STATUTORY INSTRUMENTS

2011 No. 2907 (W.311)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011

Made - - - -	*4 December 2011*
Laid before the National Assembly for Wales - -	*6 December 2011*
Coming into force - -	*31 December 2011*

The Welsh Ministers, in exercise of the powers conferred by sections 80, 83 and 203(9) and (10) of the National Health Service (Wales) Act 2006(**1**) hereby make the following Regulations:

Title, commencement, application and interpretation

1.—(1) The title of these Regulations is the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011.

(2) These Regulations come into force on 31 December 2011.

(3) These Regulations apply in relation to Wales.

(4) In these Regulations "the principal Regulations" ("*y prif Reoliadau*") means the National Health Service (Pharmaceutical Services) Regulations 1992(**2**).

Amendment of paragraph 25 of Schedule 2 to the principal Regulations

2.—(1) Paragraph 25 (clinical governance) of Schedule 2 to the principal Regulations(**3**) is amended in accordance with the following provisions of this regulation.

(2) After sub-paragraph (1) insert the following sub-paragraph—

"(1A) A system of clinical governance is "acceptable" if it provides for—

(a) compliance with the clinical governance components set out in sub-paragraph (2), and

(b) submission of an annual self assessment of compliance (to an approved level) with those clinical governance components via approved data submission arrangements which allow the Local Health Board to access that assessment.".

(**1**) 2006 c. 42.
(**2**) S.I. 1992/662. Relevant amending instruments are S.I. 2005/1013 (W.67), S.I. 2007/205 (W.19), S.I. 2009/1491 (W.144), S.I. 2010/868 (W.90) and S.I. 2010/1648 (W.156).
(**3**) Paragraph 25 was inserted into S.I. 1992/662 by S.I. 2005/1013 (W.67) and has been amended by S.I. 2010/868 (W.90).

(3) In sub-paragraph (2), for the words "For these purposes" to "the following components-" substitute the following—

"The clinical governance components comprise of the following—".

(4) In paragraph (a) of sub-paragraph (2)—

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

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

(b) at the end of sub-paragraph (iii) after the comma insert the following—

"including a requirement to publicise the results of the survey and any appropriate action the chemist intends to take,".

(5) In paragraph (c) of sub-paragraph (2)—

(a) at the end of sub-paragraph (iii) after the comma insert the following—

"which comprises of—

(a) a patient safety incident log,

(b) a near-miss log, and

(c) the reporting of patient safety incidents to the National Patient Safety Agency,";

(b) 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 Welsh Ministers, the Medicines and Healthcare products Regulatory Agency and the National Patient Safety Agency,"; and

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

"(vi) a clinical governance lead person for each pharmacy, appointed as such by the chemist (or that is the chemist), 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,".

(6) In paragraph (e) of sub-paragraph (2)—

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

(b) for the semicolon at the end of sub-paragraph (v) substitute ", and"; and

(c) 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 chemist—

(aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(**4**) (meaning of 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 Local Health Board 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;".

(7) For paragraph (f) of sub-paragraph (2) 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 Local Health Board to access that assessment; and".

(8) After paragraph (f) of sub-paragraph (2) insert the following 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 healthcare acquired infection is minimised, and

(ii) arrangements for there to be a clear separation between the areas of a pharmacy which are an appropriate healthcare environment (where patients receive NHS services) and those areas that are a non-healthcare environment.".

Transitional arrangements

3.—(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 chemist whose name was, immediately before these Regulations come into force, already on a pharmaceutical list maintained by a Local Health Board under the principal Regulations.

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

(a) any particular amendment to paragraph 25 of Schedule 2 to the principal Regulations made by regulation 2(3), (4)(b), (5)(a) and (c) and (7) 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 25 of Schedule 2 to the principal Regulations made by regulation 2(2), (4)(a), (5)(b), (6)(a) to (c) and (8).

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

(a) before the end of the transitional period, to comply with paragraph 25 of Schedule 2 to the principal Regulations, as it otherwise has effect; and

(b) at and after the end of the transitional period, to comply with paragraph 25 of Schedule 2 to the principal Regulations as amended by these Regulations.

(4) In this regulation, "transitional period" ("*cyfnod trosiannol*") means the period that begins on the day that these Regulations come into force and ends on 31 March 2012.

(**4**) 1996 c. 18; section 43A was inserted by section 1 of the Public Interest Disclosure Act 1998 (c. 23). See also section 43K(1)(c) of the Employment Rights Act 1996 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 Local Health Board under section 80 of the National Health Service (Wales) Act 2006.

Lesley Griffiths
Minister for Health and Social Services, one of the Welsh Ministers

4 December 2011

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical Services) Regulations 1992 (S.I.1992/662) ("the principal Regulations") in respect of the NHS terms of service for chemists, which are set out in Schedule 2 to the principal Regulations. Chemists providing NHS pharmaceutical services are included in a pharmaceutical list of a Local Health Board, and their NHS terms of service are the terms on which they are included in that list.

Regulation 2 amends the provisions of the NHS terms of service that relate to an acceptable system of clinical governance. It imposes new obligations, including a requirement for a chemist to submit an annual clinical governance self assessment, and modifies existing obligations, including in respect of use of information.

Regulation 3 is a transitional provision which allows chemists who are on a pharmaceutical list when these Regulations come into force until 31 March 2012 to adapt their systems of clinical governance to accommodate their new and modified obligations, provided they are complying, in the case of the modified obligations, with the version of the obligation that existed prior to these Regulations coming into force.