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WELSH STATUTORY INSTRUMENTS

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**2011 No. 2907**

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

**Amendment of paragraph 25 of Schedule 2 to the principal Regulations**

2.—(1) Paragraph 25 (clinical governance) of Schedule 2 to the principal Regulations<sup>(1)</sup> 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.”.

(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—

- (aa) a patient safety incident log,
- (bb) a near-miss log, and
- (cc) the reporting of patient safety incidents to the National Patient Safety Agency,”;

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

“(iia) arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Welsh

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<sup>(1)</sup> 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 \(W.90\)](#).

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<sup>(2)</sup> (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.”.

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(2) 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.