Department of Health

Post-Legislative Assessment of the Health Act 2006

Memorandum to the Health Committee of the House of Commons

Post-Legislative Assessment of the Health Act 2006

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

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Introduction

1. This memorandum provides a preliminary assessment of the Health Act 2006[1] and has been prepared by the Department of Health for submission to the Health Committee of the House of Commons. It is published as required by the process set out in the document *Post-legislative Scrutiny – The Government's Approach* (Cm 7320).[2]

2. This assessment does not cover aspects of the Act which are within the legislative competence of the devolved administrations.

Objectives of the Health Act 2006

3. The Act has seven parts:

- **Part 1, Chapter 1** makes provision for the **prohibition of smoking in certain premises**, places and vehicles in England and Wales (referred to as 'smoke-free' provisions).
- **Part 1, Chapter 2** provides powers (in England and in Wales) for the Secretary of State for Health to **change the minimum age of sale of tobacco products** through secondary legislation.
- **Part 2** provided the Secretary of State with powers to issue a code of practice relating to the **prevention and control of healthcare-associated infections**.
- **Part 3 contains provisions relating to drugs, medicines and pharmacies which extend to the whole of the United Kingdom. Part 3, Chapter 1** enables provision to be made for new duties and powers intended to strengthen the arrangements for the safe **management of controlled drugs** in health and social care settings.
- **Part 3, Chapter 2** amended provisions of the Medicines Act 1968, and also a provision of the Health Act 1999, in order to **allow pharmacies and pharmacists greater freedom and flexibility in conducting pharmacy business**, including better use of all staff working in pharmacies.
- **Part 4 made further provision about the NHS in England and Wales. Part 4, Chapter 1** concerns direction-giving powers in relation to fees for applications in respect of **pharmaceutical services** provided under section 41 of the National Health Service Act 1977.
- **Part 4, Chapter 2** introduced a new 'contract system' for the provision of **ophthalmic services**.
- **Part 4, Chapter 3** provided powers in connection with **counter-fraud and security management** functions in relation to the health service in England and Wales.

1 www.legislation.gov.uk/ukpga/2006/28/contents
2 www.official-documents.gov.uk/document/cm73/7320/7320.asp

- **Part 4, Chapter 4** made provision for the **auditing of the accounts** of certain NHS bodies in England and Wales.
- **Part 5 establishes the Appointments Commission** as an executive non-departmental public body and provides powers to enable it to make public appointments to the NHS, the Department of Health and other public bodies.
- **Part 6**, among other things, allowed for contributory negligence to be taken into account in **injury cost recovery** cases in England, Wales and Scotland, and includes other miscellaneous provisions.
- **Part 7** contains final provisions for various **matters of general application**, including provisions for offences by bodies corporate, partnerships and other unincorporated associations, and provisions relating to orders and regulations, interpretation, commencement and extent.

4. The regulatory impact assessments produced to accompany the Bill in 2005 are available on the Department of Health's website.[3]

5. The Health Act 2006 received Royal Assent on 19 July 2006.

Other post-legislative reviews

6. Since the Act was passed, there have been a number of additional reviews on various aspects of the policies reflected in the Act. These are listed below according to the respective part of the Act.

Part 1

- July 2008 – The Department of Health report *Smokefree England: One Year On*[4] outlined the initial effects of the legislation.
- March 2011 – An academic review of the evidence of the impacts of the smoke-free legislation was published alongside *Healthy Lives, Healthy People: A Tobacco Control Plan for England*.[5]

Part 2

- June 2009 – Report by the Comptroller and Auditor General, *Reducing Healthcare Associated Infections in Hospitals in England*, HC 560 Session 2008–2009.[6]
- October 2009 – The Care Quality Commission's (CQC's) *NHS Performance Ratings 2008/09: An Overview of the Performance of NHS Trusts in England*.[7]

3 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4121917

4 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085811

5 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_124917

6 www.official-documents.gov.uk/document/hc0809/hc05/0560/0560.asp

7 www.cqc.org.uk/publications.cfm?fde_id=13085

Part 3

- Since 2008, the CQC has published annual reports, which describe the progress made in implementing the requirements of the management of controlled drugs in England and highlight any particular problems.

Part 4

- In its *Twenty-first Report of Session 2007–08*,[8] the Joint Committee on Statutory Instruments reported on the Primary Ophthalmic Services Regulations 2008 (Statutory Instrument (SI) 2008/1186) for defective drafting. The Department of Health's response is contained in the same report.
- Department of Health ministers are considering the outcome of the review of charges for applications to provide NHS pharmaceutical services.

8 www.publications.parliament.uk/pa/jt200708/jtselect/jtstatin/121/121.pdf

Preliminary assessment of the effect of key elements of the Health Act 2006

Impact assessment and equality analysis

7. No formal impact assessment of the Act as a whole has been carried out since its implementation. However, its impact in individual areas continues to be kept under review, as described in the paragraphs that follow.

8. Policies within the Act gave only limited consideration to equalities issues, primarily concerning race equality. However, the implementation of these policies has impacted positively in some areas, such as smoke-free law, in particular in relation to disability and gender.

Smoke-free law

Objective

9. The purpose is to:

- reduce the risk to health from exposure to second-hand smoke;
- recognise a person's right to be protected from harm and to enjoy smoke-free air;
- increase the benefits of smoke-free enclosed public places and workplaces for people trying to give up smoking, so that they can succeed in an environment where social pressures to smoke are reduced; and
- save thousands of lives by reducing overall smoking rates.

Legislation

10. The Act makes provision for enclosed and substantially enclosed public places and shared workplaces to be smoke-free, and:

- provides powers for the appropriate national authority to make regulations to specify additional places as smoke-free and to require specified types of vehicles to be smoke-free;
- requires smoke-free signs to be displayed next to smoke-free premises, places and vehicles;
- gives the appropriate national authority powers to make regulations to exempt premises or parts of premises from smoke-free legislation, although, in general, no exemptions can be made for premises operating under a premises licence or club premises certificate (as specified in the Licensing Act 2003); and
- establishes offences for breach of smoke-free provisions.

11. Under powers in the Act, the following regulations have been made with respect to England:

- The Smoke-free (Premises and Enforcement) Regulations 2006 (SI 2006/3368), which set out the meaning of 'enclosed' and 'substantially enclosed' premises, and specify the enforcement authorities for the legislation.

- The Smoke-free (Signs) Regulations 2007 (SI 2007/923), which set out requirements for signs in premises and vehicles to be smoke-free.
- The Smoke-free (Exemptions and Vehicles) Regulations 2007 (SI 2007/765), which set out exemptions from the smoke-free requirements of the Act, and the vehicles that are to be smoke-free.
- The Smoke-free (Vehicle Operators and Penalty Notices) Regulations 2007 (SI 2007/760), which set out duties to prevent smoking on smoke-free vehicles and the form of fixed penalty notices.

12. The Smoke-free (Penalties and Discounted Amounts) Regulations 2007 (SI 2007/764) have been made with respect to England and Wales. These regulations specify the penalties and discounted amounts for the purposes of the smoking offences set out in Chapter 1 of Part 1 of the Act.

Implementation

13. The White Paper,[9] *Choosing Health: Making Healthy Choices Easier,* published in November 2004, set out the Government's proposals to shift the balance significantly in favour of smoke-free environments.

14. Local authorities are responsible for enforcing smoke-free legislation in England. They worked closely with businesses in the run-up to 1 July 2007 in order to build a supportive environment where people were encouraged and provided with information to enable them to comply with the new laws. The hard work of local authorities in building compliance was a major factor in the high levels of compliance we now see.

Impact

15. The legislation has proved effective, popular and well complied with. Around three-quarters of people in England say they support the legislation and, after three years of the law being in place, the national compliance rate was over 98% (measured by the number of premises and vehicles required to be smoke-free that were properly complying with the law when inspected by enforcement authorities). The latest smoke-free legislation compliance data for England is online at www.smokefreeengland.co.uk/files/83840-coi-smokefree-compliance_period_tagged-13.pdf

16. A report from the Better Regulation Executive (BRE) showed that there had been considerable benefits to business as a result of smoke-free legislation in workplaces and public places and the way in which it was implemented. The BRE report, *Better Regulation, Better Benefits: Getting the Balance Right*,[10] published in October 2009, used the implementation of the smoke-free law in workplaces and public places throughout the United Kingdom as a case study to illustrate good practice. The BRE states: 'The reduction in exposure to secondhand smoke and the general improvement in public health, along with the reductions in losses to business in terms of sickness and other costs have made a favourable impact on the UK economy. It is clear that this is a beneficial regulation.'

9 http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4094550

10 www.bis.gov.uk/files/file53251.pdf

17. *Healthy Lives, Healthy People: A Tobacco Control Plan for England*, published on 9 March 2011, sets out how tobacco control is intended to be delivered in the context of the new public health system. It focuses, in particular, on the action that the Government intends to take nationally over the next five years in order to drive down the prevalence of smoking and to support comprehensive tobacco control in local areas. Alongside the Tobacco Control Plan, an academic review of the evidence[11] of the impact of the smoke-free legislation was published. The evidence is clear that smoke-free legislation has had beneficial effects on health.

Legal challenge

18. In 2008, the High Court ruled in favour of Nottinghamshire Healthcare NHS Trust and the Secretary of State for Health after a patient sought judicial review of the smoke-free legislation using Article 8 of the European Convention on Human Rights (ECHR) against the Trust's smoke-free policy as it applied to Rampton Special Hospital. Following an appeal by the patients of Rampton Special Hospital in 2009, the Court of Appeal upheld the decision of the High Court that Rampton Special Hospital patients had no legal right to smoke in the secure hospital under Article 8 of the ECHR. The patients argued that, as smoking is permitted in prisons, they were being discriminated against because of their mental health problems, contrary to Article 14 of the ECHR. The Court of Appeal decided that since the patients' right to smoke fell outside the ambit of Article 8, Article 14 was not engaged. The Court added that, even if Article 14 had been engaged, the different treatment of patients compared with prisoners was justified, observing that mental health units and prisons provide very different services.

Age of sale of tobacco products

Legislation

19. A power to change the minimum age for tobacco sales was included in the Act. The Children and Young Persons (Sale of Tobacco etc.) Order 2007 (SI 2007/767) amends the Children and Young Persons Act 1933 and the Children and Young Persons (Protection from Tobacco) Act 1991 to:

- make it an offence for retailers to sell tobacco or cigarette papers to anyone under 18 (previously 16); and
- require notices in retail premises and on tobacco vending machines to reflect this change.

This applies to England and Wales.

Implementation

20. There was approximately eight months between the making of the regulations and the change in age coming into force. During this period, there was a communication campaign to increase awareness of the change, with information for retailers, and advertisements in the trade press and magazines and internet sites aimed at young people.

Impact

21. The age of sale of tobacco was increased from 16 to 18 on 1 October 2007.

11 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_124961

Academic research[12] has found that there was a greater fall in prevalence of smoking in 16–17-year-olds in England following the increase in the age of sale than in older age groups. This suggests that raising the age of sale can, at least in some circumstances, reduce smoking prevalence in younger age groups.

Prevention and control of healthcare-associated infections

Objective

22. The purpose is to focus the NHS more effectively on improving hospital hygiene and reducing the levels of infection significantly, and ensuring that tackling healthcare-associated infection is fully embedded in NHS management.

Legislation

23. The Health Act 2006 (Commencement No. 1 and Transitional Provisions) Order 2006 (SI 2006/2603 (C. 88)) brought into force the provisions of sections 14 to 16 of the Act. These provisions amended Chapters 2 and 3 of Part 2 of the Health and Social Care (Community Health and Standards) Act 2003 and gave the Secretary of State the power to issue a code of practice to specified NHS health bodies on the prevention and control of healthcare-associated infections. It also placed a duty on the CQC's predecessor health regulator, the Healthcare Commission, in exercising its functions, to take into account standards prepared and published by the Secretary of State in relation to the provision of healthcare by English NHS bodies and cross-border strategic health authorities (SHAs), including any code of practice issued by the Secretary of State under the new power and provided for the issue of improvement notices where it was thought that provisions of such a code were not being observed in England. The relevant provisions of the Health and Social Care (Community Health and Standards) Act 2003 were repealed and replaced by the Health and Social Care Act 2008, which brought the CQC into being in place of its predecessor bodies.

Implementation

24. A consultation took place in 2005 which included a proposal to enable the Secretary of State to publish a specific and detailed code of practice for the prevention and control of healthcare-associated infections, setting out a range of actions that NHS bodies should implement. The code of practice was published in October 2006. The code assists to ensure that patients of NHS organisations are cared for in a clean environment and that the risk of healthcare-associated infections is kept as low as possible. That code of practice has been superseded by the code of practice[13] on the prevention and control of infections, issued under Chapter 2 (section 21) of the Health and Social Care Act 2008, which sets out the criteria against which a registered provider's compliance will be assessed by the CQC.

12 Fiddler J and West R (2010) Changes in smoking prevalence in 16–17-year-old versus older adults following a rise in legal age of sale: findings from an English population study. *Addiction* 105(11): 1984–8.

13 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122604

Impact

25. The CQC's *NHS Performance Ratings 2008/09: An Overview of the Performance of NHS Trusts in England*[14] indicated that, in 2006/07 and 2007/08, all three core standards relating to the code of practice (infection control, decontamination and clean environments) appeared among the standards with the lowest compliance rates.

26. While compliance with all three core standards was low before the code of practice was first published in October 2006,[15] by 2008/09 compliance had improved on infection control and clean environments. Nationally, infection rates for both MRSA and *Clostridium difficile* fell by a third in 2008/09 when compared with 2007/08. Growing compliance with the code of practice could have contributed to those reductions.

27. The National Audit Office report of June 2009,[16] in its assessment of new national initiatives on healthcare-associated infection since 2004, stated: 'The Code of Practice has been effective in clarifying what is expected from trusts and ensuring engagement from chief executives and boards.'

14 www.cqc.org.uk/_db/_documents/0809_NHS_ratings_overview_document_161009_200910164847.pdf

15 http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4139336

16 Comptroller and Auditor General (2009) *Reducing Healthcare Associated Infections in Hospitals in England,* HC 560 Session 2008–2009, National Audit Office.

Supervision of management and use of controlled drugs

Objective

28. The purpose of the legislation is to safeguard patients in the community by improving the management and use of controlled drugs (such as morphine) and to minimise the risk of diversion to illegitimate uses. The measures provide the legislative underpinning to the programme of action set out in *Safer Management of Controlled Drugs: The Government's Response to the Fourth Report of the Shipman Inquiry*,[17] published in December 2004.

Legislation

29. The Act provides powers for a relevant authority to make regulations. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (SI 2006/3148):

- require all NHS healthcare organisations and larger private healthcare organisations to have an 'accountable officer' – to ensure that the organisation has robust arrangements for the safe and effective handling of controlled drugs;
- place a duty of co-operation on healthcare organisations, and on other local and national agencies, requiring them to share intelligence and to co-ordinate action taken for protecting patients and the public;
- give police officers, accountable officers and other authorised persons rights to enter and inspect the premises of relevant healthcare providers in order to enable them to discharge these responsibilities.

17 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4097904

Implementation

30. Regulations came into force in England and Scotland in early 2007 to give effect to provisions in the Act. In October 2007, the Department of Health published the guidance *Safer Management of Controlled Drugs: A Guide to Good Practice in Secondary Care (England)*[18] in order to help healthcare professionals and their organisations to implement the new arrangements. Since the introduction of the new arrangements, partner organisations have developed systems and services in order to manage controlled drugs more effectively and to assist the sharing of intelligence at local and national level.

31. The Department of Health monitored the initial implementation stage of the new legislation by NHS front-line staff, and private and voluntary organisations through the Healthcare Commission (now the CQC). The CQC is responsible for the full external scrutiny of the arrangements for the safer management of controlled drugs. The Department of Health monitors the arrangements through the CQC's National Steering Group, which has membership drawn from relevant national stakeholders.

Impact

32. The CQC, in its 2009 annual report *The Safer Management of Controlled Drugs*,[19] indicated that it was encouraged by the progress made by organisations in improving and embedding the systems and processes as envisaged in the legislation in managing controlled drugs. The CQC acknowledged the good work done to share intelligence at a local and national level. These developments confirmed that providers are better equipped to identify inappropriate or unusual prescribing and that patient safety remains top of their agenda. The report recommended that all chief executives and accountable officers should keep the management of controlled drugs a high priority on their organisation's agenda.

33. As a consequence, in August 2010, the Chief Pharmaceutical Officer wrote to all primary care trust (PCT) chief executives and accountable officers highlighting the recommendations being made by the CQC in its 2009 annual report and reminding them of their statutory responsibilities for the safe management of controlled drugs.[20]

Responsible pharmacist and supervision

Objectives

The purpose is to:

- give pharmacies and pharmacists greater freedom and flexibility in conducting pharmacy business, including better use of all staff working in pharmacies;
- clarify the current legal requirements about the pharmacist's 'personal control' and supervision of the preparation, sale and supply of medicines, while maintaining and safeguarding the protection of the public; and

18 http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074513

19 www.cqc.org.uk/_db/_documents/20100802_CDAR_2009_FINAL.pdf

20 www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_118490

- see increased efficiency in the dispensing of prescriptions and ensure a wider range of services on offer at their local pharmacy, including improved access to pharmacist clinical advice and treatment.

Legislation

34. The Act amends the Medicines Act 1968 in order to provide regulation-making powers for the prescription of conditions that may require that each pharmacy is to have a responsible pharmacist in charge of the business where this relates to the sale and supply of medicines. In addition, the Act amends the Medicines Act 1968 to place a duty on the responsible pharmacist to secure the safe and effective running of the pharmacy and provide regulation-making powers under which regulations may require supervision of certain activities by pharmacists. The relevant regulations are contained in The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 (SI 2008/2789).

Implementation

35. In 2007, the Department of Health published a consultation paper that set out proposals for the content of the responsible pharmacist regulations.[21]

36. Factual guidance on the regulations[22] (*The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008: Guidance*) was issued by the Department of Health in February 2009. The Royal Pharmaceutical Society[23] issued professional standards and guidance (April 2009), including in relation to hospital pharmacy practice and the activities that can be undertaken when the responsible pharmacist is present or absent.

37. The powers, under section 72A(7)(c) of the Medicines Act 1968, as amended by the Health Act 2006, relating to the supervision of certain activities by pharmacists is an unused provision. However, the Government now proposes to make orders under the existing powers of the Medicines Act 1968 so as to enable registered and suitably trained staff working in a pharmacy to supervise certain aspects of the preparation, dispensing, sale and supply of medicines, without direct supervision by a pharmacist. The intention is to enable a pharmacist to use their clinical skills and training to offer a wider range of services, including away from the pharmacy, for example in health centres and clinics.

38. The responsible pharmacist regulations of 2008 will also be reviewed in the light of the outcome of a further public consultation on proposed changes to the requirement (in the Medicines Act 1968 and related NHS legislation) on pharmacists to supervise individual transactions involving the sale and dispensing of pharmacy medicines and prescription-only medicines.

Impact

39. The Department of Health is in discussion with the Royal Pharmaceutical Society to assess the impact of the responsible pharmacist regulations.

40. Between the responsible pharmacist regulations being laid (29 October 2008)

21 http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_085144

22 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_095570

23 www.rpharms.com/home/home.asp

and their coming into force (1 October 2009), some concerns were raised about compatibility with the EU Working Time Directive. The Department of Health considered those concerns and was satisfied that the regulations did not infringe the EU Working Time Directive or the Working Time Regulations 1998 (which implement that Directive).

Provision of NHS pharmaceutical services

Objectives

41. These measures had been identified in the previous government's response[24] to the report by the Office of Fair Trading, *The Control of Entry Regulations and Retail Pharmacy Services in the UK* (January 2003).[25]

42. The purpose is twofold:

- to allow reasonable charges to be made for applications to provide NHS pharmaceutical services; and
- to include consideration of the provision and accessibility of over-the-counter medicines and other healthcare products in assessments by a PCT of competing chemist applications. The intention was to increase competition and choice between pharmacies, resulting in better market outcomes of improved access and lower prices (or reduced pressures for price increases).

Legislation

43. The Act amended the National Health Service Act 1977 so as to provide direction-giving powers to enable charges to be levied on applications to provide NHS pharmaceutical services. In addition, it also provided regulation-making powers to enable provision to be made for PCTs to consider, in their assessment of applications to join the PCT's pharmaceutical providers list, the improvements the applicants would bring to the provision of, or access to, over-the-counter medicines and other healthcare products and advice related to such supply.

Implementation

44. Directions[26] (The National Health Service Pharmaceutical Services (Fees for Applications) (Amendment) Directions 2008) to implement charges for applications were issued to PCTs in April 2008.

45. Information on charging for PCTs to accompany the Directions was also published in April 2008. This information is now incorporated into *The NHS (Pharmaceutical Services) Regulations: Information for Primary Care Trusts – revised* (September 2009).[27]

46. Following representations from NHS and pharmacy representative bodies, which were concerned about PCTs' capability and capacity, the previous government decided in early 2008 not to proceed with the powers to enable PCTs to consider improvements to the provision of over-

24 House of Commons: Written Ministerial Statement: 17 July 2003: Cols 76WS–79WS.

25 www.oft.gov.uk/shared_oft/reports/comp_policy/oft609.pdf

26 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_083854

27 www.dh.gov.uk/en/Healthcare/Primarycare/Communitypharmacy/NHSpharmaceuticalregulations/Controlofentry/index.htm

the-counter medicines in their assessments of competing applications to join pharmaceutical providers' lists. The current government has not revisited this issue as yet.

Impact

47. The Department of Health conducted a review of charges for applications 18 months after their introduction. The review included consultation with interested parties, including pharmaceutical contractors and the NHS. Overall, no detrimental impact arising from the introduction of charges was identified and most respondents felt that the then fee levels set were fair and reasonable. Anecdotally, charging for applications appeared to have had some impact on reducing the number of speculative and frivolous applications, as well as improving the quality of applications generally. Current departmental ministers will be considering the outcome of this review.

Provision of primary ophthalmic services

Objectives

48. The purpose is to:

- allow PCTs to contract with anybody they consider appropriate for the provision of ophthalmic services, subject to certain safeguards, and to their employing properly qualified clinicians to undertake clinical work;
- create a framework for commissioning similar to other parts of primary care and which allows for commissioning of enhanced services locally; and
- improve controls over who may redeem optical vouchers to prevent fraud.

Legislation

49. The Act includes powers which have since been consolidated into the National Health Service Act 2006 at sections 115–125. These powers remove restrictions on whom PCTs may contract with to facilitate market entry and increase patient choice, and create a framework for commissioning primary ophthalmic services similar to other primary care services, which allows for commissioning of enhanced services locally. The Act also contains provisions intended to strengthen the protection of public funds through improved controls over who may redeem optical vouchers, in order to prevent fraud.

50. The relevant regulations are contained in SI 2008/1185, SI 2008/1186, SI 2008/1187 and SI 2008/1657,[28] and are made under powers in the National Health Service Act 2006.

Implementation

51. Guidance on the revised regulations, *The Primary Ophthalmic Services Regulations 2008: Guidance for Primary Care Trusts*,[29] was issued in 2008 and briefing events for

28 The General Ophthalmic Services Contracts Regulations 2008 (SI 2008/1185); The Primary Ophthalmic Services Regulations 2008 (SI 2008/1186); The National Health Service (Performers Lists) Amendment and Transitional Provisions Regulations 2008 (SI 2008/1187); The National Health Service (Optical Charges and Payments) Amendment (No. 2) Regulations 2008 (SI 2008/1657).

29 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_084751

the NHS were held to facilitate a smooth transition. This involved two processes:

- Providers already on the ophthalmic list were awarded contracts without the need to make a new application, provided there were no ongoing disciplinary or contractual issues.
- PCTs formally considered applications from businesses which had contracts under the 'grandfathering arrangement' (that is, the contract with the PCT was held by a provider with whom PCTs were legally able to contract with). PCTs sought declarations about criminal convictions and references in the same way as they would for any new applicant, and had to be satisfied with the premises, equipment and record-keeping arrangements of these businesses.

Impact

52. There has been no formal review of these arrangements but there has been no indication of difficulty in applying the new regulations or in managing applications for contracts.

Countering fraud and other unlawful activities against the NHS

Objectives

53. The purpose is to:

- help to minimise fraud, thereby helping to ensure that, year on year, extra investment in the NHS goes straight to patient care;
- prevent and investigate NHS security incidents and breaches, helping to make the NHS a safer and more secure place to work;
- enable trained specialists to investigate professionally, quickly and thoroughly alleged fraud and security incidents, in order to successfully conclude their investigations in the most efficient manner possible;
- allow counter-fraud and security management specialists to further their investigations without requiring immediate police or Audit Commission input; and
- allow independent access to documentation in contractors associated with the NHS in both the public and private sectors.

Legislation

54. No regulations were made under the Act. Chapter 3 of Part 4 of the Act was consolidated into Part 10 of the National Health Service Act 2006. The National Health Service Delegation of Functions to the NHS Business Services Authority (Counter Fraud and Security Management) Regulations 2008 (SI 2008/1148) are the first to be made under the powers conferred by sections 7(1), 199(2) to (5), 209(4) and 273(4) of the National Health Service Act 2006(a). The Act provides powers to require the production of documents in connection with the exercise of the Secretary of State's counter-fraud or security management functions, without needing to involve the police.

Implementation

55. The legislation was drafted in order to allow for the full range of security management activity, including intelligence gathering, analysis and loss measurement. *A Code of Practice for the Use of Powers to Counter NHS Fraud and Security Incidents*[30] was published in April 2008.

56. The conduct of investigations was the priority so the code of practice focused on that area. In line with the remit to tackle crime against the NHS, consideration is being given to how the powers may be used for anti-crime activity other than reactive investigation.

Impact

57. The new regulations, The National Health Service Delegation of Functions to the NHS Business Services Authority (Counter Fraud and Security Management) Regulations 2008 (SI 2008/1148), require the production of documents, including personal records, in order to tackle NHS fraud and prevent security incidents and breaches. They have proved to be valuable. The powers have enabled allegations to be investigated without always having to rely on police powers. This has increased the pace of the investigative process, as documents can be obtained without reliance on a police search warrant. Patient confidentiality can be maintained by ensuring that personal records remain within the NHS. To date, the powers have been used on 23 occasions.

58. In August 2009, a review was undertaken to assess the use of the powers since they became operational. Investigative staff reported that they had found the powers valuable and had not encountered difficulties when seeking to use them to progress an investigation. No individuals had failed to comply with a notice to require the production of documents served on them. Police powers had been used, instead of powers conferred by the National Health Service Act 2006, on some occasions where it was believed that the required documents could have been destroyed if a notice had been served.

Auditing of the accounts of certain NHS bodies

59. Section 56 concerning the audit requirements for special health authorities (SpHAs), cross-border SpHAs and SpHA charitable funds amends section 98 of the National Health Service Act 1977. These changes are of a technical nature and have not been assessed.

Appointments Commission

Objective

60. The purpose of the Appointments Commission is to recruit and select people to hold public appointments.

Legislation

61. Part 5 of the Act established the Appointments Commission as a body corporate able to undertake functions in relation to public appointments to NHS and Department of Health bodies, under direction from the Secretary of State for Health, and to health regulators under

30 www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_084036.pdf

direction from the Privy Council. In addition, the Act enables the Commission to support other government departments and foundation trust governors in their appointments, on request. The Appointments Commission Regulations 2006 (SI 2006/2380) make provision concerning the membership and functions of the Appointments Commission. These regulations apply to the United Kingdom.

Implementation

62. The Appointments Commission currently manages over 2,700 public appointments, which is likely to reduce to around 180 public appointments in the future. The smaller number of remaining public appointments will no longer justify having a separate organisation to manage the processes of appointment. Therefore, *Liberating the NHS: Report of the Arms-length Bodies Review*,[31] published in July 2010, announced that the Appointments Commission would be abolished. The responsibility for remaining local NHS public appointments will be delegated by the Secretary of State to another NHS body, and national public appointments will remain with ministers, in line with the practice of other government departments. Responsibility for Privy Council public appointments will revert back to the Privy Council Office.

Impact

63. The Commission, as an SpHA and as a non-departmental public body, has been useful to the Department of Health and the NHS over the last decade. However, the emerging future model across government is one where there will be a sizeable reduction in the number of national public appointments. Together with the structural changes outlined in the White Paper *Equity and Excellence: Liberating the NHS*,[32] published in July 2010 (no local appointments to SHAs and PCTs, and the move for NHS trusts to become, or be part of foundation trusts), the Appointments Commission is no longer viable.

Injury cost recovery in the NHS

Objective

64. The purpose is to widen the scope for taking contributory negligence into account when calculating NHS charges to be paid under the NHS Injury Costs Recovery Scheme made under Part 3 of the Health and Social Care (Community Health and Standards) Act 2003[33] and to simplify and speed up civil claims, minimising the need for formal litigation.

Legislation

65. The Act amends the Health and Social Care (Community Health and Standards) Act 2003 to allow for contributory negligence to be taken into account in injury cost recovery cases where the primary compensation claim is settled by a wide range of alternative dispute resolution mechanisms, rather than only where it has been settled by mediation. The relevant regulations are contained in The Personal Injuries (NHS Charges) (General) and Road Traffic (NHS Charges) (Amendment) Regulations 2006 (SI 2006/3388).

31 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117691

32 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117353

33 www.legislation.gov.uk/ukpga/2003/43/contents

Implementation

66. Section 73 of the Act, which amended section 153 (3) of the Health and Social Care (Community Health and Standards) Act 2003, allows for 'alternative dispute resolution' mechanisms to be taken into account in NHS cost recovery cases where the primary compensation claim is settled by a wide range of alternative dispute resolution mechanisms. Previously, it would have been settled only by mediation (or following a formal finding of contributory negligence made by a court or endorsed through certain specified court processes as described in section 153 (3)). This supported the aim of reducing the number of claims going to court and encouraging the use of alternative dispute resolution techniques. This means that where the amount paid in the primary compensation claim has been reduced, compensators are able to apply to have the amount that is payable under the costs recovery scheme reduced by the same proportion.

67. Guidance[34] on the revised NHS Injury Costs Recovery Scheme was issued to the service on 29 January 2007. The scheme expanded the cases where the NHS can reclaim the cost of treating injured patients to all cases where personal injury compensation is paid.

Impact

68. The amendment to simplify and speed up claims was welcomed by the insurance industry. Although information is not collected on whether a case has been settled via alternative mediation or through court orders, anecdotal evidence suggests that cases are being settled via simple negotiations between defendant and claimant.

69. The Department of Health is currently conducting a review of aspects of the Health and Social Care (Community Health and Standards) Act 2003, which sets out the legislative framework for the current NHS costs recovery scheme. This will include an analysis of the impact of contributory negligence provisions.

34 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065273

Conclusion

70. The Act has made a significant contribution to improving and protecting the health of the nation. For example, evidence suggests that there has been a significant drop in hospital admissions for heart attacks as a result of smoke-free legislation. Also, compliance with the Code of Practice for the Prevention and Control of Health Care Associated Infections in conjunction with the CQC has contributed to national reductions of over 60% in both MRSA bloodstream and *C. difficile* infections in 2010/11 compared with 2007/08. The Act also introduced greater freedom and flexibility in conducting pharmacy and ophthalmic services across our communities. Overall, the Act has contributed to the simplification of existing regulatory regimes.

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