

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES)
AMENDMENT REGULATIONS 2011

2011 No. 2136

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1. These Regulations amend the framework Regulations which govern the arrangements for most of the provision of NHS community pharmaceutical services in England. They amend pharmacy contractors' terms of service, subject to transitional arrangements, in order to update their existing clinical governance obligations.

3. Matters of special interest to the Joint Committee on Statutory Instruments or the Select Committee on Statutory Instruments

3.1. None

4. Legislative Context

4.1. Community pharmaceutical services in England are provided primarily under arrangements governed by the National Health Services (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641, as amended) ("the 2005 Regulations"). The 2005 Regulations enable Primary Care Trusts (PCTs) to make arrangements with three types of provider: pharmacy contractors, which are retail pharmacy businesses that dispense both drugs and appliances; dispensing appliance contractors, which dispense only appliances (such as stoma care products, dressings etc); and dispensing doctors, who dispense drugs and appliances to patients who live chiefly in rural areas designated by the PCT. The changes made by these Regulations only affect pharmacy contractors.

4.2. Pharmacy contractors do not have a private contractual arrangement with their PCT but instead are included in one of the lists held by the PCT of authorised NHS pharmaceutical services providers. Provision by them of pharmaceutical services has to be in accordance with their statutory terms of service, which are part of the national contractual framework and which are set out in Schedule 1 of the 2005 Regulations. Part 4 of Schedule 1 details contractors' obligations regarding clinical governance, fitness to practise and complaints. The amendments in these Regulations principally update contractors' obligations related to clinical governance.

4.3. Pharmacy contractors are required under paragraph 26 of Schedule 1 to the 2005 Regulations to participate in an acceptable system of clinical governance in the manner reasonably required by their PCT. Details of some of the requirements of the clinical governance programmes are subject to approval by the Secretary State, and are published separately as approved particulars. These are available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_089337.pdf, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073278. There are seven key components of the clinical governance

system for pharmacy contractors, each of which is a separate programme (the last named is introduced by these Regulations):

- Patient and public involvement
- Clinical audit
- Risk management
- Clinical effectiveness
- Staffing and staff management including education, training and staff development
- Use of information
- Premises standards.

5. Territorial Extent and Application

5.1. This instrument applies to England.

6. European Convention on Human Rights

As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 Clinical governance is a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

7.2 The amendments made by these Regulations in the main build on existing clinical governance requirements and reflect a desire to move towards a position whereby all NHS primary care contractors, including pharmacy contractors, operate clinical governance arrangements that are of an equivalent high standard.

7.3 The changes:

- 7.3.1 Require pharmacy contractors to publicise the essential and advanced services (which are two types of NHS services) that they provide, and when they do publicise NHS services, to make clear that they are funded as NHS services.
- 7.3.2 Remove a duplication with regard to the contractor having a complaints procedure. This is already required by virtue of paragraph 32 of Schedule 1 to the 2005 Regulations.
- 7.3.3 Remove the need for one of the existing audits required, as part of the clinical audit programme, to be multidisciplinary.
- 7.3.4 Require that pharmacy contractors, as part of their risk management programme, deal appropriately with, and record any actions taken with regard to, patient safety communications from the Secretary of State and the National Patient Safety Agency.

- 7.3.5 Require that the appointed clinical governance lead person for the pharmacy premises has the right local knowledge.
- 7.3.6 Expand the protection procedures to encompass not just child protection but also safeguarding vulnerable adults
- 7.3.7 Expand the arrangements for supporting continuing professional development to include registered pharmacy technicians.
- 7.3.8 Expand the staffing and staff management programme to include setting out the pharmacy contractor's arrangements that enable staff and locums to report specific areas of concern to the contractor or the appropriate authorities without detriment to their employment (commonly known as a "whistle blowing" policy).
- 7.3.9 Strengthening of the information governance programme to recognise the increased requirements for all NHS bodies regarding information management and security. In practice, pharmacy contractors will be expected to comply with approved procedures for information management and security to an approved level and submit an annual self assessment of compliance as detailed in the NHS Information Governance Toolkit. This is available at <https://nww.igt.connectingforhealth.nhs.uk/Home.aspx?tk=407835056381174&cb=94478087-78a5-4b77-9d6f-00d4ee459b4c&Inv=7&clnav=YES>
- 7.3.10 A new pharmacy premises programme which comprises, firstly, ensuring that the premises are maintained to a level of cleanliness appropriate to minimising the risk of health care acquired infection. Secondly, the programme provides for compliance, in the area of the premises from where NHS services are provided, with approved particulars designed to ensure, in a proportionate manner, that the area is an appropriate environment in which to receive health care.

7.4 Transitional provisions have also been included in these Regulations which, in the main, allow existing pharmacy contractors, who have been subject to the previous requirements for clinical governance, until 31st March 2012 to adapt their systems to accommodate the new and modified requirements. This is subject to the proviso, in the case of modified obligations, that they continue to comply with the previous version of that obligation. This will allow contractors who are already providing services time to adjust to the new arrangements without delaying, for an unacceptable period, the benefits of the new arrangements.

Consolidation

7.5 These Regulations only amend a relatively small proportion of NHS pharmacy contractors' overall terms of service, so the Department did not consider it appropriate to consolidate the Regulations on this occasion, but it keeps this matter under regular review.

8. Consultation outcome

8.1 The changes in paragraph 7.3 above are part of a wider package of developments being made to NHS pharmaceutical service provision for pharmacy contractors as negotiated and agreed between NHS Employers and the Pharmaceutical Services Negotiating Committee (PSNC), which represents community pharmacy contractors. They have therefore not been subject to public consultation. The changes which NHS Employers and the PSNC agree are put to the Department for approval, where appropriate. Both bodies have had the opportunity to comment on the Regulations as these have been drafted and are content with the amendments.

9. Guidance

9.1 NHS Employers and PSNC have developed guidance, which is expected to be published shortly after the Regulations are made.

10. Impact

10.1 An Impact Assessment has not been prepared for this instrument.

10.2 The impact on the NHS from the changes to clinical governance requirements is below the minimum threshold of £20 million. Any impact on pharmacy businesses from these increased contractual obligations is met within the overall funding for the community pharmacy contractual framework, which is agreed with the PSNC. Therefore any costs which may arise to business are covered within this overall funding agreement.

11. Regulating small business

11.1 The legislation applies to small businesses, including firms employing up to 10 people. As the 2005 Regulations concern the provision of NHS pharmaceutical services, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed national standards and practices in the provision of such services as part of the nationally determined contractual framework.

12. Monitoring & review

12.1 The Department monitors the implementation of the Regulations and has regular discussions with interested parties, including the NHS and contractors' representatives, on any problems identified in their operation.

13. Contact

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