



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2007 Rhif 1112 (Cy.117)

2007 No. 1112 (W.117)

**Y GWASANAETH IECHYD
GWLADOL, CYMRU**

**NATIONAL HEALTH
SERVICE, WALES**

Rheoliadau'r Gwasanaeth Iechyd
Gwladol (Gwasanaethau Fferyllol)
(Taliadau i Bersonau sy'n darparu
Gwasanaethau Fferyllol)
(Diwygio) (Cymru)
2007

The National Health Service
(Pharmaceutical Services)
(Remuneration for Persons
providing Pharmaceutical Services)
(Amendment) (Wales) Regulations
2007

NODYN ESBONIADOL

EXPLANATORY NOTE

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

(This note is not part of the Regulations)

Mae'r Rheoliadau hyn yn diwygio ymhellach Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (O.S.1992/662) ("y prif Reoliadau") ac yn gwneud diwygiadau canlyniadol i is-ddeddfwriaeth arall.

These Regulations further amend the National Health Service (Pharmaceutical Services) Regulations 1992 (S.I.1992/662) ("the principal Regulations") and make consequential amendments to other secondary legislation.

Mae rheoliad 4 o'r Rheoliadau hyn amnewid rheoliad 18 o'r prif Reoliadau. Mae angen yr amnewidiad hwn yn sgil y newidiadau i'r sail ddeddfwriaethol ar gyfer gwneud penderfyniadau ynglyn â thaliadau i bersonau sy'n darparu gwasanaethau fferyllol ar ôl i Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006 ddod i rym. Mae rheoliad 18, fel y'i amnewidir, yn cynnwys darpariaethau ynghylch penderfynu ynglyn â thaliadau i bersonau sy'n darparu gwasanaethau fferyllol gan yr awdurdodau sy'n penderfynu.

Regulation 4 of these Regulations substitutes regulation 18 of the principal Regulations. This substitution is required because of the changes to the legislative basis upon which determinations relating to the remuneration for persons providing pharmaceutical services are made as a result of the coming into force of the National Health Service (Wales) Act 2006. The substituted regulation 18 contains provisions relating to the determination of remuneration for persons providing pharmaceutical services by the determining authorities.

Mae rheoliad 3 a rheoliadau 5 i 11 yn gwneud diwygiadau canlyniadol i'r prif Reoliadau ac i is-ddeddfwriaeth berthnasol arall.

Regulation 3 and regulations 5 to 11 make consequential amendments to the principal Regulations and to other relevant secondary legislation.

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Wedi'u gwneud 27 Mawrth 2007
Yn dod i rym yn unol â
rheoliad 1(2) o'r
Rheoliadau hyn

Made 27 March 2007
Coming into force in accordance with
regulation 1(2) of these
Regulations

Mae Cynulliad Cenedlaethol Cymru drwy arfer y pwerau a roddwyd iddo gan adrannau 88 a 203(9) a (10) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(1) drwy hyn yn gwneud y Rheoliadau a ganlyn:

The National Assembly for Wales, in exercise of the powers conferred by sections 88 and 203(9) and (10) of the National Health Service (Wales) Act 2006(1) hereby makes the following Regulations:

Enwi, cychwyn a chymhwysio

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Taliadau i bersonau sy'n darparu Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2007.

Title, commencement and application

1.-(1) The title of these Regulations is the National Health Service (Pharmaceutical Services) (Remuneration for persons providing Pharmaceutical Services) (Amendment) (Wales) Regulations 2007.

(1) Mae Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006 (p.42) ("Deddf 2006") yn Ddeddf cydgrynhoi sy'n diddymu ac yn ailddeddfu yn ei chyflawnder Ddeddf y Gwasanaeth Iechyd Gwladol 1977 (p.49) ("Deddf 1977") ac yn ymgorffori rhai o'r darpariaethau o Ddeddf y Gwasanaeth Iechyd Gwladol a Gofal yn y Gymuned 1990 (p.19), Deddf Iechyd 1999 (p.8), Deddf Iechyd a Gofal Cymdeithasol 2001 (p.15), Deddf Diwygio'r Gwasanaeth Iechyd Gwladol a Phroffesiynau Gofal Iechyd 2002 (p.17), Deddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003 (p.43) a Deddf Iechyd 2006 (p.8).

Mae Adrannau 88 a 203(9) a (10) yn cyfateb i adrannau 43A a 126(4) o Ddeddf 1977.

Mae'r cyfeiriadau at "Welsh Ministers" a swyddogaethau'r Gweinidogion hynny yn Neddf 2006 yn cael eu trin fel cyfeiriadau at Gynulliad Cenedlaethol Cymru a swyddogaethau'r Cynulliad fel y'i sefydlwyd gan Ddeddf Llywodraeth Cymru 1998 (p.38) yn unol â'r addasiadau a gynhwysir yn Neddf y Gwasanaeth Iechyd Gwladol (Darpariaethau Canlyniadol) 2006 (p.43), sef yn adran 5 a pharagraff 10 o Atodlen 3.

Bydd cyfeiriadau at Gynulliad Cenedlaethol Cymru a'i swyddogaethau yn trosglwyddo i Weinidogion Cymru yn syth ar ôl diwedd yr "initial period" (fel y'i diffinnir yn adran 161(5)) yn unol ag adran 162 a pharagraff 30 o Atodlen 11 i Ddeddf Llywodraeth Cymru 2006 (p.32).

(1) The National Health Service (Wales) Act 2006 (c.42) ("the 2006 Act") is a consolidation Act which repeals and re-enacts in its entirety the National Health Service Act 1977 (c.49) ("the 1977 Act") and incorporates some of the provisions from the National Health Service and Community Care Act 1990 (c.19), the Health Act 1999 (c.8), the Health and Social Care Act 2001 (c.15), the National Health Service Reform and Health Care Professions Act 2002 (c.17), the Health and Social Care (Community Health and Standards) Act 2003 (c.43) and the Health Act 2006 (c.8).

Sections 88 and 203(9) and (10) are equivalent to sections 43A and 126(4) of the 1977 Act.

The references to and the functions of "Welsh Ministers" in the 2006 Act are treated as references to and functions of the National Assembly for Wales as constituted by the Government of Wales Act 1998 (c.38) in accordance with the modifications contained in the National Health Service (Consequential Provisions) Act 2006 (c.43), section 5 and paragraph 10 of Schedule 3.

References to and functions of the National Assembly for Wales will transfer to Welsh Ministers immediately after the end of the "initial period" (as defined in section 161(5)) in accordance with sections 162 of and paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c.32).

(2) Daw'r Rheoliadau hyn i rym yn syth ar ôl i Reoliadau'r Gwasanaeth Iechyd Gwladol (Presgripsiynau am Ddim a Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2007(1) ddod i rym ar 1 Ebrill 2007.

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

Dehongli

2. Yn y Rheoliadau hyn-

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

ystyr "Rheoliadau Ffioedd am Gyffuriau a Chyfarpar" (*"the Charges for Drugs and Appliances Regulations"*) yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Presgripsiynau am Ddim a Ffioedd am Gyffuriau a Chyfarpar) (Cymru) 2007;

ystyr "y Rheoliadau Swyddogaethau Rhagnodedig" (*"the Prescribed Functions Regulations"*) yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Taliadau gan Awdurdodau Lleol i Awdurdodau Iechyd) (Swyddogaethau Rhagnodedig) (Cymru) 2001(3);

ystyr "y Rheoliadau Symiau Dangosol" (*"the Indicative Amounts Regulations"*) yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Symiau Dangosol) 1997(4);

Diwygio rheoliad 2 o'r prif Reoliadau

3. Yn rheoliad 2(1) o'r prif Reoliadau (dehongli), yn y man priodol yn nhrefn y wyddor, mewnosoder-

""the 2006 Act" means the National Health Service (Wales) Act 2006(5);".

Amnewid rheoliad 18 o'r prif Reoliadau

4. Am reoliad 18 o'r prif Reoliadau (safonau cyffuriau ac offer, a thaliadau amdanynt), amnewidier-

(2) These Regulations come into force immediately following the coming into force of the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007(1) on 1 April 2007.

(3) These Regulations apply in relation to Wales.

Interpretation

2. In these Regulations-

"the Charges for Drugs and Appliances Regulations" means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007;

"the Indicative Amounts Regulations" means the National Health Service (Indicative Amounts) Regulations 1997(2);

"the Prescribed Functions Regulations" means the National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001(3);

"the principal Regulations" means the National Health Service (Pharmaceutical Services) Regulations 1992(4).

Amendment of regulation 2 of the principal Regulations

3. In regulation 2(1) of the principal Regulations (interpretation), in the appropriate place in the alphabetical order, insert-

""the 2006 Act" means the National Health Service (Wales) Act 2006(5);".

Substitution of regulation 18 of the principal Regulations

4. For regulation 18 of the principal Regulations (standards of, and payments for, drugs and appliances) substitute-

(1) O.S. 2007/121 (Cy.11).

(2) O.S.1992/662.

(3) O.S.2001/1543 (Cy.108).

(4) O.S.1997/980; yr offeryn diwygio perthnasol yw O.S.2005/641.

(5) 2006 p.42.

(1) S.I.2007/121 (W.11).

(2) S.I.1997/980; relevant amending instrument is S.I.2005/641.

(3) S.I.2001/1543 (W.108).

(4) S.I.1992/662.

(5) 2006 c.42.

"Provisions relating to determinations under section 88 of the 2006 Act

18. With regard to determining remuneration under section 88 of the 2006 Act-

- (a) determinations under that section by the National Assembly for Wales (the aggregate of the determinations made by the National Assembly for Wales, acting as a determining authority, is known as "the Drug Tariff") may be made by reference to rates or conditions of remuneration of any persons or any description of persons which are fixed or determined, or will be fixed or determined, otherwise than by way of a determination under that section;
- (b) determinations under that section by the National Assembly for Wales may be made by reference to scales, indices or formula of any kind, and where a determination falls to be made by reference to any such scale, index or formula, the determination may provide that the relevant price calculation is to be made by reference to the scale, index or formula which is-
 - (i) in the form current at the time of the determination, and
 - (ii) in any subsequent form taking effect after that time;
- (c) determining authorities may make determinations which take effect in relation to remuneration in respect of a period beginning on or after the date specified in the determination, which may be the date of the determination or an earlier or later date, but it may be an earlier date only if, taking the determination as a whole, it is not detrimental to the persons to whose remuneration it relates;
- (d) where a determination included in the Drug Tariff does not specify a date as mentioned in paragraph (c), it will have effect in relation to remuneration in respect of the period beginning on the date on which the change to the Drug Tariff is published;
- (e) the National Assembly for Wales will publish the Drug Tariff, and any amendments to it, in such format as it thinks fit (including, as regards publishing any amendments, by publishing a consolidated version of the Drug Tariff with the amendments included in it) and at such intervals as it thinks fit (having regard to the provisions of paragraphs (c) and (d));

"Provisions relating to determinations under section 88 of the 2006 Act

18. With regard to determining remuneration under section 88 of the 2006 Act-

- (a) determinations under that section by the National Assembly for Wales (the aggregate of the determinations made by the National Assembly for Wales, acting as a determining authority, is known as "the Drug Tariff") may be made by reference to rates or conditions of remuneration of any persons or any description of persons which are fixed or determined, or will be fixed or determined, otherwise than by way of a determination under that section;
- (b) determinations under that section by the National Assembly for Wales may be made by reference to scales, indices or formula of any kind, and where a determination falls to be made by reference to any such scale, index or formula, the determination may provide that the relevant price calculation is to be made by reference to the scale, index or formula which is-
 - (i) in the form current at the time of the determination, and
 - (ii) in any subsequent form taking effect after that time;
- (c) determining authorities may make determinations which take effect in relation to remuneration in respect of a period beginning on or after the date specified in the determination, which may be the date of the determination or an earlier or later date, but it may be an earlier date only if, taking the determination as a whole, it is not detrimental to the persons to whose remuneration it relates;
- (d) where a determination included in the Drug Tariff does not specify a date as mentioned in paragraph (c), it will have effect in relation to remuneration in respect of the period beginning on the date on which the change to the Drug Tariff is published;
- (e) the National Assembly for Wales will publish the Drug Tariff, and any amendments to it, in such format as it thinks fit (including, as regards publishing any amendments, by publishing a consolidated version of the Drug Tariff with the amendments included in it) and at such intervals as it thinks fit (having regard to the provisions of paragraphs (c) and (d));

- (f) consultation pursuant to section 89(1) by a determining authority prior to the inclusion of or a change to the price of a drug or appliance will be by way of consultation on the process for determining the price to be included or changed, not on the proposed price itself (unless it is impossible to carry out an effective consultation in any other way);
- (g) where the National Assembly for Wales states in the Drug Tariff that the determining authority for a particular fee, allowance or other remuneration is to be the Local Health Board of the chemist to whom the remuneration relates-
 - (i) the Local Health Board must consult the relevant Local Pharmaceutical Committee⁽¹⁾ before making the determination; and
 - (ii) the determination made by the Local Health Board must include the arrangements for claiming the remuneration and will be published by the Local Health Board in such manner as it thinks suitable for bringing the determination to the attention of the chemists on its pharmaceutical list; and
- (h) payments under-
 - (i) the Drug Tariff must be made by the Local Health Board, in accordance with arrangements for claiming and making payments which are to be set out in the Drug Tariff, and
 - (ii) a determination mentioned in paragraph (g) must be made by the Local Health Board, in accordance with arrangements for claiming and making payments set which are to be set out in the determinations,

but are in either case to be subject, as appropriate, to any deduction that may or must be made from the remuneration of a chemist under these Regulations, the 2006 Act or any other Regulations under the 2006 Act."

Diwygio rheoliad 18A o'r prif Reoliadau

5. Yn rheoliad 18A o'r prif Reoliadau (taliadau i fferyllwyr a ataliwyd), hepgorer paragraff (4).

- (f) consultation pursuant to section 89(1) by a determining authority prior to the inclusion of or a change to the price of a drug or appliance will be by way of consultation on the process for determining the price to be included or changed, not on the proposed price itself (unless it is impossible to carry out an effective consultation in any other way);
- (g) where the National Assembly for Wales states in the Drug Tariff that the determining authority for a particular fee, allowance or other remuneration is to be the Local Health Board of the chemist to whom the remuneration relates-
 - (i) the Local Health Board must consult the relevant Local Pharmaceutical Committee⁽¹⁾ before making the determination; and
 - (ii) the determination made by the Local Health Board must include the arrangements for claiming the remuneration and will be published by the Local Health Board in such manner as it thinks suitable for bringing the determination to the attention of the chemists on its pharmaceutical list; and
- (h) payments under-
 - (i) the Drug Tariff must be made by the Local Health Board, in accordance with arrangements for claiming and making payments which are to be set out in the Drug Tariff, and
 - (ii) a determination mentioned in paragraph (g) must be made by the Local Health Board, in accordance with arrangements for claiming and making payments set which are to be set out in the determinations,

but are in either case to be subject, as appropriate, to any deduction that may or must be made from the remuneration of a chemist under these Regulations, the 2006 Act or any other Regulations under the 2006 Act."

Amendment of regulation 18A of the principal Regulations

5. In regulation 18A of the principal Regulations (payments to suspended chemists), omit paragraph (4).

⁽¹⁾ Yng Nghymru, cyflawnir swyddogaethau Pwyllgorau Fferyllol Lleol (y darperir ar eu cyfer yn adran 90 o Ddeddf 2006) gan bwyllgorau Fferylliaeth Gymunedol Cymru.

⁽¹⁾ In Wales the functions of Local Pharmaceutical Committees (as provided for in section 90 of the 2006 Act) are performed by the committees of Community Pharmacy Wales.

Diwygio rheoliad 22 o'r prif Reoliadau

6. Yn rheoliad 22(1)(e) o'r prif Reoliadau (cyhoeddi manylion), yn lle'r geiriau "determinations made by the Health Authority by virtue of regulation 18(1A)" rhodder "determinations made by the Local Health Board as a consequence of regulation 18(g)".

Diwygio rheoliad 24 o'r prif Reoliadau

7. Yn rheoliad 24(1) o'r prif Reoliadau (hawliadau a gordaliadau), yn lle'r geiriau "made by the Health Authority by virtue of regulation 18(1A)" rhodder "made by the Local Health Board as a consequence of regulation 18(g)".

Diwygio paragraff 22 o Atodlen 2 i'r prif Reoliadau

8. Ym mharagraff 22(4) o Atodlen 2 i'r prif Reoliadau (materion i'w hystyried wrth roi cyfarwyddiadau ynghylch amserau agor fferyllfeydd), yn lle'r geiriau "under the Drug Tariff" rhodder "in accordance with a determination made as a consequence of regulation 18(g)".

Diwygio'r Rheoliadau Symiau Dangosol

9. Yn rheoliad 1(2) o'r Rheoliadau Symiau Dangosol (dehongli), yn lle'r diffiniad o "Drug Tariff", rhodder-

"Drug Tariff" means the aggregate of the determinations made by the National Assembly for Wales which are published in accordance with regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations);".

Diwygio'r Rheoliadau Swyddogaethau Rhagnodedig

10. Yn rheoliad 2(2) o'r Rheoliadau Swyddogaethau Rhagnodedig (swyddogaethau rhagnodedig Awdurdodau Iechyd yng Nghymru), yn lle is-baragraff (ch) rhodder yr is-baragraff a ganlyn-

"(ch) darparu cyfarpar nad yw wedi'i restru yn Rhan IX o'r Tariff Cyffuriau a gyhoeddir yn unol â rheoliad 18(e) o Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (darpariaethau yn ymwneud â phenderfyniadau)."

Amendment of regulation 22 of the principal Regulations

6. In regulation 22(1)(e) of the principal Regulations (publication of particulars), for the words "determinations made by the Health Authority by virtue of regulation 18(1A)" substitute "determinations made by the Local Health Board as a consequence of regulation 18(g)".

Amendment of regulation 24 of the principal Regulations

7. In regulation 24(1) of the principal Regulations (claims and overpayments), for the words "made by the Health Authority by virtue of regulation 18(1A)" substitute "made by the Local Health Board as a consequence of regulation 18(g)".

Amendment of paragraph 22 of Schedule 2 to the principal Regulations

8. In paragraph 22(4) of Schedule 2 to the principal Regulations (matters to be considered when issuing directions in respect of pharmacy opening hours), for the words "under the Drug Tariff" substitute "in accordance with a determination made as a consequence of regulation 18(g)".

Amendment of the Indicative Amounts Regulations

9. In regulation 1(2) of the Indicative Amounts Regulations (interpretation), for the definition of "Drug Tariff", substitute-

"Drug Tariff" means the aggregate of the determinations made by the National Assembly for Wales which are published in accordance with regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations);".

Amendment of the Prescribed Functions Regulations

10. In regulation 2(2) of the Prescribed Functions Regulations (prescribed functions of Health Authorities in Wales), for sub-paragraph (d) substitute the following sub-paragraph-

"(d) the provision of appliances which are not listed in Part IX of Drug Tariff which is published in accordance with regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations)."

Diwygio'r Rheoliadau Ffioedd am Gyffuriau a Chyfarpar

11. Yn rheoliad 2(1) o'r Rheoliadau Ffioedd am Gyffuriau a Chyfarpar (dehongli), yn lle'r diffiniad o "Drug Tariff", amnewidier y diffiniad a ganlyn-

"ystyr "Tariff Cyffuriau" ("*Drug Tariff*") yw'r cyfuniad o'r holl benderfyniadau a wnaed gan Gynulliad Cenedlaethol Cymru ac a gyhoeddir yn unol â rheoliad 18(e) o Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 (darpariaethau yn ymwneud â phenderfyniadau);".

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

27 Mawrth 2007

Llywydd y Cynulliad Cenedlaethol

Amendment of the Charges for Drugs and Appliances Regulations

11. In regulation 2(1) of the Charges for Drugs and Appliances Regulations (interpretation), for the definition of Drug Tariff, substitute the following definition-

""Drug Tariff ("*Tariff Cyffuriau*") means the aggregate of the determinations made by the National Assembly for Wales which are published in accordance with regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations);".

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(1)

27 March 2007

The Presiding Officer of the National Assembly

D. Elis-Thomas

2007 Rhif 1112 (Cy.117)

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