



---

OFFERYNNAU STATUDOL  
CYMRU

---

**2011 Rhif 2907 (Cy.311)**

**Y GWASANAETH IECHYD  
GWLADOL, CYMRU**

Rheoliadau'r Gwasanaeth Iechyd  
Gwladol (Gwasanaethau Fferyllol)  
(Diwygio) (Cymru)  
2011

**NODYN ESBONIADOL**

*(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)*

Mae'r Rheoliadau hyn yn diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (O.S. 1992/662) ("y prif Rheoliadau") o ran telerau gwasanaethu'r GIG ar gyfer fferyllwyr, sydd wedi eu nodi yn Atodlen 2 i'r prif Rheoliadau. Mae fferyllwyr sy'n darparu gwasanaethau fferyllol y GIG wedi eu cynnwys mewn rhestr fferyllol Bwrdd Iechyd Lleol, a thelerau gwasanaethu'r GIG ar eu cyfer hwy yw'r telerau ar ba rai y maent wedi eu cynnwys yn y rhestr honno.

Mae rheoliad 2 yn diwygio darpariaethau telerau gwasanaethu'r GIG sy'n ymwneud â system dderbyniol o lywodraethu clinigol. Mae'n gosod rhwymedigaethau newydd, gan gynnwys gofyniad i fferylllydd gyflwyno hunanasesiad llywodraethu clinigol blynyddol, ac yn addasu rhwymedigaethau sydd eisoes yn bodoli, gan gynnwys rhai sy'n ymwneud â defnyddio gwybodaeth.

Mae rheoliad 3 yn ddarpariaeth drosiannol sy'n caniatáu tan 31 Mawrth 2012 i fferyllwyr sydd ar restr fferyllol pan ddaw'r Rheoliadau hyn i rym, addasu eu systemau llywodraethu clinigol i ymgymhwysu eu rhwymedigaethau newydd a'r rhai sydd wedi eu haddasu, ar yr amod eu bod yn cydymffurfio, yn achos y rhwymedigaethau sydd wedi eu haddasu, gyda'r fersiwn o'r rhwymedigaeth a oedd yn bodoli cyn i'r Rheoliadau hyn ddod i rym.

---

WELSH STATUTORY  
INSTRUMENTS

---

**2011 No. 2907 (W.311)**

**NATIONAL HEALTH  
SERVICE, WALES**

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

**2011 Rhif 2907 (Cy.311)**

**Y GWASANAETH IECHYD  
GWLADOL, CYMRU**

Rheoliadau'r Gwasanaeth Iechyd  
Gwladol (Gwasanaethau Fferyllol)  
(Diwygio) (Cymru)  
2011

*Gwnaed* 4 Rhagfyr 2011  
*Gosodwyd gerbron Cynulliad  
Cenedlaethol Cymru* 6 Rhagfyr 2011  
*Yn dod i rym* 31 Rhagfyr 2011

Mae Gweinidogion Cymru, drwy arfer y pwerau a roddwyd gan adrannau 80, 83 a 203(9) a (10) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(1) drwy hyn yn gwneud y Rheoliadau a ganlyn:

**Enwi, cychwyn, cymhwyso a dehongli**

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2011.

(2) Mae'r Rheoliadau hyn yn dod i rym ar 31 Rhagfyr 2011.

(3) Mae'r Rheoliadau hyn yn gymwys o ran Cymru.

(4) Yn y Rheoliadau hyn, ystyr "y prif Reoliadau" ("*the principal Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(2).

**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).

---

(1) 2006 p.42.

(2) O.S. 1992/662. Yr offerynnau diwygio perthnasol yw O.S. 2005/1013 (Cy.67), O.S. 2007/205 (Cy.19), O.S. 2009/1491 (Cy.144), O.S. 2010/868 (Cy.90) ac O.S. 2010/1648 (Cy.156).

---

(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).

## Diwygio paragraff 25 o Atodlen 2 i'r prif Reoliadau

2.—(1) Mae paragraff 25 (llywodraethu clinigol) o Atodlen 2 i'r prif Reoliadau(1) wedi ei ddiwygio yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Ar ôl is-baragraff (1), mewnosoder yr is-baragraff canlynol—

"(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) Yn is-baragraff (2), yn lle'r geiriau "For these purposes" hyd at "the following components-" rhodder y canlynol—

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

(4) Ym mharagraff (a) o is-baragraff (2)—

(a) ar ôl is-baragraff (ii), mewnosoder yr is-baragraff canlynol—

"(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,"; a

(b) ar ddiwedd is-baragraff (iii), ar ôl y coma, mewnosoder y canlynol—

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

(5) Ym mharagraff (c) o is-baragraff (2)—

(a) ar ddiwedd is-baragraff (iii), ar ôl y coma, mewnosoder y canlynol—

" which comprises of—

- (aa) a patient safety incident log,
- (bb) a near-miss log, and
- (cc) the reporting of patient safety

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

2.—(1) Paragraph 25 (clinical governance) of Schedule 2 to the principal Regulations(1) 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

(1) Mewnosodwyd paragraff 25 i O.S. 1992/662 gan O.S. 2005/1013 (Cy.67) ac fe'i diwygiwyd gan O.S. 2010/868 (Cy.90).

(1) 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).

incidents to the National Patient Safety Agency,";

- (b) ar ôl is-baragraff (iii), mewnosoder yr is-baragraff canlynol—

"(iia)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,"; ac

- (c) yn lle is-baragraff (vi) rhodder yr is-baragraff canlynol—

"(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) Ym mharagraff (e) o is-baragraff (2)—

- (a) hepgorer "and" ar ddiwedd is-baragraff (iv);  
(b) yn lle'r hanner colon ar ddiwedd is-baragraff (v) rhodder ", and"; ac  
(c) ar ôl is-baragraff (v), mewnosoder yr is-baragraff canlynol—

"(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(1) (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

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 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(1) (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

---

(1) 1996 p.18; mewnosodwyd adran 43A gan adran 1 o Ddeddf Datgelu er Lles y Cyhoedd 1998 (p.23). Gweler hefyd adran 43K(1)(c) o Ddeddf Hawliau Cyflogaeth 1996 sydd yn estyn ystyr "worker" ar gyfer y Rhan honno o'r Ddeddf sy'n ymwneud â datgeliadau gwarchoddedig fel ei fod yn cynnwys pob unigolyn sy'n darparu gwasanaethau fferyllol yn unol â threfniadau a wnaed gan Fwrdd Iechyd Lleol o dan adran 80 o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006.

---

(1) 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.

43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;".

(7) Yn lle paragraff (f) o is-baragraff (2) rhodder y paragraff canlynol—

- "(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) Ar ôl paragraff (f) o is-baragraff (2) mewnosoder y paragraff canlynol—

- "(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."

### Trefniadau trosiannol

3.—(1) Dim ond mewn perthynas â'r ddarpariaeth o wasanaethau fferyllol, ar unrhyw adeg cyn diwedd y cyfnod trosiannol, gan fferylllydd yr oedd ei enw, yn union cyn i'r Rheoliadau hyn ddod i rym, eisoes ar restr fferyllol a gynhelir gan Fwrdd Iechyd Lleol o dan y prif Reoliadau, y mae gan y rheoliad hwn effaith.

(2) Yn ddarostyngedig i baragraff (3), yn ystod y cyfnod trosiannol nid yw'r fferylllydd wedi ei rwymo gan y canlynol—

- (a) unrhyw ddiwygiad penodol i baragraff 25 o Atodlen 2 i'r prif Reoliadau a wneir gan reoliad 2(3), (4)(b), (5)(a) ac (c) a (7) os ydynt yn hytrach, wedi dewis cydymffurfio, a'u bod yn cydymffurfio, â'r ddarpariaeth a addaswyd neu a amnewidiwyd gan y diwygiad penodol hwnnw fel yr oedd yn cael effaith cyn y diwygiad penodol hwnnw; neu

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) y diwygiadau i baragraff 25 o Atodlen 2 i'r prif Reoliadau a wneir gan reoliad 2(2), (4)(a), (5)(b), (6)(a) i (c) ac (8).
- (3) Nid oes dim yn y rheoliad hwn yn effeithio ar ddyletswydd fferyllydd i wneud y canlynol—
- (a) cydymffurfio â pharagraff 25 o Atodlen 2 i'r prif Reoliadau cyn diwedd y cyfnod trosiannol, fel y mae'n cael effaith fel arall; a
- (b) cydymffurfio â pharagraff 25 o Atodlen 2 i'r prif Reoliadau fel y'i diwygiwyd gan y Rheoliadau hyn, ar ddiwedd y cyfnod trosiannol ac ar ôl hynny.
- (4) Yn y rheoliad hwn, ystyr "cyfnod trosiannol" ("*transitional period*") yw'r cyfnod sy'n cychwyn ar y diwrnod y mae'r Rheoliadau hyn yn dod i rym ac yn dod i ben ar 31 Mawrth 2012.

- (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.

*Lesley Griffiths*

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol,  
un o Weinidogion Cymru

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

4 Rhagfyr 2011

4 December 2011

---

©℥ Hawlfraint y Goron 2011

---

© Crown copyright 2011

Argraffwyd a chyhoeddwyd yn y Deyrnas Unedig gan The Stationery Office Limited o dan awdurdod ac arolygiaeth Carol Tullo, Rheolwr Gwasg Ei Mawrhydi ac Argraffydd Deddfau Seneddol y Frenhines.

Printed and Published in the UK by the Stationery Office Limited under the authority and superintendence of Carol Tullo, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.



---

OFFERYNNAU STATUDOL  
CYMRU

---

**2011 Rhif 2907 (Cy.311)**

**Y GWASANAETH IECHYD  
GWLADOL, CYMRU**

Rheoliadau'r Gwasanaeth Iechyd  
Gwladol (Gwasanaethau Fferyllol)  
(Diwygio) (Cymru)  
2011

---

WELSH STATUTORY  
INSTRUMENTS

---

**2011 No. 2907 (W.311)**

**NATIONAL HEALTH  
SERVICE, WALES**

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