These notes refer to the Health and Social Care Bill
as brought from the House of Commons on 19th February 2008 [HL Bill 33]

HEALTH AND SOCIAL CARE BILL

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Health and Social Care Bill as brought from the House of Commons on 19th February 2008. They have been prepared by the Department of Health in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.

2. The notes need to be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a clause or part of a clause does not seem to require any explanation or comment, none is given.

BACKGROUND AND SUMMARY

Part 1 – The Care Quality Commission

3. The regulation of health care in England is currently carried out by the Commission for Healthcare Audit and Inspection ('CHAI'), known as the Healthcare Commission. Social care is regulated by the Commission for Social Care Inspection ('CSCI'). CHAI and CSCI were created by the Health and Social Care (Community Health and Standards) Act 2003.

4. The Mental Health Act Commission ('MHAC') is the body currently responsible for monitoring key aspects of the operation of the Mental Health Act 1983 (the 'Mental Health Act') in England and Wales. It has other specific functions as well, notably to appoint registered medical practitioners to give second opinions where this is required by the Mental Health Act, to review decisions to withhold postal packages of patients detained in high security psychiatric hospitals, to visit and interview, in private, patients subject to the Mental Health Act, and to investigate complaints.

5. In the 2005 budget statement, the Chancellor announced plans to reduce the number of public service inspectorates. This included the creation of a single inspectorate for social care and health by merging CHAI and CSCI. The Department of Health had already announced

plans to bring together CHAI and MHAC in 2004 following a review of Arm's Length Bodies[1].

6. The *NHS Improvement Plan*[2], (published by the Department of Health in 2004) and "*Health Reform in England: update and next steps"* (published by the Department in 2005) set out the main strands of health reform, which include diversity in provision of services, increased patient choice, and a stronger patient voice and stronger commissioning. These reforms require changes to be made to the regulatory framework.

7. The Department of Health commissioned a research study in July 2006[3] to support the development of the policy on regulation of health and adult social care. It followed wide engagement with interested stakeholders as part of the Wider Regulatory Review. It drew on lessons from other sectors, and from other health and social care systems abroad to describe the regulatory functions needed to ensure the effective operation of these systems. It then proposed options for the future regulatory architecture for health and social care, and assessed the advantages and disadvantages of each option.

8. The Department of Health consultation *"The future regulation of health and adult social care in England"*, published in November 2006, built on this initial study and announced the Government's intention to create a new single regulator responsible for regulating health care and adult social care, and monitoring the operation of the Mental Health Act. The consultation ran for three months and the Department consulted widely with a range of stakeholders. In addition to receiving over 100 responses to the consultation, workshops were held for NHS Confederation members, including independent sector affiliates. Two social care workshops, one for social care service users and provider organisations, and one for commissioners of adult social care and Local Government representatives were also held. The Department also worked with the existing regulators throughout the process.

9. Chapter 1 of Part 1 of the Bill establishes a new body called the Care Quality Commission ('the Commission'). The Commission will be responsible for the registration, review and inspection of certain health and social care services in England (but not any care services that are regulated by the Chief Inspector of Education, Children's Services and Skills ('CIECSS')). It will replace CHAI and CSCI, established under the Health and Social Care (Community Health and Standards) Act 2003. The functions currently performed by MHAC will be transferred to the Commission and the Welsh Ministers.

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[1] *Reconfiguring the Department of Health's Arms Length Bodies,* published July 2004.

[2] *The NHS Improvement Plan: Putting People at the Heart of Public Services, The Stationery Office*, published June 2004.

[3] *Independent Research Study: the Future of Health and Adult Social Care Regulation,* published November 2006.

10. Chapter 2 of Part 1 creates a system of registration for providers and, in some cases, managers of health and adult social care. Regulations will set out the health and social care activities (referred to as 'regulated activities'), which a person will not be able to carry on unless that person is registered to do so. The intention is that all providers, including, for the first time, NHS providers, will be brought within the ambit of registration. The new registration system replaces (in England) the current requirement for certain establishments and agencies providing independent health care or adult social care to be registered under the Care Standards Act 2000. The Commission will need to be satisfied that applicants for registration comply with registration requirements, which will be set out in regulations. Once a provider or manager has been registered, the Commission will be responsible for checking continued compliance with these requirements, and will have a range of sanctions so that it can take appropriate action where providers or managers fail to meet the requirements. The Commission will have a wider range of powers than its predecessor organisations, including the power to issue penalty notices for non-compliance with regulatory requirements and the power to suspend registration.

11. Chapter 3 of Part 1 requires the Commission to carry out periodic reviews of care provided by or under arrangements made with Primary Care Trusts ('PCTs') or English local authorities to see how well the bodies reviewed are doing. It also requires the Commission to review health care provided by PCTs, English NHS Trusts and NHS Foundation Trusts. It provides for the Secretary of State to extend the review power to cover care provided by other registered providers by regulations. These reviews will assess performance by reference to indicators of quality that will be set or approved by the Secretary of State. The Commission may also carry out other special reviews and investigations, and must carry out such reviews and investigations if the Secretary of State requests it to do so. Chapter 3 of Part 1 replaces and expands CHAI's and CSCI's review and investigation functions under the Health and Social Care (Community Health and Standards) Act 2003.

12. Chapter 4 of Part 1 transfers to the Commission and the Welsh Ministers various functions under the Mental Health Act. It also makes some changes to those functions.

13. Chapter 5 of Part 1 confers further functions on the Commission, including a requirement for the Commission to provide information and advice to the Secretary of State on the provision of NHS care and adult social services and the carrying on of regulated activities. It also enables the Commission to report on the efficiency and economy of local authority and NHS provision and commissioning. The functions in Chapter 5 replace and expand equivalent functions of CHAI and CSCI under the Health and Social Care (Community Health and Standards) Act 2003.

14. Chapter 6 of Part 1 sets out the powers of entry and inspection which the Commission has for the purposes of carrying out its functions. It also deals with the Commission's interaction with other authorities and makes a number of other provisions relevant to Chapters 1 to 5 of Part 1.

Part 2 – Regulation of Health Professions and Health and Social Care Workforce

15. There is a statutory framework for the regulation of each of the healthcare professions and for the social care workforce. The Bill's provisions affect the following 11 independent statutory bodies:

- General Chiropractic Council
- General Dental Council
- General Medical Council ('GMC')
- General Optical Council ('GOC')
- General Osteopathic Council
- Health Professions Council
- Nursing and Midwifery Council ('NMC')
- Pharmaceutical Society of Northern Ireland ('PSNI')
- Royal Pharmaceutical Society of Great Britain ('RPSGB')
- General Social Care Council ('GSCC')
- Care Council for Wales ('CCW')

16. The main purpose of these regulatory bodies is to provide protection for both patients and the public through the execution of their statutory duties. Each regulator's constitution, functions, and duties are laid out in individual Acts and statutory instruments.

17. In addition, the Council for the Regulation of Health Care Professionals ('CRHP') was established by the National Health Service Reform and Health Care Professions Act 2002 ('the Health Care Professions Act 2002'). Its general functions (as set out in section 25 of that Act) are:

- to promote the interests of patients and other members of the public in relation to the performance of the healthcare regulatory bodies, their committees and officers;
- to promote best practice in the performance of those functions;
- to formulate principles relating to good professional self-regulation, and to encourage regulatory bodies to conform to them; and

- to promote co-operation between regulatory bodies, and between them and any other body performing corresponding functions.

18. Prior to the Health Act 1999 it was only possible to make changes to the Acts relating to the healthcare professions by presenting a Bill to Parliament. Section 60 of the Health Act 1999 allows Her Majesty, by Order in Council, to modify the regulation of the existing regulated healthcare professions, and to bring other healthcare professions into statutory regulation. An Order may repeal or revoke an enactment or instrument, amend it, or replace it (subject to the restrictions in paragraphs 7 and 8 of Schedule 3 to the Health Act 1999). The Government must consult on draft Orders prior to laying them before Parliament. The Orders are subject to the affirmative procedure.

19. The regulation of the social care workforce in England and Wales is governed by Part 4 of the Care Standards Act 2000 which established the GSCC and the CCW. The GSCC and the CCW (referred to collectively as 'the Councils') regulate the training of social workers, maintain registers of social care workers, and produce codes of good practice for social care workers and for employers of such staff. The purpose of regulation is to establish an independent standard of training, conduct and competence for the social care workforce for the protection of the public and for the guidance of employers, with the goal of improving standards in social care work. New powers in the Bill will enable modification of the regulation of the social care workforce. These powers broadly mirror the existing powers in section 60 of the Health Act 1999 which enable modification of the regulation of the healthcare professions.

20. Paragraphs 4.32 to 4.37 of the White Paper *"Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century"* (*'Trust, Assurance and Safety'*, published in February 2007) set out the Government's intention regarding the separation of adjudication of fitness to practise cases from their investigation and prosecution. Part 2 of the Bill provides the legislative underpinning for this through the creation of the Office of the Health Professions Adjudicator ('the OHPA').

21. Paragraphs 1.8 to 1.14 of *Trust, Assurance and Safety* set out the Government's position regarding the independence and composition of the health profession regulatory bodies, particularly the current proportion of lay membership of the councils of these bodies. Recommendations were made that future lay involvement in the work of the regulators should be expanded generally, but specifically that there should, as a minimum, be parity of lay members with professional members and that a lay majority should also be possible if desired. Part 2 of the Bill provides the legislative underpinning for this through amendments to the Health Act 1999.

22. Paragraphs 4.3 to 4.13 of *Trust, Assurance and Safety* set out the current inconsistency in respect of the standard of proof used in fitness to practise proceedings by the health profession regulatory bodies. Three regulators (the GMC, the GOC, and the NMC) still use the criminal standard while the other eight use the civil standard. The Government

recommended that all the regulators should use the civil standard in fitness to practise proceedings and Part 2 of the Bill provides for this to be incorporated into legislation through amendments to the Health Act 1999. A similar provision is made to use the civil standard in any proceedings which relate to a social care worker's suitability to be or remain registered. This ensures consistency between the regulation of health professionals and the social care workforce in this area.

23. The regulation of pharmacy is shared by two bodies, the RPSGB and the PSNI. The RPSGB's responsibilities cover professional regulation as well as leadership and representation of the profession. It also has an important role regulating and inspecting pharmacy premises and the Government has recently put in place legislation (in England and Wales) to enable it to take on the role of regulating pharmacy technicians. The RPSGB's responsibilities towards pharmacists for professional leadership are potentially in conflict with its role as an independent regulator for the profession itself. The professions are taking on an increased clinical role in the treatment of patients, whereby pharmacists have the autonomy to prescribe potent drugs. Therefore, this dual responsibility does not provide sufficient reassurance to the public that there is effective independent regulation of this role. Separation of the regulatory system from that of professional and clinical leadership will allow each distinct function to focus solely on its core role.

24. Amendments are required to the Health Act 1999 to allow an Order made under section 60 of that Act to remove the statutory function of pharmacy regulation from the RPSGB and the PSNI and transfer these functions to the proposed General Pharmaceutical Council. This new General Pharmaceutical Council will be responsible for the regulation of pharmacists, pharmacy technicians and pharmacy premises. This approach was set out in paragraphs 1.29 to 1.36 of *Trust, Assurance and Safety* and supported by the Working Party chaired by Lord Carter of Coles. The statutory powers of the RPSGB and the PSNI (subject to a decision by Northern Ireland Ministers to proceed in this way) would be transferred to the new regulatory body.

25. Paragraphs 3.35 to 3.39 of *Trust, Assurance and Safety* set out the Government's intention for oversight of local elements of revalidation and sharing information on concerns about doctors. Part 2 of the Bill provides the legislative underpinning for this through the establishment of the role of the "responsible officer".

26. Part 2 of the Bill contains changes to the regulation of health professions and the health and social care workforce. This is in line with the Government's response[4] to various inquiries into the actions of specific health professionals[5]. Provision is made for:

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[4] A White Paper: *Trust, Assurance and Safety - the Regulation of Health Professionals in the 21st Century*, published February 2007;

- the creation of a new body, the OHPA, which will have adjudication functions in relation to the professions regulated by the Medical Act 1983 and the Opticians Act 1989;

- amendments to Part 3 of the Health Act 1999: extending the powers under section 60 of that Act (including, in relation to pharmacy, measures to facilitate the establishment of a General Pharmaceutical Council; and the removal of the restriction that currently prevents there being a lay majority on the councils of the regulatory bodies); imposing the use of the civil standard of proof by healthcare professions regulators in proceedings relating to fitness to practise;

- the renaming of the CRHP as the Council for Healthcare Regulatory Excellence, and amendments to its constitution and functions and the way members are appointed;

- regulations to require designated bodies in the United Kingdom to nominate or appoint "responsible officers" who will have responsibilities relating to the regulation of

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Safeguarding Patients – the Government's response to the Shipman Inquiry's fifth report and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries; and

Learning from tragedy, keeping patients safe: Overview of the Government's action programme in response to the recommendations of the Shipman Inquiry

[5] *An inquiry into quality and practice within the National Health Service arising from the actions of Rodney Ledward:* published 2002;

The Report of The Royal Liverpool Children's Inquiry: published January 2001*;*

Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 - 1995: published July 2001;

The Shipman Inquiry Third Report: Death Certification and the Investigation of Deaths by Coroners: published July 2003;

The Shipman Inquiry Fourth Report: The Regulation of Controlled Drugs in the Community: published July 2004;

The Shipman Inquiry Fifth Report: Safeguarding Patients: Lessons from the Past - Proposals for the Future: published December 2004;

Committee of inquiry to investigate how the NHS handled allegations about the performance and conduct of Richard Neal: published August 2004;

Independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling – published September 2004; and

The Kerr/Haslam Inquiry: published July 2005

doctors. Designated bodies will be bodies that provide, or arrange for the provision of, health care or employ, or contract with, doctors;

- the extension of the role of responsible officers in England and Wales and Northern Ireland to clinical governance issues, in particular the monitoring of conduct and performance of doctors, through regulations;

- the creation of a general responsibility on healthcare organisations, and other specified bodies in England and Wales, to share information regarding concerns about the conduct and performance of healthcare workers, and to agree the actions needed to protect patients and the public;

- a regulation-making power to enable modification of the legislation governing regulation of social care workers in England and Wales; and requiring the application of the civil standard of proof in proceedings concerning the suitability of a social care worker to be or remain registered in England or Wales;

- a regulation making power to enable modification of the functions of the GSCC and the CCW in relation to the education and training of approved mental health professionals ('AMHPs').

Part 3 – Public Health Protection

27. The Public Health (Control of Disease) Act 1984 ('the Public Health Act 1984') consolidates earlier legislation, much of it dating from the 19th century. Many of its assumptions, both about risks and about how society operates, are now out of date. It makes highly detailed provision on some matters (for example, it is a criminal offence to expose a public library book to plague, or to hold a wake over the body of a person who has died of cholera) but does not address other matters that are now of concern, such as contamination by chemicals or radiation. Part 3 of the Bill updates the Public Health Act 1984 to take account of these points.

28. Most concerns about health threats have, since the 19th century, related to infectious disease (plague, cholera and the like). This is reflected in the way that Part 2 of the Public Health Act 1984 focuses on infectious disease. Recently awareness has grown of the risks that can be posed by contamination, either by chemicals or by radiation. The Bill amends the Public Health Act 1984 to take account of these risks.

29. Internationally the case for taking an "all hazards" approach to dealing with such health threats was taken up by the World Health Organization ('WHO') and reflected in the International Health Regulations 2005 ('IHR'). The IHR are the means by which WHO aims to prevent and control the international spread of disease, by action that is commensurate with and restricted to public health risks, and which avoids unnecessary interference with international traffic and trade. The previous International Health Regulations (1969) were

concerned with action at international borders in relation to three specific infectious diseases (cholera, plague and yellow fever), but increasingly were recognised as unable to deal with new threats, such as SARS. The new IHR are concerned with infectious diseases generally, and also with contamination. They also pay more attention than their predecessors to the arrangements needed in-country to deliver an effective response to health risks. The IHR came into effect in June 2007. The Bill amends the Public Health Act 1984 to enable IHR to be implemented, including WHO recommendations issued under them.

Part 4 – Health in Pregnancy Grant

30. The health and general well-being of pregnant women in the last months of pregnancy is widely acknowledged to have a correlation with the health and development of a child later in life. Providing pregnant women with additional financial support towards meeting the extra costs at this time, linked to the requirement to seek maternal health advice from a health professional, is intended to help provide them with the knowledge and means to invest in their pregnancy to meet their individual needs.

31. Under the Government's current strategy of financial support, families on low incomes may claim support during pregnancy in the form of the Sure Start Maternity Grant to help with additional costs at the time of the child's birth, and Healthy Start Vouchers to help with the costs of a healthy diet during pregnancy.

32. In the Pre-Budget Report 2006, the Chancellor of the Exchequer announced that additional financial support would be made available to all women in the last months of pregnancy in line with the principle of progressive universalism, delivering support for all pregnant women and more help for those who need it the most.

33. Part 4 creates the Health in Pregnancy Grant. The Health in Pregnancy Grant will sit within the existing financial support system and will make support available to all expectant mothers in the UK in recognition of the importance of a healthy lifestyle, including diet, during the final weeks of pregnancy, and to help women to afford the other additional costs faced at this time. It is a new non-contributory, non-income related benefit payable where a woman has reached a specified stage of her pregnancy and has received the necessary health advice. It will be administered by HM Revenue and Customs. It is not taxable.

34. Part 4 also contains measures regarding the conditions of entitlement, the rate and the administration of the Health in Pregnancy Grant to be provided for in:

- Part 8A of the Social Security Contributions and Benefits Act 1992 ('the Contributions and Benefits Act');

- Part 8A of the Social Security Contributions and Benefits (Northern Ireland) Act 1992 ('the Northern Ireland Contributions and Benefits Act');

- The Social Security Administration Act 1992;
- The Social Security Administration (Northern Ireland) Act 1992;
- The Northern Ireland Act 1998;
- The Immigration and Asylum Act 1999.

Part 5 – Miscellaneous
Duty of Primary Care Trusts

35. All NHS bodies are currently under a duty under section 45 of the Health and Social Care (Community Health and Standards) Act 2003 to ensure they have arrangements in place for the purpose of monitoring and improving the quality of care.

36. Clause 133 amends the National Health Service Act 2006 ('NHS Act 2006') by inserting a duty on PCTs to make arrangements to secure continuous improvement in the quality of healthcare provided by or for them. This duty replaces the current duty to improve quality in section 45 of the Health and Social Care (Community Health and Standards) Act 2003, requiring on-going improvement activity, and is aligned more closely with the duty imposed on English local authorities by section 3 of the Local Government Act 1999. The duty in section 45 of the 2003 Act will cease to apply in relation to English NHS bodies.

Pharmaceutical services

37. There are two different sources of finance which pharmacies receive for providing community-based NHS pharmaceutical services in England. One of these is the funding held centrally by the Department, known as the 'Global Sum'. The other source of finance, which funds the cost of drugs and medicines, is currently included in the sums allocated to PCTs annually to meet the general expenditure incurred in discharging their functions ('the baseline allocations'). The proposed amendment refers to the Global Sum funding only.

38. The Global Sum funding pays fees and allowances for services such as dispensing prescriptions. It also pays for other essential pharmaceutical services such as advice on medicines. It also pays the fees and allowances for appliance contractors who provide medical appliances.

39. The Department proposes that this central funding should be devolved to PCTs and be included in their baseline allocations, and published the consultation document "*Modernising financial allocation arrangements for NHS pharmaceutical services 2007*" on this proposal in July 2007. However, the Department proposes to continue to set the levels of fees and allowances for nationally agreed services provided by community pharmacies in negotiation with the Pharmaceutical Services Negotiating Committee (PSNC) and in discussion with the NHS. The Department will also continue the current arrangements for appliance contractors. The current funding arrangements are provided for by sections 228 to 231 of, and Schedule 14

to, the NHS Act 2006. Amendments to these parts of the NHS Act 2006 are required in order to move the Global Sum to the baseline allocations of the PCTs in England.

40. The way that funding for the provision of pharmaceutical services in Wales operates mirrors the current system in England. The Welsh Ministers hold centrally the funding that pays fees and allowances for services such as dispensing prescriptions and the provision of advice to patients, which is also referred to as the 'Global Sum'. The Welsh Assembly Government proposes that this centrally held funding should be devolved to Local Health Boards and be included in their baseline allocations. The current funding arrangements are provided for by sections 174 to 177 of, and Schedule 8 to, the National Health Service (Wales) Act 2006 ('NHS (Wales) Act 2006'). Amendments to these parts of the NHS (Wales) Act 2006 are required in order to move the Global Sum to the baseline allocations of the Local Health Boards in Wales.

41. Clause 134 introduces Schedule 12, which contains the changes needed to the NHS Act 2006 to move funding for pharmaceutical services to PCTs and to allocate funding by reference to the PCT of the prescriber. These changes will bring the management of funding for pharmaceutical services in line with funding for other community-based health services. Clause 134, by introducing Schedule 12, also makes the changes necessary to the NHS (Wales) Act 2006 to move the funding for pharmaceutical services to Local Health Boards, and also to introduce the allocation of funding by reference to the Local Health Board of the prescriber.

Indemnity schemes in connection with provision of health services

42. Schemes can be set up through regulations made under section 71 of the NHS Act 2006 for meeting losses and liabilities of NHS bodies. These schemes can meet:

- expenses arising from any loss or damage to their property; or
- liabilities to third parties for loss, damage or injury arising out of the carrying out of the functions of the bodies concerned.

43. The NHS Act 2006 limits the membership of the schemes to specified individual NHS bodies or groups of NHS bodies. Current schemes cover clinical negligence, liabilities to third parties, and property expenses.

44. When these liability schemes were first established, the vast majority of NHS care was provided directly by NHS bodies. However, in recent years, non-NHS bodies have started to deliver NHS care, and the Secretary of State for Health also procures some health services directly. Clause 135 will enable the regulations that establish the Clinical Negligence Scheme for Trusts to be amended to take account of these recent developments in the delivery of NHS care, so that the Secretary of State and non-NHS bodies treating NHS patients can benefit

from the same cover that is available to NHS bodies in the unfortunate event that a liability arises.

Weighing and measuring of children

45. The Foresight Report "*Tackling Obesities: Future Choices*"[6], commissioned by the Government in 2005, was published by the Government's Chief Scientific Adviser and the Foresight Team from the Government Office for Science on 17th October 2007. The report sets out that in 2004 approximately 10% of boys and girls aged 6-10 were obese, and forecasts that these figures are likely to increase to 21% (boys) and 14% (girls) by 2025, and 35% (boys) and 20% (girls) by 2050. (These figures are based on the international standard and therefore give a lower prevalence of obesity than that currently recorded by the UK standard, which estimates that just under 17% of children aged 2-10 were obese in 2005).

46. The National Child Measurement Programme ('NCMP') records the height and weight of children (currently children in Reception and Year 6) in maintained primary and middle schools in England during the academic year. Some non-maintained schools also choose to participate in the programme. Clauses 136 and 137 relate to "junior pupils". The effect of paragraph 7A(4) of Schedule 1 to the NHS Act 2006 (which is inserted by clause 136), is to apply relevant definitions under the Education Act 1996 or the Schools Standards and Framework Act 1998. "Junior pupil" is defined under the 1996 Act as a child who has not attained the age of 12. Similar definitions are applied by clause 137 in relation to the provisions for Wales.

47. The purpose of the NCMP is to gather population-level data to monitor trends in obesity and to inform local planning and delivery of services for children. It is one element of the Government's work programme to tackle childhood obesity.

48. Under current arrangements, parents may withdraw their children from participating in the programme. Children are also able to opt-out of the programme if they indicate they do not wish to participate. Parents are able to request their child's height and weight results from their PCT.

49. Personal identifiers are stripped from the data before it is sent for analysis: the name of the child is removed; the date of birth is replaced with month of birth; and the home postcode is converted into lower super output area, which represents a larger geographic area.

50. The Bill enables regulations to be made such that all parents whose children participate in the NCMP receive the results routinely, unless they have opted their child out of

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[6] *"Tackling Obesities: Future Choices" Government Office for Science, Department of Innovation, Universities and Skills,* published October 2007. *URN 07/1184*

the programme or have opted not to receive the results. The Bill also allows for the extension of the NCMP to early years settings and to other primary school year groups.

51. The powers in the Bill will enable regulations to be made to enable the aggregated data gathered during weighing and measuring to be used for performance management purposes, for example, as part of the new Local Government National Indicator Set, which will inform negotiation of Local Area Agreements.

52. In Wales, there is not currently a national programme of child height and weight measurement. Many NHS Trusts record height and weight at school entry, and some record it in Year 6, but this is not undertaken on a consistent organised basis, and data is not recorded or analysed centrally.

53. The National Public Health Service has been asked to undertake a feasibility study in 2007-08 for the creation of a national surveillance programme of children's height and weight. The Bill will allow the Welsh Ministers to define the scope of any future national weighing and measuring programme. They will also be able to make provision by regulations regarding the manner in which children are to be weighed and measured and how any information gathered is to be made available to parents.

Direct payments in lieu of provision of care services

54. Direct payments are cash in lieu of social services. They offer individuals who are assessed as needing community care services the opportunity to arrange their own personalised care, rather than receiving services directly provided by a local authority.

55. Direct payments have been available for adults of working age since 1997 (created by the Community Care (Direct Payments) Act 1996 and now made under the Health and Social Care Act 2001). The scheme was extended in 2000 to include older people and was further extended in 2001 (through the Health and Social Care Act 2001) to include carers, parents of disabled children and 16 and 17 year olds.

56. Direct payments are not currently available to people who lack capacity (within the meaning of the Mental Capacity Act 2005). A person lacks capacity in relation to a matter if they are unable to make a decision for themself in relation to a particular matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.

57. The current legislation (section 57(1) of the Health and Social Care Act 2001) states that an individual must be able to give their consent in order to receive a direct payment. People who lack capacity are unable to give this consent. In addition, regulations made under section 57 provide that individuals must also be able to manage their direct payments (with help if necessary) in order to be eligible to receive them.

58. This Bill extends the existing direct payments scheme to include people who lack capacity (within the meaning of the Mental Capacity Act 2005). It allows a direct payment to be made to a person who can receive and manage the payment on behalf of a person who lacks capacity. This fulfils a commitment made in the 2006 White Paper "*Our health, our care, our say"*. Extending direct payments will enable individuals currently unable to receive a direct payment, because they cannot consent to or manage the payment, to benefit from the flexibilities that direct payments offer. The clause only covers direct payments made to adults under section 57 of the Health and Social Care Act 2001. It does not cover the direct payments made to the groups specified by section 17A of the Children Act 1989 (as substituted by section 58 of the Health and Social Care Act 2001): people with parental responsibility for a disabled child, disabled people with parental responsibility for a child, or disabled children aged 16 or 17.

Abolition of maintenance liability of relatives

59. The liable relatives rule is set out in sections 42 and 43 of the National Assistance Act 1948 and in various other provisions mentioned in clause 139. The liable relatives rule provides that spouses are liable to maintain each other and parents are liable to maintain their children. Local authorities have discretionary powers to ask such "liable relatives" to contribute to the cost of care should a relative for whom they are liable require assistance from the council. This power is inconsistently applied by local authorities across the country. The origins of the liable relatives rule date back to the time before the welfare state, when divorce was rare and there was only one breadwinner in the family, and it was commonly accepted that one spouse should support the other. These principles are now out of date, and do not apply to other aspects of the benefits system such as Pensions Credits. The Bill will remove the powers of local authorities to seek liable relatives payments. This will bring the operating principles for the charging policy for social care in line with those that are used in the rest of the health and social care system.

Ordinary residence for certain purposes of National Assistance Act 1948 etc.

60. The National Assistance Act 1948 gives local authorities statutory responsibilities in respect of persons over 18 for the provision of accommodation to those who are in need of care and attention which is not otherwise available. It also gives them responsibility for making welfare arrangements for specified people. The provision of accommodation and care packages is generally funded by the authority in which an individual is "ordinarily resident", which is usually where a person lives.

61. Under section 24(6) of the National Assistance Act 1948, if an individual is admitted to an NHS hospital they will be deemed to be ordinarily resident in the area in which they were living immediately before being admitted as a patient to the NHS hospital. This is regardless of whether or not they in fact continue to be ordinarily resident in that area. This is referred to as the "deeming provision". In recent years the NHS has increasingly placed patients in non-NHS accommodation to receive NHS treatment. The statutory rules governing how local authorities establish the person's ordinary residence, when providing

social care services, after the patient leaves these non-NHS settings are therefore out of step with the way NHS services are provided.

62. Disputes about where an individual is ordinarily resident arise between local authorities when, for example, an individual has lived in different areas whilst receiving care or moves to a different area to receive the care needed. Section 32(3) of the National Assistance Act 1948 originally provided that all disputes between local authorities as to the ordinary residence of a person were to be determined by the Secretary of State. As a result of the transfer of functions following Welsh devolution, the Secretary of State remains responsible for determinations in relation to disputes between English local authorities while the Welsh Ministers make determinations in relation to disputes between Welsh local authorities. The Bill puts a mechanism in place to allow for the determination of disputes between English and Welsh local authorities.

63. The Chronically Sick and Disabled Persons Act 1970 does not state explicitly whom local authorities should approach to resolve ordinary residence disputes under section 2 of that Act. The Bill makes provision to fill this gap.

64. Clause 140 makes provision about a number of discrete matters, which include:

- the extension of the deeming provision in section 24(6) National Assistance Act 1948;
- a mechanism for resolving ordinary residence disputes between English and Welsh local authorities; and
- provision for ordinary residence disputes under section 2 of the Chronically Sick and Disabled Persons Act 1970 to be determined by the Secretary of State for Health or by the Welsh Ministers (in accordance with arrangements made and published under the National Assistance Act 1948).

Financial assistance related to provision of health or social care services

65. The Department of Health's White Paper, "*Our health, Our care, Our say"* (published in 2006) included a commitment to support and encourage social enterprises in health and social care.

66. There is no single definition of a social enterprise and there are many legal forms. However, a general description would be 'businesses with primarily social objectives whose surpluses are principally reinvested for that purpose in the business or in the community'.

67. In the White Paper, the Department also identified lack of access to finance as a barrier to the development of social enterprises. To address this, the Department made a commitment to establish a fund within its budget to support social enterprises delivering health and social care. This fund is now the Social Enterprise Investment Fund ('SEIF'),

which was established in August 2007 as a means of facilitating access to finance for social enterprises and to provide support for business start-ups. While it has been possible to open the SEIF and make grants to 26 social enterprise pathfinders, existing powers are not sufficient to allow further development of the SEIF; for example, to provide a range of different investments (for example, grants, loans and guarantees) to qualifying organisations.

68. Clauses 141 to 148 ensure that the Secretary of State has the powers to finance social enterprises delivering health and social care, and social enterprises providing services that are related to health and social care, provided the social enterprises meet certain qualifying conditions. The former means that the Secretary of State may, for example, finance a social enterprise delivering integrated health and social care for homeless people. The latter means that, for example, the Secretary of State may fund a social enterprise providing support services to NHS or social care providers.

69. In addition, the Secretary of State will be able to finance any person (this includes bodies) who wishes to set up a social enterprise to deliver such services. However, like the existing social enterprises, the social enterprise that is being set up must comply with the qualifying conditions.

70. The qualifying conditions set out in the clauses are intended to ensure that the funding is only for those businesses with primarily social objectives, which reinvest their surpluses or profits into the community, or into a service with social benefits.

71. The clauses allow the Secretary of State to delegate these powers to NHS trusts, PCTs, Strategic Health Authorities, Special Health Authorities, and other organisations such as companies. The latter will enable a company to manage the SEIF within the parameters set by the Secretary of State. Provision is also made for the Secretary of State to impose terms and conditions on the financial support given to social enterprises.

National Information Governance Board for Health and Social Care

72. Information governance refers to the structures, policies and practices which are used to ensure the confidentiality and security of records relating to the delivery of services. It aims to ensure the ethical and appropriate use of them for the benefit of individuals and the public good.

73. A review of information governance carried out in 2005 by Harry Cayton, then National Director for Patients and the Public at the Department of Health, identified nine different bodies or groups developing, contributing to or interpreting information governance with no single coordinating body. The bodies identified included the Patient Information Advisory Group ('PIAG'), which is a statutory body reporting to the Secretary of State. Whilst it has some responsibility for advising the Secretary of State on general information governance matters, its major role is to advise on and administer the statutory arrangements which allow the Secretary of State to lift the common law duty of confidentiality in specific circumstances. These arrangements enable identifiable patient information to be disclosed

and used for essential NHS activity and medical research without patient consent where the activity is sufficiently in the public interest.

74. The majority of the bodies identified have now been closed, merged or do not have a national role in information governance, and an interim National Information Governance Board has been put in place. However, PIAG remains as the statutory body.

75. To complete the transition to a clear, authoritative and accountable structure with a single board dealing with all information governance matters for both health and social care a statutory National Information Governance Board will replace PIAG as the statutory body. Its remit and statutory powers will be broader than those of PIAG and its membership will reflect this. The functions of PIAG will be transferred to the statutory National Information Governance Board.

76. Clause 149 establishes the National Information Governance Board for Health and Social Care ('the National Information Governance Board').

77. Currently there is a lack of clarity for individual organisations seeking advice on information governance matters and this could lead to different interpretations of legislation and policy. A single body is needed that is structured to meet current and future needs, and which also has the necessary statutory powers to oversee information governance arrangements, in order to support the NHS and social care staff by providing a national source of guidance and advice. The National Information Governance Board will aim to provide service users and the public with confidence that appropriate measures are in place to protect information. It will work to facilitate the appropriate sharing of information in order to support the delivery of seamless care.

78. The increasing use of information technology to support the delivery of care, and the existence of some public concerns about this, also serves to emphasise the need for national clarity about information governance and openness in its application. The Bill defines the role and constitution of the Board to support the pursuit of these objectives.

79. Establishing the National Information Governance Board will not remove local responsibility for information governance. This will continue to be exercised by the heads of local NHS and/or social care organisations.

80. Whilst the Secretary of State will make provision by regulations on several matters relating to the Board including the appointment of the Chair and other members of the Board, the current intention is that the Chair will be appointed by the Secretary of State and that the membership will be either lay members, appointed by an independent appointments body (for example the Appointments Commission), or representative members nominated by stakeholder organisations to represent them on the Board. It is also currently intended that the number of lay members will exceed the number of representative members.

81. The National Information Governance Board will have responsibility for the NHS Care Record Guarantee for England. This sets out the rules that will govern information held in the NHS Care Records Service, which is being implemented as part of the National Programme for IT in the NHS. An equivalent guarantee is being developed for social care.

82. Once established as a statutory body the National Information Governance Board will take over the responsibilities of the current statutory body, PIAG, which will then be abolished.

Functions of the Health Protection Agency in relation to biological substances

83. The National Biological Standards Board ('the NBSB') was established as a body corporate under the Biological Standards Act 1975 and it performs functions relating to the establishment of standards for, the provision of standard preparations of, and the testing of, biological substances. The transfer of its functions to the Health Protection Agency delivers one of the outcomes of the Department of Health's Arm's Length Body Review by reducing the number of Arm's Length Bodies.

84. Clause 151 abolishes the NBSB and gives functions to the Health Protection Agency corresponding to the NBSB's functions. It also enables the Health Protection Agency to be given any other functions that could have been given to the NBSB.

Part 6 – General

85. Part 6 provides for the territorial extent of the provisions of the Bill and lays down the Parliamentary procedure which applies to orders and regulations made under powers contained in the Bill. It also provides for the provisions of the Bill to come into force in accordance with orders made by the Secretary of State (or by the Welsh Ministers in relation to a number of provisions in so far as they apply to Wales, or by the Department of Health, Social Services and Public Safety in Northern Ireland ('DHSSPSNI') in relation to a number of other provisions in so far as they relate to Northern Ireland, or by the Treasury in relation to Part 4). It confers power on the Secretary of State to make transitional, transitory, supplementary, incidental or consequential provision or savings by order. Power is also conferred on the Welsh Ministers to make transitional or transitory provision or savings in relation to those provisions of the Bill which they have the power to commence.

OVERVIEW OF THE STRUCTURE

86. Part 1 of the Bill establishes a new regulator for health and adult social care services in England that will also take on the role (with the Welsh Ministers) of monitoring and other functions under the Mental Health Act. Part 2 contains changes to the regulation of health professions and the health and social care workforce. Part 3 amends the Public Health Act 1984. Part 4 creates a new payment for expectant mothers in the UK, to contribute towards the cost of a healthy lifestyle, including diet, during the final weeks of pregnancy and to help women to afford the other additional costs faced at this time. Part 5 of the Bill makes various

provisions regarding the National Health Service, the NCMP, social care, financial assistance related to the provision of health and social care services, the establishment of the National Information Governance Board, and the functions of the Health Protection Agency in relation to biological substances. Part 6 makes general provision about the Bill.

TERRITORIAL EXTENT

The Care Quality Commission

87. Part 1 of the Bill extends to England and Wales only, with the exception of three clauses, namely the general interpretation clause and the clauses which permit the Commission to make arrangements with Ministers of the Crown and Northern Ireland Ministers to perform certain functions on their behalf. The general interpretation clause has a UK extent. The other two clauses extend respectively to the whole of the UK (in the case of Ministers of the Crown) and to England and Wales and Northern Ireland (in the case of Northern Ireland Ministers).

Regulation of Health Professions and Health and Social Care Workforce

88. Much of Part 2 of the Bill has a UK extent. The regulation of most of the healthcare professions is reserved to Westminster, but for some professions this is devolved to the Scottish Parliament, as it will be for professions introduced to regulation in the future. A Legislative Consent Motion has been made by the Scottish Parliament, giving its agreement to the provisions of the Bill which deal with devolved professions being considered by the UK Parliament. Legislation extends to Northern Ireland by consent. A Legislative Consent Resolution has been passed by the Northern Ireland Assembly.

89. The provisions for the regulation of the social care workforce extend to England and Wales only. The regulation-making powers will enable the Secretary of State to make regulations in relation to England, and the Welsh Ministers to make regulations in relation to Wales.

90. The provision about the conferral of functions on responsible officers in relation to the regulation of medical practitioners extends to the whole of the UK. The provision enabling certain additional functions to be conferred on responsible officers extends to England, Wales and Northern Ireland only whilst that enabling a duty to be imposed on healthcare organisations to co-operate extends to England and Wales only.

Public Health Protection

91. Part 3 of the Bill has the same extent as the Acts which it amends. In particular, the Public Health Act 1984 extends to England and Wales only.

Health in Pregnancy Grant

92. Certain of the clauses in Part 4 extend to England and Wales and Scotland only, others extend to Northern Ireland only and others have a UK extent.

Amendments relating to National Health Service
93. The changes regarding the duty on PCTs to improve the quality of healthcare and funding of pharmaceutical services extend to England and Wales only.

94. The clause on indemnity schemes applies only to England.

Weighing and measuring of children
95. The clauses extend to England and Wales only, giving regulation-making powers to the Secretary of State in relation to England, and the Welsh Ministers in relation to Wales.

Social care
96. The extension of direct payments extends to England and Wales only.

97. The changes to the National Assistance Act 1948 extend to England and Wales only.

Financial assistance related to provision of health or social care services
98. These clauses extend to England and Wales, but apply only in relation to social enterprises providing services in England.

National Information Governance Board for Health and Social Care
99. The National Information Governance Board will operate in England and Wales only.

Functions of the Health Protection Agency in relation to biological substances
100. This clause extends to the UK.

Consent of the Scottish Parliament
101. The Scottish Parliament's consent has been sought for the provisions in the Bill that trigger the Sewel Convention. They are as follows:

- The requirement that all the regulators of healthcare professions apply the civil rather than the criminal standard of proof in their consideration of fitness to practise cases. Two of the regulators - the Health Professions Council and the General Dental Council - regulate professions which include professions for which regulation is devolved.

- The powers for the Scottish Ministers to request advice from the Council for Healthcare Regulatory Excellence on any matter connected with a profession appearing to be a health care profession, and to require the Council to investigate and report on a particular matter. The regulation of some professions is devolved.

- The provisions for consultation on draft section 60 Orders with all relevant representatives of the professions being regulated. The regulation of some existing professions, and the future regulation of any "new" professions, are devolved.

- The provision that only the regulatory bodies and the OHPA can administer procedures relating to misconduct, unfitness to practise and similar matters. Two of the regulatory bodies operate in devolved as well as reserved areas.

- The provisions that allow Orders made under section 60 of the Health Act 1999 to amend or repeal Acts of the Scottish Parliament and alter the procedure applicable to Orders under that section which make consequential amendments of legislation in devolved areas.

- The provisions relating to the regulation of pharmacists and, under the Medicines Act 1968, pharmacy premises. The function of enforcing the Medicines Act is devolved to the Scottish Ministers.

- The repeal of the provision in the Health Act 1999 which prevents Privy Council functions from being exercised by a different person. This will facilitate changes intended to be made in subordinate legislation to put in place new arrangements in various areas where Privy Council involvement is no longer considered to be necessary. This will affect all the regulators, including those operating in devolved areas.

102. The Sewel Convention provides that Westminster will not normally legislate with regard to devolved matters in Scotland without the consent of the Scottish Parliament. If there are amendments relating to such matters which trigger the Convention, the consent of the Scottish Parliament will be sought for them.

Territorial application: Wales

The Care Quality Commission
103. The functions of MHAC under the Mental Health Act are transferred to the Commission in relation to England and to the Welsh Ministers in relation to Wales.

Regulation of Health Professions and Health and Social Care Workforce
104. The clauses on the regulation of the social care workforce apply to England and Wales. However, regulations will be made in both territories independently by the appropriate Minister. Regulation-making powers are also conferred on the Welsh Ministers by clauses 115 (additional responsibilities of responsible officers), 116 (co-operation between prescribed bodies) and 120 (education and training of AMHPs).

Public Health Protection
105. The public health protection clauses apply to England and Wales. However, regulations will be made in both territories independently by the appropriate Minister

Weighing and measuring of children: Wales
106. Clause 137 makes separate amendments relating to the weighing and measuring of children in Wales. These confer regulation-making powers on the Welsh Ministers.

Social Care
107. The extension of direct payments covers Wales to the same extent as section 57 of the Health and Social Care Act 2001 does now. Subsection (8) of clause 138 amends section 64 of that Act to enable the National Assembly for Wales to pass a resolution annulling any statutory instrument containing regulations made by the Welsh Ministers under section 57.

National Information Governance Board for Health and Social Care
108. It is intended that the functions of the National Information Governance Board in relation to Wales will be the same as the existing functions of PIAG under section 252 of the NHS Act 2006.

PART 1 – THE CARE QUALITY COMMISSION

CHAPTER 1 – INTRODUCTORY

Clause 1: The Care Quality Commission
109. Clause 1 establishes the Commission and abolishes CHAI, CSCI, and MHAC. It also gives effect to Schedule 1.

Schedule 1: The Care Quality Commission
110. Schedule 1 deals with the constitution of the Commission. *Paragraphs 1* and *2* set out its status and general powers and duties. *Paragraphs 3* to *5* relate to the appointment and remuneration of the Commission's members and employees. In particular, *paragraph 3* provides that the appointment of the chair and other members of the Commission will be carried out by the Secretary of State. It is expected that the Secretary of State will appoint the chair following pre-appointment scrutiny by Parliament, in line with proposals in the Government Green Paper on the Governance of Britain, but will delegate appointment of other members to the Appointments Commission under the Health Act 2006.

111. *Paragraph 6* requires the Commission to establish an advisory committee whose advice, and information provided by which, it must have regard to when deciding how it should exercise its functions. The purpose of this provision is to ensure that the Commission takes account of the views of those with an interest in its work, such as the providers and users of health and social care services. *Paragraph 7* enables the Commission to arrange for any of its committees (but not the advisory committee), sub-committees, members or employees or any other person to exercise any of its functions. *Paragraph 8* enables it to arrange for persons to assist in the exercise of its functions.

112. *Paragraphs 9* and *10* deal with payments and loans to the Commission and its accounts. The Commission may only borrow money from the Secretary of State. It is required to produce annual accounts and provide copies to the Secretary of State, and the Comptroller and Auditor General. The Commission's annual accounts will also cover its functions under the Mental Health Act.

113. *Paragraphs 11* and *12* set out arrangements for the application of the Commission's seal and for documents purporting to be signed or sealed by or on behalf of the Commission to be accepted as evidence in court.

Clause 2: The Commission's functions

114. Clause 2 sets out the main areas in which the Commission has functions. It also makes reference to functions the Commission may have under other enactments. This would include, for example, functions it is intended that it will have for monitoring the application of new Deprivation of Liberty Safeguards under the Mental Capacity Act 2005, functions under regulations under the European Communities Act 1972 relating to medical exposure to Ionising Radiation, or functions that other bodies may, by agreement, delegate to the Commission.

115. Clause 2 also sets out the matters to which the Commission should have regard in performing its functions. These include requirements for the Commission to have regard to:

- the need to safeguard the rights of children and vulnerable adults;
- views expressed by or on behalf of members of the public on activities that fall within the remit of the Commission. These views might, for example, be expressed by representative bodies, such as charities or Local Involvement Networks;
- the Government's five principles of good regulation (as set out in the Legislative and Regulatory Reform Act 2006), under which regulatory activity should be proportionate, accountable, consistent, transparent and targeted where it is needed;
- aspects of Government policy.

116. The clause requires the Commission to perform its functions for the general purpose of encouraging: improvement in the activities within its remit; a focus on the needs of patients and other service users; and the efficient and effective use of resources.

Clause 3: Transfers of property, rights and liabilities

117. This clause gives effect to Schedule 2.

Schedule 2: Transfers of property and staff etc.

118. *Paragraph 1(1)* of Schedule 2 enables the Secretary of State to make transfer schemes in order to transfer the property, rights and liabilities of CSCI and CHAI to the new Commission or to the Crown. It also enables transfer schemes to be made for the transfer of property, rights and liabilities of MHAC to the new Commission, to the Welsh Ministers or to the Crown. Transfer schemes may also transfer property, rights and liabilities of the Crown to the new Commission. *Paragraphs 3* and *4* set out matters in relation to the transfer of staff to the new Commission.

CHAPTER 2 – REGISTRATION IN RESPECT OF PROVISION OF HEALTH OR SOCIAL CARE

Introductory

Clause 4 and clause 5: Introductory

119. Clause 4 enables regulations to be made to define what kind of health and social care activities will trigger the requirement to register with the Commission. These activities are to be known as regulated activities. Anybody who carries on a regulated activity will have to be registered. The Government publication "*The future regulation of health and adult social care in England*" (published November 2006) sets out initial proposals for the broad types of activities that will be regulated activities. There will be a further consultation on the types of activities to be regulated, and the registration requirements to be imposed under clause 16, during the passage of the Bill through Parliament.

120. *Subsection (2)* of clause 4 provides that an activity must involve or be connected with the provision of health or social care in, or in relation to England, in order to be defined in regulations as a 'regulated activity'. In addition it must not involve the provision of care which is regulated by CIECSS.

121. *Subsection (3)* of clause 4 explains further the sorts of activities that are to be considered as being connected with the provision of health or social care. These might include the supply of nursing or care home staff, transport services for elderly or disabled people, and healthcare advice provided by phone.

122. Clause 5 defines the terms 'health care' and 'social care' for the purposes of Part 1 of the Bill. The definition of health care includes provision of cosmetic procedures that are similar to procedures that might be provided in relation to a medical condition. It also includes public health services that provide health care to individuals. For example, this might include smoking cessation clinics, or sexual health clinics.

Registration of persons carrying on regulated activities

Clauses 6 to 8: Registration of persons carrying on regulated activities

123. Clause 6 concerns the requirement for a person (referred to as a "service provider") to register in respect of the carrying on of a regulated activity. A person in this context means a

legal 'person', which includes a company**.** Where two or more legal persons are involved, in different capacities, in carrying on the activities, regulations may set out who will be treated as the service provider. It is intended that this will be the person responsible for ensuring the service complies with the requirements laid out in this (and any other relevant) legislation.

124. Under clause 6, carrying on regulated activities without being registered will be an offence. For example, assuming that these were regulated activities, this might cover providing personal care services or carrying on a dialysis unit without being registered with the Commission to provide these services. *Subsection (4)* provides for the offence to be triable either way (by a magistrate's court or a Crown Court) and sets out the maximum penalties. The penalty on summary conviction is a fine of up to £50,000 or up to 12 months imprisonment, or both. The penalty on conviction on indictment is an unlimited fine or up to 12 months imprisonment, or both. It is intended that the Sentencing Guidelines Council should issue guidelines as to how the courts should exercise their discretion in sentencing.

125. Section 281(5) of the Criminal Justice Act 2003 extends the maximum term of imprisonment on summary conviction from 6 months to 12 months. For offences that occur before that section is commenced the maximum term of 6 months will still apply.

126. Clause 7 sets out the process for applying to register with the Commission. Under clause 7, a person required to register to carry on any of the activities set out in regulations under clause 4 will have to apply to the Commission, providing such information as the Commission determines is necessary.

127. The Commission may allow an applicant to make a single application to register to provide more than one type of regulated activity. For instance, NHS Trusts provide a wide range of activities. They will have to register separately in relation to each kind of regulated activity they provide, but could do so in one application.

128. Clause 8 deals with the grant or refusal of registration as a service provider. Under clause 8, the Commission can only register an applicant if it is satisfied that the applicant is meeting, and will continue to meet, the requirements the Secretary of State has set down in regulations under clause 16, as well as any other legislative requirements the Commission considers are relevant. The burden of proof is with the applicant rather than with the Commission. Anyone registered by the Commission to carry on any of the activities covered in regulations under clause 4 will receive a certificate of registration.

129. In granting registration as a service provider, the Commission can impose any conditions it thinks are necessary. Conditions may limit the types of services that a service provider may provide and where they may be provided. For example, the Commission will be able to impose conditions on the provision of care in residential homes, the effect of which would be to specify the categories of users of services and the number of residents that may be accommodated.

130. The Commission may also impose a specific condition to take account of the circumstances of a particular case. For example, there might be a condition, the effect of which is that the provider is only permitted to operate from three specified sites. If the service provider is required under clause 9 to appoint a registered manager, then this would also be a condition of their registration. The Commission can change the conditions of a service provider's registration at any time, which would allow additional conditions to be imposed. For example, there might be a condition requiring a particular hospital ward to be closed, or a restriction preventing further admissions until a breach of registration requirements has been corrected.

Registration of managers

Clauses 9 to 11: Registration of managers

131. Clauses 9 to 11 deal with when a service provider must appoint a registered manager to manage certain regulated activities which the service provider is registered to provide. They also set out the process for applying to register as a manager and how the Commission decides whether to grant or refuse registration.

132. Regulations will set out when the registered service provider will be required to appoint a registered manager. The Commission will also have discretion to determine whether a registered manager should be required in other instances. The factors the Commission must take into account when exercising this discretion will be set out in regulations made by the Secretary of State.

133. A service provider might still decide to appoint a manager in instances where he is not obliged to do so. Under those circumstances, there is no requirement for the manager to be registered with the Commission and the Commission will have no power to register anyone as manager.

134. As with service providers, applications to register as a manager with the Commission will have to include such details as the Commission requires. The Commission may allow someone to make one application to manage more than one kind of activity carried on by a service provider. Registered managers will be responsible for ensuring that the activities they manage comply with relevant requirements in the same way the service provider will be.

135. Under clause 11, the Commission is only obliged to register a manager if it is satisfied that the applicant is managing, or will be managing, services that meet, and will continue to meet, the requirements the Secretary of State has set down in regulations under clause 16, as well as any other legislative requirements the Commission considers are relevant. The burden of proof is with the applicant rather than with the Commission. Anyone registered as a manager by the Commission will be issued with a certificate of registration.

136. In granting registration as a manager, the Commission can impose any conditions it thinks are necessary. Where relevant, conditions that apply to the service provider will also apply to the manager but there may be additional conditions which are specific to the

registered manager. The Commission can change conditions imposed on a manager's registration in the same way it can for a provider's registration.

Further provision about registration as a service provider or manager

Clause 12: Regulations about registration

137. Clause 12 provides a power to make regulations on the details of the registration process. Regulations may be made under *paragraph (a)* to set out what information the Commission needs to keep on the register. Although the Commission will determine what must be included in applications to register, regulations may be made under *paragraphs (b*) and *(c)* to cover issues such as requirements to attend interviews or to notify the Commission of any relevant change in circumstances following the submission of the application. Under *paragraph (d),* regulations may set out requirements for registered persons to provide the Commission with an address for the service of documents.

Clauses 13 and 14: Cancellation / suspension of registration

138. Clause 13 gives the Commission the power to cancel the registration of a manager or service provider where:

- the person registered has been convicted of or admitted a relevant offence;
- any other person has been convicted of a relevant offence in relation to the regulated activity;
- the regulated activity is being or has been carried on in any way that is not in accordance with the conditions of registration or requirements under Chapters 2 or 6 or requirements under other legislation which the Commission considers to be relevant.

139. The clause defines relevant offences as:

- offences under Part 1 of the Bill or regulations made under it;
- offences under the Registered Homes Act 1984 or Part 2 of the Care Standards Act 2000 (or regulations made under them);
- such other offences as may be prescribed.

140. Further grounds for cancelling registration may be specified in regulations. For instance, regulations may require that all staff receive appropriate training in handling medicines, and state that failure to provide this training would be grounds for cancellation. Regulations may also make provision for registration to be cancelled where a person ceases to carry on or manage regulated activities.

141. Cancellation of registration would not normally be the first step in formal enforcement action. It is more likely to be used where other actions, such as issuing a warning notice or penalty notice or prosecution for an offence, have failed to ensure compliance, though this will depend on the severity of the breach. If a registered service provider or manager is convicted of a relevant offence, such as breaching a condition of registration (an offence under clause 29) and fails to remedy the breach, the Commission could then cancel the person's registration.

142. The Commission will also have the power to suspend a person's registration as a service provider or a manager under clause 14 for a fixed period of time if they are failing to comply with the requirements of Chapter 2, or a requirement imposed by or under Chapter 6, or requirements of any other relevant legislation. In this instance the person would continue to be registered but could not carry on or manage the regulated activities in respect of which they are registered until the end of the suspension. Neither could they hold themselves out as being registered to carry on these activities.

Clause 15: Applications by registered persons

143. Clause 15 enables registered service providers and registered managers to apply: to change the conditions of their registration (for example to change the number of people they are registered to accommodate); voluntarily to cancel their registration (for example, if they plan to close or sell the business); or to amend or lift any suspension of their registration (for example, if they believe they can demonstrate that they are once again complying with any relevant requirements).

144. It is not, however, possible for a service provider to apply to change any mandatory condition imposed as a result of regulations made under clause 9 requiring him to appoint a registered manager (*subsection (1)(a)*). Neither is it possible for either a service provider or a manager to apply to voluntarily cancel their registration if the Commission has given notice that it intends to, or has decided to, cancel it already (*subsections (2)* and *(3)*).

145. If the Commission decides to grant an application to change conditions of registration or to amend or lift a suspension, the Commission must write to the applicant to inform the applicant of its decision, setting out how the conditions or suspension have changed and, if relevant, issue a new certificate of registration (*subsections (5)* and *(6)*).

Regulation, code of practice and guidance

Clauses 16 to 21: Requirements in relation to regulated activities

146. Clauses 16 to 21 provide for regulations to be made setting out the detailed requirements to be met by providers and managers of regulated activities. They also provide for a Code of Practice and guidance to be issued about how compliance with those requirements will be assessed by the Commission.

147. *Subsection (1)* of clause 16 gives the Secretary of State a general power to make regulations imposing any requirements he sees fit in relation to regulated activities. He is obliged to consult on these regulations or any significant change to them (*subsection (8)*).

148. The regulations made may, in particular, include provision intended to safeguard the health, safety and welfare of people who receive regulated health and adult social care, and to ensure that those services are of the necessary quality (*subsection (2)*).

149. *Subsection (3)* sets out specific issues which any regulations made under clause 16 may deal with. It provides for regulations to be made which set out who are fit people to register as service providers or managers, including requirements relating to the financial solvency of service providers. It also provides for regulations to be made which set out who may be considered to be fit to deliver regulated activities. For example, there may be requirements regarding their management and training.

150. Regulations may cover issues such as the use of appropriate premises. They may also make provision about the way in which a regulated activity is carried on.

151. The regulations may also cover issues relating to the recipients of regulated activities, such as requirements regarding the appropriate use of control and restraint, or the provision of information.

152. They may also cover more practical issues around record keeping, accounting and arrangements for dealing with and learning from complaints and disputes, and may require registered providers to review the quality of services they offer, prepare a report of the review, and make it available to the public. They may also require providers to make information available about charges made for those services.

153. *Subsection (5)* enables regulations to include requirements for preventing and controlling health care associated infections ('HCAIs') such as MRSA and *Clostridium difficile*. These will cover the steps that service providers and managers must take to safeguard people using or providing health and social care services from such infections.

154. Under clause 17 the Secretary of State may also issue a code of practice about compliance with the requirements relating to the prevention and control of HCAIs. This code will replace the code that NHS bodies currently follow (issued under sections 47A to 47C of the Health and Social Care (Community Health and Standards) Act 2003, as amended by the NHS Act 2006). The new code will apply to all regulated activities, rather than only those carried out by NHS bodies. Clause 18 sets out the consultation process that the Secretary of State must follow when preparing to issue the code of practice, or revisions to it.

155. For the rest of the requirements set out in the regulations made under clause 16 the Commission must issue guidance on how service providers and managers should demonstrate

compliance with them (clause 19). The guidance can also relate to requirements in other legislation that the Commission believes to be relevant. For instance, it is intended that it will cover requirements imposed on relevant providers by the Mental Health Act for which the Commission will take on responsibility. Clause 20 sets out the consultation process that the Commission must follow when it proposes to issue or revise guidance on compliance with requirements.

156. Under clause 21 the Code of Practice on infection control, and the Commission's guidance on compliance with other registration requirements, have to be taken into account by the Commission when it takes decisions such as:

- whether or not a person is fit to be registered;
- whether they are complying with the conditions of their registration;
- whether they are complying with the requirements in regulations under clause 16;
- whether it should suspend or cancel someone's registration;
- whether to prosecute someone.

157. The Code of Practice and the Commission's guidance must also be taken into account in decisions such as the urgent cancellation of a person's registration under clause 26, or in appeal proceedings.

158. Although a failure to comply with either the Code of Practice or the Commission's own guidance does not in itself constitute an offence, they may both be used as evidence in criminal or civil proceedings as examples of what is expected behaviour in the areas they cover.

Registration procedure

Clauses 22 and 23: Notices of proposals and rights to make representations

159. Clause 22 requires the Commission to give written notice to applicants or registered persons of any proposal in relation to the:

- granting of an application for registration which is subject to conditions that have not been agreed with the applicant (this excludes a registered manager condition required under clause 9(1));
- refusal of an application for registration;

- cancellation of registration (except where the registered person has applied for cancellation of registration under clause 15, or the Commission has applied for an order to urgently cancel a registration under clause 26);

- suspension of registration (except where the Commission has urgently suspended a registration under clause 27);

- amendment of the conditions of registration (except where the Commission has urgently removed or varied a condition or imposed an additional one under clause 27);

- refusal of an application by a provider or manager of regulated activities made under clause 15(1) to vary or remove a condition, cancel their registration, or cancel or vary a period of suspension.

160. The written notice must set out the reasons for the proposal (*subsection (6)*). For example, in the case of a person applying to register for the first time, the notice of proposal must explain why the Commission takes the view that the person does not meet the relevant requirements or why particular conditions are thought to be necessary. Clause 22 does not apply where the Commission decides to grant an application for registration unconditionally. Neither does it apply where the registration is subject only to a registered manager condition under clause 9(1) or where the Commission and the service provider have already agreed the conditions (this must be by way of a written agreement). These situations are covered by clause 24.

161. Clause 23 sets out that a notice of proposal under clause 22 must state that the person has 28 days to make written representations to the Commission if they wish to dispute the Commission's proposal. This ensures that the person has an opportunity to make their point known. The Commission cannot make a decision until it has either received written representations, or it has received written confirmation that the person does not intend to make representations, or the 28-day period has elapsed.

Clause 24: Notice of decisions

162. Clause 24 requires the Commission to give the applicant notice of its decision to grant an application unconditionally, or subject only to a registered manager condition under clause 9(1) and/or conditions already agreed in writing with the applicant (*subsection (1)*). The notice must state the conditions *(subsection (2)*).

163. Where the Commission has decided to give effect to a proposal of which notice was previously given under clause 22, *subsection (3)* requires the Commission to serve a further notice in writing of its decision.

164. That further notice must explain the rights of appeal conferred under clause 28. In the case of a decision to grant an application subject to conditions, or to vary the conditions of an

existing registration, the notice must set out the conditions, or the changes to them. In the case of a decision to suspend registration, the notice must state the period of the suspension (*subsection (4)*).

165. A decision made by the Commission under clause 24 to adopt a proposal of which notice has been given under clause 22 will take effect, either from the date that the Commission receives notice that the provider does not intend to appeal, or after the outcome of any appeal has been determined or the appeal has been abandoned, or after 28 days if no appeal is brought.

Clause 25: Warning notice

166. Clause 25 allows the Commission to give a warning notice to a registered person when they have failed to comply with the relevant requirements. For example, the Commission may issue a warning notice where a registered person has failed to comply with regulations made under clause 16.

167. The warning notice must set out the failure that appears to the Commission to have taken place and the requirement that appears to have been breached. It may also require the registered person to comply with the requirement within a specified timeframe, stating that further action may be taken if the failure is not put right in that time. No further action may be taken by the Commission in relation to the failure set out in the notice if the failure is remedied in that time.

168. Where the warning notice relates to a failure that has already been rectified when the notice is issued, no further action may be taken by the Commission.

Clause 26: Urgent procedure for cancellation

169. Under clause 26 the Commission may apply to a justice of the peace for the immediate cancellation of registration (known as the 'urgent procedure'). The order may only be made where it appears to the justice of the peace that there will be a serious risk to a person's life, health or well-being unless the order is made. An order made under this section will have immediate effect.

170. *Subsection (3)* requires the Commission to notify the relevant local authority and/or the relevant PCT in accordance with regulations, if it makes an application to a justice of the peace under the urgent procedure. This is necessary so that the relevant bodies can comply with their statutory duties (for example, in the case of a local authority, to provide or arrange alternative care for service users in accordance with their duties under section 47(1) of the National Health Service and Community Care Act 1990). The relevant bodies will need to consider whether to make alternative provision for services.

171. Where the Commission makes an application under the urgent procedure regarding the registration of a PCT or an NHS Trust, the Commission must notify the relevant Strategic

Health Authority. If the urgent procedure will affect an NHS Foundation Trust, the Commission must notify the Independent Regulator of NHS Foundation Trusts ('Monitor'). The Commission must also notify any other persons it considers appropriate. It is important that all bodies that may be affected by the cancellation of a provider's registration have as much notice as possible to make any necessary arrangements. As soon as possible after an order is made, the Commission must provide a copy of the order to the registered person, and details of their rights of appeal under clause 28.

Clause 27: Urgent procedure for variation, suspension etc.

172. Clause 27 allows the Commission to immediately suspend, or extend the period of suspension of, a person's registration as a service provider or registered manager, or to change the conditions that apply to a person's registration, where it believes that any person will or may be exposed to the risk of harm. Notice of the action must be given in writing and the notice must state either the reasons for the change of conditions, or the reasons for the period of suspension, and explain the rights of appeal under clause 28.

Clause 28: Appeals to the Tribunal

173. Clause 28 provides for an appeal against a decision by the Commission under Chapter 2 (excluding decisions to give warning notices). It also allows for an appeal against an order made by a justice of the peace under clause 26. A person has 28 days to appeal from the date of the service of notice of the decision or order.

174. The appeal is to the Tribunal established under section 9 of the Protection of Children Act 1999, the Care Standards Tribunal, which currently hears appeals from those registered under the Care Standards Act 2000. *Subsections (3)* to *(6)* provide for the Tribunal's powers in considering an appeal. The Tribunal may confirm or overturn a decision made by the Commission or a justice of the peace. It may also vary the length of a suspension or vary or remove any of the conditions of registration, with the exception of any 'registered manager' condition required by clause 9(1), or add a new condition, again with the exception of a 'registered manager condition'.

Offences

Clauses 29 to 33: Offences

175. Clauses 29 to 33 set out the offences under this Chapter of the Bill. The Commission will be the prosecuting authority in respect of these offences, using its powers of entry and inspection under Chapter 6 to gather evidence.

176. If convicted of an offence under these clauses the registered person would be liable to a fine.

177. Clause 29 makes it an offence for a service provider or a registered manager to fail to adhere to the conditions of their registration. The penalty for an offence under this clause is a fine of up to £50,000 on summary conviction.

178. It is an offence to carry on regulated activities without being registered to do so (clause 6). *Subsection (1)* of clause 30 also makes it an offence for registered service providers to continue carrying on regulated activities whilst their registration is suspended.

179. Clause 9 obliges the Commission to place a condition on the registration of a service provider requiring them to have a registered manager to manage certain regulated activities in prescribed circumstances. Where a registered manager has had his registration cancelled or suspended, clause 30 makes it an offence for him to continue to manage the activities in respect of which he is registered. It also makes it an offence for a registered manager to knowingly continue to manage activities if the registered service provider for whom he manages those activities has had his registration cancelled or suspended. The penalty for an offence under this clause is a fine of up to £50,000 on summary conviction.

180. Clause 31 allows regulations to be made under Chapter 2 that will make failure to comply with specified regulations an offence. For instance, it is intended that it will be an offence to fail to comply with certain requirements made in regulations under clause 16 (regulation of regulated activities). The amount of the fine prescribed will not exceed £50,000 in respect of regulations made under clause 16 (regulation of regulated activities) and in any other case will not exceed level 4 (currently £2,500) on the standard scale. Regulations may not provide for offences to be triable on indictment or to carry penalties of imprisonment.

181. Clause 32 makes it an offence for a person to claim that a concern is carrying on regulated activities, or that premises are used for carrying on regulated activities, if they are not registered with the Commission to carry on those activities, or they are registered to carry them on but their registration has been suspended. This would apply to someone who provides care to people under false pretences, for example a hotel claiming to be a nursing home. It would also apply to someone who misrepresents the nature of their registration, by claiming, for instance, that they are registered to care for a particular category of resident when they are not. It also makes it an offence for any person to claim they are a service provider able to provide a particular service or do anything which would contravene a condition of their registration. The penalty for an offence under this clause is a fine not exceeding level 5 (£5,000) on the standard scale.

182. Clause 33 makes it an offence for someone to knowingly make a false or misleading statement in an application to the Commission. The clause applies to applications to register as a service provider or registered manager, to vary or remove conditions on their registration, to vary or cancel the suspension of their registration or to cancel their registration. The penalty will be a fine of up to level 4 (£2,500) on the standard scale. Application forms will inform people of this offence so that they are aware of the potential result of failing to complete their applications accurately.

Information to be available to public

Clause 34: Provision of copies of registers

183. The Commission will have to make copies of its registers of service providers and managers available to the public. Clause 34 allows members of the public to view them at the Commission's offices or to request copies of the full register or an extract. It will be up to the Commission to determine the best way to make information available but it may choose to improve accessibility through electronic means. A charge will be made for the provision of a copy or extract except in circumstances prescribed in regulations or where the Commission decides that the copy or extract should be provided for free.

184. However, there may be information that should not be released to the general public, such as certain information that identifies individuals. Clause 34(3) allows regulations to be made setting out what information should not be accessible.

Miscellaneous

Clause 35: Bodies required to be notified of certain matters

185. Under clause 35 the Commission will have to notify certain people when it issues warning notices, when it receives payment of a penalty under a penalty notice or when it decides to prosecute. The Commission must also notify certain people when it issues a notice of proposal under clause 22 or a notice of decision under clause 24. It will also have to notify these people in relation to any urgent suspension of registration or any urgent variation of the conditions of registration. For instance, if the Commission proposes to change the conditions of an NHS Trust's registration it must notify the relevant Strategic Health Authority (as determined by regulations). In the case of a Foundation Trust it must notify Monitor. In other cases, it must notify PCTs or local authorities in accordance with regulations. For example, regulations may require PCTs or local authorities who are commissioning services from the person in question to be notified.

Clauses 36 to 38: Miscellaneous

186. Clause 36 enables regulations to be made requiring persons who are registered to carry on regulated activities to make returns to the Commission. The regulations may also specify the frequency of the returns, their content, the period that the returns relate to, and the date by which returns must be made.

187. Clause 37 provides for regulations to be made which deal with the process that applies when companies or people that are registered as service providers go into liquidation or receivership, or are declared bankrupt. The regulations may require the Commission to be notified and a suitably qualified manager to be appointed to manage the regulated activities.

188. Regulations under clause 38 may require the Commission to be notified if a person who is registered as a service provider dies. They may also enable someone else to continue to carry on, for a limited period, the regulated activities which the deceased person was carrying on, and for the clauses of the Bill to apply in a modified way to allow for this.

Power to modify provisions of Chapter

Clause 39: Power to modify Chapter in relation to newly regulated activities

189. Clause 39 enables the Secretary of State to make regulations modifying Chapter 2 in its application to newly regulated activities of a prescribed description. The registration provisions are designed to work to cover care which is already subject to regulation and to cover care directly provided by NHS bodies. When other forms of care are eventually brought within the ambit of the registration regime, there may be unforeseeable issues which necessitate modification of the registration procedures. This power allows for that eventuality. The power to modify the Bill under this clause after it is enacted would not apply to the registration of NHS bodies and other providers registered with the Commission from the outset.

CHAPTER 3 – QUALITY OF HEALTH AND SOCIAL CARE

Health care standards

Clause 41: Standards set by Secretary of State

190. Clause 41 gives the Secretary of State the power to prepare and publish statements of standards in relation to the provision of health care by and for PCTs and to amend these statements from time to time.

191. It is envisaged that these standards will be benchmarks of expected behaviour and good practice. PCTs will be required to have regard to them in discharging their duty under the new section 23A of the NHS Act 2006 (see clause 133) to secure continuous improvement in the quality of health care provided or commissioned by them. *Subsection (3)* allows the Secretary of State to direct another person to develop standards and to submit them for approval, and it is envisaged that this will allow primarily professional bodies to work on new suites of standards or to submit existing suites for approval. The Secretary of State may also ask any person to keep statements of standards under review, and to provide advice on any changes they consider should be made to the standards by submitting amended statements of standards.

192. *Subsection (4)* provides that the Secretary of State must consult on the content of such statements of standards, or amended statements of standards which effect a substantial change in the standards, before they are published. The Commission has no role in monitoring or assessing compliance with these standards.

Reviews and investigations

Clause 42: Periodic reviews

193. In place of the annual reviews currently conducted by CHAI and CSCI, the Commission will carry out periodic reviews under clause 42 of PCTs, NHS providers in England and local authorities in England.

194. PCTs and local authorities provide health and adult social services but they also commission from other organisations health and adult social services that they consider necessary to meet the needs of their local populations. For example, a local authority might pay for people with particular kinds of needs to be cared for in a private facility that specialises in catering for such people.

195. The Commission will therefore carry out reviews of the effectiveness of commissioning by reviewing the overall provision of health care in PCT areas under *subsection (1)* and adult social services in local authority areas under *subsection (3).* These reviews will assess how well the services they provide and commission are meeting the needs of their local populations.

196. The Commission will also review NHS bodies that provide services, referred to as English NHS providers. This includes English NHS Trusts and NHS Foundation Trusts. PCTs will also be reviewed in respect of the health care they provide. These reviews will be about how providers are performing above the level required to comply with registration requirements.

197. Reviews will be by reference to a set of indicators which will either be devised by the Secretary of State in whole or in part or devised by the Commission and approved by the Secretary of State. For reviews of PCTs and local authorities under subsections (1) and (3) it is intended that these will primarily be based on outcomes that the Government has decided are the most appropriate measurements by which to judge the performance of PCTs and local authorities. The Government intends that the indicators set under this power in relation to local authorities (working alone or in partnership with PCTs, other NHS bodies or other local service providers) will be part of the single set of national indicators to which the Government committed itself in the Local Government White Paper – *"Strong and Prosperous Communities"* in October 2006.

198. Reviews of English NHS providers under *subsection (2)* will also look broadly at the quality of care provided, taking account of the same outcomes against which commissioners are assessed. The intention is that the Commission will be given responsibility for setting the indicators used for provider reviews from the outset. Reviews of English NHS providers under subsection (2), and reviews of the overall quality of provision in PCT or local authority areas under subsections (1) and (3) may well use much of the same information. In these cases it is intended that the Commission will only collect that information once.

199. The Commission must devise a methodology for assessing and evaluating bodies against relevant indicators, and this methodology must be approved by the Secretary of State. It must publish its methodology, as well as the indicators used for reviews, whether they are set by the Secretary of State, or set by the Commission and approved by the Secretary of State.

200. Following a review the Commission will publish a report of its assessment. Regulations may set out the procedure that should apply to allow people to make representations to the Commission before the report is published. The reason for setting out this procedure is to ensure that the reviewed body is given time to comment, and that any comments are considered by the Commission.

Clause 43: Frequency and period of review

201. Under clause 43 the Commission is required to publish details of how often it will conduct periodic reviews. It can decide to undertake reviews at different intervals in different circumstances. For instance, the Commission may decide that it will review bodies that perform consistently well less frequently. The Commission must submit its proposals on the frequency of reviews to the Secretary of State for approval.

Clause 44: Special reviews and investigations

202. Clause 44 enables the Commission to conduct additional reviews and investigations (referred to as 'special reviews and investigations'). These can cover: any aspect of health and adult social services provided or commissioned by a PCT or local authority; functions carried out by Strategic Health Authorities; or, where the majority of their functions are carried out in England, functions carried out by Special Health Authorities. Reviews and investigations under this clause could look specifically or generally at any issue to do with different kinds of health or adult social care, including the commissioning of that care, how particular functions are carried out or provision by particular people or bodies. Investigations may be carried out where the Commission identifies a risk to a care recipient's health or welfare. For instance, the Commission might investigate older people's services in a particular area, and then nationally where there is evidence to suggest a problem is more widespread. The Commission may also carry out reviews into topics of particular interest, for instance, it may carry out a review of care pathways for people with long-term conditions. The Commission must carry out a review or investigation if requested by the Secretary of State.

203. The Commission will have to publish reports of any review or investigation carried out under clause 44. Regulations will set out what procedure should apply to allow people to make representations to the Commission before it publishes a report. As with similar powers in other clauses, the reason for this is to give the reviewed body time to comment and to ensure that any comments are considered by the Commission.

Clause 45: Power to extend periodic review function

204. Clause 45 gives the Secretary of State the power to make regulations requiring the Commission to carry out such periodic reviews (as in clause 42) of regulated activities and of registered service providers, as may be specified in the regulations. The regulations can also require the Commission to publish reports of its reviews or assess the performance of registered service providers following such reviews and publish reports of its assessment.

205. Regulations under this clause can require the Commission to review some or all registered service providers, some or all regulated activities provided by such service providers, or even particular aspects of a regulated activity. *Subsection (3)* allows for particular aspects of provision to be reviewed separately, despite the fact that they may already have formed part of a broader review under clause 42.

206. This will allow the Commission to look at certain types of services. For instance, the Secretary of State may decide that all residential premises providing adult social care should be reviewed and assessed individually, whether run privately or by a local authority. Alternatively, regulations could require that all maternity services should be reviewed by the Commission. This will be possible even if these services have already been covered under the review of health care provision in a PCT area under clause 42(1).

207. In other cases, the Secretary of State may want the Commission to publish information on a particular service. For instance, many NHS Trusts sub-contract with private hospitals to provide additional capacity for routine surgery such as hip operations. Although these services would be covered by reviews by the Commission (under clause 42) of the overall provision of health care by a Trust, the Secretary of State may want the Commission to separately review the quality of provision under such arrangements. Although it may not be useful to aggregate performance across a small number of indicators into results for each provider of hip operations, the Commission could still be required to publish details of the review.

208. Where regulations are made extending periodic reviews, the Commission must publish details of how often these reviews will be conducted as with periodic reviews under clause 42. These reviews will also be by reference to a set of indicators devised or approved by the Secretary of State.

209. Also as with periodic reviews under clause 42, the Commission must devise a methodology for assessing and evaluating bodies against relevant indicators, and this methodology must be approved by the Secretary of State. It must publish its methodology, as well as the indicators used for reviews, whether they are set by the Secretary of State, or set by the Commission and approved by the Secretary of State.

210. Regulations may set out the procedure that should apply to allow people to make representations to the Commission before a report is published. The reason for setting out this procedure is to ensure that the reviewed body is given time to comment, and that any comments are considered by the Commission.

211. It is intended that, where possible and appropriate, the same information will be used to inform a review under this clause as is used in other reviews of health or adult social care provision that the Commission carries out. This will help avoid duplication in the information requests that providers and commissioners receive.

Clause 46: Failings by English local authorities

212. Clause 46 sets out steps which the Commission must or may take when, following a review under clause 42 or 45, or a review or investigation under clause 44, it judges that there are failings in a local authority's discharge of its adult social services functions.

213. If the failings are not substantial, the Commission may give a notice to the local authority, which will set out details of the failure, the action to be taken to rectify it and the time by which the Commission considers that this should be done. The Commission must also inform the Secretary of State of the action it has taken.

214. If the Commission considers that a local authority is significantly failing to discharge any of its adult social services functions to an acceptable standard it is obliged to inform the Secretary of State and recommend any special measures that it considers that the Secretary of State should take. Following a recommendation by the Commission of special measures, the Commission must, if asked to do so by the Secretary of State, undertake a further review of the local authority concerned and prepare a further report, covering any particular issues the Secretary of State might specify.

215. Measures which may be recommended by the Commission include the use by the Secretary of State of his powers of intervention (as set out in the Local Authority Social Services Act 1970 (section 7D), the Children Act 1989 (sections 81 and 84), the Local Government Act 1999 (section 15), and the Health and Social Care Act 2001 (section 46)). Under special measures the Secretary of State may issue the failing local authority with directions. In the most serious cases a direction may require that a specific function shall be exercised by the Secretary of State or a nominee. The Audit Commission report "*A Force for Change"* shows how special measures can improve performance.

216. The Commission does not have equivalent powers in relation to NHS bodies, as these are performance managed by Strategic Health Authorities on behalf of the Secretary of State.

Clause 47: Failings by Welsh NHS bodies

217. Where the Commission considers there are significant failings in the provision of health care by or for a Welsh NHS body or in the running of a Welsh NHS body or in the running of a body, or the practice of an individual, providing health care for a Welsh NHS body, *subsection (1)* requires the Commission to inform the Welsh Ministers. *Subsection (2)* allows the Commission to recommend that the Welsh Ministers take special measures to improve the situation.

CHAPTER 4 – FUNCTIONS UNDER MENTAL HEALTH ACT 1983

Clause 48 and Schedule 3 – Transfer and amendment of functions under Mental Health Act 1983

218. Clause 48 and Schedule 3 transfer the functions exercised by MHAC under the Mental Health Act to the Commission in relation to England, and to the Welsh Ministers in relation to Wales. The Commission and the Welsh Ministers are collectively referred to as the "relevant regulatory authority" where appropriate.

219. Section 121 of the Mental Health Act confers certain functions directly on MHAC, including a duty to review certain decisions relating to the withholding of post sent by or to patients detained under the Mental Health Act in high security psychiatric hospitals and a duty to publish a biennial report on its activities. Section 121 also requires that the Secretary of State direct MHAC to exercise certain functions on his behalf. In Wales, this requirement falls on the Welsh Ministers. The functions which the Secretary of State and the Welsh Ministers must direct MHAC to exercise include the appointment of registered medical practitioners to act as second opinion appointed doctors to approve certain forms of treatment under Parts 4 and 4A of the Mental Health Act. They also include functions under section 120 of the Mental Health Act in relation to the general protection of patients subject to the Act, including the duty to keep under review the discharge of certain duties and the exercise of certain powers under the Act (note that the functions conferred by section 120 are themselves amended in some respects by Schedule 3 to the Bill – see below.)

220. *Subsection (1)* of clause 48 transfers to the Commission the functions which the Secretary of State must currently direct MHAC to perform in relation to England, as well as two associated functions. *Subsection (3)* transfers to the Commission the powers conferred directly on MHAC by section 121 of the Mental Health Act. In relation to Wales, those functions are transferred to the Welsh Ministers. *Subsection (4)* provides that section 121 of the Mental Health Act ceases to have effect, which means (amongst other things) that there is no longer a requirement on the Welsh Ministers to direct MHAC (or anyone else) to exercise any of their functions under the Mental Health Act on their behalf. In practice, the effect is to transfer to the Welsh Ministers the functions which MHAC is currently required to perform on their behalf in Wales. *Subsection (2)* provides that registered medical practitioners and other people appointed or authorised by the Commission in the exercise of a function under the Mental Health Act may include members or employees of the Commission (just as section 121 of the Mental Health Act currently allows the equivalent people to be members of MHAC).

221. *Subsection (5)* of clause 48 introduces Schedule 3 which makes further amendments to the Mental Health Act. In particular, paragraph 8 of Schedule 3 replaces section 120 of the Mental Health Act. Under subsection (1) of new section 120, the relevant regulatory authority has a responsibility to review the exercise of powers and the discharge of duties in relation to detention, supervised community treatment and guardianship under the Mental

Health Act. Under subsection (3) it must make arrangements for authorised people to visit and interview relevant patients. These are equivalent to the functions exercisable by MHAC under the Mental Health Act as it stands now, except that they are extended to cover patients subject to guardianship as well as detention and supervised community treatment. The responsibility under subsection (1) does not extend to monitoring the functions conferred on any court, including the Mental Health Review Tribunal, or the Secretary of State (the performance of the Mental Health Review Tribunal is subject to separate scrutiny). The relevant regulatory authority must undertake an investigation into the exercise of the relevant functions if it thinks it is appropriate to do so. Under subsection (4), it must also make arrangements for the investigation of complaints concerning the exercise of relevant powers and duties under the Mental Health Act, but it is not required to undertake or continue investigation of a complaint if it does not consider it appropriate to do so.

222. Subsection (7) of new section 120 provides that a person authorised by the relevant regulatory authority has a right of entry to hospitals, to care homes registered under the Care Standards Act 2000 and to premises used for carrying out regulated activities in respect of which a person is registered under Part 2 of the Bill in order to carry out a review or investigation. The Bill does not confer a similar right to enter private homes. However, a patient may consent to be interviewed (in private, where appropriate). Authorised people may also require relevant records or other documents on the premises to be produced for inspection.

223. Paragraph 9 of Schedule 3 inserts sections 120A to 120D into the Mental Health Act. Under section 120A, the regulatory authority is able to publish a report of any review or investigation it undertakes under section 120(1). The Secretary of State and Welsh Ministers may make regulations about the making of representations before the publication of such a report. This will allow people who are subject to review and investigation an opportunity to respond if they think that there are mitigating factors, errors or other circumstances that might have affected the findings and which they do not think have been adequately taken into account. The Secretary of State will consult the Commission before doing this.

224. New section 120B enables the relevant regulatory authority to require hospital managers, social services departments and other prescribed people to publish a statement of the action they propose to take in response to any recommendations following a review or investigation undertaken under section 120(1). This will provide a public statement about the steps the person or body in question will take to address any concerns that are raised in reports.

225. The Mental Health Act confers powers and duties on a variety of people, including individual professionals and both statutory and independent bodies. For the most part, the people to whom these powers and duties fall are either responsible for hospitals (known as hospital managers in the Mental Health Act) which care for patients subject to the Mental Health Act, or are local social services authorities, or else are individuals working within such hospitals or on behalf of such authorities.

226. However, it is not only hospital managers and social services authorities and their staff who exercise relevant functions under the Mental Health Act and contribute to its operation. There may, therefore, be circumstances in which reviews or investigations make recommendations that are addressed (in whole or in part) to other people. In these cases, it would make sense for the people concerned to be asked directly to publish a report of the action they propose to take as a result. This might include, for example, other NHS bodies that are responsible for providing or commissioning services for patients subject to the Mental Health Act. The regulations can also set out what such statements should contain and how quickly they should be published.

227. New section 120C obliges hospital managers, local social services authorities and other prescribed people to provide the relevant regulatory authority with information, including records and documents, that the authority may require in relation to its functions under section 120. Examples of the kind of information which might be requested are:

- statistical information on people subject to the formal powers under the Mental Health Act, including data relating to particular groups of patients such as children, adolescents, women, and black and ethnic minority patients;

- information on the use of particular powers, such as the granting of leave of absence;

- the number of deaths and other serious incidents;

- information on the use of seclusion in respect of patients.

228. New section 120D requires the Commission to publish an annual report on the way it has exercised its functions under the Mental Health Act, a copy of which must be laid before Parliament. The Welsh Ministers will also have to publish such a report, a copy of which they will have to lay before the National Assembly for Wales.

229. Paragraph 12 of Schedule 3 inserts a new section 134A into the Mental Health Act. Section 134 of that Act provides, in particular, for the withholding of postal packets sent to or by patients detained in high security psychiatric hospitals in specified circumstances. Subsection (1) of the new section 134A provides that the relevant regulatory authority must review any decision to withhold a postal packet or anything contained in it on application by a specified person. These provisions are the equivalent of powers that already exist in section 121 of the Mental Health Act in relation to the review by MHAC of decisions to withhold postal packets under section 134 of that Act.

230. Subsection (5) provides that the Secretary of State may, by regulations, make provision in connection with applications to the Commission and the determination of any such application. This includes provision for the production to the Commission of any postal

packet in question. Subsection (6) gives the Welsh Ministers a similar power to make regulations about the making of applications to them.

231. This is, in effect, a restatement of the power to make regulations in subsection (9) of section 121 of the Mental Health Act as it stands now. The provision made under that power is currently to be found in Regulation 18 of the Mental Health (Hospital, Guardianship and Consent to Treatment) Regulations 1983 (SI 1983/893). Regulation 18 provides, in particular, that an application for a review of a decision to withhold a postal packet may be made to MHAC in any form that MHAC accepts as sufficient in the circumstances, and need not be in writing. Applicants must let MHAC have a copy of the notice of withholding provided by the relevant hospital. Regulation 18 also empowers MHAC to direct people to produce any documents, information or other evidence it reasonably requires for its review of the decision. The Government envisages that the powers in subsection (5) of the new section 134A will be used to make similar regulations in relation to the Commission.

CHAPTER 5 – FURTHER FUNCTIONS

Clause 49: Information and advice

232. Clause 49 places a duty on the Commission to keep the Secretary of State informed about the provision of NHS health care and adult social services in general, and about the carrying on of regulated activities. *Subsection (2)* allows the Commission to give advice to the Secretary of State on anything connected with these matters. In particular, the Commission may advise the Secretary of State of any changes it thinks should be made to: the registration requirements (made by regulations under clause 16); the code of practice on HCAIs (issued under clause 17); or statements of standards issued under clause 41. *Subsection (4)* requires the Commission to give to the Secretary of State any advice or information requested by the Secretary of State in relation to the matters about which it has a duty to keep him informed. The clause also allows the Commission to give advice to the Secretary of State, an English NHS body or an English local authority in relation to the establishment or conduct of an inquiry.

Clause 50: Studies as to economy, efficiency etc.

233. Clause 50 enables the Commission to undertake wider studies that are designed to enable it to make recommendations for improving economy, efficiency, and effectiveness in the provision of health care by an English NHS provider, or the provision of adult social services by an English local authority, or the way in which health care or adult social services are commissioned. The Commission may also undertake studies that will enable it to make recommendations for improving the management of an English local authority with regard to the provision of adult social services, or the management (but not the financial management) of an English NHS body.

Clause 51: Publication of results of studies under s.50
234. Clause 51 requires the Commission to publish recommendations made, and results of studies undertaken, under clause 50. The clause also allows regulations to be made by the Secretary of State which set out a procedure for representations to be made to the Commission before any recommendations or reports of studies are published.

Clause 52 Role of Audit Commission
235. Clause 52 allows the Audit Commission for Local Authorities and the National Health Service in England ('the Audit Commission') to carry out studies relating to health care or English NHS bodies (under clauses 50 and 51) on the Commission's behalf, with the Commission's agreement. Where a matter could be considered to fall within the remit of both organisations, as is the case for studies regarding economy, efficiency, and effectiveness in relation to adult social care, *subsection (5)* directs them to have regard to any guidance issued by the Secretary of State as to who should carry them out.

Clause 53: Reviews of data, studies and research
236. Clause 53 enables the Commission to review studies and research undertaken by others. It enables the Secretary of State to request such reviews, which the Commission must undertake. Where the Commission conducts a review, it must publish a report.

Clause 54: Publication of information
237. Clause 54 allows the Commission to make information available about the provision of NHS health care, adult social services, and the carrying on of regulated activities.

Clause 55: Additional functions
238. Clause 55 allows the Secretary of State to give additional functions to the Commission through regulations. It sets out the extent of the remit within which the Secretary of State may give the Commission these additional functions. If any of these functions relate to NHS Foundation Trusts then *subsection (2)* requires the Secretary of State to consult with Monitor first.

CHAPTER 6 – MISCELLANEOUS AND GENERAL

Inspections
Clauses 56 to 57: Inspections
239. Clause 56 enables the Commission to carry out inspections in relation to its regulatory functions. Its regulatory functions are its registration and review functions under Chapters 2 and 3 and most of its functions under Chapter 5, such as studies as to economy and efficiency. It cannot carry out inspections purely for the purposes of providing information and advice to the Secretary of State under clause 49 or conducting a review of data, studies or research under clause 53. Regulations under clause 55 will set out whether any additional functions conferred on the Commission under that clause are to be treated as regulatory functions and thereby whether inspections can be carried out in relation to them.

240. Under clause 57, the Secretary of State may set out in regulations how often the Commission should undertake inspections in relation to the Commission's registration functions under Chapter 2, the manner in which they should be carried out and who should carry them out. For instance, the Secretary of State may prescribe that hospitals must be inspected annually for compliance with requirements relating to hygiene and infection controls, by people with particular skills.

241. After carrying out an inspection under clause 56 for the purposes of the Commission's functions under Chapter 2, the Commission is required to prepare and publish a report. The Commission must send a copy of the report to the registered service provider and, if there is one, the registered manager.

242. Regulations will set out what procedure should apply to allow people to make representations to the Commission before it publishes a report under clause 57. As with similar powers in other clauses, the reason for this is to give the inspected body time to comment and to ensure that any comments are considered by the Commission.

Powers of entry etc.

Clauses 58 to 61: Powers of entry etc.

243. In carrying out its functions, the Commission will engage with patients and service users and people involved in the provision of care and will also need to inspect relevant premises. Clause 58 enables individuals authorised by the Commission to enter and inspect premises which are, or are believed to be, 'regulated premises' Regulated premises are:

- premises used for carrying on a regulated activity;
- premises owned or controlled by an English NHS body or English local authority;
- premises used, or proposed for use, for the provision of NHS healthcare or adult social services;
- premises used, or proposed for use, by any English NHS body in order to carry out its functions

Premises in which NHS care or an adult social service is provided but which are used wholly or mainly as a private dwelling are excluded. The fact that someone receives a service like domiciliary care does not mean that there is a right of entry (without consent) into that person's home under this clause. 'Premises' includes vehicles. Individuals exercising these powers must produce appropriate documentation showing they have the authority to enter and inspect the premises. .

244. Clause 59 provides further details on the power to enter and inspect premises. It enables individuals authorised by the Commission to:

- examine the premises or the treatment of persons receiving care there;

- inspect and copy records or documents, and require any person holding or accountable for them to produce them;

- have access to, and check the operation of, any computer and associated equipment that has been used in connection with any documents or records and, where records are stored on a computer, to require them to be produced in a legible, non-encrypted format;

- inspect any other item;

- seize and remove any documents, records or other items;

- interview the manager or registered service provider, or people who are managing the provision of NHS care or adult social services at the premises;

- interview people working at the premises or people receiving care who consent to be interviewed. This does not limit the Commission's ability to interview, with their consent, other people such as family members or carers if it thinks this would be appropriate.

245. Subject to a number of conditions set out in *subsection (3)* the authorised person (as long as they are a medical practitioner or registered nurse) may examine any person receiving care at the premises.

246. *Subsection (6)* provides that an authorised person may require such assistance from any person, and may take such measurements and photographs, and make such recordings, as that person considers necessary for the exercise of the powers under clauses 58 and 59.

247. Clause 60 gives the Commission a general power to require information, documents, records and other items from bodies and persons listed in *subsection (2*) if the Commission considers them necessary in order to carry out its regulatory functions.

248. Under clause 61, regulations may be made that require a prescribed person to provide the Commission with an explanation of: any documents, records or other items inspected, copied or provided under clauses 58 to 60; any information provided under those clauses; any other documents etc. provided to the Commission in order for the Commission to carry out its regulatory functions; or any other information or documents related to the Commission's regulatory functions. *Subsection (3)* enables these regulations to set a requirement that individuals must be present at a specified time and place to give an explanation. The Commission will use this power to enable it to discuss any other matters of concern that its reviews and inspections have brought to light with those responsible.

249. Clauses 59(7), 60(4) and 61(4) make it an offence for a person to obstruct the exercise of any of the powers under clause 58 or 59 or to fail to comply with any requirement imposed under clause 59, 60 or 61. The penalty on summary conviction is a fine, not exceeding level 4 (£2,500) on the standard scale.

Interaction with other authorities
Clause 62: Interaction with other authorities
250. Clause 62 gives effect to Schedule 4.

Schedule 4: Interaction with other authorities
251. *Paragraph 1* defines the inspection authorities to which Schedule 4 applies: they are the five existing criminal justice inspectorates; CIECSS; and the Audit Commission. *Paragraph 2* defines inspection functions for the purposes of the Schedule. *Paragraph 3* defines a public authority for the purposes of Schedule 4 as any person whose functions are of a public nature (excluding any person carrying out functions in connection with Parliamentary proceedings).

252. *Paragraph 4* enables the Commission to delegate any of its inspection functions to another public authority. Where the Commission delegates functions, these will be regarded as being carried out by the Commission for the purposes of any legislation.

253. *Paragraph 5* requires the Commission to produce both an inspection programme setting out the inspections it intends to carry out, and an inspection framework, which sets out how it intends to carry out its inspection and reporting functions. These must be prepared from time to time, or at times specified by order by the Secretary of State. Before preparing these documents, the Commission must consult the Secretary of State, the inspection authorities (as defined under paragraph 1) and anyone else specified by an order made by the Secretary of State (unless they have waived their right to be consulted). The Commission must then send the people it has consulted a copy of the programme or framework. This will provide advanced notice of the Commission's proposals. It will also allow an opportunity for people to raise concerns about duplication with other inspection bodies or about the overall burden of inspection.

254. The requirements under paragraph 5 do not prevent the Commission from carrying out unannounced inspections.

255. *Paragraph 6* allows the Commission to give a notice to another inspection authority (or other people specified in an order by the Secretary of State), which proposes to carry out an inspection of a prescribed organisation, where the Commission believes the inspection would impose an unreasonable burden on the organisation. This notice can require the inspection authority not to carry out the inspection in the proposed way, or at all.

256. The Secretary of State may specify, by order, circumstances in which this power should not apply. The Secretary of State may also give consent for a particular inspection to be undertaken, if he is satisfied that the inspection will not impose an unreasonable burden or will not do so if carried out in a particular way. Further provisions in relation to this paragraph may be made by order of the Secretary of State.

257. *Paragraphs 7 to 10* cover other aspects of the Commission's relationship with other public authorities. Paragraph 7 requires the Commission to co-operate with the inspection authorities or other public authorities specified by an order of the Secretary of State. Paragraph 8 enables the Commission to act jointly with other public authorities. Paragraph 9 enables the Commission to provide advice or assistance to other public authorities. Paragraph 10 allows the Commission to make arrangements with other inspection authorities to carry out inspections on their behalf. These powers allow the Commission to build links with other related public authorities in order to work to minimise the regulatory burden they jointly impose.

Clause 63: Co-ordination of reviews or assessments

258. Clause 63 requires the Commission to promote effective coordination of reviews and assessments in relation to the carrying on of regulated activities.

Clause 64: Avoidance of unreasonable burdens in exercise of regulatory powers

259. Clause 64 allows the Secretary of State to publish guidance about the steps that the Commission and other prescribed regulatory bodies may take to avoid imposing unreasonable burdens on health and social care organisations when carrying out inspections, or collecting information.

260. This guidance may cover co-operation between regulatory bodies, and the sharing of information between them. It might, for example, advise regulatory bodies how to make use of information that has already been collected, rather than making a direct request for this information to the health and social care organisations concerned.

261. The guidance will apply to the Commission and other regulatory authorities that have functions relating to the provision of health or social care. They will be obliged to take the guidance into account when carrying out inspections or requiring information. The clause makes it clear that any guidance does not limit the scope of a regulatory authority's powers, or affect a person's obligation to comply with any requirement.

Clause 65: Co-operation between the Commission and Welsh Ministers

262. Clause 65 sets out that the Commission and the Welsh Ministers must work with one another in order to carry out their corresponding functions efficiently and effectively.

Clause 66: Co-operation between the Commission and the Independent Regulator of NHS Foundation Trusts

263. Clause 66 sets out how the Commission and Monitor should work with one another and clarifies the interface between the Commission and Monitor, whose work relates closely to that of the Commission. It requires the Commission and Monitor to co-operate with one another in carrying out their functions. The Commission must keep Monitor informed about the provision of health care by NHS Foundation Trusts. Monitor must give the Commission any information it has relating to the provision of health care by NHS Foundation Trusts which will assist the Commission in carrying out its functions. The clause also sets out specific material (material relevant to reviews, investigations and studies) that the Commission must provide to Monitor, on request.

Clause 67: Provision of information by Auditor General for Wales

264. Clause 67 requires the Auditor General for Wales to share with the Commission any information that the Commission may reasonably require in relation to a study under clause 50 relating to health care or English NHS bodies so that comparisons can be made between English and Welsh NHS bodies. This replaces a similar provision in section 69A of the Health and Social Care (Community Health and Standards) Act 2003, which is being repealed (see paragraph 40 of Schedule 5 to the Bill). The Commission is placed under a reciprocal duty by virtue of an amendment to section 64 of the Public Audit (Wales) Act 2004, which currently applies to CHAI (see paragraph 74 of Schedule 5 to the Bill). This will require the Commission to provide the Auditor General for Wales with information he may require for comparative studies under sections 145 and 145A of the Government of Wales Act 1998 of care provided by Welsh NHS bodies compared with English NHS bodies.

Clause 68: Provision of material to the Comptroller and Auditor General

265. Clause 68 requires the Commission to provide material relevant to reviews, investigations or studies that it carries out to the Comptroller and Auditor General on request.

Clauses 69 and 70: Arrangements with Ministers

266. Clause 69 enables a Minister of the Crown to arrange for the Commission to carry out any of its functions in relation to prescribed health or social care schemes for which the Minister has responsibility. For example, arrangements may be made between the Commission and the Secretary of State for Defence in respect of the provision of health care to the Armed Forces. Clause 70 enables a Northern Ireland Minister to arrange for the Commission to carry out any of its functions which correspond to functions of the Commission and relate to the Northern Ireland health service.

Inquiries

Clause 71: Inquiries

267. Clause 71 enables the Secretary of State to initiate an inquiry into matters concerning the exercise of any of the Commission's functions. *Subsection (2)* gives the Secretary of State the power to direct that an inquiry be held in private. Where no such direction is given, *subsection (3)* enables the person holding the inquiry to decide whether the inquiry or any part

of it should be held in private. This might be necessary, for example, to protect patient confidentiality.

268. *Subsection (4)* applies section 250(2) to (5) of the Local Government Act 1972 to an inquiry undertaken under this clause. This will enable the person holding the inquiry to issue a summons requiring an individual to give evidence or produce any documents in their custody or under their control at a stated time and place. If that person fails to attend (for reasons other than not having the necessary expenses of their visit paid or tendered), then they may be liable to a fine or imprisonment.

269. *Subsection (5)* requires reports of inquiries set up under the powers in this clause to be published unless the Secretary of State decides there are exceptional circumstances that render publication inappropriate (for example, publication being prejudicial to any ongoing criminal investigation).

Information

Clauses 72 and 73: Disclosure of confidential personal information / Defence

270. Clause 72 makes it a criminal offence for any person, including a member or employee of the Commission, knowingly or recklessly to disclose confidential information which has been obtained by the Commission and which identifies an individual, during the lifetime of the individual. The penalty on summary conviction is imprisonment of up to 12 months, or a fine not exceeding the statutory maximum, or both. The penalty on conviction on indictment is imprisonment of up to 2 years, or an unlimited fine, or both. The clause applies to all of the Commission's functions, whereas currently a similar provision only applies to CHAI as the regulator of health services.

271. *Subsections (1) to (3)* of clause 73 set out defences to a charge under clause 72. It is a defence to prove that any of the circumstances listed in subsection (2) (for example, that the form of disclosure meant that the individual was not identified or the individual concerned had given their consent to the information being made available) applied or that the person charged reasonably believed they applied. It is also a defence to prove that the disclosure was made for a purpose in subsection (3), for example, in connection with a criminal investigation. *Subsection (4)* requires that, where someone offers one of these defences in response to a charge brought under clause 72 and evidence is adduced which is sufficient to raise an issue with respect to the defence, the defence is to be regarded as satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Clause 74: Use of information etc.

272. Clause 74 provides that the Commission may use information, documents or records obtained or produced in carrying out any of its functions for any of its other functions (subject to the limitations in relation to the disclosure of confidential personal information under clause 72).

Clause 75: Permitted disclosures
273. The Commission may disclose any information it obtains in the course of carrying out its functions where any of the circumstances set out in *subsection (3)* apply (for example, where the information has already been lawfully disclosed to the public, or where the disclosure is necessary to protect the welfare of any individual). Where none of those circumstances applies, the Commission may disclose information that relates to an individual if that individual has consented to the disclosure, or the form of disclosure means that the individual is not identified.

Clause 76: Code of practice on confidential personal information
274. Clause 76 places the Commission under a statutory duty to publish a code of practice in relation to how it will obtain, use, handle and disclose confidential personal information (defined as information that is obtained by the Commission in confidence and which identifies an individual). The Commission must consult the National Information Governance Board and anyone else it considers appropriate before publishing a code under this clause.

Further provisions about functions of Commission
Clause 77: Publication of programme of reviews etc.
275. Clause 77 requires the Commission to publish a document that sets out the reviews and studies that it intends to carry out under clauses 44, 50 and 53. The Secretary of State may specify through an order when this should be done. Before preparing the document, the Commission must consult the Secretary of State and any other person specified by order of the Secretary of State. Once prepared, the Commission must send them a copy of the document.

Clause 78: Failure by the Commission in discharge of its functions
276. If the Secretary of State considers that the Commission is failing to carry out any of its functions, or to carry them out properly, then clause 78 enables the Secretary of State to issue a direction to the Commission. The clause also enables the Secretary of State to carry out functions of the Commission or arrange for a third party to do so if the Commission fails to comply with the direction. These powers might be needed not necessarily because of any fault on the Commission's part but possibly due to circumstances outside its control, for example, a serious infection affecting many of its staff and therefore its ability to perform its duties.

Clause 79: Reports for each financial year etc.
277. Clause 79 places a duty on the Commission to report annually to Parliament on a number of matters. These are:

- the way it has exercised its functions;
- the provision of NHS health care;

- the provision of adult social services; and

- the carrying on of activities regulated by the Commission,

during the financial year in question.

278. The report can be made up of separate documents on each matter or be presented in a single document. The Secretary of State may require the Commission to include in its report separate reports on specified aspects of the matters.

279. The Commission's functions under the Mental Health Act are excluded from the annual report under clause 79. The Commission will produce a separate annual report on the operation of the Mental Health Act. MHAC currently has to report bi-annually on the operation of the Mental Health Act.

280. All reports under this clause must be laid before Parliament and sent to the Secretary of State. The Commission is also required to provide any other additional reports and information on the exercise of its functions that the Secretary of State may request during the year.

Clause 80: Reports and information

281. Clause 80 requires the Commission to make copies of any report it publishes available to view at its offices. It must provide copies of the report on request. The Commission may also provide other information that a person might request that is relevant to the discharge of its functions. It can charge a reasonable fee for providing information or copies of reports.

Fees

Clause 81: Fees

282. Clause 81 enables the Commission, with the consent of the Secretary of State, to make provision for the payment of a fee in relation to certain registration functions under Chapter 2 and other prescribed functions under Part 1. It is intended that where fees are charged, these will relate to the costs incurred by the Commission in exercising the functions to which they relate and there will not be cross subsidy of any of the Commission's other functions.

283. The Commission will be able to decide how much the fees will be, how they will be calculated, and details such as when they should be paid. The Commission may charge different fees in different circumstances, or to different people. People liable to pay fees are required to give the Commission such information as it thinks is necessary in order to determine what fees should apply to them.

284. The Secretary of State will be able to set out in regulations matters that the Commission should take into account when it determines what fees are payable and how it should make its policy on fees available. The Secretary of State can also make alternative

provision on fees (which will apply in place of provision made by the Commission) if he is of the view that it is necessary or desirable for him to do so.

Enforcement

Clauses 82 and 83: Penalty notices

285. Clause 82 gives the Commission power to issue penalty notices. This is a new power that is not available to CHAI and CSCI under the existing law. Where a person commits a prescribed offence under Part 1, or under regulations under Part 1, the Commission may give the person a penalty notice. This is an invitation to pay a penalty instead of being prosecuted for the offence. The Commission might, for example, issue a penalty notice where the Commission becomes aware of an offence that has been committed in the past (such as failure by someone to comply with one of the conditions of their registration) but is satisfied that the offence was relatively minor and that they are now complying with the condition in question. In those circumstances the person may pay the penalty specified in the penalty notice as recognition of the offence and the Commission would then take no further action in relation to that offence. If, however, that person subsequently breached the same condition of their registration then they would be liable to be prosecuted for the new (repeat) offence.

286. The Commission will receive any amounts paid, but will then pay them to the Secretary of State who will pay them into the Consolidated Fund.

287. Clause 83 confers a regulation-making power which allows the procedural details about penalty notices to be set out in regulations.

Clause 84: Guidance by the Commission in relation to enforcement action

288. Clause 84 requires the Commission to publish guidance on how it will exercise its enforcement powers under Part 1. This guidance is expected to cover how the Commission intends to work with Monitor in relation to enforcement action involving NHS Foundation Trusts. The Commission must consult on this guidance, and regulations may set out any particular people that it must include in such a consultation.

Clause 85: Publication of information relating to enforcement action etc.

289. Clause 85 enables regulations to be made which will either authorise or require the Commission to publish details of enforcement action it has taken. The regulations may set out what information the Commission can or must publish in each instance, as well as when and how it must publish it. This will enable the Commission to make information available to the public about the action it has taken using its powers under Part 1.

290. If information is to be published about warning notices, the regulations must allow the people to whom the notices were given to make representations to the Commission before the information is published. This is because there is no right of appeal in respect of a warning notice.

Clause 86: Proceedings for offences
291. Clause 86 provides that only the Commission or, if he is carrying out any of the Commission's functions, the Secretary of State, can commence proceedings in relation to offences under Part 1 or under regulations under it without written consent of the Attorney General.

292. *Subsection (2)* provides that a prosecution must be commenced within 12 months from the date on which there was sufficient evidence to prosecute, with a long stop of 3 years from the date on which the offence was committed.

Clause 87: Offences by bodies corporate
293. Clause 87 deals with corporate liability. If an offence under Part 1 of the Bill, or regulations made under it, is proved to have been committed with the consent or connivance of an officer of a body corporate then they, as well as the company, are guilty of the offence.

Clause 88: Unincorporated associations
294. Clause 88 contains provisions dealing with certain procedural matters where criminal proceedings are brought against unincorporated associations. *Subsection (1)* provides that proceedings are to be brought in the name of the association (and not any of the individual members). However, *subsection (5)* makes clear that if an offence is proved to have been committed with the consent or connivance of an officer of the association or a member of its governing body, then they, as well as the association, are guilty of the offence. Individual officers or members of the association will not be able to escape prosecution simply because the association is liable; both may be liable for prosecution.

Service of documents
Clauses 89 and 90: Service of documents
295. Where the Commission serves notices or other documents on people, clause 89 requires that this be done in person or by registered or recorded delivery. Under clause 12, regulations may state that the registered person must notify the Commission of the address it wishes to be used for the service of documents. Notices or documents sent by post can be assumed to have been delivered after three days unless the person can prove this was not the case. Under clauses 89 and 90 notices may be served electronically if the person receiving the notice has given their consent and provided a suitable address for these purposes.

Further amendments
Clause 91 and Schedule 5: Further amendments relating to Part 1
296. Clause 91 gives effect to Schedule 5. Schedule 5 makes various consequential amendments which include replacing references in other legislation to CHAI, CSCI and MHAC with references to the Commission. It also makes extensive consequential amendments to the Care Standards Act 2000 and the Health and Social Care (Community Health and Standards) Act 2003.

297. At the request of the Welsh Assembly Government, Schedule 5 also makes a number of amendments to the powers that Welsh Ministers have under the Care Standards Act 2000. These amendments provide: a new power to suspend registration and to suspend registration urgently; a provision to change registration conditions urgently by notice; a new power to impose a penalty notice where the Welsh Ministers are satisfied that a person has committed a prescribed offence; and an extension to the time limit in section 29 of the Act within which criminal proceedings must be brought, from 6 months to 12 months. These powers apply in respect of persons registered with the Welsh Ministers in relation to establishments or agencies under Part 2 of that Act.

Interpretation
Clause 92: General interpretation of Part 1
298. Clause 92 sets out the meaning of various terms used within Part 1 of the Bill.

PART 2 – REGULATION OF HEALTH PROFESSIONS AND HEALTH AND SOCIAL CARE WORKFORCE

The Office of the Health Professions Adjudicator
Clause 93: The Office of the Health Professions Adjudicator
299. Clause 93 establishes the OHPA as a body corporate. It is to have functions relating to doctors, optometrists, dispensing opticians, student opticians and optical businesses (i.e. the professions regulated by the Medical Act 1983 and the Opticians Act 1989). Clause 93 also gives effect to Schedule 6 which makes detailed provision for the constitution and membership of the OHPA. The establishment of this body requires a number of consequential amendments to other enactments. These are contained in Schedule 10.

Schedule 6: The Office of the Health Professions Adjudicator
300. Schedule 6 makes detailed provision for the constitution and membership of the OHPA.

301. *Paragraphs 2* and *3* set out the status of the body and that it is to have the powers necessary to enable it to carry out its functions.

302. The membership of the body is set out in *paragraphs 4* to *10* and must include a legally qualified chair appointed by the Privy Council, at least one but no more than three non-executive members, also appointed by the Privy Council, and at least one but no more than three executive members, subject to the proviso that there are not more executive than non-executive members. Initially the executive members will be appointed by the Privy Council. Thereafter they will be appointed by the OHPA. The Privy Council must make regulations about the precise number of executive and non-executive members. Paragraph 20 of Schedule 10 contains provisions to allow the Privy Council to delegate their appointment functions in relation to the OHPA to the Appointments Commission. By virtue of paragraph 21 of Schedule 10, the Appointments Commission will be able to assist the OHPA with its

appointment of executive members. The chair and other members may be removed from office by the Privy Council on the grounds of incapacity or misbehaviour, but will otherwise hold and vacate office in accordance with the terms of their appointment.

303. *Paragraphs 11* and *12* deal with the procedure to be followed by the OHPA and provide that the OHPA may regulate its own procedure. Proceedings of the OHPA are not affected by circumstances such as vacancies in its membership or defects in the appointment of members.

304. *Paragraph 13* requires the OHPA to maintain a system for the declaration and registration of members' private interests and to publish entries recorded in the register.

305. Under *paragraph 14,* the Secretary of State is to determine the remuneration and allowances payable to the chair and other members. The Secretary of State may also require the OHPA to make provision for pensions and, in certain circumstances, to pay compensation to a person who has ceased to hold office as chair of the OHPA. Under *paragraphs 15* and *16,* amendments to the Superannuation Act 1972 will enable the OHPA to be included in the civil service pension scheme. Under *paragraph 17,* the OHPA may appoint such employees as it considers appropriate, on such terms as it determines (including as to pay, pensions etc.)

306. *Paragraph 18* provides that the Secretary of State and DHSSPSNI may make payments to the OHPA. The Secretary of State and DHSSPSNI can also make loans to the OHPA. Paragraph 18(4) requires Treasury consent to the amount and terms of loans made to the OHPA by the Secretary of State. Paragraph 18(6) requires the consent of the Department of Finance and Personnel in Northern Ireland to the amount and terms of loans made to the OHPA by DHSSPSNI. The OHPA will have no other powers to borrow money. Paragraph 18(8) and (9) provide that the Secretary of State and DHSSPSNI may make directions to the OHPA on the application of payments or loans made to it.

307. Under *paragraph 19*, the OHPA must keep accounts in such form as determined by the Secretary of State. Copies of annual accounts must be sent to the Comptroller and Auditor General, who will lay copies of the accounts and of his report on them before Parliament. A copy of the accounts must also be sent to the Secretary of State and DHSSPSNI. DHSSPSNI will lay a copy of the accounts before the Northern Ireland Assembly. Under *paragraph 20,* the OHPA must also prepare an annual report for each financial year on how it has carried out its functions. The Privy Council may give directions as to the content of the report. The Secretary of State must lay it before Parliament. DHSSPSNI must lay it before the Northern Ireland Assembly.

308. *Paragraph 21* concerns the application of the seal of the OHPA. *Paragraph 22* concerns the receipt in evidence of documents purporting to be executed under the seal of the OHPA or signed on its behalf. *Paragraph 23* provides for public access to meetings of the OHPA in Northern Ireland. Equivalent provision in relation to meetings in England, Wales

and Scotland is made by the amendment to the Public Bodies (Admission to Meetings) Act 1960 in Schedule 10.

Clause 94: Functions under Medical Act 1983 and Opticians Act 1989
309. Clause 94 brings into effect Schedule 7.

Schedule 7
310. Schedule 7 is split into two parts. Part 1 makes amendments to the Medical Act 1983 and Part 2 makes amendments to the Opticians Act 1989. These have the effect of transferring the functions in relation to the adjudication of fitness to practise of the GMC and the GOC to the OHPA.

311. *Paragraph 4* inserts a new *section 35ZA* into the Medical Act 1983. This provides that the GMC may publish guidance on the factors that they consider to indicate:

- where a practitioner's fitness to practise is found to be impaired, what sanction would or would not be appropriate;

- where a practitioner's fitness to practise is found not to be impaired, whether a warning should or should not be given regarding future conduct or performance;

- and where a person has had his name erased from the register, whether their registration should be restored or not.

312. The GMC may also publish guidance on:

- the type of conditions to be imposed, where a practitioner's registration is to be made conditional;

- the period of time for which a person's registration should be suspended or made conditional.

313. *Paragraph 30* inserts a new *section 13AA* into the Opticians Act 1989, providing that the GOC may publish similar guidance in relation to types of sanctions available, in cases involving those regulated by the Opticians Act 1989.

314. Under *subsection (3)* of each of the new sections described above, the OHPA must take account of any guidance published by the GMC and the GOC under these powers (in their capacity as the body responsible for setting and maintaining the standards required of their registrants) when making decisions on what sanctions to impose in any particular case.

315. *Paragraph 11* inserts a new *section 40A* into the Medical Act 1983, allowing the GMC to refer a case to the High Court, or in Scotland the Court of Session, where it thinks

that the OHPA has reached a finding relating to fitness to practise that is unduly lenient, and that it is necessary in the interests of public protection for it to take action. The new section sets out the decisions which can be referred and the timescales for such referrals. The provision is in place of the CRHP's power under section 29 of the Health Care Professions Act 2002 to refer equivalent decisions of the GMC's fitness to practise panels to the court.

316. *Paragraph 46* inserts a new *section 23I* into the Opticians Act 1989, allowing the GOC similar rights of referral.

Clause 95: Fitness to practise panels

317. Clause 95 provides that the OHPA's function of adjudication of fitness to practise cases is to be carried out by panels. The members are to be drawn from lists held by the OHPA and each panel must consist of at least 3 people – a chair, a lay member and a professionally qualified member. Other lay or professionally qualified members may be appointed to the panels provided they are on the OHPA's lists (see clause 96 below). The chair can be a person who is legally qualified, a lay member or a professionally qualified member (see note on clause 96 below). *Subsection (3)* empowers the OHPA to make further provision about the selection of fitness to practise panels through its rules. Rules may provide, for example, that professionally qualified panel members are selected from the professional list with due regard to the profession of the practitioner whose fitness to practise is being considered.

318. *Subsection (4)* provides that rules made under subsection (3) may require the selection of a legally qualified chair in specified circumstances. The rules may also provide for pilot schemes under which legally qualified chairs are, or are not, selected for certain proceedings.

Clause 96: Lists of persons eligible for membership of fitness to practise panels

319. Clause 96 requires the OHPA to keep three lists:

- one of persons eligible to serve as chairs;
- one of persons eligible to serve as lay members; and
- one of persons eligible to serve as professionally qualified members.

320. *Subsection (2)* provides that the list of chairs is to consist of persons who are legally qualified and persons who are also included on the lists of lay and professionally qualified members.

321. Rules made by the OHPA under this clause may set out further details of how the lists will be kept and the information relating to each individual appointed which will appear on

the lists. Rules may also set out the requirements for appointment to any list. Rules made by the OHPA under this clause must set out the qualifications a person must have in order to be considered 'legally qualified' and therefore eligible for appointment to the chairs list. They must also provide for the experience and training that any lay or professionally qualified member must have in order for them to be appointed to the chairs list.

322. The clause provides that no member of the OHPA may be appointed to a list.

Clause 97: Further provisions about listed persons

323. Clause 97 provides that the OHPA may pay fees, allowances and expenses to people it has appointed to its lists. It also provides that allowances and expenses may be paid to those persons that the OHPA proposes to appoint to its lists, but only in connection with the provision of training for them. The OHPA must provide, or arrange for the provision of, training for those included on a list and may provide, or arrange for the provision of, training for prospective appointees to a list.

324. The OHPA must establish and maintain a system for the declaration and registration of the private interests of a person included on any of the lists and publish entries recorded in the register.

Clause 98: Legal assessors

325. Under clause 98 the OHPA must appoint or arrange for the appointment of legal assessors to give advice on points of law to the OHPA's panels. To be eligible for appointment such assessors must meet the requirements set out in rules made by the OHPA. Rules made by the OHPA must set out the required qualifications, and may make further provision about the functions of legal assessors. The OHPA may pay such fees, allowances and expenses as it deems appropriate to these legal assessors. A legal assessor may be appointed either generally or for particular proceedings or a particular class of proceedings. Rules under this clause may also provide that a panel is not to have a legal assessor, where the chair of the panel is legally qualified.

Clause 99: Clinical and other specialist advisers

326. Clause 99 provides that the OHPA may appoint persons as clinical advisers who will advise its fitness to practise panels on issues relating to health. The OHPA may also appoint other specialist advisers who will advise the panels on issues falling within their specialty on which the OHPA considers that specialist knowledge is required. To be eligible for appointment such advisers must meet the requirements set out in rules made by the OHPA. The rules may also make provision about their functions. The OHPA may pay such fees, allowances and expenses as it deems appropriate to these advisers. Advisers may be appointed either generally or for particular proceedings or a particular class of proceedings.

Clause 100: Procedural rules

327. Clause 100 requires the OHPA to make rules about the procedure to be followed in making referrals to it under the Medical Act 1983 or the Opticians Act 1989 and the

procedure to be followed before its panels (including the rules of evidence). The rules will not apply to the conduct by the regulatory bodies of their investigations or the preparation of the case before it is referred to the OHPA.

328. The rules must include:

- provision for a practitioner to be notified that proceedings are being brought against them;
- provision for notice of decisions of a fitness to practise panel to be given to the parties to the proceedings (i.e. the practitioner and the regulator) and the registrar of the relevant regulatory body;
- provision conferring the right on parties to the proceedings to put their case at a hearing;
- provision conferring the right on parties to the proceedings to be represented at any hearing by a person meeting criteria specified in the rules; and
- provision for hearings to be held in public except in circumstances that the rules state otherwise. For example, the rules could make provision for a hearing in private in some circumstances.

Clause 101: Administration of oaths and issuing of witness summonses etc.
329. Clause 101 makes provision for fitness to practise panels to require persons giving evidence during a hearing to give the evidence under oath and for witnesses to be summoned. Similar provision is made in *subsection (1)* for hearings in England and Wales or in Northern Ireland to that made in *subsection (4)* for hearings in Scotland.

Clause 102: Duty to inform the public
330. Clause 102 requires that the OHPA publish certain information about itself and the way it carries out its functions. This includes information about the decisions of its fitness to practise panels. The OHPA may withhold from publication confidential information about a person's health, and other information specified in rules. It is not required, or authorised, to publish information if publication is prohibited by any enactment or would be a contempt of court.

Clause 103: Duty to consult
331. Clause 103 requires the OHPA to seek the views of the following on matters relevant to the exercise of its functions:

- members of the public;

- bodies which appear to the OHPA to represent the interest of patients;
- the GMC and the GOC;
- any other bodies that appear to the OHPA to represent the professions regulated by the Medical Act 1983 and Opticians Act 1989.

332. The clause is not restrictive and the OHPA may choose to consult more widely than this. It is likely that the Office for National Statistics will classify the OHPA as an Executive Non-Departmental Public Body. As such it would be expected to follow existing best practice in consulting. This would include the practice to be followed in relation to the manner in which it makes public the responses and the decisions it reaches in light of them.

Clause 104: OHPA rules: supplementary

333. Clause 104 provides that before making rules, the OHPA must consult:

- the Council for Healthcare Regulatory Excellence;
- the GMC, if the rules affect the profession regulated by the Medical Act 1983;
- the GOC, if the rules affect the professions regulated by the Opticians Act 1989;
- other bodies which appear to the OHPA to represent the professions regulated by the GMC or, as the case may be, the GOC, if the rules affect these regulated professions;
- bodies that appear to the OHPA to represent the interests of patients;
- any other persons the OHPA considers appropriate.

334. Again, this clause is not restrictive and the OHPA may (having regard to existing best practice) choose to consult more widely on its rules than this.

335. The rules come into force only if approved by the Privy Council by an Order of Council, subject to the negative resolution procedure. The Privy Council may modify the rules before approving them but must first give the OHPA the opportunity to make observations on the proposed changes.

Clause 105: Fees payable by General Medical Council and General Optical Council

336. Clause 105 introduces a fees charging regime from which the OHPA will secure the majority of its funding after the initial implementation period.

337. The clause requires the Secretary of State to make regulations requiring each of the GMC and the GOC to pay to the OHPA a periodic fee in respect of the discharge of its functions (this is likely to be on an annual basis). Regulations made under this clause will be subject to prior consultation with the two regulatory bodies and such other persons as the Secretary of State considers appropriate and will be subject to Treasury approval. The regulations will be subject to Parliamentary scrutiny under the negative resolution procedure.

338. The fee must be determined in accordance with the regulations. It is intended that the regulatory bodies will pay an amount linked to their forecasted use of the OHPA's services. The OHPA will be required to notify the regulatory bodies of the proposed fee level and to consider any representations made by the regulators on this before formally setting the fee by making a determination.

339. *Subsection (7)* enables the regulations to: provide for when the fees are to be paid; enable a fee determination to be varied, replaced or revoked in year; and make provisions about unpaid fees.

Amendments of Part 3 of Health Act 1999

Clause 106: Extension of powers under s.60 of Health Act 1999

340. Section 60 of the Health Act 1999 allows Her Majesty, by Order in Council, to modify the regulation of the existing regulated healthcare professions and to bring other healthcare professions into statutory regulation. An Order made under section 60 may repeal or revoke any enactment or instrument, amend it, or replace it (subject to the restrictions in paragraphs 7 and 8 of Schedule 3 to the Health Act 1999). The Government must consult on draft Orders prior to them being laid before Parliament. The Orders are subject to the affirmative procedure. Orders which make provision for professions whose regulation is not a "reserved matter" for the purposes of the Scotland Act 1998 (in effect, those made subject to statutory regulation since 1st July 1999) are subject to affirmative procedure in the Scottish Parliament (as well as at Westminster).

341. Clause 106 brings into effect Schedule 8 which amends section 60 of, and Schedule 3 to, the Health Act 1999. The effect of the amendments is to extend the powers available under section 60.

Schedule 8: Extension of powers under s.60 of Health Act 1999

342. *Paragraph 1(2)* brings the OHPA within the scope of section 60 of the Health Act 1999. This enables changes to be made to the constitution, functions, power and duties of the OHPA by an Order in Council so that they can be updated as approaches to regulation change and evolve and so that additional professions can be brought within the remit of the OHPA.

343. *Paragraph 1(3)* removes the reference to the 'Pharmacy Act 1954' (which has been repealed by the Pharmacists and Pharmacy Technicians Order 2007) from section 60(2)(a). This is replaced by section 60(2)(aa) which refers to 'professions regulated by the Pharmacists

and Pharmacy Technicians Order 2007 and the Pharmacy (Northern Ireland) Order 1976', the first now being the relevant legislation for the regulation of pharmacists and pharmacy technicians in Great Britain and the second being the relevant legislation in respect of the regulation of pharmacists in Northern Ireland.

344. *Paragraph 1(4)* inserts a new subsection (2A) into section 60. This enables an Order in Council under this section to make provision relating to, or connected with, the specific statutory functions of the RPSGB and the PSNI. These are:

- the functions under the Medicines Act 1968 in relation to the registration and regulation of pharmacy premises, and the other inspection and enforcement functions which the RPSGB and the PSNI have under that Act;

- the functions under the Poisons Act 1972 and the Poisons (Northern Ireland) Order 1976 in so far as they relate to persons admitted to practice, such as pharmacists, and persons carrying on a retail pharmacy business;

- the grant of authorisations under section 28 of the Regulation of Investigatory Powers Act 2000 concerning directed surveillance.

345. The primary purpose of the inclusion of subsection (2A) is to ensure that these statutory functions, which are separate but connected to the regulation of individual practitioners, are brought within the scope of section 60, so that changes can be made across all of the RPSGB's and the PSNI's regulatory functions where necessary. For example, this will facilitate the transfer of all of the RPSGB's and the PSNI's (subject to a decision by Northern Ireland Ministers to proceed in this way) regulatory functions under these Acts to the proposed General Pharmaceutical Council which the Government intends to create in the future by a section 60 Order. However, it is also envisaged that these powers will be used to modernise the requirements in relation to pharmacy premises in particular.

346. *Paragraphs 2, 6(3) and (4) and 7(a)* of Schedule 8 – An Order in Council under section 60 of the Health Act 1999 can amend or repeal (by virtue of paragraph 2(1) of Schedule 3 to that Act) any enactment. Paragraph 7(a) of Schedule 8 inserts a definition of "enactment" into Schedule 3. The definition includes not only Acts of the Westminster Parliament (and instruments made under them), but also Acts of the Scottish Parliament, Measures or Acts of the National Assembly for Wales and Northern Ireland legislation (and instruments made under them). Paragraph 2 amends section 62(10) of the Health Act 1999 to provide that where an Order in Council includes provision amending Scottish legislation on devolved matters but the provision is incidental to or consequential on provision about a reserved matter, the Order does not on that account require the approval of the Scottish Parliament. Paragraph 6(3) and (4) of Schedule 8 provide that, in those circumstances, Scottish Ministers are not required to consult on a draft of the Order in Council. Rather, the Secretary of State alone will consult on the draft Order (although he will have to consult the Scottish Ministers).

347. *Paragraph 4* makes amendments to paragraph 7 of Schedule 3, which specifies matters outside the scope of the Orders under section 60. *Paragraph 4(2)* replaces the existing sub-paragraph (1) of paragraph 7. New sub-paragraph (1) has the effect that those regulatory bodies to which section 60(2)(a) applies, the RPSGB, the PSNI, the Health Professions Council, the NMC, and any other regulatory body established by an Order under section 60 (such as the proposed new General Pharmaceutical Council), cannot be abolished by an Order under section 60.

348. New sub-paragraph (1A) of paragraph 7 of Schedule 3 qualifies new sub-paragraph (1) by providing that an Order in Council may establish a new regulatory body for the professions regulated by the Pharmacists and Pharmacy Technicians Order 2007 and the Pharmacy (Northern Ireland) Order 1976 and transfer to that new body functions currently exercised by the RPSGB and the PSNI. The scope of section 60 of the Health Act 1999 is confined to regulation. For that reason, the new paragraph 7(1A) of Schedule 3 to the Health Act 1999 will only enable functions relating to regulation to be transferred from the RPSGB and the PSNI to the proposed new General Pharmaceutical Council.

349. Under the current provisions in section 60 of, and Schedule 3 to, the Health Act 1999, an Order in Council cannot require a majority of the members of a regulatory body to be lay members. *Paragraph 4(3)* removes this restriction through the removal of paragraph 7(2) of Schedule 3 to the Health Act 1999.

350. *Paragraph 4(4)* removes a restriction that has prevented Orders under section 60 from being used to make provisions allowing functions conferred on the Privy Council in relation to some of the regulated professions to be exercised by another person. The professions affected are pharmacists, doctors, optometrists, dispensing opticians, osteopaths, chiropractors, dentists and the other professions regulated, or to be regulated, under the Dentists Act 1984. In practice, it is anticipated that once this restriction has been removed the extended section 60 power will generally be used to transfer functions from the Privy Council to the regulatory bodies for the affected professions rather than to third parties.

351. *Paragraph 5* makes amendments to paragraph 8 of Schedule 3 to the Health Act 1999, which specifies other matters that are outside the scope of an Order under section 60. *Paragraph 5(2) and (3)* allow the fitness to practise functions of the regulatory bodies to be transferred to the OHPA by a section 60 Order. They also ensure that the regulatory functions currently exercised by the RPSGB and the PSNI (or any of their committees or officers) can be transferred to a new regulatory body (the proposed General Pharmaceutical Council), using an Order under section 60, which would otherwise be prohibited as regards certain protected functions.

352. *Paragraph 6* makes amendments to paragraph 9 of Schedule 3 to the Health Act 1999, which specifies the preliminary procedures for making an Order under section 60. *Paragraph 6(2)* makes changes to clarify that where an Order under section 60 deals with more than one profession (for example, pharmacists and pharmacy technicians, or doctors and dentists),

representations on the published draft Order should be invited from people considered appropriate to represent any profession covered by the Order. Representations should also be invited from people considered appropriate to represent the users of the services provided by any profession covered by the Order.

353. *Paragraph 6(3) and (4):* see the explanation in relation to paragraph 2 above.

354. *Paragraph 7(a):* see the explanation in relation to paragraph 2 above.

355. *Paragraph 8* amends paragraph 11 of Schedule 3 to the Health Act 1999, by replacing references to the National Health Service Act 1977 with references to the NHS Act 2006 and the NHS (Wales) Act 2006 (which consolidated NHS legislation in England and Wales respectively).

356. *Paragraph 9* repeals paragraph 12 of Schedule 3 to the Health Act 1999, which contains limitations on the extent to which changes can be made under section 60 in relation to the regulation of the pharmacy profession in Northern Ireland. This will allow for changes to the PSNI through an Order under section 60, specifically for the regulatory functions of the PSNI to be transferred to a new General Pharmaceutical Council (subject to a decision by Northern Ireland Ministers to proceed in this way).

Clause 107: Standard of proof in fitness to practise proceedings

357. Currently, the application of the standard of proof in fitness to practise proceedings by regulatory bodies is not consistent. At present, eight of the health regulatory bodies use the civil standard of proof and three health regulatory bodies use the criminal standard of proof in fitness to practise proceedings. These are the GMC, the GOC and the NMC.

358. Clause 107 inserts a new section 60A into the Health Act 1999. This new section imposes a requirement for all the regulatory bodies and the new OHPA to use the civil standard of proof in fitness to practise proceedings. A restriction is included in *subsection (4),* the effect of which is that an Order under section 60 of the Health Act 1999 may not amend this new section or make any provision which is inconsistent with the imposition of the civil standard of proof.

Council for Healthcare Regulatory Excellence

Clause 108: Council for Healthcare Regulatory Excellence

359. Clause 108 changes the name of the CRHP to the Council for Healthcare Regulatory Excellence. As a consequence of the name change, a number of consequential amendments are required to the Health Care Professions Act 2002 and other enactments, which are contained in Schedule 10.

360. The general functions of the Council for Healthcare Regulatory Excellence are set out in section 25 of the Health Care Professions Act 2002. Clause 108 inserts a new subsection

(2A) into section 25, which provides that the main objective of the Council for Healthcare Regulatory Excellence, in exercising its functions, is to promote the health, safety and well-being of patients and other members of the public.

Clause 109: Constitution etc. of the Council

361. Clause 109 makes provision regarding the constitution of the Council for Healthcare Regulatory Excellence. The present Council of nineteen members is reduced to nine members. It will consist of a chair appointed by the Privy Council, six non-executives appointed by the Secretary of State and the devolved administrations, and two executives appointed by the Council itself. *Paragraphs 19 and 20* of Schedule 10 allow the Secretary of State and the Privy Council respectively, if they wish, to delegate the selection process to the Appointments Commission.

362. In addition, in *subsection (3)* of this clause, amendments are made to the enabling powers to make regulations (contained in *paragraph 6* of Schedule 7 to the Health Care Professions Act 2002) relating to conditions of appointment, tenure of office etc. of the chair, Council members and deputy chair as a consequence of the change in the constitution. *Subsection (6)* inserts a new sub-paragraph into paragraph 16 of Schedule 7 to require the Council for Healthcare Regulatory Excellence in its annual report to include a statement on how it and each health professions regulatory body has, in the Council's opinion, promoted the health, safety and well-being of patients and other members of the public.

Clause 110: Powers and duties of Council

363. Clause 110 provides for a new subsection (4) to be substituted for the existing subsection (4) of section 26 of the Health Care Professions Act 2002. The new subsection clarifies that the Council for Healthcare Regulatory Excellence may investigate individual cases for the purpose of providing general reports on the performance of healthcare regulatory bodies and making general recommendations to those bodies affecting future cases.

Clause 111: Powers of Secretary of State and devolved administrations

364. Clause 111 inserts a new section 26A into the Health Care Professions Act 2002 and amends section 26 of that Act. It enables the Secretary of State, the Welsh Ministers and the Scottish Ministers and the DHSSPSNI to require the Council for Healthcare Regulatory Excellence to provide advice and investigate and report on matters relating to the regulation of the health care professions. It also enables the Secretary of State, after consulting with the Welsh Ministers, the Scottish Ministers and DHSSPSNI and the Council for Healthcare Regulatory Excellence, to make directions as to the manner in which the Council carries out its functions.

Clause 112: Duty to inform and consult the public

365. Clause 112 inserts a new section 26B into the Health Care Professions Act 2002, which imposes a duty on the Council for Healthcare Regulatory Excellence to publish, or provide in a suitable manner, information about itself and the carrying out of its functions. It

also imposes a duty on the Council for Healthcare Regulatory Excellence to seek the views of members of the public, and bodies which appear to it to represent the interests of patients, on issues relating to the Council's functions.

Clause 113: Reference of cases by Council to court

366. Clause 113 amends section 29 of the Health Care Professions Act 2002. Section 29 is extended to enable the Council for Healthcare Regulatory Excellence to refer to the High Court or, in Scotland, the Court of Session, cases relating to impairment of fitness to practise on grounds of ill health, in addition to cases relating to misconduct and professional competence.

367. The clause makes some minor amendments which update references to the committees to which section 29 applies. It also makes amendments to remove the ability of the Council for Healthcare Regulatory Excellence to refer cases of the GMC and the GOC to the High Court or, in Scotland, the Court of Session, as those cases will fall within the remit of the new OHPA. The GMC and GOC are given powers to refer these cases in Schedule 7. *Subsection (3)* clarifies which court has jurisdiction to deal with referrals by the Council for Healthcare Regulatory Excellence by reference to the address to which notification of the relevant decision was sent. *Subsection (4)* amends section 29(6) (which currently provides a time limit of four weeks within which the Council may refer the case to the High Court or, in Scotland, the Court of Session). Section 29(6) is amended to provide that the Council may not refer a case to the High Court or, in Scotland, the Court of Session, after a period of forty days. The forty day period begins on the last day on which an appeal against the decision could be made.

Conduct and performance of medical practitioners and other health care workers

Clause 114: Responsible officers and their duties relating to medical profession

368. Clause 114 inserts a new Part 5A (responsible officers) into the Medical Act 1983 (which sets out the general provisions for the regulation of the medical profession). The new Part will contain six sections.

New section 45A of the Medical Act 1983 – requirement to nominate or appoint responsible officer

369. *Subsection (1)* allows the appropriate authority by regulations to designate certain organisations ("designated bodies"), which will be required to appoint or nominate persons who are to have specified responsibilities relating to the regulation of medical practitioners. These persons are to be known as "responsible officers". The appropriate authority in relation to England, Wales and Scotland is the Secretary of State and in relation to Northern Ireland is DHSSPSNI.

370. *Subsections (3)* and *(4)* set out the types of organisations which may be required to nominate or appoint a responsible officer. These are organisations which are directly or indirectly involved in providing healthcare, or which employ or contract with doctors (including in an administrative capacity). This wide definition of designated bodies is

intended to ensure that all doctors in the United Kingdom, whether employees or self-employed, are linked to an appropriate responsible officer. The intention is that all NHS hospital trusts and PCTs in England and Wales, Health Boards in Scotland, larger private sector healthcare organisations such as independent hospitals, and larger locum agencies supplying the services of doctors, should nominate or appoint responsible officers. Guidance will cover circumstances such as those of a doctor employed by two or more organisations, each with a responsible officer.

371. *Subsection (5)* allows regulations to include criteria for appointment of responsible officers, and a requirement for designated bodies to provide them with resources. It would also allow regulations to permit two or more healthcare organisations to share the services of a single responsible officer – this could be helpful, for instance, for organisations only employing one or very few doctors. It also allows regulations to be made to authorise or require an organisation to have more than one responsible officer. *Subsection (6)* allows for regulations to require the GMC to be consulted before a responsible officer is nominated or appointed. *Subsection (7)* allows the regulations to specify cases where the Secretary of State is to nominate the responsible officer instead of the designated body itself.

New section 45B of the Medical Act 1983 – responsibilities of responsible officer

372. *Subsection (1)* allows regulations made under the new section 45A to specify the responsibilities of the responsible officer. Such responsibilities can include the evaluation of the fitness to practise of medical practitioners having a prescribed connection with the designated body and a duty to co-operate with the GMC in connection with its responsibilities either for medical revalidation (Part 3A of the Medical Act 1983) or fitness to practise proceedings (Part 5 of the Medical Act 1983). It is intended that this co-operation will include making recommendations to the GMC (with whom the final decision rests) on relicensing of medical practitioners based on individuals' records. *Subsection (3)* sets out the power to prescribe a connection between a medical practitioner and the designated body. The intention is that this power will be used to ensure that all medical practitioners in the UK come within the remit of a responsible officer. *Subsection (4)* enables the designated body to confer on the responsible officer any powers needed to undertake such responsibilities. *Subsection (5)* requires designated bodies to have regard to the responsible officer's functions under the regulations if it gives them other functions to perform.

New section 45C of the Medical Act 1983 – further provisions

373. *Subsection (1)* of this new section allows the appropriate authority to create, in regulations made under section 45A, offences for non-compliance or other procedures for enforcement. *Subsection (2)* allows for regulations to require healthcare organisations or their responsible officers to take account of guidance issued by or on behalf of the appropriate authority. *Subsection (3)* enables the regulations to require bodies employing medical practitioners (but which are not designated bodies), or medical practitioners themselves, to provide funds and resources to a responsible officer (or their employer) having prescribed responsibilities in relation to such medical practitioners. *Subsection (4)* allows for the

regulations to require specified persons to supply information or produce documents to a responsible officer in connection with the performance of that officer's responsibilities.

New section 45D of the Medical Act 1983 – Crown application

374. This section extends new Part 5A of the Medical Act 1983 to the Crown and to people in the service of the Crown. *Subsection (2)* provides that the Crown will not be criminally liable for contravention of any provision of the Part but any such contravention may be declared unlawful by the relevant court.

New section 45E of the Medical Act 1983 – regulations under section 45A: supplementary provisions

375. Section 45E requires regulations to be made by statutory instrument, or by statutory rule in relation to Northern Ireland, subject to the negative resolution procedure before Parliament or the Northern Ireland Assembly (as the case may be). Before making any regulations, the Secretary of State must consult the Scottish and Welsh Ministers if the regulations are to extend to Scotland or apply to Wales respectively.

New section 45F of the Medical Act 1983 – Interpretation of Part 5A

376. Section 45F sets out the meaning of various terms used within this new Part 5A of the Medical Act 1983.

Clause 115: Additional responsibilities of responsible officers: England and Wales and Northern Ireland

377. Clause 115 allows the Secretary of State in relation to England, the Welsh Ministers in relation to Wales, and the DHSSPSNI in relation to Ireland, by regulations to confer further responsibilities on responsible officers nominated or appointed under Part 5A of the Medical Act 1983. *Subsection (1)* sets out that these additional responsibilities may relate to the initial employment of doctors, the monitoring of the performance or conduct of doctors, and ensuring appropriate action is taken when concerns are raised in relation to such performance or conduct (in circumstances which would not call into question the doctor's fitness to practise under the Medical Act 1983). *Subsection (5)* applies sections 45A(5)(d), 45B(2) to (5) and 45C(1), (3) and (4) of the Medical Act 1983 (relating to the provision of resources, organisations having more than one responsible officer, the connection between a medical practitioner and a designated body, designated bodies conferring powers and additional functions on responsible officers, the creation of offences and procedures for enforcement and the provision of information) to regulations made under this clause in the same way as those sections apply to regulations made under section 45A of that Act. *Subsection (6)* enables regulations to require designated bodies or their responsible officers to take account of guidance issued by or on behalf of the appropriate authority.

Clause 116: Co-operation between prescribed bodies

378. *Subsection (1)* allows the appropriate Minister to make regulations requiring specified bodies:

- to share information relating to health care workers whose conduct or performance could be a threat to the health and safety of patients;

- to respond to appropriate requests for information from other specified bodies about the conduct or performance of any health care worker;

- to consider appropriate action and to take specified steps.

379. The bodies that may be specified for these purposes are those required to have responsible officers under the new Part 5A of the Medical Act 1983 (see the notes on clause 114 above) and any other organisations specified by the regulations (it is intended that all organisations employing or contracting with health care or social care workers, public bodies exercising regulatory functions in relation to the work of such persons, social services authorities, other health related organisations, and the police will be specified for these purposes).

380. *Subsection (2)* allows the regulations to require specified bodies to take active steps to disclose information in specified circumstances whether or not the information has been requested. The types of circumstances which might be specified include situations where one body has concerns about a healthcare professional and believes that another body might have information that would help its investigation, or where an investigation uncovers information that shows that a worker may be a danger to public safety. *Subsection (3)* allows the appropriate Minister to create, in the regulations, offences for non-compliance, or other procedures for enforcement. *Subsection (4)* allows for the regulations to require specified bodies to take account of guidance given by or on behalf of the appropriate Minister. The intention is that guidance will cover issues such as the need to treat information received as confidential, the proper conduct of investigations, and factors to be taken into account when deciding whether or not to share information.

381. *Subsection (5)* defines a number of terms used in the clause. The "appropriate Minister" is defined as the Secretary of State except that, in relation to co-operation by a Welsh health body or a Welsh social services body, it means the Welsh Ministers.

Clause 117: Ss.115 and 116: Crown application

382. Clause 117 applies clauses 115 and 116 to the Crown and to people in the service of the Crown. *Subsection (2)* provides that the Crown will not be criminally liable for contravention of any provision of those clauses or regulations made under them but any such contravention may be declared unlawful by the relevant court.

Regulation of social care workforce

Clause 118: Regulation of social care workers

383. Clause 118 enables the Secretary of State (in relation to England) and the Welsh Ministers (in relation to Wales) to make regulations modifying the regulation of social care

workers. Regulations may amend or repeal any enactment (subject to paragraphs 3 and 8 of Schedule 9). *Subsection (3)* defines "social care worker" by reference to the definition in section 55 of the Care Standards Act 2000. *Subsection (4)* clarifies certain matters that are within the scope of regulations under clause 118.

384. *Subsection (4)(a)* and *(b)* cover those social care workers that fall within the definition in section 55 but who are not yet subject to registration and those within the definition of social care workers in section 55 who have applied for registration but are not yet registered, as well as those who have been, but are no longer, registered.

385. *Subsection (4)(c)* is intended to enable, if thought necessary or expedient in the future, the regulation of activities carried on by people who are not social care workers in connection with activities carried on by social care workers. It would not enable the registration of people as social care workers who do not come within the definition in subsection (3).

386. It is intended that regulations will be made to enable the legislative framework governing the social care workforce to be kept up to date, to take account of changing public expectations of the workforce and to take account of the workforce's own views about the development of their regulation. New responsibilities can also be given to the Councils.

387. Schedule 9 supplements clause 118.

Schedule 9: Regulation of social care workers

388. *Paragraph 2* of the Schedule gives examples of the matters which may be dealt with in regulations. Regulations may make changes to any aspect of the regulation of the social care workforce, subject to the limitations in *paragraphs 3* and *8*.

389. *Paragraph 3* prevents the amendment by regulations of section 55 of the Care Standards Act 2000 which contains the definition of "social care worker" and is used for the purposes of clause 118 and the Schedule. But it permits the amendment or repeal of any other provision of the Act or any other enactment, instrument or document.

390. *Paragraph 4* enables regulations to make provision for the delegation of functions, including the power to make, confirm or approve subordinate legislation. This paragraph enables regulations to confer the power on the Councils to make rules, and to make provision for any such rules to be confirmed or approved. Currently, the Care Standards Act 2000 enables the Councils to make rules about issues detailed in Part 4 of that Act. Any such rules are subject to the approval of the appropriate Minister.

391. *Paragraph 5(a)* provides for regulations to make provision about the charging of fees. It is intended that where fees are charged, the level of those fees will not exceed the costs incurred in exercising the function to which the fees relate.

392. *Paragraph 6* enables regulations made by the Secretary of State to confer functions on Ministers of the Crown. It also enables regulations made by the Welsh Ministers to confer functions on the Welsh Ministers. For example, regulations might enable a Minister to pay grants to a body. Any conferment of functions would be subject to *paragraph 8*.

393. *Paragraph 7* limits the new criminal offence that can be created using this power to one which, on summary conviction, leads to a fine not exceeding level 5 on the standard scale.

394. *Paragraph 8* provides that regulations cannot abolish either the GSCC or the CCW. Paragraphs 8(2) and (3) state that regulations may not transfer to any other person certain functions conferred on the Councils (or any of their committees or officers) by the Care Standards Act 2000. These functions are: the keeping of the register of social care workers; determining standards of education and training required as a condition of registration; giving advice about standards of conduct and performance; and administering procedures relating to misconduct, removal from registration and similar matters.

395. *Paragraph 9* obliges the Secretary of State (in relation to England) to consult persons appearing to him to represent social care workers affected by the regulations, those provided with services by the social care workers, and other persons that the Secretary of State considers it appropriate to consult prior to laying draft regulations before Parliament. The consultation will be on the basis of the draft regulations. The Secretary of State must publish these in draft three months before they are laid before Parliament. Following consultation, the draft regulations will be laid before Parliament (as originally drafted or with appropriate amendments) accompanied by a report about the consultation. Draft regulations will be subject to Parliamentary scrutiny under the affirmative procedure.

396. *Paragraph 10* imposes requirements, similar to those contained in paragraph 9, upon the Welsh Ministers in relation to the procedure for making regulations in relation to Wales.

Clause 119: Standard of proof in proceedings relating to registration of social care worker

397. Clause 119 makes provision for the civil standard of proof to be used in any proceedings which relate to a social care worker's suitability to be or remain registered. The civil standard is to be used in all such proceedings whether before the GSCC or the CCW, or before one of their committees or any of their officers. It ensures that the civil standard of proof is applied consistently by all of the health and social care professions' regulatory bodies.

398. *Subsection (4)* prevents regulations made under clause 118 from amending clause 119 or making any provision that is inconsistent with the requirement to adopt the civil standard of proof. This means that any change to the requirement to use the civil standard can only be made through another Act of Parliament.

Approved mental health professionals

Clause 120: Education and training of approved mental health professionals

399. The Mental Health Act (as amended by the Mental Health Act 2007) provides for the approval of persons to act as AMHPs and confers functions on the Councils in relation to the education and training of people who are or wish to become AMHPs. When the relevant provisions come into force, AMHPs will take on the functions previously exercised by approved social workers, including making applications for a patient's admission and detention in hospital under Part 2 of the Mental Health Act. In addition to social workers, a wider group of professionals (for example nurses, occupational therapists and psychologists) will potentially be eligible for approval as AMHPs as long as they have the right skills, experience and training.

400. Clause 120 allows the Secretary of State in relation to the GSCC and the Welsh Ministers in relation to the CCW to make regulations modifying the functions of the Councils that relate to the education and training of AMHPs. This might cover, for example, their functions that relate to the approval of courses for social workers when acting as AMHPs.

401. *Subsection (2)* provides that the regulation-making power may be used to amend, repeal or apply (with or without modifications) any provision of any enactment, instrument or document.

402. *Subsection (3)* provides that certain paragraphs of Schedule 9 also apply (with modifications) to regulations made under this clause. For example, the regulations may provide for fees to be charged and payments to be made by the Councils (paragraph 5 of Schedule 9). The same procedure for making regulations under clause 118 applies to regulations made under this clause (paragraphs 9 and 10 of Schedule 9).

PART 3 – PUBLIC HEALTH PROTECTION

Clause 123: Public health protection

403. Clause 123 inserts a new Part 2A into the Public Health Act 1984. This new Part 2A replaces the existing Part 2 of the Act.

404. New *section 45A* defines certain terms used in the new Part. It provides that reference to infection or contamination is to that which presents or could present significant harm to human health. It also provides that reference to disinfection or decontamination includes the removal of any vector, agent or source of infection or contamination.

405. New *section 45B* enables the appropriate Minister (defined in new *section 45T(6)* as the Secretary of State for England, or the Welsh Ministers for Wales) to make regulations for preventing danger to public health from conveyances (or the persons or articles on those conveyances) arriving at any place or for preventing the spread of infection or contamination by conveyances leaving any place. It also provides a power for regulations to give effect to

international agreements or arrangements, for example World Health Organisation recommendations. It gives examples of particular measures the regulations might include. The powers are needed to enable similar provision to be made to that contained in the Public Health (Aircraft) Regulations 1979 (S.I. 1979/1434), the Public Health (Ships) Regulations 1979 (S.I. 1979/1435) (the "port health regulations"), or the Public Health (International Trains) Regulations 1994 (S.I. 1994/311), all of which are made under section 13 of the Public Health Act 1984.

406. New *section 45C* provides a power for the appropriate Minister to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales. The threat can come from outside England and Wales.

407. Section 45C(3) and (4) give examples of particular provision which might be made. For example new section 45C(3)(a) would enable the Secretary of State or the Welsh Ministers to set out standing national requirements for notification of cases of specified diseases by registered medical practitioners to the local authority. Section 45C(3)(c) allows the Secretary of State or the Welsh Ministers to impose restrictions or requirements directly on persons, or in relation to things or premises, or to enable another body, such as the local authority, to do so. Section 45C(4)(a) to (d) provide examples of the restrictions or requirements that might be imposed, including special restrictions or requirements.

408. Section 45C(6)(a) defines special restrictions or requirements by reference to the measures that a justice of the peace can include in a court order by virtue of new section 45G(2), 45H(2) or 45I(2). The following measures are not regarded as special restrictions or requirements: a requirement to keep a child away from school, a restriction on the holding of an event or a requirement relating to the disposal of dead bodies.

409. New *section 45D* contains restrictions on the exercise of the power under section 45C. Section 45D(1) prohibits the appropriate Minister from making regulations containing restrictions or requirements under section 45C(3)(c) unless the Minister considers that the measures are proportionate to what is being sought to be achieved. Similarly, under section 45D(2), regulations which enable imposition of a restriction or requirement under section 45C(3)(c) must provide that the person who decides to impose such a measure must consider when taking the decision that the restriction or requirement is proportionate to what is sought to be achieved by imposing it.

410. Section 45D(3) prohibits regulations from imposing a special restriction or requirement restricting or requiring medical examination, removal to or detention in hospital or another suitable establishment, or isolation or quarantine. Section 45D(4) prohibits regulations enabling a decision-maker to impose special restrictions or requirements unless there is a serious and imminent threat to public health when the regulations are made, or the power to impose the restrictions or requirements is expressed in the regulations to be contingent on there being such a threat at the time the power to impose them is exercised.

411. New *section 45E* excludes compulsory medical treatment, including vaccination, from the ambit of the regulation-making powers in sections 45B and 45C.

412. New *section 45F* makes further provision about regulations under section 45B or 45C. This includes, at new section 45F(3), details of when the regulations may be used to amend primary or secondary legislation. Section 45F(5) outlines the penalties for the offences that can be created using the regulations. These are a fine not exceeding £20,000 and a daily penalty not exceeding an amount equal to 2% of level 5 on the standard scale (£100) for continuing to commit an offence after initial conviction. Under subsection (2)(f) regulations may permit or prohibit the levy of charges. It is intended that where charges are levied, the level of those charges will not exceed the costs incurred in exercising the function to which the charges relate.

413. New section 45F(6) and (7) provide that, where a decision is taken under regulations made under section 45C by virtue of which a special restriction or requirement is imposed on or in relation to a person, thing or premises, the regulations must include provision allowing an individual (or business) to appeal to a magistrates' court against the decision. The regulations must also include a right of periodic review if the restriction or requirement continues.

414. New *sections 45G* to *45J* make new provision for court orders. The powers conferred on justices of the peace are wider than currently provided for under the Public Health Act 1984. For example, court orders cannot currently be made under the Act in relation to things or premises. In some cases, requirements which could previously be imposed by a local authority under the Public Health Act 1984 will now be subject to a court order.

415. New section 45G(1) sets out the criteria that must be met for a justice of the peace to make an order under the legislation in relation to a person. The justice of the peace must be satisfied that:

- the person is or may be infected or contaminated;
- the infection or contamination presents or could present significant harm to human health;
- there is a risk that the person might infect or contaminate others; and
- it is necessary to make the order to remove or reduce that risk.

416. The measures that an order can provide for are described at section 45G(2). They are that a person be required to submit to medical examination, be removed to or detained in a hospital or other suitable establishment, be kept in quarantine or isolation, be disinfected or decontaminated, wear protective clothing, provide information, have their health monitored,

attend training or advice sessions, or be restricted as to where they go or with whom they have contact or from working or trading.

417. Section 45G(3) and (4) enable the justice of the peace to make an order requiring an individual who is, or may be, infected or contaminated to provide information about the identity of another individual where that other individual may also be infected or contaminated and there is a risk that that person might infect or contaminate others. This is known as contact tracing.

418. New section 45G(7) requires the appropriate Minister to make regulations setting out what evidence must be available to the justice of the peace before the justice can be satisfied that there are grounds for making an order. Sections 45H(7) and 45I(7) enable the appropriate Minister to make similar regulations in relation to evidence for orders regarding things and premises, and in relation to evidence for orders regarding contact tracing in relation to things and premises.

419. New sections 45H(1) and 45I(1) enable a justice of the peace to make an order if conditions similar to those in section 45G(1) are satisfied, but in relation to things and premises respectively. An order in relation to a thing might require, under section 45H(2), that the thing be seized, retained, kept in isolation or quarantine, disinfected or decontaminated or destroyed. Similar measures are available under section 45I(2) in relation to premises (which include conveyances) except that instead of quarantine or isolation an order could require premises to be closed. New sections 45H(3) and (4) and 45I(3) and (4) also enable contact tracing in relation to things and premises respectively.

420. New *section 45J* makes provision in relation to groups of people, things or premises with regard to the powers in new sections 45G, 45H and 45I. This will assist the justice of the peace to make the same provision in one order where, for example, more than one person has been contaminated by the same contaminant.

421. New *section 45K* makes supplementary provision about what can be included in an order of a justice of the peace, known as a "Part 2A order". It includes at new section 45K(3) provision that a measure in a Part 2A order may be conditional. For example, an order might state that if an individual refuses to be decontaminated, he must stay in isolation until the risk of contaminating others has passed.

422. Section 45K(5) allows the justice of the peace to include in a Part 2A order directions as to any action that might be appropriate to give effect to the order. This might, for example, include putting in place support provisions for a person undergoing a measure such as quarantine.

423. Section 61 of the Public Health Act 1984 as amended by paragraph 17 of Schedule 11 to the Bill provides for a right of entry or warrant authorising entry to enable a relevant health

protection authority to enter premises other than a private dwelling, or a warrant authorising entry to premises including a private dwelling. Section 45K(6) provides that a Part 2A order can include authority to enter premises including a private dwelling instead of having to apply separately for a warrant under section 61. If an order includes such authority, subsections (1) and (1A) (as inserted by paragraph 18 of Schedule 11 to the Bill) of section 62 of the Public Health Act 1984 apply as if a warrant had been issued under section 61. This means, for example, that there can be tests of the premises or of anything found on them and that samples of the premises or anything found on them can be taken and retained.

424. New *section 45L* makes provision with regard to the length of time for which any restriction or requirement imposed by or under a Part 2A order may be in force. Section 45L(1) requires any restriction or requirement in an order to have a specified time limit. Section 45L(3) provides a time limit of 28 days where the order imposes detention in a hospital or other suitable establishment, or quarantine or isolation of a person. Section 45L(2) enables further orders to be made extending the period. Section 45L(4) enables the appropriate Minister to specify in regulations the maximum period of any such extension under subsection (2). Subsection (4) also enables the appropriate Minister to specify in regulations the maximum period for which any restriction or requirement other than one for detention in hospital etc., quarantine or isolation may be imposed and the maximum period of any extension of that period.

425. New *section 45M* sets out the procedures for making, changing or revoking a Part 2A order. Only a local authority may apply for a Part 2A order (subsection (1) of section 45M), but an affected person, in addition to the local authority or any other authority with the function of executing or enforcing the order in question, can apply for the order to be varied or revoked (subsection (4)). Section 45M(5) sets out who is an affected person in the case of an order under section 45G, and enables regulations by the appropriate Minister to prescribe any other person as an affected person. Sections 45M(6)(c), (7)(c) and (8) provide similar regulation-making powers in relation to the definitions of affected person for applications in respect of orders under sections 45H(2) and (4) and 45I(2) and (4). Section 45M(9) provides that varying or revoking a Part 2A order does not invalidate any action already taken under the order. Part 2A orders can be made without a person being given the notice that would ordinarily be required under rules of court. (subsection (3) of section 45M).

426. New *section 45N* enables the Secretary of State or Welsh Ministers to make regulations dealing with matters relating to the taking of measures pursuant to Part 2A orders including the provisions described at section 45N(2).

427. New *section 45O* provides that it is an offence to fail to comply, without reasonable excuse, with a restriction or requirement imposed by or under an order of a justice of the peace or to wilfully obstruct anyone executing the order. The offence is punishable with a fine of up to £20,000. Subsections (4) and (5) of section 45O provide that a constable may take into custody and return a person who leaves a place contrary to an order detaining or isolating or quarantining the person in that place.

428. New *section 45P* provides that regulations under Part 2A of the Public Health Act 1984 may make different provision for different cases or different areas.

429. *New section 45Q* sets out the different Parliamentary procedures for making regulations under the powers at new sections 45B and 45C and those covering Part 2A orders. In general, regulations, including those under section 45B, are made under the negative resolution procedure. Regulations made under section 45C are subject to the affirmative resolution procedure unless they contain a declaration under section 45Q(3) that the person making them is of the opinion that the regulations do not contain any provision made by virtue of section 45C(3)(c) imposing special restrictions or requirements, or restrictions or requirements that would have a significant effect on a person's rights. Regulations which amend primary legislation for the purpose of giving effect to an international agreement are also subject to the affirmative resolution procedure. The first set of regulations to be made under section 45G(7) will also be subject to the affirmative resolution procedure.

430. Regulations may be made and brought into effect immediately under section 45R(2) if they contain a declaration from the Minister who makes the regulations that the person making them is of the opinion that it is necessary by reason of urgency for them to be made without a draft being approved under the affirmative resolution procedure. If either House of Parliament (for English regulations) or the National Assembly for Wales (for Welsh regulations) decides to reject the regulations, then they will cease to have effect at the end of the day on which they are rejected (section 45R(5)). They will also cease to have effect after 28 days if a resolution approving them has not been passed by each House of Parliament (for English regulations) or the National Assembly for Wales (for Welsh regulations) (section 45R(4)).

431. *New section 45S* provides that the provisions in Part 2A of the Public Health Act 1984 have effect in relation to the territorial sea adjacent to England or Wales.

432. *Section 45T* defines a number of terms used in new Part 2A of the Public Health Act 1984.

Clause 124 Further amendments relating to public health protection

433. Clause 124 repeals Part 2 of the Public Health Act 1984 and gives effect to Schedule 11 to the Bill.

Schedule 11: Public health protection: further amendments

434. Schedule 11 amends or repeals provisions in other legislation consequent on changes made by the repeal and replacement of Part 2 of the Public Health Act 1984. It also amends other provisions of the Public Health Act 1984.

435. *Paragraph 2* removes from section 159 of the Local Government, Planning and Land Act 1980 a reference to provisions in Part 2 which refer to common lodging houses.

436. *Paragraphs 3 to 30* amend the Public Health Act 1984. Paragraphs 3 to 6 define local authorities in section 1 (authorities administering Act), update sections 5 (financial provisions as to port health authorities) and 7 (port health district and authority for Port of London) and make repeals consequent on the replacement of Part 2 (of sections 1(2) and (4) and 9).

437. *Paragraph 7* updates section 48 in line with modern scientific understanding of the spread of disease, so that the powers to deal with the removal of dead bodies are not limited to a particular building.

438. *Paragraphs 8 to 10* remove references to infectious disease from sections 49 to 51 of Part 4 of the Public Health Act 1984, which deals with canal boats. These references are unnecessary, as the powers in Part 2A will cover canal boats.

439. *Paragraph 11* repeals provision for criminal offences in section 52 under Part 4 which have become unnecessary in light of changes made to section 2 of the Magistrates' Courts Act 1980 by the Courts Act 2003.

440. *Paragraph 12* omits Part 5 (miscellaneous) and section 57 (general provision for compensation) in Part 6 of the Public Health Act 1984. The provisions are either out of date or are intended to be replaced by or under Part 2A.

441. *Paragraphs 13 to 15* bring sections 58 to 60 in line with new Part 2A by substituting for local authorities, relevant health protection authorities which include local authorities and making other consequential amendments.

442. *Paragraph 16* updates the Public Health Act 1984 by introducing a new section 60A which provides a regulation-making power to enable notices, orders and other documents to be given or served electronically.

443. *Paragraph 17* updates and amends the powers to enter premises in section 61 to bring them into line with Part 2A. New subsection (2A) of section 61 curtails the right of entry in subsection (1) of section 61 so that it does not apply in respect of a private dwelling, but without affecting the power of a justice of the peace to issue a warrant under subsection (3) of section 61.

444. *Paragraph 18* amends section 62 to elaborate on how the right of entry or authorisation by warrant to enter under section 61 can be used.

445. *Paragraph 19* substitutes a new section 63 to provide for the wilful obstruction offence that continues to apply to Parts 3, 4 and 6 of the Public Health Act 1984 and bring the maximum fine, other than in relation to Part 4, into line with the maximum fine payable under Part 2A.

446. *Paragraph 20* inserts new sections 63A and 63B which concern offences by bodies corporate and unincorporated associations respectively. An officer of a body corporate may be liable for an offence as well as the body corporate by virtue of new section 63A. An officer or member of an unincorporated association may be liable for an offence as well as the unincorporated association by virtue of new section 63B.

447. *Paragraph 21* updates and amends section 64 to restrict who can bring a prosecution under the Public Health Act 1984.

448. *Paragraph 22* inserts new section 64A to extend time limits in the Magistrates' Courts Act 1980 for bringing a prosecution for an offence created by or under the Public Health Act 1984.

449. The amendment at *paragraph 23* to section 67 is needed to ensure that the right of appeal under section 67 applies to decisions of a magistrates' court under regulations made in Part 2A.

450. *Paragraph 24* substitutes a new section 69 to extend protection from personal liability in or under the Act to all those who could carry out functions by virtue of new Part 2A.

451. *Paragraph 25* removes the power for the Secretary of State to hold local inquiries under section 70 by omitting the section.

452. *Paragraph 26* substitutes a new section 71 to update the default powers setting out the process to be followed if the appropriate Minister believes a relevant health protection authority is not carrying out its functions correctly.

453. *Paragraph 27* extends the "cumulative effects" provision in section 72 to include regulations made under new Part 2A and other provision under the Act.

454. *Paragraph 28* makes a consequential amendment to the provisions on Crown property in section 73 to reflect the new definition of premises which includes vessels.

455. *Paragraph 29* makes consequential amendments and adds definitions to, or updates the definitions in, section 74 (interpretation) to reflect changes in Part 2A.

456. *Paragraph 30* repeals section 76, which made provision for the Isle of Man and the Channel Islands. The Insular Authorities have confirmed that they do not need such provision.

457. *Paragraph 31* repeals a reference to a repealed provision in the Public Health Act 1984 from the Planning and Compensation Act 1991.

PART 4 – HEALTH IN PREGNANCY GRANT

England, Wales and Scotland

Clause 125: Entitlement: Great Britain

458. Clause 125 amends the Contributions and Benefits Act. It inserts new Part 8A to provide that a woman who has satisfied prescribed conditions in relation to a pregnancy is entitled to payment of the Health in Pregnancy Grant.

459. New *section 140A* of the Contributions and Benefits Act establishes conditions of entitlement to the grant. It covers such matters as prescribed conditions in relation to a woman's pregnancy, in particular, the specified stage that a woman must have reached in order to become entitled, residence conditions and the requirement that the woman receive maternal health advice from a health professional. It introduces the powers to enable HM Treasury to make regulations under this section.

460. New *section 140B(1)* and *(2)* enable HM Treasury to prescribe in regulations the amount of the grant and to prescribe different amounts in relation to different cases.

Clause 126: Administration: Great Britain

461. *Subsections (1) and (2)* enable the Commissioners for HM Revenue and Customs to make regulations about the administration of the Health in Pregnancy Grant. The regulations may, for example, provide for a claim to be made in a manner, and within a time, prescribed by the regulations. The regulations may also require persons prescribed by the regulations to provide information to enable the Commissioners to determine if the conditions for eligibility are met.

462. *Subsection (3)* inserts new section 12A (necessity of application for health in pregnancy grant) into the Social Security Administration Act 1992. The new section provides that entitlement to the grant depends on making a claim in the required manner. It specifies that no person is to have entitlement to the grant without having a National Insurance Number or providing the evidence in order for a National Insurance Number to be allocated. It also enables the Commissioners for HM Revenue and Customs to prescribe exceptions to this requirement.

463. *Subsections (4) and (5)* enable the Commissioners for HM Revenue and Customs to recover overpayments of the grant made as a result, for example, of fraud, mistake or failure to disclose accurate information.

464. *Subsection (6)* amends section 122 of the Social Security Administration Act 1992, to insert subsections (2A) and (2B) to enable the information held by the Commissioners for HM Revenue and Customs, in relation to the Health in Pregnancy Grant, to be used to determine whether entitlement conditions for payments made out of the social fund to meet maternity expenses, currently known as the Sure Start Maternity Grant, have been satisfied.

465. *Subsection (7)* applies Chapter 2 of Part 1 of the Social Security Act 1998, which makes provision about decisions and appeals and provides for those functions to be exercised by the Commissioners for HM Revenue and Customs.

Clause 127: Penalty: Great Britain

466. Clause 127 amends the Social Security Administration Act 1992. It inserts new Schedule 3A to set out circumstances in which the Commissioners for HM Revenue and Customs may impose civil penalties on a person and sets out the power for the amount of the penalty to be prescribed by the Commissioners for HM Revenue and Customs. It also introduces the right to appeal for those on whom a civil penalty has been imposed and establishes time limits in which a penalty may be imposed and recovered.

467. Paragraph 2(6) of the new Schedule 3A provides the power for the Commissioners for HM Revenue and Customs to apply, by regulations, provision contained in the Social Security Act 1998 in relation to an appeal against a penalty.

Northern Ireland

Clause 128: Entitlement: Northern Ireland

468. Part 8A of the Northern Ireland Contributions and Benefits Act will provide for the payment of the Health in Pregnancy Grant in Northern Ireland. New sections 136A and 136B mirror the provisions in sections 140A and 140B of the Contributions and Benefits Act.

Clause 129: Administration: Northern Ireland

469. Clause 129(1), (2), (3), (4) and (6) amend the Social Security Administration (Northern Ireland) Act 1992 in the same manner as clause 126 (1), (2), (3), (4) and (6) amend the Social Security Administration Act 1992.

470. Clause 129(7) applies Chapter 2 of Part 2 of the Social Security (Northern Ireland) Order 1998, which makes provision about decisions and appeals and provides for those functions to be exercised by the Commissioners for HM Revenue and Customs.

Clause 130: Penalty: Northern Ireland

471. Clause 130 amends the Social Security Administration (Northern Ireland) Act 1992 in the same manner as clause 127 amends the Social Security Administration Act 1992. It also provides the power for the Commissioners for HM Revenue and Customs to apply, by regulations, provision contained in the Social Security (Northern Ireland) Order 1998 in relation to an appeal against a penalty.

Clause 131: Northern Ireland: health in pregnancy grant to be excepted matter

472. Clause 131 inserts a reference to the Health in Pregnancy Grant into Schedule 2 to the Northern Ireland Act 1998, thus making it an excepted matter for the purposes of the devolution settlement in Northern Ireland (and therefore outside the competence of the Northern Ireland Assembly).

Clause 132: General and supplementary

473. Clause 132(1) provides for HM Revenue and Customs to be responsible for the payment and management of the Health in Pregnancy Grant.

474. Clause 132(2) and (3) amend section 115 of the Immigration and Asylum Act 1999, to insert a reference to the Health in Pregnancy Grant. The effect is that no person subject to immigration control is entitled to the Health in Pregnancy Grant unless they satisfy prescribed conditions.

475. Clause 132(4) exempts the Health in Pregnancy Grant from liability to income tax.

PART 5 – MISCELLANEOUS

Amendments relating to National Health Service

Clause 133: Duty of Primary Care Trusts

476. Clause 133 amends the NHS Act 2006 by inserting a new section 23A which imposes a duty on PCTs to make arrangements to secure continuous improvement in the quality of health care provided by or for them. This duty replaces the current duty (on PCTs and other English NHS bodies) to improve quality in section 45 of the Health and Social Care (Community Health and Standards) Act 2003, requiring on-going improvement activity, and is aligned more closely with the duty imposed on English local authorities by section 3 of the Local Government Act 1999.

477. Subsection (2) of the new section 23A provides that in discharging this duty PCTs should have regard to standards set out in statements published by the Secretary of State under clause 41.

Clause 134 and Schedule 12: Pharmaceutical services

478. The current funding arrangement for pharmaceutical services is governed by sections 228 to 231 of, and Schedule 14 to, the NHS Act 2006. Some alterations need to be made to these provisions of the NHS Act 2006 in order to move the Global Sum to PCT baseline allocations. Clause 134 introduces Schedule 12 which in turn makes amendments to sections 228 to 230 of, and Schedule 14 to, the NHS Act 2006 to change the classification of pharmaceutical services expenditure and bring it within PCT baseline allocations. In Wales, the current funding arrangements are governed by sections 174 to 177 of, and Schedule 8 to, the NHS (Wales) Act 2006. Schedule 12 makes the changes that are needed to the NHS (Wales) Act 2006 to change the classification of pharmaceutical services, which will transfer the Global Sum to the baseline allocations of Local Health Boards in Wales.

479. *Paragraph 2* of Schedule 12 revises the definition of a PCT's "expenditure" within section 228 of the NHS Act 2006 to include expenditure on pharmaceutical services. *Paragraphs 3* and *4* make consequential changes.

480. *Paragraph 5(1)* and *(2)* make further consequential amendments. *Paragraph 5(3)* inserts a new provision to make it possible to charge the dispensing fees, and other fees payable for the provision of pharmacy services, back to the PCT where a prescription was issued. This corresponds to similar provisions for the cost of medicines which are already charged to the PCT in which the prescription was issued.

481. *Paragraph 5(4)* makes consequential changes.

482. *Paragraph 5(5)* ensures that remuneration paid by PCTs for pharmaceutical services which is met by an NHS Trust or NHS Foundation Trust under section 234(4) of the NHS Act 2006 can be charged back to the PCT in which the prescription was issued.

483. *Part 2, paragraphs 6 to 10*, makes corresponding provision for Wales.

Clause 135: Indemnity schemes in connection with provision of health services

484. *Subsections (2)* and *(3)* of clause 135 expand membership eligibility of indemnity schemes to the Secretary of State, who may secure health services directly. It also expands membership to non-NHS bodies who provide services or secure the provision of services on behalf of one or more of Strategic Health Authorities, PCTs, NHS trusts, Special Health Authorities, NHS Foundation Trusts, CHAI (or, in future, the Commission), the Health Protection Agency or the Secretary of State.

485. *Subsection (4)* (which inserts new subsection (2A) into section 71 of the NHS Act 2006) limits the losses and liabilities that an indemnity scheme may cover in respect of the Secretary of State or non-NHS bodies to functions in respect of the National Health Service. This is because both the Secretary of State and some of the eligible non-NHS bodies may have functions not related to care provided through the NHS, and these functions should not be covered by these schemes.

486. Currently, membership of the existing schemes is voluntary, although the Secretary of State may direct a body that is eligible to be a member to become a member of any of the schemes established under section 71 of the NHS Act 2006. However, *subsection (6)* (which substitutes subsection (5) of section 71) provides that the Secretary of State may not direct a non-NHS body to become a member of a scheme. NHS Foundations Trusts are already excluded, and continue to be excluded, from this power of direction. This provision essentially reserves the right of the Secretary of State to direct certain eligible members to become members of an established or future scheme.

Weighing and measuring of children

Clauses 136 and 137: Weighing and measuring of children

487. Provision for medical inspections for pupils in England is set out in Schedule 1 to the NHS Act 2006. New paragraphs will be inserted into Schedule 1 to make the necessary provisions on weighing and measuring children.

488. New paragraph 7A of Schedule 1 enables the Secretary of State to make arrangements in relation to England for the weighing and measuring of children under 12 who attend school. Similar arrangements can also be made in relation to young children who attend early years settings. New paragraph 7A(1) and (2) refer to "junior pupils". The effect of paragraph 7A(4) is to apply relevant definitions under the Education Act 1996 or the Schools Standards and Framework Act 1998. "Junior pupil" is defined under the 1996 Act as a child who has not attained the age of 12. Similar definitions are applied by virtue of clause 137 in relation to the provisions for Wales.

489. New paragraph 7B(1)(a) of Schedule 1 will enable the Secretary of State to make regulations to authorise information to be provided by local education authorities, private school proprietors and persons registered under the relevant provisions of the Childcare Act 2006, to the PCT staff who it is intended will conduct a weighing and measuring exercise.

490. New paragraph 7B(1)(b) of that Schedule enables the Secretary of State to make provision about the requirements which must be satisfied before weighing and measuring can take place and the way in which the weighing and measuring is to be carried out.

491. New paragraph 7B(1)(c) of that Schedule enables the Secretary of State to make regulations providing for children's height and weight data, or any assessment or analysis of the child's height and weight data, to be fed back routinely to the parents of that child. It is intended that the regulations will provide for other carers, such as grandparents, to be treated as parents for the purposes of being able to withdraw a child in their care from a weighing and measuring programme, or receiving information provided by that programme.

492. New paragraph 7B(1)(d) of that Schedule enables the Secretary of State to make regulations providing for the processing of information gathered during weighing and measuring. The power will be exercised in line with data protection requirements.

493. New paragraph 7B(2) of that Schedule enables regulations to be made which will require those undertaking the weighing and measuring programme to have regard to any guidance issued by the Secretary of State.

494. Clause 137 inserts new paragraphs into Schedule 1 to the NHS (Wales) Act 2006. New paragraph 7A allows the Welsh Ministers to make arrangements in relation to Wales for the weighing and measuring of children under 12 who attend school. Similar arrangements can also be made in relation to children who attend early years settings.

495. In particular, the Welsh Ministers will be able to enter into arrangements with local education authorities or proprietors of any school which is not maintained by a local education authority to provide for the weighing and measuring of junior pupils in such schools. In addition, they may enter into arrangements with persons registered under the

Children Act 1989 for the purpose of providing childcare or day care for children to weigh and measure children in their care.

496. The regulations made by the Welsh Ministers can make further provision about the requirements which must be satisfied before weighing and measuring can take place and the way in which the weighing and measuring is to be carried out. New paragraph 7B of Schedule 1 to the NHS (Wales) Act 2006 mirrors the equivalent provision in the NHS Act 2006 (see above).

Social care

Clause 138: Direct payments in lieu of provision of care services

497. *Subsection (2)* of clause 138 inserts new subsections (1A) to (1C) into section 57 of the Health and Social Care Act 2001.

498. New subsection (1A) enables regulations to be made which allow a designated person (a "suitable person") to receive a direct payment on behalf of another person ("P"). In order for the suitable person to receive a payment, P must be assessed as needing community care services and must lack the capacity to consent to the making of direct payments, within the meaning of the Mental Capacity Act 2005. This subsection also enables regulations to be made that set out the conditions that must be satisfied by local authorities in determining who is a suitable person.

499. New subsection (1B) describes the consent that is necessary in order for such payments to be made. The suitable person must give his or her consent. If P has either a deputy appointed by the Court of Protection under the Mental Capacity Act 2005, or a donee of a lasting power of attorney ('LPA') created by P, and the deputy or donee qualifies as a surrogate of P but the suitable person does not qualify as a surrogate of P, then the deputy or donee must also give his or her consent. Regulations under new subsection (5C) will set out the authority that a person must have as a deputy or donee in order to qualify as a surrogate of P for the purposes of section 57 of the Health and Social Care Act 2001.

500. New subsection (1C) sets out what is meant by a "suitable person": a person is suitable if he or she fulfils one of the following criteria:

- he or she is a representative of P. The term 'representative' will be defined in regulations made under section 57 as amended by *subsection (6)* of this clause. It is envisaged that the regulations will initially apply this term to at least some of the people who are donees of LPAs or deputies appointed by the Court of Protection. Additionally, these powers would allow the category of 'representatives' to be extended more widely in the future, for example to include donees of Enduring Powers of Attorney;

- he or she is not a representative of P, but there is a donee or deputy in place who qualifies as a surrogate of P and who considers this person suitable to receive and manage the direct payment on P's behalf;

- he or she is not a representative of P, and there is no donee or deputy in place who qualifies as a surrogate of P, but the local authority considers this person suitable to receive and manage the direct payment.

501. However, simply being considered to be a suitable person who could potentially manage a direct payment on behalf of someone else, does not automatically mean that a direct payment will be made to that person. Powers taken in subsection (1A) and amended subsection (3) of section 57 of the Health and Social Care Act 2001, enable regulations to impose conditions that must be met: for example the local authority must, where appropriate, consult with family members or friends already involved in the care of the person who lacks capacity, before a payment is made to the suitable person.

502. *Subsection (3)(a) to (c)* and *subsections (4)* and *(5)* amend the regulation-making powers that already exist under section 57 of the Health and Social Care Act 2001 to ensure that they can cover direct payments made to a suitable person in respect of P, as well as covering direct payments made directly to P.

503. *Subsection (3)(d)* amends section 57 of the Health and Social Care Act 2001 to enable regulations to be made that specify matters that the local authority must or may have regard to when taking any decision about who will administer the direct payment. Regulations under that section will be able to specify the steps that local authorities must or may take before or after making such decision. For example, regulations might specify that a local authority must consult certain family members of P before making a direct payment. They might also specify that the local authority must keep these family members informed of how P's needs are being met once the payment has been made.

504. Subsection (3)(d) also amends section 57 of the Health and Social Care Act 2001 to enable regulations to specify that where a person has fluctuating capacity (e.g., in the early stages of dementia or when the use of medication affects the person's capacity), arrangements for managing their direct payment do not have to be continually revisited. For example, should P, who is receiving direct payments via a suitable person, temporarily gain capacity, then these regulations may provide for mechanisms to allow the suitable person to continue managing the processes around the payment but in accordance with P themself deciding how those payments are spent for the period of time for which they have capacity. Without the ability to make such provision, arrangements for the suitable person to manage the payment would immediately cease and payments would have to be made under the legislation governing payments directly to individuals rather than that governing payments to third parties. This would mean that the individual would continually fluctuate between two different regimes in section 57 of the Health and Social Care Act 2001 under which direct

payments may be provided. This would have the potential to cause difficulties for P, the suitable person and the local authority involved.

505. Section 57(3)(d) of the Health and Social Care Act 2001 currently allows regulations to set out conditions to be complied with by the recipient of a direct payment which may or must be imposed by local authorities in relation to the direct payment. *Subsection (7)* of clause 138 amends section 57 of the Health and Social Care Act 2001 so that these can include conditions relating to securing the provision of the service concerned, the provider of the service, the person to whom payments are made in respect of the provision of the service or the provision of the service itself. Such conditions could be imposed to ensure that 'suitable persons' act in the best interests of the person whose direct payment they are receiving and managing when making decisions about their care.

506. *Subsection (8)* amends section 64 of the Health and Social Care Act 2001 to provide that any regulations made under section 57 of that Act by the Welsh Ministers will be subject to annulment by a resolution of the National Assembly for Wales.

507. *Paragraphs 1* and *8* of Schedule 14 make amendments to other legislation in consequence of the extension of the direct payments scheme by clause 138. Paragraph 1 provides that the existing legislation relating to direct payments for disabled children or parents under section 17A of the Children Act 1989 is not affected by clause 138 (as explained in the Background and Summary section). Paragraph 8 amends section 6 of the Safeguarding Vulnerable Groups Act 2006 ("the 2006 Act"). A person for whom a direct payment is received under the new section 57(1A) of the Health and Social Care Act 2001 is a vulnerable adult for the purposes of the 2006 Act. This paragraph excludes local authorities when exercising functions under section 57 of the 2001 Act, and surrogates when acting under new section 57(1B)(b) or (1C)(b) of the 2001 Act, from being a regulated activity provider and therefore required to undertake the vetting and barring checks required by virtue of the 2006 Act. Regulations made under new section 57(3)(k) of the 2001 Act could however require local authorities to carry out vetting and barring checks before making direct payments to a person on behalf of a vulnerable adult.

Clause 139 and Schedule 13: Abolition of maintenance liability of relatives

508. This clause removes local authorities' powers to seek liable relatives payments under the National Assistance Act 1948. This will bring the operating principles for the charging policy for social care in line with those that are used in the rest of the health and social care system. The 'liable relatives rule' will come to an end in particular cases in accordance with Schedule 13.

Clause 140: Ordinary residence for certain purposes of National Assistance Act 1948 etc.

509. Section 24 of the National Assistance Act 1948 provides that a patient in an NHS hospital is to be treated for the purposes of the provision of residential accommodation under Part 3 of that Act as being ordinarily resident in the area where he was ordinarily resident

before he was admitted to hospital. *Subsection (1)* extends this rule to apply also to accommodation provided by NHS bodies in places other than NHS hospitals.

510. *Subsection (2)* gives the Secretary of State and the Welsh Ministers the power to make and publish arrangements for determining which cases where a question has arisen as to a person's ordinary residence are to be dealt with by the Secretary of State and which are to be dealt with by the Welsh Ministers. The arrangements can include provision for the determination of cross-border ordinary residence disputes between English and Welsh local authorities.

511. The Chronically Sick and Disabled Persons Act 1970 gives local authorities a statutory duty to make arrangements for individuals who are ordinarily resident in their area, if the local authority considers the arrangements necessary to meet certain specified needs of that person, as listed in section 2 of that Act. These needs might include, for example, the provision of assistance to participate in recreational or learning activities, the provision of meals at home or elsewhere, or the provision of assistance in obtaining telephone or any other special equipment. The Chronically Sick and Disabled Persons Act 1970 does not state explicitly whom local authorities should approach to resolve ordinary residence disputes under section 2. *Subsection (3)* brings provisions relating to determinations of ordinary residence disputes under section 2 of the Chronically Sick and Disabled Persons Act 1970 in line with the National Assistance Act 1948 by providing that any ordinary residence disputes are referred to the Secretary of State or the Welsh Ministers for a determination (in accordance with the arrangements made and published under the National Assistance Act 1948).

Financial assistance related to provision of health or social care services

Clauses 141 and 142: Power of Secretary of State to give financial assistance; Qualifying bodies

512. Clause 141(1) allows the Secretary of State to provide financial support to qualifying bodies who are delivering health and social care services. It also allows the Secretary of State to fund qualifying bodies delivering related services to providers of health and social care services. Clause 141(2) allows the Secretary of State to give financial support to people to set up such bodies.

513. Clause 142 sets out the conditions for being a qualifying body. The first of these is that the body must pass the community benefit test. This is satisfied if a reasonable person might consider that the activities of a body are carried on for the benefit of a section of the community in England. The regulation-making power in clause 142(2) will allow provision to be made about the sort of activities that can be treated as meeting this condition and the activities that can be treated as not meeting it, in cases where there may be some doubt. For example, it is intended to make regulations setting out that political activities are not to be treated as activities that are carried on for the benefit of the community.

514. The second condition is that the body satisfies any conditions relating to the distribution of profits as are set out in regulations. The Department proposes to make regulations which ensure that the profits of a qualifying body are principally invested for social objectives; either in the body itself or in the community. Clause 142(1)(b) allows for prescribed bodies to be excepted from the requirement to meet such conditions.

515. The third condition under clause 142(1)(c) is that the body must be carrying on a business. The intention is to distinguish these bodies from purely public sector organisations and those carrying on activities on purely a voluntary basis. Voluntary bodies who are "carrying on a business" and meet the other conditions would qualify.

516. Clause 142(1)(d) allows regulations to be made setting out other conditions that a body must meet in order to be a qualifying body, and where a person is given financial support to set up a qualifying body, additional conditions that such a qualifying body must satisfy. Under clause 142(2), regulations may also provide that only certain kinds of body can be a qualifying body.

Clauses 143 and 144: Forms of assistance under s.141; Terms on which assistance under s.141 is given

517. Clauses 143 and 144 concern the forms of financial assistance (e.g. grants, loans, guarantees, share capital) the Secretary of State could give to social enterprises and allow the Secretary of State to specify the terms on which it is provided. The clauses allow some flexibility, so that:

- the Secretary of State can provide finance packages tailored for the particular needs of social enterprises;

- the Secretary of State can set appropriate terms and conditions which will protect these investments.

518. Clause 143 allows the financial support that the Secretary of State can provide to take any form (with one exception), as well as setting out examples of the types of financial support that may be given. *Subsection (3)* ensures that the Secretary of State cannot give financial support to a company to set up a qualifying body by purchasing share capital in that company. This is because a longer term investment, such as purchasing share capital, would not be appropriate if the company itself is not a qualifying body.

519. Clause 144 enables the Secretary of State to impose terms and conditions on the financial support given to qualifying bodies and people setting up qualifying bodies. This includes terms as to when the financial assistance must be repaid. *Subsection (3)* requires the people or bodies receiving this kind of financial support from the Secretary of State to comply with the terms on which the support is provided.

Clause 145: Directions to certain NHS bodies

520. *Subsection (1)* enables the Secretary of State to direct certain NHS bodies in England to exercise his power to give financial support under clause 141. This will mean that, to the extent permitted by the Secretary of State's directions, NHS trusts, PCTs and Strategic Health Authorities in England and Special Health Authorities performing functions only or mainly in relation to England would be able to give financial support to qualifying bodies; or people who want to set up such bodies.

Clause 146: Arrangements with other third parties

521. Clause 146 allows the Secretary of State to make arrangements for a third party, other than those NHS bodies set out in clause 145(1) or an English local authority, to give financial support to a qualifying body or a person wanting to set up such a body, or to carry on functions relating to such support. These functions can be completely carried out by a qualifying third party, or to the extent set out in the arrangements, and can be carried out generally, or in specific cases. These arrangements made between the Secretary of State and the third party may set out the terms on which the third party can give financial support, including the types of support that can be given. The clause also provides for the Secretary of State to provide the necessary funding to the third party and for provision to be made as to repayment (for example if the arrangements came to an end.)

522. The reason for excluding local authorities is because they have sufficient powers to fund social enterprises and have their own legislative structure. The reason for excluding NHS bodies set out in clause 145(1) is that separate arrangements for these bodies are already set out in that clause. The provisions in this Bill are designed to give the Secretary of State and NHS bodies the necessary wider powers to fund social enterprises.

Clause 147: Power to form a company

523. Clause 147 allows the Secretary of State to set up a company to fund qualifying bodies and people wanting to set up such bodies. Under clause 146 the Secretary of State could make arrangements with such a company to exercise the Secretary of State's powers to fund such qualifying bodies and people wanting to set up such qualifying bodies. Under the arrangements with such a company, it is envisaged that the Secretary of State would transfer money to the company to enable the company to provide such financial support.

Clause 148: Interpretation of group of sections

524. Clause 148 sets out the meaning of various terms used in clauses 141 to 148.

National Information Governance Board for Health and Social Care

Clause 149 and clause 150: National Information Governance Board for Health and Social Care

525. Clause 149 establishes the National Information Governance Board for Health and Social Care.

526. Clause 149 inserts four new sections (250A to 250D) into the NHS Act 2006:

- Section 250A sets out the functions of the National Information Governance Board relating to England and how it will exercise these functions and defines the information that will be within the remit of the Board. It provides that the Board can issue advice without being requested to do so and can request information from organisations which fall within its remit and confirms that organisations have to give due regard to advice supplied by the Board.

- Section 250B has the effect of giving the National Information Governance Board functions in relation to Wales that are narrower than its functions in relation to England. In relation to Wales, its functions will correspond to those currently carried out by PIAG, which in particular has functions in relation to the use of identifiable patient information without the patient's consent.

- Section 250C details the regulations that the Secretary of State might make in respect of the National Information Governance Board. These may cover such matters as the composition of the Board, the committees or sub-committees that may be necessary, the terms of appointment of Board members, the payment of allowances or expenses, and the delegation of the Board's functions.

- Section 250D details the annual reporting arrangements for the National Information Governance Board. The Board is to report to the Secretary of State on an annual basis.

527. Clause 149 provides that, when the National Information Governance Board is established as a statutory body, PIAG (which is the current statutory body and was continued by section 252 of the NHS Act 2006) will be abolished.

528. Clause 150 substitutes a new section for section 252 of the NHS Act 2006. It requires the Secretary of State to consult the National Information Governance Board where he proposes to make patient information regulations under section 251 of that Act.

529. Schedule 14 inserts references to the National Information Governance Board into the Parliamentary Commissioner Act 1967, the House of Commons Disqualification Act 1975 and the Freedom of Information Act 2000. It also inserts references to the National Information Governance Board into section 271 of the NHS Act 2006 to indicate that some of its functions are exercisable in relation to England and Wales.

Functions of Health Protection Agency in relation to biological substances

Clause 151: Functions of Health Protection Agency in relation to biological substances

530. Clause 151 abolishes the NBSB and gives functions to the Health Protection Agency corresponding to the NBSB's functions. It also enables the Health Protection Agency to be given any other functions that could have been given to the NBSB.

531. *Subsection (1)* abolishes the NBSB and repeals the Biological Standards Act 1975. *Subsections (2)* to *(6)* amend the Health Protection Agency Act 2004, under which the Health Protection Agency was established and given its functions, to expand the Health Protection Agency's functions (and possible functions) to include functions in relation to biological substances.

532. *Subsection (3)* inserts a new section 2A into the Health Protection Agency Act 2004, giving the 'relevant authority' (the Secretary of State and DHSSPSNI, acting jointly) power to direct the Health Protection Agency to carry out functions in relation to biological substances. The new section 2A(3) of the Health Protection Agency Act 2004 deems the relevant authority to have directed that initially the Health Protection Agency is to acquire functions that are the same as the NBSB's: those functions are specified in the National Biological Standards Board (Functions) Order 1976. *Subsection (5)* amends section 8 (power to make transfer schemes) of the Health Protection Agency Act 2004, to enable the relevant authority to make a scheme for the transfer of the property, rights and liabilities of the NBSB to the Health Protection Agency.

PART 6 – GENERAL

Clause 153: Orders, regulations and directions: general provisions

533. Clause 153 makes provision in relation to powers to make orders and regulations and to give directions under the provisions of the Bill. It provides that orders and regulations made by the Secretary of State, the Treasury, the Privy Council or the Welsh Ministers are to be made by statutory instrument and that regulations made by DHSSPSNI are to be made by statutory rule. It also makes provision as to how the powers in question may be exercised.

Clause 154: Orders and regulations: Parliamentary control

534. Clause 154 provides that all regulation and order making powers of the Secretary of State and the powers of the Privy Council to make an order approving rules made by the OHPA (clause 104) and to make regulations about the membership of the OHPA (Schedule 6), will be subject to the negative resolution procedure, other than in the following cases:

- where subsection (3) applies, in which case the instrument must be approved by resolution of each House of Parliament; or

- where the order is a commencement order under clause 162, in which case there is no Parliamentary procedure.

535. *Subsection (3)* lists those orders and regulations which will be subject to affirmative resolution procedure. They are as follows:

- regulations defining "regulated activity" (clause 4(1)) for the purposes of registration in respect of the provision of health or social care;

- regulations under clause 39 modifying Chapter 2 of Part 1 (registration in respect of the provision of health or social care) of the Bill in relation to newly regulated activities;

- regulations making provision modifying the regulation of social care workers (clause 118) or making provision modifying the functions of the GSSC in relation to the education and training of AMHPs (clause 120); and

- orders containing transitional or consequential provision (clause 159) which amend or repeal any provision of an Act of Parliament.

Clause 155: Orders and regulations: control by National Assembly for Wales
536. Clause 155 provides that all regulation-making powers of the Welsh Ministers, other than regulations to which subsection (3) applies, are subject to the negative resolution procedure in the National Assembly for Wales. The negative resolution procedure also applies to orders made by the Welsh Ministers under clause 159(2) containing transitional or transitory provisions or savings

537. *Subsection (3)* provides that regulations making provision modifying the regulation of social care workers (clause 118), or making provision modifying the functions of the CCW in relation to the education and training of AMHPs (clause 120), must be approved by a resolution of the National Assembly for Wales.

Clause 156: Regulations: control by Northern Ireland Assembly
538. Clause 156 provides that regulations made under clause 115 (responsible officers) by DHSSPSNI are subject to the negative resolution procedure in the Northern Ireland Assembly.

Clause 157: Directions
539. Clause 157 provides that any directions given by the Secretary of State or the Privy Council must be in writing and that any directions given may be varied or revoked by subsequent directions.

Clause 158: Repeals
540. Clause 158 makes provision in respect of repeals. It gives effect to the repeals specified in Schedule 15.

Clause 159: Power to make transitional and consequential provision etc.
541. Clause 159 confers power to make transitional or transitory provisions and savings and supplementary, incidental or consequential provision. *Subsection (1)* confers on the Secretary of State power to make by order transitional or transitory provisions and savings in connection with the commencement of any provision of the Bill in relation to which the Secretary of State is the appropriate Minister for the purposes of clause 162(2)

(commencement). It also confers on the Secretary of State the power to make by order such supplementary, incidental or consequential provision as considered appropriate.

542. *Subsection (2)* confers on the Welsh Ministers power to make by order transitional or transitory provisions and savings in connection with the commencement of any provision of the Bill in relation to which the Welsh Ministers are the appropriate Minister for the purposes of clause 162(2) (commencement).

543. *Subsection (3)* provides that an order under this clause may amend, repeal, revoke or otherwise modify any enactment. *Subsection (7)* defines "enactment" as an enactment contained in, or in any instrument made under, an Act of Parliament, an Act of the Scottish Parliament, a Measure or Act of the National Assembly for Wales or Northern Ireland legislation. *Subsection (5)* provides that before making an order under this clause containing provision which would fall within the legislative competence of the Scottish Parliament, the Secretary of State must consult the Scottish Ministers.

544. Powers of this kind are often included in Bills which make extensive changes to existing statutory regimes. This clause will ensure that necessary or expedient transitional arrangements can be made as the Bill is commenced without creating any difficulty or unfairness and that there can be a smooth transition from the old law and procedures to the new.

545. A number of transitional provisions will be needed in relation to the establishment of the Commission and the assumption by it of the functions of CHAI, CSCI and MHAC. The Commission will assume the different functions of the three existing regulators over a period of time and will take on some earlier than others. Transitional provision will, for example, be needed in relation to the transition from the registration provisions of Part 2 of the Care Standards Act 2000 to the new regime under Chapter 2 of Part 1 of the Bill.

546. Transitional provision will also need to be made in relation to some of the provisions in Part 2 (regulation of health professions and health and social care workforce) of the Bill. This will be the case in relation to the transition from adjudication of fitness to practise cases by committees of the GMC and the GOC to their adjudication by the OHPA. Transitional provision will also have to be made in connection with: (a) preserving existing regulations, or parts of them, under the Public Health Act 1984 (Part 3 of the Bill); and, (b) the abolition of the NBSB and the assumption of identical functions by the Health Protection Agency (clause 151).

547. The power to make consequential amendments will enable changes made to the law by the Bill to be reflected in other legislation which refers to or is dependent on provisions repealed or amended by the Bill. In particular, whilst Schedules 3 and 5 make amendments to the Mental Health Act, the Care Standards Act 2000 and the Health and Social Care (Community Standards) Act 2003 in connection with Part 1 of the Bill, amendments will need to be made to other legislation which contains references to CHAI, CSCI and MHAC.

Clause 160: Financial provisions
548. Clause 160 makes provision for expenditure which will be incurred under or be attributable to the provisions of the Bill, once it has received Royal Assent, to be paid out of money provided by Parliament.

Clause 161: Extent
549. Clause 161 makes provision as to the extent of the provisions of the Bill.

Clause 162: Commencement
550. Clause 162 makes provision for the coming into force of the provisions of the Bill. This clause provides that the Bill, with certain exceptions, will come into force on a day appointed by order of the appropriate authority. The exceptions to this provision are Part 6 (general) of the Bill (except clause 158 and Schedule 15 (repeals)), and any other provision of the Bill so far as it confers power to make orders and regulations or defines any expression relevant to the exercise of any such power. In these cases the provisions come into force on the day on which the Bill receives Royal Assent.

Clause 163: The appropriate authority by whom commencement order is made
551. Clause 163 determines who the appropriate authority is for the purposes of making commencement orders under clause 162. Except as provided by subsections (3) to (5), the appropriate authority is the Secretary of State.

552. In relation to clauses 114, 115 and 117 (responsible officers), so far as they relate to Northern Ireland, the appropriate authority is DHSSPSNI.

553. In relation to the following provisions, the appropriate authority is the Welsh Ministers:

- Part 3 (public health protection), including Schedule 11, and Part 3 of Schedule 15 so far as they relate to Wales (and clause 158 (repeals) so far as it relates to that Part of Schedule 15 in its application to Wales),

- clause 134 (pharmaceutical services), so far as relating to Part 2 of Schedule 12, together with that Part of that Schedule and Part 4 of Schedule 15 so far as it relates to the repeals in the NHS (Wales) Act 2006 (and clause 158 so far as it relates to those repeals),

- clause 137 (weighing and measuring of children: Wales),

- subsections (1) to (7) of clause 138 (direct payments in lieu of provision of care services), so far as they relate to Wales, and subsection (8) of that section,

- clause 139 (abolition of maintenance liability of relatives), Schedule 13 and Part 5 of Schedule 15, so far as they relate to local authorities in Wales (and clause 158 so far as relating to Part 5 of Schedule 15 in its application to local authorities in Wales), and

- clause 140 (ordinary residence for certain purposes of National Assistance Act 1948 etc.), so far as relating to Wales.

554. In relation to Part 4 (health in pregnancy grant), the appropriate authority is the Treasury.

Clause 164: Consultation in relation to commencement

555. Clause 164 makes provision requiring the appropriate authority for the purposes of making commencement orders under clause 162 to consult others before making orders commencing certain provisions of the Bill.

556. The Secretary of State must consult the Scottish Ministers before making a commencement order relating to:

- clause 106 and Schedule 8 (extension of powers under section 60 of the Health Act 1999) so far as relating to-

  - subsection (2A) of section 60 of the Health Act 1999,
  - the repeal of paragraph 7(3) of Schedule 3 to that Act,
  - the amendments of paragraphs 8 and 9 of Schedule 3 to that Act, so far as relating to a profession that is not a reserved profession for Scotland,
  - the meaning of "enactment" for the purposes of Schedule 3 to that Act;

- clause 107 (standard of proof in fitness to practise proceedings) in relation to a profession that is not a reserved profession for Scotland; or

- clause 111 (powers of Secretary of State and devolved administrations), so far as relating to the functions of the Scottish Ministers.

557. Before making a commencement order relating to clause 140 (ordinary residence for the purposes of the National Assistance Act 1948 etc.) in relation to England, the Secretary of State must consult the Welsh Ministers; and before making a commencement order relating to that clause in relation to Wales, the Welsh Ministers must consult the Secretary of State. The Secretary of State must also consult the Welsh Ministers before making a commencement order in relation to those amendments to the powers of the Welsh Ministers under the Care Standards Act 2000 which were requested by the Welsh Assembly Government (see commentary on clause 91 and Schedule 5).

558. Before making a commencement order relating to clause 151 (functions of Health Protection Agency in relation to biological substances), or Part 7 (abolition of NBSB) of Schedule 15 (or clause 158 so far as relating to that Part of that Schedule), the Secretary of State must consult DHSSPSNI.

PUBLIC SECTOR FINANCIAL COST IMPLICATIONS

Part 1 – The Care Quality Commission

559. The establishment of a single regulator for health and adult social care will allow CHAI, CSCI and MHAC to save some of their current costs of head office, infrastructure and support services and other costs due to merger of their functions into one organisation. Latest estimates would suggest that the yearly savings would be between £10.9m and £13.4m. The necessary organisational change would cause some transitional costs but as the regulatory changes are being implemented in tandem with a process of a significant cost reduction programme it has not been possible to be clear about what further transitional costs should be attributed to the regulatory changes here. Initial estimates have suggested that transitional costs in relation to the cost reduction exercise might total up to £140m. This sum would include the costs of ICT investment, continuing costs following planned estates rationalisation and redundancy payments. The reduction in annual operating costs will be £60m per annum (on a 2004/5 baseline).

560. The change to administrative costs of the Commission and NHS providers as a result of the extension of registration will be dependent on the scope of registration and the exact registration requirements that will be set out in secondary legislation. Therefore the range of possible outcomes in terms of costs for both the Commission and NHS providers is relatively wide. The introduction of secondary care NHS providers into the registration system could increase the annual costs for the regulator by £7.3m (and even higher if scope is broadened further) or decrease costs by £3.2m pa. Annual costs overall for NHS secondary care providers could increase by £1.9m or decrease by up to £5.1m as a result of the extension of registration. The Care Standards Tribunal will face a minimal increase in costs through extending its jurisdiction to cover appeals from registered NHS bodies.

561. The Government has set a limit for the operating costs for the continuing health and adult social care regulation carried out by the Commission (excluding the costs of functions in relation to mental health legislation) as part of its policy to reduce the cost of public sector regulation. This will be made up of income generated from fees and grant in aid from the Government. The Commission will have the power to charge fees in relation to its registration activities and other functions as may be prescribed. The fees that the Commission charges in respect of particular functions will reflect the costs incurred in carrying out those functions. The Secretary of State is able to make alternative provision if the Commission does not make reasonable provision on fees, and to ensure its overall income does not exceed the operating limit the Government has set.

Part 2 – Regulation of Health Professions and Health and Social Care Workforce

562. The Department will provide funding for the set-up and transitional costs of the OHPA. Current analysis suggests this to be in the region of £3 to 4 million over approximately 2 years. Based on current costs of adjudication in fitness to practise cases for the GMC and the GOC, the annual costs of the OHPA (which it is intended will be met in the main by fees charged under clause 105) are estimated to be in the order of £11.5m, on the assumption that costs will not vary significantly in the transfer of such functions. Further work is being actively undertaken to refine these costs.

563. CRHP (which will become the Council for Healthcare Regulatory Excellence) is a non-departmental public body, funded by the Department of Health and devolved administrations. Its baseline running costs will not increase as a result of the changes in function. However, the Department of Health in England has identified specific project work for the Council for Healthcare Regulatory Excellence to undertake as part of the overall implementation of the Government's White Paper, *Trust, Assurance and Safety*. Additional costs associated with this work are being funded separately by the Department and will not be recurrent.

564. Some of the special project work referred to above will relate to the responsible officer role. The NHS will be expected to absorb the costs of the increased oversight by responsible officers (a preliminary estimate is between £3.1m and £16.7m per year) offsetting them against expected improvements in patient care and safety.

Part 3 – Public Health Protection

565. The powers to make a Part 2A order in the new legislation are for use in exceptional rather than routine situations. There is no reason to believe that following the change in legislation there will be significantly higher incidences of infection or contamination which present significant harm to human health. In the majority of cases it is expected that people will remain willing to take voluntary action when they believe they are infected or contaminated. It is likely that the cost of the provisions for Part 2A orders will therefore remain consistent with current levels of cost.

566. Provisions that could be introduced through regulations in cases of a major outbreak or incident could incur additional costs. However it is not possible to know how, when and where there will be an outbreak of a disease or an emergence of a disease and for that matter which disease it will be and how it will spread, so it is not possible to calculate costs. The Impact Assessment ('IA') contains some hypothetical scenarios that examine the potential financial effects of using the powers for Part 2A orders in a large outbreak scenario. Overall, the impacts on any sector are likely to be negligible and, given that the new legislation will have an overall beneficial impact in protecting public health, the legislation could lead to a net benefit to the economy as a whole.

Part 4 – Health in Pregnancy Grant

567. Estimated implementation and running costs for the Health in Pregnancy Grant are detailed below. Work is underway to assess the precise costs beyond 2010/11, but initial estimates suggest that costs will remain broadly similar to those estimated in 2010/11. Expenditure in 2008/09 will cost disproportionately more due to the initial development costs of the new IT system.

2007/08	**2008/09**	**2009/10**	**2010/11**
£ 1.1m	£ 8.4m	£ 5.3m	£ 4.8m

568. The Health in Pregnancy Grant payments will be funded from the Consolidated Fund. Initial estimates of the expenditure arising in 2009/10 from the introduction of the Health in Pregnancy Grant are £175 million. This estimate is based on approximately 780,000 births each year[7] and full take-up by all pregnant women at the relevant stage of pregnancy. Initial estimates of expenditure arising in 2010/11 and 2011/12 are £145 million. The estimated cost is higher in the first year as there may be more claims in that year, from those women in their final weeks of pregnancy at April 2009, who satisfy the entitlement conditions on the date of introduction.

Part 5 – Miscellaneous

Pharmaceutical services

569. There is an extra cost that PCTs will incur in managing these funds, which is estimated at £600 per PCT per year.

Indemnity schemes in connection with provision of health services

570. Clause 135 amends a framework power, which will have no impact on expenditure under any of the schemes until subordinate legislation is amended. Once new members are admitted to a scheme, this should not increase public expenditure as the total costs of the scheme are met by its members' contributions.

Weighing and measuring of children: England

571. The key area of expenditure that will be incurred under the provisions in the Bill relates to the cost of providing feedback to parents on a routine basis. These costs will fall to PCTs and consist of the costs of staff time to prepare and send the letters, and the costs of postage. The total additional cost is estimated to be £650,000.

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[7] *2006-based national population projections, Office for National Statistics, published* 23 October 2007

Social Care

572. Most individuals who are currently excluded from receiving direct payments will be in receipt of alternative packages of care at broadly equivalent cost. There may, however, be a small increase in demand as a result of these legislative changes. Increased demand, due to the widening of eligibility, may result in approximately 150 to 450 additional direct payments across all local authorities which amounts to £1.5m to £4.5m per year recurrent (the average net unit cost of a direct payment is around £180 p/w). As a lower initial take-up rate is expected the estimated total over 3 years is £8 million. It is anticipated that local authority allocations for 2008/9 to 2010/11 will reflect the additional cost pressures arising from the extension of the direct payments scheme.

573. The repeal of the liable relatives rule in the National Assistance Act 1948 has a financial implication for local authorities of between £3m and 5m in England. This represents the estimated revenue lost by not collecting contributions from liable relatives. This is being covered by additional funding of £4m allocated to local authorities by the Department of Health each year since April 2006.

Financial assistance related to provision of health or social care services

574. At this stage, the total agreed costs of the SEIF (which is part of the overall budget for the Department of Health) amount to £73m for the four years from 07/08.

National Information Governance Board

575. Establishing the National Information Governance Board will not increase public expenditure. It will use the resources of the information governance bodies which have been abolished before the relevant provisions of the Bill come into force, for example the Care Record Development Board, or after, in the case of PIAG.

PUBLIC SECTOR MANPOWER IMPLICATIONS

The Care Quality Commission

576. There will be reductions in public service manpower under Part 1 resulting from the dissolution of three existing bodies, CHAI, CSCI and MHAC, and the creation of the Commission. The Commission's functions under Chapter 5 of Part 1 dealing with interactions with other authorities and its duties under clause 2(3)(e) and (f) will result in wide reductions in the bureaucratic burden associated with inspections and demands for information by the Commission and other inspection authorities on NHS bodies and local authorities. This may have manpower implications.

Health in Pregnancy Grant

577. Work is underway to assess the precise impact of the Health in Pregnancy Grant on public service manpower. On current estimates:

- for HM Revenue and Customs, initial estimates suggest there will be an increase above current plans of approximately 125 full-time equivalent staff;

- the policy may also have an impact on the workload of the Ministry of Justice, should there be an increase in appeals.

Financial assistance related to provision of health or social care services
578. Four or five staff members will work on the administration of the SEIF; they will be employed by Community Health Partnerships, formerly Partnerships for Health (a company wholly owned by the Department of Health).

SUMMARY OF IMPACT ASSESSMENTS

579. The IAs for this Bill can be found at www.dh.gov.uk/healthandsocialcarebill.

The Care Quality Commission
580. The IA estimates that, given the available information, the proposed changes could lead to average transition costs of £2.3m over three years, and an average change in annual costs in the range of +£2.7m to -£21.2m. Over a 10 year period the net benefit range (NPV) is estimated at +£129.3m to -£24.0m. It has not been possible to quantify the cost implications of all the factors that could have an impact, and some of the ranges are necessarily large, as the extent of the impact will depend on aspects of secondary legislation.

581. The IA identifies the potential for higher efficiency of health and social care provision due to:

- more focused enforcement;

- registration at organisational level;

- fair playing field between NHS and independent sector providers;

- (in general terms) lower entry barriers.

582. It is noted that a one per cent increase in efficiency in health and social care would lead to efficiency gains of £1.2bn.

583. The IA also acknowledges potential risks of the proposals including: establishment problems; lack of resources; slipping compliance with minimum quality standards; and independent sector providers lacking confidence that Strategic Health Authorities will conduct the regulatory function assigned to them independently and may unduly restrain entry to NHS markets.

Regulation of Health Professions and Health and Social Care Workforce

584. For the change in the standard of proof, the IA considers the possible increase in the number of fitness to practise hearings that the NMC and the GOC might experience because of the change to the civil standard. It also explores the possibility of an increase or a decrease for the GMC in its hearings, due to other complementary initiatives being implemented at the same time. Overall, we think the change could be cost neutral but in our planning figures we have considered a range of between -10% and +10% in the number of hearings for doctors and of 0% to +10% for NMC and GOC. This would mean a change in costs of between -£1.86m and £2.6m.

585. The IA for responsible officers looked at the direct costs of the role of the responsible officer, and indirect costs that are inherently linked to the role of the responsible officer. These will include cooperating with the GMC, including on: (a) considering whether concerns about fitness to practise or conduct in particular cases should be referred to the GMC; and, (b) advising the GMC on whether individual doctors met the criteria for re-licensing (one of the two components of the system of periodic revalidation e.g. liaising with the GMC about the revalidation of doctors). The estimates in the IA are based on the assumption that there are 126,000 doctors in England.

586. The assessment is based on three key roles for responsible officers:

- checking of skills when doctors are initially appointed. Estimates of the cost of this are in the range of £.02m to £1.1m per year;

- overseeing appraisals. Costs will depend on the extent to which this is done already across the NHS. There is currently little hard evidence. The estimated costs for this task range from £1.7m to £10.2m per year;

- carrying out additional investigations where appraisals indicate a problem. The estimated range for these costs is from £1.2m to £5.4m per year.

587. The IA acknowledges that the costs are preliminary estimates only because the exact scope of the role and processes will be set out in secondary legislation.

Public Health Protection

588. The IA considers the impact of the primary legislation (the impact of the Part 2A order making powers). As the Part 2A orders are for use in exceptional rather than routine circumstances, the overall impact on any sector is negligible. However, overall, it is likely the new legislation will have a beneficial impact in protecting public health, and could lead to a net benefit to the economy as a whole.

Amendments relating to National Health Service

589. The overall modelling suggests that opening up the Clinical Negligence Scheme for Trusts to non-NHS providers of NHS care could present savings to the NHS of around £46m per year in the base case, rising to £79m per year for the low risk scenario or falling to £21m per year in the high-risk scenario. Even for the highest risk scenario, the modelling suggests savings achieved would still be around £15m per year.

Social Care

590. Any additional costs associated with the extension of direct payments would fall on local authorities. However, it is expected that one-off set up costs will be minimal given that the systems to administer and support direct payments are already in place in local authorities. In addition, the majority of individuals who are currently excluded from receiving direct payments will be in receipt of alternative packages of care at broadly equivalent cost. There may, however, be a small increase in demand as a result of these legislative changes. Increased demand, due to the widening of eligibility, may result in approximately 150 to 450 additional direct payments across all local authorities, which amounts to £1.5m to £4.5m per year recurrent (the average net unit cost of a DP is around £180 p/w). It is anticipated that local authority allocations for 2008/9 to 2010/11 will reflect the additional cost pressures arising from the extension of the direct payments scheme.

Financial assistance related to provision of health or social care services

591. The impact of this part of the Bill on small businesses that are social enterprises are expected to be positive; providing access to finance that would otherwise have been difficult to obtain.

EUROPEAN CONVENTION ON HUMAN RIGHTS

592. The Bill raises issues with regard to Article 5 (right to liberty and security), Article 6 (right to a fair hearing), Article 8 (right to respect for private and family life) and Article 1 of the First Protocol (protection of property) to the European Convention on Human Rights ('the Convention').

Part 1 (the Care Quality Commission)

593. Clauses 26 and 27 provide for an urgent procedure for cancellation of registration (on application to a justice of the peace) or suspension of registration (by the Commission). The use of these urgent procedures may engage rights under Article 6 of, and Article 1 of the First Protocol to, the Convention. In so far as Article 6 is concerned, the Department is of the view that the provisions are compatible since there are full rights of appeal.

594. In so far as Article 1 of the First Protocol is engaged, the requirements strike a fair balance between the private interests affected and the public interest in ensuring that adult social care and health services are properly regulated. In the case of cancellation, it must

appear to a justice of the peace that there is a serious risk to a person's life, health or well-being before an order can be made. In the case of suspension, the Commission must have reasonable cause to believe that unless it acts any person will or may be exposed to the risk of harm.

595. Clauses 58 to 61 provide the Commission with powers for the purposes of carrying out inspections of providers of regulated activities and of NHS and social services for the purposes of its registration and review functions. The exercise of the powers as regards the right of entry, the right to inspect, copy and remove items, and the right to require an explanation may engage the right to respect for private and family life guaranteed by Article 8 of the Convention and the right to peaceful enjoyment of possessions protected by Article 1 of the First Protocol.

596. The Department is of the view that the rights of entry and inspection, and to inspect and take copies of or seize documents or other material or things, are compatible with an individual's rights under Article 8 and under Article 1 of the First Protocol. These provisions of the Bill pursue the legitimate aims of protecting public safety and public funds as well as being for the general prevention of crime (offences in relation to registration) and protection of the health (by the provision of high quality health and social services) and rights and freedoms of others. Any interference is proportionate to the end of protecting these legitimate aims.

597. The Commission and the Welsh Ministers will become responsible for the general protection of patients subject to the Mental Health Act by keeping under review the exercise of powers and the discharge of duties under the Mental Health Act. The review powers include the power to enter a hospital or other establishment in order to visit, interview and examine a patient and, the power to require the production of, or inspection of, any records relating to the detention or treatment of a person who is or has been detained. The powers therefore touch on Article 8 rights. However, such powers are necessary, in the context of the Commission's and the Welsh Ministers' section 120 functions, for the protection of health and the protection of the rights and freedoms of others.

Part 2 (regulation of health professions and health and social care workforce)

598. Fitness to practise proceedings by health care regulators fall within Article 6 of the Convention. Clause 93 establishes the OHPA to deal with fitness to practise cases relating to the medical and optical professions. Paragraph 4 of Schedule 7 inserts a new section 35ZA into the Medical Act 1983 and paragraph 30 of that Schedule inserts a new section 13AA into the Opticians Act 1989. These new sections require the OHPA to take account of guidance published by the GMC and the GOC about factors which they consider to indicate that a particular sanction should be imposed on a person whose fitness to practice is found to be impaired. The Department of Health is of the view that this requirement does not compromise the impartiality of the OHPA for the purposes of Article 6 of the Convention. This requirement will be relevant only at the stage at which the OHPA is considering the imposition of sanctions and does not in any way compromise its independence in determining

whether the facts alleged against an individual have been proved. Moreover, the penalties themselves are not established by the GMC or the GOC but laid down in legislation.

599. The new section 60A of the Health Act 1999 (as inserted by clause 106), provides that the standard of proof applicable in fitness to practise proceedings for health professionals is the standard applicable in civil proceedings. Proceedings which determine a doctor's right to practise medicine involve a determination of civil rights and must therefore be compliant with Article 6 of the Convention. Article 6 does not prescribe the standard of proof to be applied in civil proceedings and the Department is of the view that the adoption of the civil standard is compatible with Article 6.

600. Under clause 116, regulations may make provision requiring specified bodies to co-operate with each other in relation to any question or matter arising as to the conduct and performance of health care workers which could pose a risk to patient safety. The duty to disclose information may engage the right to respect for private and family life under Article 8 of the Convention. The purpose of disclosure will be to protect the health and rights of patients or the general public, which fall within paragraph 2 of Article 8 as being legitimate aims.

Part 3 (public health protection)

601. Clause 123 inserts new sections 45A to 45T into the Public Health Act 1984. Measures adopted under these new provisions might engage a number of Convention rights. The Department is however satisfied that these provisions are compatible with the Convention. Particular consideration has been given to provisions relating to quarantine, isolation, detention, medical examination, and powers of entry in respect of public health investigations. The purpose of these provisions is to protect the public from significant public health risks and the Convention itself envisages that certain rights can lawfully be interfered with on public health grounds. Safeguards, such as limits on the period in respect of detention, quarantine or isolation, are also built into the legislation to minimise the impact on individuals.

602. Health protection regulations under new section 45B (international travel, etc.) for health threats at borders may make provision for preventing danger to public health or the spread of infection or contamination by means of conveyances arriving at or leaving any place in England and Wales. Domestic health protection regulations under section 45C may make provision for preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination. Measures under these powers might involve provision of information on, detention, isolation, quarantine or medical examination of or the application of disinfection, decontamination or other sanitary measures to persons.

603. There are also powers for a justice of the peace to make an order under new section 45G, 45H or 45I (referred to as a "Part 2A order") providing for measures in relation to individual persons, things, premises, or groups of these. An order under new section 45G

might include provision that a person submit to medical examination, be disinfected or decontaminated, wear protective clothing, be subject to restrictions on movement, be removed to or detained in a hospital or other suitable establishment, kept in isolation or quarantine, or be subject to health monitoring.

604. Also, a warrant under section 61 of the Public Health Act 1984, or similar provision in an order under new section 45K(6), might enable entry to premises (including a private dwelling), and include power to search, require information, or seize and detain or remove documents or property.

605. A number of these potential measures, such as requirements as to quarantine, detention, medical examination, and wearing protective clothing, might engage a person's right to private and family life including bodily integrity protected by Article 8 or, potentially, the right to liberty and security protected by Article 5. However, the Bill provides that a Part 2A order may only be made where necessary to reduce or remove the risk to public health, and that regulations under new section 45C may only provide for the imposition of such measures if their imposition is proportionate to the threat arising from the incidence or spread of infection or contamination.

606. A quarantine under these provisions may not amount to more than a restriction on freedom of movement engaging Article 8. Where there is a deprivation of liberty, Article 5(1)(e) enables a restriction of liberty to be imposed for the prevention of the spreading of infectious diseases, which the Department considers may now be read as allowing restriction of the right to liberty for the prevention of the spreading of contamination. However, proportionality is required for application of the exception for infectious disease (or contamination) in Article 5(1)(e), and the powers allow for this, for example an order could provide for the least intrusive measures, such as quarantine or isolation at home rather than in a hospital, which will achieve the permitted public health aim, and direct that appropriate support be provided.

607. Measures under these powers, including powers to enter premises, or charges for the application of such measures might potentially affect property interests (Article 1 of the First Protocol). However, a State is able to enforce laws it deems necessary to control use of property in accordance with the general interest or to secure the payment of contributions. These powers are justified due to the public interest in investigators being able to carry out effective public health investigations, or to prevent the spread of disease, and any interference with the peaceful enjoyment of possessions is a proportionate interference with property rights. In addition new sections 45F(2)(g), 45N(2)(e) and 45K(7) enable provision to be made in regulations, or for a justice of the peace to order, that compensation or expenses be paid so as to ensure that any Convention rights under Article 1 of the First Protocol are met.

608. Rights to apply for variation or revocation of a Part 2A order under new section 45M(4), to appeal under section 67 of the Public Health Act 1984, or for provision to be made

for appeals from and reviews of decisions made under regulations made under new section 45C (new section 45F(6) and (7)), ensure that Article 6 rights are met.

Part 5 (Weighing and measuring of children)

609. A power to obtain and further process personal information (including child height and weight information) without explicit consent engages Article 8 of the Convention. The Department is of the view that the proposed use of data will pursue the legitimate aim (included within Article 8(2)) of "the protection of health". A requirement to obtain explicit consent would reduce the value of the programme as the number of those taking part would then fall significantly. The interference with the right is reasonable and proportionate for the following reasons: the information will be gathered in accordance with the data protection concept of fair processing; the information will be gathered in familiar school surroundings in circumstances where the privacy of the child is protected; personal details will be removed from the information before it is used for research or surveillance; and, other uses of the information will be restricted. Finally, regulations will be able to allow consent to be refused.

Section 19 of the Human Rights Act 1998

610. Section 19 of the Human Rights Act 1998 requires the Minister in charge of a Bill in either House of Parliament to make a statement about the compatibility of the provisions of the Bill with the Convention rights (as defined in section 1 of that Act). Lord Darzi of Denham (Parliamentary Under Secretary of State) has made the following statement:

"In my view, the provisions of the Health and Social Care Bill are compatible with the Convention rights".

GLOSSARY OF TERMS AND ABBREVIATIONS

Terms used in the Notes

Audit Commission: the Audit Commission for Local Authorities and the National Health Service in England.
Baseline allocations: a recurrent amount of funding that represents the cash-limited allocation that PCTs receive to enable them to commission healthcare for their population.
The Commission: the Care Quality Commission, established by clause 1 of the Bill.
Contributions and Benefits Act: the Social Security Contributions and Benefits Act 1992 (c. 4).
The Convention: the European Convention on Human Rights.
The Councils: the GSCC and the CCW.
Global Sum: the sum that pays fees and allowances for the provision of NHS pharmaceutical services.
Health Care Professions Act 2002: the National Health Service Reform and Health Care Professions Act 2002 (c. 17).

Liable relatives rule: set out in sections 42 and 43 of the National Assistance Act 1948 and in various other provisions mentioned in clause 139(1). The liable relatives rule provides that spouses are liable to maintain each other and parents are liable to maintain their children.
Mental Health Act: the Mental Health Act 1983 (c. 20).
Monitor: the Independent Regulator of NHS Foundation Trusts.
National Information Governance Board: National Information Governance Board for Health and Social Care.
Northern Ireland Contributions and Benefits Act: the Social Security Contributions and Benefits (Northern Ireland) Act 1992 (c. 7).
Public Health Act 1984: the Public Health (Control of Disease) Act 1984 (c. 22).
Social enterprise: businesses with primarily social objectives whose surpluses are principally reinvested for that purpose in the business or in the community.

Abbreviations used in the Notes

AMHPs	Approved mental health professionals
CCW	Care Council for Wales
CHAI	Commission for Healthcare Audit and Inspection (known as the Healthcare Commission)
CIECSS	Chief Inspector of Education, Children's Services and Skills
CRHP	Council for the Regulation of Health Care Professionals
CSCI	Commission for Social Care Inspection
DHSSPSNI	Department of Health, Social Services and Public Safety in Northern Ireland
GMC	General Medical Council
GOC	General Optical Council
GSCC	General Social Care Council
HCAIs	Healthcare associated infections
IA	Impact Assessment
IHR	International Health Regulations (2005)
LPA	Lasting power of attorney
MHAC	Mental Health Act Commission
NBSB	National Biological Standards Board
NCMP	National Child Measurement Programme
NHS Act 2006	the National Health Service Act 2006 (c. 41)
NHS (Wales) Act 2006	the National Health Service (Wales) Act 2006 (c. 42)
NMC	Nursing & Midwifery Council
OHPA	Office of the Health Professions Adjudicator
PCTs	Primary Care Trusts
PIAG	Patient Information Advisory Group
PSNI	Pharmaceutical Society of Northern Ireland
RPSGB	Royal Pharmaceutical Society of Great Britain
SEIF	Social Enterprise Investment Fund

WHO World Health Organisation

HEALTH AND SOCIAL CARE BILL

EXPLANATORY NOTES

These notes refer to the Health and Social Care Bill
as brought from the House of Commons on 19th February 2008
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