



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

**2000 Rhif 1015 (Cy. 57)**

**2000 No. 1015 (W. 57)**

**Y GWASANAETH IECHYD  
GWLADOL, CYMRU**

**NATIONAL HEALTH  
SERVICE, WALES**

Rheoliadau'r Comisiwn Gwella  
Iechyd (Swyddogaethau) (Cymru)  
2000

The Commission for Health  
Improvement (Functions) (Wales)  
Regulations 2000

**NODYN ESBONIADOL**

**EXPLANATORY NOTE**

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

*(This note does not form part of the Regulations.)*

Mae'r Rheoliadau hyn yn gwneud darpariaeth ynglŷn ag arfer yng Nghymru swyddogaethau'r Comisiwn Gwella Iechyd a sefydlir o dan adran 19 o Ddeddf Iechyd 1999.

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

Rhoddir ei swyddogaethau craidd i'r Comisiwn gan adran 20 o Ddeddf Iechyd 1999 sy'n darparu bod y Comisiwn -

The Commission's core functions are conferred on it by section 20 of the Health Act 1999 which provides for the Commission -

- yn darparu cyngor a gwybodaeth am drefniadau ar gyfer monitro a gwella'r gofal iechyd a ddarperir gan Ymddiriedolaethau'r Gwasanaeth Iechyd Gwladol ac Ymddiriedolaethau Gofal Sylfaenol (lle sefydlir hwy), gan gynnwys trefniadau llywodraethu clinigol;
- yn cynnal adolygiadau ar weithrediad a digonolrwydd y trefniadau hynny;
- yn ymchwilio, cynghori ac adrodd ar faterion penodol ynglŷn a chyflwyno a rheoli'r gofal iechyd a ddarperir gan gyrff y Gwasanaeth Iechyd Gwladol;
- yn cynnal adolygiadau cenedlaethol ar fathau penodol o ofal iechyd a ddarperir gan y Gwasanaeth Iechyd Gwladol.

- to provide advice and information on arrangements for the monitoring and improvement of health care provided by National Health Service Trusts and Primary Care Trusts (where established), including clinical governance arrangements;
- to conduct reviews of the implementation and adequacy of such arrangements;
- to investigate, advise and report on specific matters relating to the delivery and management of health care provided by National Health Service bodies;
- to conduct national reviews on particular types of health care provided by the National Health Service.

Mae Adran 20(1)(e) o Ddeddf Iechyd 1999 yn darparu i swyddogaethau ychwanegol gael eu rhoi drwy gyfrwng rheoliadau. Mae'r pŵer i wneud rheoliadau o'r fath yn arferadwy gan yr Ysgrifennydd Gwladol dros Iechyd ac mae wedi'i arfer drwy

Section 20(1)(e) of the Health Act 1999 provides for additional functions to be conferred by regulations. The power to make such regulations is exercisable by the Secretary of State for Health and has been exercised by the addition of the following extra

ychwanegu'r swyddogaethau ychwanegol canlynol fel y'u nodir yn rheoliad 2 o Reoliadau'r Comisiwn Gwella Iechyd (Swyddogaethau) 2000 sy'n darllen fel a ganlyn -

“2. The following functions are prescribed pursuant to section 20(1)(e) -

(a) the function of providing advice or information with respect to the arrangements by Health Authorities, Special Health Authorities or service providers for the purpose of monitoring and improving the quality of health care for which they have responsibility;

b) the function of providing advice or information with respect to the arrangements by Primary Care Trusts for the purpose of monitoring and improving the quality of health care provided by their relevant service providers;

c) the function of conducting reviews of, and making reports on, arrangements by Health Authorities, or Special Health Authorities to which the duty in section 18 of the Act has been extended(a), for the purpose of monitoring and improving the quality of health care for which they have responsibility;

d) the function of conducting reviews of, and making reports on, arrangements by Primary Care Trusts for the purpose of monitoring and improving the quality of health care provided by their relevant service providers;

(e) the function of carrying out investigations into, and making reports on, the management, provision or quality of health care for which Special Health Authorities have responsibility;

f) the function of providing advice with respect to the establishment and conduct of health service inquiries.”

Ceir croesgyfeiriadau at reoliad 2 yn Rheoliadau'r Comisiwn Gwella Iechyd (Swyddogaethau) (Cymru) 2000.

Mae'r rheoliadau hyn yn darparu ar gyfer paratoi rhaglen waith flynyddol y Comisiwn (rheoliad 2), i'r Comisiwn ddarparu cyngor neu wybodaeth ynglŷn a threfniadau llywodraethu clinigol i'r Cynulliad Cenedlaethol, cyrff y gwasanaeth iechyd ac eraill (rheoliadau 3 a 4), cynnal adolygiadau lleol ar y trefniadau hynny, a'r adroddiadau a'r camau sydd i'w cymryd yn sgil yr adolygiadau hynny (rheoliadau 5 i 8), adroddiadau yn dilyn adolygiadau gwasanaeth cenedlaethol o fathau penodol o ofal iechyd (rheoliad 9) a chynnal ymchwiliadau i reolaeth, darpariaeth neu ansawdd y gofal iechyd y mae cyrff y Gwasanaeth Iechyd Gwladol yn gyfrifol amdanynt a'r adroddiadau ynglŷn â'r ymchwiliadau hynny (rheoliadau 10 i 15).

functions as set out in regulation 2 of the Commission for Health Improvement (Functions) Regulations 2000 which reads as follows -

“2. The following functions are prescribed pursuant to section 20(1)(e) -

(a) the function of providing advice or information with respect to the arrangements by Health Authorities, Special Health Authorities or service providers for the purpose of monitoring and improving the quality of health care for which they have responsibility;

(b) the function of providing advice or information with respect to the arrangements by Primary Care Trusts for the purpose of monitoring and improving the quality of health care provided by their relevant service providers;

(c) the function of conducting reviews of, and making reports on, arrangements by Health Authorities, or Special Health Authorities to which the duty in section 18 of the Act has been extended(a), for the purpose of monitoring and improving the quality of health care for which they have responsibility;

(d) the function of conducting reviews of, and making reports on, arrangements by Primary Care Trusts for the purpose of monitoring and improving the quality of health care provided by their relevant service providers;

(e) the function of carrying out investigations into, and making reports on, the management, provision or quality of health care for which Special Health Authorities have responsibility;

(f) the function of providing advice with respect to the establishment and conduct of health service inquiries.”

There are cross references to regulation 2 in the Commission for Health Improvement (Functions) (Wales) Regulations 2000.

These regulations make provision for the preparation of the Commission's annual work programme (regulation 2), the provision by the Commission of advice or information with respect to clinical governance arrangements to the National Assembly and health service bodies and others (regulations 3 and 4), the conduct of local reviews of such arrangements and the reports and follow up action relating to those reviews (regulations 5 to 8), reports following national service reviews of particular types of health care (regulation 9) and the conduct of investigations into the management, provision or quality of health care for which National Health Service bodies have responsibility and the reports relating to those investigations (regulations 10 to 15).

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(a) Gweler adran 18(3) o Ddeddf Iechyd 1999 (p.8) (“Deddf 1999”).

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(a) See section 18(3) of the Health Act 1999 (c.8) (“the 1999 Act”).

Mae Rheoliadau 16 i 19 yn gwneud darpariaeth i'r Comisiwn a phersonau a awdurdodir ganddo fynd ar dir ac adeiladau'r Gwasanaeth Iechyd Gwladol i gael gafael ar ddogfennau, gwybodaeth ac esboniadau.

Mae Rheoliad 20 yn atal y Comisiwn rhag rhoi cymorth i'r Comisiwn Archwilio wrth arfer rhai o'i swyddogaethau, heb gydsyniad y Cynulliad Cenedlaethol. Mae Rheoliad 21 yn gwneud darpariaeth ynglŷn a rôl y Comisiwn wrth roi cymorth mewn perthynas ag ymchwiliadau'r gwasanaeth iechyd.

Regulations 16 to 19 make provision for the Commission and persons authorised by it to enter National Health Service premises and to obtain documents, information and explanations.

Regulation 20 precludes the Commission from providing assistance to the Audit Commission in the exercise of certain of its functions, without the consent of the National Assembly. Regulation 21 makes provision regarding the role of the Commission in providing assistance in relation to health service inquiries.

2000 Rhif 1015 (Cy. 57)

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Y GWASANAETH IECHYD  
GWLADOL, CYMRUNATIONAL HEALTH  
SERVICE, WALESRheoliadau'r Comisiwn Gwella  
Iechyd (Swyddogaethau) (Cymru)  
2000The Commission for Health  
Improvement (Functions) (Wales)  
Regulations 2000

Wedi'u gwneud

30 Mawrth 2000

Made

30 March 2000

Yn dod i rym

1 Ebrill 2000

Coming into force

1st April 2000

Mae Cynulliad Cenedlaethol Cymru drwy arfer y pwerau a roddwyd i'r Ysgrifennydd Gwladol gan adrannau 17 a 126(4) o Ddeddf y Gwasanaeth Iechyd Gwladol 1977(a) ac adrannau 20(2) a 23(1), (3) a (5) o Ddeddf Iechyd 1999(b) ac a freiniwyd bellach yn y Cynulliad Cenedlaethol(c) drwy hyn yn gwneud y Rheoliadau canlynol:

The National Assembly for Wales, in exercise of the powers conferred on the Secretary of State by sections 17 and 126(4) of the National Health Service Act 1977(a) and sections 20(2) and 23(1), (3) and (5) of the Health Act 1999(b) and now vested in the National Assembly(c) hereby makes the following Regulations:

RHAN I  
CYFFREDINOLPART I  
GENERAL

## Enwi, cychwyn, dehongli a chymhwyso

## Citation, commencement, interpretation and application

1.-(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Comisiwn Gwella Iechyd (Swyddogaethau)(Cymru) 2000 a deuant i rym ar 1 Ebrill 2000.

1.-(1) These Regulations may be cited as the Commission for Health Improvement (Functions) (Wales) Regulations 2000 and shall come into force on 1st April 2000.

(2) Yn y Rheoliadau hyn -

(2) In these Regulations-

ystyr "adolygiad gwasanaeth gwladol" ("*national service review*") yw adolygiad a gynhelir gan y Comisiwn o dan adran 20(1)(d) o'r Ddeddf;

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

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

ystyr "adolygiad lleol" ("*local review*") yw

(a) 1977 p.49; amnewidiwyd adran 17 gan adran 12 o Ddeddf 1999; mae adran 126(4) yn gymwys mewn perthynas ag unrhyw bŵer i wneud gorchmynion neu reoliadau a roddir gan Ddeddf 1999 (gweler adran 62(4) o Ddeddf 1999) ac fe'i diwygiwyd gan Ddeddf y Gwasanaeth Iechyd Gwladol a Gofal Cymunedol 1990 (p.19), adran 65(2) a Deddf 1999, Atodlen 4, paragraff 37(6).

(b) 1999 p.8; gweler adrannau 20(7) a 23(6) ar gyfer y diffiniadau o "prescribed".

(c) Trosglwyddwyd swyddogaethau'r Ysgrifennydd Gwladol o dan y darpariaethau hyn, i'r graddau y maent yn arferadwy mewn perthynas â Chymru, i Gynulliad Cenedlaethol Cymru gan erthygl 2(a) o Orchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999, O.S. 1999/672, fel y'i diwygiwyd gan adran 66(5) o Ddeddf 1999.

(a) 1977 c.49; section 17 was substituted by section 12 of 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), section 65(2) and the 1999 Act, Schedule 4, paragraph 37(6).

(b) 1999 c.8; see sections 20(7) and 23(6) for the definitions of "prescribed".

(c) The functions of the Secretary of State under these provisions are, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by article 2(a) of the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672, as amended by section 66(5) of the 1999 Act.

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 "ymchwiliad" ("*investigation*") yw ymchwiliad gan y Comisiwn yn unol ag adran 20(1)(c) o'r Ddeddf neu reoliad 2(3) o'r Rheoliadau Swyddogaethau;

ystyr "Awdurdod Iechyd perthnasol" ("*relevant Health Authority*") yw'r Awdurdod Iechyd y mae darparpwydd gwasanaethau yn darparu gwasanaethau yn ei ardal;

ystyr "blwyddyn ariannol" ("*financial year*") yw'r cyfnod o 12 mis yn gorffen ar 31 Mawrth;

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

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

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

ystyr "darparpwydd gwasanaethau" ("*service provider*") yw person, heblaw corff y Gwasanaeth Iechyd Gwladol sydd -

(a) yn darparu gwasanaethau Rhan II; neu

(b) yn darparu gwasanaethau yn unol â chynllun peilot o dan Ddeddf 1997(a);

ystyr "Deddf 1977" ("*the 1977 Act*") yw Deddf y Gwasanaeth Iechyd Gwladol 1977;

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

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

mae i "gwasanaethau meddygol personol" ("*personal medical services*") yr ystyr a roddir i "personal medical services" yn adran 1(8) o Ddeddf 1977;

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 "proffesiynolyn gofal iechyd" ("*health care professional*") yw person sydd wedi'i 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;

"the 1997 Act" ("*Deddf 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;

"clinical governance arrangements" ("*trefniadau llywodraethu clinigol*") means arrangements by a National Health Service body or a service provider for monitoring and improving the quality of health care(b) for which they have responsibility;

"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;

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

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

"health care professional" ("*proffesiynolyn 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 or a National Health Service body, into any matter relating to the management, provision and quality of health care for which National Health Service bodies or service providers have responsibility;

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

"local review" ("*adolygiad lleol*") means a review conducted by the Commission under section 20(1)(b) of the Act or regulation 2(c) or (d) of the Functions Regulations;

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

"national service review" ("*adolygiad gwasanaeth gwladol*") means a review conducted by the Commission under section 20(1)(d) of the Act;

"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;

(a) Gweler adran 1 o Ddeddf 1997 ar gyfer diffiniad o "pilot scheme".

(b) 1997 p.46.

(a) 1997 c.46.

(b) See sections 18(3) and 20(7) of the 1999 Act for the definition of "health care".

(c) S.I. 2000/662.

ystyr “y Rheoliadau Swyddogaethau” (“*the Functions Regulations*”) yw Rheoliadau'r Comisiwn Gwella Iechyd (Swyddogaethau) 2000(a);

ystyr “trefniadau llywodraethu clinigol” (“*clinical governance arrangements*”) yw trefniadau gan gorff y Gwasanaeth Iechyd Gwladol neu ddarparydd gwasanaethau ar gyfer monitro a gwella ansawdd y gofal iechyd(b) y mae ganddynt gyfrifoldeb drosto;

ystyr “ymchwiliad gwasanaeth iechyd” (“*health service inquiry*”) yw ymchwiliad a gynhelir neu a sefydlir gan y Cynulliad Cenedlaethol neu gorff y Gwasanaeth Iechyd Gwladol, i unrhyw fater ynglŷn â rheoli, darparu, ac ansawdd y gofal iechyd y mae cyrff y Gwasanaeth Iechyd Gwladol neu ddarparwyr gwasanaethau yn gyfrifol amdanynt;

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

## RHAN II RHAGLEN WAITH FLYNYDDOL

### Rhaglen waith flynyddol

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

(2) Cyn gynted ag y bo'n rhesymol ymarferol wedi 1 Ebrill 2000 rhaid i'r Comisiwn baratoi rhaglen waith mewn perthynas â gweddill y flwyddyn ariannol sy'n dechrau ar y dyddiad hwnnw a dehonglir cyfeiriadau yn y rheoliad hwn at “blwyddyn” a “rhaglen waith” yn unol â hynny.

(3) Rhaid i bob rhaglen waith, mewn perthynas a'r flwyddyn honno, nodi -

(a) unrhyw faterion penodol y mae'r Comisiwn i ddarparu cyngor neu wybodaeth ar drefniadau llywodraethu clinigol ynglŷn â hwy;

(b) cynigion o ran y cyrff y Gwasanaeth Iechyd Gwladol y mae'r Comisiwn i gynnal adolygiadau lleol ynglŷn â hwy;

(c) unrhyw faterion penodol y mae'r Comisiwn i'w hystyried neu i'w cymryd i ystyriaeth wrth gynnal adolygiad lleol neu adolygiad gwasanaeth gwladol; ac

(ch) y mathau penodol o ofal iechyd sydd i fod yn destun unrhyw adolygiadau gwasanaeth gwladol ac adroddiadau o dan adran 20(1)(d) o'r Ddeddf.

“personal medical services” (“*gwasanaethau meddygol personol*”) has the meaning given in section 1(8) of the 1977 Act;

“relevant Health Authority” (“*Awdurdod Iechyd perthnasol*”) means the Health Authority in whose area a service provider provides services;

“service provider” (“*darparydd gwasanaethau*”) means a person, other than a National Health Service body, who -

(a) provides Part II services; or

(b) provides services in accordance with a pilot scheme under the 1997 Act(a).

(3) These regulations apply to Wales only.

## PART II ANNUAL WORK PROGRAMME

### Annual work programme

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

(2) As soon as is reasonably practicable after 1st April 2000 the Commission shall prepare such a work programme in relation to the remainder of the financial year beginning on that date and references in this regulation to “year” and “work programme” shall be construed accordingly.

(3) 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 National Health Service bodies in relation to which the Commission is to conduct local reviews;

(c) any particular matters which the Commission is to consider or take into account when conducting a local review or a national service review; and

(d) the particular types of health care which are to be the subject of any national service reviews and reports under section 20(1)(d) of the Act.

(a) O.S. 2000/662

(b) Gweler adrannau 18(3) a 20(7) o Ddeddf 1999 ar gyfer y diffiniad o “health care”.

(a) See section 1 of the 1997 Act for a definition of “pilot scheme”.

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

(5) Gellir amrywio'r rhaglen waith -

(a) gyda chytundeb y Cynulliad Cenedlaethol; neu

(b) fel y gall y Cynulliad Cenedlaethol benderfynu.

(6) Yn ddarostyngedig i'r rheoliadau canlynol ac unrhyw gyfarwyddiadau a roddir gan y Cynulliad Cenedlaethol, bydd y Comisiwn yn arfer ei swyddogaethau mewn unrhyw flwyddyn ariannol benodol yn unol â'r rhaglen waith ynglŷn â'r flwyddyn honno.

### **RHAN III CYNGOR NEU WYBODAETH AM DREFNIADAU LLYWODRAETHU CLINIGOL**

#### **Personau y gellir rhoi cyngor neu wybodaeth iddynt**

**3.-(1)** Bydd y Comisiwn yn darparu cyngor neu wybodaeth am drefniadau llywodraethu clinigol i -

(a) y Cynulliad Cenedlaethol;

(b) cyrff y Gwasanaeth Iechyd Gwladol; a

(c) darparwyr 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 y Gwasanaeth Iechyd Gwladol; ac

(c) i ddarparwyr gwasanaethau penodol.

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

#### **Arfer swyddogaeth darparu cyngor neu wybodaeth am drefniadau llywodraethu 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 gymryd i ystyriaeth -

(a) unrhyw ganllawiau ynglŷn â threfniadau llywodraethu clinigol a roddir gan y Cynulliad Cenedlaethol neu'r Sefydliad Cenedlaethol ar gyfer Rhagoriaeth Glinigol;

(b) unrhyw gyngor neu ganllawiau ynglŷn â

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

(5) The work programme may be varied-

(a) with the agreement of the National Assembly; or

(b) as the National Assembly may determine.

(6) Subject to the following regulations and to any directions given by the National Assembly, the Commission shall exercise its functions in any particular 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) the National Assembly;

(b) National Health Service 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 National Health Service 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 arrangements**

**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;

(b) any advice or guidance relating to clinical

threfniadau llywodraethu clinigol a roddir gan unrhyw gorff sy'n gyfrifol am reoli proffesiwn gofal iechyd.

## **RHAN IV ADOLYGIADAU LLEOL**

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

5. Wrth gynnal adolygiad lleol rhaid i'r Comisiwn asesu effeithiolrwydd trefniadau'r corff y Gwasanaeth Iechyd Gwladol o dan sylw ac ystyried a yw'r trefniadau hynny'n ddigonol.

### **Adroddiadau ar adolygiadau lleol**

6.-(1) Ar ôl i adolygiad lleol ddod i ben, rhaid i'r Comisiwn wneud adroddiad i'r corff y Gwasanaeth Iechyd Gwladol yn nodi -

(a) canfyddiadau a chasgliadau'r Comisiwn; a

(b) unrhyw argymhellion a wneir gan y Comisiwn.

(2) Rhaid i'r Comisiwn gyhoeddi crynodeb o unrhyw adroddiad o'r fath.

### **Adroddiadau o ddiddordeb arbennig**

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

(a) unrhyw un o'r personau neu'r cyrff y mae paragraff (2) yn gymwys iddynt; a

(b) y cyhoedd,

caiff y Comisiwn wneud y mater yn destun adroddiad ar unwaith yn ychwanegol at yr adroddiad sydd i'w wneud ar ddiwedd yr adolygiad.

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

(a) y corff y Gwasanaeth Iechyd Gwladol sy'n destun yr adolygiad lleol;

(b) y Cynulliad Cenedlaethol.

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

(a) y corff y Gwasanaeth Iechyd Gwladol sy'n destun yr adolygiad lleol;

(b) y Cynulliad Cenedlaethol;

(c) unrhyw gorff y gwasanaeth iechyd gwladol neu ddarparwydd gwasanaethau neu unrhyw berson neu gorff arall sy'n arfer swyddogaethau statudol, y mae'r

governance arrangements given by any body responsible for the regulation of a health care profession.

## **PART IV LOCAL REVIEWS**

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

5. In conducting a local review the Commission shall assess the effectiveness of the arrangements by the National Health Service body concerned and consider whether those arrangements are adequate.

### **Local review reports**

6.-(1) Following the conclusion of a local review, the Commission shall make a report to the National Health Service body concerned setting out-

(a) the findings and conclusions of the Commission; and

(b) any recommendations made by the Commission.

(2) The Commission shall publish a summary of any such report.

### **Special interest reports**

7.-(1) If in the course of a local 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 National Health Service body which is the subject of the local review;

(b) the National Assembly.

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

(a) the National Health Service body which is the subject of the local review;

(b) the National Assembly;

(c) any other national health service body or service provider or other person or body exercising statutory functions, to whom the Commission



Comisiwn yn credu y dylid anfon copi o'r adroddiad atynt.

(4) Yn ychwanegol at anfon copiâu o'r adroddiad at y personau y cyfeirir atynt ym mharagraff (3), rhaid i'r Comisiwn gyhoeddi crynodeb o'r adroddiad.

### **Camau pellach yn dilyn adolygiad lleol**

8.-(1) Pan ddaw adolygiad lleol i ben, rhaid i'r corff y Gwasanaeth Iechyd Gwladol o 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.

(2) Bydd datganiad a baratoir o dan baragraff (1) yn ddarostyngedig i gymeradwyaeth gan y Cynulliad Cenedlaethol.

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

## **RHAN V ADOLYGIADAU GWASANAETH GWLADOL**

### **Adroddiadau ar adolygiadau gwasanaeth gwladol**

9.-(1) Pan ddaw adolygiad gwasanaeth gwladol i ben rhaid i'r Comisiwn wneud adroddiad i'r Cynulliad Cenedlaethol.

(2) Rhaid i adroddiad o dan baragraff (1) gynnwys canfyddiadau a chasgliadau'r Comisiwn.

(3) Rhaid i'r Comisiwn gyhoeddi crynodeb o unrhyw adroddiad o'r fath.

## **RHAN VI YMCHWILIADAU**

### **Ymchwiliadau**

10.-(1) Rhaid i'r Comisiwn gynnal ymchwiliad pan wneir cais iddo wneud hynny gan y Cynulliad Cenedlaethol.

(2) Caiff y Comisiwn gynnal ymchwiliad -

(a) pan gaiff y Comisiwn gais i ymchwilio gan unrhyw berson neu gorff; neu

(b) pan yw fel arall yn ymddangos i'r Comisiwn ei bod yn briodol gwneud hynny.

considers the report should be copied.

(4) In addition to sending copies of the report to the persons referred to in paragraph (3), the Commission shall publish a summary of the report.

### **Further action following a local review**

8.-(1) Following the conclusion of a local review the National Health Service 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 by the National Assembly.

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

## **PART V NATIONAL SERVICE REVIEWS**

### **National service review reports**

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

(2) A report under paragraph (1) shall include the findings and recommendations of the Commission.

(3) The Commission shall publish a summary of any such report.

## **PART VI 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) Pan yw'r Comisiwn yn cynnal ymchwiliad ar gais y Cynulliad Cenedlaethol, rhaid iddo ymchwilio i'r materion hynny sy'n dod o dan adran 20(1) (c) o'r Ddeddf neu reoliad 2(e) o'r Rheoliadau Swyddogaethau a gaiff eu pennu yn y cais.

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

### **Hysbysiad o'r ymchwiliad**

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

(a) i unrhyw gorff y Gwasanaeth Iechyd Gwladol neu ddarparydd gwasanaethau sydd yn destun ymchwiliad;

(b) yn achos ymchwiliad o dan reoliad 10(2) ynglŷn ag Awdurdod Iechyd, Awdurdod Iechyd Arbennig neu Ymddiriedolaeth y Gwasanaeth Iechyd Gwladol, i'r Cynulliad Cenedlaethol; ac

(c) yn achos ymchwiliad ynglŷn â darparydd gwasanaethau, i'r Awdurdod Iechyd perthnasol.

### **Cynnal ymchwiliad i gorff sy'n destun adolygiad lleol**

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

(2) Os bydd y Comisiwn yn penderfynu dechrau ymchwiliad rhaid iddo roi hysbysiad ysgrifenedig, lle mae hynny'n rhesymol ymarferol, o'i benderfyniad a'r dyddiad y bwriedir i'r ymchwiliad ddechrau -

(a) i'r corff sy'n destun yr adolygiad lleol; a

(b) mewn achos lle mae'r corff sy'n destun adolygiad lleol yn Awdurdod Iechyd, yn Awdurdod Iechyd Arbennig neu'n Ymddiriedolaeth y Gwasanaeth Iechyd Gwladol, i'r Cynulliad Cenedlaethol.

(3) Pan yw'r Comisiwn yn dechrau ymchwiliad o'r fath, caiff y Comisiwn atal neu barhau â'r adolygiad lleol ac, os yw'r adolygiad lleol wedi'i atal, aildechrau'r adolygiad ar unrhyw adeg.

### **Adroddiadau ar ymchwiliadau**

**13.**-(1) Ar ôl i ymchwiliad y gwnaed cais amdano gan y Cynulliad Cenedlaethol ddod i ben rhaid i'r Comisiwn wneud adroddiad i'r Cynulliad

(3) Where the Commission is carrying out an 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) of the Act or regulation 2(e) of the Functions Regulations 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 an investigation and the proposed date on which that investigation is to commence to -

(a) any National Health Service body or service provider which is to be the subject of an investigation;

(b) in the case of an investigation under regulation 10(2) concerning a Health Authority, a Special Health Authority or a National Health Service Trust, the National Assembly; and

(c) in the case of an investigation concerning a service provider, the relevant Health Authority.

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

**12.**-(1) If in the course of conducting a local 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) If the Commission decides to commence an investigation it 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 body which is the subject of the local review; and

(b) in a case where the body subject to the local review is a Health Authority, a Special Health Authority or a National Health Service Trust, the National Assembly.

(3) Where the Commission commences such an investigation, the Commission may suspend or continue the local review and, where the local 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

Cenedlaethol ac anfon copi o'r adroddiad -

(a) at unrhyw berson neu gorff a fu'n destun yr ymchwiliad; a

(b) yn achos ymchwiliad ynglŷn â darparrydd gwasanaethau at yr Awdurdod Iechyd perthnasol.

(2) Ar ôl ymchwiliad y gwnaed cais amdano gan unrhyw berson neu gorff arall ddod i ben, rhaid i'r Comisiwn wneud adroddiad i'r person neu'r corff hwnnw ac anfon copi o'r adroddiad -

(a) at unrhyw berson neu gorff a fu'n destun yr ymchwiliad;

(b) at y Cynulliad Cenedlaethol; ac

(c) yn achos ymchwiliad ynglŷn â darparrydd gwasanaethau, at yr Awdurdod Iechyd perthnasol.

(3) Ar ôl i ymchwiliad ddod i ben mewn unrhyw achos arall, rhaid i'r Comisiwn wneud adroddiad i'r person neu'r corff a fu'n destun yr ymchwiliad ac yn anfon copi o'r adroddiad -

(a) at y Cynulliad Cenedlaethol; a

(b) yn achos ymchwiliad ynglŷn â darparrydd gwasanaethau, at yr Awdurdod Iechyd perthnasol

(4) Rhaid i adroddiad a wneir o dan baragraffau (1), (2) neu (3) nodi -

(a) canfyddiadau a chasgliadau'r Comisiwn;

(b) unrhyw argymhellion a wneir gan y Comisiwn.

(5) Rhaid i'r Comisiwn gyhoeddi crynododdeb o unrhyw adroddiad o'r fath.

#### **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, dod ag ef i sylw -

(a) unrhyw un o'r personau neu'r cyrff y mae paragraff (2) yn gymwys iddynt; a

(b) y cyhoedd,

caiff y Comisiwn wneud y mater yn destun adroddiad ar unwaith yn ychwanegol at yr adroddiad a wneir ar ddiwedd yr ymchwiliad.

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

(a) unrhyw gorff y Gwasanaeth Iechyd Gwladol neu ddarparrydd gwasanaethau sy'n destun yr ymchwiliad;

(b) y Cynulliad Cenedlaethol;

Assembly and send a copy of the report to -

(a) any person or body which has been the subject of the investigation; and

(b) in the case of an investigation concerning a service provider, the relevant Health Authority.

(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 Health Authority.

(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 Health Authority.

(4) A report made under paragraphs (1), (2) or (3) shall set out-

(a) the findings and conclusions of the Commission;

(b) any recommendations made by the Commission.

(5) The Commission shall publish a summary of any such a report.

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

(a) any National Health Service body or service provider which is the subject of the investigation;

(b) the National Assembly;

(c) mewn achos lle mae darparwydd gwasanaethau yn destun ymchwiliad, yr Awdurdod Iechyd Perthnasol.

(3) Rhaid anfon copïau o unrhyw adroddiad o dan baragraff (1) at y canlynol-

(a) unrhyw gorff y Gwasanaeth Iechyd Gwladol neu darparwydd gwasanaethau sy'n destun yr ymchwiliad;

(b) y Cynulliad Cenedlaethol;

(c) mewn achos y mae paragraff (2)(c) yn gymwys iddo ef, yr Awdurdod Iechyd perthnasol;

(ch) unrhyw gorff y Gwasanaeth Iechyd Gwladol arall neu ddarparwydd gwasanaethau neu berson arall neu gorff arall sy'n arfer swyddogaethau statudol, y mae'r Comisiwn yn credu y dylid anfon copi o'r adroddiad atynt.

(4) Yn ychwanegol at anfon copïau o'r adroddiad at y personau y cyfeirir atynt ym mhagraff (3), rhaid i'r Comisiwn gyhoeddi crynodeb o'r adroddiad.

### **Camau pellach yn dilyn ymchwiliad**

15.-(1) Pan ddaw ymchwiliad i ben, rhaid i unrhyw gorff y Gwasanaeth Iechyd Gwladol o 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.

(2) Bydd datganiad a baratoir o dan baragraff (1) yn ddarostyngedig i gymeradwyaeth gan y Cynulliad Cenedlaethol.

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

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

### **Hawliau mynediad**

16.-(1) Yn ddarostyngedig i'r paragraffau canlynol yn y rheoliad hwn, caiff personau a awdurdodwyd yn ysgrifenedig gan y Comisiwn ar unrhyw adeg resymol fynd ac archwilio tir ac adeiladau'r Gwasanaeth Iechyd Gwladol(a) er mwyn cynnal adolygiadau lleol, adolygiadau gwasanaeth gwladol 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 i gael mynediad i dir ac adeiladau'r Gwasanaeth Iechyd Gwladol at y dibenion a bennir ym mharagraff (1),

(c) in a case where a service provider is the subject of an investigation, the relevant Health Authority.

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

(a) any National Health Service body or service provider which is the subject of the investigation;

(b) the National Assembly;

(c) in a case to which paragraph (2)(c) applies, the relevant Health Authority;

(d) any other National Health Service body or service provider or other person or body exercising statutory functions, to whom the Commission considers the report should be copied.

(4) In addition to sending copies of the report to the persons referred to in paragraph (3), the Commission shall publish a summary of the report.

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

15.-(1) Following the conclusion of an investigation, any National Health Service 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 by the National Assembly.

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

## **PART VII 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 National Health Service premises(a) for the purposes of conducting local reviews, national service reviews or investigations.

(2) Each person authorised by the Commission under paragraph (1) shall be furnished with written evidence of that person's authority and on applying for entry to National Health Service premises for the purposes specified in paragraph (1) shall, if so

(a) Gweler adran 23(6) o Ddeddf 1999 ar gyfer y diffiniad o "National Health Service" premises".

(a) See section 23(6) of the 1999 Act for the definition of "National Health Service premises".

rhaiddid ynt ddangos y dystiolaeth honno os gofynnir iddynt gan feddiannydd y tir a'r adeiladau neu gan berson sy'n gweithredu ar ran y meddiannydd.

(3) Rhaid i berson a awdurdoddir gan y Comisiwn o dan baragraff (1) beidio â hawlio mynediad i dir ac adeiladau'r Gwasanaeth Iechyd Gwladol fel hawl oni fydd y corff y Gwasanaeth Iechyd Gwladol sy'n berchen ar y tir a'r adeiladau neu'n eu rheoli wedi cael hysbysiad rhesymol o'r mynediad a fwriedir.

(4) Ni chaiff neb a awdurdoddir gan y Comisiwn o dan baragraff (1) fynd i unrhyw dir neu adeiladau neu ran o dir ac adeiladau a ddefnyddir fel llety preswyl ar gyfer personau a gyflogir gan unrhyw gorff y Gwasanaeth Iechyd Gwladol, heb yn gyntaf gael cydsyniad y swyddogion sy'n preswyl ym y llety hwnnw.

(5) Yn ddarostyngedig i reoliad 19, caiff person a awdurdodwyd gan y Comisiwn o dan baragraff (1) sy'n mynd i dir ac adeiladau'r Gwasanaeth Iechyd Gwladol o dan y rheoliad hwn archwilio a chymryd copïau o unrhyw ddogfennau -

(a) y mae'n ymddangos i'r person a awdurdodwyd eu bod yn angenrheidiol at ddibenion yr adolygiad neu'r ymchwiliad o dan sylw; a

(b) sy'n cael eu cadw ar y tir neu yn yr adeiladau gan -

- (i) y corff y Gwasanaeth Iechyd Gwladol sy'n berchen ar y tir neu'r adeiladau neu sy'n eu rheoli;
- (ii) cadeirydd, aelod, cyfarwyddyd neu gyflogai'r corff hwnnw;
- (iii) unrhyw berson arall sy'n gweithredu ar ran y corff hwnnw; neu
- (iv) aelod o bwyllgor neu is-bwyllgor o'r corff hwnnw.

### **Cael gafael ar wybodaeth ac esboniadau**

17.-(1) Yn ddarostyngedig i reoliad 19, wrth gynnal adolygiad lleol neu ymchwiliad gall y Comisiwn neu berson a awdurdoddir 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 awdurdodwyd, eu bod yn angenrheidiol at ddibenion yr adolygiad neu'r ymchwiliad o dan sylw.

(2) Yn ddarostyngedig i reoliad 19, wrth gynnal adolygiad lleol neu ymchwiliad, gall y Comisiwn neu berson a awdurdoddir gan y Comisiwn, os yw'r Comisiwn neu'r person hwnnw yn credu ei bod yn angenrheidiol, ei gwneud yn ofynnol i berson y mae paragraff (5) yn gymwys iddo roi i'r Comisiwn, neu fel y bo'r digwydd, y person a awdurdodwyd, esboniad am y canlynol -

requested by the occupier of the premises or a person acting on behalf of the occupier, produce that evidence.

(3) A person authorised by the Commission under paragraph (1) shall not demand admission to National Health Service premises as of right unless the National Health Service 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 National Health Service body, without first having obtained the consent of the officers residing in such accommodation.

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

(a) appear to the person authorised to be necessary for the purposes of the review or investigation in question; and

(b) are held on the premises by-

- (i) the National Health Service body which owns or controls the premises;
- (ii) a chairman, member, director or employee of that body;
- (iii) any other person acting on behalf of that body; or
- (iv) a member of a committee or sub-committee of that body.

### **Obtaining information and explanations**

17.-(1) Subject to regulation 19, in conducting a local review or 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 local review or investigation the Commission or a person authorised by the Commission may, if it or that person 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) unrhyw faterion sy'n destun yr adolygiad neu'r ymchwiliad; neu

(b) unrhyw ddogfennau neu wybodaeth a gafodd eu harchwilio, eu copïo neu eu dangos o dan baragraff (1) neu reoliad 16(5).

(3) Caiff y Comisiwn, os yw'n credu ei bod yn angenrheidiol, ei gwneud yn ofynnol i berson y mae'n ofynnol iddo -

(a) dangos dogfennau neu wybodaeth o dan baragraff (1); neu

(b) rhoi esboniad o dan baragraff (2),

fod yn bresennol gerbron y Comisiwn neu berson a awdurdodir gan y Comisiwn o dan reoliad 16(1) yn bersonol i ddangos y dogfennau neu'r wybodaeth neu i roi'r esboniad.

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

(5) Dyma'r personau y cyfeirir atynt ym mharagraffau (1) a (2) -

(a) corff y Gwasanaeth Iechyd Gwladol;

(b) cadeirydd, aelod, cyfarwyddyd neu gyflogai i gorff y Gwasanaeth Iechyd Gwladol, neu unrhyw berson arall sy'n gweithredu ar ran corff o'r fath;

(c) aelod o bwyllgor neu is-bwyllgor o gorff y Gwasanaeth Iechyd Gwladol;

(ch) darparydd gwasanaethau;

(d) cyflogai i ddarparydd gwasanaethau, neu unrhyw berson arall sy'n gweithredu ar ran darparydd o'r fath;

(dd) person sy'n darparu neu'n cynorthwyo i ddarparu gwasanaethau, neu sydd yn aelod o neu'n gyflogai i berson neu gorff sy'n darparu neu'n cynorthwyo i ddarparu gwasanaethau o dan Ddeddf 1977, neu mewn cysylltiad â chynllun peilot o dan Ddeddf 1997, yn unol â chontract a wnaed gyda chorff y Gwasanaeth Iechyd Gwladol, darparydd gwasanaethau neu berson y mae is-baragraff (e) yn gymwys iddo;

(e) awdurdod lleol sy'n darparu, neu berson a gyflogir gan awdurdod lleol i ddarparu, gwasanaethau o dan Ddeddf 1997, neu mewn cysylltiad â chynllun peilot o dan Ddeddf 1997, yn unol â threfniadau a wnaed yn rhinwedd adran 31(1) o'r Ddeddf.

(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),

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 persons referred to in paragraphs (1) and (2) are -

(a) a National Health Service body;

(b) a chairman, member, director or employee of a National Health Service body, or any other person acting on behalf of such a body;

(c) a member of a committee or sub-committee of a National Health Service 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 any 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 a National Health Service body, a service provider or a person to which sub-paragraph (g) applies;

(g) a local authority which provides, or a person employed by a 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.

## **Gwybodaeth a gedwir drwy gyfrwng cyfrifiadur neu mewn 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 drwy gyfrwng cyfrifiadur neu mewn unrhyw ffurf electronig arall.

(2) Pan yw'r Comisiwn neu berson a awdurdodwyd o dan reoliad 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;

a bod y dogfennau hynny yn cynnwys gwybodaeth a gedwir drwy gyfrwng cyfrifiadur neu mewn unrhyw ffurf electronig arall, gall y Comisiwn neu'r person a awdurdodwyd ei gwneud yn ofynnol i unrhyw berson sydd â gofal, neu sydd fel arall yn ymwneud â gweithredu'r cyfrifiadur neu'r ddyfais electronig arall sy'n cadw'r wybodaeth honno drefnu bod yr wybodaeth honno ar gael, neu ddangos yr wybodaeth mewn ffurf weladwy a darllenadwy.

## **Cyfyngiadau ar ddadlennu gwybodaeth i'r Comisiwn**

**19.**-(1) Rhaid i'r Comisiwn neu'r person a awdurdodwyd 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 berthnasol i unigolyn byw ac yn dynodi pwy ydyw, oni bai bod un neu fwy o'r amodau a bennir ym mharagraff (3) yn gymwys; neu

(b) bod archwilio neu gopïo'r dogfennau hynny yn golygu datgelu gwybodaeth os gwaharddwyd y datgelu hwnnw gan unrhyw ddeddfiad neu o dan unrhyw ddeddfiad, onid yw paragraff (4) yn gymwys.

(2) Ni fydd yn ofynnol i berson 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 berthnasol i unigolyn byw ac yn dynodi pwy ydyw, oni bai bod un neu fwy o'r amodau a bennir ym mharagraff (3) yn gymwys; neu

(b) y gwaharddwyd y datgelu gan unrhyw ddeddfiad neu o dan unrhyw ddeddfiad, onid yw paragraff (4) yn gymwys.

(3) Dyma'r amodau y cyfeirir atynt ym

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(a) Gweler adran 23(6) o Ddeddf 1999 ar gyfer y diffiniad o "confidential information".

## **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 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)

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

mharagraffau (1)(a) a (2)(a) -

(a) y datgelir yr wybodaeth mewn ffurf lle na ellir adnabod yr unigolyn drwyddi;

(b) bod yr unigolyn yn cydsynio i ddatgelu'r wybodaeth;

(c) na ellir olrhain yr unigolyn er cymryd pob cam rhesymol;

(ch) mewn achos lle mae'r Comisiwn yn arfer ei swyddogaethau o dan adran 20(1)(c) o'r Ddeddf -

(i) nad yw'n ymarferol i ddatgelu'r wybodaeth mewn ffurf na ellir adnabod yr unigolyn drwyddi;

(ii) bod y Comisiwn o'r farn bod risg difrifol i iechyd neu ddiogelwch cleifion yn codi o'r materion sy'n destun yr ymchwiliad;a

(iii) gan ystyried y risg honno a'r brys wrth arfer y swyddogaethau hynny, bod y Comisiwn o'r farn y dylid datgelu'r wybodaeth heb gydsyniad yr unigolyn.

(4) Mae'r paragraff hwn yn gymwys -

(a) pan yw'r gwaharddiad ar ddatgelu gwybodaeth yn gweithredu o achos y ffaith bod yr wybodaeth yn gallu dynodi pwy yw unigolyn; a

(b) pan yw'r wybodaeth o dan sylw mewn ffurf na ellir adnabod yr unigolyn drwyddi.

(5) Mewn achos lle gwaherddir datgelu'r wybodaeth -

(a) gan baragraff (1); neu

(b) gan baragraff (2) a bod y gwaharddiad yn gweithredu o achos y ffaith bod yr wybodaeth yn gallu dynodi pwy yw unigolyn,

gall y Comisiwn neu berson a awdurdodwyd gan y Comisiwn o dan reoliad 16(1) ei gwneud yn ofynnol i'r person sy'n cadw'r wybodaeth roi'r wybodaeth mewn ffurf na ellir adnabod pwy yw'r unigolyn o dan sylw drwyddi, er mwyn i'r wybodaeth gael ei datgelu.

## **RHAN VIII AMRYWIOL**

### **Cynorthwyo'r Comisiwn Archwilio**

**20.** Rhaid i'r Comisiwn beidio â chynorthwyo'r Comisiwn Archwilio o dan adran 21(2) o'r Ddeddf heb gydsyniad y Cynulliad Cenedlaethol.

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) of the Act-

(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

(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 VIII MISCELLANEOUS**

### **Assisting the Audit Commission**

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



**Arfer swyddogaethau mewn perthynas ag ymholiadau gwasanaeth iechyd**

21.-(1) Rhaid i'r Comisiwn beidio ag arfer ei swyddogaeth o dan reoliad 2(f) o'r Rheoliadau Swyddogaethau mewn perthynas ag ymchwiliad gwasanaeth iechyd penodol neu ymchwiliad gwasanaeth iechyd arfaethedig heb gydsyniad y Cynulliad Cenedlaethol.

(2) Wrth arfer ei swyddogaethau o dan reoliad 2(f) o'r Rheoliadau Swyddogaethau rhaid i'r Comisiwn gymryd i ystyriaeth unrhyw gyngor neu ganllawiau ynglŷn ag ymchwiliadau gwasanaeth iechyd a roddir i gyrff y Gwasanaeth Iechyd Gwladol gan y Cynulliad Cenedlaethol.

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

30 Mawrth 2000

Llywydd y Cynulliad Cenedlaethol

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

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

(2) In exercising its function under regulation 2(f) of the Functions Regulations the Commission shall take into account any advice or guidance relating to health service inquiries given to National Health Service bodies by the National Assembly.

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

30th March 2000

*D. Elis Thomas*

The Presiding Officer of the National Assembly





CYNULLIAD CENEDLAETHOL CYMRU

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OFFERYNNAU STATUDOL

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**2000 Rhif 1015 (Cy. 57)**

**Y GWASANAETH IECHYD  
GWLADOL, CYMRU**

Rheoliadau'r Comisiwn Gwella  
Iechyd (Swyddogaethau) (Cymru)  
2000

NATIONAL ASSEMBLY FOR WALES

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STATUTORY INSTRUMENTS

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**2000 No. 1015 (W. 57)**

**NATIONAL HEALTH  
SERVICE, WALES**

The Commission for Health  
Improvement (Functions) (Wales)  
Regulations 2000

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