SI 1999/260

29 Dept of Health press notice 98/513, 13 November 1998

30 Dept of Health, *A first class service*, July 1998, p 23, para 2.29

a medical physicist. In addition, the committee would have access to a wide range of subject specialists for expert advice on the intervention under discussion.[31]

3. Comments on NICE

On the whole, organisations representing patients and healthcare professions have welcomed the idea of a National Institute of Clinical Excellence, while raising issues which would particularly affect their members. The British Medical Association welcomed the principle of a single source of advice, but expressed a number of concerns: that NICE was to be funded out of existing resources'; that authoritative guidance might limit doctors' clinical freedom; that NICE might not be genuinely independent of the Department of Health; and the possible implications for the rationing of NHS resources.[32] The College of Health, which represents patients' interests, was enthusiastic about the involvement of patients and carers in the Partners' Council, but was concerned that patients should also have an input at the "horizon-scanning" stage and emphasised the importance of the publication of a "patient version" of all NICE guidelines.[33] Comments from the Institute of Health Services Management, an organisation representing individual NHS managers, included concerns that NICE should produce guidelines on the organisation and delivery of care, as well as on clinical matters; the proposal that NICE should cover a broader range of public health issues, such as screening (currently excluded from NICE's remit, on the basis that it is already effectively covered by the National Screening Committee); and the importance in involving managers, as well as clinical professionals, as they will have a key role in disseminating and monitoring guidance.[34]

The Association of the British Pharmaceutical Industry, however, has said that the "jury is still out on NICE", and that the industry fears that unrealistic demands will be made upon it which will both delay and add cost to the process of launching new drugs. The possibility of making a realistic assessment of the cost-effectiveness of a new drug is also doubted, given that it may take a number of years before the true therapeutic use becomes apparent.[35]

Some of these concerns were discussed by the Health Select Committee on 4 February 1999 when they took evidence from Professor Rawlins and the Department of Health on NICE.[36] On the question of rationing, Professor Rawlins argued that the term "rationing" meant one person being limited to a fixed amount of whatever was being rationed, and that the NHS had never rationed in this way: "it has never had a coupon book where once you have spent your coupons on health care or the NHS has snipped them out of your

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31 Dept of Health, *Faster access to modern treatment*, February 1999, pp 15-16, paras 47- 8
32 response to *A first class service* by the British Medical Association
33 response to *A first class service* by the College of Health
34 response to *A first class service* by the Institute of Health Services Management
35 ABPI, *Hard rations: getting the right treatment for the NHS*, January 1999
36 Health Select Committee, *National Institute for Clinical Excellence*, HC 222-I 1998-99

ration book you have no further health care". However, he went on to say that NHS staff have always had to "prioritise" and that what NICE aimed to do was to ensure that prioritisation decisions were based both on scientific evidence and on cost-effectiveness to ensure the greatest degree of "health gain". He also emphasised that clinical guidelines could never cover all situations and that they would never substitute for individual professional judgement. On the issue of NICE's relationship with the Department of Health, he expressed a willingness to "bully" the Department if convinced that a particular new expensive drug should be made available, while recognising that the Department, not NICE, has the ultimate task of allocating the total amount of resources available to the NHS. In response to the sorts of concerns raised by the College of Health, he stated that he hoped to persuade the Secretary of State that about a quarter of the members of the Partners' Council should be representatives of patients or patient groups, and that he would hope to devise guidelines for patients and carers themselves, not just for health professionals.

B. The Scottish Health Technology Assessment Centre

The Scottish Office document, *A Scottish Health Technology Assessment Centre: a consultation document*, [37] defines "health technology" as "any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long term care. The term encompasses drugs, devices, clinical procedures and healthcare settings". It also identifies the same six stages of assessment as the Department of Health (see above p ?). The proposed role of the Scottish Health Technology Assessment Centre (SHTAC) therefore appears to be very similar to that of NICE, with SHTAC depending mainly on other organisations for "horizon scanning" but taking full responsibility for appraising the research evidence provided and disseminating recommendations. Emphasis is also given to the importance of engaging both professional and patient support for SHTAC's work and to liaising with NICE. At a strategic level, SHTAC's work will be co-ordinated by the Clinical Resources and Audit Group which is chaired by the Chief Medical Officer.

C. The Commission for Health Improvement

The proposed functions of the Commission for Health Improvement in England and Wales were also set out in the consultation document *A first class service: quality in the new NHS.* The Commission's core functions are listed as:

- provide national leadership to develop and disseminate clinical governance principles;
- independently scrutinise local clinical governance arrangements to support, promote and delivery high quality services, through a rolling programme of local reviews of service providers;

[37] Scottish Office, December 1998

- undertake a programme of service reviews to monitor national implementation of National Service Frameworks, and review progress locally on implementation of these Frameworks and NICE guidance;
- help the NHS identify and tackle serious or persistent clinical problems. The Commission will have the capacity for rapid investigation and intervention to help put these right;
- over time, increasingly take on responsibility for overseeing and assisting with external incident inquiries.[38]

The Government envisages that the Commission's "rolling programme" of reviews will lead to every NHS trust and Primary Care Trust being visited every 3-4 years, although where there are particular concerns about a trust, its review could be brought forward. The reviews will look both at "processes" such as complaints handling and "outcomes": the actual quality of services provided. Individual reviews will cover how National Service Frameworks and NICE guidance are being implemented locally, but the Commission will also carry out national sample surveys on how these are being implemented, in order to allow for a more systematic analysis. In taking on these national review functions, the Commission will replace the current Clinical Standards Advisory Group.

The review findings will be reported both to the trust concerned and to the appropriate Health Authority and Regional Office, with a summary being made public. The Commission itself will not have the power to impose sanctions, and it will generally be up to the Health Authority or the Regional Office to ensure that its recommendations are acted upon, through the usual performance management system. However, the Health Authority or Regional Office may involve the Commission in follow-up activity if they choose.

The Commission will also have a role in cases of "serious or persistent problems". The consultation document envisages that the first bodies to be involved when concerns are raised over standards or services in an NHS trust would be the local Health Authority or Regional Office. However, if the problem cannot be dealt with by these means, the Commission could be invited in, either by the Health Authority or by concerned PCGs or PCTs, to investigate and report. It is also envisaged that the Commission would increasingly take over responsibility for overseeing inquiries set up either by NHS organisations or the Secretary of State into serious service failures.

The Commission will be established as an independent statutory body, and the necessary provisions are found in the *Health Bill*. The chair and members will be appointed by the Secretary of State, with membership drawn from patients, the professions, the NHS and academia. A "Director of Health Improvement" will head the Commission and be responsible for its executive functions. According to the *Explanatory Notes* issued with

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[38] Dept of Health, *A first class service*, 1998, para 4.6

the Bill, it is expected that the Commission will develop a number of teams to take responsibility for its various functions, with a combination of NHS staff and patient expertise.

D. The Clinical Standards Board

The Scottish equivalent of the Commission for Health Improvement will be a "Clinical Standards Board", based on recommendations made in the Scottish Office's *Acute Services Review Report* earlier in 1998.[39] The Board will have three main functions:

- setting standards in the NHS in Scotland
- assessing performance against these standards,
- agreeing and implementing action to address identified shortcomings.

The Board will thus combine some of the functions of the Commission for Health Improvement with the creation of service standards in a way similar to the development of National Service Frameworks in England.

According to the *Acute Services Review*, the standards should relate to the "structure" and "process" of healthcare delivery, as well as its outcome, and be explicit, objective, measurable and evidence-based. It is emphasised that while standards will be set nationally and must be externally validated, it is also important for them to be accepted by the professionals concerned. The assessment of performance should have an external element, involve multi-disciplinary peer review, be repeated every 3-4 years, and should aim to disseminate good practice and encourage improvements, rather than being regarded in a punitive light. The Board will have the right to publish its conclusions and to make return visits to ensure that remedial action had been taken, but will not be directly involved in taking that action. The basis for the review will generally be the service provided (eg stroke services), but may also include the institutions involved as "components" of the whole service.

Clearly, the individual members of the Board will not directly take on these functions; rather they will be responsible for developing methodologies, appointing suitable groups to develop standards and assess services in particular fields, providing guidance on the selection and training of reviewers, providing guidance on publication, and generally co-ordinating the work of the groups. The infrastructure of the Board's work will be met centrally, but NHS trusts and Health Boards will be expected to bear the costs of their staff working on these groups, developing standards and taking part in review visits.

The *Clinical Standards Board for Scotland Order 1999* was laid on 5 March 1999 (coming into force on 1 April 1999), establishing the Board as a Special Health Authority

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[39] Scottish Office, *Acute Services Review Report*, 1998 & Scottish Office press notice 2485/98, 27 November 1998

under the *National Health Service (Scotland) Act 1978.*[40] It has been announced that a former president of the Royal College of Obstetricians and Gynaecologists, Sir Naten Patel, has been appointed as the board's first chair.[41]

E. Clinical governance

The Department of Health has defined clinical governance as "a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish".[42] More pithily, the Scottish health minister, Sam Galbraith, was quoted in the *Health Service Journal* as describing it as "corporate accountability for clinical performance".[43] The Department of Health issued guidance on 16 March 1999, setting out the main components of clinical governance, and these include:

- clear lines of responsibility and accountability for the quality of clinical care, with a senior clinician responsible for ensuing systems are in place and being monitored;
- a comprehensive programme of quality improvement activities including full participation in clinical audit programmes and the four National Confidential Enquiries, ensuring the recommendations of NICE and the National Service Frameworks are implemented, the encouragement of staff participation in well-designed research projects, and the encouragement of professional development;
- clear "risk management" policies, with a systematic approach to reducing clinical risks;
- procedures for identifying and remedying poor professional performance, such as an accessible complaints system, good "critical incident" reporting, and the encouragement of a culture where it is possible for staff to report concerns about colleagues' performance.[44]

In February 1999, the *Health Service Journal* surveyed a number of chief executives, medical directors and senior clinicians on their responses to clinical governance.[45] Most were very positive about the "concept", with some emphasising that it was not new, but rather "a term which has now been put to a number of excellent activities". Many felt that it would put considerable pressure on relationships between management and consultants unless sensitively handled because of fears of management interference. However, there appeared to be a general consensus that it would have a positive effect on standards. Delegates at a recent conference hosted by the National Association of Primary Care[46]

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40 SI 1999/726
41 "Patel chairs Scots standards board", *Health Service Journal*, 11 February 1999, p 2
42 Dept of Health, *A first class service: quality in the new NHS, June 1998*, p 33
43 "Carry that weight", *Heath Service Journal*, 18 February 1999, pp 22-27
44 Dept of Health circular HSC 99/65
45 "Carry that weight", *Heath Service Journal*, 18 February 1999, pp 22-27
46 *Primary Care Groups: making them happen*, 26 February 1999, QE II Conference Centre, London

were also generally positive about the possibilities for improving standards but raised possible stumbling blocks, many of which would be equally applicable to the hospital sector. Concerns included the issue of *who* sets the standards; whether approaches will be supportive or judgmental; whether clinicians will genuinely engage with the process or will just go through the motions; the time and resources need to implement the approach properly and the problem that in primary care systems tend to be fragmented, lacking the clear team structure generally found in hospitals.

Although some use of the term clinical governance (including the *Health Service Journal* article quoted above) includes the new statutory duty of quality to be created by clause 16 of the *Health Bill*, the Department of Health has made clear that the two are distinct. Hence although in the *Health Bill* the new duty of quality will only apply to *providers* of NHS service (ie NHS trusts and PCTs), the principles of clinical governance apply equally to Health Authorities and Primary Care Groups.

F. Regulation of healthcare professions

The Health Bill deals with the issue of the regulation of the healthcare professions, even though the White Papers made no direct references to possible changes. Recent much publicised cases in Bristol and Kent, however, where doctors have been found guilty of incompetent practice over a very long period of time,[47] have generated public concern over the apparent inability of current regulatory and disciplinary procedures to prevent such tragedies. Following the much publicised General Medical Council hearings, resulting in the "striking off" of two of the three heart surgeons involved in the Bristol case, the medical profession has accepted that there is a need for change in the regulation of the profession, while still energetically defending the principle of *self*-regulation.

After much discussion within the profession, the General Medical Council has now formally endorsed the concept of "re-validation", under which doctors' competence would be regularly checked, for example through peer review.[48] At present, doctors found to be incompetent can either be obliged to accept further training and support until they reach an acceptable standard or (if such training is impossible or rejected) be prevented from practising.[49] However, these measures are essentially reactive in nature: they will only be implemented after either patients or colleagues have highlighted a problem. The aim of the "re-validation" proposals is to introduce the concept of pro-active quality control, allowing problems to be identified and adequate help provided before patient care is put into jeopardy.

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47 the three doctors found guilty in June 1998 of serious professional misconduct after high levels of mortality in paediatric cardiac surgery at Bristol Royal Infirmary and the gynaecologist from Ashford found guilty of serious professional misconduct in September 1998 for his standards of care

48 GMC, *Report of the Revalidation Steering Group*, February 1999

49 the so-called "performance procedures" introduced through the *Medical (Professional Performance) Act 1995*

While the proposals from the GMC have been generally welcomed, it has remained a matter of concern that improvements to the regulatory structure have been over-delayed by the lack of parliamentary time. *The Medical (Professional Performance) Act 1995*, for example, which introduced procedures for dealing with doctors whose performance was unacceptably low, was introduced well after the existence of a general consensus that the changes were necessary. The same problem could easily arise in the future when trying to implement the new measures on revalidation as proposed by the GMC. Healthcare professions other than doctors have also been affected by the lack of parliamentary time. There have been a number of uncontroversial changes to the *Dentists Act 1984* agreed for some time, such as the regulation of dental auxiliaries and changes to the lay membership of the General Dental Council, which have yet to be implemented. Fundamental reworkings of the legislation governing the professions supplementary to medicine and nurses, midwives and health visitors, have also been proposed (see sections 1 & 2 below).

In autumn 1998, the Department of Health wrote to the regulatory bodies, suggesting that one way of overcoming this problem would be to empower the Secretary of State to act by Order. This would mean that changes could be made to the primary legislation regulating the professions through statutory instrument, with all the increase in speed but the decrease in parliamentary accountability that that implies. In the case of the professions allied to medicine, this power would explicitly include the power to repeal and replace the 1960 Act, thus enabling the promised reform of this Act (see below) to be realised.

During the *Health Bill*'s Committee stage in the Lords, Baroness Hayman justified the proposal as follows:

> First there is an enormous backlog of desirable changes to be made to the legislation governing professional self-regulation. The replacement of legislation for the professions allied to medicine will require a substantial order or a similar size to the present *Professions Supplementary to Medicine Act 1960*. The professions have been pressing for that for some time, as the noble Lord and the Committee are aware.
>
> We also want to replace the nurses, midwives and health visitors legislation and have recently published the review and the Government's response to it. Desirable changes for dentists, opticians and pharmacists are already well developed. There is also the challenge posed for us by professions which are not at present regulated by statute. The Government intend in time that the power can be used to introduce new regulatory schemes for such professional groups as psychologists or counsellors. A great number of professions linked to medicine are looking at ways of strengthening public protection through their systems of self-regulation.[50]

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[50] HL Deb 4 March 1999 cc 1802-3

Responses to this proposal are discussed in Part VIII below.

1. Review of the *Professions Supplementary to Medicine Act 1960*

Under the current terms of the *Professions Supplementary to Medicine Act 1960,* although unregistered practitioners would be committing an offence if they described themselves as "state registered" physiotherapists or chiropodists, there is nothing to prevent them from describing themselves simply as a "physiotherapist" or a "chiropodist" and treating private patients. Following concern expressed by professional bodies such as the Chartered Institute of Physiotherapy about the possibility of unqualified practitioners harming patients, Baroness Cumberlege, the then Parliamentary Under-Secretary of State for Health, announced on 6 February 1995 that a review of the Act would take place.[51] The review team's recommendations were published in July 1996, and these included:

> The creation of a new and stronger Council for the Health Professions (in place of the Council for the Professions Supplementary to Medicine) with an elected majority and a broader based membership, reduced Government involvement, and the cessation of individual statutory boards.
>
> Clear criteria for the inclusion of new groups, and a mechanism to enable existing appropriately competent unregistered practitioners to achieve registration.
>
> Expanded powers to deal with misconduct, sickness and incompetence.
>
> Protection of common professional titles.
>
> The linking of registration to continued competence.[52]

The then Government announced that it welcomed the report and would consult widely on draft legislation; after the election, the Health Minister Alan Milburn stated similarly that "the Government are committed to bringing forward, for consultation, proposals for legislation to replace the *Professions Supplementary to Medicine Act 1960*" and that a Bill advisory group was advising the UK Health Departments on a draft Bill.[53] These proposals have now been overtaken by the decision to use the *Health Bill* to create an Order-making power, allowing the changes to be made through secondary legislation.

2. Review of the *Nurses, Midwives and Health Visitors Act 1997*

During the *Health Bill*'s passage through the Lords, a further review, this time of the *Nurses, Midwives and Health Visitors Act 1997*[54] was published,[55] again recommending

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51 HL Deb 6 February 1995 c.3WA
52 Dept of Health press notice 96/251, 24 July 1996
53 HC Deb 31 July 1997 c.605W
54 itself a consolidation of legislation from 1979 and 1992
55 Dept of Health, *The regulation of nurses, midwives and health visitors,* 1999

major legislative change. The review team's recommendations were broadly accepted by the Government, with the exception of one proposal (no longer to categorise health visitors as a separate profession) which was firmly rejected. The proposals accepted by the Government included:

- a new single UK-wide statutory body, replacing the five bodies currently in existence;
- a more modern form of self regulation with a smaller, more strategic council, lay and employer involvement, flexible mechanisms and fewer barriers to multi-professional working;
- a duty to collaborate with other partners;
- a streamlined professional register;
- new powers to protect the public by ensuring fitness to practise; and
- applying a more flexible range of sanctions and support to practitioners.[56]

Because the review team's recommendations require the abolition of the current United Kingdom Council for Nursing, Midwifery and Health Visiting, and existing regulatory bodies were specifically protected from abolition by the initial version of the *Health Bill*, the Government had to bring forward amendments at Report stage to make appropriate provision. This is discussed further in Part VIII below.

[56] Dept of Health press notice 99/70,9 February 1999

IV Joint working with local authorities

The problems which may be experienced by patients where their care falls on the dividing line between "health" services and "social" services have been well documented, with Lord Clement-Jones during the *Health Bill*'s Committee stage giving perhaps the best-known example:

> It is said that the confusion is epitomised by the farcical question of whether a person in the community needing a bath should receive a "health" bath or a "social" bath.[57]

The Government's proposals for making joint working between the NHS and local authorities easier were set out in September 1998 in the Department of Health policy document *Partnership in action (new opportunities for joint working between health and social services): a discussion document*.[58] This discussion paper proposed amending some of the current legislation governing the financing of health and social services, in order to make it easier for organisations to work together at the local level. Proposals included:

- allowing health bodies (NHS trusts or the new primary care trusts) and social services departments to pool funds, thus creating a joint budget for services in a specified area on which representatives of either service may draw. Currently, while it is possible to agree jointly funded projects, each body is required to account for its own funds, thus making such arrangements very bureaucratic;
- allowing either health bodies or social services departments to become "lead commissioners" for particular services, with one body delegating funds and functions to the other;
- permitting health bodies to provide social services functions (or vice-versa) beyond the current limited level;
- extending the powers of Health Authorities under section 28A of the *National Health Service Act 1977* to transfer funding to social services departments by: extending the range of services for which this is permitted; delegating the power to the forthcoming primary care trusts; and creating a reciprocal power for local authorities.

Comments were invited on the document up till 31 October 1998. However, one initiative promised in the discussion document, the issuing of joint "priorities guidance" to the NHS and social services, took place in September 1998 with the publication of the *National Priorities Guidance 1999/00 - 2001/02*.[59] In the past, such guidance would have been issued quite separately to the NHS and to local authorities, without explicit linkage between the two organisations' priorities. The joint guidance was welcomed as

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57 HL Deb 1 March 1999 c 1486
58 Dept of Health, September 1998
59 Dept of Health circular HSC(98)159 & LAC(98)22, 30 September 1998

representing "joined-up thinking" by one NHS trust chair,[60] and appeared to be received generally with approval. However, the president of the Association of Directors of Social Services, while saying that the guidance was "fine as a baseline", pointed out local authorities were not part of a "command and control economy" and were expected to respond to local democracy and local resource issues. Another director of social services felt that some of the targets included in the guidance "might have benefited from discussion with the field before being included."[61] More generally, the discussion document itself appears to have been well received by both NHS and social services representatives, albeit with concerns that health and social services, both suffering from cash shortages, might be expected to bail each other out. One obvious concern raised by both professional and welfare groups is the issue of charging, as currently NHS services are free at point of delivery while social services are not.[62]

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60 "Guidance will force pace on joint working", *Health Service Journal*, 8 October 1998, p.2

61 *ibid*

62 "Welfare groups fear charges in NHS 'free service'", *The Guardian*, 17 September 1998, p 11 & "Dobson gives green light to pooled budgets but merger ruled out entirely", *Health Service Journal*, 17 September 1998, pp 2-3

V Control of prices of medicines and profits

The Pharmaceutical Price Regulation Scheme is the product of a negotiated agreement between Government and the pharmaceutical industry which indirectly controls the prices of branded prescription medicines to the National Health Service by regulating the profits that companies can make on these sales.

The non-statutory, or 'voluntary' agreement is renegotiated every five years between the Government, represented by the Department of Health, and the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI). It has operated in various forms since 1957. The current agreement commenced on 1st October 1993 and is subject to six months notice by either party to the agreement. Confidential negotiations are currently taking place to agree a successor scheme. In the meantime the Government is introducing certain changes to the scheme under the Bill.

The Government has voiced concerns that not all companies comply with the scheme and has put forward proposals for statutory underpinning of the voluntary scheme. In addition powers are proposed to control the maximum price charged for any medicine supplied to the health service, and to set up an alternative statutory scheme to limit prices and profits of manufacturers and/or suppliers of health service medicines.

A. Current Pharmaceutical Price Regulation Scheme (PPRS)

The objectives of the current voluntary scheme are set out in a report prepared by the Department of Health in December 1997:

- to secure the provision of safe and effective medicines for the NHS at reasonable prices;
- to promote a strong pharmaceutical industry in the United Kingdom capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and
- to encourage in the United Kingdom the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

  The PPRS aims to strike a balance between price levels which provide value for money for the NHS in its drug purchases, and profit levels for pharmaceutical companies which allow them to conduct long-term programmes to develop new medicines. It recognises that the NHS has an interest in the prices it pays now for its drugs, and in the emergence of new and improved medicines – as do the patients it serves. [63]

The PPRS covers all licensed branded prescription medicines sold to the NHS (approximately 80 per cent by value of pharmaceutical sales to the NHS). It excludes

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[63] *Pharmaceutical Price Regulation Scheme - Second Report to Parliament,* Department of Health, December 1997 (a third report is under preparation, but had not yet been released at 8 April 1999)

generic products sold to the NHS and over-the-counter (OTC) medicines other than those prescribed by doctors.

The PPRS' report also gives details of how the scheme operates:

> All companies which sell branded medicines to the NHS are covered by the Scheme. Those companies which have annual sales to the NHS of over £20 million are required to submit detailed annual financial returns (AFRs) to the Department of Health. In 1994 there were 50 such companies, accounting for 93% of all PPRS sales. Companies with annual sales to the NHS of between £1 million and £20 million are required to provide copies of their published accounts. Companies with annual sales to the NHS of below £1 million are not usually required to submit annual information but do have to abide by the general principles of the scheme.
>
> As part of the present scheme, a range of target profits has been negotiated with the APBI of between 17 to 20% return on capital employed. The scheme also provides a "margin of tolerance" for profits, equivalent to 25% above and below the set profit target. All profits above the margin of tolerance must be repaid either as a lump sum or as equivalent price reductions.
>
> …Target profit levels for each company are agreed through negotiation between the DOH and individual companies. Within this framework, companies establish the PPRS/factory gate price for a product. The PPRS encompasses both sales of drugs prescribed through GPs and those to hospitals. The final NHS list price will include the factory gate price plus the level of margin allowed for distribution through wholesalers. Currently pharmacists and hospitals can negotiate discounts directly with the wholesaler or manufacturer as appropriate. [64]

Research and development of new medicines is a lengthy and expensive process. The Director General of the ABPI has stated that it takes up to twelve years and may cost upwards of £350 million to bring a new medicine through the approval process.[65] The scheme allows for offsetting R&D costs:

> As part of the Government commitment to supporting research and development, the current scheme allows companies to offset a proportion of their research and development costs against their sales to the NHS. For the Industry as a whole, the maximum allowable level of R&D costs is about 20 per cent of sales to the NHS, equivalent to £556 million in 1994.[66]

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64 ibid

65 Dr Trevor Jones, Director General of the Association of the British Pharmaceutical Industry, *The House Magazine*, 15 February 1999, p 21

66 *Pharmaceutical Price Regulation Scheme - Second Report to Parliament*, Department of Health, December 1997

New medicines can be launched at the highest price that the market will stand, although subject to the company's total profit constraint. A high price at launch is seen by the industry as a means of recouping the expenses of R&D. However, there are cost implications for the NHS when products which are expected to achieve widespread use, such as Viagra, or new treatments for Alzheimer's disease, hit the market.

Some companies which undertake little or no manufacturing or research in the UK have insufficient captital in relation to their sales for their target to be expressed in terms of Return on Capital (ROC) Hence, companies with a sales to capital ratio higher than 3.75:1 have profit targets set in terms of Return on Sales (ROS).

When the 1993 PPRS was agreed a price reduction of 2.5 per cent was imposed, for companies with sales over £1 million, on all products covered by the PPRS for the previous 3 years. Products introduced after 1 October 1993 were excluded. Following a mid-term review in 1996, the price reduction was extended to the end of the current PPRS.

1. Costs of the current scheme

The cost of the scheme has risen considerably in recent years. Causes include an increase in demand through an ageing population and vastly improved ability to treat a range of conditions which could not be treated at the inception of the voluntary scheme 42 years ago.

A recent paper published by the Institute for Fiscal Studies says that over the past ten years expenditure of drugs has risen by about ten per cent a year. In 1995-96 the total bill for NHS pharmaceutical drugs was over £5 billion, about £3 billion of which went on branded pharmaceuticals covered by the PPRS.[67]

Table 2 shows trends in the number of prescriptions, net ingredient cost and average net ingredient cost of generic and proprietary prescriptions since 1991. The average annual real terms increase in average net ingredient cost (NIC) per prescription between 1991 and 1997 was 2.7%.

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[67] Nicholas Bloom, John van Reenen "Regulating drug prices: where do we go from here?", *Fiscal Studies,* Vol 19 No 3, 1998, p 322

Table 2

Number, net ingredient cost and average NIC per prescription by class of preparation [(a)]

	Prescribed and dispensed generically	Dispensed as proprietary	Dressings and appliances	Total	*% prescribed and dispensed generically [(b)]*
Number of prescriptions (millions)					
1991	138.8	255.4	12.4	406.5	*35%*
1992	146.7	265.3	13.1	425.1	*36%*
1993	166.0	265.8	13.7	445.4	*38%*
1994	185.0	256.7	14.3	456.0	*42%*
1995	204.9	254.0	14.5	473.3	*45%*
1996	217.2	253.0	14.7	484.9	*46%*
1997	237.1	248.1	14.9	500.2	*49%*
Net ingredient cost (£ million)					
1991	328.8	2,041.8	149.2	2,519.8	*14%*
1992	322.5	2,366.5	168.9	2,858.0	*12%*
1993	341.6	2,631.1	185.8	3,158.5	*11%*
1994	478.3	2,723.8	201.7	3,403.8	*15%*
1995	584.9	2,882.4	213.3	3,680.6	*17%*
1996	660.5	3,120.1	226.3	4,007.0	*17%*
1997	896.7	3,234.0	236.8	4,367.5	*22%*
Average net ingredient cost per prescription (£)					
1991	£2.37	£7.99	£12.03	£6.20	*30%*
1992	£2.20	£8.92	£12.89	£6.72	*25%*
1993	£2.06	£9.90	£13.56	£7.09	*21%*
1994	£2.58	£10.61	£14.10	£7.47	*24%*
1995	£2.85	£11.35	£14.71	£7.78	*25%*
1996	£3.04	£12.33	£15.39	£8.26	*25%*
1997	£3.78	£13.04	£15.89	£8.73	*29%*

Notes: (a) All licensed branded drugs, including branded generics, are subject to the pharmaceutical price regulation scheme. The data are from the prescription price analysis system and cover all prescriptions for drugs dispensed in the community, i.e by community pharmacists, dispensing doctors and by personal administration. The net ingredient cost refers to the cost of the drug before discounts and does not include any dispensing costs or fees. It does not include any income obtained where a prescription charge is paid at the time the prescription is dispensed or where the patient has purchased a pre-payment certificate.
(b) As percent of total excluding dressings and appliances. For average net ingredient cost per prescription table shows average NIC of generic prescriptions compared with average NIC of proprietary prescriptions

Sources: Statistics of prescriptions dispensed in the community: England: 1987-1997, DH Statistical Bulletin 1998/14

2. Price increases

Companies have discretion within the framework set by the PPRS in the pricing of new products, and of line extensions (new presentations of existing products) during the first five years from the grant of the original licence.

> In all other cases, prices may only be raised with the Department's agreement. Application for a price rise must be accompanied by a projection of sales, capital employed, costs incurred and profits for the coming year. The Department will assess those figures and only if it is satisfied that a company's profits will fall below 75% of target will a price increase be granted. The requirement to obtain the Department's agreement applies to all companies, big or small.[68]

Price increases agreed for 1993-1996 are set out below.

Table 1

Number and value of price increases under the PPRS

Year	Number of price increases		Full year value of price increases
	Total	*of which AFR companies*	(£ million)
1993	31	*8*	11.9
1994	11	*4*	2.2
1995	11	*5*	6.7
1996	11	*3*	10.7

Pharmaceutical Price Regulation Scheme - Second Report to Parliament, Department of Health, December 1997

In practice, if a product becomes unprofitable for a company it can then be sold to another firm which can raise the price in the context of its own overall profit target. In June 1998, for example, Novartis sold the licence for syntometrine (widely used in childbirth to prevent haemorrhage) to Alliance Pharmaceuticals Ltd. The cost to the NHS, previously 18p per 1ml ampoule, was raised to £1.40 per ampoule.[69] Though not against the rules of the scheme, this has focused attention on rising drug prices.

The Lancet comments:

> First came the rising drugs bill, which at £6 billion plus, now accounts for 14% of the NHS budget. Ministers pay tribute to the way some drugs cut hospital costs -

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68 ibid

69 BBC Online network http://news.bbc.co.uk/hi/english/health/newsid 20 August 1998

> such as the new AIDS drugs which have greatly reduced the need for hospital beds - but are still concerned that the medicines bill is rising faster than inflation.
>
> This general concern was exacerbated by the recent revelation that some of the biggest drug companies have been selling-on their rights over some products to smaller companies, resulting in huge price hikes for the NHS. Under the PPRS, companies are not expected to increase their prices without Health Department agreement, so the new deals are seen as a cynical manipulation of the voluntary agreement. [70]

In addition, commentators have voiced suspicions that Merk, Sharp & Dohme, a key member of the American Pharmaceutical Group, has been considering withdrawing from the voluntary scheme.[71] The US has free market pricing.

3. Problems with the current scheme

The scheme has generated several main criticisms: it allows excessively high prices, it generates too little incentive to cut costs, and it lacks transparency.

- The rising drugs bill generates criticism that the PPRS allows companies to charge excessively high prices. International comparisons are acknowledged to be fraught with methodological difficulties, and studies can produce conflicting results. However, the IFS study cited above found that the UK fell into a group of countries with intermediately priced drugs:[72]

Pharmaceutical Price Comparisons for a Sample of Countries

High-price countries	US
Intermediate-price countries	Denmark, Germany, Ireland, Netherlands, UK
Low-price countries	France, Greece, Italy, Portugal, Spain

Source: Based on price comparisons from Burstall (1997), Department of Health (1993, 1996 and 1997), Mossialos (1997) and Reekie (1997).

- Commentators have said that the PPRS appears to provide little incentive to control costs, as cost improvements are passed through into lower prices.

- The current PPRS has been criticised for lack of transparency. Negotiations are confidential. The Commons Health Select Committee in 1994, while acknowledging the success of the pharmaceutical industry, drew attention to a lack of public scrutiny:

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70 "Will UK drug-pricing regulation be abolished?", *The Lancet, 3* October 1998, p 1127

71 "War on 'greedy' drugs firms" *The Guardian* 21, September 1998

72 Nicholas Bloom, John van Reenen "Regulating drug prices: where do we go from here?" *Fiscal Studies,* Vol 19 No 3, pp 321-342

> The secrecy which surrounds the PPRS makes it very difficult for Parliament, health care professionals, or the public at large, to know what the overall effect of the scheme is; and in particular, whether the balance which the scheme was created to achieve, between the interests of the industry and those of the NHS, is being fairly struck, or whether there is a pronounced tilting in one direction or another. If the scheme does result in an unfair tilting, there are grounds for supposing that this may be in the direction of the industry rather than the NHS. [73]

However, the Department of Health now issues reports to Parliament at intervals (1993, 1996 and 1997) on the working of the scheme, which provides some clarification.

4. Compliance with the current PPRS

The Government has voiced concerns that not all companies comply with the current scheme. Problems encountered have been cited:

- Failure to submit on time financial returns on which profit levels for individual companies are assessed. One major company has refused to provide information since 1990.[74]
- Raising of prices without the agreement of the Secretary of State, and in ways contrary to the rules of the scheme. Over the past year 24 companies have increased product prices without the Department's agreement, at an estimated cost to the NHS of £30 million.[75]
- Delayed repayment of excess profits[76]
- Difficulties ensuring compliance. Existing powers under Section 57 of the *National Health Service Act 1977* enables the Secretary of State by Order to control maximum prices for medical supplies. This provision does not provide power to regulate profits. Accordingly, it cannot be used to ensure compliance by companies with all elements of the current PPRS or a similar successor scheme. In addition, each maximum price or change thereto has to be made by Order, breach of which is a criminal offence. The Government believes that this is an inappropriate way of dealing with non-compliance under a pharmaceutical price or profit regulation scheme.[77]

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73 House of Commons Health Select Committee, *Priority setting in the NHS: The NHS Drugs Budget*, second report, July 1994 para 82-83

74 *7th Report to the Select Committee on Delegated Powers and Deregulation Session* Health Bill 1998/99, (Annex, Memorandum by the Department of Health), House of Lords Paper 29 1998-99, Para 107

75 HL Deb 9 Feb 1999 c 113

76 HL Deb 1 March 1999 c 1504

77 Department of Health, *Regulatory Impact Assessment, The Health Bill: Control of Prices of Medicines and Profits*, 27 January 1999

5. Could increased regulation damage the pharmaceutical industry?

According to figures published by the European Commission,[78] expenditure on research in the UK pharmaceutical industry is second highest of EU countries for which figures were available. Only Germany spent more in absolute terms. Expenditure on research in the UK represented around a fifth of the value of production. This compares favourably with the EU average of around 12% and only Sweden spend a significantly higher percentage.

There were 19,000 person employed in pharmaceutical research in the UK in 1996, the highest number of any EU country. Around a quarter of employment in the pharmaceutical industry in the UK was in research compared with 16% in the EU as a whole. Again, only Sweden was ranked higher on this measure. The UK score was broadly in line with that in the US.

Commentators have raised the question of whether increased regulation would have adverse effects on research and development. The authors of the 1998 Institute for Fiscal Studies report discuss the possible effects of substantial cuts in the prices of medicines in the UK on the pharmaceutical industry internationally:

> Pharmaceutical sales in the UK only account for about 3 per cent of the world market. As a result a cut in prices of pharmaceutical drugs in the UK should have only a minor effect on the global returns to R&D investment into new drugs. However, if sufficient numbers of countries cut their pharmeceutical prices, this could seriously damage the innovative ability of the industry globally. It is possible that, because the UK is the world's third largest exporter of pharmaceutical drugs, global prices may be particularly sensitive to UK prices. If so, any drastic price cut in the UK could provide a cue for retaliatory price-cutting by regulators in other countries. [79]

It is also suggested that over regulation of the profits that companies can earn provides insufficient reward for successful firms and is too lenient on poor performers, effectively cushioning poor performers from the rigors of market competition.

The pharmaceutical industry points to the record of success of a flexible voluntary scheme and the stability of regulation over the past twenty years in building a strong pharmaceutical industry, and and sees dangers in increased regulation; addition of further hurdles could stultify research, fewer products would be produced and research could go overseas. Pharmaceuticals are the UK's third-biggest export, and last year contributed about £2.3bn to the balance of trade.[80]

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[78] *Communication from the Commission on the Single market in Pharmaceuticals,* EC Cons Doc 13544/98, 25 November 1998

[79] Nicholas Bloom, John van Reenen "Regulating drug prices: where do we go from here?" *Fiscal Studies* Vol 19 No 3, 1998, pp 321-342

[80] "Drugs industry 'driven from UK to cut costs'", *Financial Times,* 17 October 1998

A recent report has been produced by the accountancy firm PricewaterhouseCooper for the APBI. This report finds that a fifth of manufacturing jobs in the UK pharmaceutical industry have been lost over the past six years as companies have shifted production to countries with lower taxes and fewer regulations.[81] The report says that American owned pharmaceutical companies are particularly concerned by the so-called "export disincentive" of the current PPRS arrangements. Under these arrangements, the more goods the companies export, the less capital they are deemed to have spent in the UK. The amount of profit which major companies are allowed to make on their sales to the NHS is determined by the amount of capital they employ in the UK.[82]

The ABPI comment on a decline in growth:

> The statistics show that exports of medicines in the first six months of this year totalled £2,652 million compared with £2,777 million in the same period last year - a drop of four per cent. At the same time, imports rose two per cent to £1,630 million in the January-June period this year from £1,597 million in 1997.[83]

Industry is concerned that the provisions of the Bill, particularly the clauses relating to prices and profits, would create an increasingly hostile and unstable environment for pharmaceutical companies to operate in the UK.

However, speaking in the Second Reading debate in the House of Lords, the economist and Labour Peer, Lord Desai said:

> …Of course, the Association of the British Pharmaceutical Industry is not happy with this, but it was never happy with regulation. However, if you want to encourage research and development, you should do so through a tax concession and not through overpricing. The pricing should be left so as to allow it to be as reasonable and efficient as possible. If you want to encourage research and development, you should do something else. I believe that it would be a mixing up of two different objectives to allow people to overprice just because they are good at R&D…[84]

Options for change were identified by the Department of Health:[85]

1 Terminate the existing agreement and allow suppliers to determine all prices

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81 PricewaterhouseCooper UK (survey on pharmaceutical manufacturing investment), *Driving out the Golden Goose*, October 1998

82 "Pharmaceutical manufacturing leaving UK?" *The Pharmaceutical Journal*, Vol 261, 24 October 1998

83 ABPI press release *"Decline in pharmaceutical trade surplus continues - ABPI warns Government over regulation*", 10 December 1998

84 HL Deb 9 February 1999 c 152

85 Department of Health *Regulatory Impact Assessment, The Health Bill: Control of Prices of Medicines and Profits*, 27 January 1999

2 Continue with the current non-statutory agreement
3 Negotiate a new voluntary agreement with no enabling powers to secure compliance.
4 Take enabling powers to secure compliance of any companies which might choose not to comply with a voluntary agreement
5 To fully implement a new scheme through regulation.

A full regulatory impact assessment will be completed on conclusion of negotiations between the Government and ABPI on a new scheme.

The Bill as it enters the House of Commons provides both powers to ensure compliance with a negotiated voluntary scheme, and powers to control prices of health service medicines in other circumstances and to provide also for a statutory scheme. However, both these latter powers are only intended to be applicable to companies not complying with a voluntary scheme. Details are given in Part VII.

During the Second Reading debate in the House of Lords Baroness Hayman made clear the Government's commitment to renegotiating a voluntary system of price regulation:

> We consider that a voluntary scheme which is clear and fair is the best way of working, and this view is shared by the industry. But fairness has to mean that everyone complies with the agreement and companies in the same situation are treated in the same way.
>
> Unfortunately, this is not thought to be the case with the current agreement. One major company has refused to submit financial returns since 1990 and resisted all approaches to comply. Over the past year 24 companies have increased product prices without the department's agreement, at an estimated cost to the NHS of £30 million. That is at the expense of other NHS treatment and care.
>
> If action is not taken to secure compliance, there is a risk that the scale of losses will increase. It is the Government's duty to ensure that the NHS gets a fair deal. It also helps the pharmaceutical industry if everyone knows that there is a clear, fair and universally applied arrangement. In the long run, it makes it possible for the Government to run such matters with a much lighter touch.
>
> The powers in Clauses 26 to 31[86] will enable the Government to ensure compliance with aspects of a new agreement which would be the result of full discussion with the industry. Perhaps I may use medical terminology here and say that we are talking about informed consent. So they will not significantly affect those companies committed to complying with the agreement, but they will secure compliance from any other companies. In the ongoing negotiations we are committed to finding a fair deal for the NHS and a fair deal for the pharmaceutical industry. We believe that it is possible to put in a place a system

[86] Clauses 30-35 in Bill 77 as it arrives in the Commons

which delivers these objectives, and which ensures that this country continues to be in the forefront of research and development in this area.[87]

[87] HL Deb 9 February 1999 c 113-114

VI Other promised changes

A. Changes to the NHS trust financial regime

In the English White Paper, the Government signalled its intention to change the NHS trust financial regime "to make it more transparent and more suitable for a public service based on partnership"[88]. As part of this aim, it was announced that the "Government will take reserve powers to ensure that the estate is managed in ways which are consistent with local strategies and the broader requirements of the NHS". This is being achieved through clause 10 of the *Health Bill* which gives the Secretary of State the power to issue binding directions to NHS trusts, while formerly the circumstances in which such directions could be given were strictly limited.

The Government has also announced its intention of changing the way in which NHS trust debt is structured. When NHS trusts are established, they are assigned an "originating capital debt", equivalent to the value of the assets transferred to the new trust. Until now, this debt has been split into "interest-bearing debt" with defined interest and repayment terms, and "public dividend capital", a form of share capital on which the trust pays dividends to the Government. In practice, the dividend payments are adjusted so that trusts are required to make a 6% return on their net assets, the 6% figure being chosen on the basis of the long-term cost of borrowing to the Government. In a parliamentary answer in July 1998, the Lords health minister, Baroness Hayman, set out the Government's plans to abolish interest bearing debt and change to a single system of public dividend capital:

> The New NHS White Paper made clear the Government's intention to abolish the internal market in the National Health Service and amend the NHS trust financial regime to make it more transparent and more suitable for a public service based partnership. As part of our aim to achieve this aim, we are changing the debt structure of NHS trusts. We have already taken steps to stop issuing long term interest bearing loans to NHS trust to finance their capital expenditure. Instead we are issuing public dividend capital (PDC). The NHS Executive will now be making arrangements to replace existing interest bearing debt with PDC without the application of premia or discounts because the Exchequer funds NHS trusts' normal debt servicing costs. This will supersede the present, market-driven financial structure, reduce bureaucracy and provide simpler, clearer and more understandable arrangements, in tune with NHS trusts' status as part of the public sector.[89]

This is achieved in clauses 13-15 of the *Health Bill* for England and Wales and clauses 47-49 for Scotland. The change appears to have generated little, if any, comment.

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88 Cm 3807, para 6.38

89 HL Deb 31 July 1998 c 262WA

B. Fraud

In June 1997, following the publication of an Efficiency Scrutiny into prescription fraud in England and Wales,[90] which suggested that fraud might be costing the NHS £100 million a year, the then Health Minister, Alan Milburn, announced a major crackdown on fraud in the NHS. Action to be taken, against fraud committed by both patients and practitioners included:

- creating a new criminal offence of evading payment of prescription and other charges, together with a fixed penalty for non-payment;
- incorporating anti-theft and anti-counterfeiting devices in the printing of prescription forms;
- a reward scheme for pharmacies detecting stolen or counterfeit forms;
- examining the costs and benefits of an electronic system for transferring prescription information;
- greater use of IT by the Prescription Pricing Authority's fraud investigation unit, to improve the detection of fraud by practitioners.[91]

The *Health Bill* includes clauses which create both a criminal offence and a civil penalty in England and Wales for NHS charge evasion. The Scottish provisions provide just for a civil penalty. The Bill also includes provisions to amend the powers of the NHS Tribunal (which can prevent GPs, dentist, opticians and pharmacists from working in the NHS) to make it easier to remove fraudulent practitioners from the NHS.

Other initiatives against fraud which have been announced in the past year include the creation of a "fraud supremo"[92] and the publication of a strategy document *Countering fraud in the NHS.*[93] As part of this strategy, from 1 April 1999, all patients will be asked to show some proof of their entitlement when claiming exemption from prescription charges. Those unable to show proof will not be denied their prescription, but the form will be marked so that it can more easily be checked by the fraud investigation unit at the Prescription Pricing Authority.[94]

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90 Department of Health, *Prescription fraud: an efficiency scrutiny*, June 1997

91 Department of Health press notice 97/140, 19 June 1997

92 Department of Health press notice 98/212, 28 May 1998

93 Department of Health, *Countering fraud in the NHS*, December 1998 & Department of Health press notice 98/576, 7 December 1998

94 Department of Health press notice, 8 March 1999 & Scottish Office press notice 2575/98, 7 December 1998

VII The Bill

The *Health Bill*[95] was introduced into the House of Lords as HL Bill 15 on 28 January 1999. Its Second Reading was on 9 February, its Committee stage on 25 February, 1 March & 4 March, its Report stage on 15 & 18 March and its Third Reading on 25 March. It is due to have its Second Reading in the Commons on 13 April 1999. It includes both the necessary amendments to legislation to enable the Government's proposals in the White Papers, *The new NHS*[96] (England), *Designed to care*[97] (Scotland) and *NHS Wales: putting patients first*[98] to be implemented, and also a variety of other changes to health legislation which have been promised since the election.

The following section provides a summary of the effects of the Bill's clauses. It does not attempt to cover every provision in the Bill and more technical details can be found in the *Explanatory Notes* issued with the Bill. Amendments made during the Lords stages are highlighted in bold, unless they are essentially a re-writing of the original intention to meet concerns about drafting.

The long title was amended at Third Reading in the House of Lords to reflect the references to private health services made by Lords amendments.[99] It now reads:

> A Bill to amend the law about the national health service; make provision in relation to arrangements and payments between health service bodies and local authorities with respect to health and health-related functions; **make provision in relation to monitoring and improving the quality of health care in independent hospitals**; confer power to regulate any professions concerned (wholly or partly) with the physical or mental health of individuals; and for connected purposes.

A. GP fundholding

Clause 1 of the Bill abolishes the GP fundholding scheme in England and Wales by removing the relevant sections (sections 14-17) from the *National Health Service and Community Care Act 1990*. The same provision is made for Scotland in **clause 40**.

B. Primary Care Trusts

Clauses 2-6, 9-10 and **Schedule 1** make provision in England and Wales for the new "Primary Care Trusts" (PCTs) and also tidy up the existing position relating to the allocation of funding to Health Authorities and the remuneration of GPs and other family

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95 Bill 77 1998-99
96 Cm 3807, 9 December 1997
97 Cm 3811, 9 December 1997
98 Cm 3841, 15 January 1998
99 HL Deb 25 March 1999 c 1474

health service practitioners. **Clause 2** inserts new sections 16A and 16B and Schedule 5A into the *National Health Service Act 1977* (the main "parent Act" for the NHS in England and Wales). PCTs will be established by Order of the Secretary of State. As a result of concern expressed in the Lords, **the functions of PCTs are now listed on the face of the Bill, as**

> **(a) providing or arranging for the provision of services under this Part of the Act,**
> **(b) exercising functions in relation to the provision of general medical services under Part II of this Act and**
> **(c) providing services in accordance with section 28C arrangements [ie the "pilot schemes" for primary care, established under the Primary Care Act 1997]**

The Order will specify the geographical area which the PCT is to cover and may make restrictions or prohibitions on how the PCT is to carry out its functions. The *Explanatory Notes* issued with the Bill suggest that there will be a clear distinction between "level 3" and "level 4" PCTs: those which are only able to *commission* secondary (ie hospital and community) services and those which will both commission and provide secondary services. PCTs in the latter category, for example, would be able to provide their own district nursing services if they wished, rather than commissioning them from a community trust (and would often come about through a merger with a community trust). Both kinds of PCT would, of course, be providing GP services.

Regulations will provide for consultation arrangements when the creation of a PCT is under consideration, and these requirements must be met before the Order is made. The *Explanatory Notes* emphasise that proposals to establish a PCT will be generated locally and that it will be the responsibility of the Health Authority to select those proposals which should go forward to the Secretary of State for consideration. Where a proposal is endorsed either by the PCG or by a local community trust it must be submitted to the Secretary of State. The *Notes* also envisage that there would be consultation before a level 3 PCT could develop to level 4. **No Order establishing a PCT may be made unless a majority of the members of the PCG concerned (after consultation with all the health professionals covered by the PCG) has voted for it. PCG boards therefore have a veto over the establishment of PCTs.**

The new Schedule 5A to the 1977 Act (found in **Schedule 1** of the *Health Bill*) makes detailed provision for PCT Orders, and the membership, powers and duties of PCTs. Part I of the Schedule allows for there to be a gap between the establishment date and the operational date of the PCT, and for the PCT to have limited specified powers within this period to enable it to take over its full functions satisfactorily on its operational date. The PCT Order may require the relevant Health Authority to meet the PCT's costs during this transitional period; it may also require the Health Authority, or a local NHS trust to make premises and staff available to the PCT to assist its preparation.

Part II of the Schedule sets out the PCT's status, membership and staffing. A PCT (like Health Authorities and Special Health Authorities) will be a body corporate and will have a board made up of a Chair appointed by the Secretary of State, together with executive and non-executive Members. Regulations may make provision for the appointment of the Chair and Members, how many non-executive and executive Members there will be, their tenure, and the appointment and constitution of committees. PCTs may employ staff on such terms as they think fit, but (following consultation) the Secretary of State is empowered to direct a PCT to employ an officer from another PCT or make the services of any of its officers available to another PCT. The remuneration of the chair and non-executive members of the PCT will be set by the Secretary of State, but the PCT is empowered to set its own rate of pay and allowances for its employees.

Part III of the Schedule sets out PCTs' powers and duties. PCTs' general powers are very similar to those of NHS trusts, including such powers as acquiring or disposing of land or property and accepting gifts of money, land or other property for purposes relating to the health service. Specific powers include conducting and commissioning research, and assisting with others' research, for example through providing officers and facilities. Specific duties include preparing an annual report as soon as possible after the end of the financial year, giving details of the measures taken by the trust to "promote economy, efficiency and effectiveness in using its resources for the exercise of its functions". PCTs must also provide such information to the Secretary of State and their local Health Authority as is required by either. Regulations **must** (initially "may") be made, specifying the steps that PCTs must take to publicise accounts, reports and other prescribed documents. If the Secretary of State decides to dissolve a PCT, the Secretary of State may transfer the dissolved trusts' property, rights and liabilities to himself or another NHS body. Regulations may provide for consultation before such dissolution takes place.

Part IV allows the Secretary of State to transfer any of the property, rights and liabilities of a "health service authority" (defined as the Secretary of State, a Health Authority, a PCT or an NHS trust) to a Primary Care Trust. This should be done by agreement between the health service authority and the PCT but where agreement is not possible, the Secretary of State has the power to make directions as to the transfer.

Part V allows for the Secretary of State to make Orders concerning the transfer of staff to a PCT from a Health Authority, NHS trust or other PCT. Transferred staff will be treated as if their employment contract were originally made with the PCT, to ensure continuity of employment as far as employment legislation is concerned. If a member of staff objects to the transfer, their contract will be terminated on what would have been the transfer date, but they will not be treated as if they have been dismissed. While this provision does not prevent any employee making any claims under current employment law on the grounds that their contract has substantially changed, the fact that the identity of their employer has changed does not in itself constitute a significant change in their contract.

Clauses 3 & **4** provide the legal framework for funding to be devolved to PCTs, through inserting new sections 97C and 97D and Schedule 12A into the *National Health Service Act 1977*. Essentially, the arrangements parallel the current arrangements for the funding of Health Authorities by the Department of Health, as set out in sections 97 and 97A of the 1977 Act. New section 97C gives Health Authorities the duty of passing on to PCTs both the funding to cover GPs' remuneration (which in the past GPs would have received directly from Health Authorities) and the sums "allotted" by the Health Authority to cover the PCT's "main expenditure", ie hospital and community health services, prescribing costs and GP infrastructure such as computers. While GP remuneration is not cash-limited, "main expenditure" is subject to a limit agreed before the start of the year. However, adjustments to this limit may be made during the year (section 97C(3)), giving an element of flexibility.

PCTs may also be liable to pay "capital charges" to Health Authorities to reflect the value of their capital assets: section 97(4) gives the Secretary of State powers to direct PCTs to pay such charges. The *Explanatory Notes* to the Bill state that this power will be used to ensure that PCTs include the value of their overheads when calculating the cost of any service they are providing. Where Health Authorities receive "ear-marked" funds from the Department of Health and pass these on to Primary Care Trusts, the same restrictions on their use will apply to the PCT (section 97C(5)).

New section 97D in the 1977 Act, also introduced by clause 3, sets out the financial duties of PCTs. PCTs will be required to ensure that their spending (other than that spent on GP remuneration which is not cash-limited) does not exceed the amounts allocated to them by the Health Authority under section 97C plus any other income they receive for the purpose of carrying out their functions. Funding received through charitable trust funds is *not* included when calculating whether this duty has been met (section 97D(4)). The Secretary of State is empowered to give PCTs directions to ensure that the duty is met, both to PCTs in general and, if necessary, to individual PCTs.

New schedule 12A to the 1977 Act, inserted by **clause 4** of the Bill, was added during the Lords stages, in order to clarify the definitions of "Part II" expenditure and "main" expenditure, both for Health Authorities and NHS trusts. **In particular, it specifies that the costs of drugs will be allocated to the Health Authority and PCT where the drug was prescribed rather than where it was dispensed**. The original drafting of section 97 of the 1977 Act meant that if a drug was prescribed by a doctor in one Health Authority area but dispensed by a pharmacist in another, its cost would be ascribed to the *pharmacist's* Health Authority. The Schedule also includes the provision that it will have effect in the financial year 1999/2000, even though the financial year will have begun before the Act can come into force.

Clause 5 sets out further PCT functions, inserting new section 18A into the 1977 Act. Under section 18A(1), PCTs will be eligible to provide "personal medical services" (ie GP services) under the *National Health Service (Primary Care) Act 1997*: in other words they will be eligible to submit proposals under which they may be paid more flexibly for GP services than under the current GP contract which is set nationally. Library Research

Paper 97/16 describes these "pilot schemes" (which may in future become permanent) in more detail; essentially this provision in the *Health Bill* simply ensures that GPs who are interested in providing medical services as part of a pilot scheme rather than under the national contract, are not disadvantaged by being in a PCT.

PCTs are also permitted to provide services to other health service bodies: an example given in the *Explanatory Notes* is that a PCT which is empowered to provide health visiting services to its own area may also, under contract, provide such services to other patients (section 18A(2)). In order to enable all "family health services" (ie GP services, dentistry, pharmacy and ophthalmic services) to be provided under one roof, PCTs may make premises available to any family health service practitioners, on any terms it thinks fit (section 18A(3)). PCTs are also permitted to treat private patients and to generate income in the same way as existing NHS bodies, subject to the constraint that any of these activities must not interfere to a significant extent with the performance of their NHS functions and obligations (section 18A(4-7)).

Clause 6 covers the issue of trust funds and trustees; according to the *Explanatory Notes,* this is most likely to affect PCTs which provide, as well as commission, services, as such PCTs may inherit charitable funds from NHS trusts (for example where a PCT has been created through merger with a community NHS trust). The Secretary of State may provide for the appointment of trustees by Order and such trustees may accept, hold or administer any property on trust, either for the purposes of the PCT or for "all or any purpose relating to the health service".

Clause 9 was inserted at Third Reading by the Government to "legitimise current practice" in determining the remuneration of family health service practitioners.[100] While sections 43A and 43B of the 1977 Act (inserted by the *Health and Social Security Act 1984)* set out the basis of how remuneration should be set, they were never enacted. The legitimacy of current practice has therefore depended on section 7(4) of the *Health and Social Security Act 1984* which states that any determinations made before the amendments to the 1977 Act were made would be deemed valid if they *would* have been valid had the new sections been enacted. Clause 9 therefore "tidies up" this position, confirming existing arrangements that remuneration may be made up of payments by way of salary, fees, allowances or the reimbursement of expenses. The "determining authority" will be the Secretary of State, who also has the power to delegate this function to Health Authorities or to any "other person appointed by him". The *Explanatory Notes* state that the intention is to continue the existing practice of delegating to Health Authorities the power of allocating GP cash-limited funds, that is funding for GP premises, staff and computers, and also to delegate this function on to PCTs once they are established. The same effect is achieved in Scotland through **clause 51.**

[100] HL Deb 25 March 1999 c 1437

Clause 10 makes provision for the Secretary of State to issue directions to PCTs, by replacing section 17 and inserting new sections 16D, 17A and 17B in the 1977 Act. These new sections restate the Secretary of State's existing powers to delegate functions to Health Authorities and Special Health Authorities and to issue directions as to how they should be performed. (This is the current mechanism used under which the Secretary of State's duty to provide hospital and community services is delegated to Health Authorities, who fulfil it by commissioning services from NHS trusts.) The new sections also permit Health Authorities to delegate functions to PCTs unless they are "excepted functions" which may not be delegated (such as powers in connection with other family health practitioners such as pharmacists). PCTs and NHS trusts are added to the list of bodies to whom the Secretary of State may issue directions, and Health Authorities are permitted to issue directions to PCTs in respect of their delegated functions. **The Secretary of State is specifically required to exercise his direction-making power to ensure that patients may be referred out of their home area for specialist treatment where necessary**. Finally, new section 16C, inserted by Schedule 4 as the result of an amendment made at Third Reading**, requires PCTs to ensure that they receive appropriate clinical advice when carrying out their functions**.

The effect of clause 10 is to enable the function of commissioning health services to be delegated down to the level of PCTs, but to retain to the Secretary of State the power of issuing directions on *how* functions should be performed. The Secretary of State also has the power to require HAs to delegate particular functions, or to prevent them from doing so. The *Explanatory Notes* state that the Secretary of State intends to require HAs to delegate to PCTs the function of distributing the GP infrastructure budget, and may require the delegation of other functions relating to GPs, such as making temporary arrangements for cover when a GP is suspended or retires. However, they state firmly that GPs' independent status will not be affected by these arrangements. Finally, the inclusion of NHS trusts, as well as PCTs, in list of bodies to whom the Secretary of State may give directions, strengthens the existing control over NHS trusts and bring them into line with other NHS bodies such as Health Authorities.

Quite different provision for PCTs are made for Scotland. While English and Welsh PCTs are new statutory entities, Scottish Primary Care Trusts are being established under the existing powers of the *NHS and Community Care Act 1990* in the same way as other NHS trusts. This means that they can be established before the *Health Bill* is enacted, although of course they will at first only have the existing powers of NHS trusts allowed for by the 1990 Act. Once the *Health Bill* is in force, however, **clause 42** allows for the Secretary of State to direct Health Boards to delegate to PCTs some or all of their "Part II functions" (ie arranging the provision of family health services: GP services, pharmaceutical services, ophthalmic services and dentistry). This means that PCTs will be able to take on responsibility for such functions as contracting with practitioners to provide family health services in the area and managing the remuneration and discipline of practitioners (although the rates of remuneration will still be set nationally, as now). Thus, although Primary Care Trusts in Scotland will not have the powers of PCTs in England to commission secondary services from acute hospital trusts, they will have a far wider remit as far as family health services are concerned.

Clause 43 makes minor changes to the provisions for NHS trust boards in Scotland to rename their non-executive directors as "trustees". The *Explanatory Notes* also state that the Secretary of State intends to use his Regulation-making power to bring in a broader range of trustees. **Clause 44** enables the Secretary of State to issue binding directions to NHS trusts on any matter, while currently such a power is restricted. This parallels the provision for England and Wales found in clause 10.

Clause 46 inserts a new section 85AA in the *National Health Service (Scotland) Act 1978* to allow for previously separate funding streams to be combined into the new unified budgets. Currently, section 85 of the 1978 Act provides for two quite separate funding streams: cash-limited funding for "Part I" expenditure (hospital and community services) and a combination of cash-limited and non-cash-limited Part II expenditure (remuneration of family health services practitioners, including the cost of drugs and GP infrastructure). New section 85AA allows for unified budgets through creating a category of cash-limited "main expenditure": Part I expenditure combined with certain parts of Part II expenditure, including the cost of prescription drugs and GP infrastructure. It was, however, promised in the Lords stages that GP infrastructure costs would be "ring-fenced" within the unified budget[101]. The remaining aspects of Part II expenditure (ie the major part of family health services practitioners' remuneration) remains separate and non-cash-limited. **Government amendments made at Report stage ensured, as in England and Wales, that the cost of drugs would be allocated to the Health Board where the drugs were prescribed, not where they were dispensed**.

C. Additional funding

Clause 7 amends section 97 of the 1977 Act to permit the Secretary of State to make additional financial allocations to Health Authorities in England and Wales in recognition that they have met particular objectives in the preceding year. The *Explanatory Notes* state that this extra funding will be non-recurrent and will be used to reward Health Authorities who have made good progress with their Health Improvement Programmes. The Secretary of State may impose conditions on this additional funding, and may withdraw or reduce it if these conditions are not met.

D. Professional indemnity

Clause 8, which inserts new clause 43C into the 1977 Act, was introduced by the Government at Report Stage in the Lords. It enables the Secretary of State to make Regulations requiring NHS family health practitioners (ie GPs, and dentists, pharmacists and ophthalmologists providing NHS services in the community) to have professional indemnity cover so that, if they were to be sued for negligent treatment and found liable, they would be able to meet any award of damages made

[101] HL Deb 18 March 1999 c 913

against them. Introducing the new clause, Lord Hunt of King's Heath referred to a case in Lancashire in 1996 where a dentist was found to have injured a patient through negligent treatment, but was unable to pay the damages awarded to the patient because he had no indemnity cover.[102] It is envisaged that Regulations made under this clause may enforce the requirement to have such indemnity cover in one of two ways: either by requiring proof of cover before GPs or other family health practitioners could be added to their local Health Authority list (ie before they are allowed to practise in the NHS), or by adding the requirement to practitioners' terms of service, thus making it a disciplinary offence to ignore it.[103] The clause refers to "approved indemnity cover", rather than "indemnity insurance", reflecting the fact that many health professionals obtain such cover through membership of a "defence society", rather than through an insurance policy. The *Explanatory Notes* state that either will be acceptable, as long as the level of cover is adequate. The cover should also be "occurrence based", to ensure that it will meet claims made after the cover has lapsed (for example after a practitioner's retirement) as long as they relate to events which took place during the period of cover.

Clause 50, making parallel provision for Scotland through the insertion of a new clause 28C into the *National Health Service (Scotland) Act 1978*, was also added at the Lords Report stage.[104]

E. NHS trusts' financial regime

Clause 11 makes amendments to the *National Health Service and Community Care Act 1990*, in order to change the functions of NHS trusts as set out in their establishment orders. Formerly, NHS trust establishment orders either specified that they had to "assume responsibility … for the ownership and management of hospitals … which were previously managed or provided by Regional, District or Special Health Authorities", or to "provide and manage hospitals or other establishment or facilities" (section 5(1) of the 1990 Act). Trusts established with the first function experienced difficulties when moving to a new site or entering into a PFI agreement, as technically they were no longer managing facilities formerly managed by a District or other Health Authority. **Clause 11** of the Bill therefore replaces both functions with a new one: "to provide goods and services for the purposes of the health service". The Secretary of State is then empowered to specify a particular service (such as ambulance services) or site, if he so wishes. In order to confirm the validity of existing arrangements, the clause also provides for a degree of retrospection: where necessary, a trust establishment order may be changed as if this amendment to the 1990 Act had been in force at an earlier date. **Clause 41** makes the same changes for NHS trusts in Scotland.

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[102] HL Deb 15 March 1999 c 550
[103] HL Deb 15 March 1999 cc 550-551
[104] HL Deb 18 March 1999 cc 914ff

Clause 12 makes changes to section 5(9) of the 1990 Act to clarify beyond doubt that NHS trusts may only exercise their powers to generate income or treat private patients to the extent that there will not be significant interference with NHS obligations. While the 1990 Act included a similar provision, including references to obligations under NHS contracts and the trust's establishment order, this amendment is more widely drawn, referring to the trust's "functions". According to the *Explanatory Notes*, this would include obligations under the trust's duty of partnership with other NHS bodies and local authorities. The trust must also take account of any directions issued by the Secretary of State under section 17 of the 1977 Act; it is suggested, for example, that the Secretary of State could issue directions requiring his consent above a certain threshold of private income.

Clauses 13-15 makes changes to the way NHS trust debt is managed in England and Wales. The same is achieved for Scotland through **clauses 47-49**. When NHS trusts are established, they are assigned an "originating capital debt", equivalent to the value of the assets transferred to the new trust. Until now, this debt has been split into "interest-bearing debt" with defined interest and repayment terms, and "public dividend capital", a form of share capital on which the trust pays dividends to the Government. In practice, the dividend payments are adjusted so that trusts are required to make a 6% return on their net assets, the 6% figure being chosen on the basis of the long-term cost of borrowing to the Government. **Clause 13** now removes the concept of "interest-bearing debt" from the 1990 Act and makes the whole of a trust's originating capital public dividend capital. It also replaces the term "originating capital debt" with "originating capital". **Clause 14** then provides for existing trusts' remaining debt to be converted to public dividend capital as soon as the clause is enacted.

Clause 15 provides for other NHS trust borrowing. Currently NHS trusts are permitted to borrow commercially if this offers better value for money than borrowing from the Secretary of State (Schedule 3 of the *NHS and Community Care Act 1990*). This permission is now made subject to directions of the Secretary of State, and the *Explanatory Notes* make it clear that in future it is expected that only limited borrowing will be from anyone other than the Secretary of State.

F. Quality

Clause 16 imposes the new "duty of quality" on PCTs and NHS trusts in England and Wales. The duty is framed as a duty "to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals". The Secretary of State is given the power of extending the duty to Special Health Authorities through Regulations; the *Explanatory Notes* state that this power will be used to extend the duty to the three Special Health Authorities which manage high security psychiatric services (ie Ashworth, Rampton and Broadmoor). The same duty is imposed on Health Boards, Special Health Boards and NHS trusts in Scotland through **clause 45**. The reference to Health Boards and Special Health Boards allows for the duty to be applied to the Islands Health Board, which still directly provides services to its patients (there being no NHS trusts within its area) and the State hospital at Carstairs.

Clauses 17 to 22 and Schedule 2 make provision for the Commission for Health Improvement, whose remit will be limited to England and Wales. **Clause 17** establishes the Commission as a body corporate and the *Explanatory Notes* state that it will have the status of a quango. Further details are found in **Schedule 2**. The Secretary of State is empowered to appoint the chair and members of the Commission (apart from one member appointed by the Welsh Assembly), to make further regulations governing appointment procedures and tenure, and to set the remuneration of the chair and members of the Commission. The Commission will generally appoint its own chief executive, to be known as the Director of Health Improvement, but the Secretary of State must approve the appointment, and the first Director will be directly appointed by him. The Commission will have the power to appoint other employees, on such terms as it thinks fit. Both the Secretary of State and the Welsh Assembly are empowered to make payments to the Commission, and may make directions specifying how such funding should be used. The Commission is required to keep accounts in a form determined by the Secretary of State and supply annual accounts as soon as possible after the end of the financial year both to the Secretary of State and the Comptroller and Auditor General. Copies will then be laid before the House. A report must also be made each year to the Secretary of State on the exercise of the Commission's functions.

Clause 18 specifies the Commission's functions. These are:

- advising NHS trusts and PCTs on the arrangements they have in place for "monitoring and improving the quality of healthcare." The *Explanatory Notes* state that if necessary this "advice" could be enforced through the Secretary of State's power to issue directions to NHS trusts and PCTs;
- conducting reviews and making reports on these arrangements. The *Notes* suggest that these reviews will be on the basis of a 3-4 year rolling programme;
- carrying out investigations into the management, provision or quality of healthcare for which individual Health Authorities, NHS trusts or PCTs have responsibility. This will be triggered when concerns are expressed about the quality of healthcare provided;
- conducting reviews and making reports on the management, provision, quality or availability of, or access to, particular services, to allow for nationwide "sampling" of certain services, such as those governed by National Service Frameworks or NICE guidance;
- other functions as may be prescribed relating to the management, provision, quality or availability of, or access to, healthcare for which prescribed NHS bodies have responsibility. According to the *Explanatory Notes* this power might be exercised to extend the Commission's remit to the Special Health Authorities which manage the special hospitals.

The Secretary of State is empowered to make wide-ranging regulations governing such factors as how the Commission exercises its functions, the publication of reports and the recovery of the Commission's expenses. According to the *Notes*, the Government's

intention is that reports will be made both to the bodies involved and to the Secretary of State. On the question of the recovery of expenses, it is stated that "it is not intended that the Commission will charge individual health service bodies directly for its work from the outset. However in the longer term, the Government envisages that some of the Commission's work may be funded locally." **The provision in the original version of the Bill, that the Commission's publications should be absolute privileged as regards the law of defamation, was removed on Report. Publications will now have qualified privilege under the common law.**

Clause 19 makes provision for the Commission to obtain the information necessary to perform its functions. The Secretary of State may make Regulations, enabling persons authorised by the Commission to enter NHS premises, inspect and copy prescribed documents and to require explanations of any such documents, or of any other matters relating to the exercise of the Commission's functions. Where information is confidential (defined as "information which is held subject to a duty of confidence, and includes information contained in a health record") and relates to a living individual, then the Regulations may not make provision for the Commission to have access to it unless it has been anonymised, the individual has given their consent to its being made available or the individual cannot be traced. The only other exception to this rule is where the Commission is carrying out a special investigation as a result of concerns about the quality of healthcare in a particular institution (ie not a regular review visit). Additional safeguards in this situation are that it must be impracticable to anonymise the data, the Commission must believe there is a serious risk to the health or safety of patients, and that in view of this risk the Commission believes that the information should be made available. It is an offence, subject to a fine not exceeding level 3 on the standard scale, for anyone to obstruct the Commission in the exercise of these rights of access.

Clause 20 makes restrictions on the disclosure of information. Information which is obtained under Regulations made under clause 19 and which relates to an individual must not be disclosed during that person's lifetime except with "lawful authority". The penalty for knowingly or recklessly contravening this provision is up to two year's imprisonment or a fine, or both, if found guilty on indictment. A disclosure will be made with "lawful authority" if it is made with the individual's consent, for the purpose of facilitating the functions of the Commission or the Ombudsman, in accordance with the order of a court, in connection with the investigation of a **serious arrestable offence** (this definition being added at Third Reading to strengthen the original requirement of "investigation of any criminal offence"), in connection with criminal proceedings anywhere in the UK, or to an appropriate person where the information relates to a person likely to constitute a threat to the health and safety of others.

Clause 21 abolishes the Clinical Standards Advisory Group, whose role has been taken over by the Commission for Health Improvement.

Clause 22 was added against the Government's wish at Third Reading to give the Secretary of State the power to make Regulations extending either the duty of

quality or the powers of the Commission for Health Improvement to independent hospitals.

G. Partnership

Clauses 23 to 29cover the White Papers' proposals on partnership, both between NHS bodies and between the NHS and local authorities. Clause 23 imposes on Health Authorities, Special Health Authorities, NHS trusts, and PCTs the duty of co-operating with each other. **Following an Opposition amendment in the Lords Third Reading, it also makes particular reference to the need for co-operation where a patient needs to be referred out of their local area for specialist treatment**.

Clause 24 amends section 22 of the 1977 Act to require NHS bodies (Health Authorities, Special Health Authorities, NHS trusts and PCTs) and local authorities to co-operate with one another "to secure and advance the health and welfare of the people of England and Wales". The original requirements to co-operate, found in the 1977 Act, referred only to Health Authorities and Special Health Authorities.

Clause 25 gives Health Authorities the duty of preparing strategic plans for improving both the *health* of the people for whom they are responsible and the provision of healthcare *services* for those people. This gives statutory force to the requirement to prepare "Health Improvement Programmes" (HImps), a policy which the Government introduced in the White Papers and has since implemented through guidance. NHS trusts, PCTs and local authorities are also duty-bound to participate in the preparation and review of HImps, while the Health Authority is required to consult or seek the participation of such other persons as the Secretary of State may direct. The intention, according to the *Explanatory Notes*, is to ensure that such disparate bodies as voluntary sector organisations, local employers and local educational establishments are properly involved in the whole "HImp" process. The Secretary of State is given the power to issue directions covering such matters as the periods to be covered by the plans, their form and content, and their publication. HAs, PCTs, NHS trusts and local authorities are required to follow any such directions as may be made.

Clauses 26 and 27 amend section 28A and insert new section 28BB into the 1977 Act, in order to make it easier for health and local authorities to transfer funding from one to the other. Currently, under section 28A, Health Authorities are able in certain circumstances to transfer funding to local authorities, but no such reciprocal provision exists. **Clause 26** amends section 28A to include references to PCTs and to broaden out the definition of circumstances when funding may be transferred to include any expenditure on local authority functions which may have an effect on the health of individuals or are connected with NHS functions. **Clause 27** then inserts new section 28BB to give local authorities the reciprocal power to make payments to NHS bodies for the performance of "prescribed functions" by that body. The Secretary of State may specify such prescribed functions in Regulations, and the clause specifically allows for different provision to be made in England and Wales.

Clause 28 addresses the issue of jointly funded projects. At present there is no provision for HAs and local authorities to pool resources, despite the fact that in areas like mental health services and rehabilitation care, patients may be receiving similar services from both bodies. The clause allows the Secretary of State to approve arrangements whereby NHS bodies and local authorities set up joint funds for expenditure on such services. The Secretary of State may also approve arrangements where either the NHS body carries out local authority health-related functions on behalf of that local authority, or the local authority carries out NHS functions on behalf of an NHS body. This would, for example, allow either the NHS or a local authority to provide mental health services as a "single provider", rather than the patient receiving some services from one body and some from another. Regulations may be made under this section specifying what arrangements are permissible, in what circumstances NHS bodies and local authorities may enter into them and what approval is required. According to the *Explanatory Notes*, it is initially intended that the Secretary of State will have to approve each proposal before it may go ahead. The clause also makes clear that NHS bodies and local authorities will still remain liable for functions exercised on their behalf by the other, and existing charging arrangements will remain unaffected.

Clause 29 abolishes the Joint Consultative Committees, which were the former mechanism of consultation between the NHS, local authorities and voluntary organisations, on the grounds that their role has been taken over by the provisions in clauses 25-28.

H. Control of prices of medicines and profits

The Government has put forward proposals in **clauses 30-35** which:

- provide for the Secretary of State to make regulations and directions to ensure compliance with aspects of a negotiated voluntary pharmaceutical price regulation scheme;
- provides for powers to control the maximum price charged for any health service medicine;
- provides for a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines.

These provisions apply to England, Wales and Scotland.[105]

The *Health Bill* provides for statutory underpinning of a voluntary negotiated PPRS agreement. It includes statutory requirements for the recording, keeping and provision of information, and prohibits companies from raising the prices of medicines provided to the health service without the agreement of the Secretary of State. It makes statutory provision for repayment of unapproved increases in prices, and provides for a right of appeal.

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[105] s 61(4) extends the clauses on the control of prices of medicines and profits to Scotland

As an alternative to a voluntary scheme, the Bill also provides powers to control maximum prices of medicines supplied to the health service in other circumstances outside any voluntary agreement and provides powers for a statutory scheme for limiting prices or for limiting profits of manufacturers or suppliers of heath service medicines. These powers are only intended to be used if the Government and the ABPI are unable to agree a new voluntary scheme or to be applicable to companies not complying with a voluntary scheme.[106] It provides for enforcement by payment of penalties for contravention of the terms of either the voluntary or statutory schemes, and for a right of appeal.

Key concerns of industry in the original drafting of the Bill have been met during passage through the House of Lords, and are reflected in amendments incorporated in the current text. These amendments provide for:

- consultation with the industry body before imposing a price limitation on any health service medicine (outside a voluntary scheme - under clause 31), or before making regulations with regard to enforcement;
- a right of appeal with regard to the supply of information, the limitation of price or profit, the refusal of consent to a price increase, and the payment of any amount by way of excess profits, prices or penalties. These provisions apply to both voluntary and statutory schemes;[107]
- limitation of the provisions to the sale of medicines to the health service;[108]
- limitation of the provisions relating to control of prices, and for statutory schemes, to any company that is not currently a member of a voluntary scheme;
- costs of research and development to be considered in any decision on the reasonableness of prices;
- affirmative resolution requirement before making an Order to increase penalties.[109]

Clause 30 (powers relating to voluntary schemes) relates to powers in connection with a voluntary scheme made by agreement of the Government with the industry body[110].

It defines those companies to whom these will apply. Under subsection(2), powers relating to a voluntary scheme (with additions or modifications agreed in individual cases) apply only to those manufacturers and suppliers who have consented to the scheme **and who have not been given written notice by the Secretary of State that the scheme no longer applies to them.**

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106 Select Committee on Delegated Powers and Deregulation, *Health Bill*, 17 February 1999, HL Paper 29 1998-99, Annex: *Memorandum by the Department of Health*, para 112

107 summarised at Report Stage by Baroness Hayman: HL Deb 18 March 1999 c 861

108 *ibid*

109 Supplementary provisions under section 55(6)

110 Defined under clause 35(7) as "any body which appears to the Secretary of State appropriate to represent manufacturers and suppliers" [effectively the ABPI at present]

It sets out (subsection (3) **(4) and (5)) the correct procedure for determining that a voluntary scheme should cease to apply to a particular scheme member, including the opportunity to make representations about acts or omissions in question, and for written notification. Subsection (6) provides for a scheme member to withdraw from a voluntary scheme in a manner required by the Secretary of State.**

Clause 30 (7) read with clause 35 enables the Secretary of State by regulations or directions to require any manufacturer or supplier to record and keep information, and to provide information to the Secretary of State in connection with operation of the scheme.

Under subsection (8) read with clause 35 the Secretary of State can prohibit any manufacturer or supplier to whom a voluntary scheme applies from increasing any price of any health service medicine covered by the scheme without his approval.[111] Where this is breached, subsection (8)(b) provides for the payment of any excesses representing the increase, **so far as the increase is attributable to supplies to the health service**, to the Secretary of State within a specified period. This change excludes sales to third parties, eg shops.

The requirements under this clause could be imposed by making regulations or giving directions to a particular manufacturer or supplier (clause (35 (1)) and so the penalty provisions of clause 34 would apply. This has been called a "voluntary scheme with teeth".[112]

There is no provision for consultation written into this clause as it is already part of the process of creation of a voluntary negotiated scheme.

Clause 31 (power to control prices) would enable the Secretary of State, after consultation with the industry body, to limit prices charged by any manufacturer or supplier for the supply of any health service medicine and provide for sums in excess of those limits to be paid to him**.** Repayments are limited to supplies to the health service. Clause 31(1) allows the Secretary of State to act by making regulations or giving directions to a particular manufacturer or supplier. This clause would replace section 57 of the *NHS Act 1977* with respect to controlling the maximum prices of health service medicines. In effect this would operate as an alternative statutory scheme.

Clause 32 (statutory schemes) would provide for an alternative statutory scheme. It would enable the Secretary of State, after consultation with the industry body, by regulations or directions to make a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines. Such a statutory

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[111] "Health service medicine" means a medicinal product used to any extent for the purposes of the health service (clause 35(7))

[112] Select Committee on Delegated Powers and Deregulation, *Health Bill*, 17 February 1999, HL Paper 29 1998-99, para 17

scheme could require companies to record and keep information, and to make it available to the Secretary of State. Clause 32(6) would enable the Secretary of State to prohibit the increase of prices without his approval, and to require repayment of sums representing excess prices or profits attributable to supplies to the health service to be paid to him.

A statutory scheme may not apply to any manufacturer or supplier to whom a voluntary scheme applies.

Clause 33 (statutory schemes: supplementary) gives the Secretary of State power after consultation with the industry body to make supplementary regulations or directions necessary to establish a statutory scheme or **a price limit under clause 31**. It would provide for compulsory recording and keeping of information, and its provision to the Secretary of State.

Clause 34 (enforcement) makes provision for the Secretary of State to make regulations or directions regarding payment of penalties in connection with voluntary and statutory schemes. It provides for a maximum single penalty of £100,000, or a maximum daily penalty of £10,000. Regulations may provide for amounts payable in respect of excessive prices to be increased by up to 50%. Regulations could also make provision for payment of interest. Maximum penalties could be increased by Order **after a draft has been laid before and approved by resolution of each House of Parliament (affirmative resolution).**[113]

Provisions are included (subsection (5)) for a right of appeal against enforcement decisions. Subsection (6) and (7) define enforcement actions and decisions in this context.

A provision is included which limits application of decisions regarding enforcement to proceedings under this section. It is not intended that third parties should be able to use such decisions to seek recovery of excess prices.[114]

There is a requirement to consult with the industry body before making regulations with regard to enforcement.

Clause 35 (controls: supplementary) provides for the powers regarding voluntary and statutory schemes to be made through regulations, or, in the case of a particular manufacturer or supplier, through directions. It provides that prices and profits may only be limited to those which would be fair and reasonable in all the circumstances, **having regard to the need for medicinal products to be available for the health service on reasonable terms and the costs of research and development (subsection (5)).**

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[113] This provision is made under section 55(6)

[114] HL Deb 18 March 1999 c 861 Report stage, Baroness Hayman

This clause also provides that Section 57 and Schedule 11 of the *National Health Service Act 1977* and Section 49 and Schedule 10 of the *National Health Service (Scotland) Act 1978* (maximum prices of medical supplies) cease to have effect in relation to health service medicines.

I. Fraud

Clause 36 inserts new sections 122A,122B and 122C into the 1977 Act to make provision in England and Wales for penalties to be imposed on those who attempt to defraud the NHS, either through falsely claiming exemption from NHS charges or through falsely claiming entitlement to help such as reimbursement of travelling expenses to hospital. As originally drafted they allowed only for a criminal offence where the person, if found guilty on summary conviction, would be liable to a fine not exceeding level 4 on the standard scale. **However, Government amendments at Lords Report stage introduced the less bureaucratic system of a civil penalty whereby patients could be served with a penalty notice which would then be recoverable as a civil debt. The criminal provisions remain, but it is envisaged that they will only be used in more serious cases, for example where fraud had happened repeatedly and persistently.**[115]

Further details as to how the penalty notice system will work may be set out in Regulations but the clause places restrictions on the level of the penalty: it cannot exceed £100 or five times the level of the charge to which the fraud relates, whichever is the lower. These maxima may be changed by Order, but any such Order will be subject to the affirmative procedure. Regulations may also provide for a further penalty (not exceeding 50% of the original penalty) if the original penalty is not paid within the time required.

Clause 53 creates a similar civil penalty system in Scotland, through the introduction of new sections 99ZA and 99ZB into the 1978 Act. No provision, however, is made for the additional criminal offence found in the English clause.

Clause 37 gives the NHS Tribunal the power to disqualify fraudulent family health service practitioners from working in the NHS. This clause was also heavily redrafted at Report stage, although it was emphasised that the amendments did not change "the fundamental purpose or impact" of the clause, but rather tidied up some loopholes left by the original wording[116]. The NHS Tribunal, as currently constituted under section 46 of the 1977 Act, may ban practitioners from working in the NHS if satisfied that their remaining within the NHS is "prejudicial to the efficiency of those services". The disqualification may relate only to the Health Authority area where the practitioner is currently working, or nationwide. It may also specify only that the practitioner may not continue in their current role (eg as a "GP Principal" contracting directly with a Health

[115] HL Deb 18 March 1999 c 887
[116] HL Deb 18 March 1999 c 895

Authority) or may go wider and prevent such a GP from having any role in GP services at all.

New sections 46, 46A, 46B and 47 restate the existing functions of the NHS Tribunal, but explicitly add fraud as a reason for disqualification. New section 46C also contains a new power of "conditional disqualification", under which a practitioner would be permitted to carry on working in the NHS only if the specified conditions were met. **Extra provisions added at Lords Report stage included clarifying the "mental element" necessary for a practitioner to have committed fraud; making practitioners liable for the fraudulent activities of their employees or deputies, where they have not taken adequate steps to prevent such fraud; and including "bodies corporate" within the provisions, to ensure that ophthalmic or pharmaceutical practitioners who have been disqualified do not evade the disqualification by setting up a company and contracting again with a Health Authority**.

Clause 52 makes similar provision in Scotland, replacing sections 29 and 30 of the 1978 Act with new sections 29, 29A, 29B, 29C and 30.

J. Professional regulation

Clause 54 and **Schedule 3** together provide "Henry VIII" powers for the Secretary of State to amend the health professions' regulatory statutes by statutory instrument. These were heavily amended during the Lords stages, both to include further protections for the existing statutory bodies, and to allow for the restructuring of the regulation of nurses, health visitors and midwives, as recommended by the recent review.

Clause 54 allows Her Majesty by Order in Council to modify the regulation of pharmacists, doctors, dentists, opticians, osteopaths, chiropractors, nurses, health visitors, midwives and the professions currently covered by the *Professions Supplementary to Medicine Act 1960*. **Such modifications are only permitted if they are "necessary or expedient for the purpose of securing or improving the regulation of the profession or the services which the profession provides or to which it contributes"**. It would also allow Her Majesty by Order in Council to regulate any profession not already listed which appears "to be concerned (wholly or partly) with the physical or mental health of individuals and to require regulation in pursuance of this section". This would allow for the future regulation of currently unregulated bodies such as clinical psychologists. The clause further makes provision for the repeal of the *Professions Supplementary to Medicine Act 1960* and the *Nurses, Midwives and Health Visitors Act 1997*.

Schedule 3 sets out in further detail how the Order-making power will work, and includes a number of safeguards to ensure that the regulation of the professions remains essentially *self*-regulation. Before an Order can be made, a draft Order must first be published and persons "appearing to [the Secretary of State] to be appropriate" must be consulted **including patient representatives** (paragraph 9(1) of Schedule 3). The consultation period must last 3 months (paragraph 9(2) of Schedule 3). The draft, **together with a report about the consultation,** must be laid before Parliament and the draft must be

approved by both Houses of Parliament (clause 55(7)). An Order may not abolish any existing regulatory body (except for the two explicitly to be abolished by Clause 54); **nor may any future regulatory bodies created to replace the Council for the Professions Supplementary to Medicine or the United Kingdom Central Council for Nursing, Midwifery and Health Visiting, or to regulate new professions, be abolished by Order** (paragraph 7(1)).

Paragraph 8 of Schedule 3 specifies 4 key functions **which may only be performed by the existing regulatory bodies** (keeping the register of members admitted to practice, determining standards of education, giving advice about standards of conduct and performance, and administering procedures relating to misconduct and unfitness to practise). This last provision does not apply to the professions governed by the *Professions Supplementary to Medicine Act 1960* and the *Nurses, Midwives and Health Visitors Act 1997*, as these are to be abolished, but any future regulatory bodies to be created for these professions will have the same protection. Paragraph 7 protects other aspects of self-regulation: no Order may oblige a Regulatory Body to have a lay majority, and the professions' existing right of appeal to the Privy Council is protected, with the exception of the professions governed by the *Professions Supplementary to Medicine Act 1960*.

K. Miscellaneous provisions

Clause 38 replaces section 4 of the 1977 Act, which governs the three high security Special Hospitals, Ashworth, Broadmoor and Rampton, in order to allow NHS trusts to provide high security psychiatric services. As currently drafted, section 4 prevents the Secretary of State from delegating his duty to maintain the Special Hospitals to NHS trusts. The new section removes the specific reference to Special Hospitals, replacing it with a more general reference to "hospital accommodation and services" for patients deemed to need psychiatric services in particularly secure surroundings. As a result, NHS trusts will be able to enter into contracts to provide such services, although new section 4(3) specifies that the trust must first have received the approval of the Secretary of State.

Clause 39 regularises the current system under which the Registrar General supplies the NHS with information about births and deaths in order to update the NHS Central Register. As there is no specific statutory power under which this information may currently be transferred, the *Health Bill* has been used to provide specifically that the transfer of such information is lawful.

Clause 55 provides that any power to make Regulations or Orders under the Act must be exercised by statutory instrument. In general such instruments will be subject to the negative procedure, but a number of exceptions are made. Orders made under section 34(10) (increasing the maximum penalties payable for contravention of regulations on voluntary or statutory schemes) and section 54 (modifying the regulation of the healthcare professions) must be subject to the affirmative procedure. Where an Order would, if included within an Act of the Scottish Parliament, be within that Parliament's legislative competence, then it cannot be laid unless the Scottish Parliament passes a

resolution approving it. This would apply, for example, to Orders regulating new healthcare professions (but not to those already governed by statute, whose regulation is reserved to Westminster).

Clause 56 empowers the Secretary of State to make, by order, such consequential or transitional provisions as are necessary for giving full effect to any provisions in the Act. **Clause 57** interprets terms used in the Act and **Clause 58** brings **Schedule 4** into effect (significant provisions in Schedule 4 have been highlighted in association with earlier clauses). **Clause 59** provides for issues surrounding devolution. Any provisions within the Act which affect Scotland will be taken to be "pre-commencement enactments", even if the Bill has not actually received Royal Assent by the time devolution has taken place. The powers of the Secretary of State conferred by this Bill will therefore pass automatically to Scottish Ministers. Similarly, once the Welsh Secretary's powers in general have been transferred to the Welsh Assembly by section 44 of the *Government of Wales Act 1998*, the Welsh Assembly will gain the powers in relation to Wales which are ascribed to the "Secretary of State" in the Bill. In the provisions relating to the Commission for Health Improvement, which covers both England and Wales, some restrictions are placed on the Secretary of State: sections 18(1) and paragraphs 4-7 of Schedule 2 (which cover conferring extra functions on the Commission, together with the provisions governing membership, remuneration and the appointment of staff) may only be exercised with the consent of the Welsh Assembly if they would affect the Commission's role in Wales.

Clauses 60, 61 & 62 cover commencement, extent. and short title. Different parts of the Act may come into force at different times. Clauses 1-20, 22-29 & 36-39 apply only to England and Wales, while clauses 40-53 apply only to Scotland. Clauses 30-35 (control of prices of medicines and profits) cover England, Wales and Scotland, and clause 21 (the abolition of the Clinical Standards Advisory Group) and clauses 54-62 (regulation of the healthcare professions and supplementary provisions) apply to England, Wales, Scotland and Northern Ireland.

VIII Responses

A. General responses

The Conservatives expressed considerable opposition to the principles of the Bill in the Lords Second Reading, with Earl Howe stating:

> To the regret of all on these Benches, it is a Bill that seeks to undo much of the good resulting from the work of the previous administration … a measure that, far from providing a platform for improvement, will instead be a recipe for inflexibility, inefficiency, lack of choice and, perhaps above all, tight central control of our health service by politicians in Westminster.[117]

Indeed, Earl Howe moved a "reasoned amendment" at Second Reading regretting that "neither the definition of a Primary Care Trust nor any adequate provisions relating to the functions, powers, responsibilities and structure of such are contained in the Bill". However, at Third Reading, following considerably amendment of the Bill (including reference to the functions of Primary Care Trusts on the face of the Bill), he commented that contributions from all sides of the House "have enabled us to achieve what I hoped on Second Reading we would achieve: namely, to correct the Bill's more glaring shortcomings".[118]

The Conservatives' spokesman at Committee stage on the Scottish provisions, Lord Mackay of Drumadoon, also challenged the inclusion of any Scottish provisions within the Bill, given the imminent devolution of powers to the Scottish Parliament, pointing out:

> From my reading of the Bill, the debate on Second Reading, the White Paper and surrounding documentation, I perceive nothing urgent in the subject matter of the clauses which requires the Bill to be enacted to include Part II. The sharp political issue is that, if and when Part II becomes law, becomes part of an Act of Parliament, there may well be in position in Scotland a Scottish executive which is not composed entirely of members of the Scottish Parliament who are supporters of the present Government. It seems to me to be entirely wrong to place legislation on the statute book with no guarantee whatever that the people who will fall to bring it into effect and to implement it are full-blooded subscribers to the policy which lies behind the legislation.[119]

The Liberal Democrats were more enthusiastic about the aims of the legislation, but doubtful about the form of the Bill, especially the reliance on the use of Regulation-making powers. In the debate on the Queen's Speech, Paddy Ashdown called the

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[117] HL Deb 9 February 1999 c 114
[118] HL Deb 25 March 1999 c 1475
[119] HL Deb 1 March 1999 cc 1523-24

proposed reforms of the NHS a "vast improvement on the Tories' legacy", but claimed that the Government had "missed the chance to make the NHS more democratically accountable" and "also missed their chance for the most important restructuring of all - the integration of health and social services".[120] At Second Reading in the Lords, the Liberal Democrat spokesperson, Lord Clement-Jones, expressed particular regrets at the "skeleton" nature of the Bill:

> This Bill is one of the centrepieces of the Government's term of office. It is clearly vital in the delivery of their promises on the NHS. Yet the approach adopted for the Bill is interesting. The Government have not taken the opportunity in the legislation to adopt a collaborative and transparent style by which we feel that we can all contribute to the making of the NHS for the next 50 years: instead, they have adopted a dictatorial and opaque style for which they criticised the Conservative government over the 1990 reforms.
>
> The Bill contains unprecedented powers for the Secretary of State to determine vital matters for the health service simply through regulation. Considering the Bill is like being promised a full meal only to be given, on arrival, a voucher for consumption of the meal at a future date. As a result, we on these Benches are, sadly, dissatisfied with virtually every part of the Bill, despite recognising its good intentions.[121]

Most organisations representing professions involved in the NHS and patients have expressed a qualified welcome for the general principles of the Bill, while highlighting areas of concern throughout the Lords stages, especially as regards the level of detail found on the face of the Bill. The Royal College of Nursing "welcome[d] the ending of the internal market and endorse[d] the aim of replacing a culture of competition in the NHS with one of co-operation", while seeking clarification on a number of details.[122] The Royal Pharmaceutical Society gave a "qualified welcome",[123] while the British Medical Association stated that their "initial reaction … is one of caution, fuelled by the lack of detail in many areas such as the introduction of Primary Care Trusts".[124] The CVCP, speaking on behalf of UK universities, "welcome[d] the new framework that the *Health Bill* proposes, particularly the emphasis on partnership, quality of care, longer-term planning and improved delivery of care"[125] but highlighted areas where they believed clinical academic staff should have a clearer role. The King's Fund, an independent health charity, was also positive, "welcom[ing] the main provisions and principles of the Bill",[126] and the Association of Community Health Councils of England and Wales

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120 HC Deb 24 November 1998 c 44
121 HL Deb 9 February 1999 cc 118-19
122 Royal College of Nursing briefing for the Lords Second Reading, 9 February 1999
123 Royal Pharmaceutical Society, "Health Bill sets out framework for one-stop health shops", http://www.rpsgb.org.uk/
124 BMA press notice, 29 January 1999
125 CVCP briefing on the Lords Second Reading, 9 February 1999
126 King's Fund response to the *Health Bill,* March 1999

(ACHCEW), which represents the patient perspective, stated that it "broadly welcomes" the proposals, although it would seek to improve the arrangements for public accountability and scrutiny.[127] Particular concerns highlighted by these, and other, organisations will be discussed in section B below.

B. Specific issues

1. Abolition of GP fundholding

There was relatively little comment on the abolition of fundholding as the Bill passed through its Lords stages, perhaps because the Government's intentions in this area have been known for some time. At Committee stage in the Lords, Earl Howe for the Conservatives stated that the clause abolishing fundholding would not be directly challenged as it had been a manifesto commitment of the incoming Government.[128] One of the Government's principle reasons for the abolition of fundholding, the claim that it had created a "two-tier service", was, however, challenged in the Lords Second Reading by Earl Howe who argued that the new system would create a four-tier service, from level 1 PCGs to level 4 PCTs, with increased inequities.[129]

In Committee, Earl Howe then moved two possible amendments concerning fundholding: firstly that the abolition should be delayed by a year, and secondly that a new form of fundholding should be introduced, under which practices could apply to withdraw from a Primary Care Trust and be "direct fundholders", holding their own budgets.[130] Both ideas were firmly rejected by the Government. Concerns have also been expressed by the Conservative shadow health spokesperson, Ann Widdecombe, that fundholding has been effectively abolished through Regulations, even though the Bill has not yet passed through Parliament.[131]

2. Primary care groups and primary care trusts

(a) Management issues and bureaucracy

A number of peers at Second Reading expressed the view that the new system of primary care groups and trusts, despite Government intentions to streamline NHS bureaucracy, would actually add to the current management burden.[132] In order to make clear the costs of operating the new system, the Conservative spokesman, Earl Howe, put forward an amendment at Report stage which would require PCT management costs to be

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[127] ACHCEW, *Parliamentary Briefing: the Health Bill*, 8 February 1999
[128] HL Deb 25 February 1999 c 1246
[129] HL Deb 9 February 1999 c 116
[130] HL Deb 25 February 1999 cc 1243ff
[131] HC Deb 2 February 1999 c 710
[132] eg HL Deb 9 February 1999 c 115

published.[133] In doing so, he emphasised that he did not believe that higher management costs were inherently bad, as adequate management was crucial for the delivery of services. However, publication of management costs, using agreed definitions, would both allow comparisons to be made between PCTs and would test the Government's claim that its reforms will reduce the cost of administering the NHS by £1 billion over the lifetime of a Parliament. Baroness Cumberlege (a former health minister), supporting the amendment, quoted research showing that the "total purchasing pilots" initiated by the previous Government, which could be regarded as the predecessors of PCTs, were actually more expensive to run than GP fundholding.

In response, the Government stated that such a provision was not necessary on the face of the Bill as PCTs will be required under Directions to keep and publish accounts, and the Government intends that administrative costs will be separately identifiable. PCTs are also required under paragraph 16(2) of Schedule 1 to include in their annual reports details of the measures taken to promote economy, efficiency and effectiveness in the use of resources. However, the Government did bring forward an amendment at Third Reading which requires the Secretary of State to specify in Regulations what steps must be taken by PCTs to publicise their annual reports and accounts and any other specified documents.[134] In response to Baroness Cumberlege's point over the management costs of the total purchasing pilots, Baroness Hayman for the Government argued that these pilots certainly had higher management costs than other forms of fundholding, but this was to be expected as they were commissioning a far wider range of services.[135]

While the amendments tabled in the Lords related to the management costs of primary care trusts, primary care *groups* have also expressed concern over their management allowances as they prepared to "go live" on 1 April 1999. At a recent conference hosted by the National Association of Primary Care (NAPC),[136] the Association raised two particular concerns relating to the management of primary care groups: the very variable level of the management allowance being passed on from Health Authorities to PCGs (varying between £2.30 and £6.00 per patient, according to information received by the NAPC) and the fact that, barely 5 weeks before the reforms were due to "go live", some PCGs had not yet appointed their chief executives. While the Health Minister, John Denham, in his speech to the conference stated firmly that where PCGs were taking on "level 2" (ie purchasing) responsibilities, they should receive an appropriate amount of the management budget shared between HAs and PCGs, the experience of a number of delegates was that this was not always happening. Mr. Denham also emphasised that the Government expected Health Authorities to be fully supportive of the aspirations of the PCGs in their area and not, for example, claim that PCGs aspiring to level 2 status were "not up to it". Questions to speakers, however, suggested that a number of GP delegates

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133 HL Deb 15 March 1999 cc 505ff

134 HL Deb 25 March 1999 c 1442 & c 1468 - now found in Schedule 1 paragraph 17

135 HL Deb 15 March 1999 cc 510-11

136 *Primary Care Groups: making them happen*, 26 February 1999, QE II Conference Centre, London

were finding their Health Authorities less than supportive, especially where the local NHS trust was in deficit and the Health Authority had very little money to play with. The Health Select Committee, in its recent brief report on PCGs also raised the issue of smaller PCGs, expressing concern that they might be disadvantaged by having higher than average per capita management costs.[137]

(b) Progress from PCGs to PCTs

There was much debate at Committee stage in the Lords over how PCGs will move to PCT status.[138] Government guidance, published on 19 February, stated that it was their "assumption" that the consent of the PCG would be necessary before a decision to establish a PCT would be made, and that proposals to establish PCTs must have the support of the PCG, local community trust or Health Authority before it could progress to wider consultation.[139] As originally drafted, however, the Bill gave no veto to any specific group or profession and, in response, groups such as the British Medical Association have urged the need for the consent of the "health professionals involved with the PCG" to be essential before a PCT could be established.[140] Rhidian Morris, the chair of the National Association of Primary Care, argued at the recent NAPC conference that it was crucial that GPs should not feel forced into involvement with a PCT: the significant difference between fundholding and the current reforms was the fact that fundholding was voluntary, and hence fundholders were likely to be enthusiastic, while that enthusiasm could not be taken for granted in the development of PCTs.

A Conservative amendment, requiring the consent of the *boards* of PCGs before PCTs were established, was tabled at Report stage and accepted against the wishes of the Government.[141] While this amendment may meet the concerns of GPs, anxious not to be forced into PCTs against their will, it has been criticised by groups who already feel excluded from PCG boards, such as physiotherapists. The Chartered Society of Physiotherapy has stated that giving such a veto to GP-dominated boards goes against the principle of partnership and that it hopes that the Government will seek to reverse the amendment in the Commons.[142]

Amendments were also tabled throughout the Lords stages, attempting to clarify *who* might be consulted on the establishment of a PCT, either through writing a list of consultees into the Bill[143] or through requiring the Regulations which would specify them to be subject to the affirmative procedure.[144] Baroness Hayman resisted these proposals,

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137 Health Select Committee, *Primary Care Groups*, 14 January 1999, HC 153 1998-98, paragraph 10
138 HL Deb 25 February 1999 cc 1261ff
139 Letter from the Health Minister John Denham 19 February 1999
140 BMA *Parliamentary Brief* on primary care trusts and fundholding, 4 February 1999
141 HL Deb 15 March 1999 cc 479ff
142 CSP *Parliamentary Briefing* on House of Lords 3rd Reading
143 eg HL Deb 25 February 1999 cc 1278ff
144 HL Deb 25 March 1999 c 1427ff

arguing that the House of Lords Delegated Powers and Deregulation Committee had not made any such proposal, and that the provision for Regulations in this case were very much in line with existing NHS legislation. However, she assured the House that the Government intended to consult widely on the Regulations before they were made, and would bring forward draft Regulations as soon as possible after the Bill was enacted.[145]

(c) Functions and powers of PCTs

Throughout the Second Reading in the Lords, a great deal of concern was expressed both over the lack of information as to how PCTs will function in practice, and over the fact that so little detail was found in the Bill itself, thus leaving potentially important details to be implemented through Regulations or guidance.[146] The first point has been taken up in the health press with the *Health Service Journal* suggesting that health professionals will be both confused and frustrated by the guidance issued in February on the establishment of PCTs.[147] The second concern had been expressed earlier by the House of Lords Select Committee on Delegated Powers and Deregulation which had stated:

> The Committee draws the attention of the House to the width of the powers in this Part of the bill, and to the need to strike the appropriate balance between flexibility and an adequate level of parliamentary control. If the House is of the opinion that Parliament does not have sufficient control over the creation of Primary Care Trusts, it may wish to consider amending the bill to include a statement of the purposes and objectives of PCTs.[148]

In response, the Government brought forward an amendment at Report stage, specifying the PCT functions on the face of the Bill which are now found in clause 2.[149] Baroness Hayman described the effect of the amendment as follows:

> To paraphrase Amendment 1, it means that primary care trusts may commission or provide hospital and community health services and develop primary care by exercising some functions in relation to general medical services. We want primary care trusts, in particular, to be able to deploy cash-limited funds to improve general practice infrastructure and support practice staff costs; and provide personal medical and dental services under the National Health Service (Primary Care) Act 1997 - for example by employing GPs in the way that community trusts already do under that Act. I am assured that, as a matter of law, this will give us a comprehensive list of what a primary care trust will be.[150]

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145 HL Deb 25 March 1999 c 1430
146 eg HL Deb 9 February 1999 c 114, c 120 & c 171
147 "Guiding light", *Health Service Journal*, 4 March 1999, pp 9-11
148 Select Committee on Delegated Powers and Deregulation, *Health Bill [HL]*, 17 February 1999, HL 29 1998-99, p 3, para 15
149 HL Deb 15 March 1999 cc 474ff
150 HL Deb 15 March 1999 c 475

One particular power which has generated particular concerns among GPs is the power given to PCTs compulsorily to purchase land or property. The threat that such a power might pose to GPs who, as self-employed contractors to the NHS, own their own surgeries and have often invested substantial amounts in them, was canvassed vigorously at the NAPC conference in February. When this issue was raised in Committee by Earl Howe, Baroness Hayman stated that the Government "would not expect this [power] to be used in any way as a weapon of coercion against general practitioners or as a threat to confiscate their property"; rather the power should be used as a last resort where every other possible solution for acquiring an appropriate site had been explored. She also emphasised that the power was not new: it was a power which NHS trusts have always had under the *NHS and Community Care Act 1990*, but its use was exceedingly rare.[151]

(d) Governance of PCTs

The question of who should sit on PCT boards has been hotly debated throughout the Lords stages, especially since the decision to give GPs a majority on primary care group boards was regarded by some as a rash appeasement of the medical profession.[152] The Health Select Committee report on PCGs expressed doubts about the in-built GP majority on PCG boards and recommended that this should be reviewed to ensure boards reflected a "broader professional and community input" before PCTs are established.[153]

The guidance issued in February by John Denham[154] stated that PCT boards would have a lay majority, paralleling the current arrangements for NHS trust and Health Authority boards. However, there would also be a clinical "executive" with differing membership at level 3 or level 4: the former could have a GP majority in line with the PCG arrangements, while the latter would be expected to have a broader range of clinical input, recognising the wider responsibilities of level 4 "commissioning" PCTs.

These proposals have been criticised by a variety of groups. A spokeswoman from the NHS Confederation (which represents NHS trusts and Health Authorities) was reported as saying that "they appear to be trying to please GPs but end up not satisfying anyone."[155] Nine healthcare professional and trade union bodies (the British Dietetic Association, the Society of Chiropody and Podiatry, MSF/Community Practitioners and Health Visitors Association, the Royal College of Midwives, the College of Occupational Therapists, the British Orthoptic Society, the Chartered Society of Physiotherapy, the Society of Radiographers and the Royal College of Speech and Language Therapists) have issued a joint media statement supporting the level 4 arrangements, but expressing such firm opposition to the level 3 arrangements that they are recommending to their members that,

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[151] HL Deb 25 February 1999 cc 1320-21
[152] eg "Aggrieved GPs take a back seat in the new NHS", *Health Service Journal*, 25 February 1999, p 15
[153] Health Select Committee, *Primary Care Groups*, 14 January 1999, HC 153 1998-99, paragraph 8
[154] letter from John Denham, 19 February 1999
[155] "PCT guidance slammed as "confused", *Health Service Journal*, 25 February 1999, pp 2-3

when consulted, they should object to the establishment of *any* level 3 PCT.[156] Other comments in the health press include the proposal that PCT board members should be elected by the local population, with the role of practitioner groups such as GPs and nurses being restricted to nominating candidates,[157] while delegates at the NAPC conference suggested that many of the 170 PCGs who had expressed an interest in moving to PCT status would drop out if the governance arrangements were implemented. A more positive note has been struck by the NHS Primary Care Group Alliance whose chair argues that GPs will not be disempowered by the existence of a lay board, as that lay board will in fact be more accountable to the GPs and other professionals within the PCT than the Health Authority Board will be to PCGs.[158] One speaker at the NAPC conference, David Colin-Thome, argued similarly that "power" and "majority" are not synonyms and that it should be perfectly possible for board members to influence policy without being in a majority; ideally, board members should act as in a corporate manner, not as representatives of narrow interests.

A variety of amendments to these governance arrangements were proposed during the Lords stages: these included requiring a clinical majority on PCT boards,[159] ensuring the input of "key partners" on the board[160], and ensuring the participation of particular parts of the local population such as older people.[161] While the Government strongly resisted any amendments which would change the structure of the PCT boards, it promised at Committee stage that it would bring forward an amendment to ensure that PCTs took adequate professional advice when making commissioning decisions.[162] This was done at Third Reading by requiring both Health Authorities and PCTs to ensure that they receive advice "from persons with professional expertise relating to the physical or mental health of individuals".[163] Speaking to the amendment, Baroness Hayman emphasised that this should encourage PCTs to go much wider than their boards and engage with the "broad mass" of GPs and community health professionals. Examples given of those who might provide advice included the professions allied to medicine, other family health professions, clinicians working in the hospital sector and people working in NHS education and research.

Further amendments tabled at Committee and Report by Earl Howe concerned public access to PCT meetings.[164] While the provisions of the Bill, as currently drafted, would bring PCTs within the *Public Bodies (Admission to Meetings) Act 1960*, Earl Howe argued that this did not give sufficient protection against boards arbitrarily deciding to

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156 Media statement from nine NHS healthcare professional and trade union bodies, 8 March 1999
157 "Finding poll position", *Health Service Journal*, 11 March 1999, pp 24-25
158 Letter to the *Health Service Journal*, 18 March 1999, p 18
159 Conservative amendment at Committee stage: HL Deb 25 February 1999 cc 1303-4
160 Liberal Democart amendment at Report stage: HL Deb 15 March 1999 cc 497ff
161 Liberal Democrat amendment at Committee stage: HL Deb 25 February 1999 cc 1300ff
162 HL Deb 25 February 1999 c 1291
163 HL Deb 25 March 1999 c 1442 & 1471 - now found in Schedule 4, paragraph 7
164 HL Deb 1 March 1999 cc 1465ff & HL Deb 15 March 1999 cc 597ff

exclude the public on the grounds that the business to be discussed was confidential. His amendment at Report stage would have required PCTs to allow public access (including to committee meetings) except where private session was specifically allowed for by Regulations. Baroness Hayman, however, was not convinced that this provided better protection than existing provisions. She also drew a distinction between the work local authorities delegate to committees and the use of committees in the NHS, and emphasised that existing NHS guidance would allow for members of the public to be invited to attend committee meetings.

3. Levelling up or levelling down

The concern that the shift from GP fundholding to PCGs might lead to a "levelling down" of services which GP fundholders had succeeded in making more readily available to their patients (such as physiotherapy or consultant out-patient clinics in GP surgeries rather than hospital) has been raised in a number of different quarters. The Department of Health has stated in its guidance to the NHS[165] that PCGs should ensure that where GP fundholders have secured improvements such as these in services, the aim should be to make them available to all patients within the PCG, thus "levelling up" services to the best available in the local area. However, it has been suggested that this aim is not being realised in practice: in their recent conference, the National Association of Primary Care stated that they were receiving reports of some in-house services being closed because of local pressures on funding. In response, at the same conference, the Health Minister John Denham stated firmly that levelling up *should* be happening, and that it should be given priority in primary care investment plans. He also emphasised that the whole process should be seen as a long-term enterprise, not just as a one-year exercise, with the implication that if services couldn't immediately be levelled up, the longer-term aim should certainly be to ensure this happens.

4. Incentives

Considerable concern was expressed at the NAPC conference that the shift from fundholding to PCGs and the shift to block contracts under the new Service Level Agreements between Health Authorities/PCGs and NHS trusts have reduced the incentives currently in place to force improvements in quality in secondary care. Similar concerns were expressed during the Lords stages of the Bill. Baroness Hayman, in the Lords Second Reading, responded to these anxieties by stating that "shopping around" between hospitals was "not the way to drive up standards within the NHS" and that "issues of co-operation and collaboration are what actually deliver in terms of quality for patients and in terms of cost-effectiveness".[166]

Similarly, at the NAPC conference, Dr. David Colin-Thome, a former fundholder now working for the North West NHS Regional Office, argued that the published information

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[165] Dept of Health circular 1998/228, 8 December 1998, para 40
[166] HL Deb 9 February 1999 c 184

on the costs of "healthcare resource groups" (ie the costs of broadly similar operations) should enable PCGs to negotiate with trusts whose costs are above average. Other suggestions included the possibility of negotiating with NHS trusts (if necessary through arbitration) by agreeing service standards with penalties built in if they are not met, and the use of the health improvement programme (to which all PCGs and trusts must be signed up) as a further means for agreeing service changes.

The issue of incentives and accountability between GP practices *within* PCGs has also been raised. Given that there is no hierarchy, other than a Board, within PCGs, it seems possible that individual practices or GPs might simply ignore PCG policy, for example on prescribing. The reverse situation could arise where one practice or GP within a PCG felt that there were few or no incentives to improve cost-effectiveness of referrals or prescribing, if other practices failed to follow suit and the practice generating the savings made no direct gain from them. Possible solutions suggested by speakers at the NAPC conference included developing a more sophisticated idea of "performance management" with two way accountability between practices and the Board, rather than a more traditional top-down-only model. On the issue of prescribing, proposals included having pharmacist either on the Board or at least available for advice, so that GPs' prescribing policies could be scrutinised independently. Those with non-typical prescribing patterns might feel less defensive if queried by a pharmacist rather than by fellow GPs; it is also quite possible that a pharmacist might find that more expensive prescribing was not necessarily a fault, but rather that other GPs within the PCG were under-prescribing in particular areas.

In response to these concerns, Baroness Hayman emphasised in Committee that practices would have indicative budgets with the general PCT budget, and would be able to keep 50% of any savings achieved against that indicative budget, even if the PCT as a whole overspends.[167]

5. Funding and unified budgets

The creation of unified budgets is arguably one of the most significant changes introduced by the *Health Bill*, with the potential it offers for removing the perverse incentives inherent in separate funding streams, but at the same time the concern it has generated that prescribing costs will come within a cash-limited budget for the first time and that GPs might end up being forced into taking "rationing" decisions. Reflecting these points, speakers at the NAPC conference spoke both of the "opportunities" and the "threats" of the new unified budgets. The clear benefit was identified as the possible improvements clinicians will be able to make to patient care from being allowed to vire between budgets: for example, it will be easier to justify prescribing expensive drugs or developing more comprehensive community services if the financial benefits of avoiding hospital admission can be offset against them. "Threats" identified by the conference

[167] HL Deb 25 February 1999 c 1259; also outlined in Department of Health circular 1999/228

speakers included the very existence of cash limits, with no Health Authority safety net (unlike fundholders, where Health Authorities met excess costs of particularly expensive patients), the fact that inflation in drug costs was likely to be higher than NHS inflation overall, and the dangers of conflicts of interest: separating out "practice self-interest" from clinical need. The way budgets have been set for the first year of PCGs was raised as a particular issue, because of the danger of the use of historical spending patterns penalising efficient practices. One conference delegate stated that their PCG boards was considering resigning en masse over their budget allocation.

Concern has also been expressed, both in the health press and by organisations such as the BMA, as to the effect of unified budgets on the individual elements within it: for example, whether vulnerable areas of expenditure such as GP infrastructure might end up getting squeezed.[168] Initial concerns that the inclusion of prescribing costs within a cash-limit might lead to patients being denied the drugs they needed appear to have been allayed[169] but there is on-going discussion in the health press as to how controlling prescribing while leaving clinical freedom intact will work in practice.[170]

Some of these issues were raised in Committee and at Report stage in the Lords. In Committee, Baroness Hayman emphasised again that there would be no cash limits on individual *GPs:* the cash limit would apply to the PCT as a whole, not to GP practices. Temporary financial assistance would also be available from Health Authorities if PCTs as a whole overspent, in the same way as the regions are currently able to "broker" between under-spending and over-spending Health Authorities in their areas.[171] At Report she also stated that the NHS budgets for the next three years had taken full account of the growth in prescribing costs (currently running at 8% per annum) and that peer review and pharmacy advice can reduce prescribing costs without lowering the quality of prescribing.[172] Similarly, the Government said at Report stage that in Scotland if healthcare co-operatives were to run out of funding for prescribing, they could turn to the PCT for assistance, and that any prescribing savings generated within a PCT would be retained within the PCT and not absorbed back into Health Board expenditure.[173] On the issue of the funding of GP infrastructure, the Government had already promised that current levels of spending will be ring-fenced within PCG budgets, and at Report stage it confirmed that this would also apply to PCTs[174]. The same reassurance was given regarding Scotland.[175]

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[168] BMA notes on Lords Report stage, *Allocation of funds to PCTs: protecting the level of investment in primary care*, March 1999
[169] eg BMA, *Parliamentary Brief*, 18 May 1999
[170] eg "Group therapy", *Health Service Journal*, 4 March 1999, Special Report, p 1
[171] HL Deb 25 February 1999 c 1322-4
[172] HL Deb 15 March 1999 cc 522-3
[173] HL Deb 18 March 1999 c 914
[174] HL Deb 15 March 1999 cc 513 ff
[175] HL Deb 18 March 1999 c 913

Complex amendments were tabled by the Government at both Report and Third Reading in order to "tidy up" some of the financial provisions. Amendments made at Report enabled the costs of drugs to be attributed to the Health Authority or PCT where they were *prescribed*, whereas the provisions as originally drafted would have led to Health Authorities and PCTs being charged for drugs *dispensed* in their area.[176] Parallel amendments were also made to the Scottish clauses at Report.[177] At Third Reading, the Government then brought forward complete rewordings of sections 43A and 43B of the *National Health Service Act 1977* and sections 28A and 28B of the *National Health Service (Scotland) Act 1978*, which had never been enacted. This would "legitimise current practice" in the way the remuneration of family health services practitioners is determined and to ensure that it would be possible to devolve to PCTs the power to allocate GPs' cash-limited payments (eg infrastructure and staff costs).[178] These amendments were primarily technical and unopposed, but the debate on them elicited the reassurance that PCTs in future would have no more powers than Health Authorities currently have to vary the terms of the "Red Book" under which GPs are paid. It was also clarified that after devolution it was quite possible that different fees and allowances for GPs might emerge in Scotland from those agreed in England.

6. Quality of care

(a) The duty of quality

The creation of a "duty of quality" was not challenged during Lords stages, but it was proposed in Committee by the Liberal Democrats that it should be applied not only to NHS trusts and PCTs but to Health Authorities and PCGs as well.[179] The Government view, however, was that it was only appropriate for the duty to apply to "providers" of care, and that PCGs and Health Authorities will be adequately covered through the obligation to implement clinical governance. A similar point was raised by the Conservatives in connection with Scotland, with an amendment tabled to include local health care co-operatives within the duty of quality.[180] In response, the Government minister pointed out that the aim of the amendment had already been met: co-operatives are non-statutory bodies within the umbrella of a PCT, and hence the duty of quality imposed on the PCT would also apply to the work performed by members of the co-operatives.

At Report stage, Earl Howe raised the issue of the *cost* that the duty of quality would impose on the NHS, tabling an amendment which would require NHS trusts and PCTs to identify clearly the resources which they would be using to fulfil their duty of quality.[181]

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[176] 15 March 1999 cc 515ff & cc 528ff
[177] HL Deb 18 March 1999 cc 912ff
[178] HL Deb 25 March 1999 cc 1434ff & cc 1462ff
[179] HL Deb 25 February 1999 cc 1351-2
[180] HL Deb 1 March 1999 cc1537-9
[181] HL Deb 15 March 1999 cc 575ff

This was resisted by Baroness Hayman on the grounds that trusts do not themselves have the responsibility for determining the total amount of resources available to them. Earl Howe, on the other hand, argued that although NHS trusts and PCTs cannot determine their own budgets, they must still address the issue of how they are going to fund their own quality control systems.

The definition of "healthcare" used in clause 16 imposing the duty of quality was also a subject of some concern, with both Liberal Democrats and Conservatives tabling amendments to broaden the definition to clarify that services such as nursing care, health promotion activities and services connected with childbirth were covered.[182] Baroness Hayman, however, maintained throughout that the amplification of the definition was unnecessary, and that all the services discussed would be covered by the provision as originally drafted. She also emphasised at Third Reading that the requirements placed on NHS trusts and PCTs to implement "clinical governance" would cover organisational issues such as the treatment of complaints, so that it was hard to see "how any areas of clinically-related activity could in practice escape its impact."[183]

(b) Commission for Health Improvement

The question of how the Commission for Health Improvement should be funded was the source of some debate in the Lords, with the Liberal Democrats tabling amendments in Committee and at Report to prevent the Commission from being able to recoup their costs from the bodies being inspected.[184] It was argued by Liberal Democrat peers that allowing the Commission to charge would involve taking money away from patient care, and that claiming the funding would actually come from NHS trusts' administration budgets was misleading, as funding would still need to be allocated from other budgets into administration in order to meet the costs. While the Liberal Democrats recognised that "top-slicing" allocations to Health Authorities and PCTs in order to fund the Commission centrally would also take money from patient care, it was still argued that this was preferable as it was more transparent. In response, the Government stated that the Commission would initially be financed centrally, but that they saw merit in moving towards a system where more of its work could be financed locally. Baroness Hayman also emphasised that the Bill provided an *enabling* power, and that the extent of local charging could be determined later, through Regulations. In particular, she accepted that there was a distinction between regular "review" work and cases where the Commission is brought in to examine a potential problem, and emphasised that the Government would certainly hesitate to impose extra high costs on an organisation which was already experiencing severe difficulties.

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[182] eg HL Deb 1 March 1999 cc 1383ff & HL Deb 15 March 1999 cc 579ff
[183] HL Deb 25 March 1999 c 1457
[184] HL Deb 1 March 1999 cc 1417ff & HL Deb 15 March 1999 cc 586ff

As originally drafted, neither the Commission for Health Improvement, nor the duty of quality, applied to independent hospitals. An amendment tabled at Report by the Conservatives (supported by the Liberal Democrats) proposed that the Secretary of State should have the power, though not the duty, to make Regulations extending both the Commission's remit and the duty of quality to the private acute hospital sector.[185] The Government resisted the amendment, on the grounds both that the Commons Health Select Committee was currently looking at the issue of the regulation of the private health sector, and that the Government was planning on issuing a consultation document soon in this area. It was therefore felt that it was precipitate to legislate within the *Health Bill* when a quite different approach might be decided upon. Baroness Hayman also emphasised that NHS patients being treated in private hospitals (for example through waiting list initiatives) would be covered both by the Commission and the duty of quality, in that the Health Authority would have to be satisfied with quality standards and ensure that the Commission would have the necessary access before agreeing contracts with private hospitals. Despite Baroness Hayman's reassurances, however, the amendment was accepted on Division.[186] A parallel amendment for Scotland was withdrawn, on the basis that it was defectively drafted and that the Government promised to look at the matter again.[187]

The issue of the privilege of the Commission's reports was also subject to amendment during the Lords stages, with the Government bringing forward an amendment at Report, following concerns at Committee that it was excessive to give the Commission *absolute* privilege from defamation.[188] Its reports will now have qualified privilege at common law.

How the Commission will carry out its work and what standards it will use to judge the bodies it is inspecting generated a number of amendments. In particular there was concern from the Liberal Democrats that the Commission should be required to use the standards issued by NICE and through the national service frameworks, both to ensure that these standards had "teeth", and to put an end to "post-code prescribing".[189] The Conservatives, on the other hand, argued that other guidelines, such as those produced by the Royal Colleges, should not be forgotten.[190] Baroness Hayman for the Government expressed sympathy with the aims of the amendments, but was anxious that the Government should not be too heavy-handed in directing the Commission's work. The membership of the Commission was also discussed, with the Liberal Democrats seeking to ensure that at least 3 members should be lay people, including representation from older sections of the community.[191] Baroness Hayman stated that the Government shared

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185 HL Deb 18 March 1999 cc 830ff
186 HL Deb 18 March 1999 c 846
187 HL Deb 18 March 1999 c 901
188 HL Deb 15 March 1999 cc 589ff
189 HL Deb 15 March 1999 cc 582ff
190 HL Deb 1 March 1999 cc 1380ff
191 HL Deb 1 March 1999 cc 1406ff

the view that there should be a balance of membership and that lay members would certainly be included among those appointed. She did not, however, feel that it was necessary to include a list on the face of the Bill.

A number of concerns were raised at all stages about the Commission's access to confidential information and about the constraints on disclosure. Amendments tabled at Report stage highlighted anxieties that the confidentiality requirements did not sufficiently protect deceased patients, or those who could not be traced.[192] In response, Baroness Hayman stated that the Commission would mainly working with anonymised data, but that there might be exceptional cases where it was necessary to see the records of deceased patients or those who could not be traced, and hence it was necessary to make some provision for this since by definition their consent could not be sought. Moreover, she argued that while there is an established *ethical* obligation to maintain confidentiality after death (for example through GMC codes), it is not clear that the legal obligation persists beyond death, in which case such data would not come under the provisions governing "confidential information" at all. However, she offered peers a number of reassurances: that the Department intended to draw up guidance on the circumstances when the Commission should be able to obtain confidential information about the deceased, and that this guidance could be made obligatory through clause 15(4) (now clauses 18(4)); that it was expected that only clinical members of Commission teams would have access to confidential patient information; and all Commission staff would have duty of confidentiality written into their contracts.

The promise of guidance was reiterated at Third Reading, with the possibility that a provision relating to such guidance might be included in the Bill in the Commons stages. Future amendments were also promised to tighten up the provisions on confidentiality in the Bill, in an attempt to avoid the danger of the anonymised data used by the Commission leading to an individual being identifiable if combined with other information.[193] Finally, a Government amendment was accepted, tightening up the original provisions governing when confidentiality could be lawfully breached in connection with the investigation of criminal offences. Initially the Bill referred simply to "criminal proceedings" in the UK, but following the amendment this has been limited to "serious arrestable offences".[194]

7. Equality of access to services

A number of amendments were tabled throughout the Lords stages on the issue of equality of access to services, drafted widely enough to refer both to discrimination on the grounds of factors such as race, age or disability, and to so-called "post-code" treatment,

[192] HL Deb 15 March 1999 cc 590ff
[193] HL Deb 25 March 1999 cc 1458ff
[194] HL Deb 25 March 1999 cc 1457ff

where access to services varies significantly from area to area.[195] At Report the Government emphasised the role it believes both NICE and National Service Frameworks will play in making services more even across the country, but promised to consider whether it would be possible to include some form of commitment to equal opportunities on the face of the Bill.[196] At Third Reading, Baroness Hayman stated that the Government was still considering whether such a provision was possible and that it seemed likely that the issue would be discussed during Commons stages. She also emphasised that it was essential to consider the issue of equal opportunities in a coherent rather than piecemeal way, especially given the conclusions of the Macpherson report on the Stephen Lawrence case, and that the Government certainly embraced the *spirit* of the amendments.[197] One speaker at the NAPC conference suggested that the real challenge was not so much variation around the country as regards access to services, but rather variations *within* PCGs and that this was an issue which PCGs must give priority to addressing. It was suggested by other speakers that the creation of unified budgets, which would enable GPs to think on the basis of a whole population, not just a single patient, would assist in this process.

One particular issue brought up at Report and then again at Third Reading by the Liberal Democrats was the question of patients' access to highly specialised services which may be available at only a few centres in the country.[198] Lord Hunt for the Government sought to reassure the House that the arrangements for planning both the commissioning of specialised services (through regionally commissioned services to which the patients of all PCTs and Health Authorities within the region will have access) and for dealing with the one-off situations where a patient is treated outside normal arrangements (for example where they fall ill away from home) were adequate.[199] However, despite these reassurances, the House divided, and an amendment requiring the Secretary of State's directions to Health Authorities and PCTs to ensure that patients could be referred outside their area for specialist treatment, was accepted. A matching amendment, adding the same specific reference to out of area referrals to the duty of partnership between the various NHS bodies, was agreed without a division.[200]

8. Health improvement programmes

Both at Committee and Report stage, the Liberal Democrats proposed that there should be a requirement to consult "relevant voluntary and community organisations" or "key partners" before drafting health improvement programmes.[201] While sympathising with

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[195] eg in Committee at HL Deb 25 February 1999 cc 1291ff & at Report at HL Deb 15 March 1999 cc 492ff
[196] HL Deb 15 March 1999 cc 495-96
[197] HL Deb 25 March 1999 cc 1432-33
[198] HL Deb 15 March cc 556ff & HL Deb 25 March 1999 cc 1444ff
[199] HL Deb 25 March 1999 cc 1449-1454
[200] HL Deb 25 March 1999 c 1459
[201] HL Deb 1 March 1999 cc 1479ff & HL Deb 18 March 1999 cc 852ff

the aim of the amendment, Lord Hunt expressed doubt that writing such a requirement on the face of the Bill was the best approach, especially given the problems in defining "key partners" without having a "shopping list" of organisations listed on the Bill. However, he stated that the Government intended to carry out research on the implementation of health improvement programmes and would use such research to spread best practice. He also emphasised that the Secretary of State had power to issue directions to Health Authorities on health improvement programmes and would not hesitate to use them if they were not involving local partners properly.[202]

At Second Reading in the Lords, one of the general comments made about the Bill was that it was unclear how the new structures to be created would help deal with the sort of inequalities in health and healthcare caused by poverty which had been highlighted by the Black and Acheson Reports.[203] One answer was offered to this question at Report stage by Lord Hunt of King's Heath, who argued that the very concept of health improvement programmes, together with the provisions in clause 24 (now clause 28) allowing for shared finance between the NHS and local authority health-related functions, would help tackle the "root causes" of ill health.[204]

In Committee, the Conservative spokesperson, Earl Howe, expressed concern that the new provision allowing payments for "past performance" might allow political meddling with priorities, and drew comparisons with centrally funded initiatives such as the waiting list initiatives.[205] In response, Baroness Hayman assured the Committee that the funding would be used to reward progress against *locally* set targets in the health improvement programme, and that there would be no place for political interference.

9. Joint working

Earl Howe for the Conservatives expressed some enthusiasm for the provisions in clause 28 under which Health Authorities and local authorities would be able to have joint budgets or alternatively devolve funding to enable the other to provide a particular service.[206] However, he did express concerns that the reference to "local authorities" rather than specifically to social services departments might be rather too wide: so many of the functions of local authorities could be related to health (for example damp in a school classroom) that there was a danger that NHS patient services could lose out. His second concern was that of the accountability of funding, once it was in a joint "pool". Lord Hunt for the Government, however, felt it was important to have a flexible approach to joint funding, and that restricting the provisions to social services, ignoring the demands of housing and education for example, would be too restrictive. He also assured

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[202] HL Deb 18 March 1999 c 853
[203] HL Deb 9 February 1999 cc 146-7
[204] HL Deb 18 March 1999 c 856
[205] HL Deb 25 February 1999 cc 1340ff
[206] HL Deb 18 March 1999 c 854

the House that the audit arrangements for the pooled funding would be no less rigorous than at present.[207]

In line with comments made on the Queen's Speech by Paddy Ashdown, the Liberal Democrats put forward an amendment in Committee under which, once PCTs were up and running, local authorities should take over Health Authority functions altogether.[208] The idea received short shift from Baroness Hayman who replied that "that is quite simply not the Government's policy for the health service".

Baroness Pitkeathley (formerly of the Carers' National Association) moved an amendment at Report which would *require* Health Authorities to help local authorities with community care assessments if asked to do so.[209] Again, the Government sympathised with the aim, but felt that there were better ways of improving such co-operation, including through guidance and ultimately, if necessary, through the Secretary of State's powers of direction.

The role of voluntary organisations was raised by the Liberal Democrats in Committee, who proposed that the duty of partnership set out in clause 24 should also apply to the voluntary sector.[210] While agreeing with the aim of the amendment, to ensure that voluntary sector groups are properly involved at local level, Lord Hunt stated that it would be quite inappropriate to place a statutory duty on non-statutory and often informal organisations. Instead, he argued that "the onus has to be on the NHS to reach out to such bodies, inviting their participation in planning and delivering improvements in local services and the health of the local community". The position of voluntary organisations was raised again by the Liberal Democrats in connection with the abolition of the Joint Consultative Committees.[211] It was argued that the abolition of these committees, on which voluntary organisations have 3 places, would reduce their involvement in the planning of local health and social services. In response, Lord Hunt stated that retaining JCCs, once the alternative approach of health improvement programmes was in place, would involve unnecessary bureaucracy and that voluntary organisations would have a full part to play in the new arrangements.

One final concern on the practical implementation of joint working was raised in Committee stage: whether there was any danger that "health" services being provided by local authorities on behalf of the NHS might be means-tested in the same way as local authority services.[212] Lord Hunt responded very clearly that no such charge could be levied.

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[207] HL Deb 18 March 1999 c 857
[208] HL 25 February 1999 cc 1296ff
[209] HL Deb 18 March 1999 cc 848ff
[210] HL Deb 1 March 1999 cc 1468ff
[211] HL Deb 1 March 1999 cc 1488ff
[212] HL Deb 1 March 1999 cc 1486ff

10. Control of prices of medicines and profits

Issues raised have focused on

- Increased regulation of the pharmaceutical industry, and implications for research and development
- The degree of delegation of power to the Secretary of State
- Boundaries of voluntary and statutory schemes
- Limitation of provisions to medicines supplied to the NHS
- Consultation
- Appeal
- Transparency

In the Bill's passage through the House of Lords peers expressed concerns that provisions should be limited to the supply of health service medicines to the health service only, and that a statutory scheme should not be imposed on companies complying with a negotiated voluntary scheme. It was suggested that that the Henry VIII powers of the Secretary of State to make Orders to increase penalties should be made subject to affirmative procedure: a requirement to go through both Houses would provide an opportunity for Parliamentary scrutiny. Lack of provision on the face of the Bill for consultation with industry, and for arbitration in the case of disputes was also raised.

Most of these specific items have been met at least in part during passage through the House of Lords.

However, Earl Howe, for the Conservative Opposition, opposed provisions for statutory schemes[213] (clauses 31 and 32) altogether, arguing that this provision would, even as a reserve power, create an unfriendly business environment. On Second Reading, he stated that the proposals for the PPRS are "wrong-headed and excessive":

> The theme continues in the Government's proposals for the pharmaceutical price regulation system, where they have arrogated [abrogated] to themselves sweeping powers to bring the current voluntary scheme to an end and to control the price of any drug at will. Lower medicine prices are appealing but too much of that will kill the golden goose. The Government say that they will not use the powers widely but if that is done, the policy is bound to lead sooner or later to the withdrawal of products from the UK market and damage to the research capacity of the British pharmaceutical industry. The consequence will be that new products will take much longer to reach British patients. That cannot be right. The Bill's provisions for the PPRS are wrong-headed and excessive. [214]

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[213] HL Deb 1 March 1999 c 1506

[214] HL Deb 9 February 1999 c 118 (Second reading)

Amendments to remove provisions for statutory schemes[215] and proposals to reduce the levels of penalties by 50%[216] were both rejected by the Government.

Liberal Democrat peers took the view that the voluntary PPRS has been beneficial in building a strong industry, but the current scheme has its limitations in terms of incentives to keep costs down, and is a secretive process. However, Baroness Sharp of Guildford stated their opposition to a hybrid scheme:

> We would be ill-advised therefore to throw away a scheme which, to my mind, has benefited the industry so substantially. But that said, there are limitations. The noble Lord, Lord Ewing, emphasised the fact that their profits are considerable and there are occasions when the industry has been known to overcharge. I do not believe the scheme provides enough incentives to keep costs down and the whole process is much too secretive. It should be, within the limits of commercial confidentiality, much more open and above board. But having said that, it is important that we do not throw the baby out with the bath water. We on these Benches would favour the retention of a voluntary scheme, if possible. We do not like the idea of a hybrid scheme, half voluntary and half statutory. If a voluntary scheme cannot be negotiated, we feel that there should be a statutory scheme.[217]

An amendment tabled which opposed provisions for enforcement of a voluntary scheme was rejected by the Government.

Liberal Democrat peers raised the issue of a potential conflict of interest in the dual role of the Department of Health as purchaser and regulator. Baroness Sharp of Guildford proposed that the Department of Trade and Industry should be given responsibility for a statutory scheme, as representing industrial policy. This was supported by Lord Howe, but rejected on division of the House.[218] Lord Clement Jones further proposed that under any statutory scheme there should be a statutory duty to consult the National Institute of Clinical Excellence before setting prices.[219] This was also rejected by Government.

The issue of transparency and audit was raised by several peers. Lord Desai proposed an amendment requiring that criteria should be set out for confidential information. Lord Lucas proposed disclosure of repayments of excess profits. A proposal was also made for requirement of an annual report in the case of statutory schemes. These measures were rejected by the Government on the grounds that they might generate conflict with industry and that confidence in confidentiality is essential to the smooth running of the schemes.[220]

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[215] HL Deb 18 March c 869 (Report stage)
[216] HL Deb 18 March 1999 cc 879-881 (Report stage)
[217] HL Deb 9 February 1999 c 177
[218] HL Deb 1 March 1999 cc 1509-11 (Committee stage)
[219] HL Deb 9 February 1999 c 122
[220] HL Deb 1 March 1999 c 1508 (Committee stage)

(a) Select Committee on Delegated Powers and Deregulation

The Select Committee on Delegated Powers and Deregulation raised concerns about the width of powers proposed in the original draft of the Bill, in the context of the "particularly sensitive areas of control of prices and profits and the disclosure of information".[221] The report of the Committee states:

> The Secretary of State has to strike a difficult and indeed sensitive balance between protecting the interests of the service with those of the manufacturers. In any event, as currently drafted the bill gives the Secretary of State the final say in any disagreement between the Department and the industry.[222]

The Committee raised three major issues:

- **Appeals**: the Committee invited the House to consider amending the Bill to make provision for an appeal against a decision by the Secretary of State regarding the control of prices or profits, or the disclosure of information, to an independent tribunal (either on the face of the Bill or by requiring provision for an appeal in the regulations), "in a process which is speedy and as open as commercial confidentiality allows."

- **Application beyond the NHS**: the Select Committee commented that the clauses on prices and profits were, as originally drafted, not limited to supply to the NHS but appeared to cover supply to customers in shops, or indeed, to supply for the export trade.

- **Affirmative procedure for financial penalties**: in the original draft the clause on enforcement provided for maximum penalties for contravention of regulations or directions under the voluntary and statutory schemes to be increased by order. The Committee suggested consideration be given to an amendment making these powers subject to affirmative procedure.

All these concerns have been addressed in the Bill as it arrives in the Commons.

The Select Committee also commented that the clauses on prices and profits do not appear to exclude manufacturers or suppliers abroad who provide medicines for use in the UK. This is necessary to maintain a 'level playing field' for suppliers in this country,[223] and remains unchanged. The Department of Health has commented on compatibility with European Community law (see section on European Community below).

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[221] Select Committee on Delegated Powers and Deregulation, *Health Bill*, 17 February 1999, HL 29 1998-99, para 21

[222] ibid

[223] Department of Health personal communication, 1 April 1999

(b) The pharmaceutical industry

The ABPI has raised several key areas of concern relating to the details of the Bill,[224] some mirroring the concerns of the Select Committee on Delegated Powers and Deregulation (above):

- **Boundaries between voluntary and statutory schemes**. The Government has stated that it is committed to renegotiating the PPRS, and its intention is that the new powers will not significantly affect those companies committed to complying with the voluntary agreement, but they will ensure compliance from any other companies.[225] The Bill as originally drafted did not mention that these are reserve powers. This was raised by industry:

  > …The pharmaceutical industry has no objection to the Bill including provisions for penalties to give "teeth" to the obligations which companies undertake under the terms of the voluntary PPRS. But it is essential that any companies who comply with such a voluntary scheme (clause 26) should be expressly exempt from Clauses 27 (price control) and 28 (the statutory scheme).[226]

Amendments to this effect were tabled by peers, and the principle accepted by the Government.

- **Limitation of the provisions to medicines supplied to the NHS**. The scope of the powers contained in the clauses relating to prices and profits as initially drafted would not limit the exercise of powers to medicines supplied to the NHS. If the medicines are sold to the NHS powers also would extend to prices charged to third parties.

Earl Howe introduced an amendment to limit the provisions of clauses relating to prices and profits to supply of health service medicines to the health service. This was accepted in principle by the Government, and amendments passed to provide this limitation on the face of the Bill. Provisions were included to limit the recovery of excess prices to sales to the NHS. Third parties will not be able to claim return of excess prices under the Bill.

- **Consultations and supply of information**. The drafting of the Bill as it arrived in the Lords drew very wide powers regarding the supply of information. Industry looked to see the inclusion of consultation before the setting of information requirements of any voluntary scheme, and to restrict information obligations to those contained within the scheme itself. Similarly, the industry was concerned that there should be a requirement to consult before exercising the powers to make regulations

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[224] Association of the British Pharmaceutical Industry briefing on the Health Bill, 24 February 1999
[225] Baroness Hayman HL Deb 9 Feb 1999 c 113
[226] Association of the British Pharmaceutical Industry briefing on the Health Bill, 24 February 1999

in the clause relating to enforcement, especially since these powers allow for increasing the level of penalties.

The Government in the Lords recognised that consultation with industry over details relating to sales of medicines to the NHS would be proper and introduced a Government amendment to require consultation with the industry body in the setting of maximum prices outside a voluntary scheme, and before making a statutory scheme.[227]

Amendments tabled by Lord Howe to incorporate the requirement for written consent of manufacturers and suppliers to limit the prices of individual medicines were rejected by the Government.

A Liberal Democrat amendment to require consultation with the National Institute for Clinical Excellence was rejected.

- **Provision for arbitration in disputes**. Concern was voiced over the lack of appeals processes with regard to prices and profits in the initial draft of the Bill. The industry would want to see that powers to make payments from companies should be conditioned on a finding of a court or independent tribunal that the company is in breach of its obligations. This applies both to a voluntary scheme, and to the penalty provisions of Clauses 31 and 32. Similarly the industry considers that a dispute relating to the requirements of a voluntary scheme should be capable of being referred to a tribunal.

Following amendments proposed by Lord Howe and generally endorsed by peers at the Committee stage on the Lords, Baroness Hayman agreed to set up an independent appeals tribunal for the voluntary scheme, and for decisions taken under the statutory scheme and regulations made with regard to enforcement.[228]

- **Statutory objectives**. The current PPRS contains a statement of objectives (see Part V A above). The ABPI suggested that the inclusion of such a statement in the Bill would go further to ensure fairness in safeguarding the interests of both the NHS and patients, and the interests of the pharmaceutical industry. The draft as presented to the House of Lords included "reasonableness" in clause 31(4).

This concern was met in an amendment to make it clear that both the costs of Research and Development and the need for medicinal products to be available to the health service are considered in reaching a decision on the reasonableness of prices.

- **Regulatory Impact Assessment**. In view of the increased regulatory powers available to the Secretary of State under the proposals of the Bill, the incomplete

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[227] HL Deb 18 March 1999 c 862 (Report stage)
[228] HL Deb 1 March 1999 c 1502

> Regulatory Impact Assessment (because the new PPRS is under negotiation) is of great concern to industry.[229]

As negotiations on a new voluntary PPRS agreement have not yet been completed, a full regulatory impact assessment is still not available.[230]

(c) European Community

Concern has been raised that the new scheme might be contrary to EU law. The Department of Health has stated that provided profit and price control comply with certain conditions they will be compatible with European Community law:

> Article 30 of the EC Treaty prohibits quantitative restrictions on imports. Measure of equivalent effect and price and profits controls have the potential to breach this article. To avoid a breach of this Article, any maximum price must be set at a level which allows companies a fair and reasonable profit and which reflects the cost of importation and so does not deter imports…
>
> …the Community has adopted Directive 98/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems. This includes requirements regarding provision of information that have to be observed in the case of price and profit controls with the intention of ensuring that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures of equivalent effect.
>
> The Directive also contains provisions regarding requirements for the price increases to be approved and governing the imposition of price freezes. Where price increases on individual products are only permitted following approval from the authorities, which could be the case, if Regulations were made under the provisions in clause 27 [provisions for control of prices outside a voluntary scheme] or under a statutory scheme, decisions must be made under 90 days. In this case it is necessary to give reasons, based on objective and verifiable criteria, if the application is refused. The applicant should be advised of the remedies available to him. These conditions would have to be incorporated in any secondary legislation made under this power. In the case of a freeze on prices, there shall be periodic reviews and the opportunity for anyone marketing a product to apply for a derogation. The authorities must make a decision on such an application within 90 days. [231]

While European Union policy is committed to completing a single market in pharmaceuticals, the Council of Ministers recognises Member States' need to adopt

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[229] ABPI comunication 24 February 1999

[230] 1 April 1999

[231] Select Committee on Delegated Powers and Deregulation, *Health Bill*, HL 29 98-99, supplementary memorandum by the Department of Health, pp 29-30

economic measures to control the total costs of pharmaceutical expenditure.[232] A Communication from the European Commission on the Single Market in Pharmaceuticals issued in November 1998 provides further reading on this issue and sets out the interplay between regulatory, social and industrial interests in the context of a single market in pharmaceuticals.[233]

11. Professional regulation

The proposal to take "Henry VIII" powers to enable the Government to amend the primary legislation governing the regulation of health professionals by Order was regarded as one of the most controversial aspects of the Bill. Although a number of safeguards concerning the future of the regulatory bodies were included in Schedule 3 of the Bill as originally drafted, peers expressed serious concerns, both at the Bill's Second Reading and at Committee Stage, about the breadth of the powers being given to Ministers. At Second Reading, the Conservative health spokesperson in the Lords, Earl Howe, described the powers as "excessive and unnecessary"[234] and his Liberal Democrat counterpart, Lord Clement-Jones, described the provisions as "the most oppressive" in the Bill and "the treatment of the professions [to be] wholly inadequate".[235] A number of other peers taking part in the Second Reading raised concerns as to how water-tight the safeguards in the Bill were. Lord Walton of Detchant, for example, pointed out that, even though a body such as the General Medical Council could not be abolished, its regulatory functions could be transferred to another body entirely, as long as that body was made up of relevant professionals:

> Hence the Secretary of State could transfer such functions to a government-appointed body of a few professionals, with no lay or professionally elected representatives. I believe that this is a dangerous position.[236]

Supporting this view, Lord Colwyn proposed that only minor changes should be made by regulation, retaining the need for primary legislation where major changes were proposed.[237]

At Committee stage, a number of amendments to the Bill were tabled reflecting these concerns. Proposals put forward by peers included: limiting the powers exercisable under clause 47 (now clause 54) for one year or another limited period, thus allowing a backlog of changes to be cleared without giving wide powers to future governments;[238] the explicit protection of the common title of the individual professions supplementary to medicine to

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[232] *Communication from the Commission on the Single market in Pharmaceuticals*, EC Cons Doc 13544/98, 25 November 1998, p 9
[233] *ibid*
[234] HL Deb 9 February 1999 c 117
[235] HL Deb 9 February 1999 cc 121-2
[236] HL Deb 9 February 1999 c 126
[237] HL Deb 9 February 1999 c 145
[238] HL Deb 4 March 1999 c 1801

be included on the face of the Bill;[239] writing in on the face of the Bill the assurance that the core functions of the existing regulatory bodies could not be given to another body, as feared by Lord Walton at Second Reading;[240] and ensuring that the right of appeal to the Privy Council (currently enjoyed by all the professions excepting nurses, health visitors and midwives) be retained.[241] While none of these amendments was initially accepted in the form in which it was made, Baroness Hayman promised to look again at the drafting of the Bill to allay concerns that the current regulatory bodies might have their functions transferred to other "professional" bodies. She also emphasised that the protection of common title would be covered by the future Orders, and that the Government had no intention of changing the current right to appeal to the Privy Council as far as the existing regulatory bodies were concerned.[242]

At Report stage, a large number of Government amendments were tabled, addressing the concerns raised in earlier stages. As a result, the structure of clause 47 (now clause 54) and Schedule 3 were substantially altered. Changes included:

- The four fundamental aspects of self-regulation (keeping the register of professionals permitted to practise, setting the standards of education for entry into the profession, providing guidance on professional conduct and handling fitness to practice procedures) may not be removed from the current regulatory body, as was initially theoretically possible. Where the regulatory body is specifically to be abolished by this Bill to allow for a complete revision of the current regulatory structure (ie the Council for the Professions Supplementary to Medicine and the United Kingdom Central Council for Nursing, Midwifery and Health Visiting), the "successor bodies" to these two Councils will have the same protection.[243]

- The successor bodies to the Council for the Professions Supplementary to Medicine and the United Kingdom Central Council for Nursing, Midwifery and Health Visiting are now guaranteed the protection that they cannot be abolished by Order, in the same way as the existing regulatory bodies such as the General Medical Council and the General Dental Council;[244]

- The professions which currently have appeal rights to the Privy Council now have the guarantee that they will retain those rights, with the possible exception of the professions supplementary to medicine. As these latter professions currently have the right of appeal to the Privy Council, but the review of their regulation left open the question of whether it was desirable to retain it, the Government has promised

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239 HL Deb 4 March 1999 c 1810
240 HL Deb 4 March 1999 cc 1822ff
241 *ibid*
242 HL Deb 4 March 1999 cc 1836ff
243 HL Deb 18 March 1999 c 931 & c 945
244 HL Deb 18 March 1999 c 931 & c 944

consultation on whether the successor body to the Council for the Professions Supplementary to Medicine should retain the same line of accountability.[245]

- There will be a provision on the face of the Bill that any future Order could not impose a lay majority on a regulatory body, thus ensuring that a majority of members of regulatory bodies must always be registered practitioners, unless the body itself chose otherwise.[246]

Baroness Hayman also stated in Committee that the Government had accepted two suggestions made by the Delegated Powers and Deregulation Committee:

- firstly that a Minister wishing to lay a draft Order would also have to lay before Parliament a summary of the representations received on the Order, including whether or not the professional body concerned had agreed with the proposed changes, and if not, why not; and
- secondly the inclusion on the face of the Bill of a statement of the criteria which the Minister in question would be following when intending to implement changes which the profession opposed.[247]

These amendments were tabled and accepted at Report; in fact Baroness Hayman emphasised that the Government had gone further than the Committee had suggested by writing in the requirement that changes must always be "necessary or expedient for the purpose of securing or improving the regulation of the profession or the services which the profession provides or to which it contributes", regardless of whether the profession was in favour of or against the proposals.[248]

A final Government amendment was made at Third Reading, specifying not only that the relevant *professions* should be consulted before the making of an Order, but also "persons appearing to him [ie the Secretary of State] appropriate to represent those provided with services by the profession".[249] This fulfilled a promise made at both Committee and Report stages to ensure that the requirement to consult patients was written on the face of the Bill.[250]

One amendment tabled in Committee and again at Report, but which was not accepted by the Government, sought to give chiropodists and podiatrists a separate regulatory body, like doctors or dentists, rather than the "generic council" of professions supplementary to medicine, recommended by the review team.[251] A number of the professions involved

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[245] HL Deb 18 March 1999 c 930 & c 944
[246] HL Deb 18 March 1999 c 929 & c 944
[247] HL Deb 4 March 1999 cc 1803-4
[248] HL Deb 18 March 1999 c 928 & c 941
[249] HL Deb 25 March 1999 cc 1469-1471
[250] eg HL Deb 18 March 1999 c 928
[251] HL Deb 4 March 1999 cc 1806-7

have expressed concern that the creation of such a generic council would lead to the loss of genuine *self* regulation, as it could include only one or two representatives of each profession. At Report, Lord Morris emphasised that although his amendment related only to chiropody and podiatry, other professions, such as physiotherapy, strongly supported his principle. In response, Baroness Hayman argued that a multi-professional structure would have many benefits when considering issues common to all professions such as dealing with the abuse of patients or practitioners having criminal convictions. However, she reassured the House that within this multi-professional structure "it [is] envisaged that input on matters specific to individual professions would be secured through extensive advisory networks and provision for "peer review" in fitness to practise cases".[252] She also promised that the "issue of securing proper individual contributions from each of the professions concerned is paid the closest of attention" in future work on the replacement both of the *Professions Supplementary to Medicine Act 1960* and the *Nurses, Midwives and Health Visitors Act 1997*.[253]

Most peers expressed themselves as thoroughly satisfied with the Government amendments made at Report. Earl Howe for the Conservatives, for example described them as "a very satisfactory resolution of the difficulties highlighted at Second Reading and in Committee", while Lord Clement-Jones for the Liberal Democrats thanked the Minister for "respond[ing] so comprehensively to the concerns of the professions and their regulatory bodies".[254] Nevertheless, he still expressed "some concerns" about how the safeguards would work. More fundamental reservations about the whole issue of the use of Henry VIII powers were expressed at Report stage by the Earl of Northesk who stated that despite all the amendments made to clause 47 (now clause 54), "the fundamental issue of being required to legislate in the dark remains; indeed it remains to worry me deeply".[255]

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[252] HL Deb 18 March 1999 c 925
[253] HL Deb 18 March 1999 c 926
[254] HL Deb 18 March 1999 cc 836-7
[255] HL Deb 18 March 1999 c 944