



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

**2003 Rhif 993 (Cy.142)**

**2003 No. 993 (W.142)**

**Y GWASANAETH IECHYD  
GWLADOL, CYMRU**

**NATIONAL HEALTH  
SERVICE, WALES**

Rheoliadau'r Comisiwn Gwella  
Iechyd (Swyddogaethau) (Cymru)  
2003

Commission For Health  
Improvement (Functions) (Wales)  
Regulations 2003

**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 gwneud darpariaeth mewn perthynas â swyddogaethau'r Comisiwn Gwella Iechyd a sefydlwyd o dan adran 19 o Ddeddf Iechyd 1999 ("y Comisiwn").

These Regulations make provision in relation to the functions of the Commission for Health Improvement established under section 19 of the Health Act 1999 ("the Commission").

Mae rheoliadau 2 i 19 yn gwneud darpariaeth mewn perthynas ag arfer swyddogaethau'r Comisiwn yng Nghymru. Yn benodol, gwnânt ddarpariaeth ar gyfer rhaglen waith flynyddol (rheoliad 2), darparu cyngor neu wybodaeth o ran trefniadau at ddibenion monitro a gwella'r gofal y mae cyrff GIG neu ddarparwyr gwasanaethau iechyd teuluol yn gyfrifol amdano (rheoliadau 3 a 4), gweithredu adolygiadau o drefniadau o'r fath ac adolygiadau o reolaeth, darpariaeth neu ansawdd, neu fynediad i, neu argaeledd, y gofal iechyd y mae cyrff GIG neu ddarparwyr o'r fath yn gyfrifol amdano (rheoliadau 5 i 9), gweithredu ymchwiliadau i reolaeth, darpariaeth neu ansawdd y gofal iechyd y mae cyrff GIG yn gyfrifol amdano (rheoliadau 10 i 15).

Regulations 2 to 19 make provision in relation to the exercise of the Commission's functions in Wales. In particular, they make provision for an annual work programme (regulation 2), the provision of advice or information with respect to arrangements for the purpose of monitoring and improving health care for which NHS bodies or providers of family health services have responsibility (regulations 3 and 4), the conduct of reviews of such arrangements and of reviews of the management, provision or quality of, or access to or availability of health care for which NHS bodies or such providers are responsible (regulations 5 to 9), the conduct of investigations into the management, provision or quality of health care for which NHS bodies have responsibility (regulations 10 to 15).

Mae rheoliadau 16 i 19 yn gwneud darpariaeth i'r Comisiwn a phersonau a awdurdodir gan y Comisiwn i fynd i mewn i safleoedd perthnasol a chael hyd i ddogfennau, gwybodaeth ac esboniadau. Mae Rheoliadau 20 a 21 yn gwneud darpariaeth ynghylch darparu cymorth i'r Comisiwn Archwilio ac i ymholiadau ynghylch y gwasanaeth iechyd.

Regulations 16 to 19 make provision for the Commission and persons authorised by the Commission to enter relevant premises and to obtain documents, information and explanations. Regulations 20 and 21 make provision relating to the provision of assistance to the Audit Commission and to inquiries relating to the health service.

**2003 Rhif 993 (Cy.142)****2003 No. 993 (W.142)****Y GWASANAETH IECHYD  
GWLADOL, CYMRU****NATIONAL HEALTH  
SERVICE, WALES****Rheoliadau'r Comisiwn Gwella  
Iechyd (Swyddogaethau) (Cymru)  
2003****Commission For Health  
Improvement (Functions) (Wales)  
Regulations 2003***Wedi'u gwneud* 2 Ebrill 2003*Made* 2nd April 2003*Yn dod i rym* 3 Ebrill 2003*Coming into force* 3rd April 2003

Mae Cynulliad Cenedlaethol Cymru, wrth arfer y pwerau a roddwyd iddo gan adrannau 17 a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977(a) ac adrannau 20(2) a 23 o Ddeddf Iechyd 1999(b) drwy hyn yn gwneud y Rheoliadau canlynol:

The National Assembly for Wales, in exercise of the powers conferred on it by sections 17 and 126(4) of the National Health Service Act 1977(a) and sections 20(2) and 23 of the Health Act 1999(b), hereby makes the following Regulations:

**RHAN I****PART I**

## CYFFREDINOL

## GENERAL

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

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Comisiwn Gwella Iechyd (Swyddogaethau) (Cymru) 2003, a deuant i rym ar 3 Ebrill 2003.

1.-(1) These Regulations may be cited as the Commission for Health Improvement (Functions) (Wales) Regulations 2003 and shall come into force on 3rd April 2003.

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

(2) These Regulations apply to Wales only.

(3) Yn y Rheoliadau hyn -

(3) In these Regulations -

ystyr "adolygiad cyffredinol" ("*general review*") yw adolygiad a gynhelir gan y

"the Act" ("*y Ddeddf*") means the Health Act 1999;

(a) 1977 p. 49; amnewidiwyd adran 17 gan adran 12 o Ddeddf Iechyd 1999 (p. 8) ("Deddf 1999"); mae adran 126(4) yn gymwys mewn cysylltiad ag unrhyw bŵer i wneud gorchmynion neu reoliadau a roddwyd gan Ddeddf 1999 (*gweler* adran 62(4) o Ddeddf 1999) a chafodd ei diwygio gan Ddeddf y Gwasanaeth Iechyd Gwladol a Gofal Cymunedol 1990 (p. 19) ("Deddf 1990"), adran 65(2) a Deddf 1999, Atodlen 4, paragraff 37(6).

(a) 1977 c. 49; section 17 was substituted by section 12 of the Health Act 1999 (c. 8) ("the 1999 Act"); section 126(4) applies in relation to any power to make orders or regulations conferred by the 1999 Act (*see* section 62(4) of the 1999 Act) and was amended by the National Health Service and Community Care Act 1990 (c. 19) ("the 1990 Act"), section 65(2) and the 1999 Act, Schedule 4, paragraph 37(6).

(b) 1999 p. 8; *gweler* adran 20(7) a 23(6) i gael y diffiniadau o "prescribed". Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan adrannau 20(2) a 23 o Ddeddf 1999 ac adrannau 17 a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977 ("Deddf 1977"), i'r graddau y maent yn arferadwy mewn perthynas â Chymru, i Gynulliad Cenedlaethol Cymru gan erthygl 2(a) o, a'r elfennau sy'n berthnasol i Ddeddf 1977 a Deddf 1999 yn Atodlen 1 i, Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999, O.S. 1999/672, fel y'i diwygiwyd gan adran 66(5) o Ddeddf 1999. Diwygiwyd adran 20(2) gan adran 12(1) a (4) o Ddeddf Diwygio'r Gwasanaeth Iechyd Gwladol a Phroffesiynau Gofal Iechyd 2002 (p. 17) ("Deddf 2002") a diwygiwyd adran 23 gan adran 13(2) o'r Ddeddf honno.

(b) 1999 c. 8; *see* sections 20(7) and 23(6) for the definitions of "prescribed". The functions of the Secretary of State under sections 20(2) and 23 of the 1999 Act and sections 17 and 126(4) of the National Health Service Act 1977 ("the 1977 Act") are, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by article 2(a) of, and the entries for the 1977 Act and the 1999 Act in Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672, as amended by section 66(5) of the 1999 Act. Section 20(2) was amended by section 12(1) and (4) of the National Health Service Reform and Health Care Professions Act 2002 (c. 17) ("the 2002 Act") and section 23 was amended by section 13(2) of that Act.

Comisiwn o dan adran 20(1)(d) o'r Ddeddf(a); ystyr "adolygiad dilysu" ("*validation review*") yw adolygiad o dan adran 20(1)(da)(b) o'r Ddeddf;

ystyr "adolygiad gwasanaeth gwladol" ("*national service review*") yw adolygiad cyffredinol sy'n ymwneud â mathau penodol o ofal iechyd y mae cyrff GIG neu ddarparwyr gwasanaethau yn gyfrifol amdano;

ystyr "adolygiad llywodraethu clinigol" ("*clinical governance review*") yw adolygiad a gynhelir gan y Comisiwn o dan adran 20(1)(b) o'r Ddeddf neu reoliad 2(c) neu (d) o'r Rheoliadau Swyddogaethau;

ystyr "blwyddyn ariannol" ("*financial year*") yw'r cyfnod 12 mis sy'n dod i ben ar 31 Mawrth;

ystyr "Bwrdd Iechyd Lleol perthnasol" ("*relevant Local Health Board*") mewn perthynas â darparydd gwasanaeth yw -

- (a) os yn ardal un Bwrdd Iechyd Lleol yn unig y mae'r darparydd gwasanaeth yn darparu gwasanaethau, y Bwrdd Iechyd Lleol hwnnw, neu
- (b) os yw'r darparydd gwasanaeth yn darparu gwasanaethau yn ardaloedd dau neu ragor o Fyrddau Iechyd Lleol, pob un o'r Byrddau Iechyd Lleol hynny;

ystyr "y Comisiwn" ("*the Commission*") yw'r Comisiwn Gwella Iechyd a sefydlwyd gan adran 19 o'r Ddeddf;

ystyr "y Comisiwn Archwilio" ("*the Audit Commission*") yw'r Comisiwn Archwilio dros Awdurdodau Lleol a'r Gwasanaeth Iechyd Gwladol yng Nghymru a Lloegr(c);

ystyr "Cynulliad Cenedlaethol" ("*National Assembly*") yw Cynulliad Cenedlaethol Cymru;

ystyr "darparydd gwasanaeth" ("*service provider*") yw person, heblaw corff GIG(ch), sydd -

- (a) yn darparu gwasanaethau Rhan II;
- (b) yn darparu gwasanaethau yn unol â chynllun peilot o dan Ddeddf 1997; neu
- (c) yn darparu gwasanaethau yn unol â threfniadau o dan adran 28 o Ddeddf Iechyd a Gofal Cymdeithasol 2001(d);

ystyr "Deddf 1977" ("*the 1977 Act*") yw Deddf

"the 1977 Act" ("*Ddeddf 1977*") means the National Health Service Act 1977;

"the 1997 Act" ("*Ddeddf 1997*") means the National Health Service (Primary Care) Act 1997(a);

"the Audit Commission" ("*y Comisiwn Archwilio*") means the Audit Commission for Local Authorities and the National Health Service in England and Wales(b);

"clinical governance arrangements" ("*trefniadau llywodraethu clinigol*") means -

- (a) in the case of an NHS trust, or a service provider, arrangements for monitoring and improving the quality of health care(c) for which they have responsibility;
- (b) in the case of a Local Health Board, arrangements for the purpose of monitoring and improving the quality of health care which is provided to individuals in their area;

"clinical governance review" ("*adolygiad llywodraethu clinigol*") means a review conducted by the Commission under section 20(1)(b) of the Act or regulation 2(c) of the Functions Regulations;

"the Commission" ("*y Comisiwn*") means the Commission for Health Improvement established by section 19 of the Act;

"financial year" ("*blwyddyn ariannol*") means the period of 12 months ending with 31st March;

"Functions Regulations" ("*Rheoliadau Swyddogaethau*") means the Commission for Health Improvement (Functions) Regulations 2000(d);

"general review" ("*adolygiad cyffredinol*") means a review conducted by the Commission under section 20(1)(d) of the Act(e);

"health care profession" ("*proffesiwn gofal iechyd*") means a profession to which section 60(2) of the Act applies;

"health care professional" ("*gweithiwr proffesiynol gofal iechyd*") means a person who is registered as a member of a health care profession;

"health service inquiry" ("*ymchwiliad gwasanaeth iechyd*") means an inquiry, held or established by the National Assembly for

(a) Diwygiwyd adran 20(1)(d) gan adran 20(1) a (2) o Ddeddf 2002.

(b) Mewnosodwyd adran 20(1)(da) gan adran 12(2)(c) o Ddeddf 2002.

(c) Cafodd bodolaeth y Comisiwn Archwilio ei pharhau gan adran 1 o Ddeddf y Comisiwn Archwilio 1998 (p. 18).

(ch) *Gweler* adran 20(7) o'r Ddeddf i gael diffiniad o "NHS body"; diwygiwyd y diffiniad gan Atodlen 1, paragraff 49, i Ddeddf 2002.

(d) p. 15.

(a) 1997 c. 46.

(b) The Audit Commission was continued in being by section 1 of the Audit Commission Act 1998 (c. 18).

(c) *See* sections 18(4) and 20(7) of the 1999 Act for the definition of "health care".

(d) S.I. 2000/662 as amended by S.I. 2000/797 and S.I. 2002/2469.

(e) Section 20(1)(d) was amended by section 20(1) and (2) of the 2002 Act.

y Gwasanaeth Iechyd Gwladol 1977;

ystyr "Deddf 1997" ("*the 1997 Act*") yw Deddf y Gwasanaeth Iechyd Gwladol (Gofal Sylfaenol) 1997(a);

ystyr "y Ddeddf" ("*the Act*") yw Deddf Iechyd 1999;

ystyr "gwasanaethau Rhan II" ("*Part II services*") yw gwasanaethau meddygol cyffredinol, gwasanaethau deintyddol cyffredinol, gwasanaethau offthalmig cyffredinol neu wasanaethau fferyllol o dan Ran II o Ddeddf 1977;

ystyr "gweithiwr proffesiynol gofal iechyd" ("*health care professional*") yw person sydd wedi ei gofrestru fel aelod o broffesiwn gofal iechyd;

ystyr "proffesiwn gofal iechyd" ("*health care profession*") yw proffesiwn y mae adran 60(2) o'r Ddeddf yn gymwys iddo;

ystyr "y Rheoliadau Swyddogaethau" ("*Functions Regulations*") yw Rheoliadau'r Comisiwn Gwella Iechyd (Swyddogaethau) 2000(b);

ystyr "safle perthnasol" ("*relevant premises*") yw safle perthnasol fel y'i diffinnir gan adran 23(6) o'r Ddeddf;

ystyr "trefniadau llywodraethu clinigol" ("*clinical governance arrangements*") yw -

(a) yn achos ymddiriedolaethau'r GIG, neu ddarparwydd gwasanaeth, trefniadau monitro a gwella ansawdd y gofal iechyd(c) y maent yn gyfrifol amdano;

(b) yn achos Bwrdd Iechyd Lleol, trefniadau at ddibenion monitro a gwella ansawdd y gofal iechyd sy'n cael ei ddarparu i'r unigolion yn eu hardal;

ystyr "ymchwiliad" ("*investigation*") yw ymchwiliad gan y Comisiwn yn unol ag adran 20(1)(c) o'r Ddeddf(ch) neu reoliad 2(e) o'r Rheoliadau Swyddogaethau;

ystyr "ymchwiliad gwasanaeth iechyd" ("*health service inquiry*") yw ymchwiliad, a gynhelir neu a sefydlir gan Gynulliad Cenedlaethol Cymru neu gorff GIG, i unrhyw fater sy'n ymwneud â rheolaeth, darpariaeth ac ansawdd y gofal iechyd y mae cyrff GIG neu ddarparwyr gwasanaeth yn gyfrifol amdano.

(4) Yn y Rheoliadau hyn, mae cyfeiriadau at ofal iechyd y mae person yn gyfrifol amdano i'w dehongli

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- (a) 1997 p. 46.
- (b) O.S. 2000/662 fel y'i diwygiwyd gan O.S. 2000/797 ac O.S. 2002/2469.
- (c) *Gweler* adrannau 18(4) a 20(7) o Ddeddf 1999 i gael diffiniad o "health care".
- (ch) Diwygiwyd adran 20(1)(c) gan Atodlen 1, paragraff 49, o Ddeddf 2002.

Wales or an NHS body, into any matter relating to the management, provision and quality of health care for which NHS bodies or service providers have responsibility;

"investigation" ("*ymchwiliad*") means an investigation by the Commission pursuant to section 20(1)(c) of the Act(a) or regulation 2(e) of the Functions Regulations;

"National Assembly" ("*Cynulliad Cenedlaethol*") means the National Assembly for Wales;

"national service review" ("*adolygiad gwasanaeth gwladol*") means a general review that relates to particular types of health care for which NHS bodies or service providers have responsibility;

"Part II services" ("*gwasanaethau Rhan II*") means general medical services, general dental services, general ophthalmic services or pharmaceutical services under Part II of the 1977 Act;

"relevant Local Health Board" ("*Bwrdd Iechyd Lleol perthnasol*") means, in relation to a service provider -

- (a) where the service provider provides services in the area of only one Local Health Board, that Local Health Board, or
- (b) where the service provider provides services in the area of two or more Local Health Boards, each of those Local Health Boards;

"relevant premises" ("*safle perthnasol*") means relevant premises as defined by section 23(6) of the Act;

"service provider" ("*darparwydd gwasanaeth*") means a person, other than an NHS body(b), who -

- (a) provides Part II services;
- (b) provides services in accordance with a pilot scheme under the 1997 Act; or
- (c) provides services in accordance with arrangements under section 28 of the Health and Social Care Act 2001(c);

"validation review" ("*adolygiad dilysu*") means a review under section 20(1)(da)(d) of the Act.

(4) In these Regulations, references to health care for which a person has responsibility are to be

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- (a) Section 20(1)(c) was amended by Schedule 1, paragraph 49, of the 2002 Act.
- (b) See section 20(7) of the Act for the definition of "NHS body"; the definition was amended by Schedule 1, paragraph 49, to the 2002 Act.
- (c) c.15.
- (d) Section 20(1)(da) was inserted by section 12(2)(c) of the 2002.

yn unol ag adran 20(5) o'r Ddeddf.

## RHAN II

### RHAGLEN WAITH FLYNYDDOL

#### Rhaglen waith flynyddol

2.-(1) Cyn dechrau pob blwyddyn ariannol mae'n rhaid i'r Comisiwn baratoi rhaglen waith sy'n nodi'r gweithgareddau y mae'r Comisiwn i ymgymryd â hwy yn y flwyddyn honno wrth arfer ei swyddogaethau.

(2) Rhaid i bob rhaglen waith, mewn cysylltiad â'r flwyddyn honno, nodi -

- (a) unrhyw faterion penodol y mae'r Comisiwn am ddarparu cyngor neu wybodaeth am drefniadau llywodraethu clinigol yn eu cylch;
- (b) cynigion ynghylch cyrff GIG y mae'r Comisiwn am gynnal adolygiadau llywodraethu clinigol ynglŷn â hwy;
- (c) cynigion ynghylch y personau neu'r cyrff y mae'r Comisiwn am gynnal adolygiadau cyffredinol ynglŷn â hwy;
- (ch) unrhyw faterion penodol y mae'r Comisiwn am eu hystyried wrth gynnal adolygiad llywodraethu clinigol neu adolygiad cyffredinol;
- (d) y mathau penodol o ofal iechyd a fydd yn destun unrhyw adolygiadau gwasanaeth gwladol; a
- (dd) unrhyw faterion penodol y mae'r Comisiwn am gynnal adolygiadau dilysu yn eu cylch.

(3) Bydd y rhaglen waith yn ddarostyngedig i gymeradwyaeth gan y Cynulliad Cenedlaethol.

(4) Gellir amrywio y rhaglen waith-

- (a) gyda chytundeb y Cynulliad Cenedlaethol; neu
- (b) yn ôl yr hyn y mae'r Cynulliad Cenedlaethol yn ei benderfynu.

(5) Yn ddarostyngedig i'r rheoliadau canlynol ac unrhyw gyfarwyddiadau a roddwyd gan y Cynulliad Cenedlaethol, bydd y Comisiwn yn arfer ei swyddogaethau mewn unrhyw flwyddyn ariannol yn unol â'r rhaglen waith sy'n berthnasol i'r flwyddyn honno.

## RHAN III

### CYNGOR NEU WYBODAETH AM DREFNIADAU LLYWODRAETHU CLINIGOL

#### Y personau y gellir rhoi cyngor neu wybodaeth iddynt

3.-(1) Rhaid i'r Comisiwn ddarparu cyngor neu wybodaeth am drefniadau llywodraethu clinigol -

construed in accordance with section 20(5) of the Act.

## PART II

### ANNUAL WORK PROGRAMME

#### Annual work programme

2. -(1) Before the beginning of each financial year the Commission must prepare a work programme setting out the activities the Commission is to undertake in that year in the exercise of its functions.

(2) Each work programme shall, in relation to that year, set out -

- (a) any particular matters with respect to which the Commission is to provide advice or information on clinical governance arrangements;
- (b) proposals as to the NHS bodies in relation to which the Commission is to conduct clinical governance reviews;
- (c) proposals as to the persons or bodies in relation to which the Commission is to conduct general reviews;
- (d) any particular matters which the Commission is to consider or take into account when conducting a clinical governance review or a general review;
- (e) the particular types of health care which are to be the subject of any national service reviews; and
- (f) any particular matters with respect to which the Commission is to conduct validation reviews.

(3) The work programme shall be subject to approval by the National Assembly.

(4) The work programme may be varied with the agreement of the National Assembly and shall be varied in accordance with any determinations given by the National Assembly.

(5) Subject to the following regulations and to any directions given by the National Assembly the Commission shall exercise its functions in any financial year in accordance with the work programme relating to that year.

## PART III

### ADVICE OR INFORMATION ON CLINICAL GOVERNANCE ARRANGEMENTS

#### Persons to whom advice or information to be given

3.-(1) The Commission shall provide advice or information on clinical governance arrangements to -

- (a) i'r Cynulliad Cenedlaethol;
- (b) i gyrff GIG; ac
- (c) i ddarparwyr gwasanaethau.

(2) Rhaid i'r Comisiwn gydymffurfio ag unrhyw gais gan y Cynulliad Cenedlaethol i ddarparu cyngor neu wybodaeth am agweddau penodol ar drefniadau llywodraethu clinigol -

- (a) i'r Cynulliad Cenedlaethol;
- (b) i gyrff penodol GIG; neu
- (c) i ddarparwyr gwasanaethau penodol.

(3) Caiff y Comisiwn ddarparu cyngor neu wybodaeth am drefniadau llywodraethu clinigol i unrhyw berson neu gorff arall sy'n gofyn am gyngor neu wybodaeth o'r fath.

#### **Arfer y swyddogaeth darparu cyngor neu wybodaeth am lywodraethu clinigol**

4. Wrth arfer ei swyddogaethau o dan adran 20(1)(a) o'r Ddeddf a rheoliad 2(a) a (b) o'r Rheoliadau Swyddogaethau, rhaid i'r Comisiwn ystyried -

- (a) unrhyw ganllawiau sy'n ymwneud â threfniadau llywodraethu clinigol a roddir gan y Cynulliad Cenedlaethol neu'r Sefydliad Cenedlaethol dros Ragoriaeth Glinigol(a);
- (b) unrhyw gyngor neu ganllawiau sy'n ymwneud â threfniadau llywodraethu clinigol a roddir gan unrhyw gorff sy'n gyfrifol am reoleiddio proffesiwn gofal iechyd.

### **RHAN IV ADOLYGIADAU**

#### **Effeithiolrwydd a digonolrwydd trefniadau**

5. Wrth gynnal adolygiad llywodraethu clinigol rhaid i'r Comisiwn asesu effeithiolrwydd trefniadau corff GIG dan sylw ac ystyried a yw'r trefniadau hynny'n ddigonol.

#### **Adroddiadau am adolygiadau**

6.-(1) Ar ôl i adolygiad llywodraethu clinigol ddod i ben, rhaid i'r Comisiwn roi adroddiad i gorff GIG dan sylw.

(2) Ar ôl i adolygiad cyffredinol heblaw adolygiad gwasanaeth gwladol ddod i ben, rhaid i'r Comisiwn roi adroddiad i'r personau neu'r cyrff a oedd yn destun yr adolygiad.

(3) Pan ddaw adolygiad gwasanaeth gwladol i ben rhaid i'r Comisiwn roi adroddiad i'r Cynulliad Cenedlaethol.

(4) Rhaid i'r adroddiadau y cyfeirir atynt ym mharagraffau (1) i (3) nodi -

- (a) the National Assembly;
- (b) NHS bodies; and
- (c) service providers.

(2) The Commission shall comply with any request by the National Assembly to provide advice or information on specified aspects of clinical governance arrangements to -

- (a) the National Assembly;
- (b) specified NHS bodies; or
- (c) specified service providers.

(3) The Commission may provide advice or information on clinical governance arrangements to any other person or body requesting such advice or information.

#### **Exercise of the function of providing advice or information on clinical governance**

4. In exercising its functions under section 20(1)(a) of the Act and regulation 2(a) and (b) of the Functions Regulations the Commission shall take into account -

- (a) any guidance relating to clinical governance arrangements given by the National Assembly or the National Institute for Clinical Excellence(a);
- (b) any advice or guidance relating to clinical governance arrangements given by any body responsible for the regulation of a health care profession.

### **PART IV REVIEWS**

#### **Effectiveness and adequacy of arrangements**

5. In conducting a clinical governance review the Commission shall assess the effectiveness of the arrangements by the NHS body concerned and consider whether those arrangements are adequate.

#### **Review reports**

6.-(1) Following the conclusion of a clinical governance review, the Commission shall make a report to the NHS body concerned.

(2) Following the conclusion of a general review other than a national service review, the Commission shall make a report to the persons or bodies that were the subject of the review.

(3) At the conclusion of a national service review the Commission shall make a report to the National Assembly.

(4) The reports referred to in paragraph (1) to (3) shall set out -

(a) *Gweler* O.S.1999/220 fel y'i diwygiwyd gan O.S. 1999/2219.

(a) *See* S.I.1999/220 as amended by S.I.1999/2219.

- (a) canfyddiadau a chasgliadau'r Comisiwn; a
- (b) unrhyw argymhellion a wneir gan y Comisiwn.

- (a) the findings and conclusions of the Commission; and
- (b) any recommendations made by the Commission.

**Adroddiadau o Ddiddordeb Arbennig - Adolygiad llywodraethu clinigol**

7.-(1) Os daw mater i sylw y Comisiwn yng nghwrs adolygiad llywodraethu clinigol y mae'n credu y dylid, er lles y cyhoedd, ddod ag ef i sylw-

- (a) unrhyw un o'r personau neu'r cyrff y mae paragraff (2) yn gymwys iddo; a
- (b) y cyhoedd,

caiff y Comisiwn wneud y mater yn destun adroddiad ar unwaith yn ychwanegol at yr adroddiad sydd i'w wneud pan ddaw'r adolygiad i ben.

(2) Dyma'r personau a'r cyrff y cyfeiriwyd atynt ym mharagraff (1) -

- (a) y corff GIG sydd yn destun yr adolygiad;
- (b) y Cynulliad Cenedlaethol.

(3) Rhaid anfon copiâu o unrhyw adroddiad o dan baragraff (1) -

- (a) i'r corff GIG sydd yn destun yr adolygiad;
- (b) i'r Cynulliad Cenedlaethol;
- (c) mewn achos lle mae paragraff (2)(c) yn gymwys, i'r Bwrdd Iechyd Lleol perthnasol;
- (ch) i unrhyw gorff GIG neu ddarparwydd gwasanaeth arall neu at unrhyw berson neu i unrhyw gorff sy'n arfer swyddogaethau statudol, y mae'r Comisiwn yn credu y dylid rhoi copi o'r adroddiad iddynt.

**Adroddiadau o ddiddordeb arbennig - adolygiad cyffredinol**

8.-(1) Os daw mater i sylw'r Comisiwn yng nghwrs adolygiad cyffredinol y mae'r Comisiwn yn credu y dylid, er lles y cyhoedd, ddod ag ef i sylw-

- (a) unrhyw un o'r personau neu'r cyrff y mae paragraff (2) yn gymwys iddo; a
- (b) y cyhoedd,

caiff y Comisiwn wneud y mater yn destun adroddiad ar unwaith yn ychwanegol at yr adroddiad sydd i'w wneud pan ddaw'r adolygiad i ben.

(2) Dyma'r personau a'r cyrff y cyfeiriwyd atynt ym mharagraff (1) -

- (a) person neu gorff sydd yn destun adolygiad;

**Special interest reports - clinical governance review**

7.-(1) If in the course of a clinical governance review a matter comes to the notice of the Commission which it considers should, in the public interest, be brought to the attention of -

- (a) any of the persons or bodies to which paragraph (2) applies; and
- (b) the public,

the Commission may make the matter the subject of an immediate report in addition to the report to be made at the conclusion of the review.

(2) The persons and bodies referred to in paragraph (1) are -

- (a) the NHS body which is the subject of the review;
- (b) the National Assembly.

(3) Copies of any report under paragraph (1) shall be sent to -

- (a) the NHS body which is the subject of the review;
- (b) the National Assembly;
- (c) any other NHS body or service provider or other person or body exercising statutory functions, to whom the Commission considers the report should be copied.

**Special interest reports - general review**

8.-(1) If in the course of a general review a matter comes to the notice of the Commission which it considers should, in the public interest, be brought to the attention of -

- (a) any of the persons or bodies to which paragraph (2) applies; or
- (b) the public,

the Commission may make the matter the subject of an immediate report in addition to the report to be made at the conclusion of the review.

(2) The persons and bodies referred to in paragraph (1) are -

- (a) a person or body which is the subject of the review;

- (b) y Cynulliad Cenedlaethol;
- (c) mewn achos lle darparwydd gwasanaeth yw testun yr adolygiad, y Bwrdd Iechyd Lleol perthnasol.

(3) Rhaid anfon copiâu o unrhyw adroddiad o dan baragraff (1) -

- (a) at y person neu i'r corff sydd yn destun yr adolygiad ac y mae'r Comisiwn yn credu y dylid tynnu ei sylw at y mater;
- (b) os mai'r person hwnnw neu'r corff hwnnw yw'r darparwydd gwasanaeth, i'r Bwrdd Iechyd Lleol perthnasol;
- (c) i'r Cynulliad Cenedlaethol;
- (ch) i unrhyw gorff GIG neu ddarparwydd gwasanaeth arall neu at unrhyw berson neu i unrhyw gorff sy'n arfer swyddogaethau statudol, y mae'r Comisiwn yn credu y dylid rhoi copi o'r adroddiad iddynt.

### Camau pellach yn sgil adolygiad

9.-(1) Mae paragraffau (2) i (4) isod yn gymwys os yw corff GIG wedi bod yn destun adolygiad llywodraethu clinigol neu adolygiad cyffredinol heblaw adolygiad cenedlaethol.

(2) Ar ôl i adolygiad ddod i ben, rhaid i'r corff GIG dan sylw, gyda chymorth y Comisiwn, baratoi datganiad ysgrifenedig o'r camau y mae'n bwriadu eu cymryd yng ngoleuni'r adroddiad a wnaed gan y Comisiwn.

(3) Bydd datganiad a baratoir o dan baragraff (2) yn ddarostyngedig i gymeradwyaeth y Cynulliad Cenedlaethol yn achos Bwrdd Iechyd Lleol, Awdurdodau Iechyd Arbennig neu Ymddiriedolaeth GIG.

(4) Cyn penderfynu ynghylch cymeradwyo datganiad a baratoir o dan baragraff (2), rhaid i'r Cynulliad Cenedlaethol ymgynghori â'r Comisiwn.

## RHAN V

### YMCHWILIADAU

#### Ymchwiliadau

10.-(1) Rhaid i'r Comisiwn gynnal ymchwiliad ar gais y Cynulliad Cenedlaethol.

(2) Caiff y Comisiwn gynnal ymchwiliad -

- (a) os caiff y Comisiwn gais i ymchwilio gan unrhyw berson neu gorff; neu
- (b) os, fel arall, ymddengys i'r Comisiwn ei bod yn briodol gwneud hynny.

(3) Os yw'r Comisiwn yn cynnal ymchwiliad ar gais

- (b) the National Assembly;
- (c) in a case where a service provider is the subject of the review, the relevant Local Health Board.

(3) Copies of any report under paragraph (1) shall be sent to -

- (a) the person or body who is the subject of the review and to whose attention the Commission considers that the matter should be drawn;
- (b) where that person or body is a service provider, the relevant Local Health Board;
- (c) the National Assembly;
- (d) any other NHS body or service provider or other person or body exercising statutory functions, to whom the Commission considers the report should be copied.

### Further action following a review

9.-(1) Paragraphs (2) to (4) below apply where an NHS body has been the subject of a clinical governance review or of a general review other than a national service review.

(2) Following the conclusion of a review, the NHS body concerned shall, with the assistance of the Commission, prepare a written statement of the action which it proposes to take in the light of the report made by the Commission.

(3) A statement prepared under paragraph (2) shall be subject to approval in the case of a Local Health Board, a Special Health Authority or an NHS trust, by the National Assembly.

(4) Before deciding whether to approve a statement prepared under paragraph (2), the National Assembly shall consult the Commission.

## PART V

### INVESTIGATIONS

#### Investigations

10.-(1) The Commission shall carry out an investigation when requested to do so by the National Assembly.

(2) The Commission may carry out an investigation where -

- (a) the Commission receives a request to investigate from any person or body; or
- (b) it otherwise appears to the Commission to be appropriate to do so.

(3) Where the Commission is carrying out an



y Cynulliad Cenedlaethol, rhaid iddo ymchwilio i'r materion hynny sy'n dod o fewn adran 20(1)(c) o'r Ddeddf neu reoliad 2(e) o'r Rheoliadau Swyddogaethau yn ôl yr hyn a bennir yn y cais.

(4) Os yw'r Comisiwn yn cynnal ymchwiliad mewn unrhyw achos arall, caiff ymchwilio i'r materion hynny sy'n dod o fewn adran 20(1)(c) neu reoliad 2(e) o'r Rheoliadau Swyddogaethau o'r Ddeddf fel y gwêl yn briodol.

### **Hysbysiad ymchwiliad**

**11.** Os yw'n rhesymol ymarferol, rhaid i'r Comisiwn ddarparu hysbysiad ysgrifenedig o'i fwriad i gynnal ymchwiliad a'r dyddiad y bwriedir i'r ymchwiliad hwnnw ddechrau-

- (a) at unrhyw berson neu i unrhyw gorff a fydd yn destun ymchwiliad;
- (b) yn achos ymchwiliad o dan reoliad 10(2) sy'n ymwneud â Bwrdd Iechyd Lleol, Awdurdod Iechyd Arbennig neu ymddiriedolaeth GIG, i'r Cynulliad Cenedlaethol;
- (c) yn achos ymchwiliad sy'n ymwneud â darparrydd gwasanaeth, i'r Bwrdd Iechyd Lleol perthnasol.

### **Cynnal ymchwiliad i gorff sydd yn destun adolygiad**

**12.**-(1) Os daw mater i sylw'r Comisiwn yng nghwrs adolygiad llywodraethu clinigol neu adolygiad cyffredinol y mae'n credu ei fod yn briodol yn destun ymchwiliad, caiff y Comisiwn ddechrau ymchwiliad i'r mater hwnnw.

(2) Os yw'r Comisiwn yn cynnal adolygiad llywodraethu clinigol, rhaid i'r Comisiwn, os yw'n rhesymol ymarferol, ddarparu hysbysiad ysgrifenedig o'r penderfyniad a'r dyddiad y bwriedir i'r ymchwiliad ddechrau -

- (a) i'r person neu'r corff sydd yn destun yr adolygiad;
- (b) os Bwrdd Iechyd Lleol, Awdurdod Iechyd Arbennig neu Ymddiriedolaeth GIG sydd yn destun adolygiad, i'r Cynulliad Cenedlaethol.

(3) Os yw'r Comisiwn yn cynnal adolygiad cyffredinol, rhaid i'r Comisiwn, os bydd yn rhesymol ymarferol, ddarparu hysbysiad ysgrifenedig o'r penderfyniad a'r dyddiad y bwriedir i'r ymchwiliad ddechrau -

- (a) i unrhyw berson neu gorff sydd yn destun yr adolygiad ac a fydd hefyd yn destun yr ymchwiliad;
- (b) os darparrydd gwasanaeth yw'r person neu'r corff hwnnw, i'r Bwrdd Iechyd Lleol perthnasol.

investigation at the request of the National Assembly, it shall investigate such matters falling within section 20(1)(c) of the Act or regulation 2(e) of the Functions Regulations as may be specified in the request.

(4) Where the Commission is carrying out an investigation in any other case, it may investigate such matters falling within section 20(1)(c) or regulation 2(e) of the Functions Regulations of the Act as it considers appropriate.

### **Notice of investigation**

**11.** Where it is reasonably practicable to do so, the Commission shall provide written notification of its intention to conduct the investigation and the proposed date on which that investigation is to commence to -

- (a) any person or body which is to be the subject of the investigation;
- (b) in the case of an investigation under regulation 10(2) concerning a Local Health Board, a Special Health Authority or an NHS trust, the National Assembly;
- (c) in the case of an investigation concerning a service provider, the relevant Local Health Board.

### **Conducting an investigation of a body which is the subject of a review**

**12.**-(1) If in the course of conducting a clinical governance review or a general review, a matter comes to the notice of the Commission which it considers should properly be the subject of an investigation, the Commission may commence an investigation into that matter.

(2) Where the Commission is conducting a clinical governance review, the Commission shall, where reasonably practicable to do so, provide written notification of the decision and the proposed date on which the investigation is to commence to -

- (a) the person or body which is the subject of the review;
- (b) in a case where the body subject to the review is a Local Health Board, a Special Health Authority or an NHS trust, the National Assembly.

(3) Where the Commission is conducting a general review, the Commission shall, where reasonably practicable to do so, provide written notification of the decision and the proposed date on which the investigation is to commence to -

- (a) any person or body who is the subject of the review and who is also to be the subject of the investigation;
- (b) where that person or body is a service provider, the relevant Local Health Board.

(4) Os yw'r Comisiwn yn dechrau ymchwiliad o'r fath, caiff y Comisiwn atal neu barhau â'r adolygiad llywodraethu clinigol neu'r adolygiad cyffredinol ac, os yw'r adolygiad wedi ei atal, caiff ei aildechrau ar unrhyw amser.

### **Adroddiadau am ymchwiliadau**

**13.**-(1) Ar ôl i ymchwiliad a wnaed ar gais y Cynulliad Cenedlaethol ddod i ben, rhaid i'r Comisiwn roi adroddiad i'r Cynulliad Cenedlaethol ac anfon copi o'r adroddiad -

- (a) at unrhyw berson neu i unrhyw gorff a oedd yn destun yr ymchwiliad;
- (b) yn achos ymchwiliad sy'n ymwneud â darparwydd gwasanaeth, i'r Bwrdd Iechyd Lleol perthnasol.

(2) Ar ôl i ymchwiliad a wnaed ar gais unrhyw berson neu gorff arall ddod i ben, rhaid i'r Comisiwn roi adroddiad i'r person neu'r corff hwnnw ac anfon copi o'r adroddiad -

- (a) at unrhyw berson neu i unrhyw gorff a oedd yn destun yr ymchwiliad;
- (b) i'r Cynulliad Cenedlaethol; ac
- (c) yn achos ymchwiliad sy'n ymwneud â darparwydd gwasanaeth, i'r Bwrdd Iechyd Lleol perthnasol.

(3) Ar ôl i ymchwiliad ym mhob achos arall ddod i ben, rhaid i'r Comisiwn roi adroddiad i'r person neu'r corff a oedd yn destun yr ymchwiliad ac anfon copi o'r adroddiad -

- (a) i'r Cynulliad Cenedlaethol; a
- (b) yn achos ymchwiliad sy'n ymwneud â darparwydd gwasanaeth, i'r Bwrdd Iechyd Lleol perthnasol.

(4) Rhaid i adroddiad a wneir o dan baragraffau (1) i (3) nodi -

- (a) canfyddiadau a chasgliadau'r Comisiwn;
- (b) unrhyw argymhellion a wneir gan y Comisiwn.

### **Adroddiadau o ddiddordeb arbennig**

**14.**-(1) Os daw mater i sylw'r Comisiwn yng nghwrs ymchwiliad y mae'n credu y dylid, er lles y cyhoedd, ddod ag ef i sylw -

- (a) unrhyw un o'r personau neu'r cyrff y mae paragraff (2) yn gymwys iddo; a
- (b) y cyhoedd,

caiff y Comisiwn wneud y mater yn destun adroddiad ar unwaith yn ychwanegol at yr adroddiad sydd i'w wneud pan ddaw'r ymchwiliad i ben.

(4) Where the Commission commences such an investigation, the Commission may suspend or continue the clinical governance review or the general review and, where the review was suspended, resume the review at any time.

### **Investigation reports**

**13.**-(1) Following the conclusion of an investigation which has been requested by the National Assembly the Commission shall make a report to the National Assembly and send a copy of the report to -

- (a) any person or body which has been the subject of the investigation;
- (b) in the case of an investigation concerning a service provider, the relevant Local Health Board.

(2) Following the conclusion of an investigation which has been requested by any other person or body the Commission shall make a report to that person or body and send a copy of the report to -

- (a) any person or body which has been the subject of the investigation;
- (b) the National Assembly; and
- (c) in the case of an investigation concerning a service provider, the relevant Local Health Board.

(3) Following the conclusion of an investigation in any other case, the Commission shall make a report to the person or body which has been the subject of the investigation and shall send a copy of the report to -

- (a) the National Assembly; and
- (b) in the case of an investigation concerning a service provider, the relevant Local Health Board.

(4) A report made under paragraphs (1) to (3) shall set out -

- (a) the findings and conclusions of the Commission;
- (b) any recommendations made by the Commission.

### **Special interest reports**

**14.**-(1) If in the course of an investigation a matter comes to the notice of the Commission which it considers should, in the public interest, be brought to the attention of-

- (a) any of the persons or bodies to which paragraph (2) applies; and
- (b) the public,

the Commission may make the matter the subject of an immediate report in addition to the report to be made at the conclusion of the investigation.

(2) Dyma'r personau a'r cyrff y cyfeiriwyd atynt ym mharagraff (1) -

- (a) unrhyw berson neu gorff sydd yn destun yr ymchwiliad;
- (b) y Cynulliad Cenedlaethol;
- (c) yn achos lle darparwydd gwasanaeth yw testun yr ymchwiliad, y Bwrdd Iechyd Lleol perthnasol.

(3) Rhaid anfon copïau o unrhyw adroddiad o dan paragraff (1) -

- (a) at unrhyw berson neu i unrhyw gorff sydd yn destun yr ymchwiliad;
- (b) i'r Cynulliad Cenedlaethol;
- (c) mewn achos lle mae paragraff (2)(c) yn gymwys, i'r Bwrdd Iechyd Lleol perthnasol; ac
- (ch) i unrhyw gorff GIG neu ddarparwydd gwasanaeth neu at berson neu i gorff arall sy'n arfer swyddogaethau statudol, y mae'r Comisiwn yn credu y byddant yn cael copi ohono.

### **Camau pellach yn sgil ymchwiliad**

**15.**-(1) Pan ddaw ymchwiliad i ben rhaid i unrhyw gorff GIG, gyda chymorth y Comisiwn, baratoi datganiad ysgrifenedig o'r camau y mae'n bwriadu eu cymryd yng ngoleuni'r adroddiad a wnaed gan y Comisiwn.

(2) Yn achos Bwrdd Iechyd Lleol, Awdurdod Iechyd Arbennig neu Ymddiriedolaeth GIG, bydd datganiad a baratoir o dan baragraff (1) yn ddarostyngedig i gymeradwyaeth y Cynulliad Cenedlaethol.

(3) Cyn penderfynu ynghylch cymeradwyo datganiad a baratoir o dan baragraff (1), rhaid i'r Cynulliad Cenedlaethol ymgynghori â'r Comisiwn.

## **RHAN VI**

### **HAWLIAU MYNEDIAD A CHAEL GAFAEL AR WYBODAETH**

#### **Hawliau mynediad**

**16.**-(1) Yn ddarostyngedig i baragraffau canlynol y rheoliad hwn, caiff personau sydd ag awdurdod ysgrifenedig y Comisiwn, ar unrhyw adeg resymol, fynd i mewn ac archwilio safleoedd perthnasol at ddibenion cynnal adolygiadau llywodraethu clinigol, adolygiadau cyffredinol neu ymchwiliadau.

(2) Rhaid rhoi tystiolaeth ysgrifenedig i bob person a awdurdodir gan y Comisiwn o dan baragraff (1) o awdurdod y person hwnnw ac, wrth wneud cais am fynediad i safle perthnasol at y dibenion a bennir ym mharagraff (1), bydd yn rhaid iddo, ar gais meddiannydd y safle neu berson sy'n gweithredu ar ei ran, ddangos y dystiolaeth honno.

(3) Rhaid i berson a awdurdodir gan y Comisiwn o

(2) The persons and bodies referred to in paragraph (1) are -

- (a) any person or body which is the subject of the investigation;
- (b) the National Assembly;
- (c) in a case where a service provider is the subject of an investigation, the relevant Local Health Board.

(3) Copies of any report under paragraph (1) shall be sent to -

- (a) any person or body which is the subject of the investigation;
- (b) the National Assembly;
- (c) in a case to which paragraph (2)(c) applies, the relevant Local Health Board; and
- (d) any other NHS body or service provider or other person or body exercising statutory functions, to whom the Commission considers the report shall be copied.

### **Further action following an investigation**

**15.**-(1) Following the conclusion of an investigation any NHS body concerned shall, with the assistance of the Commission, prepare a written statement of the action which it proposes to take in the light of the report made by the Commission.

(2) A statement prepared under paragraph (1) shall be subject to approval in the case of a Local Health Board, a Special Health Authority or an NHS trust, the National Assembly.

(3) Before deciding whether to approve a statement prepared under paragraph (1), the National Assembly shall consult the Commission.

## **PART VI**

### **RIGHTS OF ENTRY AND OBTAINING INFORMATION**

#### **Rights of entry**

**16.**-(1) Subject to the following paragraphs of this regulation, persons authorised in writing by the Commission may at any reasonable time enter and inspect relevant premises for the purposes of conducting clinical governance reviews, general reviews or investigations.

(2) Each person authorised by the Commission under paragraph (1) shall be furnished with written evidence of his or her authority and on applying for entry to relevant premises for the purposes specified in paragraph (1) shall, if so requested by the occupier of the premises or a person acting on his or her behalf, produce that evidence.

(3) A person authorised by the Commission under

dan baragraff (1) beidio â hawlio mynediad i safle perthnasol os nad yw'r person neu'r corff sy'n berchen ar y safle, neu sy'n ei reoli, wedi cael hysbysiad rhesymol o'r bwriad i geisio mynediad.

(4) Ni chaff neb a awdurdodir gan y Comisiwn o dan baragraff (1) fynd i mewn i unrhyw safle neu ran o safle a ddefnyddir yn llety preswyl i bersonau a gyflogir gan unrhyw berson neu gorff, heb yn gyntaf gael caniatâd y personau sy'n preswyl yn y llety hwnnw.

(5) Yn ddarostyngedig i reoliad 19, caiff person a awdurdodir gan y Comisiwn o dan baragraff (1) i fynd i mewn i safle perthnasol o dan y rheoliad hwn, arolygu a chymryd copiâu o unrhyw ddogfennau -

- (a) y mae'n ymddangos iddo fod eu hangen at ddibenion yr adolygiad neu'r ymchwiliad dan sylw; a
- (b) sy'n cael eu cadw ar y safle -
  - (i) gan y person neu'r corff sy'n berchen ar y safle neu yn ei reoli;
  - (ii) gan gadeirydd, aelod, cyfarwyddwr neu gyflogai y person neu'r corff hwnnw;
  - (iii) gan unrhyw berson arall sy'n gweithredu ar ran y person neu'r corff hwnnw; neu
  - (iv) gan aelod o bwyllgor neu is-bwyllgor unrhyw gorff sy'n gysylltiedig.

#### **Cael gwybodaeth ac esboniadau**

17.-(1) Yn ddarostyngedig i reoliad 19, wrth gynnal adolygiad llywodraethu clinigol, adolygiad cyffredinol neu ymchwiliad, caiff y Comisiwn neu berson a awdurdodir gan y Comisiwn o dan reoliad 16(1) ei gwneud yn ofynnol i berson y mae paragraff (5) yn gymwys iddo ddangos unrhyw ddogfennau neu wybodaeth y mae'n ymddangos i'r Comisiwn, neu i'r person a awdurdodir, fod eu hangen at ddibenion yr adolygiad neu'r ymchwiliad dan sylw.

(2) Yn ddarostyngedig i reoliad 19, wrth gynnal adolygiad llywodraethu clinigol, adolygiad cyffredinol neu ymchwiliad, caiff y Comisiwn neu berson a awdurdodir gan y Comisiwn, os yw'n credu bod angen, ei gwneud yn ofynnol i berson y mae paragraff (5) yn gymwys iddo, roi i'r Comisiwn neu, yn ôl y digwydd, i'r person a awdurdodir, esboniad -

- (a) am unrhyw faterion sydd yn destun yr adolygiad neu'r ymchwiliad; neu
  - (b) am unrhyw ddogfennau neu wybodaeth sy'n cael eu harolygu, eu copïo neu eu dangos o dan baragraff (1) neu reoliad 16(5).
- (3) Caiff y Comisiwn, os yw'n credu bod angen, ei gwneud yn ofynnol i berson y mae'n ofynnol iddo-
- (a) ddangos dogfennau neu wybodaeth o dan baragraff (1); neu
  - (b) roi esboniad o dan baragraff (2),

paragraph (1) shall not demand admission to relevant premises as of right unless the person or body which owns or controls the premises has been given reasonable notice of the intended entry.

(4) No person authorised by the Commission under paragraph (1) may enter any premises or part of premises used as residential accommodation for persons employed by any person or body, without first having obtained the consent of the persons residing in such accommodation.

(5) Subject to regulation 19, a person authorised by the Commission under paragraph (1) to enter relevant premises under this regulation may inspect and take copies of any documents which -

- (a) appear to him or her to be necessary for the purposes of the review or investigation in question; and
- (b) are held on the premises by -
  - (i) the person or body which owns or controls the premises;
  - (ii) a chairman, member, director or employee of that person or body;
  - (iii) any other person acting on behalf of that person or body; or
  - (iv) a member of a committee or sub-committee of any body concerned.

#### **Obtaining information and explanations**

17.-(1) Subject to regulation 19, in conducting a clinical governance review, a general review or an investigation the Commission or a person authorised by the Commission under regulation 16(1) may require a person to which paragraph (5) applies to produce any documents or information which appear to the Commission, or to the person authorised, to be necessary for the purposes of the review or investigation in question.

(2) Subject to regulation 19, in conducting a clinical governance review, a general review or an investigation the Commission or a person authorised by the Commission may, if it or he thinks it necessary, require a person to which paragraph (5) applies to give the Commission or, as the case may be, the person authorised an explanation of -

- (a) any matters which are the subject of the review or investigation; or
  - (b) any documents or information inspected, copied or produced under paragraph (1) or regulation 16(5).
- (3) The Commission may, if it considers it necessary require a person required to -
- (a) produce documents or information under paragraph (1); or
  - (b) give an explanation under paragraph (2),

fod yn bresennol yng ngŵydd y Comisiwn neu berson a awdurdodir gan y Comisiwn o dan reoliad 16(1) er mwyn dangos y dogfennau neu'r wybodaeth neu er mwyn rhoi'r esboniad.

(4) Ni chaiff y Comisiwn na pherson a awdurdodir o dan reoliad 16(1) ei gwneud yn ofynnol i berson fod yn bresennol yn unol â pharagraff (3) heb roi i'r person hwnnw hysbysiad rhesymol o'r dyddiad y bwriedir gofyn iddo fod yn bresennol.

(5) Dyma'r person y cyfeirir ato ym mharagraffau (1) a (2)-

- (a) corff GIG;
- (b) cadeirydd, aelod, cyfarwyddwr neu gyflogai corff GIG, neu unrhyw berson arall sy'n gweithredu ar ran corff o'r fath;
- (c) aelod o bwyllgor neu is-bwyllgor corff GIG;
- (ch) darparydd gwasanaeth;
- (d) cyflogai darparydd gwasanaeth, neu unrhyw berson arall sy'n gweithredu ar ran darparydd o'r fath;
- (dd) person sy'n darparu neu sy'n helpu i ddarparu gwasanaethau o dan Ddeddf 1977, neu sy'n aelod neu'n gyflogai i berson neu gorff sy'n darparu neu sy'n helpu i ddarparu'r gwasanaethau hynny, neu mewn cysylltiad â chynllun peilot o dan Ddeddf 1997, yn unol â chontract a wnaed â chorff GIG, darparydd gwasanaeth, neu berson y mae is-baragraff (e) yn gymwys iddo;
- (e) awdurdod lleol sy'n darparu gwasanaethau neu berson a gyflogir gan awdurdod lleol i ddarparu gwasanaethau o dan Ddeddf 1977, neu mewn cysylltiad â chynllun peilot o dan Ddeddf 1997, yn unol â threfniadau a wnaed yn rhinwedd adran 31(1) o'r Ddeddf.

### **Gwybodaeth a gedwir yn gyfrifiadurol neu ar unrhyw ffurf electronig arall**

**18.**-(1) Yn y rheoliad hwn ac yn rheoliadau 16 a 17, mae unrhyw gyfeiriad at ddogfennau yn cynnwys cyfeiriad at wybodaeth a gedwir yn gyfrifiadurol neu ar unrhyw ffurf electronig arall.

(2) Os yw'r Comisiwn neu berson a awdurdodir o dan rheoliad 16(1) yn arfer -

- (a) yr hawl o dan reoliad 16(5) i archwilio a chymryd copïau o ddogfennau; neu
- (b) yr hawl o dan reoliad 17(1) i'w gwneud yn ofynnol i unrhyw berson ddangos dogfennau,

ac os yw'r dogfennau hynny ar ffurf gwybodaeth a gedwir yn gyfrifiadurol neu ar unrhyw ffurf electronig arall, caiff y Comisiwn neu'r person a awdurdodir ei gwneud yn ofynnol i unrhyw berson sy'n rhedeg, neu sy'n ymwneud â gweithredu fel arall, gyfrifiadurol neu ddyfais electronig arall sy'n cadw'r wybodaeth honno,

to attend before the Commission or a person authorised by the Commission under regulation 16(1) in person to produce the documents or information or give the explanation.

(4) The Commission or a person authorised under regulation 16(1) may not require a person to attend in person in accordance with paragraph (3) unless reasonable notice of the intended date of attendance has been given to that person.

(5) The person referred to in paragraphs (1) and (2) are -

- (a) an NHS body;
- (b) a chairman, member, director or employee of an NHS body, or any other person acting on behalf of such a body;
- (c) a member of a committee or sub-committee of an NHS body;
- (d) a service provider;
- (e) an employee of a service provider, or any other person acting on behalf of such a provider;
- (f) a person who provides or assists in the provision of, or is a member or an employee of a person or body who provides or assists in the provision of, services under the 1977 Act, or in connection with a pilot scheme under the 1997 Act, in accordance with a contract made with an NHS body, a service provider or a person to which sub-paragraph (g) applies;
- (g) a local authority which provides, or a person employed by local authority to provide, services under the 1977 Act, or in connection with a pilot scheme under the 1997 Act, in accordance with arrangements made by virtue of section 31(1) of the Act.

### **Information held by means of a computer or in any other electronic form**

**18.**-(1) In this regulation and in regulations 16 and 17, any reference to documents includes a reference to information held by means of a computer or in any other electronic form.

(2) Where the Commission or a person authorised under regulation 16(1) is exercising -

- (a) the right under regulation 16(5) to inspect and take copies of documents; or
- (b) the right under regulation 17(1) to require any person to produce documents,

and such documents consist of information held by means of a computer or in any other electronic form, the Commission or the person authorised may require any person having charge of, or otherwise concerned with the operation of, the computer or other electronic device holding that information to make that

drefnu bod y wybodaeth honno ar gael, neu ddangos y wybodaeth honno, ar ffurf weladwy a darllenadwy.

### Cyfyngiadau ar ddatgelu gwybodaeth i'r Comisiwn

**19.**-(1) Rhaid i'r Comisiwn neu berson a awdurdodir o dan reoliad 16(1) beidio ag archwilio na chymryd copïau o ddogfennau o dan reoliad 16(5) i'r graddau-

- (a) y mae'r dogfennau hynny yn cynnwys gwybodaeth gyfrinachol<sup>(a)</sup> sy'n ymwneud â unigolyn byw, a'i enwi, os nad yw un neu ragor o'r amodau a bennir ym mharagraff (3) yn gymwys; neu
- (b) y mae archwilio neu gopïo'r dogfennau hynny yn golygu datgelu gwybodaeth os yw datgelu felly wedi ei wahardd gan neu o dan unrhyw ddeddfiad, os nad yw paragraff (4) yn gymwys.

(2) Ni fydd yn ofynnol i neb ddangos dogfennau neu wybodaeth o dan reoliad 17(1) na rhoi esboniad o dan reoliad 17(2) i'r graddau y mae dangos y dogfennau hynny neu'r wybodaeth honno neu roi'r esboniad hwnnw yn datgelu gwybodaeth-

- (a) sy'n gyfrinachol ac sy'n ymwneud ag unigolyn sy'n byw, a'i enwi, os nad yw un neu ragor o'r amodau a bennir ym mharagraff (3) yn gymwys; neu
- (b) y gwaherddir datgelu gan neu o dan unrhyw ddeddfiad, os nad yw paragraff (4) yn gymwys.

(3) Dyma'r amodau y cyfeirir atynt ym mharagraffau (1)(a) a (2)(a) -

- (a) datgelir y wybodaeth ar ffurf nad oes modd adnabod yr unigolyn;
- (b) mae'r unigolyn yn caniatáu datgelu'r wybodaeth;
- (c) ni ellir cael hyd i'r unigolyn er gwaethaf cymryd pob cam rhesymol;
- (ch) mewn achos lle mae'r Comisiwn yn arfer ei swyddogaethau o dan adran 20(1)(c), (d) neu (db) o'r Ddeddf<sup>(b)</sup> neu reoliad 2(e) o'r Rheoliadau Swyddogaethau -
  - (i) nid yw'n ymarferol datgelu'r wybodaeth ar ffurf nad oes modd adnabod yr unigolyn ohoni;
  - (ii) mae'r Comisiwn yn credu bod perygl difrifol i iechyd neu ddiogelwch cleifion yn deillio o'r materion sydd yn destun yr ymchwiliad; a

(a) *Gweler* adran 23(6) o Ddeddf 1999 i gael diffiniad o "confidential information".

(b) Mewnosodwyd adran 20(1)(db) gan adran 13(1) o Ddeddf 2002.

information available, or produce that information, in a visible and legible form.

### Restrictions on disclosure of information to the Commission

**19.**-(1) The Commission or a person authorised under regulation 16(1) shall not inspect or take copies of documents under regulation 16(5) to the extent that -

- (a) those documents consist of confidential information<sup>(a)</sup> which relates to and identifies a living individual, unless one or more of the conditions specified in paragraph (3) applies; or
- (b) the inspection or copying of those documents involves the disclosure of information if that disclosure is prohibited by or under any enactment, unless paragraph (4) applies.

(2) A person shall not be required to produce documents or information under regulation 17(1) or give an explanation under regulation 17(2) to the extent that the production of those documents or that information or the giving of that explanation discloses information -

- (a) which is confidential and which relates to and identifies a living individual, unless one or more of the conditions specified in paragraph (3) applies; or
- (b) the disclosure of which is prohibited by or under any enactment, unless paragraph (4) applies.

(3) The conditions referred to in paragraphs (1)(a) and (2)(a) are -

- (a) the information is disclosed in a form in which the identity of the individual cannot be ascertained;
- (b) the individual consents to the information being disclosed;
- (c) the individual cannot be traced despite the taking of all reasonable steps;
- (d) in a case where the Commission is exercising its functions under section 20(1)(c), (d) or (db) of the Act<sup>(b)</sup> or regulation 2(e) of the Functions Regulations -
  - (i) it is not practicable to disclose the information in a form in which the identity of the individual cannot be ascertained;
  - (ii) the Commission considers that there is a serious risk to the health or safety of patients arising out of the matters which are the subject of the investigation; and

(a) *See* section 23(6) of the 1999 Act for the definition of "confidential information".

(b) Section 20(1)(db) was inserted by section 13(1) of the 2002 Act.

- (iii) wedi ystyried y perygl hwnnw ac a oes angen brys arfer y swyddogaethau hynny, mae'r Comisiwn yn credu y dylid datgelu'r wybodaeth heb ganiatâd yr unigolyn.

(4) Mae'r paragraff hwn yn gymwys os -

- (a) y gwaherddir datgelu'r wybodaeth oherwydd bod modd adnabod unigolyn o'r wybodaeth honno; a
- (b) yw'r wybodaeth dan sylw ar ffurf nad oes modd adnabod yr unigolyn ohoni.

(5) Mewn achos lle y gwaherddir datgelu gwybodaeth -

- (a) gan baragraff (1); neu
- (b) gan baragraff (2) ac mae'r gwaharddiad ar waith oherwydd bod modd adnabod unigolyn o'r wybodaeth,

caiff y Comisiwn neu berson a awdurdodir gan y Comisiwn o dan reoliad 16(1) ei gwneud yn ofynnol i'r person sy'n cadw'r wybodaeth ddarparu'r wybodaeth ar ffurf nad oes modd adnabod yr unigolyn ohoni, er mwyn galluogi datgelu'r wybodaeth.

## RHAN VII

### AMRYWIOL

#### Cynorthwyo'r Comisiwn Archwilio

**20.** Ni chaiff y Comisiwn gynorthwyo'r Comisiwn Archwilio o dan adran 21(2) o'r Ddeddf heb ganiatâd y Cynulliad Cenedlaethol.

#### Arfer swyddogaethau mewn perthynas ag ymholiadau'r gwasanaeth iechyd

**21.**-(1) Ni chaiff y Comisiwn arfer ei swyddogaethau o dan reoliad 2(1)(f) o'r Rheoliadau Swyddogaethau mewn perthynas ag ymchwiliad penodol neu ymchwiliad arfaethedig heb ganiatâd y Cynulliad Cenedlaethol.

(2) Wrth arfer ei swyddogaethau o dan reoliad 2(1)(f) rhaid i'r Comisiwn gymryd i ystyriaeth unrhyw gyngor neu ganllawiau sy'n ymwneud ag ymholiadau'r gwasanaeth iechyd a roddir i gyrff GIG gan y Cynulliad.

#### Dirymu

**22.** Diddymir Rheoliadau'r Comisiwn Gwella Iechyd (Swyddogaethau) (Cymru) 2000(a).

- (iii) having regard to that risk and the urgency of the exercise of those functions, the Commission considers that the information should be disclosed without the consent of the individual.

(4) This paragraph applies where -

- (a) the prohibition on the disclosure of information operates by reason of the fact that the information is capable of identifying an individual; and
- (b) the information in question is in a form in which the identity of the individual cannot be ascertained.

(5) In a case where the disclosure of information is prohibited by -

- (a) paragraph (1); or
- (b) paragraph (2) and the prohibition operates by reason of the fact that the information is capable of identifying an individual,

the Commission or a person authorised by the Commission under regulation 16(1) may require the person holding the information to put the information in a form in which the identity of the individual concerned cannot be identified, in order that the information may be disclosed.

## PART VII

### MISCELLANEOUS

#### Assisting the Audit Commission

**20.** The Commission may not assist the Audit Commission under section 21(2) of the Act without the consent of the National Assembly.

#### Exercising functions in relation to health service inquiries

**21.**-(1) The Commission shall not exercise its functions under regulation 2(f) of the Functions Regulations in relation to a particular inquiry or proposed inquiry without the consent of the National Assembly.

(2) In exercising its functions under regulation 2(f) the Commission shall take into account any advice or guidance relating to health service inquiries given to NHS bodies by the Assembly.

#### Revocation

**22.** The Commission for Health Improvement (Functions) (Wales) Regulations 2000(a) are revoked.

(a) O.S. 2000/1015 (Cy.57).

(a) S.I. 2000/1015 (W.57).

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

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

2 Ebrill 2003

2nd April 2003

*D.Elis-Thomas*

Llywydd y Cynulliad Cenedlaethol

The Presiding Officer of the National Assembly

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(a) 1998 p.38.

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(a) 1998 c.38.

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