

Post-legislative assessment of the Health and Social Care Act 2008

Memorandum to the House of Commons Health Select Committee



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Presented to Parliament by the Secretary of State for Health by Command of Her Majesty

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Introduction and Summary

1. This memorandum provides an assessment of the Health and Social Care Act 2008 (the 2008 Act). It has been prepared by the Department of Health (with a contribution from HM Revenue and Customs on Part 4 of the Act) for submission to the Health Committee of the House of Commons. It does not cover aspects of the Act that are within the legislative competence of the devolved administrations.

Objectives

- 2. The Act fell into five main parts, whose main objectives were:
- to establish the Care Quality Commission;
- to change arrangements for regulation of health professionals and of the health and social care workforce;
- to update the Public Health (Control of Disease) Act 1984;
- to create the Health in Pregnancy Grant; and
- to make miscellaneous other changes in relation to health and social care.

Implementation

3. Most of the provisions of the Act are now in force (in some cases with amendments made by later legislation). Annex A provides details of commencement dates.

4. The main exceptions are:

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

Sections 98-110 (which aimed to create the Office of the Health Professions Adjudicator) were repealed (for the most part, without having come into force) on 1 July 2012, following a policy change.

Section 121 (which aimed to put a general responsibility on healthcare organisations and other bodies to share concerns about the conduct and performance of healthcare workers) was not commenced, because responses to consultation showed respondents were not convinced of the need for further legislation.

Sections 124-126, which dealt with various matters in the remit of the General Social Care Council, were not commenced. Instead, the Council was abolished, and its functions were transferred to the Health and Care Professions Council, in 2012.

Part 3: Public Health Protection

The provisions relating to port health have not yet been commenced, but the intention is that they will come into force at the same time as new port health regulations (which will be subject to consultation later this year).

Part 4: Health in Pregnancy Grant

Part 4 came into force on 1 January 2009, but, in keeping with decisions announced in the 2010 budget, entitlement to the grant ceased in 2011.

Part 5: Miscellaneous

Sections 157-158 (National Information Governance Board for Health and Social Care) and 159 (Functions of Health Protection Agency in relation to biological substances) came fully into force in 2009 but were repealed on 1 April 2013 because of policy changes.

Overall assessment

5. The Act achieved its objectives (or in the case of port health, is in the process of doing so), with the exception of the creation of the Office of the Health Professions Adjudicator.

The rest of this memorandum

- 6. The rest of this memorandum considers each Part of the Act in more detail, with information about:
- secondary legislation made under the powers created by the Act, and key guidance issued in relation to it;
- any legal issues that have arisen in relation to the Act, and other reviews of the Act, that the Department of Health is aware of.

Part 1: The Care Quality Commission

Objective

- 1.1 The objectives of Part 1 were:
- to establish the Care Quality Commission (CQC) as a new body responsible for the registration, review and inspection of certain health and social care services in England;
- to create a system of registration for providers of health and adult social care;
- to require CQC to carry out periodic reviews of care commissioned or provided by Primary Care Trusts (PCTs) or local authorities and of care provided by English NHS providers; and
- to transfer to CQC various functions under the Mental Health Act 1983.

Implementation

1.2 The whole of Part 1 has been fully in force since 1 October 2010. Some elements came into force earlier (see table at Annex A for details). For example, CQC came into being on 1 October 2008 and took over from its predecessor bodies on 1 April 2009.

Secondary legislation etc

- 1.3 Other than commencement orders, the powers provided by or in relation to Part 1 have been used to make nine statutory instruments (some of which have subsequently been amended). Of these:
- two have been in force since 1 October 2008, of which:

- one makes provision on membership of CQC;¹
- the other amended secondary legislation in consequence of the establishment of CQC, and made transitory modifications to primary legislation pending the abolition of its predecessor bodies;²
- two have been in force since 1 April 2010, of which:
 - one sets out the health and social care activities that are to be regulated activities for the purposes of Part 1 and the registration requirements relating to safety and quality that providers of regulated activities must meet. Failure to do so can result in a criminal prosecution or the issue of a penalty notice. The regulations prescribe the offences, the maximum penalty on conviction, and the monetary amounts of any penalty issued under a penalty notice;³
- 1. The Care Quality Commission (Membership)
 Regulations 2008 (SI 2008/2252). Amended from 28 November 2011 by SI 2011/2547 and from 1 June 2012 by SI 2012/1186.
- 2. The Health and Social Care Act 2008 (Consequential Amendments and Transitory Provisions) Order 2008 (SI 2008/2250).
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (SI 2010/781).
 Amended from 18 June 2012 by SI 2012/921 and from 18 June 2012, 1 October 2012 and 1 October 2013 by SI 2012/1513.

- the other contains other provision in relation to registration of persons carrying on a regulated activity;⁴
- one has been in force since 9 April 2010, and specifies the organisations in respect of which CQC is under a duty to prevent or limit certain inspections;⁵
- two came into force on 1 October 2010, of which one⁶ amended primary legislation, and the other amended secondary legislation,⁷ in consequence of the new registration system;
- one came into force on 12 November 2010, and made transitory and transitional provision in connection with the extension of the regulatory system to cover primary dental services providers, private ambulance service providers and primary medical services providers;⁸
- one has been in force since 1 August 2011 and gives CQC powers to review decisions to withhold post or other items for patients, and to record and monitor patients' telephone calls, in high secure hospitals.⁹
- 4. The Care Quality Commission (Registration)
 Regulations 2009 (SI 2009/3112). Amended from
 1 June 2012 by SI 2012/1186 and from 18 June
 2012, 1 October 2012 and 1 April 2013 by SI
 2012/921.
- 5. The Care Quality Commission (Specified Organisations etc) Order 2012 (SI 2010/496).
- 6. The Health and Social Care Act 2008 (Consequential Amendments No 2) Order 2010 (SI 2010/813).
- 7. The Health and Social Care Act (Miscellaneous Amendments) Order 2010 (SI 2010/1881).
- The Health and Social Care Act 2008 (Primary Dental Services, Private Ambulance Services and Primary Medical Services) (Regulated Activities) (Transitory and Transitional Provisions) Order 2010 (SI 2010/2484). Amended from 16 January 2012 by SI 2011/2948.
- 9. The Care Quality Commission (Additional Functions) Regulations 2011 (SI 2011/1551). Amended from 18 June 2012 by SI 2012/921.

- 1.4 To date, it has not been found necessary to use a number of powers to make secondary legislation.¹⁰
- 1.5 In terms of guidance:
- the Department of Health issued a revised Code of Practice Mental Health Act 1983 in May 2008. This pre-dated the transfer of functions from the Mental Health Act Commission to CQC, but was designed to apply equally to either body;
- CQC has published a range of guidance for providers¹¹ as well as information for people detained under the Mental Health Act 1983 or subject to a community treatment order.¹²

Legal issues

1.6 No legal issues have arisen in relation to Part 1, except that in 2009 the Joint Committee on Statutory Instruments reported the draft of an instrument that it was proposed to make under the powers in Part 1 for unusual or unexpected use of powers, doubtful vires and requiring elucidation.¹³ The instrument was redrafted in the light of these comments.

Other reviews

1.7 Partly because of concerns about CQC's performance, there have been several reports about it, including:

- Chapter 3, sections 38(3); 43(1); 46(9); 48(7); and 49(1). Chapter 5, sections 55(2), 61(1), and 85(5).
 Schedule 4, Part 2, paragraphs 5, 7 and 10.
 Chapter 6, sections 61(4).
- 11. http://www.cqc.org.uk/organisations-we-regulate
- 12. http://www.cqc.org.uk/public/what-are-standards/your-rights-under-mental-health-act
- 13. http://www.publications.parliament.uk/pa/ it200910/jtselect/jtstatin/23/2304.htm

- three reports from the Health Select Committee, published between September 2010 and January 2013;¹⁴
- a report from the National Audit Office in December 2011;¹⁵
- the Department of Health's performance and capacity review of CQC in February 2012;¹⁶
- a report from the Public Accounts
 Committee in March 2012,¹⁷ informed by
 a report from the Comptroller & Auditor
 General.
- 1.8 These reports focused on practicalities rather than on the primary legislation.
 Two noted a lack of clarity about CQC's objectives, but they did not propose change to the primary legislation to deal
- 14. Of these, the first, in September 2010, approved the proposed appointment of a permanent chair of CQC and identified points of concern that the committee expected CQC to address. It also signalled the committee's intention to review the work of CQC on an annual basis. (Appointment of the Care Quality Commission, HC (2010-12) HC 461 http://www.publications.parliament.uk/pa/ cm201011/cmselect/cmhealth/461/46102.htm). The second, in September 2011, reported on the committee's first accountability hearing with CQC. (Annual accountability hearing with the Care Quality Commission, HC (2010-12) HC 592 http:// www.publications.parliament.uk/pa/cm201012/ cmselect/cmhealth/1430/143002.htm). The third ((January 2013) considered action since the previous report (2012 accountability hearing with the Care Quality Commission, HC (2012-13) HC 592. http://www.publications.parliament.uk/pa/ cm201213/cmselect/cmhealth/592/59202.htm
- 15. http://www.nao.org.uk/publications/1012/care guality commission.aspx
- 16. https://www.gov.uk/government/news/
 performance-and-capability-review-of-the-care-quality-commission
- 17. http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubacc/1779/1779.pdf

with this.¹⁸ Some reports have considered specific regulations.¹⁹ Others, including the Government's final report on Winterbourne View Hospital (December 2012)²⁰ and the final report of the Public Inquiry into the Mid-Staffordshire NHS Foundation Trust (February 2013),²¹ have considered wider issues relevant to the regulation system.

Assessment

- 1.9 Part 1 of the Act met its objectives of:
- establishing CQC as a new body responsible for the registration, review and inspection of certain health and social care services in England
 - CQC replaced its predecessor bodies on 1 April 2009;
- 18. The Health Select Committee, in the second of the reports mentioned above, concluded that "The CQC was originally established without a sufficiently clear and realistic definition of its priorities and objectives." The third conclusion in the Public Accounts Committee's report was "The Commission's role is unclear and it does not measure the quality or impact of its own work. The Commission's objective, as set out in legislation, is to 'protect and promote the health, safety and welfare of people who use health and social care services' but it has not defined what success in delivering this objective would look like. It is unclear to what extent the Commission's role involves improvement beyond the essential basic standards of quality and safety. Although the Commission is a Quality Commission it only measures itself against quantitative, activity-based performance measures, with no measures of quality or impact. The Commission, working with the Department, should set out clearly what it is seeking to achieve and develop measures of quality and impact which can be used to assess its effectiveness."
- 19. For example, the Cabinet Office Red Tape Challenge: Quality of Care and Mental Health (November 2012)
- 20. https://www.gov.uk/government/publications/winterbourne-view-hospital-department-of-health-review-and-response
- 21. http://www.midstaffspublicinguiry.com/report

- creating a system of registration for providers of health and adult social care
 - NHS providers have been registered against the full set of registration requirements since 1 April 2010. Private and voluntary healthcare providers and adult social care providers have been registered from 1 October 2010, primary dental care and private ambulance services from 1 April 2011, dedicated out of hours primary care providers and walk-in centres from 1 April 2012, and other primary medical care providers from 1 April 2013. For the first time, there is a single coherent set of requirements for all providers within the scope of registration, in order to assure people who use services of the same essential levels of safety and quality:
- requiring CQC to carry out periodic reviews of care commissioned or provided by Primary Care Trusts (PCTs) or local authorities and of care provided by English NHS providers
 - some reviews were conducted for 2009/10, but (making use of the flexibility in the primary legislation as to the period that should elapse between reviews) further reviews of NHS bodies were put on hold in June 2010 to allow time to consider the changing environment. Reviews of local authorities were also put on hold in 2011, in order to consider an alternative, sector-led, approach;
- transferring to CQC various functions under the Mental Health Act 1983
 - this was achieved on 1 April 2009, when the Mental Health Act Commission was abolished and its functions and some of those previously held by the Secretary of State transferred to CQC.

- 1.10 Subsequently, Part 1 was amended by the Health and Social Care Act 2012. Amendments particularly relevant to the objectives set by the 2008 Act are that:
- responsibility for monitoring information governance practice by registered care providers was transferred on 1 April 2013 from the National Information Governance Board to CQC (see below on sections 157-8 of the 2008 Act);
- the duty on CQC to carry out periodic reviews of PCTs was removed on 1 April 2013,²² at the same time as PCTs were abolished and most of their functions transferred to clinical commissioning groups (whose performance is assessed by NHS England).²³ From the same date CQC gained powers to conduct reviews that consider how the activities of clinical commissioning groups and NHS England affect the provision of NHS care.

In addition, the duty on CQC to carry out periodic reviews of NHS providers was removed by the 2012 Act.²⁴ However, that provision has not been brought into force (and see now the next paragraph).

1.11 More recently:

- the Department of Health has published an initial response to the report of the Mid-Staffordshire Public Inquiry, which outlines further steps that are planned.²⁵ The Department is also reviewing the
- 22. Paragraph 157(a) of Schedule 5 to the 2012 Act.
- 23. NHS England is the operating name of the body described in legislation as the NHS Commissioning Board.
- 24. Paragraph 157(b) and (c) of Schedule 5 to the 2012 Act.
- 25. Patients First and Foremost: The Initial
 Government Response to the Report of the
 Mid Staffordshire NHS Foundation Trust Public
 Inquiry, https://www.gov.uk/government/news/government-publishes-initial-response-to-the-mid-staffordshire-nhs-public-inquiry-report

- legislation, with a view to consulting in 2014 on new regulations;
- Part 2 of the Care Bill, introduced in Parliament in May 2013, amends some provisions in Part 1 of the 2008 Act, including those on periodic reviews and on the composition of CQC's board.

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

Sections 98-110: The Office of the Health Professions Adjudicator

Objective

2.1 The objective of sections 98-110 was to create the Office of the Health Professions Adjudicator (OHPA) to have adjudication functions in relation to the professions regulated by the Medical Act 1983 and the Opticians Act 1989.

Implementation

2.2 Some elements of sections 98 and 107, and the whole of section 108, were commenced in 2009 and 2010 in preparation for the establishment of OHPA. However, following a change of policy on the need for OHPA (see below), sections 98-110 were repealed on 1 July 2012.²⁶

Secondary legislation etc

2.3 None.

Legal issues

2.4 None.

Other reviews

2.5 Following the change of Government in 2010, the policy on OHPA was reassessed to ensure it was proportionate and fit for purpose. Having carried out a public consultation on the question, the Government decided that creation of a new public body

to take on the function of adjudication from another already in existence was not necessary.²⁷

Assessment

2.6 Sections 98-110 did not achieve their objective of creating OHPA because of a change of policy following public consultation.

Amendments to Part 3 of Health Act 1999

Section 111: Extension of powers under section 60 of the Health Act 1999

Objective

2.7 The objective of section 111 was to extend the powers available under section 60 of the Health Act 1999. These allow 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.

Implementation

2.8 Section 111 (and Schedule 8 which it introduces) have been fully in force since 1 January 2009 (except for a provision relating to Northern Ireland and a provision relating to OHPA).

^{26.} By section 231 of the Health and Social Care Act 2012.

^{27. &}lt;a href="http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH 122293">http://webarchive.nationalarchives.gov.uk/en/20130107105354/http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH 122293

Secondary legislation etc

2.9 An order in force from 10 February 2010 established the General Pharmaceutical Council.²⁸

2.10 See below on section 123 for an order, in force from 1 April 2010, that transferred responsibility for regulation, and the register, of hearing aid dispensers from the Hearing Aid Council to the Health Professions Council.

Legal issues

2.11 None.

Other reviews

2.12 None.

Assessment

2.13 Section 111 met its objective of extending the powers available under section 60 of the Health Act 1999.

Section 112: Standard of proof in fitness to practise proceedings

Objective

2.14 The objective of section 112 was to impose the use of the civil standard of proof by healthcare profession regulators in proceedings relating to fitness to practise.

Implementation

2.15 Section 112 came into force on 3 November 2008.

Secondary legislation etc

2.16 None.

Legal issues

2.17 None.

Other reviews

2.18 Annual reviews of regulator performance²⁹ by the Council for Healthcare Regulatory Excellence have noted the use of the civil standard as assisting in the smooth handling of fitness to practise cases.

Assessment

2.19 Section 112 has achieved its objective. The use of the civil standard across all regulators has provided a consistent approach in hearings as to whether a disputed fact is considered to be proved or not proved.

Sections 113-118: The Council for Healthcare Regulatory Excellence

Objective

2.20 The objective of sections 113-118 was to change the name of the Council for the Regulation of Healthcare Professionals to the Council for Healthcare Regulatory Excellence, and to amend its constitution and functions.

Implementation

2.21 Sections 113-118 generally came into force on 1 January 2009.³⁰

Secondary legislation etc

2.22 Regulations on the Council's membership, to help it adopt a more strategic role, came into force on 1 January 2009.³¹

- 29. http://professionalstandards.org.uk/regulators/overseeing-regulators/performance-reviews
- 30. Some elements of section 118 that made amendments consequential on the establishment of OHPA have not been commenced, because of the decision not to proceed with the creation of OHPA
- 31. The Council for Healthcare Regulatory Excellence (Appointment, Procedure etc.) Regulations 2008 (SI 2008/2927).

Legal issues

2.23 None.

Other reviews

- 2.24 Following the Coalition Government's review of arm's length bodies in 2010³² it was decided that:
- the Council should be more independent of the Department of Health. This should be achieved by making it self-funding and by giving the Privy Council responsibility for appointments previously made by the Secretary of State.
- the Council's remit should be extended to the oversight of the regulation of social workers, and its name should be changed accordingly.

Assessment

- 2.25 Sections 113-118 achieved their objective of renaming the Council and amending its constitution and functions.
- 2.26 Further changes were identified as desirable in the light of the review of arm's length bodies (see above). The relevant primary legislation was included in the Health and Social Care Act 2012 and is in the process of being implemented. In particular, the name change to the Professional Standards Authority for Health and Social Care took effect on 1 December 2012.

Conduct and performance of medical practitioners and other health care workers

Sections 119 and 120: Responsible officers

Objective

2.27 The objectives of sections 119 and 120 were to create powers to make regulations:

- to require designated bodies to nominate or appoint "responsible officers" to have responsibilities relating to the evaluation of fitness to practise of doctors (regulatory functions);
- to extend the role of responsible officers to monitoring conduct and performance (clinical governance functions).

Implementation

2.28 Section 119 (which was for the Department of Health to implement in Scotland and Wales as well as in England) and section 120 came into force on 1 April 2010.

Secondary legislation etc

2.29 Regulations made under the powers created by sections 119-120 came into force on 1 January 2011.³³ Associated guidance was issued in July 2010.³⁴

- 33. The Medical Profession (Responsible Officers)
 Regulations 2010 (SI 2010/2841). These have
 been amended from 1 April 2013 to take account
 of changes to NHS structures: see The Medical
 Profession (Responsible Officers) (Amendment)
 Regulations 2013 (SI 2013/391).
- 34. The role of responsible officer: Closing the gap in medical regulation Responsible officer guidance https://www.gov.uk/government/publications/closing-the-gap-in-medical-regulation-responsible-officer-guidance

^{32. &}lt;a href="https://www.gov.uk/government/publications/">https://www.gov.uk/government/publications/ public-bodies-reform-reports

Legal issues

2.30 None.

Other reviews

2.31 None.

Assessment

2.32 Sections 119-120 achieved their objectives of requiring designated bodies to nominate or appoint responsible officers to have responsibilities relating to the regulation of doctors, and of extending the role of responsible officers to clinical governance issues.

Section 121: Co-operation between prescribed bodies

Objective

2.33 The objective of section 121 was to create a general responsibility on healthcare organisations, and other specified bodies, 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.

Implementation and Secondary Legislation etc

2.34 Consultation took place in March-July 2010 on draft regulations to be made under section 121. Respondents to the consultation were not convinced of the need for further legislation. In the light of that, the Government announced on 1 February 2012 that it had decided not to proceed with developing the regulations.³⁵ Accordingly, section 121 has not been commenced and no secondary legislation has been made under it.

Legal issues

2.35 None.

Other reviews

2.36 None.

Assessment

2.37 Section 121 did not meet its objective because of the decision, following consultation, not to implement it. Instead, a number of measures and guidance to support sharing of information by health care organisations have been put in place since the Health and Social Care Act 2008, as summarised in *Guiding principles for sharing information on healthcare workers*, published jointly by NHS Employers and the Independent Healthcare Advisory Service, in January 2013.³⁶

Section 122: Sections 120 and 121: Crown application

2.38 Section 122 made clear that sections 120 and 121 bind the Crown (and so is not considered separately). It came into force on 1 April 2010 (except in relation to Northern Ireland).

Section 123: Dissolution of the Hearing Aid Council

Objective

2.39 The objective of section 123 was to abolish the Hearing Aid Council and transfer responsibility for the regulation of private hearing aid dispensers to the Health Professions Council.

^{35. &}lt;a href="https://www.gov.uk/government/news/summary-of-consultation-responses-proposed-duty-of-co-operation">https://www.gov.uk/government/news/summary-of-consultation-responses-proposed-duty-of-co-operation

^{36. &}lt;a href="http://www.nhsemployers.org/Aboutus/">http://www.nhsemployers.org/Aboutus/
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Implementation

2.40 Section 123 has been fully in force since 1 August 2010.

Secondary legislation etc

2.41 An order in force from 1 April 2010 transferred responsibility for regulation, and the register, of hearing aid dispensers from the Hearing Aid Council to the Health Professions Council.³⁷

Legal issues

2.42 None.

Other reviews

2.43 None.

Assessment

2.44 Section 123 achieved its objective.

Sections 124-125: Social workers

Section 126: Education and training of approved mental health professionals

Objective

2.45 The objectives of these sections, as regards England, were:

- to give the Secretary of State powers to make regulations modifying the regulation of social care workers (section 124) and the functions of the General Social Care Council in relation to the education and training of approved mental health professionals (section 126); and
- to require the General Social Care Council to use the civil standard of proof (as opposed to the criminal standard) in any proceeding relating to fitness to practise or conduct (section 125).

Implementation

2.46 Sections 124-126 have not been commenced because of a subsequent decision (see below) to abolish the General Social Care Council.

Secondary legislation etc

2.47 None.

Legal issues

2.48 None.

Other reviews

2.49 Following the Coalition Government's review of arm's length bodies in 2010³⁸ it was decided to abolish the General Social Care Council and transfer the regulation of social workers in England to the Health and Care Professions Council.

Assessment

- 2.50 Sections 124-126 did not achieve their objective in relation to England because of a subsequent decision (taken forward by Part 7 of the Health and Social Care Act 2012):
- to transfer the General Social Care Council's functions to the Health and Care Professions Council (put into effect on 1 August 2012) and abolish the General Social Care Council (on 1 October 2012); and
- to widen the power provided by section 60 of the Health Act 1999 so that Her Majesty can make Orders in Council under it that deal with regulation of social care workers in England.

(As explained under section 112 above, the Health and Care Professions Council has been required to apply the civil standard of proof to its proceedings since November 2008.)

^{37.} The Health Professions (Hearing Aid Dispensers) Order 2010 (SI 2010/233).

^{38. &}lt;a href="https://www.gov.uk/government/publications/">https://www.gov.uk/government/publications/ public-bodies-reform-reports

Part 3: Public Health Protection

Objective

3.1 The objective of Part 3 was to update the Public Health (Control of Disease) Act 1984, taking account in particular of the "all hazards approach" reflected in the International Health Regulations of the World Health Organisation, rather than focusing on specified infectious diseases.

Implementation

3.2 Section 129 has been fully in force since 6 April 2010. Most of section 130 came into force on the same date. The intention is to bring the remainder³⁹ into force at the same time as the planned new port health regulations (see below).

Secondary legislation etc

- 3.3 Four sets of regulations have been made under the powers created by section 129:
- the first, which came into force on 1 April 2009, place an obligation on the Secretary of State to accept certain recommendations of the Joint Committee for Vaccination and Immunisation regarding national vaccination programmes and to make arrangements for such programmes to be implemented;⁴⁰
- 39. Section 130(1) and Part 3 of Schedule 15 in so far as they relate to repeal of sections 13-15 and 76 of the Public Health (Control of Disease) Act 1984.
- 40. The Health Protection (Vaccination) Regulations 2009 (SI 2009/38).

- the other three came into force mostly on 6 April 2010. They:
 - create a scheme for notifying actual and suspected cases of infection and contamination in humans to specified bodies with public health responsibilities;⁴¹
 - made provision in relation to orders under the provisions introduced by section 129;⁴² and
 - give local authorities discretionary powers to take action to protect public health, by allowing them to impose restrictions or requirements in certain limited circumstances, and through formal powers to request cooperation for health protection purposes and to disinfect or decontaminate things or premises on request.⁴³

The regulations have since been amended as necessary to take account of the changes to NHS structure and to public health arrangements made by the Health and Social Care Act 2012.

- 41. The Health Protection (Notification) Regulations 2010 (SI 2010/659). (The provisions in these regulations relating to laboratory notifications came into force on 1 October 2010.)
- 42. The Health Protection (Part 2A Orders) Regulations 2010 (SI 2010/658).
- 43. The Health Protection (Local Authority Powers) Regulations 2010 (SI 2010/657).

- 3.4 The Department of Health and the Health Protection Agency, in consultation with the Chartered Institute of Environmental Health, published guidance in March 2010 to accompany the updated primary and secondary legislation.⁴⁴
- 3.5 There will be a further set of regulations to complete the modernisation of the legal framework for port health (arrangements at points of entry to the UK), on which the Department of Health plans to consult in spring/summer 2013.

Legal issues

3.6 None.

Other reviews

3.7 None of Part 3 as a whole (although see below on monitoring of applications for orders).

Assessment

3.8 Part 3 achieved its objective of updating provisions in the Public Health (Control of Disease) Act 1984 that had become substantially out of date. It replaced them with more flexible arrangements, which can respond in a proportionate and targeted way to a wider range of hazards and which offer better safeguards for people who might be affected by use of the powers.

3.9 Following consultation in 2009, and to ensure transparency about the frequency and purpose of applications for orders under the new powers, the Government decided that the Health Protection Agency would monitor applications by local authorities to justices of the peace under the powers created by Part 3, and would publish details of them, with appropriate redactions, on an annual basis.⁴⁵ Public Health England took responsibility for this from 1 April 2013.

^{44. &}lt;a href="http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 114510">http://webarchive.nationalarchives.gov.uk/en/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 114510

Part 4: Health in Pregnancy Grant

Objective

4.1 The objective of Part 4 was to create the Health in Pregnancy Grant, to make support available to all expectant mothers in the UK in recognition of the importance of a healthy life-style. HM Revenue and Customs were to be responsible for the payment and management of the grant.

Implementation

4.2 Part 4 came into force on 1 January 2009.

Secondary legislation etc

- 4.3 Part 4 provided regulation-making powers for the Treasury and for HM Revenue and Customs. Two sets of regulations came into force on 1 January 2009⁴⁶ and one on 6 April 2009.⁴⁷
- 46. The Health in Pregnancy Grant (Entitlement and Amount) Regulations 2008 (SI 2008/3108), which prescribed the conditions that needed to be satisfied for a woman to be entitled to the grant (that is, to be pregnant; to have reached the 25th week; and to have received advice on matters of maternal health); and the Health in Pregnancy Grant (Administration) Regulations 2008 (SI 2008/3109), which set out responsibility for payment and how the grant was to be administered.
- 47. The Health in Pregnancy Grant (Notices, Revisions and Appeals) (No.2) Regulations 2009 (SI 2009/751), which allowed for decisions on entitlement to the grant to be revised or challenged. These regulations replaced a previous set that had been due to come into force on the same date (The Health in Pregnancy Grant (Notices, Revisions and Appeals) Regulations 2009 (SI 2009/713)).

Legal issues

4.4 None.

Other reviews

4.5 The Government announced as part of the Budget on 22 June 2010 that the grant would be abolished. Accordingly, section 3 of the Savings Accounts and Health in Pregnancy Grant Act 2010 removed entitlement to a grant from women in the UK who reached the 25th week of their pregnancy on or after 1 January 2011.

Assessment

4.6 In 2009/10 around 850,000 women received the grant (£190) at a cost of around £160m. Following its abolition, pregnant women on low incomes continue to receive support through the Healthy Start scheme which provides vouchers for fruit, vegetables and milk from the tenth week of pregnancy.

Part 5: Miscellaneous

5.1 Part 5 made miscellaneous other provision, as follows.

Amendments relating to the National Health Service

Section 139: Duty of Primary Care Trusts

Objective

5.2 Section 139 put a new duty on Primary Care Trusts (PCTs) to make arrangements to secure continuous improvement in the quality of the healthcare they provide or arrange. The new duty was aligned more closely than its predecessor with the duty imposed on English local authorities by section 3 of the Local Government Act 1999.

Implementation

5.3 Section 139 came into force on 1 April 2010.

Secondary legislation etc

- 5.4 There was no specific power to make secondary legislation in relation to section 139.
- 5.5 The Review of Early Warning Systems⁴⁸ issued by the National Quality Board in February 2010 reminded PCTs of the new duty. (The National Quality Board brings
- 48. http://webarchives.gov.uk/en/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 113020

together national organisations across the health system responsible for quality.)

Legal issues

5.6 None.

Other reviews

5.7 None specifically of section 139.

Assessment

- 5.8 Section 139 achieved its objective of putting a new duty on PCTs in relation to quality.
- 5.9 Subsequently, PCTs were abolished on 1 April 2013. The provision that section 139 inserted into the NHS Act 2006 was repealed from the same date. However, the bodies that have taken on most of the commissioning functions previously exercised by PCTs (that is, clinical commissioning groups, NHS England and the Secretary of State) have been placed under broadly similar duties as to improvement in quality of services.⁴⁹ The National Quality Board in January 2013 published Quality in the new health system: Maintaining and improving quality from April 2013.50 This takes account of the duties that apply from 1 April 2013 and focuses predominantly on preventing, identifying and responding to serious failures in quality.
- 49. See sections 1A (Secretary of State), 13E (the NHS Commissioning Board) and 14R (clinical commissioning groups) of the NHS Act 2006, inserted by sections 2, 23 and 26 of the Health and Social Care Act 2012.
- 50. https://www.gov.uk/government/publications/guality-in-the-new-health-system-maintaining-and-improving-quality-from-april-2013

Sections 140-141: Pharmaceutical services

Objective

5.10 The objectives of these sections were:

- to devolve central funding for pharmaceutical services to PCTs (section 140); and
- to create a power for the Secretary of State by regulations to appoint PCTs or other persons to determine the funding for essential pharmaceutical services (section 141).

Implementation

5.11 Section 140 came into force on 1 April 2010, and section 141 on 1 April 2013 (to the extent that they are not in the legislative competence of the National Assembly for Wales).

Secondary legislation etc

5.12 Regulations appointing a determining authority in relation to certain fees and allowances for essential pharmaceutical services came into force on 1 April 2013.⁵¹

Legal issues

5.13 None.

Other reviews

5.14 None specifically of sections 140 and 141.

Assessment

5.15 The objectives of sections 140 and 141 have both now been achieved. As a result of the Health and Social Care Act 2012, NHS England has from 1 April 2013 taken on many of the primary care functions

51. See regulation 91 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (SI 2013/349).

previously performed by PCTs. The funding for pharmaceutical services that was included in PCT baseline allocations from April 2010 is now in NHS England's allocation, and since 1 April 2013 NHS England has been the determining body for the funding of certain essential pharmaceutical services.

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

Objective

5.16 The objective of section 142 was to make it possible to expand eligibility for membership of indemnity schemes to the Secretary of State and to non-NHS bodies when they provide NHS care.

Implementation

5.17 Section 142 came into force on 1 October 2008.

Secondary legislation etc

5.18 Regulations⁵² made under the power amended by section 142 came into force on 1 April 2013. They enable some non-NHS bodies, in specified circumstances. to join the Clinical Negligence Scheme for Trusts. Whilst the Secretary of State has not been made eligible to become a member of the scheme, the new regulations enable local authorities that provide, or arrange the provision of, services under arrangements with the Secretary of State to become members of the scheme: this would not have been possible if the primary legislation had not been amended to refer to the Secretary of State. The NHS Litigation Authority, which administers the scheme, publishes guidance on the scheme.⁵³

^{52.} The NHS (Clinical Negligence Scheme) Amendment Regulations 2013 (SI 2013/497).

^{53.} http://www.nhsla.com/Pages/Home.aspx

Legal issues

5.19 None.

Other reviews

5.20 None specifically of section 142, but the Secretary of State reported to Parliament in March 2013 on the treatment more generally of different providers.⁵⁴ The Monitor report published in association with this said the regulations (which expand access to the scheme to any provider of NHS care) help to address the fair playing field issue, by giving non-NHS organisations access to a scheme that previously only NHS organisations were able to access.⁵⁵

Assessment

5.21 Section 142 achieved its objective of making it possible to widen eligibility for membership of the NHS clinical negligence schemes.

Section 143: Weighing and measuring of children⁵⁶

Objective

5.22 The objective of section 143 was to provide a power to make regulations about the weighing and measuring of children, in particular to allow for the routine provision to parents of information about their children's results.

Implementation

5.23 Section 143 came fully into force on 1 October 2008.

- 54. Under section 1G of the NHS Act 2006, inserted by section 8 of the Health and Social Care Act 2012.
- 55. http://www.monitor-nhsft.gov.uk/sites/all/modules/fckeditor/plugins/ktbrowser/openTKFile.php?id=21414
- 56. Section 144 is within the legislative competence of the National Assembly for Wales.

Secondary legislation etc

5.24 Regulations⁵⁷ made under the power created by section 143 came into force on 5 January 2009. As envisaged when the Act was passed, they provided for:

- the Secretary of State's functions in relation to the weighing and measuring of children⁵⁸ to be exercisable by PCTs; and for
- the gathering and further processing of information collected through the National Child Measurement Programme (including the routine provision of information to parents).

5.25 The Department of Health has issued annual operational delivery guidance to reflect the provisions in the regulations.⁵⁹

Legal issues

5.26 None.

Other reviews

5.27 The National Audit Office published a briefing⁶⁰ on the Government's approach to tackling obesity in July 2012. This noted that feedback of results to parents had been implemented following a recommendation in 2007 by the House of Commons Committee of Public Accounts.

- 57. The National Child Measurement Programme Regulations 2008 (SI 2008/3080).
- 58. Under paragraph 7A(1) and (2) of the NHS Act 2006 (to make arrangements with local education authorities and proprietors of independent schools to provide for the weighing and measuring of children in schools).
- 59. The latest guidance is available at https://www.gov.uk/government/publications/national-child-measurement-programme-operational-guidance-for-the-2012-13-school-year
- 60. http://www.nao.org.uk/publications/1213/tackling_obesity_update.aspx

Assessment

5.28 Section 143 achieved its objective. The National Child Measurement Programme has been delivered by all PCTs annually, with data processed in line with the regulations. The programme is a core part of efforts locally and nationally to tackle obesity. It has National Statistics Status and underpins the Public Health Outcomes Framework Indicator on Excess Weight in 4-5 and 10-11 year olds.

5.29 To take account of the new public health system introduced by the Health and Social Care Act 2012, amendments to the 2008 legislation (both primary and secondary) came into force on 1 April 2013. The new secondary legislation⁶¹ also reduces the limitations on processing of anonymised data (which were found to be overly restrictive by stakeholders), and enables the return of additional identifiable data to the Health and Social Care Information Centre to bring improvements to the programme and add value in public health terms to the information collected. Under the revised legislation, the National Child Measurement Programme will continue as a function of local authorities in the new public health system.⁶²

Social care

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

Objective

5.30 The objective of section 145 was to ensure that the protections provided by the Human Rights Act 1998 apply to people

- 61. The Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013 (SI 2013/351).
- 62. The Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 (SI 2013/351).

receiving publicly arranged care in a private or voluntary sector care home.

Implementation

5.31 Section 145 came into force on 1 December 2008 (with one exception, which no longer applies).⁶³

Secondary legislation etc

5.32 Section 145 did not provide a power to make secondary legislation. The Department did not issue guidance on section 145.

Legal issues

5.33 Section 145 changed the law in the light of the decision in the case of YL v Birmingham City Council [2007] UKHL 27, [2008] 1 A.C. 95, which held that a private company providing residential accommodation under arrangements with a local authority was not carrying out a function of a public nature and was not a public authority for the purposes of the Human Rights Act 1998.

63. Article 2 of SI 2008/2994 provided that section 145 came into force on 1 December 2008, except in relation "to a person who is an adult placement carer within the meaning of regulation 46 of the Care Homes (Wales) Regulations 2002 (Rheoliadau Cartrefi Gofal (Cymru) 2002)." As the Welsh Assembly Government explained in a letter to Welsh local authorities and care homes in 2008 (http://www.assemblywales.org/eoc 3 opi awe 002 response from gwenda thomas am deputy minister for social services .pdf), the Welsh Assembly Government planned to remove adult placement carers from the regulations, so that they would no longer be required to register as a care home and as a consequence be unaffected by section 145. This amendment was made by the Adult Placement Schemes (Wales) (Miscellaneous Amendments) Regulations 2010 (SI 2010/2585) which came into force on 1 December 2010. Since that date, section 145 has in effect been fully in force.

Other reviews

5.34 The Equality and Human Rights Commission's report Close to home: An inquiry into older people and human rights in home care (2011)⁶⁴ acknowledged that the change in legislation gives direct protection under the Human Rights Act 1998 to residents of private and voluntary sector care homes whose places are arranged by local authorities.

Assessment

5.35 Section 145 has achieved its objective of ensuring that the protections provided by the Human Rights Act 1998 apply to people receiving publicly arranged care in an independent sector care home.

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

Objective

5.36 The objective of section 146 was to extend the direct payments scheme (whereby adults assessed as needing community care services have the opportunity to arrange their own personalised care) to adults who lack capacity (within the meaning of the Mental Capacity Act 2005).

Implementation

5.37 Subsections (1)-(7) of section 146 came fully into force in relation to England on 9 November 2009.⁶⁵

Secondary legislation etc

5.38 Regulations made under the power amended by section 146 also came into

force on 9 November 2009.⁶⁶ These included specific provisions setting out the circumstances where a local authority must, or may, make direct payments to persons lacking capacity.

5.39 Alongside the regulations, guidance was published to assist local authorities.⁶⁷ This was issued under section 7 of the Local Authority Social Services Act 1970, making it mandatory for authorities to follow.

Legal issues

5.40 None.

Other reviews

5.41 None specifically on section 146. The National Audit Office in 2011 reported on user choice in social care, including the use of personal budgets (which are an allocation of public money that may be taken by the individual as a direct payment). 68 Overall, the report found that the majority of users reported a positive impact on their well-being from having personal budgets, although a small minority felt worse off. There was no specific mention of section 146.

Assessment

5.42 Section 146 achieved its objective of changing legislation to make direct payments available to adults who lack capacity.

- 66. The Community Care, Services for Carers and Children's Services (Direct Payments) (England) Regulations 2009 (SI 2009/1887).
- 67. Guidance on direct payments For community care, services for carers and children's services, available at:
 - http://webarchive.nationalarchives.gov. uk/20130107105354/http://www.dh.gov.uk/ en/Publicationsandstatistics/Publications/ PublicationsPolicyAndGuidance/DH 104840
- 68. Oversight of User Choice and Provider
 Competition in Care Markets, available at: http://www.nao.org.uk/publications/1012/oversight_of-care_market.aspx

^{64. &}lt;a href="http://www.equalityhumanrights.com/legal-and-policy/inquiries-and-assessments/inquiry-into-home-care-of-older-people/close-to-home-report/">http://www.equalityhumanrights.com/legal-and-policy/inquiries-and-assessments/inquiry-into-home-care-of-older-people/close-to-home-report/

^{65.} Subsection (8) deals with matters in the competence of the National Assembly for Wales.

5.43 However, there is evidence that in practice some people still find it difficult to access direct payments. ⁶⁹ The Government is therefore planning further action in this area, as set out in the *Caring for our Future* White Paper and the associated draft Care and Support Bill, published in July 2012, and in Part 1 of the Care Bill, introduced in Parliament in May 2013.

Section 147: Abolition of maintenance liability of relatives

Objective

5.44 The objective of section 147 was to abolish the "liable relatives rule" in the National Assistance Act 1948 which required spouses to maintain each other and parents to support their children.

Implementation

5.45 Section 147 came into force on 6 April 2009.

Secondary legislation etc

5.46 Section 147 did not provide a power to make secondary legislation. The Department alerted local authorities to the abolition of the rule in a circular.⁷⁰

- 69. See, for example, the impact assessment that accompanied the Caring for our Future White Paper in 2012 (http://www.dh.gov.uk/health/files/2012/07/IA-Independence-choice-and-control-IA-7062-AnnexB-PDF-1458K.pdf). There was also evidence from the Caring for our future engagement exercise that local authorities are not making as much use as they might of the regulations enabling a suitable person to manage direct payments on behalf of users who lack capacity and are restricting this only to people appointed by the Court of Protection.
- 70. LAC(DH)(2009)3, available at http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/LocalAuthorityCirculars/DH_097576

Legal issues

5.47 None.

Other reviews

5.48 None.

Assessment

5.49 Section 147 achieved its objective of abolishing the "liable relatives" rule.

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

Objective

5.50 The objective of section 148 was to put in a place a mechanism to settle disputes about ordinary residence (for the purposes of the National Assistance Act 1948) between English and Welsh local authorities. It also made some adjustments to existing legislation concerning the meaning of NHS accommodation for the purposes of determining a person's ordinary residence.

Implementation

5.51 Section 148 came into force on 19 April 2010.

Secondary legislation etc

5.52 Section 148 did not create a power to make secondary legislation. A note was published providing an explanation of the transitional arrangements for bringing subsection (1) into force. Subsection (2) required the Secretary of State and the Welsh Ministers to publish arrangements for determining which disputes about ordinary

residence should be settled by the Secretary of State and which by the Welsh Ministers. This was done in 2010.⁷¹

Legal issues

5.53 None.

Other reviews

5.54 None.

Assessment

5.55 Section 148 has achieved its objective, in that the 2010 protocol has provided a clear mechanism for resolving disputes across the Wales/England border about ordinary residence.

5.56 The Department of Health is committed to giving more power to people using care and support services and to removing barriers to exercising choice and control. Working with the devolved administrations, it has included provision for cross-border placements between England and other parts of the UK in Part 1 of the Care Bill introduced in Parliament in May 2013.

Health and social care

Section 149-156: Financial assistance related to provision of health or social care services

Objective

5.57 The objective of sections 149-155 was to give the Secretary of State powers to finance:

 social enterprises delivering health and social care, and

71. The guidance and the protocol are available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH 114335

 social enterprises providing services related to health and social care, as long as the enterprises met certain conditions.

Implementation

5.58 Sections 149-156 have been fully in force since 1 April 2009.

Secondary legislation etc

5.59 Regulations under section 150 came into force on 14 April 2009 and make provision (in addition to that in sections 149-156) on the conditions that must be met if a body is to be a "qualifying body".⁷²

5.60 The power in section 153 for the Secretary of State to direct various NHS bodies to exercise his functions under section 149 (and to direct them on how to do so) has not been used. In the event, other levers were used to secure the intended objectives, including the Right to Request scheme established under the Transforming Community Services programme, requirements in the operational guidance for the Transforming Community Services programme, successive NHS Operating Frameworks, and use of the Social Enterprise Investment Fund to provide direct financial support to social enterprise spin-outs and start-ups.

Legal issues

5.61 None.

Other reviews

5.62 None.

Assessment

5.63 Sections 149-155 achieved their objective of allowing for continuation and development of the Social Enterprise Investment Fund. Between its establishment

^{72.} The Health and Social Care (Financial Assistance) Regulations 2009 (SI 2009/649).

in 2007 and 2013, the Fund invested more than £100m in health and social care social enterprises, making it the second largest funder of social enterprises in England. The Fund is acknowledged by the sector to have made a significant contribution to supplementing mainstream commercial lending activity in access to capital for social enterprises. It has enabled the transfer of £1bn of activity, 25,000 staff and 10% of community services from the NHS to over 40 social enterprises, through the Right to Request and Right to Provide spin-out programmes. Investment and policy priorities for the Fund have been reviewed annually.

5.64 In May 2012, the Government announced plans for a new pan-Whitehall fund for social enterprise, led by the Cabinet Office. 2012/13 was therefore the last active investment year of the Fund; future Fund loan-book returns and interest payments will constitute the Department's contribution to the new pan-Whitehall fund, which will operate on the basis of the powers provided by sections 149-156.

Sections 157-158: National Information Governance Board for Health and Social Care

Objective

5.65 The objective of section 157 was to create the National Information Governance Board as a single statutory body dealing with information governance matters for both health and social care.

5.66 The objective of section 158 was to require the Secretary of State to consult, and to have regard to any advice from, the Board where he proposed to make patient information regulations (under section 251 of the NHS Act 2006). This was to ensure that the views of the Board were sought and

considered before regulations relating to the processing of prescribed patient information for medical purposes (for example, sharing information) were laid before Parliament.

Implementation

5.67 Sections 157-158 came fully into force on 1 January 2009.

Secondary legislation etc

5.68 Regulations on the Board's membership and committees came into force on 27 October 2008.⁷³

5.69 The Secretary of State did not make any proposals for new regulations under section 251 during the lifetime of the Board, so the requirement to consult the Board was not engaged.

5.70 In line with its objective to advise on information governance matters, the Board in 2009 published a Care Record Guarantee⁷⁴ which sets out the rules that govern how patient information is used in the NHS and what control the patient can have over this. It also produced similar guidance for social care records.⁷⁵

Legal issues

5.71 None.

Other reviews

5.72 See below.

Assessment

5.73 Sections 157-158 achieved their objective of establishing the National Information Governance Board as a single statutory body and of requiring the Secretary of State to consult the Board before making regulations on patient information.

^{73.} The National Information Governance Board Regulations 2008 (SI 2008/2558).

^{74.} http://www.nigb.nhs.uk/guarantee

^{75.} http://www.nigb.nhs.uk/pubs/screngland

- 5.74 The Minister for the Cabinet Office announced the outcome of a cross-government review of over 900 public bodies in October 2011.⁷⁶ This proposed that the National Information Governance Board should be abolished, with its functions transferring elsewhere.
- 5.75 Consistently with this, the Board was abolished on 1 April 2013 and some of its functions were transferred to the Care Quality Commission.⁷⁷ The Secretary of State is now required (by section 215 of the NHS Act 2006) to consult CQC on proposals for regulations under section 251 of the NHS Act 2006. Advice to the Secretary of State about information governance is now provided from within the Department of Health or by other bodies (for example, the Health Research Authority).

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

Objective

5.76 The objective of section 159 was to abolish the National Biological Standards Board and give its functions to the Health Protection Agency.

Implementation

5.77 Section 159 came fully into force on 1 April 2009.

Secondary legislation etc

5.78 A scheme came into force on 1 April 2009 to transfer assets and liabilities of the National Biological Standards Board to the Health Protection Agency. The Health

Protection Agency (Regulatory Oversight Committee) Directions came into force on the same date, to manage potential conflicts of interest arising from the transfer of the Board's functions to the Agency.

Legal issues

5.79 None.

Other reviews

5.80 None specifically of section 159.

Assessment

- **5.81** Section 159 achieved its objective of abolishing the National Biological Standards Board and giving its functions to the Health Protection Agency.
- 5.82 Subsequently, the current Government announced in July 2010 its plans for improving the public health system. In line with these plans, the Health Protection Agency was abolished on 1 April 2013.⁷⁸ From that date, functions in relation to biological substances are held by the Secretary of State or the Department of Health, Social Services and Public Safety in Northern Ireland, acting alone or jointly.⁷⁹ In practice, the functions relating to biological substances are now carried out by the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health.

^{76. &}lt;a href="https://www.gov.uk/government/publications/">https://www.gov.uk/government/publications/ public-bodies-reform-reports

^{77.} By section 280 of the Health and Social Care Act 2012.

^{78.} By section 56 of the Health and Social Care Act 2012.

^{79.} See section 57 of the Health and Social Care Act 2012.

Annex A: Commencement of Provisions in the Act

Section 170 of the Act brought certain provisions of the Act into force on the day of Royal Assent. Other provisions have been commenced by order. The table appended to the most recent commencement order has been updated to include the provisions commenced by that order and is reproduced below.⁸⁰

Provision	Date of Commencement	S.I. No.
Section 1(1)	1st October 2008	2008/2497 (C. 106)
Section 1(2)	1st April 2009	2009/462 (C. 31)
Section 1(3) (partially)	1st October 2008	2008/2497 (C. 106)
Section 1(3) (fully)	1st April 2009	2009/462 (C. 31)
Section 2(1)	1st October 2008	2008/2497 (C. 106)
Section 2(2)(a) (partially)	12th January 2009	2008/3168 (C. 143)
Section 2(2)(a) (fully)	6th April 2010	2010/807 (C. 53)
Section 2(2)(b) and (c)	1st April 2009	2009/462 (C. 31)
Sections 3 to 7	1st October 2008	2008/2497 (C. 106)
Section 8 (partially)	12th January 2009	2008/3168 (C. 143)
Section 8 (fully)	6th April 2010	2010/807 (C. 53)
Section 9	1st October 2008	2008/2497 (C. 106)
Section 10(3)	12th January 2009	2008/3168 (C. 143)
Section 10 (fully)	1st April 2009	2009/462 (C. 31)
Section 11	12th January 2009	2008/3168 (C. 143)
Section 12(1) to (5)	12th January 2009	2008/3168 (C. 143)
Section 12(6)	6th April 2010	2010/807 (C. 53)
Sections 13 to 15	6th April 2010	2010/807 (C. 53)
Section 16 (partially)	1st April 2009	2009/462 (C. 31)
Section 16 (fully)	11th December 2009	2009/3023 (C. 130)
Section 17(1), (3) and (4)	1st April 2009	2009/462 (C. 31)
Section 17 (fully)	1st October 2010	2010/807 (C. 53)

^{80.} The list does not include commencements by the Welsh Ministers of provisions only in relation to Wales. See the note as to earlier commencement orders at the end of S.I. 2011/986 (W. 143) (C. 39), which lists those commencements.

Dura da la u	D-4f	O. I. M
Provision	Date of Commencement	S.I. No.
Sections 18 and 19 (partially)	1st April 2009	2009/462 (C. 31)
Sections 18 and 19 (fully)	1st October 2010	2010/807 (C. 53)
Section 20 (partially)	12th January 2009	2008/3168 (C. 143)
Section 20 (fully)	6th April 2010	2010/807 (C. 53)
Sections 21 and 22	12th January 2009	2008/3168 (C. 143)
Sections 23 and 24	11th December 2009	2009/3023 (C.130)
Section 25 (partially)	12th January 2009	2008/3168 (C. 143)
Section 25 (fully)	11th December 2009	2009/3023 (C.130)
Section 26(1), (3) and (6) (partially)	12th January 2009	2008/3168 (C. 143)
Section 26(4) and (5)	1st April 2009	2009/462 (C. 31)
Section 26 (fully)	6th April 2010	2010/807 (C. 53)
Section 27 (partially)	12th January 2009	2008/3168 (C. 143)
Section 27 (fully)	6th April 2010	2010/807 (C. 53)
Section 28(1) to (4)(a) (partially)	12th January 2009	2008/3168 (C. 143)
Section 28(4)(c) and (d) (partially)	1st April 2009	2009/462 (C. 31)
Section 28 (fully)	6th April 2010	2010/807 (C. 53)
Sections 29 to 31 (partially)	1st April 2009	2009/462 (C. 31)
Sections 29 to 31 (fully)	1st October 2010	2010/807 (C. 53)
Section 32 (partially)	12th January 2009	2008/3168 (C. 143)
Section 32 (fully)	6th April 2010	2010/807 (C. 53)
Section 33 (partially)	1st April 2009	2009/462 (C. 31)
Section 33 (fully)	1st October 2010	2010/807 (C. 53)
Section 34(1) and (5)	1st April 2009	2009/462 (C. 31)
Section 34 (fully)	1st October 2010	2010/807 (C. 53)
Section 35	12th January 2009	2008/3168 (C. 143)
Section 36	1st April 2009	2009/462 (C. 31)
Section 37 (partially)	12th January 2009	2008/3168 (C. 143)
Section 37 (fully)	6th April 2010	2010/807 (C. 53)
Sections 38 and 39 (partially)	1st April 2009	2009/462 (C. 31)
Sections 38 and 39 (fully)	1st October 2010	2010/807 (C. 53)
Section 40	1st April 2009	2009/462 (C. 31)
Sections 41 and 42	11th December 2009	2009/3023 (C. 130)
Section 43	6th April 2010	2010/807 (C. 53)
Section 44 (partially)	12th January 2009	2008/3168 (C. 143)
Section 44 (fully)	6th April 2010	2010/807 (C. 53)

Provision	Date of Commencement	S.I. No.
Section 45	1st April 2010	2010/708 (C. 46)
Section 46(4) to (8)	1st October 2008	2008/2497 (C. 106)
Section 46 (fully)	1st April 2009	2009/462 (C. 31)
Section 47	1st October 2008	2008/2497 (C. 106)
Section 48	1st April 2009	2009/462 (C. 31)
Section 49	11th December 2009	2009/3023 (C.130)
Section 50	1st April 2009	2009/462 (C. 31)
Section 51 (partially)	1st April 2009	2009/462 (C. 31)
Section 51 (fully)	11th December 2009	2009/3023 (C.130)
Sections 52 to 59	1st April 2009	2009/462 (C. 31)
Sections 60 to 65 (partially)	12th January 2009	2008/3168 (C. 143)
Sections 60 to 65 (fully)	6th April 2010	2010/807 (C. 53)
Section 66 (partially)	1st October 2008	2008/2497 (C. 106)
Section 66 (partially)	1st April 2009	2009/462 (C. 31)
Section 66 (fully)	1st October 2010	2010/807 (C. 53)
Sections 67 to 71	1st April 2009	2009/462 (C. 31)
Section 72 (partially)	1st April 2009	2009/462 (C. 31)
Section 72 (fully)	11th December 2009	2009/3023 (C. 130)
Sections 73 to 75	1st April 2009	2009/462 (C. 31)
Sections 76 to 83	1st October 2008	2008/2497 (C. 106)
Section 84	1st April 2009	2009/462 (C. 31)
Section 85	1st October 2008	2008/2497 (C. 106)
Sections 86 and 87	1st April 2009	2009/462 (C. 31)
Section 88	1st October 2008	2008/2497 (C. 106)
Section 89	1st April 2009	2009/462 (C. 31)
Sections 90 to 94 (partially)	12th January 2009	2008/3168 (C. 143)
Sections 90, 93 and 94 (fully)	6th April 2010	2010/807 (C. 53)
Section 95 (partially)	1st October 2008	2008/2497 (C. 106)
Section 95 (partially)	1st April 2009	2009/462 (C. 31)
Section 95 (partially)	2nd November 2009	2009/2862 (C. 126)
Section 95 (partially)	1st April 2010	2010/708 (C. 46)
Section 95 (partially)	6th April 2010	2010/807 (C. 53)
Section 95 (fully)	1st October 2010	2010/807 (C. 53)
Section 96	1st April 2009	2009/462 (C. 31)
Section 97	1st October 2008	2008/2497 (C. 106)

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Section 98(1)	25th January 2010	2010/23 (C.3)
Section 98(3) (partially)	28th September 2009	2009/2567 (C. 109)
Section 98(3) (partially)	25th January 2010	2010/23 (C.3)
Section 107(1)	25th January 2010	2010/23 (C.3)
Section 107(4) (partially)	25th January 2010	2010/23 (C.3)
Section 108	25th January 2010	2010/23 (C.3)
Section 111 (partially)	1st October 2008	2008/2497 (C. 106)
Section 111 (partially)	1st January 2009	2008/3244 (C. 148)
Section 112 (partially)	3rd November 2008	2008/2717 (C. 120)
Section 113	1st January 2009	2008/3244 (C. 148)
Section 114	1st January 2009	2008/3244 (C. 148)
Sections 115 to 117	1st January 2009	2008/3244 (C. 148)
Section 118 (partially)	1st January 2009	2008/3244 (C. 148)
Section 119 (partially)	1st April 2010	2010/708 (C. 46)
Section 120 (partially)	1st April 2010	2010/708 (C. 46)
Section 121	1st April 2010	2010/708 (C. 46)
Section 122 (partially)	1st April 2010	2010/708 (C. 46)
Section 123(1)	1st August 2010	2010/708 (C. 46)
Section 123(2) (partially)	1st April 2010	2010/708 (C. 46)
Section 123(2) (fully)	1st August 2010	2010/708 (C. 46)
Section 123(3) to (6)	1st October 2008	2008/2497 (C. 106)
Section 127 (partially)	25th August 2008	2008/2214 (C. 100)
Section 127 (partially)	1st January 2009	2008/3244 (C. 148)
Section 127 (partially)	4th June 2009	2009/1310 (C. 71)
Section 127 (partially)	28th September 2009	2009/2567 (C. 109)
Section 127 (partially)	25th January 2010	2010/23 (C.3)
Section 129 (partially)	1st April 2009	2009/462 (C. 31)
Section 129 (fully)	6th April 2010	2010/708 (C. 46)
Section 130(1) (partially)	6th April 2010	2010/708 (C. 46)
Section 130(2)	6th April 2010	2010/708 (C. 46)
Sections 131 to 138	1st January 2009	2008/3137 (C. 136)
Section 139	1st April 2010	2010/708 (C. 46)
Section 140 (partially)	1st April 2010	2010/708 (C. 46)
Section 141 (fully)	1st April 2013	2013/159 (C.8)
Section 142	1st October 2008	2008/2497 (C. 106)

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Section 143	1st October 2008	2008/2497 (C. 106)
Section 144	1st August 2011	2011/986 (C. 39)
Section 145 (partially)	1st December 2008	2008/2994 (C. 129)
Section 146 (partially)	9th November 2009	2009/2567 (C. 109)
Section 146 (fully)	29th March 2011	2011/986 (C. 39)
Section 147	6th April 2009	2009/462 (C. 31)
Section 148	19th April 2010	2010/708 (C. 46)
Sections 149 to 154	1st April 2009	2008/2994 (C. 129)
Section 155	1st December 2008	2008/2994 (C. 129)
Section 156 (partially)	1st December 2008	2008/2994 (C. 129)
Section 156 (fully)	1st April 2009	2008/2994 (C. 129)
Section 157(1) (partially)	1st October 2008	2008/2497 (C. 106)
Section 157 (fully)	1st January 2009	2008/2497 (C. 106)
Section 158	1st January 2009	2008/2497 (C. 106)
Section 159(5)(a)	1st March 2009	2009/270 (C. 12)
Section 159 (fully)	1st April 2009	2009/270 (C. 12)
Section 160 (partially)	1st October 2008	2008/2497 (C. 106)
Section 160 (partially)	1st January 2009	2008/2497 (C. 106)
Section 166 (partially)	1st January 2009	2008/2497 (C. 106) and 2008/3244 (C. 148)
Section 166 (partially)	1st April 2009	2009/270 (C. 12) and 2009/462 (C. 31)
Section 166 (partially)	6th April 2009	2009/462 (C. 31)
Section 166 (partially)	1st April 2010	2010/708 (C. 46)
Section 166 (partially)	6th April 2010	2010/708 (C. 46) and 2010/807 (C. 53)
Section 166 (partially)	1st August 2010	2010/708 (C. 46)
Section 166 (partially)	1st October 2010	2010/807 (C. 53)
Section 166 (partially)	1st April 2013	2013/159 (C. 8)
Paragraphs 1 to 5 of Schedule 1	1st October 2008	2008/2497 (C. 106)
Paragraph 6(3) of Schedule 1	1st October 2008	2008/2497 (C. 106)
Paragraph 6(4) of Schedule 1 (partially)	1st October 2008	2008/2497 (C. 106)
Paragraph 6(6) to 6(8) of Schedule 1	1st October 2008	2008/2497 (C. 106)
Paragraph 7 of Schedule 1 (partially)	1st October 2008	2008/2497 (C. 106)
Paragraphs 8 to 12 of Schedule 1	1st October 2008	2008/2497 (C. 106)

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1st October 2008	2008/2497 (C. 106)
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1st October 2008	2008/2497 (C. 106)
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1st April 2009	2009/462 (C. 31)
1st April 2009	2009/462 (C. 31)
1st April 2009	2009/462 (C. 31)
1st April 2009	2009/462 (C. 31)
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1st April 2009	2009/462 (C. 31)
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	1st April 2009 1st October 2008 1st April 2009 1st October 2010 1st April 2009 1st April 2009 2nd November 2009 1st April 2009 2nd November 2009 2nd November 2009 2nd November 2009 1st April 2009

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Paragraphs 48 to 53 of Schedule 5	1st April 2009	2009/462 (C. 31)
Paragraph 54(b) of Schedule 5	1st October 2008	2008/2497 (C. 106)
Paragraph 54 of Schedule 5 (fully)	1st April 2009	2009/462 (C. 31)
Paragraph 55 of Schedule 5	1st April 2009	2009/462 (C. 31)
Paragraph 56(b) of Schedule 5	1st October 2008	2008/2497 (C. 106)
Paragraph 57(1) of Schedule 5 (partially)	1st October 2008	2008/2497 (C. 106)
Paragraph 57(2)(b) of Schedule 5	1st October 2008	2008/2497 (C. 106)
Paragraph 58(b) of Schedule 5	1st October 2008	2008/2497 (C. 106)
Paragraph 59(1) of Schedule 5 (partially)	1st October 2008	2008/2497 (C. 106)
Paragraph 59(2)(b) of Schedule 5	1st October 2008	2008/2497 (C. 106)
Paragraphs 56 to 59 of Schedule 5 (fully)	1st April 2009	2009/462 (C. 31)
Paragraphs 60 to 72 of Schedule 5	1st April 2009	2009/462 (C. 31)
Paragraph 73(b) of Schedule 5	1st October 2008	2008/2497 (C. 106)
Paragraph 73 of Schedule 5 (fully)	1st April 2009	2009/462 (C. 31)
Paragraphs 74 to 79 of Schedule 5	1st April 2009	2009/462 (C. 31)
Paragraph 80(b) of Schedule 5	1st October 2008	2008/2497 (C. 106)
Paragraph 80 of Schedule 5 (fully)	1st April 2009	2009/462 (C. 31)
Paragraphs 81 to 93 of Schedule 5	1st April 2009	2009/462 (C. 31)
Paragraph 94 of Schedule 5	1st October 2008	2008/2497 (C. 106)
Schedule 5 (fully)	1st October 2010	2010/807 (C. 53)
Paragraphs 1 to 3 of Schedule 6	25th January 2010	2010/23 (C.3)
Paragraphs 4 to 10 of Schedule 6	28th September 2009	2009/2567 (C. 109)
Paragraphs 11 to 14 of Schedule 6	25th January 2010	2010/23 (C.3)
Paragraphs 17 to 23 of Schedule 6	25th January 2010	2010/23 (C.3)
Paragraphs 1 and 2 of Schedule 8	1st January 2009	2008/3244 (C. 148)
Paragraph 3 of Schedule 8 (partially)	1st October 2008 and 1st January 2009	2008/2497 (C. 106) and 2008/3244 (C. 148)
Paragraph 4 of Schedule 8	1st January 2009	2008/3244 (C. 148)
Paragraph 5(1) to (3) of Schedule 8	1st January 2009	2008/3244 (C. 148)
Paragraph 5(4) of Schedule 8	1st October 2008	2008/2497 (C. 106)
Paragraphs 6 and 7 of Schedule 8	1st January 2009	2008/3244 (C. 148)
Paragraph 8(a) of Schedule 8	1st October 2008	2008/2497 (C. 106)
Paragraph 8(b) of Schedule 8	1st January 2009	2008/3244 (C. 148)
Paragraph 9 of Schedule 8	1st January 2009	2008/3244 (C. 148)
Paragraph 1 of Schedule 10	1st January 2009	2008/3244 (C. 148)

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25th January 2010	2010/23 (C.3)
1st January 2009	2008/3244 (C. 148)
28th September 2009	2009/2567 (C. 109)
1st January 2009	2008/3244 (C. 148)
28th September 2009	2009/2567 (C. 109)
25th January 2010	2010/23 (C.3)
1st January 2009	2008/3244 (C. 148)
1st January 2009	2008/3244 (C. 148)
1st January 2009	2008/3244 (C. 148)
1st January 2009	2008/3244 (C. 148)
25th January 2010	2010/23 (C.3)
1st January 2009	2008/3244 (C. 148)
1st January 2009	2008/3244 (C. 148)
1st January 2009	2008/3244 (C. 148)
25th August 2008	2008/2214 (C. 100)
25th August 2008	2008/2214 (C. 100)
4th June 2009	2009/1310 (C. 71)
25th January 2010	2010/23 (C.3)
1st January 2009	2008/3244 (C. 148)
1st January 2009	2008/3244 (C. 148)
28th September 2009	2009/2567 (C. 109)
6th April 2010	2010/708 (C. 46)
1st April 2010	2010/708 (C. 46)
6th April 2009	2009/462 (C. 31)
1st October 2008	2008/2497 (C. 106)
1st January 2009	2008/2497 (C. 106)
1st April 2009	2009/462 (C. 31)
1st April 2009	2009/462 (C. 31)
1st April 2010	2010/708 (C. 46)
6th April 2010	2010/807 (C. 53)
1st October 2010	2010/807 (C. 53)
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Part 2 of Schedule 15 (partially)	1st April 2010	2010/708 (C. 46)
Part 2 of Schedule 15 (partially)	1st August 2010	2010/708 (C. 46)
Part 3 of Schedule 15 (partially)	6th April 2010	2010/708 (C. 46)
Part 4 of Schedule 15 (partially)	1st April 2010	2010/708 (C. 46)
Part 4 of Schedule 15 (partially)	1st April 2013	2013/159 (C. 8)
Part 5 of Schedule 15	6th April 2009	2009/462 (C. 31)
Part 6 of Schedule 15	1st January 2009	2008/2497 (C. 106)
Part 7 of Schedule 15	1st April 2009	2009/270 (C.12)



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