

**2012 No. 1399**

**NATIONAL HEALTH SERVICE, ENGLAND**

**The National Health Service (Pharmaceutical Services)  
Amendment Regulations 2012**

<i>Made</i> - - - -	<i>28th May 2012</i>
<i>Laid before Parliament</i>	<i>30th May 2012</i>
<i>Coming into force</i> - -	<i>1st July 2012</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126, 129 and 272(7) and (8) of the National Health Service Act 2006(a).

**Citation and commencement**

1. These Regulations may be cited as the National Health Service (Pharmaceutical Services) Amendment Regulations 2012 and come into force on 1st July 2012.

**Amendment of the National Health Service (Pharmaceutical Services) Regulations 2005**

2.—(1) The National Health Service (Pharmaceutical Services) Regulations 2005(b) are amended as follows.

(2) In paragraph 8 of Schedule 1(c) (terms of service of pharmacists – providing ordered drugs or appliances)—

- (a) in sub-paragraph (8)—
  - (i) omit “, subject to sub-paragraph (9),”, and
  - (ii) in paragraph (f), omit “calendar pack or”;

(b) omit sub-paragraph (9);

(c) omit paragraph (a) of sub-paragraph (10); and

(d) after sub-paragraph (10) insert the following sub-paragraph—

“(10A) Where a drug is ordered by a prescriber on a prescription form or repeatable prescription in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a holder of a marketing authorisation for the drug, the pharmacist must provide the drug in an original pack (or in original packs) of that size which has been assembled by a manufacturer of the drug for such a holder of a marketing authorisation, unless—

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(a) 2006 c. 41. Section 129 has been amended by S.I. 2010/231. By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England. *See also* section 275(1) of the 2006 Act, which contains definitions of “prescribed” and “regulations” that are relevant to the powers being exercised.

(b) S.I. 2005/641.

(c) Paragraph 8 has been amended by S.I. 2006/1056.

- (a) it is not possible for the pharmacist to obtain such a pack (or packs) with reasonable promptness in the normal course of business; or
- (b) it is not practicable for the pharmacist to provide such a pack (or packs) in response to the order (for example, because of patient needs or the method of administration of the drug).”.

(3) In paragraph 13AA(2) of Schedule 3(a) (terms of service of suppliers of appliances – clinical governance), for paragraph (f) substitute the following paragraph—

- “(f) an information governance programme, which provides for—
- (i) compliance with approved procedures for information management and security, and
  - (ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Primary Care Trust to access that assessment.”.

Signed by authority of the Secretary of State for Health.

*Earl Howe*  
Parliamentary Under-Secretary of State,  
Department of Health

28th May 2012

### EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend Schedules to the National Health Service (Pharmaceutical Services) Regulations 2005 that include NHS terms of service for suppliers of appliances and pharmacists – “pharmacists” in this context being a term which includes partnerships of pharmacists and pharmacy businesses, not just individual pharmacists. Pharmacists and suppliers of appliances providing NHS pharmaceutical services are included in a pharmaceutical list of a Primary Care Trust, and their NHS terms of service are the terms on which they are included in that list.

Regulation 2(2) amends the NHS terms of service of pharmacists so as to remove the obligation to dispense certain drugs, in certain circumstances, in a calendar pack of the size that is nearest to the quantity of the drug specified in the prescription, rather than dispensing the exact quantity of the drug specified in the prescription. A new obligation is instead placed on pharmacists to dispense drugs in readily available patient pack sizes, unless there are specified problems with doing so.

Regulation 2(3) amends the NHS terms of service of suppliers of appliances to change the information governance requirements which form part of their clinical governance obligations. The new arrangements mirror the equivalent information governance requirements for pharmacists.

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(a) Paragraph 13AA was inserted, as paragraph 13A, by S.I. 2009/3340 and renumbered, as paragraph 13AA, by S.I. 2010/914.

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