



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2001 Rhif 833 (Cy.38)

2001 No. 833 (W.38)

**Y GWASANAETH IECHYD
GWLADOL, CYMRU**

**NATIONAL HEALTH
SERVICE, WALES**

Rheoliadau Diwygio Rheoliadau'r
Gwasanaeth Iechyd Gwladol
(Gwasanaethau Meddygol
Cyffredinol) (Cymru) 2001

The National Health Service
(General Medical Services)
Amendment (Wales) Regulations
2001

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 ar Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Meddygol Cyffredinol) 1992 (O.S.1992/635), sy'n rheoleiddio'r telerau y mae Gwasanaethau Meddygol Cyffredinol yn cael eu darparu arnynt o dan Ddeddf y Gwasanaeth Iechyd Gwladol 1977.

These Regulations further amend the National Health Service (General Medical Services) Regulations 1992 (S.I.1992/635), which regulate the terms upon which General Medical Services are provided under the National Health Service Act 1977.

Mae'r telerau gwasanaeth ar gyfer meddygon a geir yn Atodlen 2 i'r Rheoliadau hynny yn cael eu diwygio er mwyn galluogi meddygon i gadw cofnodion meddygol sy'n ymwneud â'u cleifion naill ai ar bapur neu ar gyfrifiadur neu ar y ddau.

The terms of service for doctors contained in Schedule 2 to those Regulations are amended to enable doctors to keep medical records relating to their patients either on paper or on computer or both.

Pan fydd am gadw cofnodion naill ai yn gyfan gwbl ar gyfrifiadur neu yn rhannol ar gyfrifiadur, rhaid i'r meddyg sicrhau cydsyniad yr Awdurdod Iechyd yn gyntaf.

Where a doctor wishes to keep records either wholly or partly on computer, he or she must first obtain the Health Authority's consent.

Pan yw'n ofynnol i'r meddyg anfon copïau o'i gofnodion i'r Awdurdod Iechyd, dim ond os yw'r Awdurdod Iechyd wedi rhoi ei gydsyniad y caiff y meddyg eu darparu ar ffurf heblaw ffurf ysgrifenedig.

Where a doctor is required to send copies of his or her records to the Health Authority, the doctor may only provide them other than in written form where the Health Authority has consented.

Ym mhob achos, bydd yr Awdurdod Iechyd yn rhoi ei gydsyniad os yw wedi'i fodloni gan y meddyg ynghylch amryw o faterion a bennir yn y rheoliadau hyn.

In each case, the Health Authority will give its consent where it is satisfied by the doctor about various matters specified in these regulations.

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Amendment (Wales) Regulations
2001***Wedi'u gwneud**8 Mawrth 2001**Made**8th March 2001**Yn dod i rym**1 Ebrill 2001**Coming into force**1st April 2001*

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

The National Assembly for Wales, in exercise of the powers conferred upon it by sections 29 and 126(4) of the National Health Service Act 1977(a) hereby makes the following Regulations:

Enwi, cychwyn, dehongli a chymhwyso**Citation, commencement, interpretation and application**

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau Diwygio'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Meddygol Cyffredinol) (Cymru) 2001 a deuant i rym ar 1 Ebrill 2001.

1.-(1) These Regulations may be cited as the National Health Service (General Medical Services) Amendment (Wales) Regulations 2001 and shall come into force on 1st April 2001.

(2) Yn y Rheoliadau hyn ystyr "Rheoliadau 1992" yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Meddygol Cyffredinol) 1992(b).

(2) In these Regulations "the 1992 Regulations" means the National Health Service (General Medical Services) Regulations 1992(b).

(3) Bydd y Rheoliadau hyn yn gymwys i Gymru yn unig.

(3) These regulations shall apply to Wales only.

(a) 1977 p.49; gweler adran 128(1) fel y'i diwygiwyd gan Ddeddf y Gwasanaeth Iechyd Gwladol a Gofal Cymunedol 1990 (p.19) ("Deddf 1990"), adran 26(2)(g) a (i) i gael y diffiniadau o "prescribed" a "regulations".

(a) 1977 c.49; see section 128(1) as amended by the National Health Service and Community Care Act 1990 (c.19) ("the 1990 Act"), section 26(2)(g) and (i) for the definitions of "prescribed" and "regulations".

Cafodd adran 29 ei hystyngiadau 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 1, paragraff 42(b); gan Ddeddf Iechyd a Gwasanaethau Cymdeithasol a Dyfarniadau Nawdd Cymdeithasol 1983 (p. 41), Atodlen 6, paragraff 2; gan Ddeddf Feddygol 1983 (p.54), adran 56(1) ac Atodlen 5, 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.

Section 29 was extended by the Health and Medicines Act 1988 (c.49), section 17; and amended by the Health Services Act 1980 (c.53), sections 1 and 7 and Schedule 1, paragraph 42(b); by the Health and Social Services and Social Security Adjudications Act 1983 (c. 41), Schedule 6, paragraph 2; by the Medical Act 1983 (c.54), section 56(1) and Schedule 5, paragraph 16(a); by S.I.1985/39, article 7(3); by the Health Authorities Act 1995 (c.17), Schedule 1, paragraph 18; and by the National Health Service (Primary Care) Act 1997 (c.46), Schedule 2, paragraph 8.

Diwygiwyd adran 126(4) gan Ddeddf 1990, adran 65(2); a chan Ddeddf Iechyd 1999 (p. 8), Atodlen 4, paragraff 37(6). Cafodd swyddogaethau'r Ysgrifennydd Gwladol o dan adrannau 29 a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977 eu trosglwyddo i Gynulliad Cenedlaethol Cymru o dan erthygl 2 o Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) (O.S.1999/672) ac Atodlen 1 iddo.

Section 126(4) was amended by the 1990 Act, section 65(2); and by the Health Act 1999 (c. 8), Schedule 4, paragraph 37(6).

The Functions of the Secretary of State under sections 29 and 126(4) of the National Health Service Act 1977 are transferred to the National Assembly for Wales under article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I.1999/672).

(b) O.S.1992/635 y ceir diwygiadau iddynt nad ydynt yn berthnasol i'r Rheoliadau hyn.

(b) S.I.1992/635 to which there are amendments not relevant to these Regulations.

Diwygio Rheoliadau 1992

2. Yn Atodlen 2 i Reoliadau 1992 (Telerau Gwasanaeth), yn lle paragraff 36 rhoddir y paragraff canlynol-

“ Records

36.-(1) In this paragraph, “computerised records,” means records created by way of entries on a computer.

(2) A doctor shall keep adequate records of the illnesses and treatment of his or her patients, and shall do so-

- (a) on forms supplied to the doctor for the purpose by the Health Authority; or
- (b) subject to sub-paragraphs (3) and (4), by way of computerised records,

or in a combination of these two ways

(3) Where a doctor proposes to keep computerised records, he or she shall first obtain the written consent of the Health Authority.

(4) The Health Authority shall consent to a doctor’s application to keep computerised records if it is satisfied that -

- (a) the computer system upon which the doctor proposes to keep them has been accredited by the National Assembly for Wales or another person or body on its behalf in accordance with the principles set out in “General Medical Practice Computer Systems - Requirements for Accreditation - RFA99 (Wales)”(a);
- (b) the security and the audit trail measures incorporated into the computer system as accredited in accordance with sub-paragraph (a) have been enabled; and
- (c) the doctor is aware of, and has signed an undertaking, that he or she will have regard to, the guidelines contained in “Good Practice Guidelines for General Practice Electronic Patient Records (Wales)(b),

and the Health Authority may withdraw its consent if it ceases to be so satisfied.

(5) Where a doctor keeps computerised records he or she shall, as soon as possible following a request from the Health Authority, allow the Health Authority access to the information recorded on his or her computer system including access to the audit trail measures referred to in paragraph 4(b).

(6) A doctor shall send the records relating to a patient to the Health Authority -

-
- (a) Gellir cael copïau drwy ysgrifennu at Gangen Datblygiadau Gwybodaeth Glinigol, Yr Is-adran Technoleg a Rheoli Gwybodaeth, Cyfarwyddiaeth yr NHS, Cynulliad Cenedlaethol Cymru, Parc Cathays, Caerdydd, CF10 3NQ.
 - (b) Gellir cael copïau drwy ysgrifennu at Gangen Datblygiadau Gwybodaeth Glinigol, Yr Is-adran Technoleg a Rheoli Gwybodaeth, Cyfarwyddiaeth yr NHS, Cynulliad Cenedlaethol Cymru, Parc Cathays, Caerdydd, CF10 3NQ.

Amendment of the 1992 Regulations

2. In Schedule 2 to the 1992 Regulations (Terms of Service), for paragraph 36 there shall be substituted the following paragraph-

“ Records

36.-(1) In this paragraph, “computerised records,” means records created by way of entries on a computer.

(2) A doctor shall keep adequate records of the illnesses and treatment of his or her patients, and shall do so-

- (a) on forms supplied to the doctor for the purpose by the Health Authority; or
- (b) subject to sub-paragraphs (3) and (4), by way of computerised records,

or in a combination of these two ways

(3) Where a doctor proposes to keep computerised records, he or she shall first obtain the written consent of the Health Authority.

(4) The Health Authority shall consent to a doctor’s application to keep computerised records if it is satisfied that -

- (a) the computer system upon which the doctor proposes to keep them has been accredited by the National Assembly for Wales or another person or body on its behalf in accordance with the principles set out in “General Medical Practice Computer Systems - Requirements for Accreditation - RFA99 (Wales)”(a);
- (b) the security and the audit trail measures incorporated into the computer system as accredited in accordance with sub-paragraph (a) have been enabled; and
- (c) the doctor is aware of, and has signed an undertaking, that he or she will have regard to, the guidelines contained in “Good Practice Guidelines for General Practice Electronic Patient Records (Wales)(b),

and the Health Authority may withdraw its consent if it ceases to be so satisfied.

(5) Where a doctor keeps computerised records he or she shall, as soon as possible following a request from the Health Authority, allow the Health Authority access to the information recorded on his or her computer system including access to the audit trail measures referred to in paragraph 4(b).

(6) A doctor shall send the records relating to a patient to the Health Authority -

-
- (a) Copies may be obtained by writing to Clinical Information Developments, Health I M & T Division, NHS Directorate, National Assembly for Wales, Cathays Park, Cardiff, CF10 3NQ.
 - (b) Copies may be obtained by writing to Clinical Information Developments, Health I M & T Division, NHS Directorate, National Assembly for Wales, Cathays Park, Cardiff, CF10 3NQ.

- (a) as soon as possible, at the request of the Health Authority; or
- (b) where a person on the doctor's list dies, before the end of the period of 14 days beginning with the date upon which the doctor was informed by the Health Authority of the death, or (in any other case) before the end of the period of one month beginning with the date on which he or she learned of the death.

(7) To the extent that a patient's records are computerised records, a doctor complies with subparagraph (6) if he or she sends to the Health Authority a copy of those records -

- (a) in written form; or
- (b) with the written consent of the Health Authority, in any other form.

(8) The Health Authority shall consent to the transmission of information other than in written form for the purposes of paragraph (7)(b) if it is satisfied with the following matters -

- (a) the doctor's proposals as to how the records will be transmitted;
- (b) the doctor's proposals as to the format of the transmitted records;
- (c) how the doctor will ensure that the records received by the Health Authority are identical to those transmitted; and
- (d) how a written copy of the records can be produced by the Health Authority,

and the Health Authority may withdraw its consent if it ceases to be satisfied as to any of the above matters.

(9) Where a doctor keeps computerised records he or she shall not disable, or attempt to disable, either the security or the audit trail measures referred to in paragraph (4)(b)."

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

- (a) as soon as possible, at the request of the Health Authority; or
- (b) where a person on the doctor's list dies, before the end of the period of 14 days beginning with the date upon which the doctor was informed by the Health Authority of the death, or (in any other case) before the end of the period of one month beginning with the date on which he or she learned of the death.

(7) To the extent that a patient's records are computerised records, a doctor complies with subparagraph (6) if he or she sends to the Health Authority a copy of those records -

- (a) in written form; or
- (b) with the written consent of the Health Authority, in any other form.

(8) The Health Authority shall consent to the transmission of information other than in written form for the purposes of paragraph (7)(b) if it is satisfied with the following matters -

- (a) the doctor's proposals as to how the records will be transmitted;
- (b) the doctor's proposals as to the format of the transmitted records;
- (c) how the doctor will ensure that the records received by the Health Authority are identical to those transmitted; and
- (d) how a written copy of the records can be produced by the Health Authority,

and the Health Authority may withdraw its consent if it ceases to be satisfied as to any of the above matters.

(9) Where a doctor keeps computerised records he or she shall not disable, or attempt to disable, either the security or the audit trail measures referred to in paragraph (4)(b)."

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

D. Elis Thomas

8 Mawrth 2001

Llywydd y Cynulliad Cenedlaethol

8th March 2001

The Presiding Officer of the National Assembly

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