OFFERYNNAU STATUDOL CYMRU

2003 Rhif 2624 (Cy.252)

GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Diwygiadau ynghylch Rhagnodi gan Nyrsys Atodol ac Annibynnol) (Cymru) 2003

Wedi'u gwneud - -	*8 Hydref 2003*
Yn dod i rym - -	*10 Hydref 2003*

Mae Cynulliad Cenedlaethol Cymru, drwy arfer y pwerau a roddwyd iddo gan adrannau 29, 41, 42, 43, 77 a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977 (**1**), drwy hyn yn gwneud y Rheoliadau canlynol:

Enwi, cychwyn, dehongli a chymhwyso

1.—(1) Enw'r rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Diwygiadau ynghylch Rhagnodi gan Nyrsys Atodol ac Annibynnol) (Cymru) 2003.

(2) Mae'r Rheoliadau hyn yn dod i rym ar 10 Hydref 2003.

(3) Mae'r Rheoliadau hyn yn gymwys i Gymru yn unig.

(**1**) 1977 p.49; *gweler* adran 128(1) fel y'i diwygiwyd gan Ddeddf Gwasanaeth Iechyd Gwladol a Gofal Cymunedol 1990 (p.19) ("Deddf 1990"), adran 26(2)(g) ac (i), a chan Ddeddf Iechyd 1999 (p.8) ("Deddf 1999"), Atodlen 4, paragraff 38(2)(b), i gael y diffiniad o "prescribed" a "regulations".
Estynnwyd adran 29 gan Ddeddf Iechyd a Meddyginiaethau 1988 (p.49), adran 17; a'i diwygio gan Ddeddf Gwasanaethau Iechyd 1980 (p.53), adrannau 1 a 7 ac Atodlen 2, paragraff 16(a); gan O.S. 1985/39, erthygl 7(3); gan Ddeddf yr Awdurdodau Iechyd 1995 (p.17), Atodlen 1, paragraff 18 a chan Ddeddf y Gwasanaeth Iechyd Gwladol (Gofal Sylfaenol) 1997 (p.46), Atodlen 2, paragraff 8.
Diwygiwyd adran 126(4) gan Ddeddf 1990, adran 65(2) a Deddf 1999, Atodlen 4, paragraff 37(6).
Diwygiwyd adran 41 gan Ddeddf 1980, adrannau 1 a 20(1) ac Atodlen 1, paragraff 53 ac Atodlen 7; gan O.S. 1985/39, erthygl 7(13); gan Ddeddf 1990, Atodlen 9, paragraff 18(1) ac Atodlen 10; gan Ddeddf Cynhyrchion Meddyginiaethol: Rhagnodi gan Nyrsys etc.1992 (p.28), adran 2; gan Ddeddf 1995, Atodlen 1, paragraff 29 a chan Ddeddf 1997, Atodlen 2, paragraff 13.
Amnewidiwyd adran 42 gan Ddeddf y Gwasanaeth Iechyd Gwladol (Diwygio) 1986 (p.66), adran 3(1); ei hestyn gan Ddeddf 1988, adran 17 a'i diwygio gan OS 1987/2202, erthygl 4; gan Ddeddf 1990, adran 12(3) a chan Ddeddf 1995, Atodlen 1, paragraff 30.
Diwygiwyd adran 43 gan Ddeddf 1980, Atodlen 9, paragraff 18(2); gan Ddeddf 1995, Atodlen 1, paragraff 31; a chan Ddeddf 1997, adran 29(1) ac Atodlen 2, paragraff 14.
Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan adrannau 29 a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977 i Gynulliad Cenedlaethol Cymru drwy Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999, O.S. 1999/672, erthygl 2 ac Atodlen 1, fel y'i diwygiwyd gan Ddeddf 1999, adran 66(5).

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992

2.—(1) Diwygir Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(**2**) yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Yn rheoliad 2(1) (dehongli) —

(a) rhowch bob un o'r diffiniadau canlynol yn y lle priodol yn nhrefn yr wyddor —

""independent nurse prescriber" means—

(a) a person whose name is registered—

(i) in Part 1 or 12 of the nurses and midwives' professional register and has a district nurse qualification additionally recorded in the nurses and midwives' professional register pursuant to rule 11 of the Nurses, Midwives and Health Visitors Rules 1983(**3**) or

(ii) in Part 11 of the nurses and midwives' professional register as a health visitor,

and against whose name is recorded in the nurses and midwives' professional register an annotation signifying that he or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVII B(i) of the Drug Tariff; or

(b) a person—

(i) whose name is registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14, or 15 of the nurses and midwives' professional register, and

(ii) against whose name is recorded in the nurses and midwives' professional register an annotation signifying that he or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Extended Formulary in Part XVIIB (ii) of the Drug Tariff;";

""nurses and midwives' professional register" means the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001(**4**);" and

""supplementary prescriber" means a person whose name is registered in —

(a) Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the nurses and midwives' professional register;

(b) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954(**5**); or

(c) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**6**),

and against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a supplementary prescriber;";

(b) yn y diffiniad o "prescription form", yn lle "dentist or nurse prescriber" rhodder "dentist, supplementary prescriber or independent nurse prescriber"; ac

(c) hepgorir y diffiniad o "nurse prescriber".

(**2**) O.S. 1992/662; yr offerynnau diwygio perthnasol yw O.S.1996/698, 1998/681, 1999/696, 2001/1396 (Cy.91) a 2002/3189 (Cy.305).
(**3**) Cymeradwywyd gan O.S.1983/873 a nodir hi yn yr Atodlen iddo; nid oes offerynnau diwygio perthnasol.
(**4**) O.S.2001/253.
(**5**) 1954 p.61.
(**6**) O.S.1976/1213.

(3) Yn Atodlen 2 (telerau gwasanaeth)—

(a) ym mharagraff 3—

(i) yn is-baragraff (1)(a) a (b), ar ôl "doctor", yn y ddau le y mae'n digwydd, rhodder "or a supplementary prescriber";

(ii) yn is-baragraff (1)(d) ac (e), yn lle "a nurse prescriber" yn y ddau le y mae'n digwydd, rhodder "an independent nurse prescriber";

(iii) yn is-baragraff (4), yn lle "dentist or nurse prescriber" rhodder "dentist, a supplementary prescriber or an independent nurse prescriber",

(iv) yn is-baragraffau (6) a (7), yn lle "dentist or nurse prescriber" rhodder "dentist, supplementary prescriber or independent nurse prescriber", and

(v) yn is-baragraff (9), yn lle "doctor or nurse prescriber" rhodder "doctor, supplementary prescriber or independent nurse prescriber";

(b) ym mharagraff 7(2), yn lle "Regulations or by a nurse prescriber", rhodder "Regulations, or by a supplementary prescriber or an independent nurse prescriber,"; ac

(c) ym mharagraffau 11A a 11B, o flaen "a nurse prescriber" ym mhob lle y mae'n digwydd, rhodder "an independent nurse prescriber or".

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Meddygol Cyffredinol) 1992

3.—(1) Diwygir Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Meddygol Cyffredinol) 1992(**7**) yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Yn rheoliad 2(1) (dehongli) hepgorir y diffiniad o "nurse prescriber".

(3) Yn Atodlen 2 (telerau gwasanaeth)—

(a) ym mharagraff 1, rhowch bob un o'r diffiniadau canlynol yn y lle priodol yn nhrefn yr wyddor —

""'independent nurse prescriber" means—

(a) a person whose name is registered—

(i) in Part 1 or 12 of the professional register and has a district nurse qualification additionally recorded in the professional register pursuant to rule 11 of the Nurses, Midwives and Health Visitors Rules 1983, or

(ii) in Part 11 of the professional register as a health visitor,

and against whose name is recorded in the professional register an annotation signifying that he or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVII B(i) of the Drug Tariff; or

(b) a person—

(i) whose name is registered in Parts 1,3, 5, 8, 10, 11, 12, 13, 14, or 15 of the professional register, and

(ii) against whose name is recorded in the professional register an annotation signifying that he or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Extended Formulary in Part XVIIB (ii) of the Drug Tariff;";

(**7**) O.S. 1992/635; yr offerynnau diwygio perthnasol yw O.S. 1992/2412, 1993/2421, 1994/2620, 1995/3093, 1998/682 a 2838, 1999/326, 2001/833 (Cy.35), 2002/916 (Cy.104) a 1896 (Cy.197) a 2003/784 (Cy.95).

""licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968(**8**);";

""the POM Order" means the Prescription Only Medicines (Human Use) Order 1997(**9**);";

""prescription only medicine" means a medicine referred to in article 3 of the POM Order (medicinal products on prescription only);"; and

""supplementary prescriber" means a person whose name is registered in —

(a) Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;

(b) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954; or

(c) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976,

and against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a supplementary prescriber;";

(b) ym mharagraff 28A(1) a (2), yn lle "a nurse prescriber", ym mhob lle y mae'n digwydd, rhodder "a nurse who is a supplementary prescriber or an independent nurse prescriber"; ac

(c) ar ôl paragraff 28A, rhodder y paragraff canlynol —

"**28B.**—(1) Where a doctor employs a supplementary prescriber and that person's functions include prescribing, the doctor shall have arrangements in place to ensure that that person will only—

(a) give a prescription for a prescription only medicine;

(b) administer a prescription only medicine for parenteral administration; or

(c) give directions for the administration of a prescription only medicine for parenteral administration,

as a supplementary prescriber under the conditions set out in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that —

(a) the person satisfies the applicable conditions set out in article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;

(b) the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971(**10**);

(c) the medicine is not specified in Schedule 10 (drugs and other substances not to be prescribed for supply under pharmaceutical services);

(d) the medicine is not specified in an entry in column 1 of Schedule 11(drugs to be prescribed under pharmaceutical services only in certain circumstances), unless—

(i) the patient is a person of a description mentioned in column 2 of that entry,

(ii) the medicine is prescribed for that patient only for the purposes specified in column 3 of that entry, and

(**8**) 1968 p. 67.
(**9**) O.S. 1997/1830; yr offerynnau diwygio perthnasol yw O.S. 2000/549 a 2003/696.
(**10**) 1971 p. 38.

(iii) if the prescriber is giving a prescription, he or she endorses the face of the form with the reference "SLS".

(3) Where a doctor employs a supplementary prescriber and that person's functions include prescribing, the doctor shall have arrangements in place to ensure that that person will only give a prescription for —

(a) an appliance; or

(b) a medicine that is not a prescription only medicine,

as a supplementary prescriber under the conditions set out in sub-paragraph (4).

(4) The conditions referred to in sub-paragraph (3) are that —

(a) he or she acts in accordance with a clinical management plan (which may be amended from time to time) which is in effect at the time he acts, which has been agreed by the patient to whom the plan relates, the doctor or dentist who is a party to the plan and any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan, and which contains the following particulars—

(i) the name of the patient to whom the plan relates,

(ii) the illness or conditions that may be treated by the supplementary prescriber,

(iii) the date on which the plan is to take effect, and when it is to be reviewed by the doctor or dentist who is a party to the plan,

(iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan,

(v) any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan, and any period of administration or use of any medicine or appliance which may be prescribed or administered under the plan,

(vi) relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances,

(vii) the arrangements for notification of —

(aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan,

(bb) incidents occurring with the appliance which might lead, might have led, or has led to the death or serious deterioration of state of health of the patient, and

(viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan;

(b) he has access to the health records of the patient to whom the plan relates which are used by any doctor or dentist who is a party to the plan;

(c) if it is a prescription for a medicine, the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;

(d) if it is a prescription for a medicine, the medicine is not specified in Schedule 10 (drugs and other substances not to be prescribed for supply under pharmaceutical services);

(e) if it is a prescription for a medicine, the medicine is not specified in an entry in column 1 of Schedule 11 (drugs to be prescribed only in certain circumstances), unless —

(i) the patient is a person of a description mentioned in column 2 of that entry,

(ii) the medicine is prescribed for that patient only for the purposes specified in column 3 of that entry, and

(iii) when giving the prescription, he or she endorses the face of the form with the reference "SLS";

(f) if it is a prescription for a medicine —

(i) the medicine is the subject of a product licence, a marketing authorisation or a homeopathic certificate of registration granted by the licensing authority or the European Commission, or

(ii) the use of the medicine is for the purpose of a clinical trial, and —

(aa) that trial is the subject of a clinical trial certificate issued in accordance with the Medicines Act 1968, or

(bb) a clinical trial certificate is not needed in respect of that trial by virtue of any exemption conferred by or under that Act;

(g) if it is a prescription for an appliance, the appliance is listed in Part IX of the Drug Tariff; and

(h) if it is a prescription for a restricted availability appliance —

(i) the patient is a person of a description mentioned in the entry in Part IX of the Drug Tariff in respect of that appliance,

(ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry, and

(iii) when giving the prescription, he or she endorses the face of the form with the reference "SLS".".

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2001

4.—(1) Diwygir Rheoliadau'r Gwasanaeth Iechyd Gwladol (Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2001(**11**) yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Ym mharagraff (2) (1) (dehongli)—

(a) rhowch bob un o'r diffiniadau canlynol yn y lle priodol yn nhrefn yr wyddor —

"ystyr "Tariff Cyffuriau" ("*Drug Tariff*") yw datganiad a lunnir, ei gyhoeddi a'i ddiwygio o dro i dro gan Gynulliad Cenedlaethol Cymru yn unol â rheoliad 18 o Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (safonau a thaliadau am gyffuriau a chyfarpar);";

"ystyr "nyrs sy'n rhagnodi'n annibynnol" ("*independent nurse prescriber*") yw —

(a) person y cofrestrwyd ei enw—

(i) yn Rhan 1 neu 12 o gofrestr proffesiwn nyrsys a bydwragedd y mae ganddi gymhwyster nyrs ardal a gofnodwyd yn ychwanegol ar gofrestr proffesiwn nyrsys a bydwragedd yn unol â rheol 11 o Reolau Nyrsys, Bydwragedd ac Ymwelwyr Iechyd 1983, neu

(**11**) O.S. 2001/1358 nad oes offerynnau diwygio perthnasol iddo.

(ii) yn Rhan 11 o gofrestr proffesiwn nyrsys a bydwragedd fel ymwelydd iechyd,

ac y cofnodwyd yn erbyn ei enw ar gofrestr proffesiwn nyrsys a bydwragedd nodyn i ddynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar o Lyfr Fferyllol Nyrsys sy'n Rhagnodi ar gyfer Nyrsys Ardal ac Ymwelwyr Iechyd yn Rhan XVII B(i) o'r Tariff Cyffuriau; neu

(b) person—

(i) y cofrestrwyd ei enw yn Rhannau 1, 3, 5, 8, 10, 11, 12, 13, 14, neu 15 o gofrestr proffesiwn nyrsys a bydwragedd, a

(ii) y cofnodwyd yn erbyn ei enw ar gofrestr proffesiwn nyrsys a bydwragedd nodyn i ddynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar o Lyfr Fferyllol Estynedig Nyrsys sy'n Rhagnodi yn Rhan XVII B(i) o'r Tariff Cyffuriau;";

"ystyr "cofrestr proffesiwn nyrsys a bydwragedd" ("*nurses and midwives' professional register*") yw'r gofrestr a gedwir gan y Cyngor Nyrsio a Bydwreigiaeth yn unol â pharagraff 10 o Atodlen 2 i Orchymyn Nyrsio a Bydwreigiaeth 2001;" ac

"ystyr "rhagnodydd atodol" ("*supplementary prescriber*") yw person a gofrestrwyd yn —

(a) Rhannau 1, 3, 5, 8, 10, 11, 12, 13, 14 neu 15 o gofrestr proffesiwn nyrsys a bydwragedd;

(b) Cofrestr y Fferyllwyr a gedwir yn unol ag adran 2(1) o Ddeddf Fferyllfeydd 1954; neu

(c) y gofrestr a gedwir yn unol ag Erthyglau 6 a 9 o Orchymyn Fferyllfeydd (Gogledd Iwerddon) 1976,

ac y cofnodir yn erbyn ei enw yn y gofrestr berthnasol nodyn i ddynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel rhagnodydd atodol;";

(b) yn y diffiniad o "ffurflen bresgripsiwn" ("*prescription form*"), yn lle "deintydd neu nyrs sy'n rhagnodi" rhodder "deintydd, neu ragnodydd atodol neu nyrs sy'n rhagnodi'n annibynnol"; ac

(c) hepgorir y diffiniad o "nyrs sy'n rhagnodi".

(3) yn rheoliad 6(1) (cyflenwi cyffuriau a chyfarpar mewn canolfannau cerdded i mewn), yn lle "meddyg neu nyrs sy'n rhagnodi" rhodder "meddyg, rhagnodydd atodol neu nyrs sy'n rhagnodi'n annibynnol".

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(**12**)

D.Elis-Thomas
Llywydd y Cynulliad Cenedlaethol

8 Hydref 2003

(**12**) 1998 p. 38.

EXPLANATORY NOTE

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

Mae'r Rheoliadau hyn yn diwygio'r setiau canlynol o Reoliadau:

1. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 ("Rheoliadau'r Gwasanaethau Fferyllol").

2. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Meddygol Cyffredinol) 1992 ("Rheoliadau'r Gwasanaethau Meddygol") a

3. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2001 ("Rheoliadau'r Ffioedd").

Mae angen y newidiadau o ganlyniad i ychwanegu categori newydd o ragnodydd meddyginiaethau a chyfarpar i'w ddefnyddio gan bobl at Orchymyn Meddyginiaethau a Ragnodir yn Unig (Defnydd Dynol) 1997.

Cyfeirir at y categori newydd o ragnodydd fel "rhagnodydd atodol". Mae rhagnodwyr atodol yn nyrsys cymwysedig addas a fferyllwyr cofrestredig a fydd yn gallu rhagnodi meddyginiaethau rhagnodol yn unig yn unol â chynllun rheoli clinigol ar gyfer cleifion unigol. Byddant hefyd yn gallu rhagnodi meddyginiaethau eraill a chyfarpar arall o dan y cynlluniau hynny.

Mae Rheoliadau'r Gwasanaethau Fferyllol yn cynnwys categori o "nyrs sy'n rhagnodi" sydd eisoes yn bodoli a ailenwir gan y diwygiadau yn y Rheoliadau hyn yn "nyrs sy'n rhagnodi'n annibynnol" er mwyn arbed dryswch rhwng y gwahanol gategorïau o nyrsys sy'n gallu rhagnodi meddyginiaethau at ddefnydd dynol.

Diwygir hefyd delerau'r gwasanaeth ar gyfer fferyllwyr o fewn Rheoliadau'r Gwasanaethau Fferyllol i alluogi fferyllwyr i weinyddu presgripsiynau a ddyroddir gan y categorïau newydd o ragnodydd.

Diwygir Rheoliadau'r Gwasanaethau Meddygol i gymhwyso rheolau sydd eisoes yn bodoli am feddyg yn cyflogi nyrs sy'n rhagnodi i'r categori newydd o ragnodydd atodol a'r nyrs sy'n rhagnodi'n annibynnol a ailenwyd. Gwneir ychwanegiadau i'r Rheoliadau i sicrhau bod gan feddyg sy'n cyflogi rhagnodydd atodol drefniadau ar waith i sicrhau cydymffurfedd â threfn y rheolaeth sy'n ymwneud â'r dull hwn o ragnodi.

Gwneir diwygiadau i'r Rheoliadau Ffioedd i adlewyrchu'r ffaith y caiff rhagnodwyr atodol ddyroddi ffurflenni presgripsiwn ac y cânt gymryd y cyfrifoldeb dros ragnodi i gleifion mewn canolfannau cerdded i mewn, os yw'r rhagnodwyr atodol yn bartïon i gynllun rheoli clinigol y claf hwnnw.