

**2007 Rhif (Cy. )**

**Y GWASANAETH IECHYD  
GWLADOL, CYMRU**

Rheoliadau'r Gwasanaeth Iechyd  
Gwladol (Diwygiadau Amrywiol  
Ynghylch Nyrsys Sy'n Rhagnodi'n  
Annibynnol, Rhagnodwyr Atodol,  
Nyrsys-ragnodwyr Annibynnol a  
Fferyllwyr-ragnodwyr Annibynnol)  
(Cymru) 2007

**NODYN ESBONIADOL**

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

Mae'r Rheoliadau hyn yn gwneud diwygiadau i'r setiau canlynol o Reoliadau:

1. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2001 (“y Rheoliadau Ffioedd am Gyffuriau a Chyfarpar”);
2. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (“y Rheoliadau Gwasanaethau Fferyllol”); a
3. Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Cymru) 2004 (“y Rheoliadau Contractau GMS”).

Mae angen y newidiadau o ganlyniad i ychwanegu dau gategori newydd o ragnodwyr at Orchymyn Meddyginiaethau drwy Bresgripsiwn yn Unig (I'w Defnyddio gan Bobl) 1997 (“y Gorchymyn POM”).

Y ddau gategori newydd yw: nyrsys-ragnodwyr annibynnol a fferyllwyr-ragnodwyr annibynnol.

Caiff nyrsys-ragnodwyr annibynnol ragnodi'n unol ag Erthygl 3A o'r Gorchymyn POM. Caiff fferyllwyr-ragnodwyr annibynnol ragnodi'n unol ag Erthygl 3B(2)(c) o'r Gorchymyn POM.

Mae'r Rheoliadau hyn yn darparu y bydd nyrs yng Nghymru, sydd wedi'i chofrestru yn y Gofrestr Nyrsio a Bydwreigiaeth, yn gallu rhagnodi fel nyrs-ragnodydd annibynnol pan fydd wedi llwyddo mewn cwrs a achredwyd. Bydd fferylllydd yn gallu rhagnodi fel fferylllydd-ragnodydd annibynnol ar yr amod y bydd y gofrestr fferyllol berthnasol yn dangos ei fod wedi cymhwyso i archebu cyffuriau, meddyginiaethau a chyfarpar fel fferylllydd-ragnodydd annibynnol.

Mae'r Rheoliadau hyn hefyd yn diweddarau'r diffiniad o "supplementary prescriber" a geir yn y Rheoliadau Gwasanaethau Fferyllol a "rhagnodydd atodol" a geir yn y Rheoliadau Ffioedd am Gyffuriau a Chyfarpar i gynnwys optometryddion. Mae optometryddion eisoes yn gynnwysedig yn y diffiniad o ragnodydd atodol yn y Rheoliadau Contractau GMS Cymru.

Mae'r Rheoliadau hyn hefyd yn diweddarau'r diffiniad o "nyrs sy'n rhagnodi'n annibynnol".

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Gwladol (Diwygiadau Amrywiol  
Ynghylch Nyrsys Sy'n Rhagnodi'n  
Annibynnol, Rhagnodwyr Atodol,  
Nyrsys-ragnodwyr Annibynnol a  
Fferyllwyr-ragnodwyr Annibynnol)  
(Cymru) 2007

*Wedi'u gwneud*

*2007*

*Yn dod i rym*

*1 Chwefror 2007*

Mae Cynulliad Cenedlaethol Cymru, ac yntau'n arfer y pwerau a roddwyd gan adrannau 28V, 41, 42, 43, 77 a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977(1), drwy hyn yn gwneud y Rheoliadau a ganlyn:

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- (1) 1977 p.49; mewnosodwyd adran 28V gan adran 175(1) o Ddeddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003 (p.43) ("Deddf 2003"); amnewidiwyd adran 41 gan Ddeddf Iechyd a Gofal Cymdeithasol 2001 (p.15) ("Deddf 2001") ac fe'i diwygiwyd gan Atodlen 11, paragraffau 7, 18(1), (2) a (3) o Ddeddf 2003, gan O.S. 2003/1590 ac O.S. 2005/2011; amnewidiwyd adran 42 gan Ddeddf y Gwasanaeth Iechyd Gwladol (Diwygio) 1986 (p.66), adran 3(1); fe'i hestynnwyd gan Ddeddf Iechyd a Meddyginiaethau 1988 (p.49), adran 17; ac fe'i diwygiwyd gan O.S.1987/2202, erthygl 4; gan Ddeddf y Gwasanaeth Iechyd Gwladol a Gofal yn y Gymuned 1990 (p.19) ("Deddf 1990"), adran 12(3); gan Ddeddf Awdurdodau Iechyd 1995 (p.17) ("Deddf 1995"), Atodlen 1, paragraff 30; gan Ddeddf 2001, adrannau 20(6), 43(2), (3) a (4) a chan Atodlen 6, Rhan 1; a chan Ddeddf Diwygio'r Gwasanaeth Iechyd Gwladol a Phroffesiynau Gofal Iechyd 2002, Atodlen 2, paragraff 17; diwygiwyd adran 43 gan Ddeddf 1995, Atodlen 1, paragraff 31; gan Ddeddf Gwasanaethau Iechyd 1980 (p.53), adran 21(2); gan Ddeddf y Gwasanaeth Iechyd Gwladol (Gofal Sylfaenol) 1997, adran 29(1) ac Atodlen 2, paragraffau 3 ac 14; gan Ddeddf 1990, Atodlen 9, paragraff 18(2) a chan Ddeddf 2001, adrannau 20(1) a (7), 42(2) a 43(5); diwygiwyd adran 77 gan Ddeddf 2003, Atodlen 11, paragraffau 7 a 28; diwygiwyd adran 126(4) gan Ddeddf 1990, adran 65(2) a Deddf Iechyd 1999 (p.8), Atodlen 4, paragraff 37(6). Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan adran 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977 i Gynulliad Cenedlaethol Cymru gan Orchymyn Cynulliad

## Enwi, cychwyn, cymhwyso a dehongli

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Diwygiadau Amrywiol Ynghylch Nyrsys Sy'n Rhagnodi'n Annibynnol, Rhagnodwyr Atodol, Nyrsys-ragnodwyr Annibynnol a Fferyllwyr-ragnodwyr Annibynnol) (Cymru) 2007.

(2) Daw'r Rheoliadau hyn i rym ar 1 Chwefror 2007.

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

(4) Yn y Rheoliadau hyn —

ystyr “Rheoliadau Contractau GMS Cymru” (“*GMS Contracts Wales Regulations*”) yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Cymru) 2004(1);

ystyr “Rheoliadau Ffioedd am Gyffuriau a Chyfarpar” (“*Charges for Drugs and Appliances Regulations*”) yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2001(2);

ystyr “Rheoliadau Gwasanaethau Fferyllol 1992” (“*Pharmaceutical Services Regulations 1992*”) yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(3).

## Diwygio'r Rheoliadau Ffioedd am Gyffuriau a Chyfarpar

2.—(1) Diwygir rheoliad 2(1) o'r Rheoliadau Ffioedd am Gyffuriau a Chyfarpar yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Yn lle'r diffiniad o “nyrs sy'n rhagnodi'n annibynnol” rhodder —

“ystyr “nyrs sy'n rhagnodi'n annibynnol” (“*independent nurse prescriber*”) yw person —

(a) sydd wedi'i gofrestru yn y Gofrestr Nyrsio a Bydwreigiaeth, a

(b) y mae nodyn yn ei gylch yn dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar—

(i) o'r Llyfr Fferyllol Nyrsys sy'n Rhagnodi sydd ar gyfer Nyrsys Ardal ac Ymwelwyr Iechyd yn Rhan XVIIIB(i) o'r Tariff Cyffuriau; neu

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Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999, O.S. 1999/672.

(1) O.S.2004/478 (Cy.48); yr offeryn diwygio perthnasol yw O.S. 2006/358 (Cy.46).

(2) O.S. 2001/1358 (Cy.86); yr offerynnau diwygio perthnasol yw O.S. 2003/2624 (Cy.252), 2004/1018 (Cy.115), 2004/1771, 2005/1915 (Cy.158).

(3) O.S. 1992/662; yr offerynnau diwygio perthnasol yw O.S.1996/698, 1998/681, 1999/696, 2001/1396 (Cy.91), 2002/3189 (Cy.305), 2003/2624 (Cy.252) a 2005/1013 (Cy.67).

- (ii) o'r Llyfr Fferyllol Nyrsys sy'n Rhagnodi sydd ar gyfer Ymarferwyr Cymunedol yn Rhan XVIIIB(i) o'r Tariff Cyffuriau

hefyd wedi'i gofnodi yn y gofrestr honno. At ddibenion y Gorchymyn POM mae nyrs sy'n rhagnodi'n annibynnol yn nyrs sy'n ymarferydd cymunedol ac sy'n rhagnodi;"

(3) Yn lle'r diffiniad o "cofrestr proffesiwn nyrsys a bydwragedd" rhodder —

"ystyr "Cofrestr Nyrsio a Bydwreigiaeth" (*"Nursing and Midwifery Register"*) yw'r gofrestr a gedwir gan y Cyngor Nyrsio a Bydwreigiaeth o dan Orchymyn Nyrsio a Bydwreigiaeth 2001(1);"

(4) Yn lle'r diffiniad o "rhagnodydd atodol" rhodder

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

(a) y mae ei enw wedi'i gofrestru yn —

- (i) y Gofrestr Nyrsio a Bydwreigiaeth,
- (ii) y Gofrestr Fferyllwyr Fferyllol a gedwir yn unol ag adran 2(1) o Ddeddf Fferylliaeth 1954(2),
- (iii) y gofrestr a gedwir yn unol ag Erthyglau 6 a 9 o Orchymyn Fferylliaeth (Gogledd Iwerddon) 1976(3),
- (iv) y rhan o'r gofrestr a gedwir gan y Cyngor Proffesiynau Iechyd yn unol ag Erthygl 5 o Orchymyn Proffesiynau Iechyd 2001 sy'n ymwneud ag —
  - (aa) ciropodyddion a phodiatryddion;
  - (bb) ffisiotherapyddion; neu
  - (cc) radiograffyddion: diagnostig neu therapiwtig, neu
- (v) yn y gofrestr optometryddion a gedwir gan y Cyngor Optegol Cyffredinol yn unol ag adran 7 o Ddeddf Optegwyr 1989, a

(b) y cofnodir yn erbyn ei enw yn y gofrestr berthnasol nodyn neu gofnod

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(1) O.S. 2001/253.  
(2) 1954 p.61.  
(3) O.S. 1976/1213.

yn dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel rhagnodydd atodol;”.

(5) Yn y safleoedd priodol yn nhrefn yr wyddor, mewnosoder y diffiniadau canlynol —

“ystyr “cofrestr berthnasol” (*“relevant register”*) yw—

- (a) mewn perthynas â nyrs neu fydwraig, y Gofrestr Nyrsio a Bydwreigiaeth;
- (b) mewn perthynas â fferyllydd, y gofrestr a gedwir yn unol ag adran 2(1) o Ddeddf Fferylliaeth 1954 neu'r gofrestr a gedwir yn unol ag Erthyglau 6 a 9 o Orchymyn Fferylliaeth (Gogledd Iwerddon);
- (c) mewn perthynas â pherson y mae ei enw wedi'i gofrestru yn y rhan o'r gofrestr a gedwir gan y Cyngor Proffesiynau Iechyd yn unol ag Erthygl 5 o Orchymyn Proffesiynau Iechyd 2001 sy'n ymwneud â —
  - (i) ciropodyddion a phodiatryddion;
  - (ii) ffisiotherapyddion; neu
  - (iii) radiograffyddion: diagnostig neu therapiwtig;y gofrestr honno; ac
- (ch) mewn perthynas ag optometrydd cofrestredig, y gofrestr optometryddion a gedwir o dan adran 7(a) o Ddeddf Optegwyr 1989;”;

ystyr “cwrs a achredwyd” (*“accredited course”*) yw cwrs a achredwyd gan y Cyngor Nyrsio a Bydwreigiaeth;”;

ystyr “fferyllydd-ragnodydd annibynnol” (*“pharmacist independent prescriber”*) yw person —

- (a) sy'n fferyllydd, a
- (b) y cofnodir yn erbyn ei enw yn y gofrestr berthnasol nodyn yn dynodi ei fod yn gymwys i archebu cyffuriau, meddyginiaethau a chyfarpar fel fferyllydd-ragnodydd annibynnol;”;

ystyr “Gorchymyn POM” (*“POM Order”*) yw Gorchymyn Meddyginiaethau drwy Bresgripsiwn yn Unig (I'w Defnyddio gan Bobl) 1997(1);”;

ystyr “nyrs-ragnodydd annibynnol” (*“nurse independent prescriber”*) yw person —

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(1) O.S. 1997/1830, yr offeryn diwygio perthnasol yw O.S. 2006/915

- (a) y mae ei enw wedi'i gofrestru yn y Gofrestr Nyrsio a Bydwreigiaeth, a
- (b) sydd, o ran y person sy'n ymarfer yng Nghymru ar 1 Chwefror 2007 neu ar ôl y dyddiad hwnnw, wedi llwyddo mewn cwrs a achredwyd ar gyfer ymarfer fel nyrs-ragnodydd annibynnol;”.

(6) Yn y diffiniad o “rhagnodydd” (*“prescriber”*), hepgorer y gair “ac” sy'n dod ar ôl y geiriau “nyrs annibynnol sy'n rhagnodi” a mewnosoder ar ôl y geiriau “rhagnodydd atodol;” —

“(ch) nyrs-ragnodydd annibynnol; ac

(d) fferyllydd-ragnodydd annibynnol;”.

### **Diwygio Rheoliadau Gwasanaethau Fferyllol 1992.**

3.—(1) Diwygir Rheoliad 2(1) o Reoliadau Gwasanaethau Fferyllol 1992 yn unol â darpariaethau'r rheoliad hwn.

(2) Yn lle'r diffiniad o “independent nurse prescriber” rhodder —

““independent nurse prescriber” means a person —

- (a) who is registered in the Nursing and Midwifery Register, and
- (b) in respect of whom an annotation signifying that he or she is qualified to order drugs, medicines and appliances from —
  - (i) the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIIB(i) of the Drug Tariff, or
  - (ii) the Nurse Prescribers' Formulary for Community Practitioners under Part XVIIIB(i) of the Drug Tariff

is also recorded in that register. For the purposes of the POM Order, an independent nurse prescriber is a community practitioner nurse prescriber;”.

(3) Yn lle'r diffiniad o “nurses and midwives' professional register” rhodder —

““Nursing and Midwifery Register” means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001;”.

(4) Yn lle'r diffiniad o “supplementary prescriber” rhodder —

““supplementary prescriber” means a person —

- (a) whose name is registered in —

- (i) the Nursing and Midwifery Register,
  - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954,
  - (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976,
  - (iv) the part of the register maintained by the Health Professions Council in pursuance of Article 5 of the Health Professions Order 2001 relating to —
    - (aa) chiropodists and podiatrists;
    - (bb) physiotherapists; or
    - (cc) radiographers: diagnostic or therapeutic, or
  - (v) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989, and
- (b) against whose name is recorded in the relevant register an annotation or entry signifying that he or she is qualified to order drugs, medicines and appliances as a supplementary prescriber;”.

(5) Yn y safleoedd priodol yn nhrefn yr wyddor mewnosoder y diffiniadau canlynol —

““accredited course” means a course accredited by the Nursing and Midwifery Council;”;

“nurse independent prescriber” means a person —

- (a) whose name is registered in the Nursing and Midwifery Register, and
- (b) who, in respect of a person practising in Wales on or after 1 February 2007, has passed an accredited course to practise as a nurse independent prescriber;”;

“pharmacist independent prescriber” means a person —

- (a) who is a pharmacist, and
- (b) 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 pharmacist independent prescriber;”;



“POM Order” means the Prescription Only Medicines (Human Use) Order 1997;”;

“relevant register” means —

- (a) in relation to a nurse or a midwife, the Nursing and Midwifery Register;
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954 or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order;
- (c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of Article 5 of the Health Professions Order 2001 relating to —
  - (i) chiropodists and podiatrists;
  - (ii) physiotherapists; or
  - (iii) radiographers: diagnostic or therapeutic;that register; and
- (d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”.

(6) Yn y diffiniad o “prescriber” ar ôl y geiriau “an independent nurse prescriber” mewnosoder y canlynol “, a nurse independent prescriber, a pharmacist independent prescriber”.

#### **Diwygio rheoliad 2(1) o’r Rheoliadau Contractau GMS Cymru**

4.—(1) Diwygir Rheoliad 2(1) o’r Rheoliadau Contractau GMS Cymru yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Yn lle’r diffiniad o “independent nurse prescriber” rhodder —

““independent nurse prescriber” means a person —

- (a) who is either engaged or employed by the contractor or is a party to the contract,
- (b) who is registered in the Nursing and Midwifery Register, and
- (c) in respect of whom an annotation signifying that he or she is qualified to order drugs, medicines and appliances from —
  - (i) the Nurse Prescribers’ Formulary for District Nurses and Health

Visitors in Part XVIIB(i) of the Drug Tariff, or

- (ii) the Nurse Prescribers' Formulary for Community Practitioners under Part XVIIB(i) of the Drug Tariff

is also recorded in that register. For the purposes of the POM Order, an independent nurse prescriber is a community practitioner nurse prescriber ;”.

(3) Yn y safleoedd priodol yn nhrefn yr wyddor, mewnosoder y diffiniadau canlynol—

““accredited course” means a course accredited by the Nursing and Midwifery Council;”;

“nurse independent prescriber” means a person —

- (a) who is either engaged or employed by the contractor or is a party to the contract,
- (b) whose name is registered in the Nursing and Midwifery Register, and
- (c) who, in respect of a person practising in Wales on or after 1 February 2007, has passed an accredited course to practise as a nurse independent prescriber;”;

“pharmacist independent prescriber” means a person —

- (a) who is either engaged or employed by the contractor or is a party to the contract,
- (b) who is a pharmacist, and
- (c) 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 pharmacist independent prescriber;”.

(4) Yn y diffiniad o “relevant register”, ar ôl y geiriau “the Pharmacy (Northern Ireland) Order 1976;” mewnosoder y canlynol —

“(c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of Article 5 of the Health Professions Order 2001 relating to —

- (i) chiropodists and podiatrists;
- (ii) physiotherapists; or
- (iii) radiographers: diagnostic or therapeutic;

that register; and

- (d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;”.

(5) Yn y diffiniad o “prescriber”, ym mharagraff (b) dileer y gair “and”, ac ar ôl paragraff “(c) supplementary prescriber,” mewnosoder—

- “(d) a nurse independent prescriber, and
- (e) a pharmacist independent prescriber,”

### **Diwygio Atodlen 6 i'r Rheoliadau Contractau GMS Cymru**

5.—(1) Diwygir Atodlen 6 (amodau contract eraill) i'r Rheoliadau Contractau GMS Cymru yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Ym mharagraff 49(3) a (4) (amodau sy'n berthnasol i ddarparu gwasanaethau gweinyddu) ar ôl “independent nurse prescriber”, ym mhob man y ceir y geiriau hynny, mewnosoder “, nurse independent prescriber, a pharmacist independent prescriber or a supplementary prescriber whose name is registered in the Nursing and Midwifery Register and against whose name is recorded in that register an annotation or entry signifying that he or she is qualified to order drugs, medicines and appliances as a supplementary prescriber”.

(3) Ym mharagraff 64(1) a (2) (sy'n ymwneud â nyrsys sy'n rhagnodi'n annibynnol a rhagnodwyr atodol), ar ôl “independent nurse prescriber”, ym mhob man y ceir y geiriau hynny, mewnosoder “, a nurse independent prescriber, a pharmacist independent prescriber”.

(4) Yn y pennawd i baragraff 64, ar ôl “independent nurse prescribers” mewnosoder “, nurse independent prescribers, pharmacist independent prescribers”.

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

Dyddiad

Llywydd y Cynulliad Cenedlaethol

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(1) 1998 p.38.

**Date:**            15 November 2006

**Venue:**

**Title:**            **THE NATIONAL HEALTH SERVICE (MISCELLANEOUS AMENDMENTS CONCERNING INDEPENDENT NURSE PRESCRIBERS, SUPPLEMENTARY PRESCRIBERS, NURSE INDEPENDENT PRESCRIBERS AND PHARMACIST INDEPENDENT PRESCRIBERS) (WALES) REGULATIONS 2007**

### **Purpose**

The Committee is invited to consider the National Health Service (Miscellaneous Amendments Concerning Independent Nurse Prescribers, Supplementary Prescribers, Nurse Independent Prescribers and Pharmacist Independent Prescribers) (Wales) Regulations 2007

### **Summary**

The Health and Social Services Committee have requested the opportunity to scrutinise these Regulations.

The intended effect of this Instrument is to ensure:

- Nurses and midwives who are registered in the Nursing and Midwifery Register will be able to prescribe as nurse independent prescribers in Wales provided they pass an accredited training course. Nurse independent prescribers will be able to prescribe prescription only medicines and certain, specified, controlled drugs without supervision. Article 3A of the Prescription Only Medicines Human Use Order 1997 governs their prescribing authority. Pharmacist independent prescribers will, in accordance with article 3B(2)(c) of the Prescription Only Medicines Human Use Order 1997, be entitled to prescribe prescription only drugs, excluding controlled drugs, without supervision provided there is an annotation in the relevant pharmaceutical register indicating that they are qualified to order drugs, medicines and appliances as a pharmacist independent prescriber. (currently primary legislation does not permit pharmacist independent prescribers to prescribe controlled drugs);
- extend the definition of supplementary prescriber in the National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001 and the National Health Service (Pharmaceutical Services) Regulations 1992 to include suitably qualified and registered optometrists. This will enable community pharmacists to dispense NHS (WP10) prescriptions for optometrist supplementary prescribers and levy a charge for the prescription items; and

- ensure that Community Pharmacies are able to dispense NHS (WP10) prescriptions for
  - a) [nurse independent prescribers and pharmacist independent prescribers prescribing any medicine for any condition for any individual patient including a range of controlled drugs by nurses as laid out in the Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2006]; and
  - b) optometrists supplementary prescribers, prescribing any medicine for any condition for any individual patient in accordance with a clinical management plan.

Currently Community Pharmacists can dispense NHS (WP10) prescriptions for supplementary prescribing nurses, pharmacists, physiotherapists, chiropodists/podiatrists and radiographers.

## **Background**

Non –medical prescribing has been practised in Wales for some time with the introduction of District Nurse and Health Visitor prescribing independently from a limited list and at a later date nurse and pharmacists supplementary prescribing any medicine for any condition provided the prescription is given in accordance with a clinical management plan.

In October 2005, following consultation, the Committee on the Safety of Medicines (CSM) recommended changes be made to the Prescriptions Only Medicines ( Human Use) Order 1997 (UK wide) to facilitate the introduction of independent prescribing by qualified nurse independent prescribers and pharmacist independent prescribers.

Nurse independent prescribers and pharmacist independent prescribers will only prescribe independently within their therapeutic area of competence and will be recommended to work within established referral pathways as part of a multi-disciplinary team providing a package of care to patients. Professional regulation will govern this.

In January 2006, the Minister announced during a visit to Boots the Chemists, Queen Street, Cardiff proposals to take independent prescribing by nurses and pharmacists forward in Wales and therefore assist in the implementation of Designed for Life.

Changes were made to Prescriptions Only Medicines (Human Use) Order 1997 on 1 May 2006 and apply UK wide to enable independent prescribing by nurses and pharmacists in other UK territories.

Amendments to the following NHS Regulations are required to take this forward in Wales:

- The National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001;
- The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004; and
- The National Health Service (Pharmaceutical Services) Regulations 1992.

## **Compliance**

### **The proposed legislation will (as far as is applicable):**

- have due regard to the principle of equality of opportunity for all people (Government of Wales Act 1998 section 120);
- be compatible with the Assembly's scheme for sustainable development (section 121);
- be compatible with Community law (section 106);
- be compatible with the Assembly's human rights legislation (section 107); and
- be compatible with any international obligations binding the UK Government and the Assembly (section 108).

## **Financial Implications**

The costs associated with the implementation of independent prescribing in Wales will be accommodated from within the existing Supplementary Prescribers budget (2006/07 - £450,000) of the Health and Social Care MEG. This budget will cover costs incurred by the project board and the associated training costs of the initial cohort of individuals undertaking this training to become qualified as nurse independent prescribers and pharmacist independent prescribers. The Health & Social Care Resources Directorate has seen and noted the contents of this submission (LMD 2798)

In the longer term it is anticipated the introduction of independent prescribing by nurses and pharmacists will provide more cost effective NHS services, which are currently being provided solely by the medical profession.

### **Action for Subject Committee**

Scrutinise the National Health Service (Miscellaneous Amendments Concerning Independent Nurse Prescribers, Supplementary Prescribers, Nurse Independent Prescribers and Pharmacist Independent Prescribers) (Wales) Regulations 2007

### **Brian Gibbons**

**Minister for Health and Social Services**

Contact Point: Sian Evans (OCMO HPG)

**To: Business Committee**

From: Brian Gibbons AM  
Minister for Health and Social Services

## **EXPLANATORY MEMORANDUM**

### **National Health Service, Wales**

THE NATIONAL HEALTH SERVICE (MISCELLANEOUS AMENDMENTS CONCERNING INDEPENDENT NURSE PRESCRIBERS, SUPPLEMENTARY PRESCRIBERS, NURSE INDEPENDENT PRESCRIBERS AND PHARMACIST INDEPENDENT PRESCRIBERS) (WALES) REGULATIONS 2007

### **Summary**

**These Regulations will ensure that qualified and registered Nurse Independent Prescribers and Pharmacist Independent Prescribers are able to prescribe once their training has been completed. These Regulations will also make provision for prescribing by other non – medical prescribers.**

1. This Memorandum is submitted to the Assembly's Business Committee in relation to The National Health Service (Miscellaneous Amendments Concerning Independent Nurse Prescribers, Supplementary Prescribers, Nurse Independent Prescribers And Pharmacist Independent Prescribers) (Wales) Regulations 2007, in accordance with Standing Order 24.6.
2. A copy of the Instrument is submitted with this Memorandum.

### **Enabling Power**

3. The powers enabling this Instrument to be made are contained in sections 28V, 41,42,43,77 and 126(4) of the National Health Service Act 1977. These powers have been transferred to the National Assembly for Wales. Responsibility for issues relating to the contents of these Regulations has been delegated to my portfolio as Minister for Health and Social Services.

### **Effect**

4. The intended effect of these Regulations is to:
  - introduce two new categories of prescriber: nurse independent prescribers and pharmacist independent prescribers.
  - nurses and midwives who are registered in the Nursing and Midwifery Register will be able to prescribe as nurse independent prescribers in Wales provided they pass an accredited training course. Nurse independent prescribers will be able to prescribe prescription only

medicines and certain, specified, controlled drugs without supervision. Article 3A of the Prescription Only Medicines Human Use Order 1997 governs their prescribing authority. Pharmacist independent prescribers will, in accordance with article 3B(2)(c) of the Prescription Only Medicines Human Use Order 1997, be entitled to prescribe prescription only drugs, excluding controlled drugs, without supervision provided there is an annotation in the relevant pharmaceutical register indicating that they are qualified to order drugs, medicines and appliances as a pharmacist independent prescriber. (currently primary legislation does not permit pharmacist independent prescribers to prescribe controlled drugs);

- updates the definition of independent nurse prescriber;
  - extend the definition of supplementary prescriber in the National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001 and the National Health Service (Pharmaceutical Services) Regulations 1992 to include suitably qualified and registered optometrists. This will enable community pharmacists to dispense NHS (WP10) prescriptions for optometrist supplementary prescribers and levy a charge for the prescription items; and
  - ensure that Community Pharmacies are able to dispense NHS (WP10) prescriptions for
    - c) nurse independent prescribers and pharmacist independent prescribers prescribing any medicine for any condition for any individual patient including a range of controlled drugs by nurses as laid out in the Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2006; and
    - d) optometrists supplementary prescribers, prescribing any medicine for any condition for any individual patient in accordance with a clinical management plan.
5. Currently Community Pharmacists can dispense NHS (WP10) prescriptions for supplementary prescribing nurses, pharmacists, physiotherapists, chiropodists/podiatrists and radiographers.

### **Target Implementation**

6. It is intended that the proposed Regulations be made on 30 January 2007 and come into force on 1 February 2007. If these target dates are not met nurse independent prescribers and pharmacist independent prescribers may qualify and be unable to prescribe. These Regulations mirror changes already implemented in England where regulations came into force 1<sup>st</sup> May 2006. Regulation changes in Scotland and Northern Ireland have yet to come into force. There are variations in the terminology used in Wales with reverence to the definitions of the different type of prescribers.



### **Financial Implications**

7. The costs associated with the implementation of independent prescribing in Wales will be accommodated from within the existing Supplementary Prescribers budget (2006/07 - £450,000) of the Health and Social Care MEG. This budget will cover costs incurred by the project board and the associated training costs of the initial cohort of individuals undertaking this training to become qualified as nurse independent prescribers and pharmacist independent prescribers. The Health & Social Care Resources Directorate has seen and noted the contents of this submission (LMD 2798)
8. In the longer term it is anticipated the introduction of independent prescribing by nurses and pharmacists will provide more cost effective NHS services, which are currently being provided solely by the medical profession.

### **Regulatory Appraisal**

9. A Regulatory Appraisal has been carried out in relation to this Instrument and is attached.

### **Consultation**

#### **With Stakeholders**

10. Changes to be made to the Prescriptions Only Medicines (Human Use) Order 1997 to introduce independent prescribing by nurses and pharmacists UK wide were issued for formal consultation between 2 March 2006 and 23 May 2006. This exercise was undertaken on a UK wide basis by means of written communication from the Medicines Healthcare products Regulatory Agency.
11. The Committee on the Safety of Medicines (CSM) reviewed written responses of the consultation exercise and in October 2005 made recommendations to facilitate the introduction of independent prescribing by qualified Independent Nurse Prescribers and Independent Pharmacist Prescribers. This resulted in changes being made to Prescriptions Only Medicines (Human Use) Order 1997 on May 1<sup>st</sup> 2006.
12. The decision to introduce nurse independent and pharmacist independent prescribers in Wales arose following a management board approval and a meeting of policy leads and was endorsed at the Minister's announcement during a visit to Boots the Chemist on Queen Street, Cardiff, on 19 January 2006.

#### **With subject committee**

13. These Regulations were first notified to the Health and Social Services Committee via the list of forthcoming legislation on 12 January 2005 (HSS(2)-01-05 (p.2a), item no. HSS 71 (04)) and have remained on the list

ever since. However, they appeared on the list as Independent Prescribers Regulations 2005. They are due to be scrutinised on 15 November 2006.

### **Recommended Procedure**

14. Subject to the views of the Business Committee, it is recommended that these Regulations proceed to Plenary under the Standard procedure so that Assembly Members are given every opportunity to examine and discuss the proposed changes.

### **Compliance**

15. The proposed legislation will (as far as is applicable):

- have due regard to the principle of equality of opportunity for all people (Government of Wales Act 1998 section 120);
- be compatible with the Assembly's scheme for sustainable development (section 121);
- be compatible with Community law (section 106);
- be compatible with the Assembly's human rights legislation (section 107); and
- be compatible with any international obligations binding the UK Government and the Assembly (section 108).

16. The information in this Memorandum has been cleared with the Legal Services Department (LS).

17. Drafting Lawyer – Rhian Williams Ext 3967

18. Head of Branch – Caroline Poulter Ext 5404

19. Drafting Policy Official – Sian Evans Ext 5260

**MINISTER FOR HEALTH AND SOCIAL SERVICES**

**REGULATORY APPRAISAL**

National Health Service, Wales

THE NATIONAL HEALTH SERVICE (MISCELLANEOUS AMENDMENTS CONCERNING INDEPENDENT NURSE PRESCRIBERS, SUPPLEMENTARY PRESCRIBERS, NURSE INDEPENDENT PRESCRIBERS AND PHARMACIST INDEPENDENT PRESCRIBERS) (WALES) REGULATIONS 2007

**Background**

1. Non –medical prescribing has been practiced in Wales for some time with the introduction of District Nurse and Health Visitor prescribing independently from a limited list and at a later date nurse and pharmacists supplementary prescribing any medicine for any condition provided the prescription is given in accordance with a clinical management plan.
2. In October 2005, following consultation, the Committee on the Safety of Medicines (CSM) recommended changes be made to the Prescriptions Only Medicines ( Human Use) Order 1997 (UK wide) to facilitate the introduction of independent prescribing by qualified nurse independent prescribers and pharmacist independent prescribers.
3. Nurse independent prescribers and pharmacist independent prescribers will only prescribe independently within their therapeutic area of competence and will be recommended to work within established referral pathways as part of a multi-disciplinary team providing a package of care to patients. Professional regulation will govern this.
4. In January 2006, the Minister announced during a visit to Boots the Chemists, Queen Street, Cardiff proposals to take independent prescribing by nurses and pharmacists forward in Wales and therefore assist in the implementation of Designed for Life.
5. Changes were made to Prescriptions Only Medicines (Human Use) Order 1997 on 1 May 2006 and apply UK wide to enable independent prescribing by nurses and pharmacists in other UK territories.

Amendments to the following NHS Regulations are required to take this forward in Wales:

6.
  - The National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001;
  - The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004; and
  - The National Health Service (Pharmaceutical Services) Regulations 1992.

**Purpose and intended effect of the measure**

7. The purpose of these Regulations is to:

- add two new categories of prescriber to the relevant Welsh regulations which will ensure that qualified and registered nurse independent prescribers and pharmacist independent prescribers are able to prescribe once their training has been completed;
- ensure that nurses and midwives who are registered in the Nursing and Midwifery Register will be able to practise as nurse independent prescribers in Wales provided they have passed an accredited training course. Nurse independent prescribers will be able to prescribe prescription only medicines and certain, specified, controlled drugs without supervision. Article 3A of the Prescription Only Medicines (Human Use) Order 1997 governs their prescribing authority. Pharmacist independent prescribers will, in accordance with article 3B(2)(c) of the Prescription Only Medicines (Human Use) Order 1997, be entitled to prescribe prescription only drugs, excluding controlled drugs, without supervision provided there is an annotation in the relevant pharmaceutical register indicating that they are qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;
- update the definition of independent nurse prescriber.
- extend the definition of supplementary prescriber in the National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001 and the National Health Service (Pharmaceutical Services) Regulations 1992 to include suitably qualified optometrists. This will enable community pharmacists to dispense WP10 prescriptions for optometrist supplementary prescribers and levy a charge for the prescription items: and
- ensure that Community Pharmacies are able to dispense WP10 prescriptions written by:
  - a) nurse independent prescribers and pharmacist independent prescribers prescribing any medicine for any condition for any

individual patient. This includes a limited range of controlled drugs by nurses as laid out in the Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2006; and

- b) optometrists supplementary prescribers prescribing any medicine for any condition for any individual patient in accordance with a clinical management plan.
8. Currently Community Pharmacists can dispense and charge for WP10 prescriptions for supplementary prescribing nurses, pharmacists, physiotherapists, chiropodists/podiatrists and radiographers.

### **Risk Assessment**

9. The pressures on NHS Wales to provide high quality, efficient and cost – effective services for patients in accordance with the vision of the Welsh Assembly Government has long since been appreciated. This has been reinforced in ‘Designed for Life’ – particularly in respect of unscheduled care, the management of long-term conditions and the modernisation through service reconfiguration. This risk of not making this Order would impact on the delivery of some aspects of service modernisation.
10. The Department of Health in England and Northern Ireland and Scottish Executive are proceeding with the changes and the risk of not making the Order is that comparability of the corresponding professions across the border would not be maintained.

### **Options**

#### Option 1: Do Nothing

11. Nurses and pharmacists would be unable to prescribe as nurse independent prescribers and pharmacist independent prescribers and the service provided to patients by nurses and pharmacists would remain as it is. This would limit the access to medicines and add pressures to the medical profession workload.
12. Pharmacists would be unable to dispense prescriptions written by optometrists and the service provided to patients by nurses and pharmacists would remain as it is. This would limit the access to medicines and add pressures to the medical profession workload.
13. Changes have already been made to Prescriptions Only Medicines (Human Use) Order 1997 on 1 May 2006. This applies UK wide. This would mean that qualified nurses and pharmacists could prescribe independently in accordance with the relevant provisions of the POM Order in England, Scotland and Northern Ireland but not in Wales. This will become confusing for the professions and for patients resident on the border. This may cause a shift in manpower to jobs over the border thereby increasing workforce-planning pressures.

### Option 2: Make the Legislation

14. Introducing changes to the Regulations will mean that qualified and registered nurse independent prescribers and pharmacist independent prescribers will be able to prescribe independently once their training and registration with professional bodies has been completed.
15. Introducing changes to the Regulations will mean that qualified and registered optometrists supplementary prescribers will be able to prescribe and have their prescriptions dispensed in Community Pharmacies.

### **Benefits**

16. Benefits that should stem from these new Regulations include having an:
  - adequately trained and skilled workforce to provide efficient, cost effective and accessible services across NHS Wales. This will take pressure off doctors to be able concentrate on more complex cases.
  - It will improve access to advice & services
  - increase patient choice, which should
  - contribute to the introduction of more flexible team working across the NHS.
17. Patients will be able to get quicker and more efficient access to medicine.
18. The introduction of prescribing rights by non – medical professions provides an opportunity to take full advantage of the powers to extend prescribing for nurses and pharmacists and to amend Regulations to ensure prescribing optometrists can have prescriptions dispensed by Community Pharmacies, which will bring clarity for Community Pharmacists in Wales regarding dispensing non-medical prescriptions both from English non-medical prescribers and Welsh non-medical prescribers.
19. Optometrists would be able to prescribe medicines to support and enhance treatment packages specific to their speciality, which will help to avoid patients needing to have access to a GP.
20. This would allow specialist nurses / pharmacists to run clinics such as diabetes and coronary heart disease clinics both in primary and secondary care and prescribe independently for their patients. This will take pressure off doctors (GPs and consultants), allowing them to focus on more complex cases and improving the availability of care for patients with the reduction of waiting times. This would also provide capacity for services to respond to the introduction of the European working time directive, which is expected to reduce doctors working hours and increase the demand for doctors expertise.

21. All of this will lead to consistency with practice across the border in England, Scotland and Northern Ireland.

### **Costs**

22. The costs associated with the implementation of independent prescribing in Wales will be accommodated from within the existing Supplementary Prescribers budget (2006/07 - £450,000) of the Health and Social Care MEG. This budget will cover costs incurred by the project board and the associated training costs of the initial cohort of individuals undertaking this training to become qualified as nurse independent prescribers and pharmacist independent prescribers. The Health & Social Services Resources Directorate has seen and noted the contents of this submission (LMD 2798).
23. In the longer term it is anticipated the introduction of independent prescribing by nurses and pharmacists will provide more cost effective NHS services, which are currently being provided solely by the medical profession.

### **Consultation**

#### With Stakeholders

24. Changes to be made to the Prescriptions Only Medicines (Human Use) Order 1997 to introduce independent prescribing by nurses and pharmacists UK wide were issued for formal consultation between 2 March 2006 and 23 May 2006. This exercise was undertaken on a UK wide basis by means of written communication from the Medicines Healthcare products Regulatory Agency.
25. The Committee on the Safety of Medicines (CSM) reviewed written responses of the consultation exercise and in October 2005 made recommendations to facilitate the introduction of independent prescribing by qualified Independent Nurse Prescribers and Independent Pharmacist Prescribers. This resulted in changes being made to Prescriptions Only Medicines (Human Use) Order 1997 on May 1<sup>st</sup> 2006.
26. The decision to introduce nurse independent and pharmacist independent prescribers in Wales arose following a management board approval and a meeting of policy leads and was endorsed at the Minister's announcement during a visit to Boots the Chemist on Queen Street, Cardiff, on 19 January 2006.

#### **With Subject Committee**

27. These Regulations were first notified to the Health and Social Services Committee via the list of forthcoming legislation on 12 January 2005 (HSS(2)-01-05 (p.2a), item no. HSS 71 (04)) and have remained on the list ever since. However, they appeared on the list as Independent Prescribers Regulations 2005. They are due to be scrutinised on 15 November 2006.

## **Review**

28. The impact of the nurse and pharmacist independent prescribing will be monitored and reviewed through the collection of dispensing data by Health Solutions Wales.

## **Summary**

29. The proposed amendments will result in nurses and pharmacists in Wales being able to write prescriptions independently for patients with conditions within the nurses / pharmacist therapeutic area of competence and therefore providing efficient, accessible, cost effective services to patients in NHS Wales. This is dependent on nurses and pharmacists attaining additional specific accredited qualifications and annotation on the professional register to allow them to prescribe. Training courses are being developed and it is anticipated these will be available Spring 2007.

30. The proposed amendments will result in enabling Community Pharmacies to dispense prescriptions written by supplementary prescribing optometrists in Wales in accordance with a clinical management plan for patients with conditions within the therapeutic area of competence. This would therefore be inline with the provision of dispensing services for other Allied Health Professionals supplementary prescribers namely registered physiotherapists, chiropodists/podiatrists , radiographers. This would therefore providing efficient, accessible, cost effective services to patients in NHS Wales.