OFFERYNNAU STATUDOL CYMRU

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**).

Diwygio paragraff 25 o Atodlen 2 i'r prif Reoliadau

2.—(1) Mae paragraff 25 (llywodraethu clinigol) o Atodlen 2 i'r prif Reoliadau(**3**) 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

(**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).
(**3**) 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).

(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 incidents to the National Patient Safety Agency,";

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

"(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,"; 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(**4**) (meaning of

(**4**) 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 gwarchodedig 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.