

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES)
AMENDMENT REGULATIONS 2012

2012 No. 1399

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 with regard to the arrangements for dispensing in particular pack sizes and appliance contractors' terms of service with regard to information governance.
3. **Matters of special interest to the Joint 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 Service (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 medicines and appliances; dispensing appliance contractors, which dispense only appliances (such as stoma care products, dressings etc); and dispensing doctors, who dispense medicines and appliances to patients who live chiefly in rural areas designated by the PCT. The changes made by these Regulations affect pharmacy contractors and appliance contractors.
 - 4.2. Pharmacy and appliance 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:
 - Pharmacy contractors has to be in accordance with their statutory terms of service, which are set out in part in Schedule 1 of the 2005 Regulations. Part 2 of Schedule 1 sets out contractors' obligations regarding the provision of essential services including supply of medicines and appliances ordered by a prescriber.
 - Appliance contractors has to be in accordance with their statutory terms of service, which are set out in part in Schedule 3 of the 2005 Regulations.
 - 4.3. Pharmacy contractors are required under paragraph 5 of Schedule 1 to the 2005 Regulations to supply, with reasonable promptness, medicines that have been ordered on NHS prescription – subject to the provisions of the rest of Part 2 of that Schedule. Generally, a pharmacy contractor is required

to dispense the exact quantity ordered. However, there have been two exceptions to this rule – special containers and calendar packs.

- 4.4. These exceptions have been set out in paragraph 8 of Schedule 1 to the 2005 Regulations. Paragraph 8(10) defines special containers and calendar packs, while paragraph 8(8) permits a pharmacy contractor, in specified circumstances, to supply the special container or calendar pack whose quantity is nearest to the quantity ordered by the prescriber, where the drug is packaged in a calendar pack or a special container.
- 4.5. As regards appliance contractors, in 2009, amendments were made to the 2005 Regulations which required them to provide their pharmaceutical services in a clinical governance framework. The amendments made in 2009 required there to be, as part of the contractor's clinical governance system, a use of information programme which had to include appropriate arrangements for compliance with 'Confidentiality: the National Health Service Code of Practice'. This code of practice has been superseded by the 'Information Governance Toolkit' produced by the Department of Health.

5. Territorial Extent and Application

- 5.1. This instrument applies to England.

6. European Convention on Human Rights

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

7. Policy background

What is being done and why

- 7.1 These Regulations will:

remove the provision concerning calendar packs from pharmacy contractors' terms of service and require pharmacy contractors instead to supply the exact quantity ordered by the prescriber in all cases, except when supplying (in the circumstances specified) medicines packed in special containers.

require contractors to supply medicines in the original packaging supplied by manufacturers unless they are unable to source packs in the appropriate size with reasonable promptness or it is not practicable for the contractor to supply such a pack or packs in response to the order from the prescriber.

update appliance contractors' terms of service by removing the out of date reference to 'Confidentiality: the National Health Service Code of Practice' and replacing it with requirements which will allow for the imposition of obligations set out in the Information Governance Toolkit produced by the Department of Health. This will bring appliance contractors into line with pharmacy contractors and other NHS providers.

- 7.2 The changes in respect of pharmacy contractors are linked to their reimbursement arrangements under the Drug Tariff. Essentially, reimbursement for medicinal products is relatively simple, with pharmacy contractors being paid the manufacturer's list price minus a discount (where appropriate) for the quantity prescribed of the product – except for special containers and (until now) most dispensing of calendar packs, where, the pharmacy contractor has been required to supply (and so has been paid for) a quantity which is the pack size nearest to the quantity prescribed. Allowing these exceptions adds complexity to the reimbursement system and results in a lack of transparency to the prescriber as to the quantity dispensed to the patient.
- 7.3 Maintaining the exception for special containers is essentially for reasons of pragmatism, as in such cases it is generally not practical to dispense the exact quantity ordered. As regards calendar packs, removing the provisions requiring a pharmacy contractor to supply a quantity other than that prescribed, when a calendar pack is available, and replacing it with a requirement to supply an original pack produced by a manufacturer, where possible and practicable, will require pharmacy contractors to improve the efficiency of the dispensing process by reducing occasions on which they will be able to 'snip' blister packs and dispense split packs. In addition, dispensing original packs will ensure improved access to the approved patient information leaflets provided with authorised medicines in their original packaging.
- 7.4 In 2009, Regulations were introduced requiring appliance contractors to provide their pharmaceutical services in a clinical governance framework. As part of this, they were required to have an information governance programme regarding the management of personal information. The reference in the relevant provision of their terms of service is now out of date – it refers to 'Confidentiality: the National Health Service Code of Practice', which has been superseded by the Information Governance Toolkit produced by the Department of Health. Under the arrangements set out in this Toolkit, all providers of NHS services need to comply to a level appropriate to the information they retain and submit an annual return to the PCT to demonstrate the level achieved.
- 7.5 These Regulations update appliance contractors' requirements for information governance in a similar way to those for pharmacy contractors, which were changed by amendments to the 2005 Regulations introduced on 1st October 2011. The new provisions, which are worded in the same way as the amendments introduced in October 2011, refer to 'approved procedures' for information management and security, and submission of an annual self assessment to 'an approved level'. Approval is by the Secretary of State and the intention is to approve the Information Governance Toolkit, which is already the approved set of information governance arrangements for pharmacy contractors.
- 7.6 The Toolkit is revised from time to time, usually on an annual basis, at which point the Secretary of State's approvals will also need to be revised accordingly. This practice of rolling revision makes reference to any particular version of the Toolkit in subordinate legislation, in the Department's view, inappropriate. The current version of the toolkit is available on the following website:
<https://www.igt.connectingforhealth.nhs.uk>.

Consolidation

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

8 Consultation outcome

- 8.1 The changes for pharmacy contractors are part of a wider package of changes to reimbursement arrangements for pharmacy contractors as negotiated and agreed between DH and the Pharmaceutical Services Negotiating Committee (PSNC), which represents community pharmacy contractors. They have not been subject to public consultation. Similarly, the Department considers that the nature of the changes being proposed for appliance contractors, which have been discussed with appliance contractors' representatives, means that they do not warrant a public consultation. Unlike pharmacy contractors, there is no single representative organisation for dispensing appliance contractors. Members of the Department's Appliance Contractor's Representative Group were consulted and were content with the proposed changes. The organisations included the Urology Trade Association, British Healthcare Trades Association, Independent Dispensing Appliance Contractors, and the Specialist Independent Appliance Wholesalers.

9 Guidance

- 9.1 DH and PSNC have developed guidance about the changes for pharmacy contractors, which is expected to be published shortly after these Regulations are made. Guidance has already been issued for changes to Information Governance for appliance contractors.

10 Impact

- 10.1 An Impact Assessment has not been prepared for this instrument.
- 10.2 The impact on the changes to pharmacy contractors for calendar packs is intended to be cost neutral. We have not identified any significant costs for the NHS as a result of the proposed changes in relation to Information Governance.

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 operation of the 2005 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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