RESEARCH PAPER 01/01
8 JANUARY 2001

Improving NHS Performance, Protecting Patients, Modernising Pharmacy and Prescribing Services: the *Health and Social Care Bill*

Bill 9 of 2000-2001

The Bill delivers the aspects of the NHS Plan and the Government's response to the Royal Commission on Long Term Care that require changes to primary legislation. This Research Paper covers Parts I, II and V of the Bill; Research Paper 01/02 covers Parts III and IV.

The purpose of Parts I, II and V is to improve the performance of the NHS; to provide better protection for patients by means of a more effective system for regulating GPs; to provide better protection for patients in the use of confidential information; to create a new system of patient involvement in the way the NHS works; and to modernise pharmacy and prescribing services. This paper sets the proposed changes in the context of the wider developments on modernising the NHS.

Margaret Jackson-Roberts

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Summary of main points

In July 2000 the Government published *The NHS Plan, A plan for investment, A plan for reform* and *The NHS Plan, The Government's response to the Royal Commission on Long Term Care.* The Government also published *Pharmacy in the Future-Implementing the NHS Plan* in September 2000. In October the Scottish Executive published its *Response to the Royal Commission on Long Term Care.*

The Bill[1] introduces the aspects of the NHS Plan and the Government's response to the Royal Commission on Long-term Care (the latter is the subject of Research Paper 2001/02) that require changes to primary legislation. For most aspects that relate to the NHS, apart from a provision for dispensing of NHS prescriptions by prescribed practitioners in Scotland which has been made at the request of the Scottish Executive, the Bill applies to England and Wales only. It has been drafted in consultation with the National Assembly for Wales, which has, where appropriate, agreed the provisions made in it.

The purpose of this Bill is

- to improve the performance of the NHS
- to provide better protection for patients through a revised system for regulating GPs
- to supply better protection around the use of patient information
- to create a new system of patient involvement in the way the NHS works
- to modernise pharmacy and prescribing services
- to extend direct payments for social service users
- to provide a fairer system of funding for long term care.

There are five parts to the Bill:

Part I makes changes to the way the NHS, both hospital and community health services and family health services, is funded and run in England and Wales

Part II deals with pharmaceutical services in England and Wales and some aspects of such services in Scotland

Part III provides for the establishment of Care Trusts

Part IV makes changes to the way in which long term care is funded and provided in England and Wales, and to the way in which "preserved rights" are to be ended in Scotland

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1 *Health and Social Care Bill 2000* HC Bill 9 of 2000/01, introduced on 29 December 2000

Part V deals with the control of patient information and the extension of prescribing rights, as well as some miscellaneous and supplementary provisions.

This paper is concerned only with Parts I, II, and V. A separate paper [Research Paper 01/02] covers Parts III and IV, including "preserved rights" in Scotland.

CONTENTS

I Introduction

In March 2000 the Chancellor of the Exchequer announced spending plans for increases in real terms of 6.1% for the NHS in each year up to 2003-04.[2] On the following day the Prime Minister announced a plan for effecting modernisation of the NHS, which was published on 27 July 2000.[3] This Bill[4] provides the legislative powers necessary to implement some aspects of the Plan.

The Queen's Speech introduced the intentions underpinning the Bill:

> My Government remains committed to the founding principles of the National Health Service. My Government's NHS Plan showed how it would take forward further reform of health services to improve standards. Legislation will be introduced to support many of the commitments in the Plan, in particular to improve the performance of the NHS. The legislation will also take forward my Government's response to the Royal Commission on Long Term Care for the Elderly.[5]

The Bill will implement some of the proposals in the NHS Plan[6] for which the legislative powers do not already exist. For many elements the legislative framework for the NHS remains the *National Health Service Act 1977*[7] as amended. General Medical, General Dental, General Ophthalmic and Pharmaceutical Services are provided under Part II of this Act, and all generic references in this paper to Part II services are to be understood as referring to this provision, unless the context makes it clear that a reference to Part II of the Health and Social Care Bill is intended. Functions and financial arrangements for Primary Care Trusts have their legislative basis in the *Health Act 1999.*[8] The legislative basis for Social Services in England and Wales is set out in the *National Assistance Act 1948,*[9] the *NHS Act 1977,*[10] the *NHS and Community Care Act 1990,*[11] and the *Community Care (Direct Payments) Act 1996.*[12]

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2 Budget statement, HC Deb 21 March 2000 cc 871-2
3 *The NHS Plan; a plan for investment, a plan for reform* July 2000 Cm 4818
4 No. 9 of 2000/01
5 HL Deb 6 December 2000 620 cc1-4
6 op cit.
7 1977 Chapter 49
8 1999 Chapter 8
9 1948 11 & 12 Geo. 6 C.29
10 1977 chapter 49; as amended by the *National Health Service and Community Care Act 1990* Chapter 19; the *Health Authorities Act 1995* Chapter 17; *the National Health Service (Primary Care) Act 1997* Chapter 46; and the *Health Act 1999* Chapter 8.
11 1990 Chapter 46
12 1996 Cap 30

The NHS Plan[13] covers a programme of extensive reform to match the additional resources that are being made available to the NHS. In particular the Plan emphasises

- an expansion of Personal Medical Services (PMS) contracts for GPs,
- clinical governance and annual appraisal for all doctors working in primary care,
- reforms to the national hospital consultant contract,
- extension of nurse prescribing to other health professions,
- replacement of Community Health Councils (CHCs) by a Patient Advocacy Liaison Service
- booked hospital admissions for all treatments
- joint inspection of health and social care services and incentive payments to encourage joint working
- formation of new Care Trusts to enable closer integration of health and social services.

Comments on the NHS Plan after publication on July 27th 2000 were generally favourable, though some critical voices expressed a view. Dr Ian Bogle, chairman of the BMA, said[14]:

> Some aspects of the plan are, however, unacceptable in their current form and will require detailed discussion with the Government. We have major concerns about the proposals to alter doctors' contractual arrangements, which will bring no benefit to patients.

Apropos the issue of alternative sources of funding for the NHS Dr Bogle is reported as having said:

> The BMA considers this has not been studied in sufficient depth.[15]

The NHS Confederation, which represents NHS Managers, called the plan radical and brave. Nigel Edwards, the Confederation's policy director, said:

> There are no simple and quick fixes for the problems of the NHS. The Government has been brave to face head-on the really difficult problems facing the NHS – how to move to common standards of performance and how to persuade clinicians to do the most effective things, not what they have always done.[16]

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13 Cm 4818.The Government's distinct objectives for Wales were set out in the White Paper *NHS Wales – putting people first* January 1998 Cm 3841

14 reported in *The Independent* Friday 28 July 2000

15 ibid.

16 ibid.

Ruth Lea, head of policy at the Institute of Directors, expressed her views thus:

> However, we are concerned that the national plan is not radical enough. There will surely come a point when governments will have to concede that all patient expectations, which are rising inexorably, cannot be met through taxpayer-funded health care.[17]

A spokesman for the Patients' Association said:

> There are some very good ideas in this plan but now these things have really got to happen and the money has got to be there. It's all very well the Government saying they are going to tie consultants into the NHS but unless they give them the financial incentives the consultants will just go abroad. It is great they are acting but they have to ensure that all these pledges and promises now happen.[18]

Christine Hancock, general secretary of the Royal College of Nursing, said of the Plan:

> Today we have got a survival plan that puts patients first and tackles the hardest issues facing the health service. We're optimistic because every good idea in the plan is happening somewhere in the health service. These ideas work and with the right support and opportunities nurses and doctors will turn them into a reality for all patients.[19]

The president of the Royal College of Physicians, Professor Sir George Alberti, was quoted as saying:

> At last we have government recognition of the shortage of doctors and beds in England and a commitment to tackle these problems.[20]

The response of the BMA's General Practitioners Committee to the Bill was expressed[21] by its chairman, Dr John Chisholm:

> Much of the Bill derives from the NHS Plan for England, but some clauses give us cause for concern on behalf of patients. The Secretary of State for Health will have additional powers to authorise sharing of information in the health service. Fast transfer of patient data has the potential to enhance patient care and reduce waiting times but the BMA will have to scrutinise the new clauses closely to

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17 ibid.
18 ibid.
19 ibid.
20 ibid.
21 BMA Press Notice Thursday 21 December 2000

> ensure proper ethical safeguards and adequate standards for patient confidentiality are preserved.
>
> The General Practitioners Committee is particularly keen to see rapid progress on implementation of supplementary lists in order to give non-principal GPs access to clinical governance arrangements and the NHS superannuation scheme. The inclusion of self-employed locum doctors in the NHS pension scheme will right a longstanding injustice and should help recruitment in general practice.

II Health service funding

A. Resources

1. Distribution

The earlier NHS White Paper[22] contained a commitment to distribute NHS cash more fairly. A new Advisory Committee on Resource Allocation has been set up to review the formula used to make cash allocations to Health Authorities and Primary Care Groups/Trusts[23]. There is a freeze on making further changes to the existing funding formula while the review takes place.[24]

The White Paper went on to say:

> The healthcare needs of populations, including the impact of deprivation, will be the driving force in determining where cash goes. There will be a national formula to set fair shares for the new Primary Care Groups, as there is now for Health Authorities. It will be for Health Authorities to determine the pace of change at which individual Primary Care Groups within their area should move towards their fair share. Regional Offices will monitor progress.

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22 *The New NHS, Modern, Dependable* Cm 3807 December 1997 page 70

23 Primary Care Groups (Local Health Groups in Wales) were set up as committees of Health Authorities from 1 April 1999 using existing statutory powers (section 16 and paragraph 12 of Schedule 5 to the *National Health Service Act 1977* 1977 Chapter 49); Primary Care Trusts were set up under sections 2-7, 12 and Schedule 1 to the *Health Act 1999*

24 Department of Health

2. Merging of budgets

The White Paper[25] also indicated that three previously separate funding streams (for hospital and community health services, family health services prescribing, and cash-limited funding for GPs) would be merged into

> one stream of cash-limited funds flowing through Health Authorities to Primary Care Groups. [This] will align clinical and financial responsibility so that those who prescribe, treat and refer have control over the financial decisions they make.

This unification has been achieved and was implemented from 1999/2000.[26]

3. Additional resources

Additional resources have been made available to enable implementation of the NHS Plan. These extra resources include the NHS Performance Fund.[27] The Bill[28] makes provision for allocating moneys according to Health Authorities' performance in delivering improvements in health care.[29] In August, the NHS Confederation, which represents health service managers, commented[30] on the proposals for earned autonomy according to a "traffic light" system in the NHS Plan (which is explained further under **clause 2** Performance, below):

> As networks and partnership working develops, assessing individual organisations will be less appropriate than looking at health economies. The system has the potential for creating perverse incentives and to shift problems onto third parties. We would also like to see all organisations being able to earn autonomy rather than there being an arbitrary fixed proportion; we would argue that rather than promoting quality improvement, a rigid quota is more likely to be demotivating.

The BMA has reservations about the proposed grading system for access to supplementary funding, and fears that too much emphasis is being placed on micro-management from the centre.[31]

> The BMA fears it could be seriously counter-productive to label hospitals as "red" or failing organisations as this would damage recruitment and retention, making it more difficult for the hospital to overcome its difficulties….Attention must be

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25 see footnote 22

26 Department of Health circular HSC 1998/205 paragraph 12

27 *NHS Performance Fund 2000/01* Letter dated 16 May 2000 from Director of Finance, NHS Executive, to all Chief Executives; HSC 1999/039 *Health and Personal Social Services Modernisation Fund*

28 *Health and Social Care Bill*, introduced into the House of Commons as HC Bill 9 on 20 December 2000

29 Department of Health Press Notice 2000/0666, 14 November 2000; HSC 2000/034 *Health Authority Revenue Resource Limits 2001/*02; *N*ew *Investment for a New NHS* NHS Executive December 2000

30 NHS Confederation *Viewpoint* August 2000

31 BMA Parliamentary Brief, 5 January 2001

given to how hospitals at the bottom of league tables, which may be in need of funding and support, will have access to the (Performance) Fund.

B. Reward mechanism

There is also provision in the Bill for extending the flexibility and control mechanisms available for rewarding good performance and, by implication, for withholding additional payments where improvements are seen as needed. These powers were first introduced by section 8 of the 1999 Act and the Bill extends these powers to enable an intervention order to be made where a health service organisation is failing to perform its statutory duties.

III Part I of the Bill

A. Health Service funding

1. General

Clause 1 will permit the Secretary of State for Health and the National Assembly for Wales to extend the concept of fair shares of health allocations by taking account of how much is being spent on demand-led family practitioner services that are not subject to an annual cash ceiling in dividing up the available money. Those who are spending in excess of their fair share may get a lesser increase for their other services, and those spending less than the prescribed amount may get an increase. This is a part of the Government's strategy to end the "postcode lottery" of care and changes the way resource limits are applied. It serves as a "monetary device" by spending more to increase the number of GPs working in under-doctored areas and is the reciprocal benefit to the proposed abolition of the Medical Practices Committee [32] (**Clauses 17 and 18**).

This clause also provides for changes to the way in which unified cash-limited allocations are made to Health Authorities and Primary Care Trusts[33] by taking account of the non-cash limited expenditure on family health services[34] for the first time.

The Department of Health has asked the Advisory Committee on Resource Allocation to devise a new funding formula for General Medical Services Non-Cash Limited (GMSNCL) expenditure to allow for the determining of targets (or "fair shares" of available resources) for each area, in conjunction with the existing formula for Health Authority and Primary Care Trust unified allocations. Adjustments will be made

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[32] Originally set up under section 43(2) of the *National Health Service Act 1946* 9 & 10 Geo.6 Ch.81

[33] Unified allocations were introduced from 1999/2000; see paragraph 12 of HSC 1998/205 *Health Service Allocations 1999/2000*

[34] As defined in Part II of the *National Health Service Act 1977*; General Medical, General Dental, General Ophthalmic and Pharmaceutical Services

gradually by means of reduced funding growth to avoid unduly penalising any Health Authority that is over target.

The Explanatory Notes state explicitly[35] that these changes will not lead to the cash limiting of Part II general expenditure or change the entitlement of primary care practitioners. The Secretary of State is required to pay each Health Authority the cost of remuneration for persons providing family health services under Part II of the Act and this amount is not subject to cash limits; s/he must also pay an allotted sum to meet the main expenditure incurred by a Health Authority in the exercise of its functions, but this amount does serve as a cash limit.[36] Health Authorities are required in turn to provide funds to Primary Care Trusts.[37] General Part II expenditure is excluded[38] from the power to set resource limits in addition to cash limits. Resource limits are applied to the unified allocations only.

Subsection (3) amends section 97AA of the 1977 Act by inserting a new subsection (2A) which allows the Secretary of State to take account of general Part II expenditure in setting resource limits for Health Authorities. This mirrors the new subsection (3AA) of section 97 which allows the Secretary of State to take account of Part II expenditure in determining the amount to be allocated to a Health Authority. A similar cascade provision is made by subsection (5), which inserts a new subsection (2A) of section 97E to the 1977 Act to allow a Health Authority to take account of general Part II expenditure in setting the resource limits for its Primary Care Trusts.

2. Performance

Clause 2 enables the Secretary of State to make payments to Health Authorities based on their past performance. A Performance Fund for the NHS was foreshadowed in the NHS Plan[39] for introduction from April 2001. This fund would build up to £500 million a year by 2003/04 and would be allocated on a "traffic light" system; "green" organisations would receive a share of the fund as of right; "yellow" organisations would be required to agree plans, and have these signed off by the relevant Regional Office, showing how they propose to use their share of the fund; "red" organisations would have their share of the fund held by the new Modernisation Agency[40] and spending would be overseen by the Agency and subject to conditions.

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35 *Health and Social Care Bill Explanatory Notes* Bill 9 of 2000/01 paragraph 23.

36 Section 97(1) and (3) of the 1977 Act, respectively

37 ibid. section 97C

38 by sections 97AA(2) (Health Authorities) and section 97C (Primary Care Trusts) to the 1977 Act, which were inserted by the *Government Resources and Accounts Act 2000* Chapter 20

39 op cit paragraph 6.31

40 *NHS Plan* paragraphs 6.14-6.17. The Agency will "encompass the existing National Patients' Action Team, the Primary Care Development Team, the 'Collaborative Programmes' and the clinical governance support unit."

The existing section 97(3C) to the 1977 Act enables the Secretary of State and the National Assembly for Wales to increase the initial allocation made to a Health Authority where that Authority has satisfied certain conditions. The new subsection 97(3C) in the Bill, which replaces the existing section 37(3C), allows for increases to an Authority's allocation to be made either where that Authority has in any preceding year satisfied objectives notified to Health Authorities in advance, or where it has performed well against performance criteria notified in advance by the Secretary of State (although he does not have to notify the Authority of the method by which performance will be measured). The new subsection also allows increases to be made on the basis of performance in the whole or part of a preceding year or any part of the current financial year.

Clause 2(3) allows the Secretary of State to specify objectives, criteria or periods of time in a notice that applies to a single Health Authority rather than a notice to all Health Authorities.

Clause 3 is intended to provide a more efficient resource allocation route to NHS Trusts and Primary Care Trusts for supplementary payments, ie payments made under arrangements other than NHS contracts[41]. The clause allows the Secretary of State and the National Assembly for Wales to make payments to NHS trusts and Primary Care Trusts directly, or through Health Authorities, outside the existing arrangements for funding such bodies.[42]

3. Public Private Partnerships

Clause 4 inserts a new section 96C into the *National Health Service Act 1977* that allows the Secretary of State and the National Assembly for Wales to participate in public–private partnerships with companies that provide facilities or services to persons or bodies carrying out NHS functions. These powers may be delegated to Health Authorities and through them to Primary Care Trusts and Special Health Authorities.

The powers given by subsection (1) will enable the Secretary of State to form or participate in forming companies to provide facilities or services to any person providing services or exercising functions under the *NHS Act 1977* or NHS trusts exercising functions under the *NHS and Community Care Act 1990*. Subsection (2) allows investment in companies providing such facilities or services and the provision of loans or guarantees. Subsection (3) provides that the powers are exercisable irrespective of

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41 These were introduced under section 4 of the *National Health Service and Community Care Act 1990* Chapter 19. They are explicitly not contracts enforceable at law but are subject to arbitration by the Secretary of State for Health.

42 Contained in section 97 to the 1977 Act (Health Authorities) and section 97C(5A) (Primary Care Trusts). Supplementary payments can be made through Health Authorities rather than directly to trusts. The Secretary of State can control how Health Authorities make these supplementary payments to trusts by giving directions under section 17 of the 1977 Act.

whether the company is also serving persons or bodies, such as pharmacists, whose activities are not solely confined to the NHS.

The first intended use of this clause is to set up NHS LIFT (NHS Local Investment Finance Trust) which will be used to invest in primary care premises.

4. Income-generation

Clause 5 amends the income-generation powers contained in section 7 of the *Health and Medicines Act 1988*[43] to enable the Secretary of State, by delegation as necessary, to form, invest in and otherwise make financial provision in relation to companies. This issue has arisen in respect of outsourced trading activities formerly carried out by health authorities and trusts. Examples are financial services and IT.

5. Terms of employment

Clause 6 provides for the Secretary of State and the National Assembly for Wales to make regulations and give directions to health service bodies about the terms and conditions on which they employ staff, to enable modernisation of the NHS pay system by ensuring that NHS bodies implement changes to terms and conditions of service approved by the Secretary of State. A new human resources regime for NHS staff was launched by the Department of Health following publication of a strategy resource pack.[44]
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[43] 1988 Cap 49

[44] *Improving Working Lives in the NHS* Department of Health 2 November 1999: Press Notice 1999/0196

B. Scrutiny of health service provision

1. Background

Chapter 10 of the *NHS Plan* proposes giving patients more say in their own treatment and more influence over the way the NHS works. **Clauses 7-15** of the Bill set out a panoply of measures designed to provide a new system of patient and public consultation and involvement in the operation of the NHS. **Clause 9** confers on each Health Authority, Primary Care Trust and NHS trust a new statutory duty to make arrangements for involving patients and the public in the planning and decision-making processes of that body.

2. Arrangements

Patients' Forums are to be established for each NHS trust and Primary Care Trust in England (Clauses 10-13) to ensure that patients' views are taken into account in the development and operation of local health services. Each Patients' Forum will appoint a Non-Executive Member to sit on the board of its local Trust. Clause 11 allows the Secretary of State to make regulations requiring Health Authorities, Primary Care Trusts and NHS trusts or providers of family health services (GPs, pharmacists, dentists and opticians) to allow authorised members of Patients' Forums to inspect premises owned or controlled by them. Access will generally be restricted to areas where patients are permitted to go and to reasonable times, normally by agreement with the occupier, and will not extend to accessing patient records. The BMA has commented that these functions must be carried out by an independent body:[45]

> It will be essential to ensure that the proposed Patient Advocacy and Liaison Services and Patients' Forums in each Trust are independent of those Trusts rather than their creature.

Local authority Overview and Scrutiny Committees will be established under section 21 of the *Local Government Act 2000*[46] to scrutinise the NHS, including decisions on NHS reorganisations and service changes (**Clauses 7 and 8)**. Local authorities are expected to absorb the costs of this additional function but as the powers are essentially permissive the exact costs involved will depend upon local decisions as to the level of NHS scrutiny each authority undertakes.[47]

The new arrangements will be supplemented by two new non-statutory elements. Patient Advocacy and Liaison Services (PALS) will be a new service, based in main reception areas of hospitals, for providing information to patients and resolving problems experienced in using NHS facilities including how to process a complaint. Independent

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45 BMA Parliamentary Briefing, 5 January 2000
46 2000 Chap. 22
47 Explanatory Notes paragraph 308

Local Advisory Forums (ILAFS) will be established for every Health Authority in England to provide independent advice to the Health Authority in determining the health priorities for the area. Local residents, including representatives of the local Patients' Forums, will constitute ILAFS.

3. Abolition of Community Health Councils (CHCs)

The element in the package of proposed changes which has attracted most critical comment is the abolition of CHCs, which was announced in paragraph 10.35 of the *NHS Plan.* The reason given is that CHCs' functions have been supplanted by subsequent developments, and that

> Trying to combine three distinct functions in one organisation has not delivered the goods for patients.[48]

Clause 14 will enable abolition to go ahead with effect from 31 March 2002.[49]

CHCs were established in 1974 and have their statutory basis in section 20 and Schedule 7 to the 1977 Act. The Secretary of State has a duty to establish a CHC for Health Authority areas, either whole or in part. CHCs have a statutory duty to represent the interests of the public in the health service, to monitor its local operation, to give advice to health authorities, and to be consulted about substantial service changes. They also have the right to inspect health service premises.[50] About 500 people are employed full time by CHCs and 5,000 act as unpaid volunteers. A body representative of CHCs, the Association of Community Health Councils in England and Wales (ACHCEW) was set up under Regulations and is also intended to be abolished, under **Clause 14(3)**.[51]

Subsection (5) provides for the transfer of liabilities of CHCs that may fall on individual members. ACHCEW, unlike individual CHCs, has its own property, which must be transferred to a person specified in subsection (6) (the Secretary of State, a Health Authority, a Special Health Authority, an NHS trust, or a Primary Care Trust) or the National Assembly for Wales.

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48 Mr Secretary Milburn, HC Deb 21 November 2000 c 158

49 Explanatory Notes paragraph 309

50 *National Health Service, England and Wales The Community Health Councils Regulations 1996* SI 1996 No. 640 regulation 20; this was extended to include Primary Care Trusts in England by *The Community Health Councils (Amendment) Regulations 1999* SI 1999 No. 2906. In Scotland there are equivalent bodies called Local Health Councils, established by *The National Health Service (Local Health Councils)(Scotland) Regulations 1990* SI 1990 No.2230, made under the *National Health Service (Scotland) Act 1978* Cap.29. There are no proposals to abolish Local Health Councils.

51 *The National Health Service (Association of Community Health Councils) Regulations 1977* SI 1977 No. 824

4. Wales

Clause 14 subsection (4) allows the National Assembly for Wales to continue to exercise the power contained in paragraph 5 of Schedule 7 to the 1977 Act and to establish a new body to advise and assist CHCs in Wales. **Clause 15 subsection (1)** confers an order enabling, but not requiring, the National Assembly for Wales to abolish CHCs in Wales following the conclusion of a consultation exercise being conducted by the Assembly. The Bill leaves the decision as to the future retention of CHCs in Wales for the National Assembly to make.

5. Comment

The Government's intention, as expressed in the NHS Plan, is to build on the experience gained from the present system of patient representation and to strengthen it. Abolition of CHCs is meant to be seen in the context of setting up PALS, ILAFs, local authority Overview and Scrutiny Committees, and Patients' Forums. A further £10 million is to be made available annually over the next three years in addition to the £23 million currently committed to funding CHCs to support the new arrangements.

Some considerable criticism has been expressed, not least in both Houses, about the proposal to abolish CHCs. Criticism has focused on the independence of CHCs from the bodies they scrutinise; their democratic composition and governance; their cost-effectiveness; the effectiveness of the best of them in testing proposals for change; the fragmentation of function implied by the Government's proposed successor bodies as contrasted with the CHCs' holistic view; the absence of any mention of statutory rights for the new bodies; the ability of ACHCEW to recognise failures in the system from a national standpoint and represent them to government; the loss of a high street "shop front" for drawing public attention to local NHS matters; the widespread public support CHCs command; and the absence of a national consultation exercise concentrating exclusively on proposed abolition of CHCs[52]

A warning has been issued to the Government by the (Labour) chairman of the Health Select Committee of a Labour backbench revolt if the proposals to abolish CHCs are not rethought.[53] Mr Hinchliffe is quoted as saying

> What is currently being proposed will not address the genuine worries of patients and their representatives over the complaints system or the long-standing anxieties of many, like myself, over the democratic deficit in the NHS.

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[52] Eg HC Deb 28 November 2000 c163-187W; 21 November 2000 c 156-160; 16 November 2000 c 1072-3; HL Deb 26 October 2000 c557-574

[53] Reported in the Guardian, *Mutiny threat on health councils*, and also the Independent, 28 December 2000

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> When the health committee looked at the handling of complaints, we suggested that independent patient advocates should be based within CHCs…While there are many positives in the NHS Plan, I believe the alternative proposed to the CHC system does not offer a coherent response to anxieties over patient representation.

In the second article Donna Covey, Director of the Association of Community Health Councils of England and Wales, is reported as having said that the Government

> was riding rough-shod over the concerns of patients, professional bodies and backbenchers on this issue.

Some have called for all CHCs to be brought up to the level of the best.[54] Other voices have however expressed the difficulty of finding sufficient CHC members from younger age bands and from ethnic minorities.[55] The need for reform has been accepted on both sides of the House[56], not least to attempt to capture the views of marginalised groups of people, and a suggestion has been made that a local secretariat presence (CHI-Plus) should be established to enable the Commission for Health Improvement to carry out co-ordination, integration and information-sharing functions, using the offices (and possibly the staff) of CHCs.

The British Medical Association has expressed the view[57] that CHCs should not be abolished until all the new systems replacing them are in place, which could be taken as tacit acceptance of abolition in principle, either as being good in itself or by default. In its latest briefing note, however,[58] the BMA states that its General Practice Committee (GPC) had discussed the abolition of CHCs and expressed concern at the government's proposals:

> The committee applauded the work and achievements of CHCs, in particular work undertaken which revealed breakdowns within the NHS, for example, casualty watch. The committee was dismayed that this valuable service would be lost, and felt that the proposed arrangements were unsatisfactory, as a local and national structure was required with statutory rights and funding to act as an NHS watchdog. Any service would need to ensure that the functions of CHCs are preserved, namely advocacy, scrutiny and inspection.

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54 HC Deb 21 November 2000 c 160
55 HL Deb 26 October 2000 c 568
56 HC Deb 28 November 2000 c 175W, c 178W, c 182W
57 BMA Parliamentary Brief, October 2000
58 M6 of Friday 22 December 2000

C. Intervention powers

Clause 16 supplies the powers of intervention that will provide a sanction against the most serious and persistent failures; the performance payments that will underpin the new system of earned autonomy are enabled by **Clause 2**, q.v. This power is intended to be exercised as a last resort. The clause inserts new section 84A and 84B into the 1977 Act, enabling the Secretary of State to make an intervention order in respect of a Health Authority, Special Health Authority, Primary Care Trust or NHS trust where he is satisfied that one of these bodies is failing to perform one or more of its functions satisfactorily or at all. The form of intervention adopted may vary but must be appropriate to the individual case. Subsection 16(2) provides that intervention orders made under this clause are not statutory instruments.

The clause builds upon the new duty of quality introduced for PCTs and NHS trusts in England and Wales by section 18 of the *NHS Act 1999.*

D. Family Health Services

1. General Practitioner vacancies

Under present arrangements the numbers and distribution of the general practitioner workforce in England and Wales are governed by the Medical Practices Committee (MPC), which was set up under sections 7 and 34 of the 1977 Act. This function is to be assumed by Health Authorities and so **Clause 17** abolishes the MPC and transfers its functions to Health Authorities. This clause should be considered alongside **Clause 1**, which provides for Health Authority allocations to be determined in part by their Part II general expenditure (expenditure on family practitioner health services). **Subsection (2)** provides for the transfer of all property, rights, and liabilities relating to the MPC to the Secretary of State and includes certification relating to the sale of medical practices involving the goodwill factor.

Clause 18 provides for regulations to enable Health Authorities to determine the existence and means of filling vacancies in their area for GPs operating under General Medical Services (GMS) terms and requires them to undertake consultation before making their determinations. A right of appeal is provided by **subsection (3)** against a decision of the Health Authority to the Family Health Service Appeal Authority. Taken with **Clause 1** this clause puts in place a new method for controlling the distribution of GPs with financial incentives for equalising the distribution between adequately doctored and under-doctored areas of the country.

2. Remuneration of General Medical Practitioners

General Medical Services are provided either under the traditional GMS framework involving payment on an item of service basis, including capitation fees for each category of patient, in addition to a Basic Practice Allowance or under the new arrangements for Personal Medical Services (PMS: see below). **Clause 20** ends the requirement[59] that the majority of the remuneration for GPs should be linked with the number of patients on that GP's list of persons to whom he has undertaken to provide General Medical Services. The NHS Plan sets out[60] the Government's intention to renegotiate the GMS contract to provide a greater focus on quality.

3. Abolition of the NHS Tribunal and rationalisation of the functions of the Family Health Services Appeal Authority

The NHS Tribunal was established by section 46(1) of the 1977 Act in order to carry out inquiries into whether the continued inclusion of a person's name on a list maintained by a Health Authority for the provision of general medical, general ophthalmic, general dental or pharmaceutical services would be prejudicial to the efficiency of the services in question**.** [61]

Clauses 22-27 introduce a new system requiring all practitioners working in family health services to be on the list of a health authority and for Health Authorities to take decisions about the suspension or removal of a practitioner from these lists, with the intention of taking rapid remedial action where there is some question about fitness to practice. This system supersedes the NHS Tribunal which is accordingly to be abolished.[62]

Clause 22 provides new powers enabling Health Authorities to refuse a practitioner admission to the appropriate list on the grounds of unsuitability.

Clause 23 enables Health Authorities to make arrangements with dental corporate bodies to provide general dental services (GDS) as well as with individual dental practitioners. **Subsection 23(2)(c)** provides a definition of a dental corporation as a body corporate which carries on the business of dentistry within the meaning of section 40 of the *Dentists Act 1984*[63] (ie to receive payments for providing dental treatment).

Clause 24 amends the 1977 Act and introduces new arrangements requiring practitioners providing family health services to declare any gifts or financial benefits they receive. This brings the Part II services into alignment with requirements that already obtain in the

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59 under section 29(4) of the 1977 Act
60 in paragraphs 8.3-8.6
61 1977 Act section 46(1) in part, *verbatim*
62 as prefigured in paragraph 10.12 of the NHS Plan
63 1984 c24

hospital sector. Regulations will be required and these will be subject to consultation (**subsection 24(2))** for all four professional groups providing family health services.

Clause 25 amends section 43 of the 1977 Act by extending the existing Health Authority list systems to include on a supplementary list all people who provide family health services otherwise than as principals in their own right. Examples of these categories of people are trainee GPs and locums. Paragraph (c) of new section 43D enables provision to be made about the grounds on which a Health Authority may or must refuse an application for inclusion in a list, either for reasons of unsuitability or on other grounds. These other grounds could for example include an applicant who had received a conviction for murder. Applicants for inclusion in a list and practitioners already included may, under paragraph (h), be required to supply the Health Authority with criminal conviction or criminal record certificates.

The BMA has sought Counsel's advice on whether refusal to admit to a list or suspension or removal from a list constitutes a breach of the European Convention on Human Rights:

> Cherie Booth QC's opinion was that there would be a breach without an independent appeals mechanism in place, such as that provided by the NHS Tribunal. In light of this, while the planned abolition of the NHS Tribunal will be enacted by this Bill the Family Health Service Appeals Authority is being re-constituted as a tribunal.[64]

Paragraph (k) of section 43D allows for regulations to be made to allow the Health Authority to disclose to prescribed persons specified information about applicants. Section 43D(6) provides for regulations requiring that practitioners on one of the main lists may not employ or engage a person to assist them professionally unless that person is included in one of the main lists, a supplementary list, or a PMS, PDS or LPS list (for which see **Clause 27** below).

Clause 26 makes provision for health authorities to suspend and remove (including conditional removal) from the relevant principal family health services list. This will enable a Health Authority to take rapid action where concern has arisen about a practitioner involved in the provision of those services. A new section, 49F, of the 1977 Act provides powers for a Health Authority to remove practitioners from the relevant list on the grounds of inefficiency (49F(2)), fraud 49F(3), or unsuitability (49F(4)). In unsuitability cases the Health Authority must remove the practitioner from the list in prescribed circumstances (49F(6)) and it must specify the condition under which removal or suspension is relied upon (49F(7)). Section 49G allows a Health Authority to remove a practitioner contingently from a principal list, and may determine that removal shall only come into effect if the practitioner fails to comply with conditions imposed by that Authority. These conditions may include varying the individual practitioner's terms of

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[64] Briefing Note M6 Friday 22 December 2000

service. Section 49H allows a Health Authority to suspend a practitioner from a list whilst considering removal or contingent removal of that person. In such cases the period of suspension must be stated and may not exceed six months' duration, except in prescribed circumstances. Such circumstances could include an ongoing criminal investigation, fraud investigation, investigation by a professional regulatory body, or health grounds, and would need to be prescribed by regulations to avoid any imputation of arbitrary action on the part of the Health Authority. Section 49I provides an obligation for a Health Authority to review any decision to conditionally remove or suspend a practitioner if the practitioner makes a request in writing for this to be done.

4. Right of appeal

New section 49J to the 1977 Act provides practitioners with a right of appeal to the Family Health Services Appeal Authority within 21 days of the notice of a decision by the Health Authority, and section 49K sets out the powers of the FHSAA. Section 49L provides for regulations requiring a Health Authority to notify the relevant professional body of any decision to suspend, remove or contingently remove a practitioner from a list.

A right of appeal from the decision of a Health Authority to the Family Health Services Appeal Authority is maintained. The FHSAA, which is at present a Special Health Authority, will take over the NHS Tribunal's functions, adapted to take account of the new powers of Health Authorities to suspend or remove practitioners, and will be reconstituted as an independent body under **Clause 28.**[65] Membership must include people with a lay background as well as those with relevant professional expertise.

5. Out of Hours medical services

The purpose of **Clause 21** is to provide powers to ensure that GPs use only accredited providers of out-of-hours services. The terms under which GPs operate are contained in Regulations[66]. The underlying principle is that a GP has 24-hour responsibility for the patients on his/her list but in practice it is increasingly difficult to exercise this responsibility in person. Use of a deputising arrangement to provide out-of-hours cover is allowable under an amendment[67] to the Principal Regulations that enables a doctor to transfer part or all of his obligations under the terms of service to another doctor at night, weekends and on public holidays. The doctor to whom the responsibility is transferred must be included in a Local Medical List of approved practitioners, which is maintained by the Health Authority. In practice only around a third of GPs now employ a commercial deputising service, with the majority belonging to a GP Co-operative.

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65 Clause 28 inserts a new Schedule 9A to the 1977 Act giving the FHSAA a new constitution, including a President and other members appointed by the Lord Chancellor

66 *The National Health Service (General Medical Services) Regulations 1992* SI 1992 No. 635 as amended; the Principal Regulations

67 SI 1996 No. 702

The clause carries into effect one of the recommendations made by an independent review commissioned by the Department of Health.[68]

> **Recommendation Eight**
>
> Health Authorities should be responsible for the accreditation of all organised out-of-hours providers and should monitor the quality of out-of-hours services provided by those GPs who do not use such providers. Detailed guidance should be developed for the manner in which such accreditation is to be implemented.

Regulations will prescribe the procedure for applying for accreditation and any accompanying conditions. They may also provide for the withdrawal or suspension of approval by Health Authorities. Once the clause has come into effect the existing powers under the 1977 Act and the 1997 Act will be used to make consequential changes to the Terms and Conditions of Service for GPs and to the Directions for the Implementation of Personal Medical Services.

Reaction from the medical profession to ending 24-hour cover has been mixed, with GPs described as "divided" over keeping control of out-of-hours service.[69] Proposals for implementing accreditation and revalidation of all doctors are being drawn up by the General Medical Council as part of a Structural and Legal Review of its Fitness to Practise procedures.[70]

6. PMS and PDS lists

Personal Medical Services (PMS) and Personal Dental Services (PDS) were introduced by the *National Health Service (Primary Care) Act 1997*[71] as a new way of delivering family health services. They introduce a new form of contract which sets standards for accessibility, including patients' right of access to a primary care practitioner within 24 hours and a GP within 48 hours. The incentive payments for providing immunisation, cervical cytology and continuing professional education remain, as under the traditional GMS contract. The agreements under which they are established are known in the early stages as pilot schemes but the intention is to replace these with a permanent regime, on a voluntary basis, at least initially.

Clause 27 introduces new arrangements that further extend the Health Authority approved list system for including those practitioners who may perform personal medical services (PMS) and personal dental services (PDS). Subsection (2) inserts a new section 8A into the *National Health Service (Primary Care) Act 1997* introducing similar

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68 *Raising Standards for Patients, New Partnerships in Out-of-Hours Care* An independent review of GP Out-of-hours Services in England October 2000

69 BMA News Review, May 13 and July 8 2000

70 HC Deb 26 July 2000 c 636W; *Quality in General Practice* K Birch. S. Field and E Scrivens, 2000

71 *NHS (Primary Care) Act 1997* Chapter 46 section 15

arrangements for those PMS and PDS schemes which are not pilot schemes, thus allowing for a more general roll-out.

PMS pilots were set up using sections 17 and 17A of the 1977 Act and section 6((1) of the 1997 Act. Thus they pre-date the *NHS Plan.* Directions made by the Secretary of State under this legislation came into force on 10 May 2000 concerning the implementation of pilot schemes. The PMS contract document formalises developments introduced as a result of the pilots and is now available to doctors as a matter of personal choice. PMS contracts give GPs the opportunity to develop more flexible primary care provision, tailored to meet specific health needs of the local population, than is possible under traditional GMS arrangements, but PMS providers are accountable to the Health Authority for the delivery of National Service Frameworks, public health targets, and national clinical governance requirements in the same way as their colleagues who operate under GMS rules. The main personal implications of becoming a PMS provider of Part II services are the ending of an individual's independent contractor status and that all income and practice expenses are cash-limited. On the plus side there is less bureaucracy and form-filling (the BMA's GPC website[72] refers to "less bean-counting").

PDS pilot schemes under the 1997 Act began in October 1998 and there have been two successive annual waves. As with PMS, they offer a more flexible alternative to the current national GDS system by allowing practitioners to focus on making different local arrangements to suit particular local needs. In common with PMS the core services provided remain the same as under the old arrangements and participation is voluntary. Any dentist who chooses to become a member of PDS may revert to working under the GDS.

IV Part II of the Bill

A. Chapter I: Local Pharmaceutical Services

1. Background

At present pharmaceutical services, including the dispensing of NHS prescriptions, are provided by community pharmacies, appliance contractors, and dispensing doctors under arrangements made with Health Authorities for the provision of services under Part II of the 1977 Act, particularly regulations made under sections 41 and 42 of that Act[73].

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[72] http://web.bma.org.uk/gpc.nsf

[73] The Principal Regulations are *The National Health Service (General Medical and Pharmaceutical Services) Regulations 1974* SI 1974 No. 160; amended by SI 1985/290, 803, 955, 1712, and SI 1987/401
Sales and supply of medicines to the public are regulated under SI 1980 No. 1923, as amended by SI 1992 No. 2983

The new arrangements, to be known as Local Pharmaceutical Services, will put in place an alternative legal framework for providing community pharmacy and related services on a pilot basis, under locally agreed contracts, in a similar way to PMS and PDS schemes under the 1977 Act. These schemes were a consequential development from the NHS Plan.

> …the Government will introduce legislation to allow a new form of agreement between the NHS, pharmacists and pharmacy owners. Local Pharmaceutical Services will be similar to Personal Medical Services and Personal Dental Services. They will allow pharmaceutical services to be provided under locally tailored arrangements, free from the restrictions of the rigid national remuneration system and terms of service.
>
> The first challenge is to meet the changing needs of patients. For pharmacy this means…making sure that people can get medicines or pharmaceutical advice easily and, as far as possible, in a way, at a time and at a place of their choosing.[74]

2. Pilot schemes

Clause 29 outlines the general nature of LPS pilot schemes. A Health Authority is precluded from itself providing LPS but may make one or more agreements with any person or persons, other than with another Health Authority, for the provision of LPS under a pilot scheme. There is a difference from PMS and PDS schemes, in that provision of LPS is not restricted to particular classes of person. This means that participants in pilot schemes may include, amongst others, individual pharmacists, retail pharmacy businesses, and dispensing appliance contractors. Parties to an arrangement for providing LPS may also include NHS trusts and Primary Care Trusts under **subsection (7)**. Nothing in these provisions alters the restrictions in the *Medicines Act 1968*[75] and other legislation on who may supply medicines.

Regulations made under **subsection (8)** will define what is meant by LPS. **Subsection (3)** allows a pilot scheme to include health services which are not LPS nor of necessity normally associated with pharmacies but which may be provided under Part I of the 1977 Act. Examples of such services could include diagnostic testing, therapeutic monitoring, health education, chiropody and the like. Since the NHS is able to provide alternative therapies under Part I of the 1977 Act, nothing in the Bill would preclude the possibility of alternative and complementary therapies being incorporated into an LPS scheme.[76]

Clause 30 introduces **Schedule 2**, which sets out the provision for initiating and making a scheme, either on the initiative of a Health Authority or that of a person who wishes to be

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74 *Pharmacy in the Future – Implementing the NHS Plan* NHS Executive September 2000
75 1968 c67
76 Department of Health

a participant in a scheme. **Clause 40** makes provision for LPS which are not pilot schemes by inserting a new section 28J and a new schedule 8A (which is set out in full in Schedule 3 to this Bill) into the 1977 Act. Thus, as with PMS and PDS, LPS will provide a longer-term alternative to the traditional method of providing services. **Clause 39** provides that **Clause 40** may not be brought into effect unless either the Secretary of State or National Assembly for Wales is satisfied that pilot schemes have shown that the continued provision of LPS would be in the interests of the health service, as a whole or in any part.

Clause 31 allows the Secretary of State or the National Assembly for Wales to make regulations that allow Health Authorities to designate neighbourhoods, particular premises, or descriptions of premises for the purpose of setting up an LPS scheme. This provision could, for instance, permit community pharmaceutical services to be provided in a high street or out of town shopping complex or from a surgery operated by another professional group, including the 500 new one-stop primary care centres which will be open by 2004 under the Government's investment plans for the NHS.

Clause 34 allows persons providing pilot schemes to apply to become a health service body. The effect of such an application being granted is to make contracts entered into between the Health Authority and the service providers NHS contracts rather than legal contracts and hence not justiciable at law.

3. Reviews, variation and termination of pilot schemes

Clause 32 deals with the review of pilot schemes, which must be done at least once within three years of services first being provided under the scheme. The procedure for the review is at the discretion of the Secretary of State or the National Assembly for Wales, subject to giving people providing the services an opportunity to comment as part of the review.

Clause 33 permits directions to be issued to vary or terminate the pilot schemes. If for any reason the Secretary of State or the National Assembly for Wales is satisfied that a pilot scheme is unsatisfactory subsection (3) allows them to issue directions requiring the responsible Health Authority to terminate the scheme.

4. Funding and charges

Clause 35 permit regulations to be made to allow Health Authorities to give financial assistance in respect of preparatory work for pilot schemes. **Clause 36** makes provision for regulations to make and recover charges for piloted services. Government policy is that arrangements for making prescription charges under LPS arrangements will be the same as those for Part II Pharmaceutical Services. People who are exempt from paying charges or otherwise not required to pay will receive free prescriptions irrespective of the nature of the service provider, and pre-payment certificates will be valid interchangeably for both types of service.

5. General provisions

The effect of **Clause 37** is to provide, under **subsection (2)**, that unless otherwise specified, the 1977 Act applies to services provided under pilot schemes as if the Secretary of State or the National Assembly for Wales had directed a Health Authority to arrange those services. Subject to directions under section 17A of the 1977 Act Health Authorities may delegate their functions in this regard to Primary Care Trusts.

The existing national contractual framework[77] for community pharmacy is to be modernised, and a part of this modernisation programme the Government has stated that it is prepared to change the current "control of entry" rules which limit the award of NHS dispensing rights where there is evidence that these rights present an obstacle to providing better services:

> Control of entry may be removed entirely in places where the restrictions it imposes on competition between pharmacies clearly cannot be justified. This may be the case in major retail complexes, such as Bluewater or Meadowhall, or similar centres in or out of town.[78]

Clause 38 provides that regulations made under section 42 of the 1977 Act may include provision about the extent to which services provided under LPS are to be taken into account when determining whether to grant an application for inclusion in a list referred to in subsection (2) of section 42. The section 42 provisions allow a Health Authority to prepare a list or lists of persons undertaking to provide pharmaceutical services or the supply of appliances from premises in that Authority's area and require that such persons shall specify the services to be provided and the premises from which those services will be provided. An application will be granted only if the Health Authority is satisfied that it is necessary or desirable to secure the adequate provision for the neighbourhood concerned of some or all of the services specified.

Clause 41 provides a power to make regulations applying existing statutory provisions to LPS schemes, including pilots, where these provisions already exist for PMS or PDS schemes and allows for appropriate modifications

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77 The Principal Regulations are *The National Health Service (Pharmaceutical Services) Regulations 1992* SI 1992 No. 662, as amended. Limits on what may be prescribed by nurses are detailed in the *Nurse Prescribers' Formulary*; a consultation process on extending the range is currently in train

78 *Pharmacy in the Future* op. cit. paragraph 4.13

B. Chapter II: Changes to existing arrangements

1. Extension of prescribing

Following the success[79] of nurse prescribing[80] a review was commissioned by the Department of Health and the second report[81] made proposals for providing a secure means of increasing the range of health professionals who are authorised to prescribe.

The principles[82] that underpinned the review team's recommendations were that

i. the co-ordination of patient care should normally rest with the general practitioner or, during episodes of hospital care, with a named consultant;

ii. in the great majority of cases, medicines should be prescribed and dispensed on an individual, patient-specific basis;

iii. patient safety should not in any way be compromised;

iv. the provision of medicines to patients should make the best use of professional expertise and the most effective use of resources.

The review did not deal with the dispensing of medicines, which remains the preserve of pharmacists and dispensing doctors.

The report made a distinction between two new categories of prescribers:

(i) independent prescribers - professionals who are responsible for the initial assessment of the patient and for devising the broad treatment plan, with the authority to prescribe the medicines required as part of that plan;

(ii) dependent prescribers – professionals who are authorised to prescribe certain medicines for patients whose condition has been diagnosed or assessed by an independent prescriber within an agreed assessment and treatment plan.

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79 eg *BMA backs further extension of nursing roles* Press Notice Friday 19 November 1999. Dr John Chisholm, Chairman of the General Practitioners' Committee off the BMA, was quoted as saying "For more than a decade the GPC has supported extensions in the role of nurses including the development of nurse practitioners and nurse prescribing."

80 The statutory basis for which is contained in *The National Health Service (Pharmaceutical Services and Charges for Drugs and Appliances) Amendment Regulations 1994* SI 1994 No. 2402 regulation 3(3). In April 2000 the Secretary of State for Health announced £10 million of funding from 2001 to 2004 to support a training programme to extend nurse prescribing. DH Press Notice 2000/0209

81 *Review of Prescribing, Supply and Administration of Medicines*, chaired by Dr June Crown Final Report March 1999

82 ibid paragraph 6.4

The Government accepted the proposals in the report after consulting on them.[83]

Clause 42 widens the categories of registered professional persons who are to be allowed to prescribe items under NHS rules and extends the scope of services provided by Health Authorities to persons for whom they are responsible. It inserts a revised section 41 into the 1977 Act on the arrangements for pharmaceutical services.

The clause also allows the Secretary of State to determine which categories of drugs, medicines and appliances may be prescribed by each professional group, and provides that a determination may make different provision for different cases or circumstances.

> The categories of professional person to whom the extended prescribing rights are to be extended under **subsection (1)(d)** are:
>
> (a) persons who are registered by any board established under the *Professions Supplementary to Medicine Act 1960* (chiropodists/podiatrists; radiographers; orthoptists; physiotherapists; occupational therapists; speech and language therapists; dietitians; medical laboratory scientific officers; prosthetists and orthotists; arts therapists (art, drama, and music); clinical scientists and paramedics[84]
>
> (b) persons who are registered pharmacists
>
> (c) persons whose names are entered in a roll or record established by the General Dental Council under section 45 of the *Dentists Act 1984*[85]
>
> (d) persons who are ophthalmic opticians
>
> (e) persons who are registered osteopaths within the meaning of the *Osteopaths Act 1993*[86]
>
> (f) persons who are registered chiropractors within the meaning of the *Chiropractors Act 1994*[87]
>
> (g) persons who are registered in the register of qualified nurses, midwives, and health visitors maintained under section 7 of the *Nurses, Midwives and Health Visitors Act 1997*[88]

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83 Department of Health Press Notice 1999/0134

84 The 1960 Act was widened to include clinical scientists and paramedics on 19 June 1999: *Modernising Regulation – the new Health Professions Council a consultation document* NHS Executive August 2000 page 7 paragraph 8

85 1984 c. 24

86 1993 c. 21

87 1994 c. 17

> (h) persons who are registered in any register established, continued or maintained under an Order in Council under section 60(1) of the *Health Act 1999.*[89]

2. Remote prescribing and provision of pharmaceutical services

Subsection (5) of **Clause 42** provides that arrangements made by a Health Authority can include provision of a service by remote means, so that the recipient of a service may receive that service otherwise than at the premises from which the service is provided. **Subsection (6)** allows provision to be made, subject to regulations, for persons who have contracted with a Health Authority to provide a pharmaceutical service may also provide services to people who are outside the Health Authority's area. This would enable prescriptions to be sent by post to a pharmacy of the patient's choice, or a pharmacy to collect a prescription from the doctor's surgery on the patient's behalf and then deliver the dispensed medicine to the patient's home. The intention is to facilitate and provide a means for controlling the future development of internet, mail order, home delivery and other similar arrangements, and to provide the patient with greater flexibility in the way they are able to present prescriptions and obtain prescribed drugs, medicines and appliances.

Clause 43 amends section 41a of the 1977 Act by giving the Secretary of State powers to give directions to Health Authorities authorising or requiring them to arrange for the provision of services to any person, whether or not in their area, and allows for the provision of these services by remote means. New subsection (3B) (to section 42 of the 1977 Act) allows regulations to be made requiring people providing remote services to be approved for that purpose, in accordance with criteria to be specified in regulations.

This provision will provide the legislative framework for electronic prescribing, which is intended to have the same legal force as traditional prescriptions signed in writing. *Pharmacy in the future* says[90]

> As a result of the NHS Plan the NHS will have the most up-to-date information technology (IT) systems to deliver services faster and more conveniently to patients.
>
> By 2004, electronic prescriptions will be routine in the community as well as hospitals. Transfer of prescription data between GPs, pharmacies and the Prescription Pricing Authority will be carried out electronically, using the NHS Net, in the large majority of cases by 2008, or even earlier.
>
> Electronic prescribing offers exciting possibilities for more convenient services for patients, and for more timely and complete information about prescribing and

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88 1997 c.24

89 1999 c. 8

90 op cit paragraphs 2.15 –2.18

use of medicines. Electronic prescriptions will have the same legal force as prescriptions signed in writing. Patients will benefit from easier ordering of repeat prescriptions. Pharmacists will benefit from the new opportunities to use information technology to support their practice. And it will also mean an end to illegible and incomplete prescriptions, which waste everybody's time, as well as being a risk to patient safety.

As a first stage, the NHS Executive has invited IT companies to come forward with proposals for pilot schemes for the electronic transfer of prescriptions in primary care. Up to three pilots will start in 2001, the first to be up and running no later than June. They will each run for six months and be fully and independently evaluated by the end of 2002. From that, NHS-wide standards will be developed to allow routine electronic transfer of prescriptions.[91]

3. Dispensing of NHS prescriptions in Scotland

Clause 44 amends section 27 of the *National Health Service (Scotland) Act 1978*[92] to make provision for items prescribed by certain categories of prescriber to be dispensed as part of NHS community pharmaceutical services in Scotland and gives Scottish Ministers the powers to specify in regulations to which categories of person these provisions shall apply, and which drugs, medicines and appliance shall be prescribable by each category.

V Part V of the Bill

A. Extension of prescribing rights

Clause 60 amends section 58 of the *Medicines Act 1968* which governs the sale, supply and administration of prescription-only medicinal products both privately and within the NHS and introduces new arrangements for the prescribing of medicines. New subsection 1(e) enables new categories of registered professional groups to be designated by order for the purpose of prescribing prescription-only medicines for human use. The example given in the Explanatory Notes is where a physiotherapist may be given prescribing rights for certain drugs such as anti-inflammatories. An effect of this extension of prescribing rights could be to remove or reduce the need for routine visits to a GP for continuing care.

Subsection (6) makes it an offence for a person to prescribe a medicinal product for which s/he is not an appropriate practitioner, if this contravenes any condition imposed under new subsection (4A) (of section 58 to the *Medicines Act).* **Subsection (8)** enables the Secretary of State to establish an advisory body under section 4 of the 1968 Act to consider whether prescribing rights should be granted to any additional group of health

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91 Department of Health Press Notice 2000/0512 Tuesday 12 September 2000 *Patients the Priority in the NHS Plan for Pharmacy of the Future*

92 1978 c.29

professionals and to advise on any conditions or limitations that should be applied to their prescribing, prior to the clause coming into force.

Initial costs for training, and establishing the advisory committee, are estimated at £5.5 million over three years.[93]

B. Control of patient information

There are statutory constraints on passing on information relating to patients. The ground rules are laid down by Caldicott rules[94] and in guidance issued by the Department of Health.[95] The latter treats the unauthorised passing on of patient information as a serious matter, always warranting consideration of disciplinary action and possibly risking legal action by others.

> In their own interests and those of patients, all staff must be made aware of the possibly severe consequences of breaching patient confidence. NHS bodies are strongly advised to include a duty of confidence requirement in employment contracts or other documents setting out terms and conditions.[96]

Three examples of statutory restrictions on passing on information are given in Annex C of the guidance:

1. The ***NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000***[97] **- made under the National Health Service Act 1977, <u>for England only</u>, and revoking the *National Health Service (Venereal Diseases Directions 1991*** **-** prevent the disclosure of any identifying information about a patient with a sexually transmitted disease (including HIV and AIDS) other than to a medical practitioner (or to a person employed under the direction of a medical practitioner) in connection with and for the purpose of the treatment of the patient, or to prevent the spread of the disease. These provisions do **not** prevent the normal notification of other communicable diseases in such patients.

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93 Explanatory Notes paragraph 318

94 HSC 1998/089; *Protecting and using patient information*: A Manual for Caldicott Guardians NHS Executive 14 January 2000; HSC 1998/089 *Implementing the recommendations of the Caldicott Report* 15 May 1998. "Guardians" of patient information should be created to safeguard and govern the uses made of confidential patient information. The Caldicott Report is available on the Department of Health website at www.doh.gov.uk/nhsexipu/resource/caldico/index.htm and the summary of responses to the consultation exercise is at www.doh.gov.uk/confiden/conrepsum.htm

95 T*he Protection and Use of Patient Information;* Guidance from the Department of Health 7 March 1996

96 op cit paragraph 4.7

97 available from the Department of Health website under Public health/sexual health: Directions

2. The ***Human Fertilisation and Embryology Act 1990***[98]**,** as amended by the ***Human Fertilisation and Embryology (Disclosure of Information) Act 1992***[99] limits the circumstances in which information may be disclosed by centres licensed under the Act. Reference is made to the Human Fertilisation and Embryology Authority's *Code of Practice.*

3. The ***Abortion Regulations 1991***[100]**,** made under the ***Abortion Act 1967***[101], limit and define the circumstances in which information submitted under the Act to the Chief Medical Officer may be disclosed.

The Explanatory Notes state that the existing legal framework relating to the control of patient information is complex and contains some uncertainties. Clinicians are unclear about what to release, particularly in respect of confidential information. This lack of clarity is said to be jeopardising the flow of information to bodies such as cancer registries.

The *Data Protection Act 1998*[102] governs the processing of information relating to individuals; **Clause 59** supplements but does not amend that Act and neither will regulations made under the clause amend the Act. Information provided by patients is also subject to common law requirements derived from case law. **Subsection (8)** provides that regulations made under this clause cannot make provision for the processing of information which are inconsistent with the *Data Protection Act*. **Subsection (10)** defines patient information as any information that relates to, or is derived from, information concerning a patient's physical or mental health or condition, the diagnosis of his condition, or his care or treatment. It includes information that is anonymised or coded, and however recorded, whether manually or electronically. **Subsection (11)** defines confidential patient information as information that has been obtained by a person who owes a duty of confidence to an individual and from which the identity of that individual may be ascertained.

Regulations made under this clause may place additional restrictions or obligations on those wishing to use confidential patient information in prescribed circumstances, or require, subject to safeguards, that information should be disclosed by prescribed bodies for prescribed medical purposes when this is in the public interest or in the interests of patient care. **Subsection (9)** requires that, before the Secretary of State may make regulations under this clause, s/he must consult such appropriate bodies as appear to him/her to represent the interests of those likely to be affected by the regulations.

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98 1990 c. 37
99 1992 cap.54
100 1991 SI No. 499
101 1967 c.87
102 1998 cap.25

Regulations may also provide that processing of information is lawful despite any common law obligation of confidence. **Subsection (4)(a)** enables regulations to be made that require specified communications about patients to be disclosed to them by NHS bodies in certain circumstances. This is intended to support the commitment in the NHS Plan that clinicians will in future be required to share information about patients with those patients. There may be profound implications for the current review of mental health legislation and the proposed extension of the law to include persons with severe personality disorder, and more generally, in respect of how records are entered and maintained.

C. European Convention on Human Rights

In accordance with Section 19 of the *Human Rights Act 1998*[103] the Secretary of State for Health has declared himself satisfied that the provisions of the Bill are compatible with the Convention rights.

[103] 1998 cap.42

VI LIST OF ABBREVIATIONS

ACHCEW: Association of Community Health Councils of England and Wales

BMA: British Medical Association

CHC: Community Health Council

CHI: Commission for Health Improvement

FHSAA: Family Health Services Appeals Authority

GDS: General Dental Services

GMS: General Medical Services

GMSNCL: General Medical Services Non-Cash Limited

ILAFS: Independent Local Authority Advisory Forums

LPS: Local Pharmaceutical Services pilot schemes

MPC: Medical Practices Committee

NHS LIFT: National Health Service Local Investment Finance Trust

PALS: Patient Advocacy and Liaison Services

PCT: Primary Care Trust

PDS: Personal Dental Services