These notes refer to the Health and Social Care Act 2008 (c.14) which received Royal Assent on 21 July 2008

HEALTH AND SOCIAL CARE ACT 2008

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Health and Social Care Act 2008. They have been prepared by the Department of Health in order to assist the reader in understanding the Act. They do not form part of the Act and have not been endorsed by Parliament.

2. The notes need to be read in conjunction with the Act. They are not, and are not meant to be, a comprehensive description of the Act. So where a section or part of a section 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

---

1 [1] *Reconfiguring the Department of Health's Arms Length Bodies, published July 2004.*
2 [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.

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 Act 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. The functions currently performed by MHAC will be transferred to the Commission and the Welsh Ministers.

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 commissioned by 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 Act's provisions affect the following 12 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')
- Hearing Aid Council

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 this Act 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 Act 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 Act 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 inconsistency in respect of the standard of proof used in fitness to practise proceedings by the health profession regulatory bodies. Only two regulators (the GOC and the NMC) still use the criminal standard while all other regulators 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 Act 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. The Hearing Aid Council was established by the Hearing Aid Council Act 1968. Since 2003 it has been operating as an Executive Non-Departmental Public Body. Its general functions are:

- to set requirements for registration and practice as a "dispenser of hearing aids" (as defined in section 14 of the 1968 Act, and referred to elsewhere in these notes as a "private hearing aid dispenser");
- to maintain a register of hearing aid dispensers and of employers of registered hearing aid dispensers;
- to maintain standards of practice for dispensers;
- to investigate whether standards have been breached by registered dispensers;
- to take disciplinary action against dispensers who have breached its regulations/ standards.

26. Amendments are required to section 60 of, and Schedule 3 to, the Health Act 1999 to allow for the transfer of the regulation of private hearing aid dispensers, currently regulated by the Hearing Aid Council, to the Health Professions Council. The Government committed, following the Hampton Report[4], to abolishing the Hearing Aid Council by April 2009. The decision was taken to transfer responsibility for the regulation of private hearing aid dispensers to the Health Professions Council. This will reduce the number of regulators but more importantly provide improved protection for the hearing impaired. Part 2 of the Act therefore also contains provision for the dissolution of the Hearing Aid Council following this transfer.

27. 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 Act provides the legislative underpinning for this through the establishment of the role of the "responsible officer".

28. By way of overview, Part 2 of the Act contains changes to the regulation of health professions and the health and social care workforce. This is in line with the Government's response[5] to various inquiries into the actions of specific health professionals[6]. Provision is made for:

---

4 *Reducing administrative burdens: effective inspection and enforcement*, published March 2005.

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

6 *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;

- 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; measures to allow the transfer of the regulation of private hearing aid dispensers from the Hearing Aid Council to the Health Professions 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 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;
- the abolition of the Hearing Aid Council on the basis of the transfer of responsibility for the regulation of private hearing aid dispensers to the Health Professions Council;
- 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

29. 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. 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. 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 this Act updates the Public Health Act 1984 to take account of these points.

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

30. 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. This Act amends the Public Health Act 1984 to enable IHR to be implemented, including WHO recommendations issued under them.

Part 4 – Health in Pregnancy Grant

31. 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.

32. 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.

33. 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.

34. 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.

35. 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

36. 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.

37. Section 139 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

38. 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 also 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.

39. 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, and pays the fees and allowances for appliance contractors who provide medical appliances.

40. 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. 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.

41. 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.

42. Section 140 introduces Schedule 12, which contains the changes to the NHS Act 2006 that are needed to move funding for pharmaceutical services to PCTs and to allocate funding by reference to the PCT of the prescriber. These changes bring the management of funding for pharmaceutical services in line with funding for other community-based health services. Section 140, 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.

43. The Secretary of State has committed 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 and in discussion with the NHS, and similarly for nationally agreed services provided by appliance contractors. An equivalent commitment has been given in respect of the setting of fees and allowances for pharmaceutical services in Wales. However, if in the future the Secretary of State decides to appoint PCTs or other persons to determine the funding for essential services, section 141 requires the instrument of appointment to be made in regulations, and likewise for Wales.

Indemnity schemes in connection with provision of health services

44. 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.

45. 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.

46. 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. Section 142 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

47. The Foresight Report "*Tackling Obesities: Future Choices*"[7], 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 17 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).

48. 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. The Act allows for the extension of the NCMP to early years settings and to other primary school year groups.

49. 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.

50. 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. These features of the NCMP will continue. At present,

---

7 [7] *"Tackling Obesities: Future Choices" Government Office for Science, Department of Innovation, Universities and Skills, published October 2007. URN 07/1184*

parents are able to request their child's height and weight results from their PCT. The Act enables regulations to be made such that all parents whose children participate in the programme receive the results routinely.

51. 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.

52. The powers in the Act 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.

53. 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.

54. 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 Act 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.

Human Rights Act 1998: provision of certain social care to be public function

55. The Human Rights Act 1998 places a duty on all public authorities, which includes independent sector organisations when carrying out a public function, **not** to act incompatibly with the European Convention on Human Rights ('the Convention'). The Government's intention at the time of the passage of the Human Rights Bill through Parliament was that this would mean the protections provided by the Convention should apply to independent sector care homes when providing accommodation and care to an individual under a local authority contract. In the case of *YL v Birmingham City Council* [2007] UKHL 27, the House of Lords decided that when providing accommodation and care under a local authority contract independent sector care providers were not carrying out a public function and were therefore not public authorities for the purposes of the Human Rights Act. Accordingly, these providers are not required by the Human Rights Act to act compatibly with the Convention rights. Section 145 ensures that the protections provided by the Human Rights Act apply to people receiving publicly arranged care in an independent sector care home.

Direct payments in lieu of provision of care services

56. 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.

57. 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.

58. 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.

59. 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.

60. This Act 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 section 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

61. 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 section 147. 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 Act 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.

62. 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.

63. 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 accommodated patients in places other than NHS hospitals. 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.

64. 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. This Act puts a mechanism in place to allow for the determination of disputes between English and Welsh local authorities.

65. 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. This Act makes provision to fill this gap.

66. In summary, section 147 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

67. 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.

68. 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'.

69. 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.

70. Sections 149 to 156 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. This means that the Secretary of State may, for example, finance a social enterprise delivering integrated health and social care for homeless people and/or a social enterprise providing support services to NHS or social care providers.

71. 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.

72. The qualifying conditions set out in the sections 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.

73. The sections 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

74. 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.

75. 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.

76. 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.

77. 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.

78. Section 157 establishes the National Information Governance Board for Health and Social Care ('the National Information Governance Board').

79. 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.

80. 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 Act defines the role and constitution of the Board to support the pursuit of these objectives.

81. 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.

82. 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. However, the 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 intended that the number of lay members will exceed the number of representative members.

83. 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.

84. 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

85. 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.

86. Section 159 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

87. Part 6 provides for the territorial extent of the provisions of the Act and lays down the Parliamentary procedure which applies to orders and regulations made under powers contained in the Act. It also provides for the provisions of the Act 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 Act which they have the power to commence.

OVERVIEW OF THE STRUCTURE

88. Part 1 of the Act 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 Act 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 Act.

TERRITORIAL EXTENT

The Care Quality Commission

89. Part 1 of the Act extends to England and Wales only, with the exception of three sections, namely the general interpretation section and the sections 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 section has a UK extent. The other two sections 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

90. Much of Part 2 of the Act has a UK extent.

91. 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.

92. 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 and 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

93. Part 3 of the Act 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

94. Certain of the sections 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

95. The changes regarding the duty on PCTs to improve the quality of healthcare and about funding of pharmaceutical services extend to England and Wales only.

96. The section on indemnity schemes applies only to England.

Weighing and measuring of children

97. These sections 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

98. The provision modifying the application of the Human Rights Act 1998 extends to England and Wales, Scotland and Northern Ireland.

99. The extension of direct payments extends to England and Wales only.

100. 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

101. These sections 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

102. The National Information Governance Board will operate in England and Wales only.

Functions of the Health Protection Agency in relation to biological substances

103. This section extends to the UK.

Territorial application: Wales

104. The Annex to these Explanatory Notes describes the effect of the Act on Wales and provides a table of new functions conferred on the Welsh Ministers.

Part 1 – the Care Quality Commission

Chapter 1 – Introductory

Section 1: The Care Quality Commission

105. Section 1 establishes the Commission and abolishes CHAI, CSCI, and MHAC. It also gives effect to Schedule 1.

Schedule 1: The Care Quality Commission

106. 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. In appointing the chair and other members of the Commission, the Secretary of State is required to ensure that, collectively, they include people with experience and knowledge relating to health care, social care and the Mental Health Act. Such experience and knowledge could, as an example, include experience a person has gained by involvement with groups who represent service users or carers.

107. *Paragraph 6* requires the Commission to establish an advisory committee, and to have regard to the advice and information provided by it 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 those with relevant expertise in the provision of health or social care. *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.

108. *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.

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

Section 2: The Commission's functions

110. Section 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 could 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.

Section 3: The Commission's objectives

111. Section 3 provides that the main objective of the Commission, in carrying out its functions, is to protect and promote the health, safety and welfare of people who use health and social care services. It also 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. Subsection (3) provides a definition of health and social care services, which applies throughout Chapter 1.

Section 4: Matters to which the Commission must have regard

112. Section 4 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 experiences of people who use health and social care services and their families and friends;
- views expressed by members of the public about health and social care services, or on their behalf by representative bodies, such as charities, and views expressed by Local Involvement Networks about the provision of health and social care services in their areas;
- the need to protect and promote the rights of people who use health and social care services including, in particular, the rights of children and the rights of people detained under the Mental Health Act or deprived of their liberty under the Mental Capacity Act 2005;
- 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;
- such aspects of Government policy as may be directed.

Section 5: Statement on user involvement

113. Section 5 requires the Commission to publish a statement on user involvement, following consultation with such people as the Commission considers appropriate. The statement must include the Commission's proposals for promoting awareness among service users and carers of its functions and for engaging in discussion with them both about the provision of health and social care services and about the way in which the Commission exercises its functions. It must also set out the Commission's proposals for ensuring that proper regard is had to the views expressed by service users and carers and for arranging for any of its functions to be exercised by, or with the assistance of, service users and carers. The Commission is free to revise the statement from time to time but must consult again on any revision and publish the revised version. The Commission

is required to report, as part of its annual report to Parliament under section 83, on the steps it has taken to implement the proposals in its statement on user involvement.

Section 6: Transfers of property, rights and liabilities

114. This section gives effect to Schedule 2.

Schedule 2: Transfers of property and staff etc.

115. *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

Sections 8 and 9: Introductory

116. Section 8 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) set out initial proposals for the broad types of activities that will be regulated activities. Subsequent to this, the Government published *"A consultation on the framework for the registration of health and adult social care providers"* (published March 2008), on the types of activities to be regulated, and the registration requirements to be imposed under section 20.

117. *Subsection (2)* of section 8 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.

118. *Subsection (3)* of section 8 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.

119. Section 9 defines the terms 'health care' and 'social care' for the purposes of Part 1 of the Act. 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

Sections 10 to 12: Registration of persons carrying on regulated activities

120. Section 10 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.

121. Under section 10, 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.

122. 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.

123. Section 11 sets out the process for applying to register with the Commission. Under section 11, a person required to register to carry on any of the activities set out in regulations under section 8 will have to apply to the Commission, providing such information as the Commission determines is necessary.

124. 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.

125. Section 12 deals with the grant or refusal of registration as a service provider. Under section 12, 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 section 20, 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 section 8 will receive a certificate of registration.

126. 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.

127. 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 section 13 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

Sections 13 to 15: Registration of managers

128. Sections 13 to 15 provide that in certain circumstances a service provider can be required to 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.

129. Regulations can set out cases where 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.

130. 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.

131. 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. A registered manager will be responsible, in the same way as the service provider, for ensuring that the regulated activity in question is carried on in compliance with relevant requirements.

132. Under section 13, 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 section 20, 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.

133. 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

Section 16: Regulations about registration

134. Section 16 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 include 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.

Sections 17 and 18: Cancellation / suspension of registration

135. Section 17 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.

136. The section defines relevant offences as:

- offences under Part 1 of the Act 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 the Commission considers to be relevant.

137. 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.

138. 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 section 33) and fails to remedy the breach, the Commission could then cancel the person's registration.

139. The Commission will also have the power to suspend a person's registration as a service provider or a manager under section 18 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.

140. Under section 17 the Commission must cancel the registration of a manager in respect of a regulated activity where there is no longer a registered service provider in respect of that activity, or a registered manager condition ceases to apply to the registration of the service provider.

Section 19: Applications by registered persons

141. Section 19 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).

142. It is not, however, possible for a service provider to apply to change any mandatory condition imposed as a result of regulations made under section 13 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)*).

143. 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

Sections 20 to 25: Requirements in relation to regulated activities

144. Sections 20 to 25 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.

145. *Subsection (1)* of section 20 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)*).

146. 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)*).

147. *Subsection (3)* sets out specific issues which any regulations made under section 20 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.

148. Regulations may also make provision about the way in which a regulated activity is carried on. They may cover issues such as the use of appropriate premises and practical issues around record keeping or accounting. They may cover arrangements for dealing with and learning from complaints and disputes. For example, such regulations could require a service provider to maintain arrangements for ensuring that lessons learnt from justified complaints are properly applied. They may also require registered providers to review the quality of services they offer, prepare a report of the review, and make it available to the public; and require providers to make information available about charges made for those services.

149. The regulations may also cover other issues, such as requirements regarding the appropriate use of control and restraint, or the provision of information.

150. *Subsection (5)* allows 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.

151. Under section 21 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. Section 22 sets out the consultation process that the Secretary of State must follow when preparing to issue the code of practice, or revisions to it.

152. Section 23 requires the Commission to issue guidance on how service providers and managers should demonstrate compliance with all other requirements set out in the regulations made under section 20. 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. Section 24 sets out the consultation process that the Commission must follow when it proposes to issue or revise guidance on compliance with requirements.

153. Under section 25, 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 section 20;
- whether it should suspend or cancel someone's registration;
- whether to prosecute someone.

154. 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 section 30, or in appeal proceedings.

155. 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

Sections 26 and 27: Notices of proposals and rights to make representations

156. Section 26 requires the Commission to give written notice to applicants or registered persons where it proposes to do any of the following:

- to grant 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 section 13(1));
- to refuse an application for registration;
- to cancel a registration (except where the registered person has applied for cancellation of registration under section 19, or the Commission has applied for an order to urgently cancel a registration under section 30, or the Commission has cancelled a registered manager's registration in accordance with the conditions set out in section 17(2));
- to suspend a registration (except where the Commission has urgently suspended a registration under section 31);
- to amend the conditions of registration (except where the Commission has urgently removed or varied a condition or imposed an additional one under section 31);
- to refuse an application by a provider or manager of regulated activities made under section 19(1) to vary or remove a condition, cancel their registration, or cancel or vary a period of suspension.

157. 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. Section 26 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 section 13(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 section 28.

158. Section 27 sets out that a notice of proposal under section 26 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.

Section 28: Notice of decisions

159. Section 28 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 section 13(1) and/or conditions already agreed in writing with the applicant (*subsection (1)*). The notice must state the conditions *(subsection (2)*).

160. Where the Commission has decided to give effect to a proposal of which notice was previously given under section 26, *subsection (3)* requires the Commission to serve a further notice in writing of its decision.

161. That further notice must explain the rights of appeal conferred under section 32. 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)*).

162. A decision made by the Commission under section 28 to adopt a proposal of which notice has been given under section 26 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.

Section 29: Warning notice

163. Section 29 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 section 20.

164. 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.

165. 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.

Section 30: Urgent procedure for cancellation

166. Under section 30 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.

167. *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). The relevant bodies will need to consider whether to make alternative provision for services.

168. 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 section 32.

Section 31: Urgent procedure for suspension, variation etc.

169. Section 31 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 section 32.

Section 32: Appeals to the Tribunal

170. Section 32 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 section 30. A person can appeal within 28 days from the date of the service of notice of the decision or order.

171. 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 relating to registration under Part 2 of 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 section 13(1), or add a new condition, again with the exception of a 'registered manager condition'.

Offences

Sections 33 to 37: Offences

172. Sections 33 to 37 set out further offences relating to registration under Chapter 2. 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.

173. Section 33 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 section is a fine of up to £50,000 on summary conviction.

174. It is an offence to carry on regulated activities without being registered to do so (section 10). *Subsection (1)* of section 34 also makes it an offence for registered service providers to continue carrying on regulated activities whilst their registration is suspended.

175. Section 13 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. Section 34 provides that a person who is a registered manager is guilty of an offence if he continues to manage the activity during a period in which his registration is suspended, unless another person has been registered as a manager in his place (*subsection (2)*). A registered manager is also guilty of an offence if he continues to manage the activity while the registration of the

service provider is suspended, if he knows or could reasonably be expected to know of the suspension (*subsection (4)*). A person whose registration as a manager has been cancelled is guilty of an offence if he continues to manage the activity after cancellation, but only if a service provider remains registered in respect of the activity, a registered manager condition is still in place and no new registered manager has been appointed (*subsection (3)*). The penalty for an offence under section 34 is a fine of up to £50,000 on summary conviction.

176. Section 35 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 section 20 (regulation of regulated activities). The amount of the fine prescribed will not exceed £50,000 in respect of regulations made under section 20 (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.

177. Section 36 makes it an offence for a person, with intent to deceive another, to claim that a concern is carrying on regulated activities, or that premises are used for carrying on regulated activities, if a person is not registered with the Commission to carry on those activities, or a person is 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 also makes it an offence for a person, with intent to deceive another, to claim that any person who is registered as a service provider is able to provide a particular service or do anything which would contravene a condition of their registration. The penalty for an offence under this section is a fine not exceeding level 5 on the standard scale (currently £5,000).

178. Section 37 makes it an offence for someone knowingly to make a false or misleading statement in an application to the Commission. The section 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 is a fine of up to level 4 on the standard scale (currently £2,500). 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

Section 38: Provision of copies of registers

179. The Commission will have to make copies of its registers of service providers and managers available to the public. Section 38 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.

180. However, there may be information that should not be released to the general public, such as certain information that identifies individuals. Section 38(3) allows regulations to be made setting out what information should not be accessible.

Miscellaneous

Section 39: Bodies required to be notified of certain matters

181. Under section 39 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 section 26 or a notice of decision under section 28. 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. Provision is also made for notifying 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.

182. *Subsection (1)(d)* also provides the Commission with the discretion to determine other people it should notify in particular circumstances. Where the Commission has taken enforcement action against a specific person, for example, it would be expected to notify the relevant professional body. In the case of a registered manager who is also a registered social care worker, this would be the General Social Care Council.

Sections 40 to 42: Miscellaneous

183. Section 40 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.

184. Section 41 provides for regulations to be made which deal with the process that applies when companies or individuals 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.

185. Regulations under section 42 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 sections of the Act to apply in a modified way to allow for this.

Power to modify provisions of Chapter

Section 43: Power to modify Chapter in relation to newly regulated activities

186. Section 43 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 unforeseen issues which necessitate modification of the registration procedures. This power allows for that eventuality. The power to modify the Act under this section does not apply to the registration of NHS bodies or providers currently subject to regulation under the Care Standards Act 2000 but it will apply to regulated activities carried on by or on behalf of the Crown.

Chapter 3 – Quality of Health and Social Care

Health care standards

Section 45: Standards set by Secretary of State

187. Section 45 gives the Secretary of State the power to prepare and publish statements of standards in relation to health care provided or commissioned by PCTs and to amend these statements from time to time.

188. PCTs will be required to have regard to these standards in discharging their duty under the new section 23A of the NHS Act 2006 (see section 139) 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. In "*High Quality Care for All*", published on 30 June 2008, the Government indicated its intention to ask the National Institute for Clinical Excellence to develop these standards, with reference to the clinical priorities set out by a new National Quality Board, to be chaired by the NHS Chief Executive.

189. *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

Section 46: Periodic reviews

190. In place of the annual reviews currently conducted by CHAI and CSCI, the Commission will carry out periodic reviews under section 46 of PCTs, NHS providers in England and local authorities in England.

191. 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.

192. 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 of adult social services in English local authority areas under *subsection (3)*. These reviews will assess how well the services they put in place, whether provided directly or commissioned from other people, are meeting the needs of their local populations.

193. The Commission will also carry out individual reviews of NHS bodies that provide services, referred to as English NHS providers, under *subsection (2)*. This includes English NHS Trusts and NHS Foundation Trusts. PCTs will also be reviewed in respect of the health care they provide, so that their performance in this regard can be distinguished from their effectiveness as commissioners.

194. 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.

195. 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 English 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.

196. For each type of review, 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.

197. 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.

Section 47: Frequency and period of review

198. Under section 47 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.

Section 48: Special reviews and investigations

199. Section 48 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 English 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 section 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 particular review or investigation if requested by the Secretary of State.

200. The Commission will have to publish reports of any review or investigation carried out under section 48. It must also consider whether its report raises matters which make it appropriate for the Commission to exercise its powers under section 53 to advise the Secretary of State. This duty does not affect or duplicate the duties the Commission has under section 50 (in relation to a failing English local authority). 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 sections, the reason for this is to give the reviewed body time to comment and to ensure that any comments are considered by the Commission.

Section 49: Power to extend periodic review function

201. Whereas section 46 provides for periodic reviews of publicly funded health and social care, this section enables the Secretary of State to make regulations requiring the Commission to carry out periodic reviews of the carrying on of regulated activities by any registered service provider. 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.

202. Section 49 also allows for a greater degree of specificity about what is covered by the review. Regulations under this section can require the Commission to carry out periodic reviews of some or all registered service providers, in respect of some or all of the regulated activities they provide, or even in respect of particular aspects of a regulated activity. Direct overlap with section 46 is prevented by *subsection (3)* but this subsection

still permits a particular aspect of the carrying on of a regulated activity by a PCT, other English NHS provider or English local authority to be reviewed separately, despite the fact that it may already have formed part of a broader review under section 46.

203. This will allow the Commission to look at certain types of services. For instance, it is the Government's intention to use this power to require the Commission to review and assess all residential premises providing adult social care, whether run privately or by a local authority, as the CSCI has done through its "Quality Ratings" scheme. Similarly, 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 section 46(1).

204. In other cases, the Secretary of State may want the Commission to publish information on a particular aspect of a 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 section 46) of the overall provision of health care by a Trust, the Secretary of State may want the Commission separately to review the quality of provision under such arrangements. The Secretary of State may also prefer the Commission to carry out periodic reviews of such care, rather than a one-off review under section 48, because they will demonstrate how performance changes over time. 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.

205. 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 section 46. These reviews will also be by reference to a set of indicators devised or approved by the Secretary of State.

206. As with periodic reviews under section 46, 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.

207. 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

208. It is intended that, where possible and appropriate, the same information will be used to inform a review under this section 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.

Section 50: Failings by English local authorities

209. Section 50 sets out steps which the Commission must or may take when, following a review under section 46 or 49, or a review or investigation under section 48, it judges that there are failings in an English local authority's discharge of its adult social services functions.

210. If the failings are not substantial, the Commission may give a notice to the local authority, setting 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 inform the Secretary of State of the giving of the notice.

211. 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.

212. 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 report by the Audit Commission for Local Authorities and the National Health Service in England ('the Audit Commission') "*A Force for Change*" shows how special measures can improve performance.

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

Section 51: Failings by Welsh NHS bodies

214. 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

Section 52 and Schedule 3 – Transfer and amendment of functions under Mental Health Act 1983

215. Section 52 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 "regulatory authority" is defined for the purposes of the Mental Health Act as meaning the Commission (in relation to England) or the Welsh Ministers (in relation to Wales): see the amendments made by paragraph 13 of Schedule 3.

216. 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 this Act – see below.)

217. *Subsection (1)* of section 52 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 members of MHAC to be appointed).

218. *Subsection (5)* of section 52 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 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 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.

219. Subsection (7) of new section 120 provides that a person authorised by the 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 this Act in order to carry out a review or investigation. The Act 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.

220. *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 the 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.

221. New section 120B enables the 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.

222. 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.

223. 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.

224. New section 120C obliges hospital managers, local social services authorities and other prescribed people to provide the 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.

225. 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.

226. *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 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.

227. 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.

228. 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

Section 53: Information and advice

229. Section 53 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 section 20); the code of practice on HCAIs (issued under section 21); or statements of standards issued under section 45. *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 section 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 certain inquiries.

Section 54: Studies as to economy, efficiency etc.

230. Section 54 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.

Section 55: Publication of results of studies under s.54

231. Section 55 requires the Commission to publish recommendations made, and results of studies undertaken, under section 54. The section 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.

Section 56: Role of Audit Commission

232. Section 56 allows the Audit Commission to carry out studies relating to health care or English NHS bodies (under sections 54 and 55) 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.

Section 57: Reviews of data, studies and research

233. Section 57 enables the Commission to review certain 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.

Section 58: Publication of information

234. Section 58 allows the Commission to make information available about the provision of NHS care, adult social services, and the carrying on of regulated activities.

Section 59: Additional functions

235. Section 59 allows the Secretary of State to confer additional functions on 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

Sections 60 and 61: Inspections

236. Section 60 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 section 53 or conducting a review of data, studies or research under section 57. Regulations under section 59 will set out whether any additional functions conferred on the Commission under that section are to be treated as regulatory functions and thereby whether inspections can be carried out in relation to them.

237. Under section 61, 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 regulations may require hospitals to be inspected annually, by people with particular skills, for compliance with requirements relating to hygiene and infection controls.

238. After carrying out an inspection under section 60 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.

239. Regulations will set out what procedure should apply to allow people to make representations to the Commission before it publishes a report under section 61. As with similar powers in other sections, 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.

Sections 62 to 65: Powers of entry etc.

240. 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. Section 62 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 care 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. So 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 section. 'Premises' includes vehicles. Individuals exercising these powers must produce appropriate documentation showing they have the authority to enter and inspect the premises.

241. Section 63 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, 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.

242. 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.

243. *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 sections 62 and 63.

244. Section 64 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.

245. Under section 65, regulations may require a prescribed person to provide the Commission with an explanation of: any documents, records or other items inspected, copied or provided under sections 62 to 64; any information provided under those sections; 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 the regulations to require individuals to be present at a time and place specified by the Commission to give an explanation. This will enable the Commission to discuss any matters of concern that its reviews and inspections have brought to light with those responsible.

246. Sections 63(7), 64(4) and 65(4) make it an offence for a person to obstruct the exercise of any of the powers under section 62 or 63 or to fail to comply with any requirement imposed under section 63, 64 or 65. The penalty on summary conviction is a fine, not exceeding level 4 on the standard scale (currently £2,500).

Interaction with other authorities

Section 66: Interaction with other authorities

247. Section 66 gives effect to Schedule 4.

Schedule 4: Interaction with other authorities

248. *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 those purposes as any person whose functions are functions of a public nature (excluding any person carrying out functions in connection with Parliamentary proceedings).

249. *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 for the purposes of any legislation as carried out by the Commission.

250. *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 by 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 advance 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.

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

252. *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.

253. 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.

254. *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.

Section 67: Co-ordination of reviews or assessments

255. Section 67 requires the Commission to promote effective coordination of reviews and assessments in relation to the carrying on of regulated activities.

Section 68: Avoidance of unreasonable burdens in exercise of regulatory powers

256. Section 68 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.

257. 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.

258. The guidance will apply to the Commission and other prescribed 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 section 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.

Section 69: Co-operation between the Commission and Welsh Ministers

259. Section 69 provides that the Commission and the Welsh Ministers must work with one another in order to carry out their corresponding functions efficiently and effectively. *Subsection (3)* enables them to share information for the purpose of fulfilling this obligation.

Section 70: Co-operation between the Commission and the Independent Regulator of NHS Foundation Trusts

260. Section 70 provides 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 section also sets out specific material (material relevant to reviews, investigations and studies) that the Commission must provide to Monitor, on request.

Section 71: Provision of information by Auditor General for Wales

261. Section 71 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 section 54 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 this Act). 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 77 of Schedule 5 to this Act). 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.

Section 72: Provision of material to the Comptroller and Auditor General

262. Section 72 requires the Commission to provide material relevant to reviews, investigations or studies that it carries out to the Comptroller and Auditor General on request.

Sections 73 and 74: Arrangements with Ministers

263. Section 73 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. Section 74 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

Section 75: Inquiries

264. Section 75 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.

265. *Subsection (4)* applies section 250(2) to (5) of the Local Government Act 1972 to an inquiry undertaken under this section. 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.

266. *Subsection (5)* requires reports of inquiries set up under the powers in this section 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

Sections 76 and 77: Disclosure of confidential personal information / Defence

267. Section 76 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 section applies to all of the Commission's functions, whereas under the existing law a similar provision only applies to CHAI as the regulator of health services.

268. *Subsections (1) to (3)* of section 77 set out defences to a charge under section 76. 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 section 76 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.

Section 78: Use of information etc.

269. Section 78 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 section 76).

Section 79: Permitted disclosures

270. 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.

Section 80: Code of practice on confidential personal information

271. Section 80 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 which 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 section.

Further provisions about functions of Commission

Section 81: Publication of programme of reviews etc.

272. Section 81 requires the Commission to publish a document that sets out the reviews and studies that it intends to carry out under sections 48, 54 and 57. 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. *Subsection (4)* makes clear that the requirement to publish such a programme does not prevent the Secretary of State from requiring the Commission to carry out a particular review or investigation, or the Commission from carrying out a special investigation under section 48 where it considers there to be a risk to the health, safety or welfare of people receiving health or social care.

Section 82: Failure by the Commission in discharge of its functions

273. 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 section 82 enables the Secretary of State to issue a direction to the Commission. The section 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.

Section 83: Reports for each financial year etc.

274. Section 83 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 care;
- the provision of adult social services;

- the carrying on of activities regulated by the Commission; and
- the steps it has taken to implement the proposals in its statement on user involvement required under section 5,

in each case, during the financial year in question.

275. 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.

276. The Commission's functions under the Mental Health Act are excluded from the annual report under section 83. The Commission will produce a separate annual report on the operation of the Mental Health Act. MHAC currently has to report biennially on the operation of the Mental Health Act.

277. All reports under this section 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.

Section 84: Reports and information

278. Section 84 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

Section 85: Fees

279. Section 85 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.

280. 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.

281. The Secretary of State can by regulations 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

Sections 86 and 87: Penalty notices

282. Section 86 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.

283. 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.

284. Section 87 confers a regulation-making power which allows the procedural details about penalty notices to be set out in regulations.

Section 88: Guidance by the Commission in relation to enforcement action

285. Section 88 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.

Section 89: Publication of information relating to enforcement action etc.

286. Section 89 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.

287. 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.

Section 90: Proceedings for offences

288. Section 90 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.

289. *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.

Section 91: Offences by bodies corporate

290. Section 91 deals with corporate liability. If an offence under Part 1 of the Act, 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.

Section 92: Unincorporated associations

291. Section 92 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

Sections 93 and 94: Service of documents

292. Where Part 1 provides for notices or other documents to be given to or served on people, section 93 generally requires that this be done in person or by registered post or recorded delivery. Under section 16, 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 sections 93 and 94 notices may be served electronically by the Commission if the person receiving the notice has consented to receive notices in this way and has provided a suitable address for this purpose. They may be served electronically by persons other than the Commission if served in such manner as the Commission may require.

Further amendments

Section 95 and Schedule 5: Further amendments relating to Part 1

293. Section 95 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. Section 227 of the Local Government and Public Involvement in Health Act 2007 is also amended to include the Commission in the list of people to whom Local Involvement Networks must send copies of their annual reports.

294. Schedule 5 also makes a number of amendments of the Care Standards Act 2000 in relation to Wales. 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.

Crown application

Section 96: Application of Part 1 to Crown

295. Section 96 enables the provisions of Chapters 2, 3 and 6 to apply to the Crown. If services such as prison health care or military hospitals provided by Defence Medical Services became subject to registration or review, individuals, such as civil servants who are in the service of the Crown as public servants, could be prosecuted under the Act in the same way as private individuals, private organisations and their staff. The Crown would not, however, be liable to criminal prosecution in relation to offences under those Chapters, although the High Court could find that the Crown had acted unlawfully following a judicial review. *Subsection (5)* enables the Secretary of State, in the interests of national security, to limit the powers of entry and inspection conferred by sections 58 and 59 so far as relating to premises held or used by or on behalf of the Crown.

Interpretation

Section 97: General interpretation of Part 1

296. Section 97 sets out the meaning of various terms used within Part 1 of the Act.

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

The Office of the Health Professions Adjudicator

Section 98: The Office of the Health Professions Adjudicator

297. Section 98 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). Section 98 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

298. Schedule 6 makes detailed provision for the constitution and membership of the OHPA.

299. *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.

300. *Paragraphs 4* to*10* make provision about the membership of the body. The members are to be 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 21* 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 22* 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.

301. *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.

302. *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.

303. 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.)

304. *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 give directions to the OHPA on the application of payments or loans made to it.

305. Under *paragraph 19*, the OHPA must keep accounts, and prepare annual 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.

306. *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.

Section 99: Functions under Medical Act 1983 and Opticians Act 1989

307. Section 99 brings into effect Schedule 7.

Schedule 7

308. 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 to the OHPA the functions of the GMC and the GOC in relation to the adjudication of fitness to practise cases.

309. *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.

310. 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.

311. *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.

312. 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.

313. *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.

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

Section 100: Fitness to practise panels

315. Section 100 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 note on section 101 below). The chair can be a person who is legally qualified, a lay member or a professionally qualified member (see note on section 101 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.

316. *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.

Section 101: Lists of persons eligible for membership of fitness to practise panels

317. Section 101 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.

318. *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.

319. Rules made by the OHPA under this section 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 section 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.

320. This section provides that no member of the OHPA may be appointed to a list.

Section 102: Further provisions about listed persons

321. Section 102 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.

322. 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.

Section 103: Legal assessors

323. Under section 103 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 section may also provide that a panel is not to have a legal assessor, where the chair of the panel is legally qualified.

Section 104: Clinical and other specialist advisers

324. Section 104 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.

Section 105 Procedural rules

325. Section 105 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.

326. 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.

Section 106: Administration of oaths and issuing of witness summonses etc.

327. Section 106 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.

Section 107: Duty to inform the public

328. Section 107 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.

Section 108: Duty to consult

329. Section 108 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 interests 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.

330. The section 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.

Section 109: OHPA rules: supplementary

331. Section 109 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.

332. The rules come into force only if approved by the Privy Council by an Order of Council, subject to the negative resolution procedure (apart from any rules under section 100(4) containing provision for the piloting of legally qualified chairs, to which section 162(4) applies the affirmative 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.

Section 110: Fees payable by General Medical Council and General Optical Council

333. Section 110 introduces a fees charging regime from which the OHPA will secure the majority of its funding after the initial implementation period.

334. The section 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 section 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.

335. 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.

336. *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

Section 111: Extension of powers under s.60 of Health Act 1999

337. 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 1 July 1999) are subject to affirmative procedure in the Scottish Parliament (as well as at Westminster).

338. Section 111 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

339. *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, powers 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.

340. *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. It also inserts a new section 60(2)(ca), referring to private hearing aid dispensers. The intention is to make an Order in Council under section 60 giving the Health Professions Council responsibility for the regulation of this profession.

341. *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.

342. The primary purpose of the inclusion of subsection (2A) is to ensure that these statutory functions, which are separate from 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.

343. *Paragraphs 2*, *7(3) and (4) and 8(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 8(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 7(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).

344. *Paragraph 4* inserts a reference to "a Northern Ireland department" into paragraph 5 of Schedule 3 to the Health Act 1999. This allows an Order in Council under section 60 of the Health Act 1999 to confer functions on or modify the functions of a Northern Ireland department. This brings the position in relation to Northern Ireland departments into line with the ability to confer functions on or modify the functions of Ministers of the Crown, as well as the Scottish Ministers and the Welsh Ministers, by means of an Order under section 60.

345. *Paragraph 5* makes amendments to paragraph 7 of Schedule 3, which specifies matters outside the scope of the Orders under section 60. *Paragraph 5(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.

346. 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 regulatory 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.

347. 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 5(3)* removes this restriction through the removal of paragraph 7(2) of Schedule 3 to the Health Act 1999.

348. *Paragraph 5(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.

349. *Paragraph 6* 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 6(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, the PSNI and the Hearing Aid Council can be transferred to a new regulatory body, using an Order under section 60, which would otherwise be prohibited as regards certain protected functions.

350. *Paragraph 7* 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 7(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.

351. *Paragraph 7(3) and (4):* see the explanation in relation to paragraph 2 above.

352. *Paragraph 8(a):* see the explanation in relation to paragraph 2 above.

353. *Paragraph 9* 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).

354. *Paragraph 10* 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).

Section 112: Standard of proof in fitness to practise proceedings

355. Currently, the application of the standard of proof in fitness to practise proceedings by regulatory bodies is not consistent. At present, all except two of the health regulatory bodies (the GOC and the NMC) use the civil standard of proof rather than the criminal standard of proof in fitness to practise proceedings.

356. Section 112 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

Section 113: Council for Healthcare Regulatory Excellence

357. Section 113 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.

358. The general functions of the Council for Healthcare Regulatory Excellence are set out in section 25 of the Health Care Professions Act 2002. Section 113 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.

Section 114: Constitution etc. of the Council

359. Section 114 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 20 and 21* 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.

360. In addition, in *subsection (3)* of this section, 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.

Section 115: Powers and duties of Council

361. Section 115 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.

Section 116: Powers of Secretary of State and devolved administrations

362. Section 116 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 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.

Section 117: Duty to inform and consult the public

363. Section 117 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.

Section 118: Reference of cases by Council to court

364. Section 118 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.

365. The section 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

Section 119: Responsible officers and their duties relating to medical profession

366. Section 119 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

367. *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.

368. *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/Local Health Boards 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.

369. *Subsection (5)* allows regulations to include criteria for appointment of responsible officers, and a requirement for designated bodies to provide them with resources. It also allows 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

370. *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

371. *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

372. This section applies 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

373. Section 45E requires regulations to be made by statutory instrument, or by statutory rule in relation to Northern Ireland. The first regulations made by each of the appropriate authorities which confer responsibilities on responsible officers by virtue of section 45B are to be subject to the affirmative resolution procedure before Parliament or the Northern Ireland Assembly (as the case may be), but regulations are otherwise subject to the negative resolution procedure. 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

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

Section 120: Additional responsibilities of responsible officers: England and Wales and Northern Ireland

375. Section 120 allows the Secretary of State in relation to England, the Welsh Ministers in relation to Wales, and DHSSPSNI in relation to Northern 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 section 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.

Section 121: Co-operation between prescribed bodies

376. *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.

377. 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 section 119 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).

378. *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. *Subsection (5)* requires the appropriate Minister, when making regulations under this section, to have regard to the importance of avoiding unfair prejudice to health care workers against whom unsubstantiated allegations are made.

379. *Subsection (6)* defines a number of terms used in the section. 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.

Section 122: Ss.120 and 121: Crown application

380. Section 122 applies sections 120 and 121 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 sections or regulations made under them but any such contravention may be declared unlawful by the relevant court.

Hearing Aid Council

Section 123: Dissolution of Hearing Aid Council

381. Section 123 provides for the dissolution of the Hearing Aid Council and the repeal of the Hearing Aid Council Act 1968 and the Hearing Aid Council (Extension) Act 1975. *Subsection (3)* prevents the dissolution of the Council from taking place before an Order in Council under section 60 of the Health Act 1999 has come into force. This will ensure that the Hearing Aid Council will not be abolished until provision has been made for the Health Professions Council to assume responsibility for the regulation of private hearing aid dispensers. Employers of private hearing aid dispensers will no longer be subject to statutory regulation. *Subsection (5)* allows the Secretary of State to make an order for the transfer of any property, rights and liabilities of the Hearing Aid Council to another regulatory body or the Secretary of State. *Subsection (6)* defines that other body as the body which is designated by the Order made under section 60 as being responsible for the regulation of private hearing aid dispensers.

Regulation of social care workforce

Section 124: Regulation of social care workers

382. Section 124 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.

383. *Subsection (4)* makes it clear that certain matters are covered by the references to the regulation of social care workers and are therefore within the scope of regulations under section 124. Paragraphs (a) and (b) cover social care workers who fall within the definition in section 55 of the Care Standards Act 2000 but who are not yet subject to registration, those who have applied for registration but are not yet registered, and those who have been, but are no longer, registered. Paragraph (c) makes it possible (if thought

necessary or expedient in the future) to regulate activities carried on by persons who are not social care workers in connection with activities carried on by social care workers.

384. 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.

385. Schedule 9 supplements section 124.

Schedule 9: Regulation of social care workers

386. *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*.

387. *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 section 124 and the Schedule. But it permits the amendment or repeal of any other provision of the Act or any other enactment, instrument or document.

388. *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.

389. *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.

390. *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*.

391. *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.

392. *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.

393. *Paragraph 9* obliges the Secretary of State, before making regulations under section 124 (in relation to England), to consult persons appearing to him appropriate to represent social care workers affected by the regulations and to represent those provided with services by them and to consult other persons that the Secretary of State considers it appropriate to consult. 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.

394. *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.

Section 125: Standard of proof in proceedings relating to registration of social care worker

395. Section 125 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.

396. *Subsection (4)* prevents regulations made under section 124 from amending section 125 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

Section 126: Education and training of approved mental health professionals

397. 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.

398. Section 126 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.

399. *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.

400. *Subsection (3)* provides that certain paragraphs of Schedule 9 also apply (with modifications) to regulations made under this section. 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 section 124 applies to regulations made under this section (paragraphs 9 and 10 of Schedule 9).

Part 3 – Public Health Protection

Section 129: Public health protection

401. Section 129 inserts a new Part 2A into the Public Health Act 1984. This new Part 2A replaces the existing Part 2 of the Act.

402. 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.

403. 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), 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.

404. 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.

405. 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, or indeed the Secretary of State or the Welsh Ministers, 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.

406. 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 restriction or requirement relating to the handling, transport, burial or cremation of dead bodies or the handling, transport or disposal of human remains.

407. 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 when making the regulations 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.

408. Section 45D(3) prohibits regulations from directly 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. However, regulations may enable the imposition of these restrictions or requirements by a decision-maker, if either of the conditions in section 45D(4) are met. Those conditions are that there is a serious and imminent threat to public health when the regulations are made or the decision to impose the restrictions or requirements is expressed in the regulations to be contingent on there being such a threat at the time the decision to impose them is made.

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

410. 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.

411. New section 45F(6), (7) and (8) make provision about the reviews and appeals in relation to special restrictions or requirements imposed by virtue of a decision taken under regulations made under section 45C. Subsection (6) provides that, where a special restriction or requirement is imposed on or in relation to a person, thing or premises the regulations must include provision for an individual (or business) to have a right of appeal to a magistrates' court against the decision. Subsection (7) requires that the regulations also make available a right of review at specified intervals to specified persons for special restrictions or requirements which continue in force in relation to any person, thing or premises for more than a specified period. Furthermore, subsection (8) provides that where the restriction or requirement imposed is detention, isolation or quarantine, the period prior to review and the interval between reviews must not exceed 28 days, and the regulations must require the continuation to be reviewed without the need for an application.

412. New*sections 45G* to *45J* make new provision for court orders. The powers conferred on justices of the peace are wider than previously provided for under the Public Health Act 1984. For example, court orders could not previously 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.

413. 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.

414. 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.

415. 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.

416. 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.

417. 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 or retained, kept in isolation or quarantine or disinfected or decontaminated. It might also require, in the case of a dead body, that the body be buried or cremated or, in any other case, that the thing be destroyed or disposed of. 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.

418. 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.

419. 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.

420. 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.

421. Section 61 of the Public Health Act 1984 as amended by paragraph 17 of Schedule 11 to this Act 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 this Act) 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.

422. 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(2) enables further orders to be made extending the period for which the restriction or requirement is imposed beyond that time limit. Section 45L(3) provides a maximum period of 28 days where the order imposes detention in a hospital or other suitable establishment, or quarantine or isolation of a person. This applies both to the initial period specified in the order and any extension of it. There is a power by regulations to prescribe a shorter period. Section 45L(4) 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.

423. 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 (5)). Section 45M(6) 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(7)(c), (8)(c) and (9) provide similar regulation-making powers in relation to who may be an affected person for applications in respect of orders under sections 45H(2) and (4) and 45I(2) and (4). Section 45M(10) provides that varying or revoking a Part 2A order does not invalidate any action already taken under the order. Section 45M(3) requires the appropriate Minister to prescribe in regulations the persons to whom a local authority is required to give notice of the making of an application for a Part 2A order. However, Part 2A orders can be made without a person being given the notice that would ordinarily be required under regulations made under section 45M(3) or under rules of court if the justice of the peace considers it necessary to do so (subsection (4) of section 45M).

424. New*section 45N* enables the Secretary of State or the 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).

425. 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.

426. 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.

427. 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 other restrictions or requirements that would have a significant effect on a person's rights. Regulations which amend an enactment 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 sections 45G(7), 45L(4) and 45N will be subject to the affirmative resolution procedure.

428. Regulations of a kind to which draft affirmative procedure would normally apply 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 that 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)).

429. 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.

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

Section 130: Further amendments relating to public health protection

431. Section 130 repeals Part 2 of the Public Health Act 1984 and gives effect to Schedule 11 to this Act.

Schedule 11: Public health protection: further amendments

432. 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.

433. *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.

434. *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).

435. *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.

436. *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.

437. *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.

438. *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.

439. *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.

440. *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.

441. *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.

442. *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.

443. *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.

444. *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.

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

446. *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.

447. 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.

448. *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.

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

450. *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.

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

452. *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.

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

454. *Paragraph 30* repeals section 76, which made provision for the Isle of Man and the Channel Islands.

455. *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

Section 131: Entitlement: Great Britain

456. Section 131 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.

457. 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.

458. 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.

Section 132: Administration: Great Britain

459. *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.

460. *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.

461. *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.

462. *Subsections (6) and (7)* amend sections 121E and 121F of the Social Security Administration Act 1992, to include information obtained by HMRC in connection with its functions relating to the Health in Pregnancy Grant. This will allow DWP and HMRC to share information to help develop and refine policies for pregnant women.

463. *Subsection (8)* 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.

Section 133: Penalty: Great Britain

464. Section 133 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.

465. 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

Section 134: Entitlement: Northern Ireland

466. 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.

Section 135: Administration: Northern Ireland

467. Section 135(1), (2), (3), (4), (6) and (7) amend the Social Security Administration (Northern Ireland) Act 1992 in the same manner as section 132 (1), (2), (3), (4), (6) and (7) amend the Social Security Administration Act 1992.

468. Section 135(8) 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.

Section 136: Penalty: Northern Ireland

469. Section 136 amends the Social Security Administration (Northern Ireland) Act 1992 in the same manner as section 133 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.

Section 137: Northern Ireland: health in pregnancy grant to be excepted matter

470. Section 137 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).

Section 138: General and supplementary

471. Section 138(1) provides for HM Revenue and Customs to be responsible for the payment and management of the Health in Pregnancy Grant.

472. Section 138(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.

473. Section 138(4) exempts the Health in Pregnancy Grant from liability to income tax.

Part 5 – Miscellaneous

Amendments relating to National Health Service

Section 139: Duty of Primary Care Trusts

474. Section 139 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.

475. 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 section 45.

Section 140 and Schedule 12: Pharmaceutical services

476. In England the funding arrangement for pharmaceutical services is governed by sections 228 to 231 of, and Schedule 14 to, the NHS Act 2006 and in Wales by sections 174 to 177 of, and Schedule 8 to, the NHS (Wales) Act 2006. Section 140 provides for changes to these provisions in order to move the Global Sum to baseline allocations.

477. Section 140 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. Schedule 12 also 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.

478. *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.

479. *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 pharmaceutical 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.

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

481. *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.

482. *Part 2*, *paragraphs 6 to 10*, of Schedule 12 makes corresponding provision for Wales.

Section 141: Remuneration for persons providing pharmaceutical services: appointment of determining authorities

483. Section 141 amends section 164 of the NHS Act 2006 and section 88 of the NHS (Wales) Act 2006. These sections make provision relating to the making or varying of determinations on the remuneration of those providing NHS pharmaceutical services. Under section 164, remuneration may be determined by the Secretary of State or by persons appointed by him referred to in the legislation as "determining authorities". Where the Secretary of State devolves this function to determining authorities, he is required to do so via an "instrument of appointment". Previously, the legislation provided that this "instrument of appointment" may be, but was not required to be, set out in regulations. Similar powers are conferred on the Welsh Ministers under section 88 of the NHS (Wales) Act 2006. Section 141 amends section 164 of the NHS Act 2006 to remove this discretion in the case of services that are provided pursuant to the power in section 126 of that Act. It also makes a similar amendment to section 88 of the NHS (Wales) Act 2006 in relation to services provided pursuant to section 80 of that Act. The new provisions require the Secretary of State and the Welsh Ministers respectively to set out an instrument of appointment in respect of these services in regulations.

Section 142: Indemnity schemes in connection with provision of health services

484. *Subsections (2)* and *(3)* of section 142 expand membership eligibility of indemnity schemes to the Secretary of State, who may secure health services directly. They also expand 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

Sections 143 and 144: Weighing and measuring of children

487. Provision for medical inspections for pupils in England and Wales is set out in Schedule 1 to the NHS Act 2006 and in Schedule 1 to the NHS (Wales) Act 2006 respectively. New paragraphs are inserted into each of these Schedules to make provision about weighing and measuring children.

488. Section 143 inserts new paragraphs into Schedule 1 to the NHS Act 2006. 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 School 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 section 144 in relation to the provisions for Wales.

489. New paragraph 7B(1)(a) of Schedule 1 enables 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 a child'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. Section 144 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. New paragraph 7B of Schedule 1 to the NHS (Wales) Act 2006 mirrors the equivalent provision in the NHS Act 2006 (see above). In particular, the regulations made by the Welsh Ministers can 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.

Social care

Section 145: Human Rights Act 1998: provision of certain social care to be public function

497. Section 145 provides that where a private or voluntary sector care home provider provides accommodation together with nursing or personal care to a person under arrangements made with a local authority or, in Northern Ireland, DHSSPSNI, under certain statutory provisions the provider is taken to be exercising a function of a public nature under section 6(3)(b) of the Human Rights Act 1998. This means that such providers are required not to act incompatibly with rights under the Convention in providing these services. It also means that the person receiving such accommodation and care can take proceedings against the provider under the Human Rights Act 1998 if the provider breaches his or her rights under the Convention. Section 145 does not affect the question of whether persons in the private or voluntary sector who provide other forms of publicly-funded social care or health care are to be regarded as exercising a public function.

Section 146: Direct payments in lieu of provision of care services

498. *Subsection (2)* of section 146 inserts new subsections (1A) to (1C) into section 57 of the Health and Social Care Act 2001.

499. 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.

500. 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.

501. 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 section. 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, along with the local authority, 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.

502. 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.

503. *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.

504. *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 a 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.

505. 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.

506. 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 section 146 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.

507. *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.

508. *Paragraphs 1* and*8* of Schedule 14 make amendments to other legislation in consequence of the extension of the direct payments scheme by section 146. 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 section 146 (as explained in the Background and Summary section). Paragraph 8 amends section 6 of the Safeguarding Vulnerable Groups Act 2006. 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.

Section 147 and Schedule 13: Abolition of maintenance liability of relatives

509. This section 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.

Section 148: Ordinary residence for certain purposes of National Assistance Act 1948 etc.

510. 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 the NHS in places other than NHS hospitals.

511. *Subsection (2)* requires the Secretary of State and the Welsh Ministers to make and publish arrangements for determining which ordinary residence disputes arising under part 3 of the National Assistance Act 1948 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.

512. 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

Sections 149 and 150: Power of Secretary of State to give financial assistance; Qualifying bodies

513. Section 149(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. Section 149(2) allows the Secretary of State to give financial support to people to set up such bodies.

514. Section 150 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 section 150(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.

515. 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. Section 150(1)(b) allows for prescribed bodies to be excepted from the requirement to meet such conditions.

516. The third condition under section 150(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 a purely voluntary basis. Voluntary bodies who are "carrying on a business" and meet the other conditions would qualify.

517. Section 150(1)(d) allows regulations to be made setting out other conditions that a body must meet in order to be a qualifying body. If a person is given financial support to set up a qualifying body, additional conditions that such a qualifying body must satisfy may be prescribed in regulations under section 149(2). Under section 150(2), regulations may provide that only certain kinds of body can be a qualifying body.

Sections 151 and 152: Forms of assistance under s.149; Terms on which assistance under s.149 is given

518. Sections 151 and 152 concern the forms of financial assistance (e.g. grants, loans, guarantees, share capital) the Secretary of State can give to social enterprises and allow the Secretary of State to specify the terms on which it is provided. The sections 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.

519. Section 151 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.

520. Section 152 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.

Section 153: Directions to certain NHS bodies

521. *Subsection (1)* enables the Secretary of State to direct certain NHS bodies in England to exercise his power to give financial support under section 149. 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.

Section 154: Arrangements with other third parties

522. Section 154 allows the Secretary of State to make arrangements for a third party, other than those NHS bodies set out in section 153(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 section 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.)

523. 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 section 153(1) is that separate arrangements for these bodies are already set out in that section. The provisions in the Act are designed to give the Secretary of State and NHS bodies the necessary wider powers to fund social enterprises.

Section 155: Power to form a company

524. Section 155 allows the Secretary of State to set up a company to fund qualifying bodies and people wanting to set up such bodies. Under section 154 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.

Section 156: Interpretation of group of sections

525. Section 156 sets out the meaning of various terms used in sections 149 to 156.

National Information Governance Board for Health and Social Care

Section 157 and section 158: National Information Governance Board for Health and Social Care

526. Section 157 establishes the National Information Governance Board for Health and Social Care.

527. Section 157 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.

528. Section 157 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.

529. Section 158 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.

530. 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

Section 159: Functions of Health Protection Agency in relation to biological substances

531. Section 159 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.

532. *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.

533. *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

Section 161: Orders, regulations and directions: general provisions

534. Section 161 makes provision in relation to powers to make orders and regulations and to give directions under the provisions of the Act. 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.

Section 162: Orders and regulations: Parliamentary control

535. Section 162 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 (section 109) 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) or (4) 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 section 170, in which case there is no Parliamentary procedure.

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

- regulations defining "regulated activity" (section 8(1)) for the purposes of registration in respect of the provision of health or social care;
- regulations under section 20 which provide for the establishment of a criminal offence carrying a maximum fine in excess of level 4 on the standard scale (currently £2,500);
- regulations under section 43 modifying Chapter 2 of Part 1 (registration in respect of the provision of health or social care) of the Act in relation to newly regulated activities;
- regulations made under section 87(1)(b) which provide for a penalty in excess of level 4 on the standard scale (currently £2,500);
- the first regulations made under section 120 (additional responsibilities of responsible officers);
- regulations making provision modifying the regulation of social care workers (section 124) or making provision modifying the functions of the GSSC in relation to the education and training of AMHPs (section 126); and
- orders containing transitional or consequential provision (section 167) which amend or repeal any provision of an Act of Parliament.

537. *Subsection (4)* provides that the Privy Council may not, under section 109, make a statutory instrument approving rules of the OHPA that contain (either alone or with other provision) provision for the piloting of legally qualified chairs, made by virtue of section 100(4), unless a draft has been approved by a resolution of each House of Parliament.

Section 163: Orders and regulations: control by National Assembly for Wales

538. Section 163 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 section 167(2) containing transitional or transitory provisions or savings.

539. *Subsection (3)* provides that the first regulations made under section 120 (responsible officers) and regulations making provision modifying the regulation of social care workers (section 124), or making provision modifying the functions of the CCW in relation to the education and training of AMHPs (section 126), must be approved by a resolution of the National Assembly for Wales.

Section 164: Regulations: control by Northern Ireland Assembly

540. Section 164 provides that the first regulations made under section 120 (responsible officers) by DHSSPSNI are subject to the affirmative resolution procedure in the Northern Ireland Assembly. Subsequent regulations made under section 120 are subject to the negative resolution procedure.

Section 165: Directions

541. Section 165 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.

Section 166: Repeals

542. Section 166 makes provision in respect of repeals. It gives effect to the repeals specified in Schedule 15.

Section 167: Power to make transitional and consequential provision etc.

543. Section 167 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 Act in relation to which the Secretary of State is the appropriate Minister for the purposes of section 170(3) (commencement). It also confers on the Secretary of State the power to make by order such supplementary, incidental or consequential provision as considered appropriate.

544. *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 Act in relation to which the Welsh Ministers are the appropriate Minister for the purposes of section 170(3) (commencement).

545. *Subsection (3)* provides that an order under this section 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 section containing provision which would fall within the legislative competence of the Scottish Parliament, the Secretary of State must consult the Scottish Ministers.

546. Powers of this kind are often included in Acts which make extensive changes to existing statutory regimes. This section will ensure that necessary or expedient transitional arrangements can be made as the Act 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.

547. 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 this Act.

548. 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 Act. 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 this Act); and, (b) the abolition of the NBSB and the assumption of identical functions by the Health Protection Agency (section 159).

549. The power to make consequential amendments will enable changes made to the law by the Act to be reflected in other legislation which refers to or is dependent on provisions repealed or amended by the Act.

Section 168: Financial provisions

550. Section 168 makes provision for expenditure which will be incurred under or be attributable to the provisions of the Act to be paid out of money provided by Parliament.

Section 169: Extent

551. Section 169 makes provision as to the extent of the provisions of the Act.

Section 170: Commencement

552. Section 170 makes provision for the coming into force of the provisions of the Act. This section provides that the Act, 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 Act (except section 166 and Schedule 15 (repeals)), and any other provision of the Act (except section 111 or Schedule 8) 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 came into force on the day on which the Act received Royal Assent.

Section 171: The appropriate authority by whom commencement order is made

553. Section 171 determines who the appropriate authority is for the purposes of making commencement orders under section 170. Except as provided by subsections (3) to (5), the appropriate authority is the Secretary of State.

554. In relation to sections 119, 120 and 122 (responsible officers), so far as they relate to Northern Ireland, the appropriate authority is DHSSPSNI.

555. 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 section 166 (repeals) so far as it relates to that Part of Schedule 15 in its application to Wales),
- section 140 (pharmaceutical services), so far as relating to Part 2 of Schedule 12, together with that Part of that Schedule,
- section 141(2) (remuneration for persons providing pharmaceutical services: appointment of determining authorities in relation to Wales),
- section 144 (weighing and measuring of children: Wales),

- subsections (1) to (7) of section 146 (direct payments in lieu of provision of care services), so far as they relate to Wales, and subsection (8) of that section,
- section 147 (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 section 166 so far as relating to Part 5 of Schedule 15 in its application to local authorities in Wales),
- section 148 (ordinary residence for certain purposes of National Assistance Act 1948 etc.), so far as relating to Wales, and
- the repeals in the NHS (Wales) Act 2006 in Part 4 of Schedule 15 (and section 166 so far as relating to those repeals).

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

Section 172: Consultation in relation to commencement

557. Section 172 makes provision requiring the appropriate authority for the purposes of making commencement orders under section 170 to consult others before making orders commencing certain provisions of the Act.

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

- section 111 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;
- section 112 (standard of proof in fitness to practise proceedings) in relation to a profession that is not a reserved profession for Scotland; or
- section 116 (powers of Secretary of State and devolved administrations), so far as relating to the functions of the Scottish Ministers.

559. Before making a commencement order relating to section 148 (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 section 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 the amendments to the powers of the Welsh Ministers under the Care Standards Act 2000 (see notes on section 95 and Schedule 5 above).

560. Before making a commencement order relating to section 159 (functions of Health Protection Agency in relation to biological substances), or Part 7 (abolition of NBSB) of Schedule 15 (or section 166 so far as relating to that Part of that Schedule), the Secretary of State must consult DHSSPSNI.

HANSARD REFERENCES

The following table sets out the dates and Hansard references for each stage of the Act's passage through Parliament.

Stage	***Date***	***Hansard reference***
House of Commons		
Introduction	15 November 2007	Vol. 467 Col. 834
Second Reading	26 November 2007	Vol. 468 Cols. 37 – 105
Committee	8 January 2008	Official Report, Health and Social Care Bill Committee: 1st to 12th sittings
	10 January 2008	
	15 January 2008	
	17 January 2008	
	22 January 2008	
	24 January 2008	
Report and Third Reading	18 February 2008	Vol. 472 Cols. 44 – 122
House of Lords		
Introduction	19 February 2008	Vol. 699 Col. 135
Second Reading	25 March 2008	Vol. 700 Cols. 448 – 458 and 475 – 554
Committee	21 April 2008	Vol. 700 Cols. GC197 – 248
	29 April 2008	Vol. 701 Cols. GC1 – 58
	30 April 2008	Vol. 701 Cols. GC59 – 106
	6 May 2008	Vol. 701 Cols. GC107 – 166
	12 May 2008	Vol. 701 Cols. GC207 – 262
	14 May 2008	Vol. 701 Cols. GC321 – 386
	21 May 2008	Vol. 701 Cols. GC529 – 594
	22 May 2008	Vol. 701 Cols. GC595 – 656
Report	16 June 2008	Vol. 702 Cols. 803 – 828 and 871 – 910
	24 June 2008	Vol. 702 Cols. 1339 – 1412
Third Reading	1 July 2008	Vol. 703 Cols. 133 – 162
Consideration of amendments		
Commons Consideration of Lords Amendments	15 July 2008	Vol. 479 Cols. 147 – 192

Royal Assent – 21 July 2008

House of Commons Hansard Vol. 479 Col. 553
House of Lords Hansard Vol. 703 Col. 1579

ANNEX: TERRITORIAL APPLICATION TO WALES AND FUNCTIONS OF THE WELSH MINISTERS

PART 1 – THE CARE QUALITY COMMISSION

1. By section 1, the Commission is established and CHAI, CSCI and MHAC are abolished. The Welsh Ministers will remain responsible for reviewing the provision of health care in Wales and regulating the provision of social care in Wales (the Care Standards Act 2000 is preserved and amended in relation to Wales (see below)). Section 52(3) transfers the functions of MHAC under the Mental Health Act in relation to Wales to the Welsh Ministers.

2. Section 51 provides that where, following a review or investigation under Chapter 3, 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, the Commission is required to inform the Welsh Ministers. The Commission may recommend that the Welsh Ministers take special measures to improve the situation.

3. Section 69 requires the Commission and the Welsh Ministers to co-operate with each other for the efficient and effective discharge of their corresponding functions. Duties are also placed on the Commission and the Auditor General for Wales, by section 71 and by paragraph 77 of Schedule 5 (which amends section 64 of the Public Audit (Wales) Act 2004), to share information for the purpose of comparative studies of care provided by English NHS bodies and Welsh NHS bodies.

4. Schedule 5 (which is introduced by section 95) 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 the 2000 Act and are comparable to new powers conferred by this Act on the Commission.

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

5. All of Part 2 applies to Wales. Under section 124 on the regulation of the social care workforce, powers to make regulations in relation to Wales are given to the Welsh Ministers. Regulation-making powers are also conferred on the Welsh Ministers by sections 120 (additional responsibilities of responsible officers), 121 (co-operation between prescribed bodies), in relation to Welsh health bodies and Welsh social services bodies, and 126 (education and training of AMHPs). By virtue of the new section 45E(2) of the Medical Act 1983 inserted by section 119 of this Act, the Secretary of State must consult the Welsh Ministers before making regulations which apply to Wales under new section 45A of the 1983 Act (about responsible officers).

6. Section 125 provides that the standard of proof applicable to any proceedings before a committee of CCW, CCW itself or any officer of CCW is that applicable to civil proceedings.

PART 3 – PUBLIC HEALTH PROTECTION

7. All of Part 3 applies to Wales. Regulation-making powers exercisable under Part 3 in relation to Wales (including the sea adjacent to Wales out as far as the seaward boundary of the territorial sea) are conferred on the Welsh Ministers.

PART 4 – HEALTH IN PREGNANCY GRANT

8. Sections 131 to 133 (health in pregnancy grant: England, Wales and Scotland), which amend the Contributions and Benefits Act and the Social Security Administration Act 1992, and section 138 (general and supplementary) apply in relation to Wales. The Health in Pregnancy Grant will be administered by HM Revenue and Customs.

PART 5 – MISCELLANEOUS

Pharmaceutical services

9. Part 2 of Schedule 12 contains amendments to the NHS (Wales) Act 2006 to provide for the movement of the Global Sum to the baseline allocations of the Local Health Boards in Wales, as well as to introduce the allocation of funding of pharmaceutical services by reference to the Local Health Board of the prescriber.

10. By section 141, section 88 of the NHS (Wales) Act 2006 is amended to provide that an instrument of appointment of persons, referred to in the legislation as "determining authorities", appointed by the Welsh Ministers for the purpose of determining the remuneration of those providing NHS pharmaceutical services pursuant to section 80 of that Act must be set out in regulations.

Weighing and measuring of children: Wales

11. Section 144 amends Schedule 1 to the NHS (Wales) Act 2006 to provide for the weighing and measuring of children in Wales. The new provisions confer regulation-making powers on the Welsh Ministers, which can be exercised independently to England.

Social care

12. Section 145, which provides that where a private or voluntary sector care home provides accommodation together with nursing or personal care to a person under certain arrangements made with a local authority the provider is taken to be exercising a function of a public nature under section 6(3)(b) of the Human Rights Act 1998, applies in relation to Wales.

13. The extension of direct payments to include people who lack capacity (within the meaning of the Mental Capacity Act 2005) covers Wales to the same extent as section 57 of the Health and Social Care Act 2001 (which provides for direct payments in respect of adults) does now. Subsection (8) of section 146 amends section 64 of the 2001 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 of the 2001 Act.

14. Section 147, which abolishes the maintenance liability of relatives, applies in relation to Wales in the same way as it applies in relation to England.

15. Section 148 makes provision about a number of discrete matters in relation to ordinary residence for the purposes of the National Assistance Act 1948 and the Chronically Sick and Disabled Persons Act 1970. It extends the deeming provision in section 24(6) of the 1948 Act to accommodation provided by NHS bodies in places other than NHS hospitals. It also gives the Secretary of State and the Welsh Ministers the power to make and publish arrangements for determining which ordinary residence disputes arising under Part 3 of the 1948 Act shall be determined by the Secretary of State and which shall be determined by the Welsh Ministers; and provides that the same arrangements shall apply to ordinary residence disputes arising under section 2 of the 1970 Act.

National Information Governance Board for Health and Social Care

16. 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, which are limited to being consulted on matters relating to the processing of patient information.

FUNCTIONS OF THE WELSH MINISTERS

17. The Bill confers a number of new or expanded powers on the Welsh Ministers. The table below lists the provisions of the Bill which affect the existing powers of, or confer new powers or duties on, the Welsh Ministers.

TABLE – PROVISIONS WHICH AFFECT THE EXISTING POWERS OF, OR CONFER NEW POWERS OR DUTIES ON, THE WELSH MINISTERS

Section(s)/ Schedule	***Subject of provision***	***Effect on the powers of the Welsh Ministers***
Section 52(3) and (4)	Transfer of functions of MHAC	The functions of MHAC under the Mental Health Act are transferred to the Welsh Ministers. Section 121 of the Mental Health Act, which requires the Welsh Ministers to delegate some of their functions to MHAC, ceases to have effect.
Section 69	Co-operation between the Commission and Welsh Ministers	The Commission and the Welsh Ministers are required to co-operate with each other for the efficient and effective discharge of their corresponding functions. They may share information with each other for these purposes.
Section 114(2)	Constitution etc. of Council for Healthcare Regulatory Excellence	Replaces paragraph 4 of Schedule 7 to the Health Care Professions Act 2002. Power of the Welsh Ministers to appoint one non-executive member of the Council for Healthcare Regulatory Excellence.
Section 116	Powers in relation to the Council for Healthcare Regulatory Excellence	Inserts new section 26A into the Health Care Professions Act 2002. Includes: power to request the Council for advice on any mater connected with a health care profession (Council must comply with request); and, power to require the Council to report on a particular matter in respect of which the Council's functions are exercisable.
Section 119	Responsible officers: new section 45E(2) of the Medical Act 1983	The Secretary of State must consult the Welsh Ministers before making regulations under the new section 45A of the 1983 Act which apply to Wales.
Section 120	Additional responsibilities of responsible officers	Power by regulations to impose additional responsibilities on responsible officers and to make further provision in relation to this. May include a requirement to have regard to any guidance given from time to time by the Welsh Ministers. Welsh Ministers must be consulted by Secretary

Section(s)/ Schedule	***Subject of provision***	***Effect on the powers of the Welsh Ministers***
		of State before regulations are made, or guidance issued, in relation to cross-border bodies.
Section 121	Co-operation between prescribed bodies	Power by regulations to make provision in relation to co-operation between prescribed bodies in connection with the sharing and provision of information relating to health care workers. Bodies which may be prescribed are Welsh health care bodies and Welsh social care bodies.
Section 124	Regulation of social care workers	Power by regulations to make provision, in relation to Wales, modifying the regulation of social care workers.
Section 126	Education and training of AMHPs	Power by regulations to make provision modifying the functions of CCW in relation to the education and training of persons who are or wish to become AMHPs.
Section 129	New section 45B of the Public Health Act 1984 (health protection regulations: international travel etc.)	Power to make regulations, in respect of Wales, for preventing danger to public from conveyances arriving at any place or for preventing the spread of infection or contamination by conveyances leaving any place. Power by regulations to give effect to international agreements or arrangements.
Section 129	New section 45C of the Public Health Act 1984 (health protection regulations: domestic)	Power to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in Wales (whether from risks originating there or elsewhere).
Section 129	New section 45F of the Public Health Act 1984 (health protection regulations: supplementary)	Makes further provision about health protection regulations made under new sections 45B and 45C of the Public Health Act 1984. Includes details of when such regulations may be used to amend primary or secondary legislation (subsection (3)) and outlines the penalties for offences that can be created using such regulations (subsection (5)).
Section 129	New section 45G(7) of the Public Health Act 1984 (power to order health measures in relation to persons)	Duty to make provision by regulations about the evidence that must be available to a justice of the peace before the justice can be satisfied that there are grounds for making an order under this section.
Section 129	New section 45H(7) of the Public Health Act 1984 (power to order health measures in relation to things)	Power to make provision by regulations about the evidence that must be available to a justice of the peace before the justice can be satisfied that there are grounds for making an order under this section.

Section(s)/ Schedule	***Subject of provision***	***Effect on the powers of the Welsh Ministers***
Section 129	New section 45I(7) of the Public Health Act 1984 (power to order health measures in relation to premises)	Power to make provision by regulations about the evidence that must be available to a justice of the peace before the justice can be satisfied that there are grounds for making an order under this section.
Section 129	New section 45L(3) of the Public Health Act 1984 (period for which Part 2A order may be in force)	Power by regulations to prescribe a period shorter than 28 days as the maximum period for which restrictions or requirements relating to detention, isolation or quarantine imposed or extended by or under a Part 2A Order under new section 45G may be in force.
Section 129	New section 45L(4) of the Public Health Act 1984	Power by regulations to specify the maximum period or the maximum period of any extension of the length of time for which any restriction or requirement imposed by or under a Part 2A order (orders under new sections 45G, 45H and 45I of the Public Health Act 1984) other than detention, isolation or quarantine may be in force.
Section 129	New section 45M(3) (procedure for making, varying and revoking Part 2A orders)	Duty to prescribe persons to whom a local authority must give notice of the making of an application for a Part 2A Order.
Section 129	New section 45M(6)(e), (7)(c), (8)(c) and (9) of the Public Health Act 1984	Powers to prescribe any other persons as affected persons for the purposes of making applications to justices of the peace for variation or revocation of Part 2A orders made under sections 45G, 45H(2) and (4), and 45I(2) and (4) of the Public Health Act 1984.
Section 129	New section 45N of the Public Health Act 1984 (power to make further provision by regulations)	Power to make regulations dealing with matters relating to the taking of measures pursuant to Part 2A orders.
Section 129	New section 45R(2) of the Public Health Act 1984 (emergency procedure)	Power to make and bring into effect immediately regulations to which section 45Q(4) applies by virtue of section 45Q(2)(a) or (b) if they contain a declaration by the Welsh Ministers that they are of the opinion that it is necessary by reason of urgency for them to be made without a draft being approved by the National Assembly for Wales under the affirmative resolution procedure. Such regulations will cease to have effect after 28 days if a resolution approving them has not been passed by the National Assembly for

Section(s)/ Schedule	***Subject of provision***	***Effect on the powers of the Welsh Ministers***
		Wales (or earlier in the event of a decision by the Assembly rejecting them).
Section 144	Weighing and measuring of children in Wales: new paragraph 7A in Schedule 1 to the NHS (Wales) Act 2006	Power for the Welsh Ministers to make arrangements with any local education authority, the proprietor of any school which is not maintained by a local education authority, or any person registered under Part 10A of the Children Act 1989, for the weighing and measuring of junior pupils in attendance at school or of children looked after by that person.
Section 144	Weighing and measuring of children in Wales: new paragraph 7B in Schedule 1 to the NHS (Wales) Act 2006	Power to make regulations to provide for the disclosure of information for the purposes of weighing and measuring, for weighing and measuring to be carried out in a prescribed manner, for disclosure of resulting information to parents, and for regulating further processing of such resulting information. Regulations may also require persons exercising functions in relation to weighing and measuring to have regard to any guidance given by the Welsh Ministers.
Section 146	Direct payments in lieu of provision of social care: new subsection (1A) in section 57 of the Health and Social Care Act 2001	Power by regulations to provide for requiring or authorising direct payments to be made to a designated person (a "suitable person") on behalf of another person, who lacks the capacity to consent to the making of direct payments. Regulations may set out the conditions that must be satisfied by local authorities in determining who is a suitable person and specify the matters that the local authority must have regard to when taking any decision about who will administer the direct payment. Regulations may provide that where a person has fluctuating capacity, arrangements for managing their direct payments do not have to be continually revisited.
Section 148	Ordinary residence for certain purposes of National Assistance Act 1948 etc	Section 32 of the National Assistance Act 1948 is amended to provide that any question as to a person's ordinary residence for the purposes of Part 3 of that Act is to be determined by the Secretary of State or the Welsh Ministers, who must make arrangements between them for determining which cases each of them is to deal with.
		These new provisions for determining such questions are also applied to any such questions which arise under section 2 of the

Section(s)/ Schedule	***Subject of provision***	***Effect on the powers of the Welsh Ministers***
		Chronically Sick and Disabled Persons Act 1970.
Section 167(2)	Power to make transitional and consequential provision etc	Power by order for the Welsh Ministers to make such transitional or transitory provisions or savings as they consider appropriate in connection with the coming into force of any provision of the Act in relation to which they are responsible for commencement.
Section 170(3)	Commencement	Power of the Welsh Ministers by order to determine the date on which the provisions of the Act referred to in section 171(4) are to come into force.
Section 172(3) and (4)	Consultation in relation to commencement	The Secretary of State must consult the Welsh Ministers before making a commencement order in relation to the provisions of the Act referred to in subsections (3) and (4). The Welsh Ministers must consult the Secretary of State before making a commencement order relating to section 148 in relation to Wales.
Schedule 3, paragraph 8	New section 120 of the Mental Health Act: general protection of relevant patients	General duty to keep under review and investigate the exercise of powers and the discharge of duties in relation to detention of patients, their reception into guardianship, and community patients. Duty to arrange for visits and interviews of patients and to investigate complaints. Power to remunerate persons carrying out reviews or investigations.
Schedule 3, paragraph 9	New section 120A(1) and (4) of the Mental Health Act: investigation reports	Power to publish a report of a review or investigation carried out under section 120(1) of the Mental Health Act.
		Power by regulations to set out the procedure to be followed in respect of the making of representations to the Welsh Ministers before the publication of such a report.
Schedule 3, paragraph 9	New section 120B(1) and (3) of the Mental Health Act: action statements	Power to direct a person mentioned in subsection (2) to publish a statement of the action that person proposes to take as a result of a review or investigation under section 120(1) of the Mental Health Act. Power by regulations to make provision about the content and publication of such statements.
Schedule 3, paragraph 9	New section 120C(2) of the Mental Health Act: provision of information	Power of the Welsh Ministers to make reasonable requests for information from persons specified in subsection (1) (who must provide such information), for or

Section(s)/ Schedule	***Subject of provision***	***Effect on the powers of the Welsh Ministers***
		in connection with the exercise of their functions under section 120 of the Mental Health Act.
Schedule 3, paragraph 9	New section 120D(1) and (4) of the Mental Health Act: annual reports	The Welsh Ministers are to publish an annual report on their activities in the exercise of their functions under the Mental Health Act. A copy must be laid before the National Assembly for Wales.
Schedule 3, paragraph 12	New section 134A(1), (3) and (6) of the Mental Health Act: review of decisions to withhold correspondence	The Welsh Ministers must review a decision to withhold a postal packet, or any contents of it, on receipt of an application to do so. Power to direct that the postal packet or its contents are not to be withheld.
		Power by regulations to make provision in connection with the making of such applications to them.
Schedule 5, paragraph 13	New section 14A of the Care Standards Act 2000: suspension of registration	Power to suspend, for a specified period, the registration of a person in respect of an establishment or agency, for which the Welsh Ministers are the registration authority, which is being, or has been, carried on otherwise than in accordance with the registration requirements.
Schedule 5, paragraph 14(a) and (c)	Amendment of section 15 of the Care Standards Act 2000: applications by registered persons	Requirement to consider an application for the cancellation or variation of any suspension of registration and to serve a notice in writing on the applicant of the Welsh Ministers' decision.
Schedule 5, paragraph 19	New sections 20A and 20B of the Care Standards Act 2000: urgent procedure for cancellation and for suspension or variation: Wales	Power to apply to a justice of the peace for an urgent cancellation of the registration of a person in respect of an establishment or agency (this replicates provision currently made by section 20 of the 2000 Act).
		Power, by notice in writing, in a case of urgency: to vary or remove a condition in relation to the registration of a person in respect of an establishment or agency; to impose an additional condition; or, to suspend such a registration or extend the period of suspension.
Schedule 5, paragraph 24	Amendment of section 29 of the Care Standards Act 2000: proceedings for offences	Extension of the time limit on the Welsh Ministers bringing criminal proceedings, in relation to offences under Part 2 of the Care Standards Act or regulations made under it, from six to twelve months.
Schedule 5, paragraph 25	New sections 30ZA and 30ZB of the Care Standards Act 2000: penalty notices	Power to give a penalty notice to a person where the Welsh Ministers are satisfied that the person has committed a fixed penalty offence.

Section(s)/ Schedule	***Subject of provision***	***Effect on the powers of the Welsh Ministers***
		Power by regulations to specify what are fixed penalty offences and to make supplementary provision in relation to penalty notices.
Schedule 5, paragraph 42	Amendment of section 96(2)(a) of the Health and Social Care (Community Health and Standards) Act 2003: additional functions of Welsh Ministers	The Welsh Ministers to have such additional functions in relation to the provision of Welsh local authority social services as correspond to the functions of the Commission under Part 1 of the Health and Social Care Act 2008.
Schedule 5, paragraph 48	New section 143 of the Health and Social Care (Community Health and Standards) Act 2003: use by Welsh Ministers of information	Power of Welsh Ministers to use information obtained in the course of exercising specified functions for the purposes of any other of such functions extended to include the following functions: those exercisable as regulatory authority under the Mental Health Act; and, certain specified functions under the Mental Capacity Act 2005.
Schedule 11, paragraph 16	New section 60A of the Public Health Act 1984: electronic communications	Power of the Welsh Ministers by regulations to make provision for specified documents to be given or served by an electronic communication.
Schedule 11, paragraph 26	New section 71 of the Public Health Act 1984: default powers	Powers of the Welsh Ministers to make orders declaring a relevant health protection authority to be in default, for failure to discharge its functions, and make other provision.
Schedule 12, paragraph 10(6)	New paragraph 3A of Schedule 8 to the NHS (Wales) Act 2006 (further provision about expenditure of Local Health Boards)	Power to designate any element of remuneration paid by Local Health Boards to persons providing pharmaceutical services which is not remuneration referable to the cost of drugs. If an element is designated, requirement for each financial year to apportion among all Local Health Boards the total of remuneration referable to that element which is paid by each Local Health Board in that year.
Schedule 12, paragraph 10(8)	New paragraph 4(4) of Schedule 8 to the NHS (Wales) Act 2006	Power to treat remuneration (not treated as referable to drugs) paid by Local Health Boards to persons providing pharmaceutical services, so far as met by an NHS trust, as remuneration falling within paragraph 3A(1) of Schedule 8.

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/Local Health Boards receive to enable them to commission healthcare for their population.

The Commission: the Care Quality Commission, established by section 1 of the Act.

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 section 147(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 established by the new section 250A inserted in the NHS Act 2006 by section 157 of this Act.

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	Health care associated infections
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 Organization