STATUTORY INSTRUMENTS

2011 No. 2136

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical Services) Amendment Regulations 2011

Made - - - -	*31st August 2011*
Laid before Parliament	*5th September 2011*
Coming into force - -	*1st October 2011*

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.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) Amendment Regulations 2011 and come into force on 1st October 2011.

(2) In these Regulations, "the principal Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2005(**b**).

Amendment of regulation 2 of the principal Regulations

2. In regulation 2(1) of the principal Regulations(**c**) (interpretation), insert the following definitions in the appropriate alphabetical position—

> ""advanced services" means the directed services for which the Secretary of State determines the remuneration under section 164 of the 2006 Act(**d**) (remuneration for persons providing pharmaceutical services);"; and
>
> ""registered pharmacy technician" means a person registered as a pharmacy technician in Part 2 or 5 of the register maintained under article 19 of the Pharmacy Order 2010(**e**) (establishment, maintenance of and access to the Register);".

Amendment of paragraph 26 of Schedule 1 to the principal Regulations

3.—(1) Paragraph 26(2) of Schedule 1 to the principal Regulations(**f**) (clinical governance) is amended as follows.

(**a**) 2006 c. 41. Section 129 has been amended by S.I. 2010/231 (the amendments made by the Health Act 2009 (c. 21), section 26, are not yet in force). *See s*ection 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**) Regulation 2 has been amended by S.I. 2005/1501 and 3491, 2006/552, 562, 913, 1501 and 3373, 2007/289 and 674, 2008/528, 2009/2205 and 2010/914.
(**d**) The amendments made to section 164 by the Health and Social Care Act 2008 (c. 14), section 141, and Schedule 15, Part 4, are not yet fully in force.
(**e**) S.I. 2010/231.
(**f**) Paragraph 26 has been amended by S.I. 2008/528 and 683 and 2009/3340.

(2) In paragraph (a)—

(a) for sub-paragraph (ii) substitute the following sub-paragraphs—

"(ii) a requirement that the pharmacist publicises the essential services and any advanced services that are available at or from the pharmacist's pharmacy,

(iia) a requirement that where a pharmacist publicises the essential services or any directed services that are available at or from the pharmacist's pharmacy (whether the pharmacist is producing their own publicity material or advertising services in material published by another person), the pharmacist does so in a manner which makes clear that the services are funded as part of the health service,"; and

(b) omit sub-paragraph (v).

(3) In paragraph (b), for "multi-disciplinary" substitute "other".

(4) In paragraph (c)—

(a) after sub-paragraph (iii) insert the following sub-paragraph—

"(iiia) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Secretary of State(**a**) and the National Patient Safety Agency,";

(b) for sub-paragraph (vi) substitute the following sub-paragraph—

"(vi) a clinical governance lead person for each pharmacy, appointed as such by the pharmacist (or that is the pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,"; and

(c) omit the "and" at the end of sub-paragraph (vii), and after that sub-paragraph insert the following sub-paragraph—

"(viia) appropriate vulnerable adult (as construed in accordance with section 59 of the Safeguarding Vulnerable Groups Act 2006(**b**) (vulnerable adults)) protection procedures, and".

(5) In paragraph (e)—

(a) in sub-paragraph (iv), after "registered pharmacists" insert "and registered pharmacy technicians,";

(b) omit the "and" at the end of sub-paragraph (iv);

(c) for the semicolon in sub-paragraph (v) substitute a comma; and

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

"(vi) arrangements (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the pharmacist—

(aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(**c**) (meaning of

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(**a**) The Medicines and Healthcare Products Regulatory Agency, which is an executive agency of the Department of Health, issues safety advice, warnings, alerts and recalls in respect of medical devices on behalf of the Secretary of State, and also safety advice, warnings, alerts and recalls in respect of medicines on behalf of the Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly. The Department of Health also, separately, issues other communications concerning patient safety, on behalf of the Secretary of State.

(**b**) 2006 c. 47; section 59 has been amended by: the Education and Skills Act 2008 (c. 25), section 147(8); the Health Act 2009 (c. 21), Schedule 1, paragraphs 12 and 15, and Schedule 6; and S.I. 2008/919.

(**c**) 1996 c. 18; section 43 was inserted by the Public Interest Disclosure Act 1998 (c. 23), section 1. *See also* section 43K(1)(c)(i) of the Employment Rights Act 1996 (inserted by the Public Interest Disclosure Act 1998, section 1, and amended by: the National Health Service Reform and Health Care Professions Act 2002 (c. 17), Schedule 2, paragraph 63; the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraphs 177 and 178(b); and S.I. 2007/961), which extends the meaning of "worker" for the Part of that Act that deals with protected disclosures so that it covers all individuals who provide pharmaceutical services in accordance with arrangements made by a Primary Care Trust under section 126 of the National Health Service Act 2006.

protected disclosure) have the rights afforded in respect of such disclosures by that Act, and

(bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Primary Care Trust which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;".

(6) For sub-paragraph (f) substitute the following sub-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; and".

(7) After sub-paragraph (f) add the following sub-paragraph—

"(g) a premises standards programme, which includes—

(i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of health care acquired infection is minimised, and

(ii) arrangements for compliance, in the areas of the pharmacy in which patients receive NHS services, with any approved particulars that are designed to ensure, in a proportionate manner, that those areas are an appropriate environment in which to receive health care,".

Transitional arrangements

4.—(1) This regulation has effect only in relation to the provision of pharmaceutical services at any time before the end of the transitional period by a pharmacist whose name was, immediately before these Regulations come into force, already on a pharmaceutical list maintained by a Primary Care Trust under the principal Regulations.

(2) Subject to paragraph (3), during the transitional period the pharmacist is not bound by—

(a) any particular amendment to paragraph 26(2) of Schedule 1 to the principal Regulations (clinical governance) made by regulation 3(2)(a), (4)(b), (5)(a) or (6), if they choose instead to comply, and do comply, with the provision modified or substituted by that particular amendment as it had effect prior to that particular amendment; or

(b) the amendments to paragraph 26(2) of Schedule 1 to the principal Regulations made by regulation 3(4)(a), (4)(c), (5)(b) to (d) and (7).

(3) Nothing in this regulation affects the duty of a pharmacist—

(a) before the end of the transitional period, to comply with paragraph 26(2) of Schedule 1 to the principal Regulations, as it otherwise has effect; and

(b) at and after the end of the transitional period, to comply with paragraph 26(2) of Schedule 1 to the principal Regulations as amended by these Regulations.

(4) In this regulation, "transitional period" means the period that begins on the day that these Regulations come into force and ends at the end of 31st March 2012.

Signed by authority of the Secretary of State for Health

Earl Howe
Parliamentary Under Secretary of State
Department of Health

31st August 2011

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

Regulation 2 inserts two new definitions that relate to the amendments made by regulation 3. Regulation 3 amends the provisions of the NHS terms of service for pharmacists that relate to participation in an acceptable system of clinical governance. These obligations are modified so as to include new obligations to deal with patient safety communications, premises standards and protection of staff and locums who make certain allegations of a serious nature (often called "whistle blowing"). There are also modifications to existing obligations in respect of patient and public involvement, clinical audit, risk management, staffing and staff management, and use of information. The opportunity has also been taken to remove an area of duplication in the NHS terms of service with regard to complaints procedures.

Regulation 4 is a transitional provision which essentially allows pharmacists who are on pharmaceutical lists when these Regulations come into force until 31st March 2012 to adapt their systems of clinical governance to accommodate their new and modified obligations, provided they are complying, in the case of modified obligations, with the version of the obligation that existed prior to these Regulations coming into force.

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